Diversified Reporting Services, Inc.

RPTS GONZALEZ

HIF254140

EVALUATING FDA HUMAN FOODS AND TOBACCO PROGRAMS

TUESDAY, SEPTEMBER 10, 2024

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:02 a.m. in Room 2123 of the Rayburn House Office Building, Hon. Brett Guthrie [chairman of the subcommittee] presiding.

Present: Representatives Guthrie, Burgess, Latta, Griffith, Bilirakis, Bucshon, Hudson, Carter, Dunn, Pence, Crenshaw, Joyce, Balderson, Harshbarger, Miller-Meeks, Obernolte, Rodgers (ex officio); Eshoo, Sarbanes, Cardenas, Ruiz, Dingell, Kuster, Kelly, Barragan, Craig, Schrier, Trahan, and Pallone (ex officio).

Also present: Representatives Cammack, Pfluger; Castor, and Schakowsky.

Staff Present: Jolie Brochin, Junior Professional

Staff; Sarah Burke, Deputy Staff Director; Grace Graham, Chief Counsel, Health; Sydney Greene, Director of Operations; Nate Hodson, Staff Director; Calvin Huggins, Staff Assistant; Tara Hupman, Chief Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Karli Plucker, Director of Operations (shared staff); Carla Rafael, Senior Staff Assistant; Emma Schultheis, Clerk; Johanna Wells, Staff Assistant; Caitlin Wilson, Counsel; Lydia Abma, Minority Policy Analyst; Jennifer Black, Minority FDA Detailee; Jacquelyn Bolen, Minority Health Counsel; Keegan Cardman, Minority Staff Assistant; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; Una Lee, Minority Chief Health Counsel.

*Mr. Guthrie. The subcommittee will come to order.

I see that only my friend, Bob Latta, and I got the memo on what to wear today. So dark shirt, same tie, same clothes. So thank you.

Thank you all for being here today, and I will recognize myself for five minutes for an opening statement.

Today's hearing is an opportunity to learn more about how two of the U.S. Food and Drug Administration centers are improving their regulation of products that have an impact on millions of American families.

Between foodborne illnesses, outbreaks, the infant formula crisis, and FDA's failure to authorize tobacco harm reduction products, the FDA's Center for Food Safety and Applied Nutrition and the Center for Tobacco Products have repeatedly failed to rise to that occasion, to the detriment of the American people.

It has been a -- it has been over a decade since Congress gave new authorities to the FDA to strengthen the agency's ability to regulate tobacco and food. Yet over the past few years I have personally heard gut-wrenching stories about Kentucky moms not being able to access formula for their newborns and from parents concerned about illicit nicotine products flooding their communities. Families have also had to deal with food recalls, such as lead contamination in applesauce pouches.

Additionally, we have lost 9 American lives to a listeria outbreak just this year, which also resulted in nearly 60 hospitalizations and over 7 million pounds of deli meat being taken off the market. I believe that many of these problems are the direct result of misaligned priorities and culture at the FDA, rather than a lack of resources and authorities.

A Reagan-Udall report published in December 2022 on the Center for Food Safety and Applied Nutrition states, "FDA has dedicated staff who are committed to protecting public health, but the current culture of the FDA Human Foods Program is inhibiting its ability to effectively accomplish this goal.'' One example is the fact that it took almost six months for the issues identified in the Abbott baby formula manufacturing facility to reach the highest levels of the FDA. Quicker action and stronger communication could have avoided this catastrophic crisis that endangered the lives of millions of infants across the United States.

Another Reagan-Udall report, published in December 2022, outlines challenges facing the Center for Tobacco Products, and provides recommendations to improve how the center functions. The report recommends that the CTP should be proactive and engage more with stakeholders and the public. It also mentions that the center should make "process improvements and identify and address the policy and

scientific questions that underpin its regulatory framework.’‘

Manufacturers filing pre-market tobacco applications with the goal of meeting the standard of "appropriate protection of public health’‘ still have no clear guidance, and are waiting for hundreds of days for outreach on their applications.

More importantly, these products pending at FDA could present an opportunity to improve public health by providing less harmful alternatives to traditional cigarettes. This lack of transparency has consequences.

First, because the FDA hasn't set a clear criteria for science by which it will measure the products, the Justice Department has been forced to litigate on behalf of the Center, wasting millions of taxpayer dollars and causing an even greater uncertainty.

Second, because of the FDA's failure to approve new products and expand the legal market, people are turning to illicit products coming from China instead. Without clear rules of the road and a robust authorized market known to consumers, wholesalers, and sellers, the CTP won't be able to enforce fast enough to keep up with the harmful products out of the hands of unknowing consumers.

To those that claim that all of these issues can be addressed through more taxpayer and user fee dollars alone, I

want to be very clear that members of this subcommittee need to know exactly how the significant authorities and hundreds of millions of dollars provided by Congress have been deployed and exactly why they have fallen short in preventing widespread foodborne illness outbreaks or the ability to authorize products. Until we know better how dollars are prioritized and have agreement on these priorities, it is premature to provide any more funding. I am looking for clear results from a more transparent and predictable regulatory process, rather than more academic exercises and public awareness campaigns.

I want these critical centers to succeed in their mission to protect and promote public health. I hope that today's hearing can shed light on our shared objectives and how your centers are making improvements to how your programs operate.

[The prepared statement of Mr. Guthrie follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. I will yield back, and I will recognize the ranking member for five minutes for her opening statement.

*Ms. Eshoo. Thank you, Mr. Chairman, and good morning, colleagues. Today we welcome two leaders from the Food and Drug Administration to our subcommittee, and this is the very first time that they are testifying before us.

So welcome to you, Mr. Jones, and welcome, Dr. King, and today we are going to discuss the work of the Center for Tobacco Products and the Human Foods Program.

The FDA oversees the safety of more than $3.6 trillion worth of food and drug products produced in the United States and abroad. Twenty-one cents out of every dollar spent by American consumers goes toward a product that is regulated by the FDA. The Human Foods Program represents the often neglected, at least in my view -- the F in FDA -- and oversees more than 78 percent of our nation's food supply. FDA regulations cover about 35,000 product farms, 300,000 food establishments, and 10,500 vending machine operators -- that one I was not aware of.

The Center for Tobacco Products oversees more than 100,000 tobacco products in the United States, including cigarettes, cigars, smokeless tobacco products, e-cigarettes, and vapor products. Central to the work is the leading cause of preventable death in the United States each year, with 1

in 5 deaths due to tobacco use; 1 in 6 Americans suffer foodborne illnesses each year, contributing to more than 128,000 hospitalizations and 3,000 deaths annually. Americans depend on a strong FDA to protect their families.

Last year parents in Maryland discovered their child had six times the minimum level of lead in his blood after he consumed applesauce pouches containing contaminated cinnamon. Now they worry that their son will be developmentally delayed due to preventable lead poisoning.

In 2022 infant formula containing bacteria killed two babies and caused infections in many others, despite FDA receiving a whistleblower complaint a year before. The complaint was "inadvertently archived,'' according to the IG of HHS.

A high school student from Oklahoma had to relearn how to talk and move after she was placed in a medically induced coma after one of her lungs collapsed from vaping.

So this work, the work of the two witnesses before us, touches the lives of every single American, and it is done with less than a third -- less than a third -- of FDA's entire budget. The centers have long been overlooked and, in my view, under-resourced. Today we are going to examine several proposals to support your immense mission.

The Tobacco User Fee Modernization Act, introduced by Representative Jennifer McClellan, reauthorizes the

assessment and collection of user fees for tobacco products critical to fund faster, thorough FDA reviews of tobacco products, which we all agree is necessary.

The Federal and State Food Safety Information Sharing Act, introduced by Representative Deborah Ross, authorizes HHS to share timely information on foodborne illnesses and recalls with state, local, and tribal authorities.

The INFANTS Act, produced by our ranking member, Mr. Pallone, and Representatives Cardenas and Sykes, require baby food products to be tested for toxic heavy metals to better protect the youngest amongst us.

Several other bills we will discuss take action on decisions the FDA has long delayed regarding dairy products domestically produced oranges and honey. I hope the FDA will make it easier for people to be informed consumers and not more difficult, and I hope the FDA will act rather than wait for Congress to essentially force its hand to make these changes.

So I look forward to this hearing with our distinguished witnesses today on how Congress can help the agency better manage its massive responsibilities.

[The prepared statement of Ms. Eshoo follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Thank you, Mr. Chairman, and I yield back.

*Mr. Guthrie. Thank you. The gentlelady yields back, and I now -- the chair will now recognize the chair of the full committee, Chair Rodgers, for five minutes for her opening statement.

*The Chair. Thank you, Chairman Guthrie. Today we are here to discuss and evaluate the work that the Food and Drug Administration is doing related to its human foods and tobacco programs, areas that have substantial impact on the health and safety of the American people.

Last week the CDC announced the results from its National Youth Tobacco Survey, which gave us a few reasons to be optimistic. Use of vaping products among America's middle and high school students is down almost 70 percent since the 2019 peak of 5.3 million users. Also according to the CDC, cigarette use among adults has dropped to 11.5 percent in 2021. There is more we can and must do to discourage young Americans from starting, help the 30 million or so Americans who already use cigarettes, and, I will add, address the alarming increase of marijuana usage among teenagers and young adults, whether in food or vaping products.

According to a 2022 Reagan-Udall report, the Center for Tobacco Products, which was established in 2009, is "confronting enormous challenges.'' For example, out of the over 26 million applications for electronic nicotine delivery

systems, or ENDS products, the Center has authorized fewer than 50 products. However, according to recent market data, those products only account for about 10 percent of sales, showing how behind the FDA is in keeping up with demand. The lack of clear enforcement policy and authorized products leaves tobacco users, distributors, and convenience stores in the dark on what products they can use and sell to those that are looking for alternatives to traditional cigarettes.

Companies need clear guidelines on what is required to meet the standard for authorization and what products -- what changes to products require new applications. If the standards and current law need to be made clearer, Congress should have that discussion. It is evident that FDA's regulation of tobacco needs significant attention, and that is what we are starting today.

Turning to the Human Foods Program, the FDA is responsible for regulating nearly 80 percent of the U.S. food supply and approving new food additives. This year alone there has been nearly 200 food recalls, including deli products linked to a listeria outbreak that has resulted in 57 hospitalizations and 9 deaths.

In addition, the agency is still taking steps following the investigation of lead and chromium found in cinnamon applesauce pouches that the CDC estimates poisoned more than 400 children. These incidences have raised concerns over the

safety of our food supply.

We must also not forget about the infant formula crisis that occurred in 2022. An independent report found factors within the FDA's control. The lack of clear vision and mission, the lack of collaboration between offices, and a culture of indecisiveness and inaction are what contributed to the infant formula crisis.

I am glad the FDA has acknowledged it needs to improve, and has recently announced plans to implement a new, unified Human Foods Program starting this October. As a part of this new effort the FDA has stated it will prioritize helping American consumers make more informed food choices, in addition to food safety and response activities.

It is essential that the FDA is transparent regarding what data and information it is relying upon as it considers various nutrition and food-labeling proposals. I look forward to hearing more about the agency's vision for the Human Foods Program, and how it plans to manage these nutrition initiatives while not losing sight of the core mission of keeping our food supply safe and secure.

Congress has provided the FDA with substantial resources to effectively run these programs, yet the FDA is requesting millions more in budget authority and user fees for its Human Foods Program and Center for Tobacco Products, while providing little information about how their current

resources are spent, existing authorities are used, and regulations are being enforced.

I look forward to having this discussion today to better understand how existing resources and authorities can be better used to improve the safety and quality of our food supply and finally get the Center for Tobacco Products working after falling short, unfortunately, over the last decade.

[The prepared statement of The Chair follows:]

**********COMMITTEE INSERT**********

*The Chair. Thank you, and I yield back.

*Mr. Guthrie. Thank you. The chair yields back, and the chair will now recognize the ranking member of the full committee, Mr. Pallone, for five minutes for an opening statement.

*Mr. Pallone. Thank you, Mr. Chairman.

We are here today for an update on the Food and Drug Administration's work to assure our food supply is safe and nutritious, and its work to protect consumers from negative health effects of tobacco use.

And this hearing comes at an opportune time. Starting next month FDA will begin to implement its human food reorganization to better position the agency to adapt to our increasingly complex food supply. And it is clear that FDA needs to be nimble and evolve to prevent food-borne illnesses and diet-related chronic diseases, and I look forward to hearing the agency's priorities as they work to make this change. But in light of the listeria outbreak which has killed nine people, including one person in New Jersey, and the continuing response to the outbreak of H5N1 in dairy cattle, the importance of ensuring the safety of our food is clear.

But protecting our food supply takes resources and authorities, which House Republicans repeatedly oppose. Even today the bills that committee Republicans have put forth

would undermine FDA's efforts to improve the public health and other bills do not get at the critical issues that need to be addressed.

So I am particularly concerned with H.R. 7563, the Food Traceability Enhancement Act, which would delay and dismantle implementation of the FDA's food traceability rule. Congress intended for FDA to create traceability requirements for retailers and their suppliers when we enacted the Food Safety Modernization Act in 2010.

Thankfully, some of the bills will bolster consumer safety by protecting our nation's food supply. Specifically, I am pleased we are discussing both H.R. 6770, the INFANTS Act, introduced by myself and Representative Sykes; and H.R. 9443, the Federal and State Food Safety Information Sharing Act of 2024, introduced by Representative Ross.

I am also pleased that the FDA has undergone rulemaking to update front-of-package food labeling requirements and apply consumer-friendly labeling requirements. This rule addresses some of the key components included in H.R. 2901, the Food Labeling Modernization Act, which I introduced last year with several of my colleagues, and these efforts will provide consumers with clear nutritional information and rein in misleading marketing claims.

We are also here today for an update on FDA's work to protect consumers from negative health effects of tobacco

use, and how we must continue to curb the youth tobacco epidemic that we have watched unfold in recent years. And I have repeatedly voiced my concern with the increase in tobacco products that have come to market, including those that demonstrate the industry's ingenuity in developing new, slick products that appeal to kids. We need quicker action, more inspections, and increased enforcement to clear the market of unauthorized tobacco products that lack marketing authorization from FDA, and I look forward to hearing the agency's concrete plans to work through the backlog of pre-market tobacco applications currently pending before the agency for review.

And while I am frustrated that so many products have not already been removed from shelves, I understand that there were millions of applications, that FDA needs additional resources to protect the public health from the risks of tobacco usage, and that is why I am pleased we are discussing H.R. 9425, the Tobacco User Fee Modernization Act, introduced by Representative McClellan. This bill would update the tobacco user fee framework to extend tobacco user fee assessments to all regulated tobacco products, including e-cigarettes. There is no reason that manufacturers of e-cigarette products should not pay their fair share of user fees when these products are undoubtedly taking up the lion's share of FDA's time and resources. This should be a common

sense and bipartisan policy that I hope my colleagues on both sides of the aisle will support.

But in closing, let me just simply say we cannot expect more from the agency without providing the necessary tools and resources. That is the key. They need more tools. They need more resources. Otherwise, they are not going to be able to do their job faced with so many applications and so many, you know, efforts by industry to undermine what they do, in my opinion.

[The prepared statement of Mr. Pallone follows:]

**********COMMITTEE INSERT**********

*Mr. Pallone. So with that I yield back the balance of my time. Thank you, Mr. Chairman.

*Mr. Guthrie. Thank you. The gentleman yields back, and that concludes our opening statements, and now we will move to witnesses' opening statements.

I will introduce both of you, and then call on you one at a time for your five minutes of opening statements.

Our witnesses today are Mr. Jim Jones, deputy commissioner for human foods, U.S. Food and Drug Administration, and Dr. Brian King, director, Center for Tobacco Products, U.S. Food and Drug Administration.

I don't know if you have testified before, but you will have -- I think you have -- you have five minutes. After four minutes you will have a green light for four. After four, you have a yellow light. And after it is red, it will be time to make sure you wrap up, so you get the one-minute warning.

So Mr. Jones, you are recognized for five minutes for your opening statement.

STATEMENT OF JAMES "JIM'‘ JONES, DEPUTY COMMISSIONER FOR HUMAN FOODS, U.S. FOOD AND DRUG ADMINISTRATION; AND BRIAN KING, PH.D., DIRECTOR, CENTER FOR TOBACCO PRODUCTS, U.S. FOOD AND DRUG ADMINISTRATION

STATEMENT OF JAMES "JIM'‘ JONES

*Mr. Jones. Thank you, Chair Guthrie, and Ranking Member Eshoo, and members of the subcommittee for the opportunity to testify on the historic changes we are making within the Human Foods Program at FDA.

I am honored to sit before you as FDA's first deputy commissioner for human foods under the new Human Foods Program, or HFP. While the official implementation date for the HFP is October 1, we have been hard at work making the necessary changes and improvements to fulfill our mission. This is a monumental undertaking, the single largest reorganization in the agency's modern history, touching almost every facet of the agency and impacting over 8,000 Federal workers.

I have spent the last year as deputy commissioner not just moving us forward in the reorganization, but really honing in on a vision and culture that will drive our priorities as a program. Simply put, food should serve as a vehicle for wellness. We must do all we can to ensure

Americans do not get sick from their food, whether it is from acute foodborne illness, chemical contamination, or chronic, diet-related disease. We all want a food supply that is safe and nutritious.

The HFP realigns our expertise to support a more consistent and systematic risk management approach to preventing foodborne illness, ensuring chemical -- exposure to chemicals in food is safe, and decreasing diet-related chronic disease through improved nutrition. This will enable us to zero in on those issues where intervention has the greatest opportunity for prevention of disease and for the promotion of wellness. Going forward you will be able to draw a direct line between our priorities and our actions.

Almost 15 years ago Congress passed the Food Safety Modernization Act, a bold vision for a food safety system rooted in prevention, and built on the premise that food safety is a shared responsibility between industry and government. Public health again needs congressional leadership. We need additional regulatory authorities and critical resource investments to meet the demands of today's growing, dynamic, technology-driven food system.

The U.S. food industry produces more than $800 billion in revenue a year. FDA's $1.2 billion budget is a fraction of 1 percent of that total. In other words, to ensure the safety of 80 percent of the food we feed our families, FDA

has a budget just shy of $3.50 per person per year, $3.50, less than a cup of coffee. Certainly, the FDA is no stranger to doing more with less, but we also need modern authorities to enable further agility and to help us regulate our rapidly evolving 21st century food supply.

When we learned there were dangerous levels of lead in certain cinnamon applesauce products, we worked quickly with state partners to remove the dangerous products and warn the public. But we can do more. We need Congress to grant us the authority to prevent food with dangerous levels of environmental contaminants from ever reaching store shelves. And we need to remove the limitations on sharing certain regulated commodity information in real time with our state partners during urgent food safety events.

We worked with industry and partners to -- abroad to boost the supply of infant formula when shortages hit. But again, we can do more. We need Congress to require manufacturers of critical foods to provide FDA certain critical information like duration of the disruption to mitigate potential shortages of critical foods.

We removed products marketed as dietary supplements tainted with sildenafil from the market, but under current law we still don't know what is in most supplements or the scope of what is on the market. We need Congress to grant us registration and listing authority.

Finally, we need to ensure we aren't getting sick from chemicals in our food. Our statute generally only requires manufacturers to generate safety data for the initial approval or authorization of a chemical used in food. The burden of post-market reassessment falls entirely on FDA. We have the resources to support only a handful of chemical reassessments each year. Here again we, FDA and Congress, must do more.

Ensuring the safety of food is a tremendous responsibility, and I am optimistic about the HFP's future. We have a stellar dedicated staff. Our program is committed to increase transparency and communication with the public, industry, and policymakers. Through strengthened relationship with this committee, with Congress, and with our regulatory partners, as well as ongoing engagement with our vast array of stakeholders, we will continue to foster a safe and nutritious food system, one that is truly a vehicle for wellness.

Thank you, and I am happy to take any questions.

[The prepared statement of Mr. Jones follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. Thank you. I appreciate your opening statement.

And Dr. King, you are recognized for five minutes for your opening statement.

STATEMENT OF BRIAN KING

*Dr. King. Chair Guthrie, Ranking Member Eshoo, and members of the subcommittee, thank you for the opportunity to discuss FDA's work to regulate tobacco products.

Tobacco product use remains the single most preventable cause of disease, disability, and death in the United States, killing nearly half a million Americans per year. And given the enormous public health burden of tobacco product use, Congress rightly gave FDA the authority to regulate the manufacture, marketing, distribution, and sale of tobacco products in 2009.

And since that time and over the past 15 years, the Center has worked tirelessly to prevent youth from starting to use tobacco products, to help people to quit tobacco use, and to reduce the harm caused by tobacco product use. To do this we take a comprehensive approach using the tools that have been provided to us by Congress. For example, FDA reviews new tobacco products before they can be legally sold, resolving more than 26 million pre-market tobacco applications over the past few years, an unprecedented volume never experienced by any other FDA center, ever.

We also continue to enforce the law. To date FDA has conducted more than 1.5 million inspections of tobacco retailer establishments, resulting in over 140,000 warning

letters and 34,000 civil money penalties for under-age sales violations. We have also conducted over 6,600 inspections of tobacco manufacturers and distributors, resulting in more than 880 warning letters. And in just the last two years we have taken many first-of-their-kind actions, including the first injunctions and civil money penalties against e-cigarette manufacturers, the first civil money penalties to retailers for sales of illegal e-cigarettes, and the first judicial seizure of e-cigarettes from a distributor.

We also continue to inform the public about the risks of tobacco product use, including through our flagship, The Real Cost campaign, which has prevented hundreds of thousands of kids from smoking and saved tens of billions of dollars in smoking-related costs for youth, their family, and for society. This campaign, alongside our adult-targeted work on cessation and the relative risks of tobacco products, will continue to be critical to our efforts.

And the numbers show that our work has made a difference alongside those of others at the national, state, and local levels. Smoking rates have plummeted, with the use of cigarettes and other combustible products dropping by over half over the past 15 years since we have authority to regulate these products at FDA. That is the lowest levels ever recorded in the United States. And just last week FDA and CDC released data showing youth e-cigarette use is at the

lowest it has been in a decade. These are monumental public health wins.

But as we move forward on this progress, equipped with a new five-year strategic plan, we face a critical resource challenge. CTP is 100 percent funded by user fees, which have not been updated by Congress to reflect the realities of the current tobacco product marketplace. The agency's fiscal year 2025 budget includes an additional $114 million in tobacco user fees indexed for inflation, and a request for authority to assess user fees for manufacturers and importers of all regulated tobacco products, including e-cigarettes. These additional resources will help us achieve more, including in the areas of enforcement and new product review, which I know are areas of priority for members of this committee.

Now, in closing, CTP has made important progress in tobacco regulation, and I am confident in the Center's dedicated staff and our ability to build on this progress. But more resources are needed to optimize that work, and it is important that every entity with responsibility in this space comes to the table. That said, we stand ready to work with our Federal Government partners, including Congress, on that effort.

Thank you, and I look forward to answering your questions.

[The prepared statement of Dr. King follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. Thank you. I appreciate your opening statement. That concludes opening statements. We will now begin questioning, and I will recognize myself for five minutes to start.

So Director King, I understand that we are trying to get harm reduction and moving people out of combustible cigarettes into other nicotine products if they so choose to use them. And I do believe we have -- we all recognize we have an overwhelming number of illicit products on the marketplace, and I do believe there is a causal relationship between the lack of getting products approved and the number of illicit in the marketplace.

On the enforcement side, it seems like the FDA has chosen to focus on small actors rather than those who manufacture and distribute more widely. We know a lot of it is China, comes from China or based out of China, and the FDA's website states that the only legal products are the 34 that are authorized, and that is about 11 percent of the market. So that leaves 89 percent. So further CTP data shows it issued 67, as you talked about, civil monetary penalties and injunction against manufacturers, but mostly smaller vape shops.

So I know you have cited larger manufacturers and warning letters, but have yet to take enforcement action against these products. So my question is, I know you cited

some success, but we still have an overwhelming number of illicit products, and the vape shops shouldn't be selling them, but it seems like the big -- the major move that you can make to stop this is to the major manufacturers. So I would just like for you to talk about why CTP is targeting smaller retailers instead of the larger manufacturers.

*Dr. King. Yes, thanks for the question. We take a comprehensive approach to regulation, and that is across the supply chain, and that includes retailers, it includes importers, distributors, and also manufacturers. We have taken action across that supply chain, and we have also taken escalated action in more recent years.

That said, there is no safe harbor for simply submitting an application, and any entity that does not have authorization is indeed subject to enforcement action, regardless of size of the business.

*Mr. Guthrie. Do you think the current enforcement is adequate?

*Dr. King. I believe there is opportunity to enhance it, and that is why we need more resources to do that. I strongly believe we have made a really good foundation, particularly in the last few years, taking a lot of first-of-their-kind actions, but we don't have the resources to do it, particularly given that we aren't collecting any fees for e-cigarettes, and 90 percent of our enforcement dollars are

being spent on that product class.

*Mr. Guthrie. Okay, thank you. I may come back, but let me go to Director Jones and a couple of minutes.

You recently said -- and I am paraphrasing -- that companies that are intending to break rules, then "they are usually going to get away with it for a little while before they are stopped.'' This is in the context of lead contamination in applesauce pouches. What steps have you taken to ensure these bad actors know they shouldn't even try to break the rules before there are such widespread public health and supply chain challenges?

*Mr. Jones. Thanks for the question, Chair.

So we have issued a warning letter to the manufacturer of the applesauce pouches that were contaminated with lead, and made it clear to them that they had a duty to have been looking for lead in cinnamon prior to manufacturing. And that letter was not only -- well, it was sent to that manufacturer, but it was intended for the entire industry, for everyone to understand that if you are using cinnamon in manufacturing, you have a responsibility to be looking for lead and putting in place a preventative control so that we don't find ourselves in a situation where a product is coming into this country or being manufactured in this country with contaminated cinnamon.

*Mr. Guthrie. But we don't want a situation where

manufacturers -- and hopefully they don't -- have the kind of vision that we will do this until we get caught. I mean, and hopefully we have a -- I don't think that is what you are quoting. Maybe you want to clarify that. What we want to make sure is that don't even attempt to do it, so we don't have -- we are not always playing try to catch you, we are all -- we have a system in place that people want to honor and not produce this kind of product. So do you want to kind of clarify that quote a little bit?

*Mr. Jones. Absolutely. You know, and when I say -- when we say -- and we say this routinely -- that the food safety system in the United States is based on both the government and the industry following the rules. And so if the -- if a manufacturer is going to choose not to follow the rules, they are going to likely have some opportunity to get away with it until they are caught. It is sort of like in any laws we have in the United States, if there is someone who is just choosing "I am not going to follow the rule,'' whether it is about speeding or jaywalking or any rule, there will be a period of time where they are going to get away with it. Obviously, that is not what we are looking for, but we need everybody in the system to be playing their role.

And for the manufacturing community it is about following the rules that have been created. And for us it is about setting clear and enforceable rules, and then also

doing enforcement --

*Mr. Guthrie. And if the penalties are so severe that that encourages them not to do it --

*Mr. Jones. Absolutely.

*Mr. Guthrie. That is one thing. Because the jaywalking is a little different. If you are going to go to jail if you jaywalk, you may not jaywalk.

So -- well, thank you. My time, unfortunately, has expired, and I will yield back and recognize the ranking member for five minutes for her questions.

*Ms. Eshoo. Thank you, Mr. Chairman.

And to both of you, thank you for your testimony. On this issue of penalties, is my understanding correct describing it this way? If a manufacturer, say, has 1,000 of the exact same product, that product is deficient per the FDA, do they pay a fine for each one of those products, or is it considered 1? Because one violation is something like, what, 20-some-thousand dollars? That is really a slap on the wrist, I mean, you know.

*Mr. Jones. So it will -- thank you for the question.

*Ms. Eshoo. Is that the way it works?

*Mr. Jones. No, it will depend on the product we are talking about, whether it is a food or tobacco product or a drug.

As a general matter, in the food space violations are --

the initial penalty is what we refer to as a warning letter, which doesn't sound like it is very much, but the warning letter tells the manufacturer that you have X period of time to correct the deficiency that we have observed, and then we are going to go back and ensure that they have corrected the deficiency. It is --

*Ms. Eshoo. I am not so sure I have the answer to my question, though.

*Mr. Jones. Well, it would be a pretty egregious violation for us to go straight to some form of civil penalty, which is what you are referring to --

*Ms. Eshoo. I see.

*Mr. Jones. -- is where there is a dollar amount associated with it.

And then the scope of the violation would inform the size of the penalty.

*Ms. Eshoo. The FDA, as you know, spent the past two years reorganizing and restructuring the Human Foods Program, and I think that was following the agency's lackluster, I think, formula response in, what was it, 2022? What are the main changes that the FDA has made?

How are they going to strengthen the agency's ability to regulate our food supply?

And the other question that I would like to ask is -- there has been support in Congress for some time -- and now a

bill has been introduced -- to separate food out of the FDA and have a free-standing agency. What is your position on that?

*Mr. Jones. Thanks for the question, Ranking Member Eshoo.

So there are a number of changes that are captured in this reorganization. One of the most important ones is the creation of a single decision-maker for foods-related activities. That is the deputy commissioner for human foods. I happen to hold that position right now.

*Ms. Eshoo. Right.

*Mr. Jones. In the organization we are changing there were multiple leaders with very similar roles and responsibilities, which created a lot of the challenges that the foods program had, historically.

The other thing, the other major part of --

*Ms. Eshoo. So that has changed now, all of --

*Mr. Jones. On October the -- well, as -- because I was appointed about a year ago, I am the sole decision-maker within the foods program, and have been since I started last September.

The other major changes largely involve consolidating functions that were very similar, not the least of which were what we refer to as signals -- a whistleblower, a consumer complaint, adverse effects reporting -- how we pick up

signals from what is happening in the foods supply --

*Ms. Eshoo. Well, not only picking them up, but there has to be action taken.

*Mr. Jones. Well, so the -- part of what we struggled with in the infant formula scenario was that a whistleblower complaint came in and it was not attended to. We are now consolidating these functions --

*Ms. Eshoo. And it was not only attended to, though, Mr. Jones, it was an outfit that was a -- my understanding, a rather serial violator. So, you know, it is -- anyway, I just wanted to --

*Mr. Jones. We are consolidating functions now that we were in different parts of the organization to increase the likelihood of our ability to be coordinated and effective and responsive.

We are also moving the interface with the state programs from the inspectorate into the program, because the interface with the states is fundamentally a programmatic activity. It is not an inspection-related activity.

So there are a number of areas where we are consolidating activities within the organization to increase our efficiency, our effectiveness at -- all operating under one individual leader, so there is not confusion as to sort of where decision-making authority lies.

*Ms. Eshoo. Well, I have 7 -- now 16 seconds left. I

don't really -- I am not a big fan of the U.S. Senate. But one thing they do that I do like is that members have 10 minutes to question, and we don't.

[Laughter.]

*Ms. Eshoo. So Dr. King, you will receive my questions in writing.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And thank you, thank you to both of you for the work that you are doing. It is so, so important.

*Mr. Guthrie. Thank you. The gentlelady yields back. We have -- sometimes we wish we had more time, and I will yield five minutes to the chair of the Rules Committee for his questions.

Chair Burgess, you are recognized for five minutes.

*Mr. Burgess. Thank you, Chairman Guthrie. I think I am the only remaining Republican who was here when this tobacco bill was passed, when Chairman Waxman was chairman of our committee. I had some severe misgivings about it when we did that legislation.

And let me just ask you, Dr. King. The monies that you talk about, the $712 million that comes to you, over $2 million a day that comes to you from user fees, now that is not drawn from an appropriations by the United States House of -- the United States Congress, is it?

*Dr. King. Correct. All user fees are paid by the tobacco manufacturers.

*Mr. Burgess. See, and that has always been a problem for me because the Constitution says no money shall be distributed except as drawn by an appropriation by Congress. So you really are doing that outside of congressional control. And although the intentions may be the best, and although your work may be the best, it sort of takes Congress

out of the loop, and I don't think that is the way the -- our entire system, our entire republican government, was set up. Members of Congress, House and Senate, are supposed to have the oversight as to how the money is spent.

So along those lines, let me just ask you, what have we gotten for this investment of over $2 million a day in your division? How many people have -- how many lives have been saved?

*Dr. King. So combustible cigarette smoking is the leading cause of preventable disease and death in this country, and we have seen smoking rates among U.S. adults cut in half since CTP was given that authority. And so my estimate is that is tens of millions of lives saved over time.

*Mr. Burgess. Let me just -- and I get it, we can give estimates. But let me just ask you specifically. When this bill was passed over 10 years ago, the idea was that you were going to prevent youth smoking in the first place. What programs are going on right now for your $2 million a day that are preventing youth smoking from happening in the first place?

*Dr. King. So we follow a comprehensive approach. I will give you one example. So it is our prevention campaigns. The Real Cost, it has been in place -- just celebrated a 10-year anniversary. That has been implemented,

and it has prevented tens of thousands of kids from starting to smoke and saved tens of billions of dollars. For every $1 we invest we save $180 for tobacco-related disease and death and --

*Mr. Burgess. Let me ask you this. The number of kids today that are addicted to nicotine because of vape products, is that higher or lower than what it was when this bill was passed?

*Dr. King. It is lower, but e-cigarettes were not even a twinkle in the eye. They had just entered the U.S. marketplace, and kids didn't even start using them until 2011.

*Mr. Burgess. And yet we recognize the problem with tobacco abuse, with cigarette -- I am speaking as somebody who lost both parents to tobacco-related illness. I mean, I know how serious the disease is, how addictive nicotine is. But at the same time, we are creating an entire new population of people who are addicted to nicotine who have never purchased or touched a cigarette. So is that a problem?

*Dr. King. It is certainly a problem, and we have made great progress. We have reduced the number of kids using these products by 70 percent over the past half decade alone, and I am hopeful to continue. But we need the resources to do it.

*Mr. Burgess. Honestly, I don't see that in my neighborhoods. I see vape shops literally on every street corner in -- I represent a district in north Texas.

So in June the FDA announced a multi-agency task force to combat illegal distribution and sale of e-cigarettes. And we, as Members of Congress, know nothing about the basic structure and operation of the task force. So who is leading the task force?

*Dr. King. The Department of Justice and the FDA, in coordination with about a half dozen other agencies who are participating.

*Mr. Burgess. Can you give us a name? If we wanted to call someone up and say, "How are you doing on the task force?'‘

*Dr. King. We are happy to follow up with staffers on that information.

*Mr. Burgess. Maybe you could follow up with me, because I would like to make that phone call.

*Dr. King. I am happy to do so.

*Mr. Burgess. When does the task force first meet, and how often does it meet?

*Dr. King. They began meeting shortly after the announcement. They are meeting on a regular basis, and I think they are making very good progress. But they just started.

I welcome the opportunity to engage. There is a lot of players, and we will continue to provide updates as they are available from that group. But they are in the initial stages of formulating --

*Mr. Burgess. Are they under any requirement to provide a periodic report to Congress, as you are in the enabling legislation that was passed over 10 years ago?

*Dr. King. Well, I see it as an extension of the work of the Center, and we are required to report regularly, and we are certainly committed to including our enforcement and compliance work, as we have done.

*Mr. Burgess. Will this task force report to Congress? Will we have -- I mean, you are getting the money outside of Congress. Do we get to know if you are doing any good or not?

*Dr. King. I can't speak for other Federal agencies, but I can assure you that the work of the task force that involves FDA would certainly be included in our reports and our ongoing efforts on this issue.

*Mr. Burgess. Since it was the fact that it just happened, that it has just occurred -- but historically your Center has not been good about keeping up with the reports. They are congressionally mandated reports that were as part of the enabling legislation that Henry Waxman passed when he was chairman.

I am going to submit some other questions for the record, Mr. Chairman.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Burgess. But I thank you. I will yield back.

*Mr. Guthrie. Thank you. The chair yields back, and the chair recognizes Mr. Sarbanes for five minutes for questions.

*Mr. Sarbanes. Thank you, Mr. Chairman. Thank you all for being here.

Obviously, one of the reasons for this hearing and for the legislation that we are looking at today, as we have seen in recent years, several challenges to the nation's food system, ones that have left consumers vulnerable to foodborne illnesses when these contaminated foods get onto grocery shelves, and something we have to address. And FDA, obviously, is in a position of needing to work hard to protect the public health, and we need to work hard here to make sure we get to the agency the tools that you need to carry out that mission.

States are a critical partner, as you know, in FDA's efforts. They conduct 60 percent of food processing inspections annually. However, a lack of information sharing between FDA and its state and local partners has often slowed down responses to these food safety crises and contributed to the inefficient deployment of limited food safety resources.

As you know, one of the bills under discussion today, the Federal and State Food Safety Information Sharing Act, is trying to fill these gaps by allowing FDA to share food

safety information with state, local, and tribal regulatory agencies.

Mr. Jones, could you highlight how the authority that this would provide would enhance our food safety system and more efficiently use food safety funding by avoiding these duplicate inspection regimes?

*Mr. Jones. Thanks, Congressman, I appreciate the question.

So yes, we have had numerous experiences over the years where, under our statute, information that we are getting in the process of an investigation is considered commercial, confidential information, and we are unable to share that outside of HHS.

As you mentioned, in the food safety system states are a critical partner, and our inability to sometimes share confidential information with them delays the speed with which, collectively, we can manage an outbreak. So if we were able to share this information with the state, they may be able to actually take it -- take an action more quickly than we are. And this can be information as simple as the customer list of a company that we are working with, or the supplier list. And our ability to share that information can really speed the pace of managing a recall.

So we have actually been working with our colleagues in the states to identify legislative change that could

potentially -- that could deal with this issue.

*Mr. Sarbanes. Terrific. I am also glad to see FDA's work effectuating what Congress tasked it with under the Food Safety Modernization Act. FDA's final food traceability rule implements findings from a collaborative approach to improve and standardize record-keeping across the supply chain, which makes it easier to identify the origins of foodborne illness and stop these outbreaks.

I don't quite understand why our Republican colleagues want to work against that effort, but there is this bill they have proposed, the Food Traceability Enhancement Act, which, to my mind, would gut and needlessly delay this rule by requiring FDA to pilot a traceability system without lot codes, even as industry leaders are already initiating steps to meet the requirements by the rule's January 2026 effective date.

So could you briefly comment on why the lot codes are important or necessary for an effective food traceability system, and the impact across the board, be it for producers who are already complying with the rule or our Federal health agencies?

And what would happen if FDA was not permitted to require retailers to supply lot code information?

Actually, I was looking at a COVID test a few weeks back, and went on the Internet to see if it was still good,

and they asked me to look at the lot code, so I have gotten more familiar with this, too. But talk a little bit about why that traceability is so important.

*Mr. Jones. Thanks, Congressman.

We all want to be able to, when a foodborne illness event occurs, be able to quickly shut it down, which means basically tracing that food from the consumer to the retailer through distribution to -- whether it was a factory or, ultimately, a farm. And the key to that is the lot code.

Now, one of the real challenges of this rule is that every part of the supply chain has to be in compliance for it all to work. But the key element to it is the lot code. If you don't have the lot code, you are going to end up pursuing information that is going to take you to a lot of dead ends. And that is what we do today. We actually will -- we will get to the distribution center. We will have to follow multiple different leads, many of which are, as I said, dead ends before you find ultimately where the source of the contaminated product is.

*Mr. Sarbanes. Thanks very much, I appreciate it.

I yield back. Thank you.

*Mr. Guthrie. The gentleman yields back.

And before I move on I would like to seek unanimous consent to insert into the record a letter from -- to the FDA for Majority Leader Steve Scalise of Louisiana dealing with

shrimp imports and inspections. And I have shared that with the Democrat staff.

And I would also like to seek unanimous consent to insert in the record a Politico Pro article citing a 25 percent decrease in underage vaping, and unanimous consent for an article from the National Association of Convenience Stores dealing with policy concerns relating to the Center for Tobacco Products. And I shared that with staff.

So without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Guthrie. And the chair will now recognize the chair, Chair Rodgers, for five minutes for questions.

*The Chair. Thank you.

Mr. Jones, you stated in your testimony any substance that will be added to food is subject to pre-market approval by the FDA, unless it is generally recognized among qualified experts to be safe under conditions of its intended use. Therefore, industry is expected to submit a pre-market safety assessment.

I no longer hear so much about vaping when I am at home. I feel like we have made some significant progress. Now school superintendents are showing me the THC-filled food, packets of candy that they have confiscated. In 2022 over 30 percent of the 12th graders reported using marijuana in the last year. And it is creating concerns, parents are worried.

Mr. Jones, has the FDA determined that THC is generally recognized as safe?

*Mr. Jones. No, we have not.

*The Chair. Has anyone submitted a pre-market safety assessment for THC, and has the FDA approved a pre-market safety assessment?

*Mr. Jones. I can't speak to THC. I don't believe one has been submitted. We have had a number for CBD, but they have not been approved as food additives.

*The Chair. So it is accurate to say that any food on

the market today that contains THC is a violation of the Food, Drug, and Cosmetic Act.

*Mr. Jones. That is correct.

*The Chair. Has the FDA taken any action against those making, distributing, or selling food and beverages that include THC?

*Mr. Jones. I am not certain on THC. I know on CBD we have taken numerous actions.

*The Chair. Could the FDA seize those products, like I just mentioned, issue fines against manufacturers and distributors?

What additional authorities do you have to take action against foods containing THC?

*Mr. Jones. We can certainly remove those products from the market.

*The Chair. When the FDA is inspecting convenience stores or working with states to do so, if an inspector sees food marketed that contains THC, what is the inspector instructed to do?

*Mr. Jones. I would have to check with the field office on that. I expect that they would ultimately issue a report that would then be followed by a compliance action.

*The Chair. Are you aware of these products in our schools right now?

*Mr. Jones. I can't say that I am aware of products in

the school. I have certainly read about them in schools, in various retail operations, but I can't say I have direct knowledge.

*The Chair. They are pretty common where I live right now, in eastern Washington.

Does the FDA lead on enforcement or does Drug Enforcement Agency get involved?

*Mr. Jones. It really depends. There definitely is joint jurisdiction on this, and so we would work with our Federal law enforcement colleagues.

*The Chair. The FTC has sent warning letters. Would you -- when do they get involved?

*Mr. Jones. I can't say I have got direct knowledge of the FTC engagement on this particular matter. I would have to get back to you on that.

*The Chair. Well, I would like you to get back to me on some of these questions.

And do you have any words for parents or schools that are trying to figure out what to do and what they should -- who do they report to if they are seeing these products in the schools?

*Mr. Jones. I think that the -- report to local law enforcement, as these are not legal products.

*The Chair. So what is the role of FDA?

*Mr. Jones. So, I mean, we do not have even remotely

the same presence in communities as local law enforcement do. These ingredients used in food make the food adulterated. We have opportunity periodically to take them off the market. But again, we are not going to have nearly the presence in communities that local law enforcement would have.

*The Chair. Well, you have a responsibility to make sure that products are safe, and I would like you to look at what is going on and what action you are taking.

Dr. King, while I don't hear about vaping as much in my district, any use of tobacco products by middle and high schoolers is -- high school students is problematic. A study published earlier this year in tobacco control showed that Internet sales helped those under 21 get tobacco products. For example, a discreet shipping service on TikTok helped kids evade age restrictions. I am hopeful that innovation and products themselves can lower youth sales, whether in person or online.

A number of companies have publicly announced that they have submitted PMTAs for products that require age verification on a smartphone to be used. If the FDA were to authorize a product with such technology, would a company need to submit new PMTAs for each individual product they intend to sell with the same age verification technology?

And does anything stop the FDA from prioritizing applications with innovations such as these?

*Dr. King. So I would say that it is application-specific. We welcome innovation, including age-gating technology, but it would depend on the merits of the application to make a determination about authorization.

*The Chair. Okay. Well, I have run out of time. More questions. I will follow up.

[The information follows:]

**********COMMITTEE INSERT**********

*The Chair. Thank you for being here.

I yield back.

*Mr. Guthrie. The chair yields back, and the chair will now recognize the Ranking Member Pallone for five minutes for questions.

*Mr. Pallone. Thank you, Mr. Chairman.

Over the last decade we have witnessed the emergence of a youth tobacco epidemic, spurred on by the proliferation of cheap, slick, and flavored e-cigarettes and other kid-friendly products that are intended to hook young people onto a lifetime of nicotine addiction and give the tobacco industry its next generation of customers. And that is why FDA's work here is so critical, because the agency has the important responsibility of determining what tobacco products should be available on the market for the protection of public health. And I remain concerned that, despite that mandate, there are thousands of unauthorized tobacco products sitting on store shelves.

So let me ask Dr. King, why do thousands of illegal products remain on the market, even though FDA has only authorized the sale of roughly three dozen e-cigarette products?

*Dr. King. So very succinctly, there is three major factors.

One is the sheer size of this marketplace, which is

unprecedented. We alone have received applications for 27 million products.

We also need time to conduct investigations, which requires resources, which -- why we need more.

The latter is also the legal implications. And in order for us to seize products, that would require thousands and thousands of individual seizures that would then result in thousands and thousands of cases in Federal district courts across the country, which would be untenable.

And so the realities are that we continue to make progress, we are making a dent. We have done a lot of first-of-their-kind actions, but we need more resources and we need other agencies to step to the table, as well.

*Mr. Pallone. Well, let me ask how many pre-market tobacco applications are currently pending before the FDA, and has FDA taken any enforcement action against manufacturers with pending applications or only those with marketing denial orders?

*Dr. King. We have received close to 27 million and we have resolved over 26 million. There is about 500,000 pending related to e-cigarettes.

With regard to your question on enforcement, 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, and we base those actions based on the

merits of the individual evidence collected.

*Mr. Pallone. All right, so in 2022 we provided FDA the authority to regulate synthetic nicotine products, closing a loophole that the industry was using as a way to evade regulation. So Dr. King, why hasn't FDA issued a marketing order for a single synthetic nicotine product, while thousands of these products remain on the market?

*Dr. King. We haven't issued an authorization because no applicant has provided sufficient evidence to meet the necessary scientific bar. And we continue to take enforcement action against these products, and have issued hundreds of warning letters and done dozens of civil money penalties, and those will increase with time.

*Mr. Pallone. But, you know, Congress was clear, I think, in the requirements laid out in that statute. And I am obviously disappointed by the lack of progress.

So FDA -- it just seems it has to move more quickly to clear the market of all these unauthorized products. And I -- look, you know, as you know, I am the biggest advocate for more resources and more authority. But you know, it is hard to make that case if we don't see some progress on moving. You know, we have Representative McClellan's bill to enhance tobacco user fees, and hopefully that is going to make a difference. But, you know, I hate to say it, but, you know, maybe if you can respond to -- I mean, you just make it seem

hopeless to me. I mean, should I -- is there some hope here that we are going to be able to achieve some of these goals? I feel like you are kind of pessimistic.

*Dr. King. Oh, I have been called many things, but never a pessimist. I am very optimistic over this, and we have made great progress. We have completed 99 percent of the applications, we have issued many first-of-their-kind actions, and youth e-cigarette use is plummeting nationally. So I am very hopeful. And if we had more resources, I am hopeful we could do more.

*Mr. Pallone. So the key, in your opinion, is more resources. And obviously, I am very supportive of that. So thank you. Thanks so much.

I yield back, Mr. Chairman.

*Mr. Bucshon. [Presiding] The gentleman yields back. I now recognize Mr. Griffith for five minutes.

*Mr. Griffith. Mr. Jones, I know you are in a tough spot, and you are trying to come up with questions, but tell me what authority a local law enforcement has to pull a product off the shelf in a convenience store. Because I don't know of any authority they would have in Craig County, Virginia or Lee County, Virginia. Where are they going to get this authority?

And once they pull it off, don't they have to know what the chemical makeup is?

So now we are going to have to deal with the forensic labs trying to determine if there is actually CBD or THC in the product. I mean, you told Mrs. McMorris Rodgers that was the answer. I am telling you it is not the answer. It won't work.

Besides being under-staffed themselves, local law enforcement has no authority to go in there and start yanking products off the shelf, particularly if it is a retailer who is multi-state. So tell me where you got that theory from.

And I understand you are under pressure. And maybe it was just an idea that popped in your head, because I am going to come up with an idea in a minute that just popped into my head that might not be any good. But you are here testifying, so I don't understand your answer.

*Mr. Jones. I believe that THC in a product would be a class 1 drug.

*Mr. Griffith. Whoa, whoa. That is if you know there is THC in the product. Just because it says so on the outside doesn't make it so. And until they buy the product, have it tested in the forensic lab, which is way behind working on lots of other things, particularly in the criminal setting, then they get it back and by that time they have changed the brand name of the product, and there is no way the local -- there is no way local law enforcement can do what you said that they ought to do. It can't happen. And

just understand, as I say that, I practiced in the local criminal courts for almost 30 years, and that is just not going to -- that dog will not hunt.

All right, Dr. King, so one of my questions is you have had 25 million applications -- we are talking about tobacco and that program -- for products to be authorized, and the vast majority are for e-cigarettes and smokeless tobacco, which is a lower-risk alternative to smoking. And my understanding is you have completed the review, the FDA has completed its review on 99 percent of them, but only about 50 total applications have actually been approved.

So here is the problem I am having. If we wanted to use some alternative, if we want to go to enforcement, how do you enforce something where you only -- you have had 26 million applications, but you have only approved about 50 of them, even though you reviewed 99 percent of those 26 million. How are you supposed to enforce it when you have only authorized 50, about 50?

*Dr. King. Well, I will say it is the responsibility of the applicant to meet the bar with submitting applications. And so we have authorized 34. So it is possible to meet that bar. And those that have to --

*Mr. Griffith. Thirty-four out of twenty-six million you have authorized. So you are saying it is the industry's fault that you all haven't gotten your work done?

*Dr. King. It is the responsibility of the applicant to provide the evidence, and that is as prescribed by law by Congress. I did not write the law, but I am responsible for implementing it, and we are required to review pre-market --

*Mr. Griffith. So you are saying all but 34 have failed to present you with the evidence to authorize it, even though you --

*Mr. Jones. No, the 34 --

*Mr. Griffith. -- reviewed 99 percent of them.

*Mr. Jones. The 34 have met the standard bar and the others have not.

*Mr. Griffith. Right.

*Mr. Jones. And we have issued guidance and a final rule articulating what is needed to meet that bar. And it is possible, but a vast majority of the applicants have not met that scientific standard that was intended by Congress.

*Mr. Griffith. So you are saying there needs to be a legislative fix, and it is not just on the fee side, it is -- we have to make it easier for you to put out --

*Mr. Jones. No.

*Mr. Griffith. -- authorize products?

*Mr. Jones. No. As a scientist, I think that a scientific bar is critical, and I think Congress got it right in requiring that scientific standard to make sure that the products we are authorizing are meeting the appropriate for

protection, health -- protection of public health standard that Congress --

*Mr. Griffith. Hear is the frustration I have with that. You would agree, would you not, that the e-cigarettes and smokeless tobacco present a lower risk. I am not saying they don't have any risk, but they present a lower risk than smoking.

*Dr. King. As a general product class, correct, yes.

*Mr. Griffith. So why would the science make it so hard to get those products approved?

*Dr. King. Because they are required to submit individual evidence to the FDA to review to meet the standard that Congress intended. And so, although a general product class, they are indeed lower risk, we are required by law to review the individual merits of the application to make sure that product is the case.

*Mr. Griffith. But you just said to me you didn't think the standard should be changed.

*Dr. King. I did not. That was your words. I don't think the standard should be changed. I think Congress got it right, and I think we need scientific --

*Mr. Griffith. That is what I understood. That is what I just repeated to you, that you don't think the standard should be changed, but the standard we set up is keeping the safer product off the market according to you --

*Dr. King. No, I --

*Mr. Griffith. -- as opposed to the unsafer product, which is the smoked cigarette.

*Dr. King. No, I don't think that is correct. I think what it is doing --

*Mr. Griffith. So you think smoked cigarettes are better.

*Dr. King. -- protecting public health by having a scientific standard and evidence used to determine what should be authorized. I think science --

*Mr. Griffith. How do you protect public health when you want to have the less safe product not on the market and the more harmful product, the cigarette, out there on the market without making it easy to get the less safe product?

*Dr. King. The different pathways were prescribed by Congress for the pre-market review application.

*Mr. Griffith. All right.

*Dr. King. We apply the appropriate --

*Mr. Griffith. Let me just say this -- and I know my time is just about up, so I apologize -- you know, Mr. Chairman, we may want to look -- and it is one of those crazy ideas that Mr. Jones -- like Mr. Jones had, but I think it might be something we need to look at.

If we can get the authorization done correctly on some of these other products, maybe we need to look at private

right of action because, particularly with CBD, my wife is a juvenile -- judge dealing with juvenile cases, and she has seen cases where there is apparent brain damage from products bought at convenience stores with CBD and others. And I think maybe we need to look at private right of action because we can let the trial lawyers solve our problem on enforcement.

I yield back.

*Mr. Bucshon. The gentleman yields back. I recognize Mr. Cardenas for five minutes.

*Mr. Cardenas. Thank you very much, Mr. Chair, and also Ranking Member Eshoo for holding this hearing to discuss FDA's work in food safety and tobacco products.

I would also like to thank Deputy Commissioner Jones and Dr. King for your testimony and your work to ensure the products are -- everyday Americans -- are purchased that are safe.

I appreciate the opportunity to discuss the proposals included in today's hearing, because I feel strongly that families should trust the safety of the items they purchase. Deputy Commissioner Jones, in your testimony you shared that, "By working collaboratively with our stakeholders we are better positioned to meet our shared public health goals.'' I hope my colleagues hear -- I hope that they hear that message clearly. We should be looking to advance proposals

that foster collaboration, not reverse the progress we have made. Unfortunately, some of the proposals put forth by my colleagues seek to undermine, delay, and dismantle progress.

From farm to table, Congress, FDA, industry, and all others involved in our food safety system have a responsibility to provide food that is safe -- safe, plain and simple. Our constituents trust us to do our due diligence and work together to accomplish these goals.

However, the crisis families across America experienced two years ago with infant formula shortages serves as a lasting reminder of just how important it is that we work together. The disastrous events that led to the disclosure of Abbott Laboratories in the Sturgis, Michigan facility, and similarly troubling reports of contamination in baby food pouches have made it clear that more action is needed.

I am concerned that, despite these clear signs, we still have not given our public health agencies the tools to ensure the safety of infant formula and food. The FDA has informed us that the inability to remotely request records delayed the agency's response to complaints about adulterated products from Abbott Laboratories.

As a father and grandfather, let me be clear. When it comes to the safety of our children, delays are unacceptable, which is why I am grateful to co-lead the INFANTS Act with Representative Sykes and Ranking Member Pallone this Congress

to take crucial steps to address this issue. The INFANTS Act would give the FDA the ability to request remote records and to require infant formula manufacturers to productively -- excuse me, proactively report positive test results for certain pathogens within 24 hours. These provisions would help the agency prioritize its inspection resources and address contamination problems when they first arise.

As Congress considers strategies to ensure our food safety, it is essential we learn from the mistakes of the past and strengthen the system moving forward. Commissioner Jones -- Deputy Commissioner Jones, does the FDA currently have adequate resources and authority to take proactive measures to prevent the incidents and delays experienced in 2022?

*Mr. Jones. Thanks, Congressman. We have brought together teams of both inspectors and program staff that we believe allows us to be very effective in the infant formula space. It has been a significant investment of resources on our part, but is a reflection of just how important we think -- and how critical this food is for the most vulnerable of our citizens, which are infants.

*Mr. Cardenas. Okay. So do you feel that -- do you have the adequate resources?

This a vast country with a lot of products on any given moment that could be in question. Do you feel that it is

adequate, or you are describing that it has improved?

*Mr. Jones. For infant formula, I feel like we have adequate resources. We have taken those resources from other parts of the food program --

*Mr. Cardenas. That was going to be my next point.

*Mr. Jones. And I think we have -- also, we have identified some of the statutory changes that you identified that would make that job actually more -- we would be more efficient in the execution of that.

*Mr. Cardenas. Like I said, it is a vast country, and there are many, many responsibilities of the FDA. And it is unfortunate that Congress forces you to actually move resources from one end to the other, which probably and very likely -- we don't want all of you in front of us -- but very likely is causing the inability for FDA to keep up with the other responsibilities that it has. Thank you very much.

What are the current challenges in holding manufacturers accountable for contamination in infant food products?

And how could mandatory testing and enhanced reporting requirements address these issues?

*Mr. Jones. So this speaks to the issue that has been spoken to this morning a number of times: the lead contamination of an apple puree product, a food commonly consumed by children. The Administration has asked for legislation that would mandate manufacturers of food that are

commonly consumed by children to test for before putting into commerce the types of lead, chromium, other heavy metals. So we would not have to catch someone breaking the rules, they would have to be testing and reporting to us so that we would be able to ensure those products never got into the market.

*Mr. Cardenas. I will be brief, Mr. Chairman.

*Mr. Bucshon. Yes.

*Mr. Cardenas. So basically, catching someone after means that a child may have been -- an infant may have been harmed already, or many infants have been harmed.

*Mr. Jones. That is correct.

*Mr. Cardenas. Yes, that is not a good system. We need to figure out a system and give you the resources to do it prior.

Thank you very much, Mr. Chairman, I yield back.

*Mr. Bucshon. The gentleman yields back. I now recognize myself for five minutes.

I am going to ask unanimous consent to put a statement in the record on behalf of Congressman Garret Graves as it relates to H.R. 4547.

Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Bucshon. Dr. King, clearly, several of us are perplexed by CTP's handling of the PMTA process. Yes, you have resolved a respectable number of pre-market tobacco product applications, but the agency seems to have made no effort to prioritize those applications that should be most important, either because they affect the greatest number of people or because they have most promise in providing safer alternatives to those who wish to quit smoking combustible products.

I was a doctor before, by the way.

That is a little discouraging. Do you -- harm reduction is important. Would you agree?

*Dr. King. I think harm reduction is one important component to reducing the risk of tobacco products nationally, yes.

*Mr. Bucshon. Yes, I would agree with that.

Also that even after four years there must be several hundred thousand PMTAs waiting for your office to resolve them, despite clear instructions to process in 180 days. And I understand you say you need more resources, but we need to do better trying to move those along.

As you know, the other FDA product centers are transparent about their review times. Will you -- can you commit to also publicly posting average times and range of review times for pre-market tobacco product applications and

modified risk tobacco products?

*Dr. King. I can commit to making sure that we eventually get to the 180-day statutory deadline intended by Congress.

There are different considerations related to the merits of individual applications. Some are nearly a million pages.

*Mr. Bucshon. Yes.

*Dr. King. And so there is not any single timeline that can be prescribed across the board to get them done. But we are committed to getting to the 180-day as quickly as possible.

*Mr. Bucshon. Yes, I would imagine you are, and I am not being critical of you personally on that. I know that everyone is working as hard as they can to try to make that happen.

Mr. Jones, I understand the FDA is preparing a long-term national infant formula strategy as required by Congress, and it will be submitted later this year. As you develop this strategy, I am curious whether you are engaging with manufacturers to identify evidence-based practices that can be implemented to maximize infant formula safety and supply.

I ask this because I am aware that previous FDA actions in this space, including a March 8, 2023 letter subjecting the industry and its dairy suppliers to new requirements for wet cleaning and powdered infant formula plants has been met

with some criticism and some confusion. My concern is if you don't enact practices that the U.S.-based industry can or will comply with, more products -- production will shift offshore, and then we have even less control or insight over the formula on our shelves.

So are you working closely with industry on this strategy?

*Mr. Jones. Thanks, Congressman. So, as you noted, we are going to have a long-term strategy for infant formula --

*Mr. Bucshon. Yes.

*Mr. Jones. -- that is due out at the end of this calendar year.

We are working specifically with the manufacturers on the issue that you referred to, this wet cleaning versus dry cleaning.

*Mr. Bucshon. Yes, and it is an important issue. Specifically, I believe there is a need to discuss with them the value of high-frequency testing, the impact of corrective action on contamination events, and evidence-based recommendations for enhancing infant formula safety and supply. I mean, obviously, it was a -- it is a critical issue.

Also, since I have some time, Dr. King, in your testimony -- I think it was Dr. King -- you cite the need for legislation to increase user fees, adding over 114 million to

CTP's budget in line with Representative McClellan's recently-introduced legislation. I support revisiting tobacco user fees and addressing significant changes that have occurred in the industry over the last 15 years, but I think we maybe need some additional accountability from the agency.

At a minimum, we need some performance metrics from CTP. How specifically would the agency use funding to do things like clean up the market of illicit products, authorize new products, switch adult smokers away from combustible cigarettes to less harmful alternatives, and continue to combat youth use?

*Dr. King. So for the 114 million, we propose dedicating about half to enforcement and compliance, 25 percent to application review, and about the remaining 25 for education to the public, which could include reduced risk alternatives to smoking.

*Mr. Bucshon. Okay, good. And you probably know that our committee has -- oversees the user fee processes for prescription drugs and medical devices, among other things, and it is generally perceived as quite effective. Those processes involve the FDA and the private sector sending individuals to negotiate terms every five years and bringing it to Congress for approval. I don't see why we shouldn't use a model similar to that. Do you?

*Dr. King. I think Congress got it right the first time around tobacco products use. I don't think we need to fix a broken wheel, we just need to grease the squeaky one. And that includes bringing the current user fees structure to include e-cigarettes.

We have reporting structures. We continue to update Congress on our progress, but I don't think we have a broken process. We have just got to update it to reflect the marketplace.

*Mr. Bucshon. Okay, fair enough. I yield back. I now recognize Mrs. Dingell for five minutes.

*Mrs. Dingell. Thank you, Mr. Chair, and thanks to the majority for holding this important hearing regarding the FDA.

The FDA plays a critical role in ensuring the safety of our food supply, including for our youngest Americans. It is vital that the FDA provide parents and caregivers with the resources and information that they need to provide our children, our babies, nutritious formula that supports healthy growth.

For many families, formula isn't a choice. It is a necessity for the health and well-being of their baby. Families must be able to find safe and affordable formula in their local grocery stores, and we must give our Federal agencies, including the FDA, the tools that they need to keep

formula on the shelves.

So Mr. Jones, there is a need for increased oversight of safety standards for infant formula, especially in light of the 2022 closure of Abbott Laboratories in my home state of Michigan as a result of an FDA investigation that uncovered several violations, including bacterial contamination. The resulting shortages caused a crisis, and we all know what that crisis was -- parents were just in total panic -- that forced families to wonder how they were going to feed their children. I will not forget that time ever in my life.

The INFANTS Act would give the FDA authority to request sampling and testing records. It would also require infant formula manufacturers to proactively report positive test results for certain pathogens within 24 hours, helping the agency to prioritize its inspection resources and address contamination problems when they first arise.

Can you elaborate on the FDA's current process that occurs after formula inspectors detect contamination in a formula sample?

And how would mandatory testing of formula and increased access to records improve the ability of the FDA to proactively respond to contamination and prevent another disastrous shortage?

*Mr. Jones. Thanks for that question.

So right now a manufacturer, when the infant formula is

within their control, if they are doing testing -- and we understand that they are doing routine testing on their facility. If they are to find a positive for Cronobacter, for example, they -- we have encouraged them to voluntarily submit that information to us, but they are not required to.

We have several examples of companies doing that. And what we have learned is that we are then able to quickly get in that facility, work with the manufacturer to figure out how to ensure that a positive sample inside the facility does not ultimately lead to contaminated product. Because you have a positive find of Cronobacter in a facility doesn't mean the product is contaminated, it means you found the bacteria somewhere in the facility.

So we know from experience that if a manufacturer voluntarily gives us this information, we are much more quickly able to get in that facility and work with that manufacturer to prevent a contaminated product from actually being manufactured and leaving the facility.

*Mrs. Dingell. So requiring it is a good thing.

*Mr. Jones. It would be a good thing, yes.

*Mrs. Dingell. Thank you. You also mentioned in your testimony that the supply of infant formula is still highly concentrated with a small number of manufacturers, which we all know, and that is what led to such a crisis last time, but that the FDA is prioritizing review of the new infant

formula submissions.

How is the FDA balancing the need to quickly diversify the infant formula market, while ensuring that the safety of supply is the top priority?

*Mr. Jones. Thanks again for that question.

So safety is the highest priority, but we have made it also a priority to bring resources to bear to the pre-market review process so that we are not creating unnecessary delays to a product that can meet our safety standards to getting onto the market. We have approved, since 2022, 19 new product infant formula products.

So again, safety comes first, but we are trying to ensure that the pre-market review that is required for any new infant formula product is occurring in a very timely manner.

*Mrs. Dingell. So are those new 19 going to be in the same plants that are already there, or are we also diversifying where they are being manufactured so we are protecting our supply and preventing what happened the last time?

*Mr. Jones. Many of the 19 are in the same plants by the same basic manufacturers, although we have had several products approved that are coming from not the two major, dominant manufacturers in the United States.

*Mrs. Dingell. Mr. Chairman, I am out of time, so I

yield back. Thank you.

*Mr. Guthrie. [Presiding] The gentlelady yields back, and the chair will now recognize Mr. Latta for five minutes for questions.

*Mr. Latta. Well, thank you, Mr. Chairman, and thanks to our witnesses for being with us today.

I would also like to thank the gentleman from Pennsylvania's 13th district for his work on the DAIRY PRIDE Act. I am glad to see it is on the -- one of the bills listed for today's discussion. This is important to accurately portray the difference between the dairy products produced by farmers across the country and those using misleading terms when labeling other dairy alternative products.

In 2013 I led the Safeguarding America's Pharmaceuticals Act, known as the Track and Trace Act, that was signed into law after Americans saw a drastic increase in counterfeit pharmaceuticals being imported in the United States. Since its passage much has been done to lower counterfeit and illicit medicines in the market.

We are now seeing the same illegal importation and use of vapor products flooding our streets and being deemed safe and FDA approved. This will only increase youth accessibility to nicotine products and fulfill a false sense of security for average American consumers. Since the

creation of the Center for Tobacco Products at the FDA in 2009, the list of products has exponentially grown.

Dr. King, what are you doing to address the illicit market in the United States today?

*Dr. King. Well, I think an important action that was recently taken was the interagency task force that was developed. I think a comprehensive approach is key. I think we have taken a lot of first-of-their-kind actions, escalated actions, over the past two years, but we need resources to do more, and I am committed to doing that. But we need everyone to put in their weight, and that includes other Federal agencies and ensuring we are well resourced.

*Mr. Latta. Let me follow up. What steps are being taken at the FDA in regards to avoiding these products from getting into the hands of American youth?

*Dr. King. So we take a comprehensive approach across the supply chain. It includes everyone from retailers and distributors to importers and also manufacturers. And we work closely with Federal partners, including Department of Justice and also Customs and Border Protection. We have had a lot of first-of-their-kind actions -- oh, and first -- distributor seizures, first manufacturer injunctions.

But again, we can do more, but we need everybody to come to the table, and we need to ensure we have got resources that reflect the profound nature of this marketplace in terms

of size.

*Mr. Latta. Well, let me just follow up on that, because I know you just said that you are working with all the departments, a lot of different departments and agencies out there, and there is more to be done. But when we are talking about more to be done, there is also like a timeline. Is there some type of a timeline that you are looking at to try to get this done by?

*Dr. King. There is no specific timeline, but I can assure you that we are committed to doing it as expeditiously as possible to protect the public health of this country. And I think we have got a lot of important foundational actions and escalated enforcement and compliance. But it is a diverse landscape, it is a very sizable landscape of products, and we need the resources to effectively combat it, and that is going to take time.

*Mr. Latta. Thank you. Last week the FDA and the CDC reported that in 2024 e-cigarette usage by middle and high school students was estimated at 1.6 million, about a 500,000 decrease from 2023's reported numbers. In 2022 the CDC reported that 30.7 percent of 12th graders reported using cannabis in the past year, and 6.3 percent reported using cannabis daily in the past 30 days. Dr. King does the FDA see a correlation between youth e-cigarette usage and youth cannabis use?

*Dr. King. So the cannabis use would not be under our authority, and I am not up to speed on the available science with regard to the substance use patterns for cannabis.

But I can tell you that FDA is concerned about any substance use among kids, and that includes both nicotine and tobacco products, but also cannabis.

*Mr. Latta. Well, thank you. Another question. What can FDA do to increase approvals with their pre-market tobacco application approval process in order to assist with getting safer alternatives to market in connection with harm reduction and reduce the growth of illicit -- of the illicit market?

*Dr. King. I will say briefly that one of the rate-limiting factors is the quality of the science being submitted by the applicants. We are seeing an improvement over time.

I will say, for FDA's part, we are committed to engaging with industry. We just had a public meeting last year that engaged with industry to make sure they were aware of what is needed, and to ensure that the quality of the applications increases to ensure they meet that scientific bar that is needed.

We have got a lot of other activities underway, consistent with our five-year strategic plan that I am hopeful will continue to see engagement with industry and

increase the number of folks who are meeting that scientific bar prescribed by Congress.

*Mr. Latta. Okay, thank you, and I look forward to working with my colleagues to fix the backlog of products awaiting approval to legally sell in the marketplace and to stop the importation of illegal tobacco products.

And with that, Mr. Chairman, I yield back the balance of my time.

*Mr. Guthrie. Kuster just showed up.

Thank you. The gentleman yields back, and I think Ms. Kuster -- are you -- Ms. Kuster from New Hampshire is recognized for five minutes for questions.

*Ms. Kuster. Thank you, Mr. Chairman, and thank you, Ranking Member, for holding this important legislative hearing. I am pleased that my legislation, the DAIRY PRIDE Act, which I co-led with Representative Joyce, is being considered today.

Deputy Commissioner Jones, looking at a peer-reviewed article published in the Journal of Pediatric Gastroenterology and Nutrition, the article discusses the adverse effects that substituting plant-based beverages, which are deceptively labeled as milk, with real dairy products can have on young children. These adverse effects include failure to gain weight and major nutrition deficiencies. I am concerned that parents, who are working

hard to raise healthy young children, may be misled by plant-based beverages that are labeled like nutritious milk, but don't provide the same health benefits.

My first question to you, what steps is the FDA taking to make sure that parents know about the adverse health outcomes caused by substituting real milk for plant beverages?

*Mr. Jones. Thanks for that question.

We issued draft guidance recently that reflects that we know from the surveying that we have done that consumers are not -- they are not confused about alternative plant-based products. They know that they are not actually milk, even if they have milk in the name. But we also have learned from that survey that individuals generally are not aware that plant-based alternatives are often nutritionally not equivalent to milk.

So this draft guidance basically encourages manufacturers of plant-based alternatives to provide such nutritional information about -- nutritional differences between a plant-based alternative and milk. Ultimately, we will finalize this guidance based on what we get back from comments from stakeholders in the industry, as well as in the consumer interest community.

*Ms. Kuster. Thank you. While I believe the FDA has done good work in this space, I know that so many public

health organizations, including the American Academy of Pediatrics, have urged the FDA to remove the term "milk'' from plant-based beverages. I would like to work with you and this committee to get this done this year before I complete my service in Congress.

Deputy Commissioner Jones, I am also interested in your other efforts to safeguard infant nutrition. Since the infant formula recalls of 2022, I have expressed my concern to the FDA regarding the lack of oversight of human milk nutrition for infants. From my ongoing conversation and correspondence with the agency, I am concerned that the vast majority of donor human milk banks and products are actually unregulated by the FDA. This lack of oversight poses a risk to infant health and to a stable supply of nutritious food for infants.

Can you tell me what progress the FDA has made or, alternatively, what assistance you need from Congress to properly regulate non-profit human donor milk banks?

*Mr. Jones. Well, currently, such milk banks are not within our purview. They are not required to be registered facilities in the FDA world, and so authorization to allow that would be necessary for us to regulate them in the way I think you are referring to.

*Ms. Kuster. Okay, thank you.

Director King, I would like to turn to you. The FDA has

authorized 34 e-cigarette products, but stores across New Hampshire and the nation continue to sell unauthorized, illegal products. One way the FDA could crack down on illicit e-cigarettes is by taking enforcement action against all parties in the supply chain.

A recent report by the Reagan-Udall Foundation suggests high-profile enforcement actions against wholesalers and distributors who are handling illegally-marketed products could help clear the downstream distribution pathways of illegal products.

I understand the FDA has taken some enforcement actions against the wholesalers and distributors who are handling illegal tobacco products. What resources do you need to step up these actions and keep illicit tobacco products off store shelves?

*Dr. King. So I completely agree with you that distributors are a key conduit for action. That said, we work very closely with Federal partners. As you may know, we recently had a $700,000 seizure in California of a distributor in coordination with the Department of Justice.

That said, if we had more resources we could do more. We are currently requesting 114 million, and I would say half of that is estimated to be towards enforcement and compliance, which could include coordination with other Federal agencies.

So it is a point well taken, and I agree, but we need the resources to optimize the work.

*Ms. Kuster. Thank you so much.

And with that I yield back.

*Mr. Guthrie. Thank you. The gentlelady yields back, and the chair will recognize Mr. Hudson of North Carolina for five minutes for questions.

*Mr. Hudson. I thank the chair.

And hi, Dr. King, thank you for being with us here today. Last month I sent a letter to the President and to Commissioner Califf on the harm reduction and pending applications for smoke-free tobacco products. I was joined by over 60 of my colleagues. I emphasized the need to speed up this process and stop politicizing the issue. I firmly believe adult smokers and nicotine consumers deserve access to harm-reducing products.

But here is my concern. Millions of illegal products are on the market, targeting our youth, while some legitimate companies have been waiting for years for review or even a word from FDA about their application. The illicit market has been enabled by the Center for Tobacco Products's lack of action.

I was a tobacco user myself for almost 40 years, and I tried many times to quit the product without success, but I have been off since non-combustible nicotine products were

introduced to me as an alternative, as -- it was three years, August 3. These products work for me, these new alternatives.

Yesterday I received a non-answer to my letter. Frankly, I was disappointed. It was a lot of broad talking points, rather than specific solutions. It seems the FDA is focused on complete prohibition of rather than a safer alternative for these tobacco products. I disagree. I believe that more authorized products are needed to help others on the same journey that I myself have been on.

The fact is the inefficiency of CTP has driven an illicit market that has been filled by China. While much of the focus on enforcement has been on the vapor market such as e-cigarettes and disposables, there has been a dramatic rise in illicit or counterfeit nicotine pouches. The agency has finally gotten around to proposing a rule to try and limit this deluge of illicit e-cigarettes from overseas. But why has CTP chosen to limit the scope only to e-cigarettes? Half measures are kind of what got us in this mess in the first place.

So I would like to know why other safe alternatives like smoke-free product types were not included. Has CTP authorized any nicotine pouch product for the U.S. market?

*Dr. King. To date we have not issued an authorization for a nicotine pouch product, but we have issued multiple

authorizations for oral nicotine products. That said, I am fully supportive of lower-risk alternatives, but it is the responsibility of the applicant to meet the scientific bar.

*Mr. Hudson. Right. So what year was the first nicotine pouch product filed?

*Dr. King. I am not privy to the specifics. We would have to get back to you on when it was submitted.

*Mr. Hudson. I would appreciate that.

When looking at enforcement actions, what -- does CTP plan to differentiate between pouch products that are playing by the rules and have filed for authorizations and those that are on the market illegally?

*Dr. King. So I will say that simply submitting an application doesn't garner a safe harbor, but we have taken enforcement action against nicotine pouch entities who are breaking the law. We released a series of warning letters and also civil money penalties earlier this year, and we are committed to continuing to do that for those who do not have authorization.

*Mr. Hudson. That is great. I do think the FDA should help the market differentiate between the actors who are trying to play by the rules and those who aren't even making an effort.

Three months ago DoJ and FDA established the task force that we have talked about a little bit today already to

prevent illicit products in this market. In a Senate Judiciary hearing a few months ago where you testified DoJ said this issue is the agency's number-one priority. It is concerning to me that we aren't even able to figure out who is leading that task force.

So your office has issued warning letters and seized the legal products at the border, as well as a couple of legal actions. This is progress, but it is clearly not close enough. You have issued warning letters to about 90 retailers, but there are over 6,000 retailers just in Maryland alone, where the FDA is located. You seized about $1 million worth of illegal vapes, but analyst reports say the U.S. market for disposables is worth over $2.4 billion, and $2.4 billion of illegal products on the market is a staggering number. And when weighed against your warning letters and seizures, you have addressed less than 0.0005 percent of the illegal market.

I think Mr. Guthrie made a good point in his questioning. With your limited resources, you ought to prioritize the bigger actors, the manufacturers, the importers, the distributors. The task force should have a pretty good idea of who the largest importers and distributors of these products are. So I know Mr. Guthrie asked are you going after these larger actors.

Have you personally attended any of these task force

meetings?

*Dr. King. No, I am not on the task force, but I am regularly briefed on the proceedings.

And again, the task force just formed. They meet many times, and I am hopeful that now that we have got everyone on the table with responsibility in this space, that we will see a continued momentum in --

*Mr. Hudson. Has the task force met in person, or are these virtual meetings?

*Dr. King. Person, in person.

*Mr. Hudson. And I would -- I am running out of time, so I will submit some more questions for the record.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Hudson. But I would like to underscore a point that I think Mr. Latta made, which is there ought to be a timeline. The task force ought to have a timeline developed, a plan and implementation timeline to act against manufacturers and distributors of these products. If you have limited resources, I would focus those resources on the bigger actors. You don't have time to go to every mom and pop in America, but if you focus on who are the major importers and distributors of these illegal products, let's go to the source. I think we will have a lot more success, so I would encourage you to do that. I would encourage you to push the task force to do that.

*Dr. King. No, I appreciate the input. Thank you.

*Mr. Hudson. Thanks. With that I yield back.

*Mr. Guthrie. The gentleman yields back, and the chair will now recognize Dr. Schrier.

Dr. Schrier, you are recognized for five minutes for questions.

*Ms. Schrier. Thank you, Mr. Chairman, and thank you, Ranking Member Eshoo, and thank you to both of our witnesses today. I would like to touch on two topics: infant formula and highly addictive nicotine products. We will see how far I get.

As a pediatrician I have seen firsthand the vulnerability and fragility of extremely premature infants,

rescuing them in the delivery room, rushing them to the neonatal intensive care unit. And these extremely premature infants, often less than six months gestation and weighing around half a pound, are at risk for a whole host of serious complications, catastrophic complications. And so there needs to be careful attention from -- everything from ventilator management to feeding to skin care.

And especially for these really fragile preemies, there is no question that the absolute best and safest nutrition is breast milk. And this isn't just the version of "best'' that we talk about with term babies, this is best like lifesaving. And breast milk helps prevent specifically one of the most dangerous conditions in extreme preemies called necrotizing enterocolitis, or NEC. When there is no access to mom's milk or donor milk, sometimes these babies just have to be given specialized formula.

Now, only two companies produce formula for premature infants in the United States, and we all saw the devastating consequences of the infant formula shortage a couple of years ago. The potential risk of market instability for preemie formula is even higher due to limited suppliers for a very, very small patient population.

So Mr. Jones, this question is for you. I was wondering if you could just talk about the impact to clinical care for these very low-birth-weight, extremely premature babies if

these -- one of these two cow-milk-based pre-term infant nutritional products were to leave the U.S. market.

And then also, if you could touch on it, are there FDA barriers to getting donor breast milk to these high-risk infants?

*Mr. Jones. Thanks for that question. We are very concerned about the potential for -- we don't -- we do not know that it will happen, but the potential for one or both of the manufacturers to leave that market for business reasons, so that is very concerning to us.

Secretary Becerra has asked the -- our colleagues at the NIH to pull together a group of experts, neonatologists and others, to give him a report about the risks and the benefits associated with these products. That report is due to the Secretary next week.

*Ms. Schrier. Thank you for doing that, because it feels like there should be some requirement for a minimum amount of time notice in order for the other to ramp up, and I would love to continue the discussion with you about making it easier to use donor milk.

I wanted to turn to e-cigarettes and other forms of nicotine. Again, as pediatrician, I am deeply concerned about the number of youth who use e-cigarettes. I was encouraged by the numbers that I heard earlier. But, you know, while some look at these products as a way to get off

of cigarettes, the reality is that cigarette companies who are manufacturing, the major ones on the market and their goal, is to get more kids addicted. These offer a heavy hit of nicotine, which increases the chances of addiction. And there is also not much known about the other ingredients and what they might do long term, particularly on such fragile lungs, and whether we are going to end up with a whole generation of scarred lungs, for example. I would also touch on developing brain and learning impacts.

I was proud for that reason to sign on to an amicus brief for an upcoming Supreme Court case, FDA versus Triton, and FDA's authority to regulate tobacco and other inhaled nicotine products is integral to the fight against youth vaping. I will continue to stand against tobacco and e-cigarette companies who are trying cynically to chip away at FDA's enforcement and rigorous review product.

As many of my colleagues have mentioned, what you have been able to do has been quite limited in terms of numbers that are regulated. And so, with the exception of the four menthol flavored e-cigarettes, I was wondering who can help you take more enforcement action. Like, is it all on you or are there other law enforcement potential?

*Dr. King. So several agencies have responsibility in this space. I would say Department of Justice is another key partner, and also Customs and Border Protection. But there

are several other in the Federal alphabet soup, if you will, and they are now part of the new task force. And so I am hopeful, now that we have got everyone in one place and a coordinated objective, that we will see more progress in that front in a coordinated way.

*Ms. Schrier. Thank you. Thank you both.

I yield back.

*Mr. Guthrie. The gentlelady yields back, and the chair recognizes Mr. Bilirakis for five minutes for questions.

*Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it very much.

I am proud to be an original cosponsor, Mr. Chairman, of H.R. 1750, the Defending Domestic Orange Juice Production Act, led by my friend and colleague, Scott Franklin, of course, from the great State of Florida. This bipartisan bill is critical to ensuring that citrus growers in my home state of Florida are able to stay afloat and not constrained by arbitrary and outdated FDA rules.

These rules, last updated by the agency in the 1960s, set specific requirements for juice content, including a minimum fruit sugar level called the Brix standard. In recent years, changes to Florida's citrus trees caused by disease and severe weather events have resulted in fruit with sugar levels below the minimum standard for pasteurizing orange juice. These higher fruit sugar levels provide no

health or nutrition benefits to consumers and no difference in taste. Despite this, the FDA's 10.5 percent Brix standard has caused manufacturers to import fruits with higher sugar levels from international sources and blend them at the detriment of our American domestic citrus producers here at home.

While H.R. 1750 would require FDA to lower the standard to 10 percent, we also know this change can come from the regulatory process. So my question is to Deputy Commissioner Jones.

In March, during an Agriculture Appropriations Committee hearing, Commissioner Califf was questioned about the H.R. 1750, this particular piece of legislation. He stated that the FDA was very close, when asked about the initiating rulemaking, to ease the Brix requirement, and that -- and I will quote here -- "We are going to get it done.'` Can you provide an update as to where FDA is in this process?

*Mr. Jones. Thank you, Congressman.

I can tell you that we are working on a rulemaking that will ultimately make a modification to the Brix requirements. I do not have a schedule for that rulemaking. But that rulemaking is under active development right now.

*Mr. Bilirakis. So you don't really have a schedule. Can you get back to me as soon as possible, please?

*Mr. Jones. Absolutely.

*Mr. Bilirakis. This is very important to our citrus growers in the State of Florida, but all over the country. As you know --

*Mr. Jones. Absolutely.

*Mr. Bilirakis. -- you know, orange juice is vital to our industry in Florida. So we appreciate that.

Dr. King, as you know, the courts have overturned the FDA's deeming rule related to premium cigars. Are you still sending these premium cigar manufacturers invoices for user fees?

*Dr. King. Yes, we are continuing to engage with industry, and we have developed a process where the industry can submit filings to be accepted from paying those fees. But we had to follow a specific process, given that we have a broad approach across tobacco products. And so it is possible for the cigar companies that they -- believe they are no longer subject to those authorities to submit a request for an exception.

*Mr. Bilirakis. So does this mean you are collecting less than the authorized amount since premium cigars have no obligation to pay under a court ruling --

*Dr. King. Currently --

*Mr. Bilirakis. -- while also asking Congress to give you more user fees?

*Dr. King. Well, and currently we are appealing that

decision, because we do profoundly disagree with it. But as a result we are collecting less, given the current exceptions by certain premium cigar entities, yes.

*Mr. Bilirakis. Well, you know, again, I have been glad to cosponsor a bill from the Tampa-based representative who sits on the full committee, Kathy Castor, in the past years to ensure the exemption for small premium cigars remains intact. I think it is only fair. And then, you know, the court ruling definitely backs that up.

Yes, you know, I remain concerned that the agency does not appear to want to let this go. And again, they did not have the authority, according to the court. So in any case, we are going to stay on that.

And I believe I don't have much time left, so I am going to go ahead and yield back my time. Thank you.

*Mr. Guthrie. Thank you. The gentleman yields back and the chair recognizes Ms. Kelly from Illinois for five minutes for questions.

*Ms. Kelly. Thank you, Chair Guthrie and Ranking Member Eshoo, for holding this hearing today. The American Lung Association released a statement in response to the new encouraging data showing the decline in the use of e-cigarettes among middle and high school students, yet there is still much to be concerned about the high addiction rate, and I agree with that observation.

In July 2023 most of my CBC colleagues joined me in sending a letter to the FDA -- excuse my voice -- expressing strong support for the FDA's proposed rule banning menthol cigarettes. I was deeply disappointed that the agency chose to abandon its established plan to ban menthol cigarettes; 72,000 Black Americans are diagnosed and 39,000 die from tobacco-related cancer each year.

FDA has made it abundantly clear that they need more financial resources to enforce against illegal e-cigarettes, and I want to say I remain committed to working with the Biden-Harris Administration and beyond to advance racial equity and address systemic disparities in public health.

Dr. King, based on last week's data, what do you attribute this decline over the past few years, and how do we keep this momentum going while ensuring addiction rates also decline?

*Dr. King. Yes. So first I just want to start and reinforce that FDA has not abandoned the menthol product standard. Indeed, we remain -- it is a priority for us. We followed the -- through rulemaking processes, and it is presently with the White House, and it continues to be a priority for us.

That said, we are concerned about tobacco product use among kids, regardless of whether it is cigarettes or e-cigarettes. And in terms of the promising findings, I think

one of the primary drivers was actions at the state, local, and national level. And for FDA's part, we have been taking many first-of-their-kind actions across the supply chain against various manufacturers, distributors, importers, and also retailers. And I think that is starting to reflect in the data.

But if we want to do more, we need the resources to do it, and that is what we are requesting.

*Ms. Kelly. Thank you. What steps is the FDA taking to promote health equity and prevent these products from disproportionately harming under-represented and unserved populations?

*Dr. King. Well, I have been very vocal in my support for health equity activities. It was a pillar of one of the four when I came into the center director position. And I can assure you that, as long as I am here, it will remain a priority.

We are leaving people behind when it comes to overall reduced rates, and we need to make sure that health equity is at the focus of everything we do. That is why it is a key theme in our five-year strategic plan that was just released. And I think there is a variety of activities in our portfolio that would get at that, including, importantly, the product standards that you noted at the onset of your remarks.

*Ms. Kelly. Thank you so much, and you have an ally

here.

Mr. Jones, you have had a lot of questions about baby formula and milk and those kind of things. Are there other authorities that FDA needs to modernize regulation of critical foods like that and others, and fulfill its mission to protect this population?

*Mr. Jones. Thanks, Congresswoman. And yes, we have asked for authorities related to infant formula not only for mandatory reporting of positive microbial contamination results, but also allowing us to require manufacturers to give us information related to supply chain-related issues so that we are able to identify a potential supply chain problem sooner, rather than later.

*Ms. Kelly. Thank you so much.

And I yield back.

*Mr. Guthrie. The gentlelady yields back, and the chair will recognize Dr. Joyce of Pennsylvania for five minutes for questions.

*Mr. Joyce. Thank you, Chairman Guthrie and Ranking Member Eshoo, for holding this hearing, and to our panel for testifying.

I also want to thank Chair Rodgers for her continued work to move strong legislation through this committee.

One of the bills that is being considered during this hearing is H.R. 1462, the DAIRY PRIDE Act. This bipartisan

bill, which I introduced along with Representative Kuster and Representative Craig of this subcommittee, would require the FDA to enforce existing standards of the identity of dairy products. These standards of identity are critical, as they establish common understandings for the American public as to what constitutes specific foods. Consumers rely on these standards to infer a certain nutritional value based simply on how a product is labeled.

My first question is for you, Deputy Commissioner Jones. The FDA's existing standard is that a food should be deemed an imitation if it is a substitute for and resembles another food, but is nutritionally inferior to that food. Given this standard, given this FDA standard, how does the FDA view plant-based dairy substitutes that are currently being marketed and currently being sold in the dairy counters?

*Mr. Jones. Thanks, Congressman.

So the research that we have done of consumers is that consumers are not confused the plant-based alternatives are not milk. As a matter of fact, they are purchasing them for exactly that reason, because they are looking for an alternative. That being said, our research also shows that consumers are not aware that often times plant-based alternatives to milk are not nutritionally equivalent to milk.

And so we have a scenario where they are looking for an

alternative to milk purposefully, they are not confused by the soy milk, they are not confused that that is actually milk. They understand it is a plant-based alternative, that is what they are looking for. But they are not aware that such a product is nutritionally not equivalent to milk.

*Mr. Joyce. So buying a -- or allowing that to be sold in a dairy case, is that not misleading them? Because nutritionally it is not the same as a dairy product.

*Mr. Jones. Thanks. So currently our guidance, which is drafted, has not been finalized, encourages plant-based milk alternatives to identify nutritional equivalents or lack thereof in their -- on their product. We are taking right now comment on that, and ultimately will finalize, depending on sort of where we ultimately think it is appropriate, to inform consumers on the issue of nutritional equivalence.

*Mr. Joyce. Public health organizations, including the American Academy of Pediatrics, have called on the FDA to reserve the use of the term "milk'' for real dairy products, that which comes from a lactating mammal that we learned in fifth or sixth grade, because there is confusion regarding the nutritional content, just as you pointed out, of other beverages.

Understanding that courts may not allow FDA to require products to be called a specific term, has the FDA considered requiring disclaimers such as "substitute'' or "alternate''

for plant-based dairy imitations?

*Mr. Jones. So before finalizing this guidance we are considering both the nomenclature for the product along the lines you described, but also how to effectively convey information related to nutrition.

*Mr. Joyce. I think it is so important that the message resonates with the consumer that the nutritional value of dairy products is superior to these fake products. The nutritional value of dairy products is superior to these imitators, and should not be sold in the dairy cases.

Today's hearing is an important -- is important that we can move forward and incorporate this feedback, and work to find a solution for the labeling of these products, and to address the mislabeling of products that are fakes or imitators. Simply urging companies to spell out the nutritional deficiency will not solve the problem of consumer confusion, which stems from assumptions based on the use of the term "milk''. And milk, I am concluding with you today, comes from a lactating mammal. And the imitators, the fakes are simply not milk.

Thank you, Mr. Chairman, and I yield.

*Mr. Guthrie. The gentleman yields back, and the chair will recognize Ms. Barragan from California for five minutes for questions.

*Ms. Barragan. Thank you, Mr. Chairman, and thank you

to the witnesses for being here and your centers' work to regulate the safety of food and tobacco products. These are programs that are critical to protect public health and reduce health disparities.

Mr. Jones, I would like to start with you. It is National Folic Acid Awareness Week. It is an initiative that raises awareness about the role folic acid plays in a healthy diet. Now, corn masa products like tortillas are staples in many Latino diets, but still lack folic acid. And the lack of folic acid fortification puts Latino babies at a significantly higher risk of serious birth defects such as spina bifida. What steps is the FDA taking to promote folic acid intake to protect the health of Latina mothers and their children, if any?

*Mr. Jones. Thanks, Congresswoman.

Yes, we agree that this is a very significant public health issue. In 2016 we authorized the use of folic acid in corn masa as it had been authorized in other foods previously. But as you noted, it has not been embraced by the corn masa industry, the manufacturers.

So earlier this year Secretary Becerra pulled together the major corn masa manufacturers to encourage them to include folic acid, as allowed by the FDA, in their products. We then followed that up with a more in-depth webinar with the retailer community and their trade association to reach a

larger number of corn manufacturers, but also to dive deeper into the science behind it and the public health urgency of doing so.

So it is very much on our radar, and we are going to continue to encourage manufacturers to do what they are allowed to do under our regulations.

*Ms. Barragan. Well, thank you for that, and I appreciate those efforts that have been made. Sometimes the voluntary action isn't as great as we want it to be.

As a chair of the Congressional Hispanic Caucus, I am currently leading a letter to the HHS Secretary Becerra and FDA Commissioner Califf that urges the agency to prioritize mandatory bilingual labels on corn masa flour products, warning that they are made without folic acid. And this letter will be sent to the agency secretaries this -- later this week. So just to give you a heads up. Thank you for that.

Mr. King, I want to talk about Latino youth. We have definitely heard today about the concern about marketing to our youth in general. We have seen data that shows that Latino youth are especially at risk of flavored tobacco product use. And we have seen a 30 percent increase in flavored tobacco product use amongst the Latino community, compared to the increases for, say, White youth. And I think my -- this might be because we have seen what I believe is

more targeted marketing toward a Latino youth compared to other groups.

Now, is the FDA doing anything, or what is the FDA doing to prohibit the marketing of tobacco products to youth, and particularly, you know, our youth of color?

*Dr. King. Yes. So we take a comprehensive approach here.

One way on the front end is making sure that we are reviewing marketing plans from companies with regard to pre-market applications. And so that, of course, considers the implications not only on youth more broadly, but also those across subpopulations.

But one important strategy that we know from decades of science is counter marketing and messaging around prevention. And so, for FDA's part, we did have the Fresh Empire campaign, which was focused at a youth populations including Hispanic youth, African American youth. And we also have other groups focused, as well. But that is really a critical conduit for us to engage with the community, make sure we have salient messages, and then broad scaling them in a way that reaches a broader population and, in turn, helps to prevent tobacco product use.

*Ms. Barragan. Well, thank you. My colleague, Congresswoman McClellan, has a bill called the Tobacco User Fee Modernization Act that would increase funding for the

FDA's Center for Tobacco Products. With more funding, what are some additional actions the agency could take to address youth smoking, you know, particularly for our Latino youth?

*Dr. King. So we propose about half of those funds would be used for enforcement and compliance, 25 percent for application review, and the remainder for public health campaigns and other activities, including the ones we just discussed focused on specific population groups.

*Ms. Barragan. Great. Thank you so much.

I yield back.

*Mr. Guthrie. Thank you. The gentlelady yields back, and the chair recognizes Mr. Carter for five minutes for questions.

*Mr. Carter. Thank you, Mr. Chairman. I appreciate this.

Mr. Chairman, I ask unanimous consent to enter into the record a letter from the National Fisheries Institute regarding the LESS Act, Laws Ensuring Safe Shrimp Act.

*Mr. Guthrie. Any objection?

Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Carter. Thank you. I appreciate that. Sorry to wake you.

[Laughter.]

*Mr. Carter. Thank you for being here. Thank both of you all for being here. I am going to take a little bit different route here, okay? So bear with me.

I have the honor and privilege of representing the entire coast of Georgia, over 100 miles of pristine coastline. Shrimping is a big industry in our state, and shrimpers right now are really suffering. And I want to talk about a law -- a proposal, I should say -- that -- legislation that has been introduced called the LESS Act that I think, Mr. Jones, you are familiar with.

And with all due respect to Representative Graves and Representative Castor, the cosponsors of this bill, Georgia's shrimp are the best in the world, and that is all there is to it, and that is not really up for debate. But if we were to quote the great philosopher Bubba Gump out of the movie "Forrest Gump,'' you will remember what he said: "Shrimp is the fruit of the sea.'' So it is extremely important, and it is extremely important to the shrimpers in my district in McIntosh and Glenn Counties, and all throughout the coast.

Unfortunately, Georgia shrimpers, who are entirely based in my district, face significant challenges to their ability to operate and compete in a global market for seafood, and

this is truly a shame, as more and more Americans turn to our country's number-one seafood product. While I am unsure of the issues that are completely under the jurisdiction of our committee, but I do want to bring awareness to this issue, and I want to ask Mr. Jones about the inspection of seafood entering the U.S.

Mr. Jones, this bill, the LESS Act that has been introduced by Representative Graves and Representative Castor, it aims to ensure that shrimp in the United States are free of illegal antibiotics or products of illegal fishing operations. Could you speak to the extent of these issues, and how HACCP, the hazard analysis and critical control points, works to identify and mitigate food safety issues before they happen, rather than relying on the finished product testing?

*Mr. Jones. Thanks, Congressman, and yes, the -- that is the underlying principle, really, of all of our food safety requirements. HACCP was really the first one that embraced that principle, where you are identifying a hazard at production, and then you are attempting to eliminate those hazards.

And we work with industry to help them to understand what to look for and how to mitigate those hazards.

*Mr. Carter. So is there anything we could do differently?

I mean, is there anything that -- these guys are really struggling, and I think it is going to be a shame if we -- and look, I am not trying to do away with competition. But at the same time we really need this industry to survive.

*Mr. Jones. Thanks. It is a great question. And in the last several years Congress has given us $7 million to enhance our shrimp import programs.

And what we have been focusing on is working with the major exporters to the United States to work with their governments to increase the likelihood -- I would say ensure, but it is really to increase the likelihood -- that the safety standards that we insist on in this country are being adopted in our major -- the countries we are importing the most from, so that there is a level playing field in terms of the safety requirements of our domestic producers, as well as those who we are importing from.

*Mr. Carter. Well, this is very important because, as I said, you know, we know there is illegal fishing that is going on. We know that they are using illegal antibiotics that are not allowed here in this country. So, you know, all we are asking for is a competitive playing field. And all we are asking for is to be able to compete.

So I hope that the FDA understands that, and understands the value of this because if they are dumping all these shrimp from -- that are being raised in Indonesia or wherever

they may be, then that is really a problem. And that is really unfair.

*Mr. Jones. We agree with that 100 percent. And having investments that help us to increase the likelihood that shrimp in this case that is being imported to the United States are meeting the same standards that our growers are is, I think, a really smart way to approach this issue.

*Mr. Carter. Okay. Well, thank you for that. And again, you know, wild Georgia shrimp, the best in the world. So thank you all.

*Mr. Guthrie. Thank you. The gentleman yields back, and the chair recognizes Mr. Balderson for five minutes for questions.

*Mr. Balderson. Thank you, Mr. Chairman. Thank you both for being here today.

Dr. King, my questions will be directed for you. I understand the FDA has cited products made by 13 of the 20 largest manufacturers as illegal, and warning letters. However, there were no enforcement actions against foreign or domestic manufacturers of illicit disposable products which dominate the e-vapor market. I think we both can agree that mere letters are insubstantial.

So I am curious, Dr. King, if any additional enforcement actions will be taken by the FDA.

*Dr. King. Yes, yes. And I am hopeful that the new

task force that has been built will set us in a stronger foundation to accomplish that.

We have also got some rules in the works that are on the unified agenda, including registration and listing and others that I think will help us streamline our processes and help facilitate a well-regulated marketplace.

*Mr. Balderson. Okay. Thank you. Following up on my previous question, I would like to know why the FDA has continued to focus their enforcement efforts on small retailers, rather than the manufacturers and distributors that are most responsible for the growth of this illicit markets.

Dr. King, are you aware that 8 injunctions and all 67 civil money penalties for the Center for Tobacco Products website says were issued to manufacturers were actually issued to individual vape shops that only qualify as manufacturers because they mix e-liquids?

*Dr. King. Yes. According to the law they would be defined as manufacturers. They could also be retailers. Yes, I am aware of that.

*Mr. Balderson. Okay. I think we all can agree that we have a shared interest in protecting the American people, especially our children. However, I am not convinced that the FDA, specifically the Center for Tobacco Products, or CTP, is doing that with their actions over the last decade or

more.

I am aware that the PMTA process has been an issue for quite some time. How can the CTP better engage with applicants during the PMTA process to assist in successful applications for reduced harm products?

*Dr. King. So I think one opportunity here is engagement with industry. We did just have a public meeting with industry that I thought went extremely well, and it was a follow-up from the external evaluation that we did receive.

And one of the recommendations, in alignment with what you are saying, is more engagement. That said, we regularly engage with industry, but we are committed to further opportunities to ensure that we are identifying ways to also gain efficiencies in the review pathway, as well as a result of that engagement.

*Mr. Balderson. Okay. Thank you. Given the agency's existing failures in adequacy and enforcing and monitoring tobacco products, I have strong concerns with increasing the funding levels and bills that increase FDA authority without proper congressional oversight.

Dr. King, I would like to know whether you believe the FDA and the CTP's unsuccessful track record warrants such an increase.

*Dr. King. I believe that we need the resources to address an unprecedented marketplace. And a comprehensive

approach is key, including the different players and Federal partners to accomplish that, but also the resources to ramp up the efforts.

We have had a lot of really strong successes, first-of-their-kind actions across the supply chain in the past two years. But if we want to do more, we are going to need more on the resource front. And I am hopeful that key folks will rise to the occasion to help accomplish that.

*Mr. Balderson. Okay. Thank you. I will go to my last question with more time.

Mr. Jones, as you work to structure new processes for reassessing the safety of food ingredients, it will be critical for the FDA to develop protocols that are efficient and transparent. Can you please tell me how you plan to accomplish the goals of the agency while also ensuring transparency and accountability?

*Mr. Jones. Thanks for that question.

You probably don't know, but I spent the first 30 years of my career running the 2 other post-market chemical review programs in the United States, the pesticides program and the industrial chemicals program --

*Mr. Balderson. I did not.

*Mr. Jones. -- TSCA. I am going to use many of the lessons learned from those programs, which -- the bedrock are fundamentally about having processes, transparency, clarity

of understanding how the process is going to work in terms of how do we select chemicals for review, how do we review the chemicals when the public has an opportunity to participate so that the manufacturers, as well as the public interest community understands how the process is going to work and when they have an opportunity to participate.

So we will be bringing many of those -- the principles we used in those post-market review programs to the food chemicals post-market review program.

*Mr. Balderson. Okay. Thank you very much.

Mr. Chairman, I yield back.

*Mr. Guthrie. The gentleman yields back, and the chair recognizes the gentlelady from Tennessee, Mrs. Harshbarger, for five minutes for questions.

*Mrs. Harshbarger. Thank you, Mr. Chairman.

Thank you, guys, for being here today.

Mr. King, I will start with you. Director King, Tennessee has one of the highest smoking rates in the nation, with 22.6 percent of Tennesseans smoking cigarettes. I am concerned there is a bias against this population, that the FDA policy has ignored these people when reduced harm options could potentially help them. So I guess I have got a series of questions, but help me understand why the authorization pathway for a pre-market tobacco application takes so long.

And as Mr. Griffith has stated, it should be adjudicated

within 180 days, but some PMTAs have been waiting for more than 4 years. So my question, my first question, is what is the average time it takes for an accepted PMTA to be reviewed by the Office of Science?

*Dr. King. Well, I will say that at present the primary rate-limiting factor is just the volume. We received nearly 27 million applications, which is unprecedented volume.

*Mrs. Harshbarger. Well, what is the average time, though? I know you --

*Dr. King. The average time is going to vary. Some of the applications are a million pages.

*Mrs. Harshbarger. Yes.

*Dr. King. And we have to do a comprehensive scientific review, and so there is no one size fits all. But we are committed to getting within a 180-day statutory deadline. But with 26 million applications done, that is difficult.

*Mrs. Harshbarger. So it depends.

*Dr. King. And we don't have the resources.

*Mrs. Harshbarger. It depends, okay. How many applications are currently now being reviewed, do you know?

*Dr. King. In terms of the ones still in our queue, it is approximately 500,000. We have received 27 million and we have resolved over 26 million.

*Mrs. Harshbarger. So you got 500,000 --

*Dr. King. Yes.

*Mrs. Harshbarger. -- left?

Once the Office of Science completes its review, what is the average time an application remains pending before the findings are presented to the office of the center director?

*Dr. King. That would be a matter of weeks. We have standard review processes that move through the various channels.

*Mrs. Harshbarger. Okay. How many applications are pending at this stage currently?

*Dr. King. With the office of the center director?

*Mrs. Harshbarger. Mm-hmm.

*Dr. King. Zero pre-market applications.

*Mrs. Harshbarger. What is the average time a presented application awaits a final determination?

*Dr. King. That varies, depending on the application and the individual merits.

But again, the bulk of the time is on the front end with the scientific review. There are dozens of scientists that review across different disciplines, and they work with the technical project lead to make a determination that ultimately proceeds.

*Mrs. Harshbarger. Is there an average time that you can --

*Dr. King. It varies, depending on the merits. Again, some of these applications are a million pages long, and so

there --

*Mrs. Harshbarger. So --

*Dr. King. -- is going to be variability.

*Mrs. Harshbarger. Okay. So currently, how many applications are pending at this final stage?

*Dr. King. I am not privy to that exact number, but we have 500,000 total that are still to be reviewed. And I will note that we will never be completed with the pre-market review because the industry will continue to innovate and Congress intended to review. So our goal is to get within the 180 statutory deadline, and get through the bolus. And we are hopeful that, once we get through this 27 million, we will then get back to the 180-day statutory --

*Mrs. Harshbarger. So if there is -- just like in a drug application, so if there are advances in the science, I mean, can they change that application without starting over?

*Dr. King. Yes, yes, yes, they can submit an amendment, and many do. But again, that then requires time.

And I have been an ardent advocate of ensuring that if a substantive amendment is submitted, that we review it and make sure the scientific merits are considered.

*Mrs. Harshbarger. Good lord, how many people work in this department, do you -- it sounds like you need to get more people, or --

*Dr. King. So our center is 1,100, and half of them are

science, Office of Science, 550. But, you know, 25 percent of the resources we are requesting with that additional 114 million would be application --

*Mrs. Harshbarger. Or we need to streamline the process, one of the two.

*Dr. King. Yes, or both.

*Mrs. Harshbarger. Are you able --

*Dr. King. Or both.

*Mrs. Harshbarger. Yes.

*Dr. King. Yes, and we are working on that.

*Mrs. Harshbarger. Okay. Are you able to provide a breakdown of how the user fees are currently being spent?

*Dr. King. Yes, yes. It varies depending on the, you know, specific component. But we are spending it on regulations and guidance, compliance and enforcement, Office of Science work for review of applications, and also public health communication. And we are happy to follow up --

*Mrs. Harshbarger. How much is being spent --

*Dr. King. -- with specifics.

*Mrs. Harshbarger. -- on public awareness campaigns in the menthol cigarette ban, do you know?

*Dr. King. We have had no public education campaigns on the menthol cigarette ban because the rule is not finalized.

*Mrs. Harshbarger. Okay, Mr. Jones, I am very interested in promoting Americans' healthy eating habits and

good nutrition and how we can best go about decreasing diet-related chronic illnesses. We know the source and amounts of foods we eat contribute to the rates of obesity that can lead to chronic diseases, and then that causes a higher direct and indirect health care cost.

You mentioned in your testimony a joint initiative with NIH to host a scientific workshop in December of 2024 on nutrition regulatory science, including ultra-processed foods. And that is very interesting to me, since I have been a pharmacist for 37 years, and I have been involved with a lot of functional medicine for over 30 years. How do you envision this work informing the periodic updates to our dietary guidelines every five years?

And how might the American people benefit?

And, you know, once you go down that road, how is that going to affect the SNAP program and things of that nature?

*Mr. Jones. Thanks for that question. So we have been pretty clear, I think, in the last year or so that we think that there is -- there are a number of studies that show an association between ultra-processed foods and some adverse health outcomes, but an association. We do not think there are -- the data right now is robust enough to demonstrate causality, and that therefore what we need is more research to more definitively answer that question one way or another. We are not saying there is causality. We need better

research to inform the question of causality between ultra-processed foods and a range of chronic-related diet -- chronic-related diseases associated with diet.

So at this workshop what we are going to be doing is to begin to build out what would the research agenda look like to answer the question related to causality. So ultimately, we will need this research if we are going to be able to answer the question of what do ultra-processed foods do as it relates to a range of diet-related chronic diseases.

*Mrs. Harshbarger. Okay. What else are you going to do at that hearing?

*Mr. Bucshon. [Presiding] The gentlelady's time has expired.

*Mrs. Harshbarger. Oh. So sorry, Dr. Bucshon.

*Mr. Bucshon. That is --

*Mrs. Harshbarger. All right, I yield back.

I have got more questions for you.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Bucshon. The gentlelady yields back. I will now recognize Mrs. Trahan, five minutes.

*Mrs. Trahan. Thank you, Mr. Chairman and Ranking Member Eshoo, for hosting today's important hearing, and thank you to the witnesses for being here today.

In 2024 e-cigarettes were the most commonly used tobacco product among middle and high school students in the United States. The significant uptick in vaping among youth has been largely driven by flavored products and marketing that appeals to younger demographics.

Since 2019 in my home state of Massachusetts we have enforced a ban on the sale of all flavored vaping products aimed at curbing youth access and usage. However, both teachers and parents still recognize this as a glaring and ongoing problem. Just last week a Massachusetts school teacher shared a concerning pattern. She wrote to me saying, "I find myself confiscating vapes from students almost every week. Most of them are flavored, despite the fact that flavored vapes are illegal here, so they must be coming from outside the state. These devices are colorful, fun looking, and clearly designed to appeal to kids. Some are even disguised as school supplies. We are fighting a losing battle, trying to keep them out of students' hands.''

Additionally, a school committee member in the district wrote in our local paper over the weekend about the link

between the youth mental health crisis and the increasing number of kids turning to vaping as a form of relief. "The rise in youth vaping is a serious issue that requires action at the Federal level, and it is clear that a patchwork of state bans isn't doing enough to effectively address the problem.''

I am interested in understanding how the FDA can leverage its authority to support and enforce state-level bans. Dr. King, can you explain why unauthorized flavored vapes are still widely available for school-aged kids, despite the Federal prohibition on their sale?

*Dr. King. Because of the volume of the marketplace, and we are under-resourced for the magnitude of the situation, which is why we are asking Congress for additional money.

Currently, e-cigarette manufacturers do not pay a single dollar in user fees, and the process needs to be updated to reflect the diversity of the marketplace.

*Mrs. Trahan. Thank you. And in your testimony you highlight the important steps FDA has taken in collaboration with Federal agencies like the DoJ to reduce youth tobacco use. While some progress has been made, usage rates have still continued to rise sharply.

What additional measures can the FDA take to strengthen enforcement of its ban on unauthorized flavored e-cigarettes,

particularly in states like Massachusetts, which already have a state-level ban in place?

*Dr. King. Well, I would clarify that the metrics are going in the right direction. We have been seeing nationally a decline in e-cigarette use since 2019. It is 70 percent lower than it was. And just this week we announced another 25 percent decline within the past year. So the metrics are headed in the right direction. What we need is more resources to keep the pedal to the metal.

That said, we have got a new interagency task force that I am very hopeful for. But again, we are under-resourced for the magnitude of the situation. And if we want to see continued progress, we have got to bring all the tables to the player -- all the players to the table and make sure we are well resourced.

*Mrs. Trahan. Thank you, Dr. King. I am going to switch gears.

My colleague touched on it a little bit in terms of ultra-processed foods, but food allergy prevalence among children increased by approximately 50 percent between 1997 and 2011, and this upward trend has continued steadily. Notably, Black and Hispanic children are affected at higher rates compared to other demographics.

Multiple studies have identified a correlation between the consumption of processed foods and higher rates of food

allergies. In fact, food allergies are thought to result from an exaggerated response of the body's immune system, which is designed to detect and prevent harmful substances.

Mr. Jones, what specific support or actions does the FDA need from Congress to enhance its understanding of the factors contributing to the increase in food allergies among children over the past two decades?

*Mr. Jones. Thanks for that question, and the increase that we have seen in food allergies amongst children is quite dramatic and worrisome.

I will say our colleagues at the National Institute of Health are focused on this very question right now. They have got numerous research projects underway to try to identify what are the factors behind this increase that we have all observed in allergy prevalence in children.

*Mrs. Trahan. Okay. Thank you, Mr. Jones.

I yield back.

*Mr. Bucshon. The gentlelady yields back. I recognize Dr. Dunn, five minutes.

*Mr. Dunn. Thank you, Mr. Chair, and thank the witnesses for joining us here today.

I have grave concerns over the unchecked flow of illicit vapor nicotine products that are currently sold in the U.S. Even worse, many of these illegal products originate directly from our greatest adversary, China. I serve on the House

Select Committee on China. Our committee conducted an investigation revealing the tactics used by the CCP to access American markets, and they use these tactics to market unregulated and unsafe products of all types, but specifically here today the nicotine products in the United States.

And it is particularly concerning that many of these products are specifically designed to appeal to children and teenagers just to get them hooked on nicotine. I am afraid that the FDA's response to these illicit vapes has fallen somewhat short -- in fact, created a black market where bad actors dominate and legitimate manufacturers are left behind. Illicit Chinese vapes make up a significant portion of the $7 billion e-cigarette market and -- while the FDA continues to focus its enforcement mechanisms on small retailers, rather than those most responsible for this black market.

Dr. King, has the FDA committed specific resources to combat the influx of illicit Chinese vapes into the U.S. market?

And if so, what are those resources?

And specifically, I would like to know, if you can tell me, how many full-time employees are dedicated to combating this illegal influx of Chinese vape products through our ports, our shipping containers, our international airports, air cargo, and, frankly, Internet vendors?

*Dr. King. Yes, so I will start by just saying that a comprehensive approach is key here, and it is not just FDA that is involved in this space. Customs and Border Protection colleagues are particularly critical.

For my center, we have approximately 300 staff out of our 1,100 who are involved with enforcement and compliance, and that includes those working on work on imports. That said, if we had more we could do more. And so, regardless of whether a product originates from China or not, if it is unauthorized, it is on the market illegally and we are committed to taking action as appropriate.

*Mr. Dunn. So one of the things we think might help, actually, is coordination with, as you said, the -- some of the people protecting our borders, the Customs and Border Patrol. What do you do -- what information do you give them to equip them to recognize and confiscate illegal vape products, as opposed to whatever might be legal?

And have they been a great contribution to your task force?

*Dr. King. Well, I think one important thing to consider is whether the products are accurately declared or not. And what we know, particularly through our recent seizure action we did at the border at LAX airport of $18 million illicit products, is 99 percent of them were misdeclared, which means that we have got to open boxes. And

it is not just import alerts for accurately declared content. That said, if you want to open boxes you need resources and you need people. And that is also why we need Customs and Border Protection as a key partner here.

So we have had some actions already. I am hopeful there will be more with the new task force. But we are unresourced, given the magnitude of the situation. And we also have to make sure that all the key players in this space are committed to making it a priority, as well.

*Mr. Dunn. Well, we are working with CBP, you may be sure, and also on the de minimis rules, et cetera.

So how does the FDA expect retailers -- now this is once it is in the country -- how do you expect retailers to know which products are legal? You know, there is something like 34 or 35, or whatever, authorized products. How do they know those from the illegal products in their store?

*Dr. King. So we --

*Mr. Dunn. Or when they come to their --

*Dr. King. Yes, so I appreciate the question. So we have released an online searchable database where anyone, including a retailer, can go in and see what products -- and e-cigarettes, as well as other authorized products -- what is authorized and what is not. And so it is an easy point click, a user-friendly resource that has been developed and --

*Mr. Dunn. And you think they are easily recognizable to these -- to the retailers?

*Dr. King. Well, we have issued a one-page fact sheet that we have distributed to partners in the retail sector, and I regularly engage with retail organizations, and we are always open to further input on how best to get that information into the hands of those who would benefit from it.

*Mr. Dunn. Well, I mean, do they ever come back to you and say, "Hey, I can't tell. This is counterfeit, but I can't tell it is counterfeit. How the heck am I supposed to know?'‘

*Dr. King. Well, we regularly engage with retailer orgs. And again, we have got a list of authorized products. And if it is not on that list right now of 34, it is on the market illegally and they shouldn't be selling it.

*Mr. Dunn. Well, thank you. I will say that the threat from the illegal Chinese vapes is tremendous. I am expecting fentanyl to be the next major brand any day.

I am hopeful the FDA will refocus resources and maybe information resources with CBP and the retailers, whatever, to make sure they are going after the very bad actors that we have in this market. Thank you.

With that, Mr. Chair, I yield back.

*Mr. Bucshon. The gentleman yields back. I now

recognize Mr. Pence, five minutes.

*Mr. Pence. Thank you, Mr. Chair.

Dr. King, I have a confession to make. I spent most of my life in the retail convenience store business, and had 231 stores called Tobacco Road. That was many, many years ago.

And everything -- you know, when I read the testimony, some of it -- I haven't been here the whole time, but some of the things I heard sounded so much like the Master Settlement Agreement or some of the issues that occurred in retailing, selling gray market cigarettes. Are you familiar with all that back then? And it is just such the same thing. Would you kind of agree with that?

*Dr. King. Well, I think it depends on the specific issue. I mean, I have been in this field for two decades, and so I wouldn't equate the Master Settlement Agreement with the Family Smoking Prevention Tobacco Control Act. But, you know, we are -- we have made good inroads since then, and we are making --

*Mr. Pence. So -- okay, good. I like that. You have been a couple decades. I have been -- I am not going to tell you how many decades, I would embarrass myself.

But where did all the people go that filed civil monetary penalty complaints against retailers, conducted 101.5 million tobacco retailer inspections? Where did all the people go that were back then when -- before we came to

an agreement on the MSA?

*Dr. King. Well, those entities weren't regulated at that point. And so in 2009 --

*Mr. Pence. What entities? You mean the e-cigarette entities?

*Dr. King. Yes, so tobacco product retailers in general. The Tobacco Control Act was issued in 2009, and that gave --

*Mr. Pence. But the product was. I mean, the gray market -- when you say there are lists of legal and illegal or, you know, the gray market cigarettes, some of them -- some of the retailers that weren't party to the MSA. They were some of the folks.

You could tell -- I almost answered Dr. Dunn's question because you could tell which ones didn't comply because they were a lot cheaper was one of the reasons.

*Dr. King. Well, we didn't start authorizing tobacco products until we got authority in 2009. So the FDA was not responsible for issuing the pre-market applications in addition to the pre-existing products.

*Mr. Pence. But regulating what was a partner or part and parcel to the MSA. What was gray market was legal cigarettes and illegal cigarettes. Wasn't there enforcement about that then?

*Dr. King. It was not enforcement conducted through the

Tobacco Control Act in the Center for Tobacco Products.

*Mr. Pence. Were states enforcing it?

*Dr. King. There were state activities.

*Mr. Pence. So what happened to all those people that were doing that then? Are they -- they are no longer around.

And -- because here is little bit where I am going. When you stood up another government agency, the CTP, with -- over the last 15 years of 1,200 people, I go, well, where are all the other people that were kind of regulating and inspecting retailers and inspecting compliance for presentation, marketing, placement of tobacco products? Why have we had -- why do we have to have a Federal organization now that does what was being done by states?

*Dr. King. Well, because it wasn't done at the magnitude to adequately address the leading cause of preventable disease and death in the United States. And that is why Congress made the decision to regulate the products --

*Mr. Pence. Well, I am not going to defend Congress here, I am just -- I just -- so do we have duplicative inspections of regulation, or are the states out of the business now?

*Dr. King. No, we work regularly with states, including on inspections through our enforcement and compliance arm. We have arrangements with all 50 states and U.S. territories, and we engage regularly on inspections and coordinate to

enforce the law.

*Mr. Pence. Okay, so there are as many in the state as there were before. This is just 1,200 more people to --

*Dr. King. For when, pre-Tobacco Control Act?

*Mr. Pence. Mm-hmm.

*Dr. King. No, there is now more resources because Congress allocated them.

*Mr. Pence. And you are asking for more resources here, if I understood your testimony --

*Dr. King. Absolutely.

*Mr. Pence. It is not enough?

*Dr. King. We have made great progress, but we need more if we are going to combat this issue in the most impactful way possible.

*Mr. Pence. Combat illegal e-cigarettes coming into the country, right?

*Dr. King. Illicit tobacco products, including e-cigarettes coming in through the ports, absolutely. Yes.

*Mr. Pence. Okay, all right. You know, I will just say it is just more of -- I understand -- oh, how about -- what about lithium batteries in e-cigarettes, are you looking at that?

*Dr. King. We do engage with Federal partners. We are aware of reports of lithium batteries exploding on airplanes. But we also, as part of our pre-market review that Congress

established, we evaluate safety and other standards related to e-cigarette products which --

*Mr. Pence. So how have you weighed in on that? Just curious.

*Dr. King. Well, in pre-market review, we evaluate the integrity of the product itself, and that includes the battery, to make sure that the product is safe.

*Mr. Pence. So insurance companies are quadrupling the amount of insurance that a vape shop has to have because they have already figured out it is very dangerous. So you haven't done anything with that.

*Dr. King. What Congress has required us to do is review the applications and --

*Mr. Pence. Okay, safety --

*Dr. King. -- and an overall package of safety.

*Mr. Pence. Forget about safety --

*Dr. King. And that --

*Mr. Pence. -- in that respect.

*Dr. King. No.

*Mr. Pence. Thank --

*Dr. King. That is incorrect. I said safety, and that is included in the pre-market paradigm, including --

*Mr. Pence. And I said what have you done about that, what have you done about --

*Dr. King. And I said that we review --

*Mr. Pence. The insurance companies very much understand that.

*Dr. King. We are not involved with insurance companies. I am involved with pre-market review of applications, which is what Congress intended. That is what we have done. That is what we are doing, and that is what we will continue to do in accordance with the law.

*Mr. Pence. Great answer, thank you.

Mr. Chairman, I yield back.

*Mr. Bucshon. The gentleman yields back. I recognize Mr. Crenshaw for five minutes.

*Mr. Crenshaw. Thank you, Mr. Chairman, and thank you for being here.

I will dive into this subject. I just want to get a feel for your philosophical direction on where we want to go with e-cigarettes and vaping, and especially these non-combustible nicotine products, especially many popular ones that have been on the -- that have been in the application process for, like, for years, like Zyn, for example. And I asked that question in the context of how other countries like the UK are dealing with it, where they state that, well, nicotine is the addictive substance in cigarettes, most of the harm comes -- in smoking comes from the thousands of other chemicals in tobacco smoke, many of which are toxic.

So they have taken an approach that, while none of these

are perfect, it is a realistic approach wherein looking to -- again, these non-combustible forms of nicotine, they are far less harmful than cigarettes and can help you quit smoking for good.

I mean, would you agree with that logic? And is that -- does that drive some of the philosophical thinking in your organization?

*Dr. King. Yes, we certainly consider the opportunity for lower-risk alternatives to help adult smokers transition completely, yes. But we have a paradigm to review applications to make sure they have met the necessary public health standard that is required by law.

So just because a product class has lower risk doesn't mean it is a rubber stamp endorsement for authorization. But it is an important component, and the onus is on the industry to submit their application to demonstrate that.

*Mr. Crenshaw. Well, yes, that is a great segue to the fact that many of these have been in the product application process for far longer than the 180-day deadline.

And so, you know, a question would be how many products have you authorized within the 180-day deadline and which products have been authorized -- well, how many have been authorized within that deadline?

*Dr. King. Well, our goal is to eventually get there. But with 27 million applications, it was an unprecedented

volume. And so we are working very diligently to get to that 180 statutory deadline. We have reviewed and resolved 26 million of those, which -- again, no other FDA center or other regulatory entity has dealt with that volume. So once we get through that bolus, I am hopeful that we will get to that 180 statutory, which is indeed our target.

*Mr. Crenshaw. Okay. And what is -- you know, one of the longest ones, again, is one of the more popular ones that we see out in the market. Zyn, for instance. Why is that a four-year-long process?

*Dr. King. Well, we prioritize them based on different factors. But of course, you know, we are committed to getting through them as quickly as possible.

I can't comment on the merits of any individual application. I can't disclose confidential company information. But I will say that we are aware of these applications that have been submitted, and we are working through them as diligently as possible. But we have got to stick to the science. We have got to follow the science and make sure that we are following the standard that Congress intended.

*Mr. Crenshaw. There are definitely some politicians that believe that the fact that many of these products have some kind of flavor associated with them indicates more harm. You know, I think that -- is there any scientific basis for

believing that?

*Dr. King. Well, we do know that, when it comes to flavored products, that the vast majority of youth users are using flavored varieties, and that is the case for e-cigarettes. But we are also mindful that --

*Mr. Crenshaw. Aren't the vast majority of adults also using some kind of flavored variety?

*Dr. King. Well, there is higher rates among youth compared to adults, about 90 percent among kids.

But to the point, we do not have a prohibition on flavored products. Indeed, we just authorized menthol flavored e-cigarettes. We have authorized flavored oral tobacco products. But again, the onus is on the applicant to meet that public health standard, and that involves weighing the risks, which can be -- but also benefits. And the fact that we have authorized flavored products demonstrate that that benefit is possible, but we have to look at the whole algorithm across the population.

*Mr. Crenshaw. All right. No further questions. I yield back. Thank you.

*Mr. Bucshon. The gentleman yields back. I recognize Dr. Miller-Meeks, five minutes.

*Mrs. Miller-Meeks. Thank you, Mr. Chairman, and I thank our witnesses for testifying before the subcommittee today.

A comment by one of my colleagues much earlier talking about the infant milk formula shortage, and said that the FDA was not the source of that. I would say, from articles I read in the Wall Street Journal and other publications, that there is some blame that lies with the FDA, as well. However, that is not what I want to talk about, I just wanted to insert that into the record.

In recent years we have seen a large uptick in illicit tobacco distribution, which we have heard some about already, which inevitably leads these products to ending up in the hands of children and teens. Frequently, retailers are unaware that they are actually selling illicit products that have been -- that have not been approved by the FDA, partially due to the fact that only three percent of shipping containers, including ones from China, are physically inspected by the Customs and Border Protection agents. Many of these products are put on full display at vape shows all across America, and are being sold by people who do not know that they are neither regulated nor approved by the FDA.

While all forms of tobacco, whether smokeless or combustible, present some health risks to the users, the FDA needs to ensure that products on the market have actually gone through FDA's approval process, and needs to work more with other government entities to step up enforcement to remove illicit products, especially those from China.

FDA announcing a collaboration with the DoJ and the CBP and sending warning letters is a good start, but it is not enough. Manufacturers need to know that the FDA is willing to work with them on having a fair and smooth application process, while also increasing public awareness on illicit products from China.

Dr. King our Chinese manufacturers subject to regular FDA inspections?

*Dr. King. The manufacturer facilities, currently not unless they have submitted an application to us.

*Mrs. Miller-Meeks. And does this lead to illicit products flooding the U.S. market?

*Dr. King. Well, there is multiple factors leading to products entering the U.S. market. It is not just coming from China. There is many U.S.-owned entities, about two-thirds of the market share in the United States are right now U.S.-owned e-cigarette manufacturers, which is all the more reason why a comprehensive approach is key.

*Mrs. Miller-Meeks. So -- but if they are not going through an FDA inspection, does that allow them to sell their product at a lower cost?

*Dr. King. Regardless of whether they have an FDA inspection, if they don't have an authorization it is on the market illegally and subject to enforcement action.

*Mrs. Miller-Meeks. And are you aware that eight China-

based companies account for 43 percent of all e-cigarette products sold in the United States?

*Dr. King. I think that depends on what data source you are using. The data source we use suggests that about 85 percent of the market is U.S.-owned entities. Most of these e-cigarettes are manufactured in China, but the estimates being proposed are those that are Chinese-owned, not U.S.-owned companies. So I think it is important --

*Mrs. Miller-Meeks. Is it an issue?

*Dr. King. -- source. It is certainly an issue.

*Mrs. Miller-Meeks. Whether it is 15 percent or 43 percent --

*Dr. King. Regardless of the numbers, it is certainly an issue, and that is why a comprehensive approach is key.

But everyone with authorities in this space has to step up to the table, and that includes Customs and Border. And they have specific authorities that they work closely with FDA. And we need more of that, and I am hopeful with the task force we will get there.

*Mrs. Miller-Meeks. Okay. As a physician and a former public health director, I am a huge proponent of protecting public health. And as I mentioned, while no tobacco product is safe, some international health systems view e-cigarettes or other products as a tool for harm reduction and eventual cessation.

Dr. King, I couldn't help but notice that in your opening statement very little was said about tobacco harm reduction. Is it because tobacco harm reduction is not a priority for the Center?

*Dr. King. No, absolutely not. We just released a five-year strategic plan, and there was a public education component, and one of the three pillars was educating adult smokers about the reduced risk of lower-risk alternatives. So it is a priority as part of our strategic plan.

*Mrs. Miller-Meeks. And one of the things that was mentioned here was the number of applications that are due in a 4-year timeline process, rather than 180 days. Your budget is 776 million, and this comes from user fees. You have asked for an increase in your budget of 121 million in user fees. I think there is about 560,000 PMTAs that are waiting for a decision.

If we didn't approve more applications, if -- approving more applications, wouldn't you increase the amount of user fees, therefore increasing the amount of budget you have that could then go to hire more people?

*Dr. King. Well, as a scientist myself, I am not going to jeopardize the integrity of the science, and it is up to the applicant to submit the science to get an authorization. We are not in the business of rubber-stamping applications. So if there is more authorized, that is certainly on the onus

of the applicants. But we want to make sure we find and adhere to a science-based approach.

*Mrs. Miller-Meeks. Do you have a streamlined application process that says exactly what the applicant needs to submit so that they can have their decisions?

I would venture a guess that they are doing everything in their power to make sure that their applications have a decision immediately, or at least within the 180 days.

*Dr. King. I would say --

*Mrs. Miller-Meeks. Thank you so much. I yield back.

*Dr. King. Yes, and I would just say that we have a guidance that we issued publicly that clearly articulates that. And it is available on our website, and we are happy to share it with you or your staffers.

*Mr. Bucshon. The gentlelady yields back. I recognize Ms. Schakowsky for five minutes.

*Ms. Schakowsky. Thank you so much, and I am grateful once again to be on this -- to come on to this -- to waive onto this committee, which I am not on, but I have a number of questions. Just three.

So let me just tell you I have a piece of legislation called the Truth in Labeling Act, which requires the FDA to list on the front of a package the nutrition labels, and so I wanted to ask about this.

I am happy that the FDA is working on this, but I am

concerned that the FDA was supposed to actually have information on the packages in December of 2023. That didn't happen, that was postponed. And then in June of 2024, but that didn't happen either, and now it is postponed, supposedly, once again, to October 2024.

So my question is, is this going to happen?

And what has been the delay?

*Mr. Jones. Thank you, Congresswoman. We are working very diligently on our proposed rule that would require front-of-pack labeling, as you have described. It is within a relatively short period of time before it will be submitted to the Office of Management and Budget for their review. So we are very confident that by the end of this calendar year we will have a proposed rule.

*Ms. Schakowsky. So when do you think -- what is the deadline now?

*Mr. Jones. We are hoping to have this package submitted to OMB within the next couple of weeks, and they have a 90-day review period, which would have us with a proposal rule --

*Ms. Schakowsky. What was the problem?

*Mr. Jones. I wouldn't say that there has been a problem. The amount of analysis necessary to support this rulemaking is quite extensive, and so it has really been grinding through all of the work to pull this package

together for the proposed rule.

*Ms. Schakowsky. Okay. We think it is -- I think it is very important.

So food packaging that contains some dangerous chemicals are still on the market. And so, Mr. Jones, I wanted to ask you -- let me see. Let me see. What is the question there? I can't see it.

*Voice. What are you doing about getting chemicals out of front of -- out of food packaging?

*Ms. Schakowsky. Yes, are we getting these chemicals out of food packaging? Not necessarily on the food, but on the food packaging.

*Mr. Jones. Thanks for that question. So in about three weeks we are going to be holding a public meeting where we are just going to -- we are outlining the criteria that we are using to identify chemicals for review. And those could be chemicals that are in food, chemicals that are authorized in food packaging. That can include contaminants in food.

We are also going to be describing the process that we will be using to review these chemicals. As we have stated, we have an ambition as it relates to what we refer to as post-market chemical review. We understand we need to get much more ambitious in that space. We are constrained by resources, but we want to have an approach that the public has had an opportunity to say this is how you should select

chemicals, and this is how -- the process you should use to review chemicals.

*Ms. Schakowsky. So my final question revolves around the idea that we want to make sure that infants and children, small children, are making -- make sure that they have safe products. And I know that has been an emphasis, but I also know that people shop in every line, in every corner, and there are things that have been very dangerous, and I know that there have been toxins in -- what is the red?

*Voice. Red dye number three?

*Ms. Schakowsky. Yes, red tie [sic] number three. And so it is a snack that -- it may be in a snack, and that can be very dangerous for kids. What do we do to protect beyond the things that we, of course, look at?

*Mr. Jones. Within the next couple of months we should have a proposed announcement related to red dye number three. But I -- as it relates to other chemicals that are authorized for use in food or are there as contaminants, again, I go back to we are going to be having a public meeting in a couple of weeks that is, again, going to describe how we propose to select chemicals for review. We want to make sure we are working on those that have the -- potentially, the greatest risk, and the process that we will use to evaluate those chemicals.

So again, we are very interested in having a much more

ambitious post-market chemical review program at the FDA.

*Ms. Schakowsky. I hope so. We have been looking at red dye for a long time, and we certainly don't want our children -- because if it is there, and people think it is a nice snack for a kid, they are going to get it. So I am happy that there is going to be this kind of review, and I would like to stay in touch on that. So thank you.

And I yield back.

*Mr. Jones. Absolutely.

*Mr. Bucshon. The gentlelady yields back. I recognize Mrs. Cammack for five minutes.

*Mrs. Cammack. Thank you, Mr. Chairman. Thank you to our two witnesses for being here today.

I am going to start with you, Deputy Commissioner Jones. I know it was mentioned earlier talking about the Brix issue and H.R. 1750, Defending Domestic Orange Juice Production Act. But I wanted to dig into this a little bit more. Representing Florida, it is hard to talk about Florida without mentioning, of course, sunshine, beaches, Disney, and our oranges. And it has been a pretty disappointing run here as of late for our producers in the Sunshine State.

So talking about the Brix issue, it is not on your regulatory agenda. And given that -- and we have been going through this issue for a very long time at this point -- don't you think at this point it would be easier just to pass

H.R. 1750?

*Mr. Jones. I would leave that to Congress to decide.

*Mrs. Cammack. But, I mean, your agency has had a petition since July of 2022, and it has received only positive comments, and still we don't have any action. Is there any reason that would prevent the FDA from updating the SOI to lower the Brix standards?

*Mr. Jones. And I am happy to get our schedule to you. I did not come prepared with the schedule for that rulemaking, but I can tell you that that rulemaking is under active development right now, and I can give you a schedule for our completion on that.

*Mrs. Cammack. That is a pretty long runway, if I am being honest, and it can't be that difficult. You have an entire staff behind you. They can't relay what that schedule -- what that date looks like?

*Mr. Jones. They would have to call back to HQ to get any of that kind of information.

*Mrs. Cammack. Okay. So if you don't have the schedule, then maybe you could answer why there is possibly a reason or an issue or a concern with lowering the Brix standard from 10.5 to 10.

*Mr. Jones. You know, it really gets to just overall resource constraints that we have. So we prioritize our work where the public health risks are the highest, and there is

not a public health risk related to standards of identity, generally.

And so, as a general matter, standards of identity, when we are trying to figure out where to deploy resources with the -- where there is the greatest potential for risk reduction in public health in this country, standards of identity such as this one often get on a slower track than, for example, managing a microbiological contamination or an outbreak or a chemical --

*Mrs. Cammack. Right, but -- and I understand this isn't, you know, the sexiest topic on the planet, but here we are, several years into this. And as you know, the Brix requirement, as it stands, requires our producers and processors to blend imported product to meet the standard. And at the rate that we are going, we are going to lose the entire infrastructure of our domestic supply.

So agriculture is not something you can turn on and off with a light switch. And so while I appreciate that it is not top of mind for you guys, there is a lot of producers around the country that are watching this very closely and have been waiting very patiently. So I would absolutely request that you get back to us with a timeline and some better answers when you appear before this committee.

And I am running short on time, so I want to jump to a dairy issue, as well. So I know that the DAIRY PRIDE Act has

been mentioned here today. One of the provisions of the legislation requires that FDA issues guidance explaining how it will carry out the other provisions of the bill regarding the enforcement of dairy terms.

Now, I know that your agency has drafted guidance, draft guidance, but I am concerned that it doesn't get us to where we need to be as far as preventing plant-based alternatives from being labeled as milk. This is a fight that has been going on, again, for years. Now, to my knowledge, the FDA has never finalized this guidance. Is there a plan, and do you have a timeline?

*Mr. Jones. So we are going to finalize this guidance. I don't have a timeline for it.

There are two issues that we are working through. One is -- relates to when can a plant-based milk alternative use the term "milk'' in its labeling; and what should the -- such a product say about nutritional equivalence? So we are working through both of those issues, and ultimately we will be able to finalize the guidance when we have landed both of those.

*Mrs. Cammack. So you haven't been able to give me a timeline on either the Brix issue or now the dairy term issue. I need you to give me a timeline of when you are going to get those answers back to us.

*Mr. Jones. I would be happy to do that.

*Mrs. Cammack. No, right now.

*Mr. Jones. Oh, I can give you -- we can give you a timeline on both of those by next week.

*Mrs. Cammack. By next week?

*Mr. Jones. Yes.

*Mrs. Cammack. We will call it COB Monday of next week. How about that?

*Mr. Jones. That is fine.

*Mrs. Cammack. All right. With that I yield back. Thank you.

*Mr. Bucshon. The gentlelady yields back. I recognize Ms. Castor for five minutes.

*Ms. Castor. Thank you, Mr. Chairman, and thank you, gentlemen, for all that you do to help keep Americans safe and healthy.

There are products on the shelves across the country that are not so safe. They kind of exploit the gaps that are out there. They say, well, we are not really a food additive, we are not really a dietary supplement, we are not a drug. But some of them are very dangerous.

My local newspaper, the Tampa Bay Times, did a big expose on kratom across the State of Florida. Over the last decade over 580 people have died from overdoses related to kratom, with at least 46 Floridians dying from kratom-specific use.

I know back in July that FDA issued a safety alert, and you have said that that substance is not being lawfully marketed. But it just seems like we are in this limbo, where people assume, okay, it is on the shelf, it must be safe. FDA says, "Wait, no, it is not so safe,'' but don't you have -- is this what you highlighted at the beginning of your testimony as you need more registration and listing authority, or is that something -- what is the answer here?

*Mr. Jones. Thanks, Congresswoman, and I think that that is a great question, and I think you are right, that there are manufacturers who are exploiting either ambiguity within the system or they actually -- really, their product does not fit within any of the legal pathways that we have.

Kratom has attempted to be -- we have had applications as a dietary supplement new ingredient. It has not met the standard for that, so it is not allowed for use in the United States. We recently took a significant action against a manufacturer who had psilocybin illegally in a number of products, but we are seeing more.

We had an earlier conversation about THC being added to food. I think it is an area where we have to collectively figure out sort of how do we address the use of ingredients that are not legally allowed to be used in food, and how we are going to get our arms around those issues.

*Ms. Castor. Ranking Member Pallone has introduced a

bill that would give FDA enforcement authorities for products that are being incorrectly marketed as dietary supplements. I am a cosponsor of H.R. 8123 because it would explicitly allow the FDA to prevent the marketing and import of these products masquerading as dietary supplements, as well as the ability to seize them.

Unfortunately, this bill wasn't included in the hearing list. Is -- are you familiar with this bill, and is this part of the answer? Or would that still -- would they still be able to exploit loopholes?

*Mr. Jones. I am not familiar with that bill, but I would be happy to work with your office and Congressman Pallone on that.

As I said, I think that there is a meaningful problem we have right now with ingredients not having -- that are not legally allowed to be used in foods of which dietary supplements are a food. But I would be happy to work with your office and Congressman Pallone to see if that bill addresses these kind of issues.

*Ms. Castor. When you see that kind of harm to the public, and you can issue a warning and you can say, okay, this -- we can clear the shelves of this, but you don't -- you simply don't have the ability to use any discretion to regulate it, what is the heart of the matter on that?

*Mr. Jones. So this space is dominated not by major

players, but by relatively small players. There is a little bit of a whack a mole going on, where you stop it here and it pops up over here.

We have experienced in the food space the major players, when presented with an enforcement action, go to pretty great lengths to make sure they correct it going forward. So relatively minor enforcement engagement can be very effective to correct the behavior.

*Ms. Castor. Do you have the ability to initiate a scientific study to -- on some of those substances to prove that they are a threat to the health, safety, and welfare?

*Mr. Jones. I don't believe so. I think we have robust science that demonstrates that these products are harmful. It is why they are unable to get authorization as dietary supplements. It is why they are unable to get authorized for use in food otherwise. I think it really is about how do we have the correct infrastructure in place to be able to address an emerging issue that is, I think, presenting significant challenges to all of us.

*Ms. Castor. Thank you very much.

I yield back my time.

*Mr. Bucshon. The gentlelady yields back. I recognize Mr. Pfluger, five minutes.

*Mr. Pfluger. Thank you, Mr. Chairman.

Dr. King, I will be focusing on the illicit uses of

products including vaping products that many of my constituents are just fed up with, actually.

I think it is incumbent that the FDA urgently address the regulatory challenges in the tobacco industry, and I think that immediate action is needed for compliant tobacco products to be sold. So there is a lot of questions that I have when it comes to confusion in the vapor market, exacerbated by the prevalence of illicit and illegal Chinese products that are entering our markets, some estimates including upwards of 40 percent of all of those products that come into the United States that include entry from manufacturers like Geek Bar, Razz, Elf Bar, Lost Mary, Funky Republic, Mr. Fog, Fume, Hide, and many others.

My question is -- and we will start with this -- you know, in your testimony you claim that the FDA has made impactful import prevention and enforcement actions. However, the facts would seem to point out that that is not actually the case, with estimates upwards of 40 percent of those products still entering the markets. What actions is the FDA taking to correct this failure and curb the proliferation of illegal vapor market products which now constitute, like I said, 40 to 50 percent of U.S. market goods?

*Dr. King. Yes, well, we are certainly concerned about this issue. And I would say we have taken many first-of-

their-kind actions within the past two years against manufacturers, distributors, but also addressing the imports. We have done joint operation at LAX airport with Customs and Border Protection that seized $18 million of illicit products, most of which were coming from China.

*Mr. Pfluger. Eighteen million?

*Dr. King. I am sorry?

*Mr. Pfluger. Eighteen million?

*Dr. King. Eighteen million.

*Mr. Pfluger. What is the market cap here?

*Dr. King. Well, in terms of the total e-cigarette market, we would have to get back to you. It is certainly a fraction of it, but we have got to start somewhere, and that is where we need resources.

*Mr. Pfluger. Have you guys listed these companies? Have you gone after the manufacturers? Because it seems to me that the retailers are bearing the brunt of this, but they don't know which products the FDA has actually taken a stand on to say these products are not compliant, they are not legal, but these products are. Do you have a list?

*Dr. King. Yes, yes. So we released a searchable database on this that we update quarterly. And we also issued a fact sheet to make it easier for retailers if they had any issues with utilizing that database. But it exists, and we update it for e-cigarettes, as well as other tobacco

products, as well --

*Mr. Pfluger. I think that is the heart of the issue, where the friction point is, is that our folks, our retailers don't believe that that is actually published, that they -- that there is actually not an FDA-approved list or an FDA non-compliant list that they can look at and see that there are still a very high quantity and volume of illicit Chinese materials moving in.

Let me move to the next question. To date the FDA has not pursued legal action such as lawsuits or injunctions against large manufacturers or distributors of illicit disposable e-cigarettes. Yet it has issued over 690 warning letters and more than 140 civil money penalties to retailers for selling the unauthorized e-cigarettes. Why has the FDA focused its enforcement efforts primarily on retailers, rather than the manufacturers?

*Dr. King. Well, we haven't. We take a comprehensive approach, and we have taken action against manufacturers, distributors, importers, and also retailers. But a comprehensive approach is key, and that does include retailers at the point of sale, as well. But they are not the only focus.

*Mr. Pfluger. So do you dispute my facts of the question --

*Dr. King. I am happy to follow up with you with the

specific numbers of warning letters and actions. But we have taken action across the supply chain, including manufacturers.

*Mr. Pfluger. We are seeing something that is different facts that don't match that.

How are you going to prevent illicit Chinese materials, specifically when it comes to e-cigarettes or vaping products, from entering the U.S. market?

*Dr. King. Yes, so -- and just to go back, so we have issued 800 warning letters to manufacturers and 65 civil money penalties, all e-cigarette manufacturers. So we are happy to follow up with those stats.

In terms of future action, I agree with you completely there is opportunity for more. And I think the critical components are bringing everyone to the table, including those involved in the task force, including Customs and Border which has authorities in this space, Department of Justice. But also we need more resources if we want to ramp up activity. And that is --

*Mr. Pfluger. Have you heard --

*Dr. King. That is the reality.

*Mr. Pfluger. -- from retailers these -- the questions that I am asking you?

*Dr. King. Yes.

*Mr. Pfluger. The complaints?

*Dr. King. Yes, I regularly engage with retailers. I am actually giving a talk in Illinois with a retailer association later this week, and I travel frequently, and --

*Mr. Pfluger. So you hear the frustration from them that kids are being harmed and --

*Dr. King. Yes, it is --

*Mr. Pfluger. -- that revenues are going to the Chinese Communist Party?

*Dr. King. You know, this is one item that has been raised. There is also positive feedback, as well. It is not all negative, but it is certainly heard. And we are happy to continue to engage to identify best ways to inform the retail sector. They are a key stakeholder of ours, and they will continue to be.

*Mr. Pfluger. We will continue to do oversight on this.

Mr. Chairman, thank you.

*Mr. Bucshon. The gentleman yields back.

I ask unanimous consent to insert in the record the documents included on the staff hearing documents list.

Without objection, that will be the order.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Bucshon. I remind members that they have 10 business days to submit questions for the record, and I ask the witnesses to respond to the questions promptly. Members should submit their questions by the close of business on September 24.

Without objection, the subcommittee is adjourned.

[Whereupon, at 1:07 p.m., the subcommittee was adjourned.]