

**COMBATTING THE YOUTH VAPING
EPIDEMIC BY ENHANCING ENFORCEMENT
AGAINST ILLEGAL E-CIGARETTES**

HEARING

BEFORE THE

**COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE**

ONE HUNDRED EIGHTEENTH CONGRESS

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**COMBATTING THE YOUTH VAPING EPIDEMIC
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AGAINST ILLEGAL E-CIGARETTES**

WEDNESDAY, JUNE 12, 2024

UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice at 10 a.m., in Room 106, Dirksen Senate Office Building, Hon. Richard J. Durbin, Chair of the Committee, presiding.

Present: Senators Durbin [presiding], Blumenthal, Booker, Ossoff, Cornyn, Lee, Hawley, Tillis, and Blackburn.

**OPENING STATEMENT OF HON. RICHARD J. DURBIN,
A U.S. SENATOR FROM THE STATE OF ILLINOIS**

Chair DURBIN. This hearing of the Senate Judiciary Committee will come to order. Today the Committee will hear from witnesses about the alarming level of youth e-cigarette use, and examine how federal agencies have failed to enforce the law designed to protect our children from a lifetime of nicotine addiction. Let's turn to a video that shines light on just how addictive these e-cigarettes are to children and why today's hearing is so timely.

[Video is shown.]

Chair DURBIN. Cigarettes are responsible for more than 480,000 deaths per year. These deaths touch virtually every family in this country, including my own. This hearing is part of my continued effort in Congress to stop these needless deaths, particularly the addiction of children. We have made progress and the tobacco giants have fought back. That's why we're here today.

In the year 2000, 28 percent of high school students smoked cigarettes. Thanks to the efforts of Congress and the public health community, that number has declined to only 2 percent. From 28 percent to 2 percent, of high school students today.

But anyone who thought Big Tobacco would accept this trend and dissipate like a cloud of smoke was mistaken. Instead, they re-branded and introduced new products known as e-cigarettes, and they followed the same playbook. The exact same playbook they successfully used to drive sales of Marlboro and Camel cigarettes in the earlier years; target kids.

Thanks to the addictive nature of nicotine, these companies knew, they've known a long time, if they could just hook a child at a young age, they had a customer for life. It started with JUUL, backed by \$13 billion from tobacco giant, Altria, in a partnership

which the American Heart Association has characterized as a match made in tobacco heaven. I would say tobacco hell.

The company introduced flashy devices, kid-friendly flavors, and advertisements featuring young, attractive people that that unleashed a wave of nicotine addiction that then FDA Commissioner Scott Gottlieb described in 2018 as an epidemic with more than 5 million teens reported that they were using e-cigarettes.

The FDA and the Justice Department has the tools to prevent this epidemic. They have failed to use them. The Family Smoking Prevention and Tobacco Control Act requires e-cigarette companies to get FDA authorization before, before bringing products to market. Authorization can only be granted if the companies making the product first prove that their products are, “appropriate for the protection of public health.”

But for years, under both Democratic and Republican administrations, FDA ignored its responsibility until public health groups actually had to sue the agency to force it to do its job and protect our kids. In that court case, the U.S. District Court in Maryland found that the FDA was in fact violating the Tobacco Control Act and ordered the agency to complete its review of e-cigarette applications by September 9, 2021.

That was 33 months ago. Almost 3 years, FDA still has not completed its review. Almost 3 years later, still has not completed its review. After the court-ordered deadline passed on September 9, 2021, FDA could have ordered every single unauthorized e-cigarette off the market.

And that’s what it should have done, and as the law clearly intends. Instead, thousands of unauthorized e-cigarettes flooded the markets. Flavors like: blue razz ice, strawberry watermelon, bubblegum, and cotton candy designed and effectively addicting millions of children in America.

Let me be clear, despite claims from Big Tobacco, there is zero evidence that e-cigarettes and their fruity flavors are targeted at adults. None, no evidence. In fact, the rate of e-cigarette use is nearly twice as high for middle and high school students as it is for adults.

Today, I’m releasing the findings from an NIH-funded monitoring the future study, one of the country’s preeminent public health surveys. The researchers there estimate that 2.1 million children have picked up vaping since the Food and Drug Administration missed its September 2021, court-imposed deadline. 2.1 million new children addicted, and that’s where the Justice Department is supposed to step in.

FDA relies on Department of Justice to bring enforcement actions for violations of the law. Sadly, the Justice Department seems to have followed FDA’s lead and has failed to effectively crack down on illegal e-cigarettes.

To date, only 23—remember that number, 23—e-cigarette brands have been authorized for sale in the United States. Yet, there are more than 6,000 e-cigarette brands on the market today. A trip to any gas station in America, convenience store, or vape shop makes the scope of this illegal market clear.

I simply do not understand how the Food and Drug Administration and our Department of Justice have permitted thousands,

thousands of products to remain on store shelves when their manufacturers have not received authorization, or in some cases even filed an application.

While these two agencies sit on their hands, during both the Trump and Biden administrations, e-cigarette companies addicted a new generation of children to nicotine, erasing the hard work so many of us undertook to convince kids not to smoke tobacco cigarettes and ultimately save their lives.

I'd like to thank Ranking Member Graham for working with me on organizing the hearing. Unfortunately, he cannot be with us today, but Senator Tillis of North Carolina will be serving as a Ranking Member in his place. I now turn to Senator Tillis for opening remarks.

**OPENING STATEMENT OF HON. THOM TILLIS,
A U.S. SENATOR FROM THE STATE OF NORTH CAROLINA**

Senator TILLIS. Chairman Durbin, thank you for holding this hearing. We're talking about a serious issue that impacts the youth of our Nation, but it also threatens the legal tobacco industry.

When the FDA banned legitimate flavored vapes, it opened the doors to cheap Chinese knockoffs that flooded the market. And even though these imported vapes are mostly illegal, there's been little done in the way of enforcement. There's been a 1,500 percent, a 15-time increase in kid-friendly flavors sold from 2020 to 2023.

Among youth who reported e-cigarette use, more than 25 percent of them used it daily, and over 1/3 used it at least 20 days a month. It's also worth noting that tobacco is my State's oldest industry. North Carolina leads the country in tobacco farming and manufacturing supporting over 27,000 jobs in the State.

Nobody wants kids and teenagers using e-cigarettes, especially illegal and counterfeit products that are being dumped in the U.S. by China's State-controlled tobacco monopoly, which is why I voted in favor of raising the age to purchase tobacco products to 21.

While youth e-cigarette use has decreased by 60 percent since 2019, the peak of 5.3 million according to the National Youth Tobacco Survey, FDA's lack of guidance, lack of transparency, and lack of enforcement has allowed the CCP and organized crime to flood the U.S. with dangerous illicit vapes.

FDA's refusal to follow Congressional intent and implement the Tobacco Control Act has led to disastrous consequences for public health and American jobs. Now, conveniently, 2 days before this hearing, the FDA has announced an inter-agency task force to tackle this issue that has plagued our country for years.

This thinly veiled political stunt comes 2½ years after the Reagan-Udall Foundation report was released. With this very recommendation, if the timing of the task force formation wasn't evidence enough of how unserious the FDA is about tackling the flood of illicit e-cigarettes in the U.S., FDA's exclusion of CBP from the task force makes it crystal clear.

The FDA cannot create a functioning market of regulated tobacco products through fines and warning letters alone. The FDA must create a consistent, transparent, science-based review process for reviewing applications for new tobacco products.

FDA's current process is broken. The FDA has currently 560,000 pending applications, including more than 557,000 for e-cigarettes. To date, the FDA has only approved 1,000th of 1 percent of all e-cigarette applications that is received. In fact, it's been more than 2 years since the FDA authorized a new product, and the Center for Tobacco Products has never authorized a new e-cigarette product under director King's leadership.

The result of FDA's de facto ban on regulated, reduced-risk alternatives for adult smokers is exactly what has caused the convening of this Committee today; the youth vaping epidemic and the lack of enforcement against illegal cigarettes.

Furthermore, it's worth mentioning today that there is also a plague of illicit counterfeit THC vape products entering the U.S. Much of this is related to Chinese imports, and many of the health problems often associated with vaping actually stems from fake, dirty THC vapes that contain dangerous additives.

We now see the Eastern Band of the Cherokee has decided to start selling THC-based products in Western North Carolina because they're within their sovereign territory. I have no doubt that they are probably putting something on the shelf that people think are safe, that are THC-based products, that the behavioral health profession says is becoming one of the leading causes of psychotic events, these supposedly legal products that you could buy in North Carolina where THC products are not technically allowed.

So I look forward to a robust conversation today, and maybe we can get to a point to where we can bend the curve and hold anyone out to dry, quite frankly, if we find evidence that they are marketing to our Nation's youth. This is a major public health threat. It's a major threat that I think is being perpetrated, in large part, by China, and Mr. Chair, I appreciate you convening the hearing today so that we can air it.

Chair DURBIN. Thank you, Senator Tillis. I'm glad that we have a bipartisan motivation to meet today and get to the bottom of this. Today's hearing includes two panels of witnesses. Before I introduce the first panel, let me briefly lay out the mechanics.

After I introduce and swear in the first panel, each will have 5 minutes to provide opening statements. Then there's a round of questions from the Senators. Each Senator will have 5 minutes. I ask them to please remain as close as possible to their allotted time. Then, we'll turn to second panel. After I introduce and swear them in, they'll each have 5 minutes themselves.

I'll introduce the first panel. Now, on the first panel, we will hear from Dr. Brian King, who serves as director of the Center for Tobacco Products at the Food and Drug Administration, and Arun Rao, who serves as deputy assistant attorney general of the Consumer Protection Branch in the Civil Division of the U.S. Department of Justice. Could the witnesses please stand to be sworn in? Please raise your right hand.

[Witnesses are sworn in.]

Chair DURBIN. Let the record reflect that both of the witnesses have answered in the affirmative. I now give you an opportunity for an opening statement. Dr. King, please proceed.

STATEMENT OF BRIAN KING, PHD, MPH, DIRECTOR, CENTER FOR TOBACCO PRODUCTS, U.S. FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MARYLAND

Dr. KING. Chair Durbin, Ranking Member Tillis, and Members of the Committee, thanks for the opportunity to discuss FDA's efforts to address unauthorized e-cigarettes. This morning, I'd like to provide an update on how FDA is working in collaboration with our federal partners on this critically important public health issue.

Now, the bad news is that e-cigarettes have been the most commonly used tobacco product among our Nation's youth since 2014, but the good news is that there's been more than a 60 percent decline in the number of middle and high school students using e-cigarettes over the past 5 years, including 580,000 fewer high school students in 2023 alone.

But despite this progress, more work is definitely needed. And for FDA's part, we're employing a comprehensive enforcement approach in addition to other activities.

Chair DURBIN. Dr. King, could you bring the microphone just a little closer?

Dr. KING. Is that better?

Chair DURBIN. Yes. Thank you.

Dr. KING. And I want to reinforce that we cannot do this alone. An all-of-Government approach across the supply chain is critical. With that goal in mind, FDA has been actively working with colleagues across the Federal Government, including the Department of Justice, Customs and Border Protection, the Federal Trade Commission, and the U.S. Postal Inspection Service.

And for FDA's part, I'd like to highlight some important actions that we've taken to address unauthorized e-cigarettes. At the manufacturer and distributor level, we've conducted thousands of inspections resulting in nearly 900 warning letters, and at the retailer level, we've issued over 550 warning letters.

Many recipients heed warning letters and take corrective actions. But if they don't, we can escalate, and we've made important strides in this space, including several first-of-their-kind actions over the past 2 years.

For example, we've built cases to support the first injunctions against e-cigarette manufacturers and distributors in coordination with DOJ, which now number 8 complaints filed. We've conducted the first seizure of an e-cigarette distributor in coordination with DOJ and the U.S. Marshal service. We've issued the first civil money penalties against e-cigarette manufacturers, which now number nearly 60.

And at the retailer level, we've issued the first civil money penalties for sales of illegal e-cigarettes, which now number more than 100. And on imports, we participated in a landmark joint operation with Customs and Border Protection resulting in the seizure of more than \$18 million worth of unauthorized e-cigarettes.

And this work is in addition to our robust program to prevent underage sales, for which we've conducted nearly 1.5 million inspections resulting in 138,000 warning letters, 33,000 civil money penalties, and 200 no-tobacco-sale orders for a variety of tobacco products.

Now, I want to assure you that FDA is committed to taking more of these escalated enforcement actions in conjunction with our federal partners. But the road to get there is complicated by several factors. FDA has received nearly 27 million pre-market applications for e-cigarettes, which we are required by law to review.

This combined with the rapidly evolving tobacco product landscape presents an unprecedented time and resource challenge that no other center at FDA has ever faced. There's also an inequity in resources. We are a 100 percent funded by user fees, which have not been updated to reflect the realities of the tobacco product marketplace. We need Congress's support to address this inequity, which we've included in the agency's Fiscal Year 2025 budget proposal.

First, we seek authorization for FDA to collect user fees from e-cigarette manufacturers, all of whom are currently paying no fees, to increase the current collections by \$114 million to account for the increased workload, and to index all future collections for inflation.

Second, we seek to extend the agile hiring authorities of the 21st Century's Cures Act to our center, to improve our ability to recruit, to hire, and to retain personnel. We're the only FDA center without such authority.

So in conclusion, FDA has taken important strides to address unauthorized e-cigarettes, especially recently, but we acknowledge there's more to do. And guided by our new 5-year strategic plan, I'm confident that with Congressional support, our critical all-of-Government approach will help us to achieve our shared goals of removing unauthorized e-cigarettes from the marketplace. And critically importantly, keeping these products out of the hands of our Nation's youth.

We stand ready to partner with our federal colleagues, including Congress, to explore additional opportunities to optimize that enforcement, including the ability to better identify and prevent the importation of unauthorized tobacco products.

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

[The prepared statement of Dr. King appears as a submission for the record.]

Chair DURBIN. Thank you, Dr. King.

Mr. Rao.

STATEMENT OF ARUN RAO, DEPUTY ASSISTANT ATTORNEY GENERAL, CONSUMER PROTECTION BRANCH, CIVIL DIVISION, UNITED STATES DEPARTMENT OF JUSTICE, WASHINGTON, DC

Mr. RAO. Good morning, Chair Durbin, Senator Tillis, and Members of the Committee.

Chair DURBIN. Pull the microphone as close as you can.

Mr. RAO. Certainly. Is that better?

Chair DURBIN. Yes. Thank you.

Mr. RAO. My name is Arun Rao, and I am the deputy assistant attorney general for the Civil Division's Consumer Protection Branch.

There is an urgent need to combat the illegal distribution and sale of unauthorized electronic nicotine delivery systems, or e-cigarettes, and I appreciate the opportunity to appear before you today.

Safeguarding the well-being of our Nation's youth is a paramount concern for the Department, especially in this area. Illegal e-cigarettes are a significant public health risk to Americans. They contribute to addiction and health issues, and they pose a dire threat to youth who are often the primary targets of aggressive marketing campaigns.

As you are aware, illegal e-cigarettes have flooded our Nation. Many of these products originated from abroad, and in particular from China. Tens of millions of e-cigarette applications have been filed with FDA for authorization. Many manufacturers have exploited the pre-market authorization process.

For example, some have tried to evade FDA denial orders by making minimal alterations to previously denied products, and then filing another application with FDA. Some overseas manufacturers routinely mis-declare shipments at port of entry to evade import alerts, and retailers across the country continue to manufacture their own products in individual stores.

Taken together, these factors have made illegal e-cigarettes all too accessible, allowing young people to obtain them at brick-and-mortar retailers across the country and online.

The Justice Department performs an important role in supporting the FDA's efforts to ensure that illegal e-cigarettes stay off the market. When manufacturers challenge FDA orders denying their marketing applications, the civil division defends the FDA's decisions in court. We've defended the FDA in over 80 legal challenges filed by manufacturers.

While many of those matters have yet to be decided, we have prevailed in more than a dozen cases, including in unanimous decisions in seven courts of appeal. In a case in which we have received a significant adverse decision in the Fifth Circuit, the Department is seeking review from the Supreme Court.

The Department also plays an important role in enforcing the Tobacco Control Act. For example, the FDA has pursued monetary penalties against over 55 manufacturers and 100 retailers, and has sent warning letters to hundreds more. Although the Department cannot impose penalties itself, we are prepared to assist the FDA in collection actions to ensure compliance. Additionally, we have partnered with the FDA in significant enforcement actions. This includes the first domestic seizure of unauthorized e-cigarettes, which included more than 45,000 illegal e-cigarettes.

We also have the authority to bring civil injunction actions in matters referred to the Department by the FDA. These actions do not allow us to recover monetary penalties, limiting their deterrent effect in some circumstances, but they are an important tool. In appropriate cases, the Department has secured injunctions against six entities, continues to litigate against another, and just yesterday, filed a proposed consent decree in our most recent case. We stand ready to act on additional referrals in consultation with the FDA.

We recognize that illegal distribution and sale of e-cigarettes is a complex and evolving problem that poses a grave threat to public

health and safety. It demands urgency. While some progress has been made, there is still much work ahead of us. That is why earlier this week, the Department and FDA announced the creation of a multi-agency task force with the sole purpose of addressing the threat posed by the sale of illegal e-cigarettes.

The task force combines the expertise of multiple law enforcement partners, including ATF, the U.S. Postal Inspection Service, the U.S. Marshal Service, U.S. Customs and Border Protection, as well as the Federal Trade Commission, to help combat this problem through comprehensive enforcement strategies, from seizing unlawful products to pursuing criminal investigations and prosecutions under the Prevent All Cigarette Trafficking Act, or the PACT Act.

We will use every tool available to bolster our efforts to halt the illegal sale of unauthorized e-cigarettes. We also stand ready to work with Congress in its legislative efforts, to address this important issue. Congress has an important role to play to ensure that the Department and FDA are able to effectively pursue critical enforcement actions.

In closing, I want to express my gratitude for the opportunity to testify. I am confident that working together, we will make additional progress in the fight against the illegal sale of unauthorized e-cigarettes, and will safeguard the well-being of all Americans, and especially, our youth. Thank you.

[The prepared statement of Mr. Rao appears as a submission for the record.]

Chair DURBIN. Thanks, Mr. Rao.

I'll ask a few questions. I'm going to make a statement, which I hope you'll both listen to carefully. Under the Tobacco Control Act, a manufacturer has the burden of proving to the FDA, that its e-cigarette is, "appropriate for the protection of the public health," before it can enter the market.

In other words, unless the manufacturer meets its burden and the FDA authorizes the product, it is illegal for that e-cigarette to be sold in the United States. Dr. King, Mr. Rao, is everything I've said so far accurate?

Dr. KING. Yes, correct.

Mr. RAO. Yes.

Chair DURBIN. To date, the FDA has authorized 23 e-cigarette brands and no flavored cigarettes have been authorized by the FDA.

[Poster is displayed.]

Chair DURBIN. Take a look at this photo. It was taken by my staff just a few days ago at a vape shop less than one mile removed from the FDA's headquarters. It shows: Fat Boys Red Bull Strawberry Vape, and VIHO Dragon Fruit Watermelon Vapes. Right here is this so-called Elf Bar Watermelon Bubblegum Vape purchased from that store, less than one mile away from the FDA headquarters.

[Holds up vape product.]

Not a single one of these products has been authorized by the FDA. None of them. These illegal products, clearly designed for kids by their flavors, are being sold in FDA's shadow of their building headquarters [points at poster and holds up vape products].

Less than a mile from your headquarters. How is that allowed to happen, Dr. King?

Dr. KING. I'll reinforce that we do have a pre-market paradigm for reviewing applications, and the sheer volume of those applications, and the volume of the market, requires us to prioritize our enforcement efforts.

Chair DURBIN. That's what I really want to get to here. So you're saying that if they're burden of proof on the manufacturer under the law, they have to prove appropriate for public health before they will be approved by the FDA? That proof is not made, and yet these products are for going for sale.

[Points at poster.]

You've completely fallen down on the job. Your responsibility is to impose the burden of proof and not allow the sale of these e-vape cigarettes to kids unless they're approved by the FDA. Correct?

Dr. KING. Correct.

Chair DURBIN. So, let's hear the answer. Why are you doing this.

Dr. KING. I'll reinforce that the sheer volume of this product landscape requires time to ensure that we conduct scientifically defensible and legally defensible reviews of the 27 million applications.

Chair DURBIN. It's not your burden, it's their burden. They have to prove they're appropriate for public health. You don't have to disprove it.

Dr. KING. I'll reinforce that the applications are substantial, and we have hundreds of scientists that are working on a daily basis to review these applications. And we've made good progress. We're 99 percent—

Chair DURBIN. So, if I make a filing, if I file legal briefs thick enough, I can go ahead and sell my product without approval?

Dr. KING. No, that's not accurate. But we want to make sure we review the science that's submitted. And so there are some applications that don't meet the initial bar. There are three phases of review, and we can remove those applications earlier if they don't have the necessary information. But if they provide enough science for us to do a substantial review, we have to take the time to scientifically review them. And that does take time.

Chair DURBIN. Mr. Rao, are these tobacco company lawyers beating you to death to the point where you don't enforce the law as it is written and I described it? Please use your microphone.

Mr. RAO. Senator, this is obviously a very litigious environment. We have been actively defending the FDA in courts of appeal in district courts across the country—

Chair DURBIN. Thirty three months. Thirty three months since the Maryland court said you are required through the FDA to get your job done, and nothing has happened. You call this an urgent need. What is urgent about waiting almost 3 years and doing nothing?

Mr. RAO. Senator, we share your concerns with respect to the widespread prevalence of these illegal products, and we take seriously our obligations to enforce aggressively in this space.

Chair DURBIN. I assume you're an attorney, are you not?

Mr. RAO. That's correct.

Chair DURBIN. What does it mean when we say burden of proof?

Mr. RAO. What needs to be established in a court.

Chair DURBIN. Who has the responsibility of approving the safety of this product now under American law?

Mr. RAO. In this case, it would be the manufacturers.

Chairman DURBIN. Have they proven it with all these?

[Points at poster.]

Mr. RAO. I do not believe that's the case, no, they have not.

Chair DURBIN. So, what should we do as a Nation to say to them you cannot in this situation openly defy the law and the agencies, and sell your product anyway to children? What is it we should do to stop them?

Mr. RAO. Senator, I think we should signal aggressive and—aggressive enforcement in this space is a priority across the executive branch. I think we should send that signal. I appreciate the opportunity to lift up—

Chair DURBIN. I'm sorry. I'm sorry. I'm against signals. Do something. To announce 7 days before this hearing that you're going to have real law enforcement and now get involved in this. What in the hell have you been waiting for?

Mr. RAO. Senator, we have been acting on a number of fronts. There's been the civil monetary penalty actions that Dr. King referred to earlier, and the Department stands ready to assist in collection actions in those matters. We have been working with the U.S. Marshal Service and the FDA on seizures—

Chair DURBIN. You're failing. You're failing. Within a mile of the FDA headquarters is evidence that you're failing. What's serious about this is not only the failure of the attorneys, but the failure that is leading to addiction of children.

Mr. RAO. Senator, this is a multi-pronged approach, is what's going to be required in this case. And again, that's why we're working with multiple law enforcement partners, not just the FDA, but also the Bureau of Alcohol, Tobacco and Firearms, U.S. Postal Inspection Service.

We have had ongoing engagement with those agencies, looking at potential additional enforcement actions, both criminal and civil, that we can take using other authorities. And we are optimistic that working with these partners, we're going to be able to make progress.

Chair DURBIN. Well, it's been quite a few years since I finished my law school courses, but I do believe I understand burden of proof. They have the burden of proof. They have failed to meet it and sell their product regardless.

Our Government, Department of Justice, and FDA, standby and say this is too complicated. It's not complicated. It's basic. If they have the burden of proof and haven't met that. They're violating the law. Correct?

Mr. RAO. Correct.

Chair DURBIN. Enough said. Senator Tillis.

Senator TILLIS. Mr. Rao, I'm not an attorney so I have a habit of asking questions I don't know the answer to. And this is one that I'm curious. If you take a look at the shelves that are full there, [refers to poster.] you could leave this hearing or you could view this hearing through a lens of attacking Big Tobacco, and taking advantage of the youth population, and try to get them ad-

dicted to nicotine. But it seems to me that a lot of these products that were up there are not being dumped on the market by Big Tobacco. Am I wrong?

Mr. RAO. Senator, there are a number of players in the market, not just the large tobacco—

Senator TILLIS. Let me just ask. We never totally solve problems here. That's why we've been coming back every, you know, every year for several hundred years to try and get things right in this country. But if you really wanted to take a big chunk out of the danger that our youth faces today, would it be double down on Big Tobacco or in this?

Mr. RAO. Senator, I think—

Senator TILLIS. If you actually pull that whole box forward, I think that's what you're struggling with.

Mr. RAO. Okay. How about now? Senator, I think given the complexity of the market, I think you have to take a multi-pronged approach. We have to use all available tools—

Senator TILLIS. I get all that. I get all that. But if you're in a world—we've heard Mr. King say that the FDA is stretched for resources. I think fee structures probably should be modernized. That's not going to happen overnight. So if you can only focus on one area that would have the biggest return. I'm just asking, between Big Tobacco, which has been characterized as one of the lead causes of this problem are what's being dumped substantially from China, which of the two would you try to solve first?

Mr. RAO. Senator, you know, we would work with the FDA on determining the most effective use of our resources.

Senator TILLIS. Well, Mr. King, let me move to you. I'm assuming a lot of these applications you're being flooded with, are they from the normal players or are they from other players that are dumping products in the market?

Dr. KING. It's all of the above.

Senator TILLIS. But give me some rough idea of stratification in terms of numbers the resources.

Dr. KING. So, in terms of the big players, we do receive applications, but we also receive from small entities as well, including small manufacturers. Mom-and-pop shops and vape shops are submitting applications as well.

Senator TILLIS. Between the two of them, just intuitively, Mr. King, which of the two do you think would be more risky in terms of what's in the product? A big tobacco company that's a perennial target, or mom-and-pop shops and import. Just intuitively, which of the two do you think would represent the most dangerous product?

Dr. KING. It's dependent upon the information that's supplied in the application to us and the science. And I cannot make a sweeping generalization because there's no way—

Senator TILLIS. So there's no way. You think that products that have been researched, that are going through an industry that's been heavily regulated are likely to be as dangerous as products that are being dumped from companies that are manufacturing it in China?

Dr. KING. Again, I can't speak in broad generalizations—

Senator TILLIS. Okay.

Dr. KING [continuing]. But there is variability within these products. It's a diverse landscape of different products with different device types. And so, making those generalizations is not consistent with the available scientific evidence.

Senator TILLIS. No, actually, I just think it's fascinating that we haven't done the work to understand that. Because you're not going to solve the whole problem. And it would seem to me that it would be useful to actually figure out if you were able to reduce the risk of one sector, then you would have some idea of where the most dangerous products are and how they are systematically coming to market. But apparently that's not a factor. And I'm not going to go any further on that question.

Why 2 years after the report are we just hearing about this task force, after the report recommendation?

Dr. KING. We've been working systematically since the release of the Reagan-Udall evaluation to address all 15 recommendations. And I publicly said, I welcome the evaluation. That is accurate. And we've worked diligently to implement all of them, including this.

But it's a variety of different actions. We've made progress, we've been reporting quarterly on that progress. And on the task force, it's multi-agency. And that takes time to make sure we get the right folks to the table and we set the foundation for more progress.

Senator TILLIS. On the point that you're—and I'm just trying to give you an opportunity to explain this, and Senator Durbin has mentioned that, that you have responded to Senator Durbin's questions that you have to review every application. And so, are we saying that right now we're in a posture where these products are given the benefit of the doubt pending review?

Dr. KING. No. There's no safe harbor—

Senator TILLIS. Senator Durbin just said yes. So, [Senator Tillis looks to Senator Durbin]. I'm just trying to make the connection because I'm trying to understand why you think you have to do the science, and I don't think you're suggesting that because they've applied, that they can sell the market until they've been disproven. Is that accurate?

Dr. KING [continuing]. There is no safe harbor by simply submitting an application. Anyone who does not have authorization through the appropriate PMTA pathway or other pathways is on the market unlawfully and risk of enforcement.

Senator TILLIS. Okay. So just to be clear, if I can rob Senator Durbin [points at poster.]—what the hell are we talking about here then? [points at poster.] Is this legal? Is it illegal? Is it subject to review and approval of an application? I'm sorry to go over Senator Durbin, but I'm trying to get an answer to your question, actually.

Dr. KING. I can't go through every single product on that chart, but I will tell you that it's a—

Senator TILLIS. The point here is this is a shelf full of potentially dangerous substances in a store in the shadow of the FDA building. I'm just trying to figure out if any of this is illegal or how in the hell it's legal. I mean, that seems like a legitimate question, right?

Senator DURBIN. Yes.

Dr. KING. Okay. I'm happy to answer.

Senator TILLIS. I mean, maybe we should go to the audience. I'm just trying to get an answer to that. I'm trying to understand why this is happening in North Carolina. I just don't understand it.

Dr. KING. No, I'd appreciate the opportunity to respond.

Senator TILLIS. I'll come back to you in second round of questions. You know, I do want to back up though and understand. I used to dip tobacco, and then I went to a nicotine pouch substance. And last September when the sales went off, I told myself I was going to quit cold turkey, and I got off of nicotine.

Now, I had that option to get off tobacco, that some people could throw a baby out with the bath water and not have that even for adult. This is something that lets people move off of the cancer-causing substances in tobacco into something safer. And then, ultimately, maybe for somebody like me, just quit.

So I hope as we're having this discussion that we recognize if we take this stuff off the market and people are not going to say, well, nicotine's not available anymore. I guess I'll just stop. They're going to go back to a more harmful substance, and we need to make sure that baby doesn't get thrown out with the bath water.

Chair DURBIN. Senator, the only thing I'll add is when you start advertising flavor watermelon and bubble gum, you're not talking about adults making conscious choices.

Senator TILLIS. Yes, but I'm not aware of any—is there any Big Tobacco company that has child flavors on the market today?

Dr. KING. Yes.

Senator TILLIS. And what are they?

Dr. KING. There's a variety. We know that kids use fruit and candy-flavored products, as well as mint, and other flavors. And there are several Big Tobacco entities that are manufacturing e-cigarettes with flavors that have been documented to appeal to kids.

Chair DURBIN. Senator Booker.

Senator BOOKER. Thank you very much, Mr. Chairman. Gentlemen, thank you very much for being here. Everybody on this panel knows the horrors of fentanyl analogs coming from China flowing into our streets and doing untold harm, danger, and death to Americans, and it is something that in bipartisan ways we've tried to find ways of stopping that.

What is stunning to me about this business is as much as focus is on American companies, there are all of these products coming from other Nations that do not have the same levels of scrutiny, and I believe don't have the kind of safety precautions that are critically necessary.

Could you talk to me a little bit about the products that are being sold in our stores, and corner grocery stores, in bodegas, that come from other countries and the risks that they pose to American citizens? Please, Dr. King.

Dr. KING. Happy to answer. So we know e-cigarettes as a general product class have lower risk than conventional cigarettes, but that does not mean that they're safe. We know the levels of toxicants are markedly lower, but we know that the aerosol can contain harmful and potentially harmful constituents. But it's a vast marketplace, and there's marked variability across product types and brands.

Senator BOOKER. But be specific. Some of these products that are coming from other countries like China, do they pose a threat? Could they pose a threat?

Dr. KING. I would say that any of the products, regardless of whether they're coming from China or not, could. And that's why we have a pre-market paradigm to review the scientific evidence, to understand what is in the product itself, and to make a determination based on the science whether they meet the appropriate statute by law.

Senator BOOKER. And so, the safeguards and regulations, I would imagine, are being subverted though by these knockoffs that are often coming in from other countries. Is that correct?

Dr. KING. Yes. Other countries and also domestically as well. And the sheer volume of the marketplace is a key challenge in this issue. And that's why I believe strongly that an all-of-Government approach is key. And we're making progress, getting the applications done, ramping up enforcement. We need more resources and we need more people at the table.

Senator BOOKER. And so that's a really important point that I want to flush out a little bit more. In other words, there could be products coming into our market from other nations that pose a threat to Americans that are flooding our market in many ways. But the challenge we have is the resources to do the kind of law enforcement work that could stop some of these knockoffs coming in. Is that what you're saying?

Dr. KING. I agree. People and dollars resources, correct.

Senator BOOKER. Right. And the products that are being marketed at a time where we are focused so much on, again, as I think we should be, the safety of the products that are coming through American companies. When you talk about law enforcement, it's not just here, could more be done at the point of the source of some of these products coming from other nations?

Dr. KING. It could be, but our current authorities are once the products reach the border, we are working on some rules, specifically rulemaking, around registration and listing, which would allow us to engage further with international manufacturers, particularly China, where the bulk of these products are coming from.

But ultimately one of our inhibitors is being able to act, you know, once it hits the border, which we are doing. But again, if we had more resources and with the all-of-Government approach, we can do a heck of a lot more.

Senator BOOKER. All right. Mr. Chairman, thank you very much.
Chair DURBIN. Senator Cornyn.

Senator CORNYN. So, from 2020 to 2023, 18.4 million vaping products were sold per month. In September, 2023, there's been a 1,500 percent increase in kid-friendly flavors sold from 2020 to 2023. My staff happened to stop by an Exxon station and picked up a couple of examples of those products. One called True Story. This one happens to be watermelon, bubble gum-flavored. This one is called Tyson Heavyweight that is an apple, melon berry.

Dr. King, those are clearly designed for consumption by children. Correct?

Dr. KING. I can't speak to the intent of the manufacturer, but I can say that flavors do appeal to kids. 90 percent of youth who use e-cigarettes use flavored varieties.

Senator CORNYN. And if you look at the warnings on these products, it says this product can expose you to nicotine which is an addictive substance. Correct, Dr. King?

Dr. KING. A highly addictive drug.

Senator CORNYN. Highly addictive drug, known by the State of California to cause birth defects or other reproductive harm. This Tyson Mellon Berry warning says it can cause cancer. So, let me just ask you, are any of these products safe to consume?

[Holds up vape products.]

Dr. KING. There's no e-cigarette that is safe. They have lower risk than the general class.

Senator CORNYN. There's no e-cigarette that's safe at all. And I realize the argument is that for people who are trying to wean themselves, let's say from tobacco, some adults find some of these products, maybe not these products, but some other products useful to wean themselves.

Because as I understand, the two biggest problems with smoking a cigarette, for example, is the products of combustion and the nicotine, the products of combustion associated with cancer according to the Surgeon General. And of course, if you're vaping and not smoking, then really nicotine, which is this addictive substance, is the problem.

So interestingly, both of these products say, "For sale in the United States only. Designed in the USA. Made in China." Same thing for the True Story, the watermelon bubble gum vaping device manufactured in China, "Sale only allowed in the United States." To your knowledge, are these products available for sale in China?

[Holds up vape products.]

Dr. KING. I can't speak to if there is evading of the law, but the Government of China currently has a law that prohibits the sale of flavored e-cigarettes.

Senator CORNYN. So, you can't sell them in China, but you can sell them in the United States, and essentially, victimize and addict our children to these nicotine delivery devices, which that's what they are. Aren't they?

Dr. KING. They're nicotine delivery devices. That is correct.

Senator CORNYN. Nicotine delivery device, a device designed and sold to deliver an addictive substance called nicotine, as well as other associated health risks. Let me just walk you through, briefly, the FDA approval issues involving an American company, JUUL.

About a year ago, the Center for Tobacco Products issued a marketing denial order. Meant that JUUL wasn't able to sell its products, but it filed suit during the litigation. The marketing denial order was stayed and JUUL was able to continue to legally sell its products.

Last week, the Center for Tobacco Products rescinded its denial, which sounds like good news for JUUL, but my understanding is the rescission of this order moves JUUL from back to pending, neither approved nor denied, which means it's no longer able to sell its products. So we have a situation where the FDA denied JUUL,

during which JUUL's e-cigarettes were legal. Then the FDA rescinded its denial, and now JUUL e-cigarettes are illegal.

Dr. King, this strikes me as a Kafkaesque situation for an American company filing for approval and then finding themselves in this maze of regulation and litigation. Meanwhile, illegal Chinese vapes make \$3 billion a year advertising directly to American citizens. Is that accurate? Is what I said accurate?

Dr. KING. In general, yes.

Senator CORNYN. Thank you. Seems to me that we need some legislation. I've got some that I tend to work on with my colleagues here, Mr. Chairman, to try to address this problem more directly and look forward to coming up with a legislative response to what is an outrageous and unacceptable status quo.

Chair DURBIN. I look forward to working with you, Senator. Senator Ossoff.

Senator OSSOFF. Thank you, Mr. Chairman. Thank you to our witnesses.

Mr. Rao, Dr. King, no flavored vape or e-cigarette products are currently FDA-approved. Is that correct?

Dr. KING. That's correct. I mean, tobacco is a flavor. So, no non-tobacco flavored e-cigarettes have been authorized.

Senator OSSOFF. No non-tobacco flavored e-cigarettes, therefore, other flavors have been authorized and under the TCA. Is it correct, Mr. Rao, that they are therefore not legal to sell in the United States?

Mr. RAO. That's correct.

Senator OSSOFF. And yet they're widely sold in the United States?

Mr. RAO. That's correct.

Senator OSSOFF. Why?

Mr. RAO. Senator, as we have discussed, it's a complex issue in terms of the legal landscape. We are taking enforcement efforts on a number of vectors to try to address the problem. Principally, the department has been engaged in defense of the FDA's marketing denial orders in district courts, in courts of appeal across the country. That has been more than 80 cases to date, and we've prevailed in a dozen of those.

In addition, we are working with the FDA and the U.S. Marshal Services on domestic seizures. There was a seizure earlier this year in Southern California in which 45,000 illegal cigarettes were seized. That's part of what we're doing to try to combat this problem.

We recognize that there's more that can be done. We have brought a number of civil injunction actions as well. But we, as part of this task force that that has been previously mentioned, we are looking to engage with law enforcement partners across the executive branch to do more in this area.

Senator OSSOFF. Thank you, Mr. Rao. So none of the non-tobacco flavors, the flavors that are clearly in my view, meant to appeal to kids are FDA-approved. None of them are legal to sell in the United States. Flavored products are still widespread in our communities.

In Georgia, a 2019 study found that 1-in-5 high school students had vaped, often drawn in by flavors and bright packaging. And be-

cause the products that some students are accessing are unregulated and illegal, they're sometimes laced with other drugs or contaminants.

Last March in Lee County in Southwest Georgia, a student was hospitalized after using a vape reportedly laced with THC and fentanyl. And a 13-year-old in Whitfield County, Georgia suffered a stroke and paralysis after reportedly using a brightly colored blueberry raspberry vape. The toxicology report was positive for THC and PCP. How will the department prioritize enforcement aimed specifically at those products that are contaminated or which contain other deadly and illegal drugs?

Mr. RAO. Senator, it's the highest priority for the Department. We share your concerns regarding the health risks with respect to vaping products that may contain additional dangerous products, again, that often originate in China.

The Department has brought criminal actions against individuals involved in the importation of counterfeit vaping related items and we would look forward again to working with the task force to, to bring more such actions going

Senator OSSOFF. Mr. Rao, what's your candid message for Georgia families right now who fear that their middle school or high school student may unintentionally and inadvertently vape and consume something like fentanyl or PCP?

Mr. RAO. I want to send the message that the executive branch is taking a very aggressive approach to trying to combat this problem using all available tools and working closely with law enforcement partners to consider all potential avenues for enforcement against this threat.

Senator OSSOFF. What does it look like to work with, for example, local law enforcement agencies in Georgia to make sure that there's not fentanyl in e-cigarettes and vape products that are being marketed to children?

Mr. RAO. Certainly, the Department and other law enforcement partners would appreciate the opportunity to engage with local law enforcement which has a—

Senator OSSOFF. Are you doing it yet?

Mr. RAO. It's certainly something that our law enforcement partners are constantly considering in terms of a potential option and are always open to.

Senator OSSOFF. It is not a trick question. Just so I understand, so that I can be helpful in connecting your team with the right local law enforcement agencies in Georgia. Are you currently working directly with local law enforcement agencies to identify, for example, fentanyl-laced vape pens in Georgia or elsewhere in the country? Is that something that my office can help facilitate that liaison between you and local law enforcement in Georgia?

Mr. RAO. Yes. It's certainly something that we would welcome facilitation on. I want to be sure that I'm, you know, providing correct information and connecting you with the right people. Again, you know, I know our law enforcement partners constantly work with local law enforcement in all of their matters and would welcome engagement from law enforcement partners in Georgia to combat this issue.

Senator OSSOFF. Thank you, Mr. Rao. Thank you, Dr. King. Thanks.

Chair DURBIN. Thanks, Senator Ossoff. Senator Blackburn.

Senator BLACKBURN. Thank you, Mr. Chairman. And we appreciate you all being here.

Dr. King, I want to come to you first. And Senator Booker was asking about the China-produced products that are coming into our supply chain and the lack of verification around those, and you kind of skirted that issue a little bit.

So, I'm going to give you the opportunity to submit in writing to us, what is that pre-market paradigm, what is that third party verification that you-all are using to make certain that tainted products and illegal products are not in this stream? Because you've not wanted to answer that question fully.

Also, when you saw Senator Durbin's chart that Senator Tillis held up, you couldn't say if there, things were being safe harbored. So, let's get some clarification around that so that we understand the extent of the problem that we're dealing with. And you can just submit that in writing for the record. That would be helpful.

Senator BLACKBURN. I also want to ask you, Dr. King, about the role that social media is playing in this epidemic and see what you are doing to address that. We know that TikTok, Instagram are being used to market these illegal fruit and dessert-flavored e-cigarettes to children. And any of us can go into any market or any of these vape stores that are in our State, and we see what is happening there.

So, I would think that one of the central tenets and activities of the task force work should be looking at how social media is being used to promote and to leverage these products into the marketplace to children. Are you focused on social media's role?

Dr. KING. So, I'll say that we have authority over remanufacturing, marketing, and sale. We do not have authority to take action against individuals, but if that influencer is connected to a manufacturer, we can take action. We have issued warning letters in the past, and I will note that the Federal Trade Commission will be on this interagency task force, and they have key authorities in that space that will be useful as part of a coordinated approach.

Senator BLACKBURN. Okay. So, you issue warning letters. So then are you turning those entities over to DOJ so that they can be a part of this? Are you turning them over to FTC so that they can go after penalties and enforcement?

Dr. KING. So we regularly engage with all of those agencies even before the task force, but it depends on the merits of the case. And so, if the case warrants that—

Senator BLACKBURN. Okay. How many have you turned—

Dr. KING [continuing]. After the warning letters—

Senator BLACKBURN [continuing]. Over, and how many have been penalized?

Dr. KING [continuing]. We have escalated. So are you speaking with regard to influencers specifically—

Senator BLACKBURN. Yes.

Dr. KING [continuing]. Or any enforcement action against any entity?

Senator BLACKBURN. Influencers. Social media is what we're discussing.

Dr. KING. Yes. So depending on the action, that would be more appropriate through the Federal Trade Commission, not the FDA.

Senator BLACKBURN. Yes, I said DOJ or the FTC. How many have been shut down? See, this is a part of the problem. It is if you're talking in circles, and we can't figure out what you're doing to actually stem the flow of these products and to bring people to account, and to hold them responsible for what they are doing. And if you're issuing warning letters and somebody gets that, but they know that DOJ and FTC is not going to execute any type of accountability on them, then they're going to delete that email warning, or they're going to crumple that letter and throw it in the trash.

Dr. KING. I will reinforce that a majority of those who receive warning letters do heed and correct the violative actions, and we have escalated our actions in the past 2 years alone. We've issued the first injunctions against manufacturers, the first civil money penalties against manufacturers, the first civil money penalties against retailers.

We definitely need more. I completely agree. But we need an all-of-Government approach, and I'm hopeful the task force will get us there. But we've set a solid foundation to move forward further.

Senator BLACKBURN. Okay. And Mr. Rao, coming to you. What about the new task force? Are you planning to use civil and criminal penalties?

Mr. RAO. We are exploring all tools, Senator, both civil and criminal. One aspect—

Senator BLACKBURN. Okay. So my time is running out. So you're exploring, but this is an issue that's kind of gotten away from you—all, and you've been slow to respond, and I think it's disappointing to hear you kind of talk in circles about what you are planning to do. But you haven't established a plan, and you're not certain what your way forward is going to be. Thank you, Mr. Chairman.

Chair DURBIN. Thanks, Senator Blackburn. Senator Lee.

Senator LEE. Thank you, Mr. Chairman, and thanks to you for joining us today.

Let me start off by saying that teen vaping is a problem. It's a problem that our society needs to address. Those who try to get kids hooked on nicotine should be ashamed of themselves. Studies have shown that the use of e-cigarettes can easily transition to marijuana and other drugs, especially among these younger users.

My concern here is that the Federal Government has said that it wants to be tough on tobacco. And in saying that, it's issued a bunch of regulations for legal approval, only then to sit on those applications for legal products in the U.S. produced by U.S. companies, while turning a blind eye to illegal Chinese imports.

Small businesses selling products are left with little to no guidance as to what's legal and what's illicit. And this is bad, and it's led to more teen vaping.

The FDA has publicly committed to clearing the backlog of pending product applications by June 30 of this year. Many of these applications have been pending for several years, even though the deadline set by statute is 180 days. June 30 is in less than 18 days,

I wonder, I question whether they can get that done by the June 30 deadline. I hope they can. But it makes me wonder why it's taken this long.

Look, if we're going to establish a byzantine labyrinth of federal regulations to make it more difficult to do this stuff, then for heaven's sakes, at least make the regime work. The worst thing you can do is set those up so as to choke out U.S. producers who are trying to comply with the law, and then open the floodgates so that the illegal Chinese products can move in and be sold on unabated. So, I wonder about this backlog, and I think the backlog is a significant problem.

Now, between 2019–2020, there was a 1,000 percent increase in high school students' use of disposable e-cigarettes. That's a very significant jump, and most of these e-cigarettes are illegal flavored e-cigarettes from China aimed at children. China's sales of e-cigarettes into the U.S. market generate an estimated \$3.5 billion annually.

And yet, despite all of this, despite the 1,000 percent increase in teen usage of these illegal e-cigarettes, we've seen little to no civil enforcement action taken by the consumer protection branch of the Department of Justice against these large Chinese importers. Mr. Rao, I'd like to know why. Why is that?

Mr. RAO. Senator, we take very seriously the vast widespread prevalence of the products that you've described. And we have been working with our law enforcement partners, including the U.S. Marshal Service on looking at seizures of these products. There was a seizure—

Senator LEE. Hey, how many enforcement actions have you brought?

Mr. RAO. Senator, we brought multiple enforcement actions, civil injunctive enforcement actions. And again, we're also looking at the use of criminal tools, as well as other authorities, including the PACT Act.

Senator LEE. Okay. And some of those authorities that the Department has access to or that the U.S. Government has access to are civil and others are criminal. So, I have to ask the question—I'll ask it to you, since no one from ATF is here, why is it that ATF is not bringing more criminal enforcement actions against the large Chinese importers?

I mean, are they too busy revoking the licenses of Federal firearms, licensees based on paperwork violations so much so that they've chosen to ignore those who are selling illegal Chinese e-cigarettes to minors?

Mr. RAO. Senator, we're working closely with the ATF on the use of the PACT Act. We are considering all available options under that statute, and we're committed to working with them to try to make additional headway in this area.

Senator LEE. Okay. Can you grasp my concern here, which is that when we set up this very large net, a net you might call it a dam, a barrier to entry that affects U.S. companies trying to comply with the law, and then you subject them to a lengthy licensing process, then they have to wait for years while getting their products licensed.

Then you have Chinese manufacturers not making any effort to comply with that law, not even making an effort to apply for approval when those are flooding the market and the U.S. manufacturers trying to comply with the law get nowhere. Can you understand why that's a problem,

Mr. RAO. Senator, this is an extremely complex and rapidly evolving area, and it is challenging in a number of levels. And again, that's why we are eager to continue the work with our law enforcement partners to try to address this going forward.

Senator LEE. Okay. Well, I hope they'll deal with it and by, among other things, bring in enforcement actions. But also, I hope that the folks at FDA can clear the backlog. Thank you.

Chair DURBIN. Thanks, Senator Lee. Senator Blumenthal.

Senator BLUMENTHAL. Thanks, Mr. Chairman, and thank you for holding this hearing, and for your longstanding commitment to stopping nicotine addiction and tobacco use, particularly among our children.

This cause is a longstanding one for me. I helped lead attorneys general in the 1990's to sue Big Tobacco and win a major settlement. And progress has been made, but obviously, not enough progress. And this hearing, I hope, will advance the cause of preventing vaping use of e-cigarettes, particularly flavored e-cigarettes, and bolster enforcement, which has been sadly lacking by the Federal Government. Lagging and lacking.

Last week, the FDA rescinded its marketing denial orders issued to JUUL Labs. This rescission means that JUUL's products will remain on the market while the FDA continues its review of JUUL's products. I'm concerned that the FDA's excision will cause a surge in illegal e-cigarettes be sold and used by vulnerable population and fueling the youth vaping epidemic.

I understand the FDA is in the midst of its review, but leaving these products on the market when they have not met statutory health standards is simply unacceptable and dangerous. As Chair of the Permanent Subcommittee on Investigation, I released a report in February, finding that the regulatory efforts of the FDA, including extensions of compliance deadlines and prioritizing enforcement of certain types of e-cigarette products have failed to curtail unauthorized e-cigarette products and prevent youth usage.

That is just one example of what we found in our investigation on the Permanent Subcommittee on Investigations, and that was set forth in the report. Obviously, I don't have enough time even to scratch the surface of the report that we produced, but I want to ask you, Dr. King, what evidence does the FDA have to allow these products to remain on the market? Aren't you concerned that this action will increase the use of JUUL products, even though the FDA has yet to complete its review? How can you leave them on the market?

Dr. KING. As a scientist, myself, I'm committed to following the science. And when I took this job, I vowed that, and I'm continuing it now, and that includes this review.

As was noted in the release, we're doing a full substantive review of the entire application. And I'll note that unless a product has authorization, it's not on the market legally, and therefore any product that does not have authorization has a risk of enforcement. And

I can't comment on specifics of any individual product, but we have an important paradigm in place. We've got to prioritize our resources accordingly, but we are monitoring the use of products, including those that are appealing to kids.

Senator BLUMENTHAL. What are you doing to mitigate the harms that JUUL is causing while you complete your review?

Dr. KING. Well, part of it is the scientific review to make sure that we're doing a robust review of the evidence, including the toxicologic risks and various other risks at the population as a whole. And concurrent to that, we're working on enforcement and we're taking action.

Senator BLUMENTHAL. When will your review be done?

Dr. KING. I can't comment on the specifics of an application, but I can tell you that we're working as tirelessly as possible.

Senator BLUMENTHAL. Well, that's the story of federal enforcement here, and you're not the one who should be bearing the brunt of the blame necessarily. But the history is a long one, and it's filled with delay, and procrastination, and failure to provide sufficient enforcement in a timely way.

Let me ask you, Mr. Rao. What provisions are you making for attorney general enforcement as part of this renewed effort?

Mr. RAO. Senator, I think as part of what we're looking to do going forward, is working with our federal law enforcement partners to identify potential gaps or potential areas in which additional support may be useful.

And, you know, as part of the regular discussions that we're going to be having, we'll certainly look to identify ways in which other agencies, whether attorney generals, whether State law enforcement as Senator Ossoff mentioned earlier.

You know, I think, again, it's a difficult issue, and it requires an all-of-Government approach. And so, we would certainly welcome opportunities to engage with other law enforcement partners, State and local.

Senator BLUMENTHAL. Thank you. My time has expired. I thank you both for your commitment to this cause. I think our view and our role in the Congress is to provide additional impetus and momentum. It's not personal. I respect your commitment and your credentials, your lifelong work in this area, but I think the Federal Government has continued to be less vigorous than it should be.

Thanks, Mr. Chairman.

Chair DURBIN. Thanks, Senator Blumenthal. We're going to wrap up the panel. Senator Tillis has a question. I have one before.

I've listened carefully, Mr. Rao, to your description of this issue that we're considering today. You have said, and I quote, "It is the highest priority of the U.S Department of Justice." You have said that it's an urgent issue. You have said we need a very aggressive approach. You said we need to use all available tools.

So, I'd like to issue a specific challenge to you. We're going to give you the address of the store that has the products here, and it's in Silver Spring, Maryland, within one mile of FDA headquarters. You have announced this new enforcement agency team that includes almost every law enforcement agency of our Federal Government. I hate to pick on one store, but I want you to prove to me that is urgent.

You're going to use all available tools and its highest priorities. We know that they are selling illegal products to children. We know that's happening, and it's happening across this country. So, now I'm going to find out this agency task force that has all the law enforcement agency, the Federal Government is on the case.

My crack investigators here found this store, and they found what they're selling to be illegal. Now, what are you [poster is displayed and points at witness.] going to do about it? What is U.S. Department of Justice going to do about it? Anything? I hope you'll report back to the Committee what you decide. Do you want to say something? You're welcome to.

Mr. RAO. Senator, again, I want to stress the Department's commitment to this issue, and to pursuing enforcement without fear or favor where the facts lead and where the law supports.

Chair DURBIN. And I will tell you, my investigative team here will be happy to work with you to identify the exact address of this store, which I'm not going to read into the record, but we'll give it to you so that we'll see what happens a week or two from now. We'll check on the store and see how they're doing. We'll see what the highest priority the Department of Justice means. Senator Tillis.

Senator TILLIS. Yes. You may be able to stop into that Exxon that Senator Cornyn's staff went to also.

First off, Dr. King, it is very clear to me that you are data-driven, science-driven, and I appreciate that. I'm trying to get to common sense-driven here, and you've got to operate within the context of the rules that we set here in Congress.

I understand that, and I'm not going to attack you, but it just seems to me that you couldn't throw a rock and not hit something. Like you see in Maryland. But right down here, I know there's the Exxon right down here, you may have gotten it there. Geek Bar was formed in China in 2015. They're responsible for this one that has advertising—is this “OMG Blow-Pop?” Oh, that's not focused on kids at all, right? The language, the marketing on the box, now they're in China. This one, however, is designed in the United States and manufactured in China. It's called EB Design.

[Holds up vape products.]

They're business is labeled apparently headquartered in California. Why aren't we going after them? If they're contracting to get a product made in China that has labeled on it, just sell it where it's legal in the United States. If in fact it's illegal throughout the United States, why aren't we at least able to go after any U.S.-based companies that are involved in this supply chain that's poisoning our kids?

Dr. KING. So, I'll reinforce that we have taken action against that company. It's actually a progeny from the Elf Bar product. We've done a series of blitzes since last April on a monthly basis where we have issued warning letters to not only the retailers, but also enhanced with civil money penalties.

And to your point around the data, that's what we're following. We know Elf Bar and those progeny products are the most commonly used product among kids, and that's where we prioritize the resources.

I do want to make it clear though, when we follow the science that the top two brands used among kids are Chinese manufacturers, but number three and four are domestic. And so, it's important that we follow the science and we'll continue to have a nimble approach to our enforcement.

Senator TILLIS. And what's the mix in those four then as a stratification of their market share? The top two are from China. The other two are from the U.S. What's the mix in terms of the market share?

Dr. KING. Higher market share is the U.S.-based companies and higher prominence among youth in terms of use is the Chinese-based.

Senator TILLIS. Thank you.

Chair DURBIN. It's my understanding that you have a history of finding retailers, but not manufacturers. Is that true?

Dr. KING. We have initiated the first civil money penalties against manufacturers within the past year, and I'm hopeful we'll continue that in the future.

Chair DURBIN. I hope so, too, because I not only want to go after this store, but I'd like to go after the product manufacturers that fill their shelves.

Dr. KING. I agree completely. Comprehensive approach is key. Agree completely.

Chair DURBIN. I want to thank this first panel for gathering, and Dr. King, and Mr. Rao, we're going to be back in touch with you to see if you're using all available tools to put these people out of business. Thank you very much.

Dr. KING. Thank you.

Chair DURBIN. We are now going to set up for the second panel. Let me read briefly the biographies of the second panel. Yolonda Richardson is president and CEO of the Campaign for Tobacco-Free Kids organization that has fought for over 25 years to protect kids and save lives by working to reduce tobacco use.

David Spross, executive director of the National Association of Tobacco Outlets, a national trade association of tobacco retailers. Tony Abboud, executive director of the Vapor Technology Association, a national trade association dedicated to protecting vaping and the alternative nicotine products industry.

Dr. Susan Walley, chief of the Division of Hospital Medicine at Children's National Hospital. She's an expert on the prevention of youth tobacco use and tobacco-related disease. Has served as chair of the American Academy of Pediatrics, Section on Nicotine and Tobacco Prevention and Treatment. And Josie Shapiro, a high school student from Seattle, Washington. She's fought nicotine addiction after picking up vaping as a teenager.

I'd also like to note for the record that we invited e-cigarette manufacturers, Altria, R.J. Reynolds, Japan Tobacco International, and Miracle Shenzhen Technology to send representatives to testify at the hearing. None of them agreed to do so.

So, I ask all the five witnesses to stand to be administered the oath. Raise your right hand.

[Witnesses are sworn in.]

Chair DURBIN. Let the record reflect that all five have answered in the affirmative. And Ms. Richardson, you have 5 minutes. Please proceed.

STATEMENT OF YOLONDA RICHARDSON, PRESIDENT AND CEO, CAMPAIGN FOR TOBACCO-FREE KIDS, WASHINGTON, DC

Ms. RICHARDSON. Thank you so much, Chairman Durbin, Ranking Member Tillis, Members of the Committee, thank you for inviting me to testify today.

I am Yolonda Richardson, and I'm president and CEO of the Campaign for Tobacco Free Kids. The Campaign is the leading advocacy organization working to reduce tobacco use and its deadly consequences in the United States and around the world. The Campaign was and is a strong advocate for the Family Smoking Prevention and Tobacco Control Act, which was the landmark legislation that gave FDA the authority to regulate tobacco products.

One of the most important tools that Congress gave FDA was the authority to conduct pre-market reviews of new tobacco products before they can be legally sold because of the Tobacco Control Act decisions about which new products enter the market are no longer supposed to be made by tobacco manufacturers based on economic considerations, but rather, ultimately made by FDA based on the need to protect public health after a careful review of the scientific evidence.

Unfortunately, as you've heard this morning, pre-market review has not been effectively applied to e-cigarettes. FDA failed to assert its regulatory authority over e-cigarettes until a substantial e-cigarette market had already formed, and e-cigarettes had already become the most popular tobacco product among youth.

FDA then further delayed implementation of the pre-market review requirements of e-cigarettes, allowing these markets to remain on the market for years. Only when the Campaign and other public health groups successfully challenged the delay, did FDA initiate pre-market review process in 2020, years after these products were already on the market illegally?

Now that pre-market review has started, we are encouraged that the FDA has appropriately applied the public health standard as intended by the Tobacco Control Act. We agree with FDA's determination that flavored products should not be permitted because they increase the appeal and use of e-cigarettes by youth.

Yet, as we've noted this morning, the process has been slow, and several e-cigarette companies have flooded FDA with pre-market applications for millions of products gumming up the process. The result, thousands of e-cigarettes are still under review, and there appears to be an unstated policy of not taking enforcement action against products with pending applications, including flavored e-cigarettes.

The large number of unauthorized e-cigarettes on the market continue to present risk to public health. These products are highly addictive, can expose users to harmful substances, and have consistently been shown to appeal to youth. Appealing flavors and addictive levels of nicotine is a dangerous combination, which is why the FDA has rejected applications for millions of flavored e-cigarettes.

Over the past year the FDA has taken some important enforcement actions, but the current level of enforcement activity has not proven to be sufficient. More and stronger enforcement action is needed. The Campaign and 77 other organizations recently sent a letter to FDA, the Department of Justice, and Customs and Border Protection urging them to make several changes.

I will quickly highlight for you some of the changes that we proposed. First, the FDA must see greater monetary penalties. FDA has been sticking penalties of only about \$20,000, which is too low to serve as a deterrent.

Second, the Department of Justice must prioritize tobacco product enforcement, and act more quickly and aggressively when violations are found. Despite widespread non-compliance, DOJ has sought injunctions against only seven manufacturers today.

Third, Custom and Borders Protection and FDA must prioritize and stop illegal importation of unauthorized products. Many of the products you discussed early in the day that are coming in from outside of the United States.

Fourth, the enforcement action must be brought against all parties in the supply chain from manufacturers to wholesalers, and distributors, down to retailers. Fifth, FDA must end the broad exercise of enforcement discretion for products with a pending application. These products are no more legal than products for which no application was ever filed.

And lastly, FDA must complete its review of e-cigarettes. FDA needs to move quickly to a true pre-market review process where products are reviewed prior to entering the market rather than the current post-market review.

We welcome this week's announcement about the creation of the Multi-Agency Task Force, a whole-of-Government approach. This could be important, but it must be immediately followed with concrete and comprehensive enforcement actions. Federal agencies should also coordinate closely with States and localities on enforcement where appropriate.

Pre-market review has great potential to reduce youth e-cigarettes, but without adequate enforcement, companies will continue to flout FDA requirements and put young people at risk.

Thank you, Mr. Chairman.

[The prepared statement of Ms. Richardson appears as a submission for the record.]

Chair DURBIN. Thank you, Ms. Richardson. Mr. Spross—did I pronounce your name correctly?

Mr. SPROSS. You did, Senator.

Chair DURBIN. Please proceed.

STATEMENT OF DAVID SPROSS, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF TOBACCO OUTLETS, WINSTON-SALEM, NORTH CAROLINA

Mr. SPROSS. Good morning, Chairman Durbin, Ranking Member Tillis, and Members of the Committee. I appreciate the opportunity to join you today. I am David Spross and I serve as the executive director of the National Association of Tobacco Outlets, a national retail trade association that represents more than 66,000 retail stores throughout the country.

At the outset, I want to clearly affirm our strong support for a well-functioning regulatory system in which FDA oversight leads to accelerated reductions in underage use and into tobacco-related harm. NATO and our members are invested in this system, and in these goals. Illicit markets are a major threat to that goal, and thus, a threat to the responsible retail community committing to operating within, not outside, the legal system.

NATO members take compliance seriously. Our members include licensed retailers who age verify their customers to prevent sales to minors. We have also been regularly informing our memberships of the brands FDA has targeted in its warning letters and other enforcement actions to ensure our members know in detail what products FDA is taking action against.

Today's hearing addresses a very important topic. The marketplace is overrun by illicit and unregulated products, the vast majority of which are flavored vapor products made in China. To date, we have seen piecemeal enforcement that often ignores the most egregious actors.

The task force announced this week is a good start for it to be successful. The task force should use the full range of enforcement tools, It has particularly focused on the worst offenders, the largest manufacturers, and distributors of these illicit products. With more aggressive enforcement action, we believe order can be restored to this marketplace.

An effective regulatory system also requires a more coherent compliance framework that clearly communicates FDA's enforcement priorities. That is, the products that are once immediately removed and the products that can remain on the market. That information is critical to helping address the marketplace chaos we see every day.

FDA has said that only 23 authorized vapor products are legal. But we also understand that FDA is not currently prioritizing enforcement against vapor products that have fully complied with its 2016 deeming rule, and that have filed timely PMTA applications, which remain pending before the agency.

FDA has repeatedly acknowledged that the removal of products pending PMTA review would stimulate illicit market activity and take potentially reduced harm products away from smokers. Simply put, NATO members who are seeking to abide by the law need greater clarity from the FDA. In addition, we believe FDA must reform its PMTA process. In our view, the process has fallen short of its intended purpose, and that is why we've seen a flourishing illicit market.

To date, FDA has only authorized a small handful of small smoke-free products despite millions of adult consumers seeking better alternatives to smoking. As FDA and Dr. King have acknowledged, smoke-free products are much less harmful than cigarettes for smokers who want to switch. But with so few FDA-authorized choices, consumer demand is now being met by Chinese companies that want the FDA's regulatory system to fail. Authorizing more products will help build a well-regulated market.

In closing, NATO strongly supports solutions that reduce underage use and deliver on tobacco harm reduction. We look forward to

working with the FDA, the task force, and this Committee to address these issues.

Thank you very much.

[The prepared statement of Mr. Spross appears as a submission for the record.]

Chair DURBIN. Thank you, Mr. Spross.

Mr. ABBOUD.

**STATEMENT OF TONY ABBOUD, EXECUTIVE DIRECTOR,
VAPOR TECHNOLOGY ASSOCIATION, CHICAGO, ILLINOIS**

Mr. ABBOUD. Thank you, Chairman Durbin, Ranking Member Tillis, and Members of the Committee for allowing me to testify today and answer your questions on a topic that is crucial to our public health. I hope that my opening statement and responses to your questions will inform a balanced conversation about tobacco policy in the United States that is rooted in the science on e-cigarettes.

My name is Tony Abboud, and I'm the executive director of the Vapor Technology Association. VTA is a trade association that protects and promotes a vibrant U.S. vapor industry with companies at every level of the distribution chain, including manufacturers, distributors, suppliers, and mom-and-pop-retailers.

Discussions like the one we are having today are critical to our members throughout the country. In informing our efforts and our engagement with the esteemed Members of this Committee, I hope I can serve as a useful and important resource for you all.

Let us begin with the fact that youth vaping in the United States has dramatically resolved from the peak of the JUUL epidemic in 2019. Since then, youth vaping has plummeted 61 percent, largely due to the common-sense federal law raising the age to buy tobacco products to 21, a law that VTA championed with the White House and with Congress.

According to the CDC's National Youth Tobacco Survey, the youth vaping rate now sits at the lowest level in more than a decade, before e-cigarettes were even regulated by the FDA. Even better now, only 4.4 percent of youth use e-cigarettes regularly, and even fewer use them daily.

Interestingly, in that same CDC survey, youth have consistently reported that flavors are not the reason they first try an e-cigarette or the reason they currently use e-cigarettes. Even more interesting, the dramatic rise in flavored disposable vaping products since 2019 in this country has corresponded with that dramatic decline in youth vaping.

But as dramatic as the decline in youth vaping has been, VTA has not been satisfied and has been advocating on the Hill for serious common-sense marketing and access restrictions to further protect youth from e-cigarettes. Why is this important? In February, Dr. Nancy Rigotti of Harvard Medical School wrote in the *New England Journal of Medicine*. "It is now time for the medical community to add e-cigarettes to the smoking cessation toolkit. U.S. public health agencies and medical societies should reconsider their cautious positions on e-cigarettes for smoking cessation. The evidence has brought e-cigarettes to a tipping point. The burden of to-

bacco-related disease is too big for potential solutions such as e-cigarettes to be ignored.”

Further, last fall, the Medical University of South Carolina published the largest clinical trial in the United States, covering 4 years and 11 cities, finding that e-cigarettes help people quit smoking better than the FDA-approved medicines on the market, even if the individuals had no intention of quitting. In other words, the mere availability of these vaping products caused them to quit smoking.

Another study by Abigail Friedman from Yale, showed that flavored e-cigarette restrictions result in a direct increase in cigarette sales in those jurisdictions, which have limited them. The authors warned any perceived public health benefits of reducing flavored e-cigarettes may be offset by the public health costs from e-cigarette sales.

The reason we are having this enforcement discussion today is because U.S. tobacco regulation in the hands of this FDA is broken. The FDA was supposed to implement the Tobacco Control Act to allow Americans access to alternatives to cigarettes that are less harmful. Instead, the FDA has done the exact opposite. It has misused its power to impose a de facto ban on flavored vaping products without reviewing the science.

Since passage of the Tobacco Control Act, the FDA has authorized 16,000 combustible tobacco products and only a handful of vaping products. In the past 2 years alone, this FDA has not authorized a single vaping product or nicotine pouch product like Zyn, but it has rushed 2,000 new combustible products, including 821 new cigarettes to the market for Americans to smoke.

The FDA has not done its job as a regulator, and now it wants more funding to enforce the very actions which federal courts have declared illegal and which are going for supreme court review. To be clear, the FDA has repeatedly stated that every single vaping product on the market is illegal regardless of whether the company has a pending application. That means it is enforcing prohibition. I contend you can give it all the enforcement power in the world, but prohibition cannot be enforced.

Instead of pursuing this failed regulatory policy, the FDA must reverse course, make harm reduction its north star, and authorize a wide variety of products that are less harmful products. Filling the market with flavored products, which American adult consumers are clearly demanding is the only way to curb the illicit demand and give Americans what they need, what they want, and what the law was intended for them to have. Only then will half a million Americans who die from smoking every year have a regulated choice and a fighting chance.

Thank you for the opportunity to testify. I look forward to answering your questions and working with the Committee going forward.

[The prepared statement of Mr. Abboud appears as a submission for the record.]

Chair DURBIN. Thanks, Mr. Abboud.
Dr. Walley.

STATEMENT OF SUSAN WALLEY, MD, MHCM, NCNTT, FAAP, IMMEDIATE PAST CHAIR, SECTION ON NICOTINE AND TOBACCO PREVENTION AND TREATMENT, AMERICAN ACADEMY OF PEDIATRICS, WASHINGTON, DC

Dr. WALLEY. Thank you, Chairman Durbin, Senator Tillis, and Members of the Committee. My name is Dr. Susan Walley, and I serve as the Division Chief of Hospital Medicine at Children's National Hospital here in Washington, DC. I'm a pediatrician, and an expert in adolescent tobacco use. I'm here today representing the American Academy of Pediatrics, an organization that represents 67,000 pediatrician members.

E-cigarettes are addictive and they are dangerous for children. Unfortunately, we are here today because we're not doing enough to protect our youth from a tobacco industry intent on profiting off the use of these harmful and addictive products among children.

Contrary to what you have heard today from the tobacco industry, over 2 million children and adolescents currently use e-cigarettes. The tobacco epidemic is not over while down from its peak a few years ago, it is still a shockingly and unacceptably high number. What's more? Over a quarter of youth e-cigarette users use the products every day.

One of the primary reasons, as you have heard, children are attracted to e-cigarettes is the sweet fruit candy and mint flavors they come in. The flavors smell and taste great, and they mask the harshness of tobacco. These products are also often marketed with packaging that resembles candy and snack food. As a pediatrician, I see all too frequently how nicotine addiction takes hold in teenage patients who vape e-cigarettes.

The adolescent brain is more susceptible to nicotine addiction. So, symptoms of dependence can appear in days to weeks of first experimentation with e-cigarette use. When the brain does not get the nicotine, it craves. Teens experience unpleasant withdrawal symptoms such as irritability and anxiety, which leads to continued use for many young people. This is not just sporadic use, but consistent, frequent, and dependent use.

Unfortunately, the trusted adults that teens usually rely on; parents, teachers, and pediatricians like myself, have limited options to assist in their quitting. I'm certified in nicotine and tobacco treatment, which means I have special training on how to help people, including children, quit using tobacco products.

But pediatricians have found that helping adolescents stop using e-cigarettes is exceedingly difficult due to the high level of nicotine in these products, targeted marketing, and easy access. Many of these children are very addicted, and we have limited effective tools in our toolbox to help them because youth tobacco cessation, treatment, particularly for e-cigarettes, has had limited research funding.

So, our best strategy to avoid youth nicotine addiction is to prevent the use of any tobacco products in the first place. And we know the most effective way to stop youth e-cigarette use is to get all flavored tobacco products off the market. This is where we need the Food and Drug Administration's help.

To date, as you have heard, FDA has reviewed millions of e-cigarette applications and has appropriately rejected the vast majority

of them. It is determined that no e-cigarettes that are flavored are appropriate for the protection of public health.

FDA has authorized only 23 e-cigarette products. These 23 products are sold under only three brands, and none of these products come in a flavor other than tobacco. These are the only products that are allowed to be legally sold in the United States, but yet thousands of flavored e-cigarettes make their way to the hands of children every day. And just like Senator Tillis, I think we shopped at the same place, this OMG Blow-Pop e-cigarette that I purchased within walking distance of a school.

Today, 90 percent of youth e-cigarette users report using a flavored product despite none of them being authorized by the FDA. Simply put, this is unacceptable. The solution should start where the problem starts; with the tobacco industry and its supply chain.

Manufacturers should end the production of unauthorized e-cigarettes. Distributors should stop distributing them. Retailers like vape shops and convenience stores should stop selling them to the public where they ultimately lie in the hands of children.

But history has taught us that the tobacco industry and its partners are unlikely to do the right thing on its own. That's why we need the Federal Government to get these illegal products off the market. We appreciate that the FDA recently stepped up enforcement and is creating a multi-agency task force with law enforcement partners to expand e-cigarette enforcement.

Congress can also help by ensuring these enforcement efforts have sufficient funding. We really need every relevant partner to step up and make this a priority. Youth e-cigarette use is still a very real problem, but it is a solvable problem, and we have solutions. We just need the will to implement these solutions.

America's pediatricians look forward to working with you to ensure that our children grow up without the harms of tobacco products. Thank you.

[The prepared statement of Dr. Walley appears as a submission for the record.]

Chair DURBIN. Thanks, Dr. Walley.
Ms. Shapiro.

**STATEMENT OF JOSIE SHAPIRO, HIGH SCHOOL STUDENT,
LINCOLN HIGH SCHOOL, SEATTLE, WASHINGTON**

Ms. SHAPIRO. Hi. My name is Josephine Shapiro. I am a high school senior from Seattle, Washington, and I'm addicted to nicotine because of e-cigarettes.

I grew up hating cigarettes and other commercial tobacco products. I would cough as I walked by smokers trying to alert them of the harm that they're doing to their bodies. I never thought I would touch a cigarette or any other tobacco product.

As early as middle school, this started to change. My friends started vaping in seventh grade. They thought vapes were harmless because of the fun flavors and colorful packaging. They wanted to be cool like the pretty girls they saw vaping on social media, but they didn't realize they were becoming addicted.

Vaping soon started to take over their lives. They would leave class early to vape in the bathrooms or anywhere else they could get away with it. It's easy to hide these products in your sock or

your bra, which makes it difficult for teachers or parents to know when kids are vaping.

In ninth grade, I began to hang out with a new group who used all sorts of e-cigarettes. The more I hung out with these people, the more vaping became normal to me, and I had to try it. The first flavor I tried was blueberry ice, but I tried pretty much every flavor my friends had. I thought I was just enjoying the flavors. But soon, my 14-year-old brain craved the nicotine more and more. I promised myself I wouldn't buy my own vape because I wasn't addicted if I was just hitting my friends', right?

It wasn't long before I broke that promise to myself. I was already addicted, and little did I know it was about to get worse. These products are easy to get. You can ask someone older than you to buy it, buy it off a friend, or go to a store where they don't ID you.

Once I had my own vape, I would leave class to vape in the bathrooms with my friends. I would get invited to lunch so people could hit my vape, and all of a sudden, my entire circle was centered around vaping. The hold nicotine had on my young mind was intense and scary. I felt completely out of control, helpless and alone, even though I knew I wasn't.

Vaping affected my mood, my ability to catch my breath, and even my skin. I couldn't spend quality time with my friends without thinking about when we were going to get our next hit. I really miss the times when we could have fun without the presence of nicotine.

One of the saddest things about vaping and nicotine addiction is how it ruins relationships between friends and families. I can't tell you how many ways it impacted my friends, but let me tell you one example. One of my friends was so addicted she would say things like, "I'll just die at 20, whatever." I watched her isolate herself from the rest of her life, but as long as she had her vape, she said she was okay.

Vaping for her was not just an addiction, it was her lifeline. We would skip class and activities to sit in her car and vape. Then the vapes turned into cigarettes, and then the cigarettes turned into other drugs.

My story is still ongoing today. Our story is still ongoing today. As I look forward to all the wonderful things have ahead of me, I'm still struggling to get over my nicotine addiction, and I blame it all on the blueberry ice vape.

I've tried to quit vaping over and over again, but it's really, really hard. Everything in my life is a trigger; hanging out with friends, driving my car, going to the bathroom, going into a convenience store, all of it makes me want to vape. Honestly, I haven't been able to stay clean for more than 2 months since I decided to quit. I feel terrible about it.

My addiction consumes a lot of my life. It has impacts on my physical and mental health. It makes me feel like I am less than, but the reality is that my ambition and goals have been suppressed by an industry that profits from me and my peers. That's why I'm sharing my story today. I'm doing everything I can to prevent young people from ever starting to vape or use any tobacco product.

My story is mine, but I also tell it to protect the new generations. I have two younger siblings and imagining them with a blueberry ice vape breaks my heart. There are over 2 million kids who vape in the United States, and millions more will go through the same thing if we do nothing.

From my perspective, we have to get rid of every single flavored e-cigarette. Until then, kids will continue to use these products, and they will continue to get addicted just like me. Thank you.

[The prepared statement of Ms. Shapiro appears as a submission for the record.]

Chair DURBIN. Ms. Shapiro, thanks. It couldn't have been easy for you to decide to do this, but it's important that you did. To hear firsthand the story of what you've been facing makes a real difference. I mean, to all of us. Dr. King is still in the room. People representing the industry are still in the room. They need to listen very carefully to what you had to say. Stick with it. You can beat this. I know you can. You have enough determination to be here today, and we're cheering you on.

Dr. Walley, what about this argument that vaping is a good way to stop tobacco use?

Dr. WALLEY. Thank you for the question, Senator Durbin. As a trained nicotine and tobacco specialist, and a former medical director of a tobacco consult service, you know, I understand the devastation of an adult who has been smoking for 50 years and has what we call like 100-pack history, where they smoke two packs of cigarettes a day for 50 years, and so no one would be more happy to see additional FDA-proven, safe, and effective smoking cessation therapies.

The FDA has already approved safe and effective smoking cessation therapies, and this is crucial that we as a medical community and as a society, make sure that we provide the access to those safe and effective FDA-approved smoking cessation therapies.

Chair DURBIN. So, Mr. Abboud, when you listen to Ms. Shapiro talk about her addiction, what do you think as the head of the association for vaping?

Mr. ABBOUD. Well, first of all, Senator, I think about her as a parent of three teens and young adults. These are not new issues for me, for my family, for any parents in the United States.

Chair DURBIN. Are your kids vaping?

Mr. ABBOUD. Some of them do vape, yes, and we talk about this issue like we do all the other issues that teens have to struggle with.

Chair DURBIN. Do you encourage them to stop?

Mr. ABBOUD. Of course we do. Of course, we encourage them to stop.

Chair DURBIN. Well, doesn't that tell the whole story here? You don't want your own kids doing this. Why do we want any kids doing this?

Mr. ABBOUD. We don't want any kids doing this. This is why we raised the age to 21 and we advocated for that. That's why we've made this product illegal. That's also why we work hard at doing the other things, making more common-sense regulations to make sure that these products don't get into their hands increasing things.

Chair DURBIN. Mr. Spross, your retailers, what do they think about this product? Do they just assume that since it's going to be legally sold in the United States or apparent, legally sold, they have no moral obligation to the kids that are buying them?

Mr. SPROSS. Quite the opposite, Senator. We take a zero-tolerance policy in terms of ensuring that our retailers are trained to prevent sales to youth, whether that be through card access or using the available tools that are out there through the FDA website.

Chair DURBIN. Do your retailers sell flavored products?

Mr. SPROSS. They do. And I would say, like I said in my statement, yes, we've communicated the 23 products that have been granted marketing orders. But we also, as I referenced, there's been products that have filed timely PMTAs according to the statutory deadlines. And those products are not in receiving the enforcement right now.

Chair DURBIN. Mr. Spross, I don't know if you were here earlier, Mr. Abboud as well. We established that applying for the PMTA is one thing, but there is a burden of proof by the manufacturers as to the safety of their products. And that is the one element that is clearly not being met by many of the products that are on sale across America today. Do you understand that distinction?

Mr. SPROSS. I do. What I would also add, just in terms of the— if you can't sell it through licensed, regulated retail shops where you are age-verifying to prevent youth from purchasing the products, it will go into the illicit market.

And so, quite frankly, as I said in my statement, authorizations are the key to this. There's 250,000 applications currently before the FDA that have been sitting there, in some cases more than 4 years, and the time is now.

Chair DURBIN. Do you understand the law says that they'll continue to sit there until the manufacturer meets a burden of proof?

Mr. SPROSS. Yes.

Chair DURBIN. You can't go selling those in the meantime, assuming that they've proven something that they haven't proven. Do you understand that distinction?

Mr. SPROSS. I do, yes.

Chair DURBIN. Mr. Abboud, what about that? I mean, you said this is prohibition. Is it prohibition to say you have the burden of proof that your product is safe for public health before it can be sold in the United States?

Mr. ABBOUD. Yes. The problem, of course, Senator, is the fact that the FDA created the regulations. They set the deadlines for complying with the regulations they asked for and received funding from this body for enforcing those regulations. They changed the rules of the regulations and the requirements after applications were submitted, and they did so in a manner that did not involve any sort of public policy oversight.

The net result was the mass removal of products from the marketplace, and which of course, spawned this illicit marketplace.

Chair DURBIN. The original law, the Tobacco Control Act, puts a burden of proof on the manufacturer to prove that their product is safe for public health. Do you understand that responsibility?

Mr. ABBOUD. I do. I do. And the Reagan—

Chair DURBIN. And do you disagree with that? Do you think that's not the case?

Mr. ABOUD. But manufacturers need to know from the FDA what is required to make that proof. And the Reagan-Udall Foundation, which was an independent body that was asked for by the commissioner, said that the agency has not told companies what is required to prove APPH or how they are interpreting it.

And instead of responding to that criticism, the FDA waited 1 year and said nothing. They are not telling manufacturers what they need to do to comply. And they're not even telling retailers what products they're even reviewing, much less how they're reviewing them.

Chair DURBIN. Twenty-three of those manufacturers have been approved. So, obviously, they knew what they needed to comply.

Mr. ABOUD. Well, that's a little bit of a stretch, Senator. Only because they're 23 is really basically only 8 devices, which is—and only a few, 5 of them, are on the market today. That's not enough for 30 million smokers. That is not enough of options.

Chair DURBIN. I think the bottom line is if you want to discourage your own children from using vaping products, we ought to understand the danger of that product. And I think you inherently do. Most parents would. Senator Tillis.

Senator TILLIS. Thank you, Mr. Chair. I want to go back to—I think it related to a question that you asked Dr. Walley. But a part of what we don't want to do is to remove options that are safe for alternatives to an otherwise—to an activity that you as a physician, you wish they wouldn't even vape. Right?

But there's a reason why there are nicotine lozenges. There's a reason why there are nicotine pouches. They are providing people with off ramps to habits that, hopefully, they can quit. It's how I quit last year starting with pouch tobacco, actually starting with rough cut tobacco, moving to pouch spitless tobacco, then ultimately to a nicotine pouch. And now I'm as of last September, I've never—I haven't touched it since. And Josie, I wish you the same. I know it's not going to be easy.

But let's not forget that these are healthier alternatives in the hands of adults. What we're trying to do is remove it as an option, easily accessible option to children. We'll have a separate discussion maybe on another day about the ultimate disposition, but we shouldn't lose that. And Mr. Abboud, when we see these shelves of products, and I guess Dr. Walley, it was the Senator Durbin staff that went to the vape shop—I haven't been to one yet, but I will go—we're talking about an illegal product here. We're talking about something that shouldn't be on the shelves.

So, Mr. Spross, could you just, for the record, could you submit communications from your association to your members that say this is bad, don't do it." Just evidence that you've already suggested that you're doing that, but that you are universally communicating to anybody that's associated or any other retailer will ask the same of others that they're saying this is bad, get it off the shelves. It's not only illegal, it's unhealthy. Can you submit that for the record?

[Holds up vape products.]

Mr. SPROSS. Yes. We communicate to our members anytime there's an enforcement action against the products that are deemed illegal by the FDA.

Senator TILLIS. Mr. Abboud, your industry's future rest on getting this right. And again, I've got to believe that you don't see your future as successfully marketing to kids. That is not a sustainable path for a credible, legitimate business in the United States, probably nowhere, but certainly not in the United States.

So, if you were waiving a wand and you were Dr. King, or you were in charge of the Federal Government regulatory agencies, or you were a Member of the U.S. Senate and wanted to fix this problem, what would your suggestion be? Number one; do you suggest that there is a problem? Is there a problem that needs to be fixed? That's the first question. Otherwise, it disqualifies the second one; is there a problem that exists with youth vaping and a vector to more dangerous outcomes?

Mr. ABBOUD. There is definitely an issue that persists.

Senator TILLIS. Now, you've got an opportunity to wave a wand. What should we do?

Mr. ABBOUD. There's two, maybe three principal things that we do. The first is that we implement serious marketing and access restrictions. The kind that we've been meeting with Members on the Hill about, and we've been recommending for years. Unfortunately, this body has typically only wanted to talk about banning flavors as if flavors was in itself the only thing about marketing.

We know that youth are impacted by this issue. They say they are impacted and attracted to vaping for many other reasons other than vaping. We can get to those concerns, we can get to access restrictions and do things that doesn't require removing all of the products that adults are using.

The second thing is, from an FDA perspective, I think we've clearly heard the testimonies today. This is a hot mess right now, and there is no clear pathway out, particularly through this PMTA process.

And you heard Director King say, well, we're going to try to resolve these applications, but we have to worry about litigation. Of course, they do, because they put themselves in a box now where they have rejected en masse all flavored vaping applications. So they can't make any more decisions along those lines without worrying about what the supreme court thinks.

But the answer is already in the Tobacco Control Act. They could implement a tobacco product standard. They can move on it aggressively. They could state what should and should not be in the products, how products should and should not be manufactured. They can lay out those standards that manufacturers can comply with.

There won't be any black box questioning as to what happens when an application goes in. It won't take 4 or 5 years for an application to get resolved, and then we can move forward with an actual regulated market.

But unless they make harm reduction their north star, unless they say we believe in vaping products—and we want to encourage them like they are doing in other countries—we are going to persist in having an illicit market. It will just be a purely black market,

not sold through any of the legal or regulated licensed and tax-paying retailers and distributors that our entities represent.

Senator TILLIS. Thank you.

Chair DURBIN. Senator Blumenthal.

Senator BLUMENTHAL. Thanks, Mr. Chairman. Mr. Abboud, the reason why you don't want your kids to vape is because of the health risk. Correct?

Mr. ABBOUD. What I want my kids is to be healthy, as healthy as possible. And when they're suffering from a variety of issues that many adolescents are dealing with, then we have to address those as parents.

Senator BLUMENTHAL. Well, I think you've just answered my question. I have limited time, but I think the answer is yes. And the health risks are; Number 1, nicotine addiction; Number 2, the substances that may be in the vaping material. We have no idea what they are when they come from China. They may be as harmful as the carcinogens in tobacco.

So, I respect you as a parent also of four children, that you want your kids to be in good health, and vaping is bad for their health. And I also respect your criticisms of federal regulation. As the Chairman of the Permanent Subcommittee on Investigation, I released a report in February that documented the regulatory failures that have created the hot mess that we have right now. It's on us, the Federal Government, as well as on the vaping manufacturers.

But what we documented was the missed opportunities by federal agencies to stem the tide of addiction. This years-long investigation highlighted the shameless marketing tactics of new e-cigarette companies like Puff Bar, and the half measures by the FDA that allowed Puff Bar to build on the popularity and addiction that JUUL caused, and the need for enhanced federal enforcement.

Am I correct in believing that you would support additional resources and stronger regulation?

Mr. ABBOUD. Senator, to the earlier point, I also don't want my kids drinking alcohol or using cannabis in flavors of all varieties. I know kids are going to try things and to do things. I don't try to base our national public health policies or my beliefs on those based upon what's popular.

Senator BLUMENTHAL. Well, let's break down the question. You were critical, very specifically, of the lack of resources. Let's just talk about resources. Would you support additional resources going to FDA and other enforcement agencies to better enforce restrictions on sales of vaping products?

Mr. ABBOUD. I honestly don't think it's a resource issue. The FDA has had resources for years. They just haven't used them in a manner that's efficient and that is effective. For example, they use a lot of resources to go out and do retail inspections, and they talk about vape shops being a problem. What we found from their data is that the vape shops have the best compliance rate with respect to the underage sales to youth.

Senator BLUMENTHAL. Well, I want to, you know, just take this back to the manufacturers and the retailers of these products. Wouldn't you agree that they've marketed to the kids?

Mr. ABBOUD. I think there is some poor marketing, which is why we've been advocating for marketing restrictions in this country. But—

Senator BLUMENTHAL. The plain fact is—

Mr. ABBOUD [continuing]. There's not enough resources—

Senator BLUMENTHAL [continuing]. They've taken a page from Big Tobacco's playbook, and—

Mr. ABBOUD. There are not enough resources to enforce their way out of this without other laws that can help put restrictions on that. Enforcing a prohibition is going to lead to simply a black market. It will not work. So until—

Senator BLUMENTHAL. That's the same argument that was used about tobacco and some of those restrictions have worked, restrictions on marketing to kids.

Mr. ABBOUD. No, we're fine with that.

Senator BLUMENTHAL. It's no accident that the vaping companies are buying—I'm sorry, that the tobacco companies are buying the vaping manufacturers because they know how it's done. They can market in the way that they did with Joe Camel and the Marlboro Man to kids.

That's Big Tobacco's playbook, and the vaping companies are using it relentlessly, purposefully, and tirelessly with the huge resources that they have now more than ever, because the Big Tobacco companies are buying them.

Mr. ABBOUD. And we'd love to work with you on marketing restrictions. That is something that has been important to us for a while. We just don't think more resources thrown at the FDA in its current makeup and with its current direction is an answer.

Senator BLUMENTHAL. Well, my time has expired, but I just make the point to you as a former attorney general for 20 years, if you don't have resources, you don't have enforcement. Resources are absolutely necessary. It's the lifeblood of enforcement. Thanks.

Chair DURBIN. Thank you, Senator Blumenthal. And thanks to the panel. I want to thank Dr. Walley. Bringing science into this from the medical perspective is a critical element. Ms. Shapiro, thank you as well. Stepping up and making clear the battle that you're fighting. You're going to win that battle, and your coming here today is an act of courage, personally and politically. It makes a difference.

I thank all the members of the panel. Ms. Richardson, I'm sorry we didn't get into Campaign for Tobacco-Free Kids and the great work that's been done through that organization over the years.

Mr. Spross, Mr. Abboud, thank you for joining us. We may have some written questions coming your way by Wednesday, June 19, and if you could respond to them quickly, we would appreciate that.

Chair DURBIN. Senator Tillis, do you have any closing remarks?

Senator TILLIS. Yes. Just very briefly. Thank you all for being here, and I believe that everybody wants to try and produce a good outcome for the threat that our youth faces. I can't imagine anybody on the panel would be pursuing others.

I mentioned earlier that I think we have to have a broader discussion about vaping because it's now the delivery mechanism of choice for THC derivatives. And Dr. Walley, I don't know if you've

seen the research, I've spoken with behavioral health experts that say that we're seeing an increase in psychotic responses to so-called legal drugs.

The Eastern Band of the Cherokee now are starting to sell THC products in North Carolina. I mentioned it in my opening comments. They're marketing things in their native tongue among a community that has a higher instance of substance abuse than the U.S. population as a whole. I don't know if these are healthy products or not, but I do know that when we're talking about vaping, we need to go beyond just nicotine delivery to a broader issue.

And Josie, I'm sure that you know a lot of friends who moved off of nicotine to THC or to these other hybrids that they're creating. It's a broader problem that we need to fix. And Mr. Abboud, as I said earlier, your entire industry's future rests on getting it right. So, we hope that you-all can suggest to us things that we can do to come forward and address the fundamental issue and the longer-term threat of these practices happening in my own State of North Carolina. Thank you, Mr. Chair.

Chair DURBIN. Thanks, Senator Tillis. The meeting—

Dr. WALLEY. Could I respond to that, or no?

Chair DURBIN. Very briefly.

Dr. WALLEY. Okay. Senator Tillis, I wanted to first start and just congratulate you on your quit journey because nicotine is highly addictive. In terms of your specific question about THC, we do know, of course, this is a panel, to talk about tobacco. That there is significant co-use, and we certainly, the American Academy of Pediatrics have resources and strong concerns. Thank you.

Chair DURBIN. Thanks very much to the panel and those who attended this important and historic hearing. The meeting the Senate Judiciary Committee stands adjourned.

[Whereupon, at 12 p.m., the hearing was adjourned.]

[Additional material submitted for the record follows.]

A P P E N D I X

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Testimony of Tony Abboud
Executive Director, Vapor Technology Association

Unites States Senate Judiciary Committee
Hearing on
Combating the Youth Vaping Epidemic by Enhancing Enforcement
Against Illegal E-Cigarettes

June 12, 2024

Thank you, Chairman Durbin, Ranking Member Graham, and Members of the Committee for allowing me to testify today and answer your questions on a topic that is crucial to our nation's health.

I'm honored to testify, and I hope that my opening statement and responses to your questions will help drive an informative and thought-provoking conversation about e-cigarette policy in the U.S. that is rooted in truth, transparency, and importantly, science.

My name is Tony Abboud, and I am the executive director of the Vapor Technology Association. VTA is the leading vapor industry trade association that protects and promotes the U.S. vapor industry. Discussions like the one we are having today are critical in informing our efforts and our engagement with esteemed members of this Committee. I hope I can serve as a useful and important resource for you all.

Let's get into the facts. I want to be very clear: youth vaping in the United States is dramatically resolved.

In total, the youth vaping rate has plummeted 61% since 2019, partly thanks to a federal law raising the age to buy all tobacco products to 21 – a law the Vapor Technology Association championed with the White House and Congress.¹

According to the Centers for Disease Control and Prevention's National Youth Tobacco Survey, the U.S. youth vaping rate dropped yet again from 2022 to 2023 – now sitting at the lowest level in more than a decade, before e-cigarettes were even regulated by the Food and Drug Administration. Even better, now only 4.4% of youth use e-cigarettes regularly.²

¹ Birdsey, Jan, et al., Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023, *MMWR Weekly* / November 3, 2023 / 71(44), 1173-1182.

² "E-Cigarette Use down among U.S. High School Students in 2023." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 3 Nov. 2023, www.cdc.gov/media/releases/2023/s1102-e-cigarettes-down.html.

To ensure that this decline continues, we continue to advocate for serious and specific marketing and access restrictions to ensure that vaping products are not appealing or accessible to youth.

Now you might be thinking, "Why not restrict marketing of vaping products altogether? Aren't vapes bad for everyone?" Misinformation and Disinformation surrounding e-cigarettes is rampant.

The reality is, science indisputably proves that flavored e-cigarettes are a smoking cessation and harm reduction tool for American smokers looking to quit cigarettes.³

A number of studies, including one from a leading tobacco control researcher and several academics at America's top colleges and universities, prove that adults trying to quit smoking cigarettes are significantly more likely to be successful if they switch to flavored vaping products.⁴

The mere availability of e-cigarettes causes Americans to quit smoking. According to the largest study of the value of e-cigarettes as smoking cessation aid, study subjects given e-cigarettes were more likely to report complete abstinence from combustible cigarettes than study subjects given nothing.⁵

Another study from Abigail Friedman, a researcher and professor at Yale University, shows that the removal of flavored vaping products altogether results in a direct increase in combustible cigarette sales.⁶

Furthermore, recent polling also shows that when given access to the data and science, American consumers are more likely to support policies which protect adult access to flavored e-cigarettes.

The public health benefits of e-cigarettes as a smoking cessation tool cannot be ignored.

Despite both public and scientific support for the availability of e-cigarettes to adults, The Food and Drug Administration has implemented a de-facto ban on flavored vaping products, a ban that it is not legally authorized to implement.

³ Rigotti, Nancy A. "Electronic cigarettes for smoking cessation — have we reached a tipping point?" *New England Journal of Medicine*, vol. 390, no. 7, 15 Feb. 2024, pp. 664–665, <https://doi.org/10.1056/nejme2314977>.

⁴ Rigotti, Nancy A. "Electronic cigarettes for smoking cessation — have we reached a tipping point?" *New England Journal of Medicine*, vol. 390, no. 7, 15 Feb. 2024, pp. 664–665, <https://doi.org/10.1056/nejme2314977>.

⁵ "Largest US Study of E-Cigarettes Shows Their Value as Smoking Cessation Aid." *MUSC Hollings Cancer Center*, hollingscancercenter.musc.edu/news/archive/2023/08/18/largest-us-study-of-e-cigarettes-shows-their-value-as-smoking-cessation-aid#:~:text=I%20otherwise%20quit.%22-.Matthew%20Carpenter,%20Ph.,complete%20abstinence%20from%20combustible%20cigarettes.

⁶ Friedman, Abigail and Liber, Alex C. and Crippen, Alyssa and Pesko, Michael, E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales (January 29, 2024). Available at SSRN: <https://ssrn.com/abstract=4586701> or <http://dx.doi.org/10.2139/ssrn.4586701>

Instead of pursuing enforcement action based on failed regulatory policy, the FDA must make harm reduction its north star.

And to continue preventing youth vaping, regulators must adopt a series of marketing reforms and youth access restrictions that will further drive down youth vaping while ensuring that a wide variety of flavored vaping products remain available to adult smokers.

Only then will the FDA be doing the job required of it under the Tobacco Control Act – a law which many of you here in this room signed into law and supported, leading the way for real and meaningful reforms for our industry. And only then will tens of millions of adult American smokers have a fighting chance.

It is my hope – on behalf of the entire U.S. vaping industry – that in providing information based in science and data to these baseless claims levied against the e-cigarette industry, we will help restore scientific integrity to the U.S. regulatory process.

Thank you again for the opportunity to speak before you today, and I look forward to answering your questions.

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**TESTIMONY
OF
BRIAN A. KING, PHD, MPH
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CENTER FOR TOBACCO PRODUCTS (CTP)
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE**

**“COMBATTING THE YOUTH VAPING EPIDEMIC BY ENHANCING
ENFORCEMENT AGAINST ILLEGAL E-CIGARETTES”**

JUNE 12, 2024

RELEASE ONLY UPON DELIVERY

Introduction

Chair Durbin, Ranking Member Graham, and Members of the Committee, thank you for the opportunity to testify before you to discuss the Food and Drug Administration's (FDA or the Agency) efforts, in collaboration with our federal partners, to address the sale of unauthorized e-cigarettes. FDA's Center for Tobacco Products (CTP)'s mission is to protect the public health of the U.S. population from tobacco-related death and disease by comprehensively regulating the manufacture, distribution, and marketing of tobacco products, including through enforcement actions; educating the public, especially youth, about the dangers of using tobacco products; and promoting and supporting strategies that ensure an equitable chance at living a healthier life for everyone. FDA shares the goals and the urgency of keeping all tobacco products out of the hands of our youth and preventing the sale of unauthorized e-cigarettes. An "all of government" approach is critical to achieving these goals. FDA has actively been working, including with our colleagues across the federal government, to meet those shared goals.

Background

Tobacco use is the single largest preventable cause of disease and death in the United States. Each year, more than 480,000 people in the United States die prematurely from diseases caused by cigarette smoking and exposure to tobacco smoke alone. In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which authorized FDA to oversee the manufacture, marketing, distribution, and sale of tobacco products. Under the statute, FDA had immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. On August 8, 2016, pursuant to the Tobacco Control Act, FDA published the final "deeming" rule, which brought e-cigarettes and other products that meet the statutory definition of a tobacco product (except accessories of newly deemed tobacco products) under FDA's regulatory authority.

Regulatory Requirements for E-cigarette Products

Manufacturers are required to submit a premarket tobacco product application (PMTA) for "new tobacco products," which is reviewed by FDA to determine if authorization for marketing is granted. Pursuant to the Tobacco Control Act, a "new tobacco product" is one that was not commercially marketed as of February 15, 2007, or one that was modified after February 15, 2007. Since no e-cigarette product is known to have been commercially marketed in the United States as of February 15, 2007, all such products are understood to be new tobacco products. All "deemed" products, including e-cigarettes, became subject to FDA regulation, including the premarket authorization requirements in the Tobacco Control Act in August 2016. All "new tobacco products" are required to obtain authorization from FDA before they can be legally marketed. Following reports of e-cigarette manufacturers switching to nicotine not derived from tobacco in an attempt to evade FDA regulation, in 2022, Congress enacted legislation providing the Agency with authority to regulate tobacco products containing nicotine from any source, including "non-tobacco nicotine" (e.g., synthetic nicotine). To date, 23 e-cigarette products have been authorized to be marketed. FDA provides guidance and information to support industry's compliance with tobacco laws and regulations.

Data on Youth Use of E-Cigarettes

FDA collaborates with the Centers for Disease Control and Prevention (CDC) to administer the National Youth Tobacco Survey (NYTS), a school-based survey of U.S. middle school (grades 6 to 8) and high school (grades 9 to 12) students.

In 2019, NYTS data indicate that use of e-cigarettes peaked at 5.3 million youth. Since then, youth use of these products has declined substantially, overall. In 2023, an estimated 2.1 million kids were using e-cigarettes, which includes 580,000 fewer U.S. high school students using e-cigarettes since 2022.

For middle school students, the 2023 NYTS data show a slight increase (4.5 percent to 6.6 percent) in overall tobacco product use from 2022 to 2023. There was no specific product, including e-cigarettes, for which a significant increase occurred. However, this finding reinforces the importance of redoubling FDA's comprehensive efforts to address all tobacco product use among youth, including those of middle school age.

FDA will continue its surveillance of youth use of tobacco products, including through the most timely and scientifically rigorous methods available. This surveillance informs our compliance and enforcement work, which is an important component of our comprehensive efforts to address youth use of e-cigarettes. We remain committed to working alongside our federal government partners, to reduce the health burden of tobacco product use, especially among youth, in the United States.

Collaboration with Federal Partners

FDA is actively engaged with other government agencies and organizations to enhance enforcement and compliance activities. The Agency works closely with the Department of Justice (DOJ) to inform its compliance and enforcement actions. DOJ also files and litigates judicial enforcement actions, such as injunctions and seizures, on behalf of the Agency.

On June 10, 2024, FDA and DOJ announced the establishment of a Task Force to bring together and coordinate relevant expertise, operational abilities, and enforcement authority to strengthen our efforts related to unauthorized e-cigarettes. The Task Force will bring together multiple law enforcement partners, including the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), the Federal Trade Commission (FTC), the U.S. Marshals Service, and the U.S. Postal Inspection Service (USPIS).

Actions to Address the Sale of Unauthorized E-cigarette Products

FDA has a comprehensive tobacco compliance and enforcement program, which monitors for violations of federal tobacco laws and regulations and takes enforcement action across the supply chain—including manufacturers, distributors, retailers, and importers.

FDA prioritizes compliance and enforcement actions against products that appeal to youth. According to the 2023 NYTS, disposable e-cigarettes were the most common type of e-cigarette used by youth. Elf Bar, a disposable product, was the most commonly used brand and has been the focus of targeted FDA compliance and enforcement actions for the past several months.

Compliance and enforcement actions the Agency has taken, including against Elf Bar, are summarized below. In general, the Agency's comprehensive approach to enforcement focuses on three areas: 1) providing education and training to promote voluntary compliance; 2) conducting surveillance, inspections, and investigations to monitor the marketplace online and in brick-and-mortar establishments; and 3) taking action when violations are found.

Education and Training to Promote Voluntary Compliance

FDA provides educational materials and webinars, training videos, and guidance documents to help industry, including retailers, comply with the law. CTP's Office of Small Business Assistance provides technical and other nonfinancial assistance to small tobacco product manufacturers and other small businesses to help them comply. FDA also publicizes its actions on its website, which includes, among other things, information about advisory and enforcement actions and a searchable retailer inspection database. Earlier this year FDA launched the Searchable Tobacco Products Database, which is a list of tobacco products, including e-cigarettes, that may be legally marketed in the United States.

Conducting Surveillance, Inspections, and Investigations

FDA conducts inspections of distributors and manufacturing establishments, including vape shops. During these inspections, FDA seeks to determine the type of activities that are performed at the establishment (i.e., manufacturing, packaging, distributing) and whether they are in compliance with federal law. In addition, FDA contracts with states to conduct compliance check inspections, including undercover buy inspections, of tobacco product retailers. In Fiscal Year (FY) 2023, FDA conducted 108,000 inspections of tobacco retailer establishments and over 800 inspections of tobacco product manufacturers, including vape shops.

Taking Action When Violations are Found

FDA takes compliance and enforcement actions on a case-by-case basis, including increasing consequences, across the supply chain, to manufacturers, distributors, retailers, and importers, according to our enforcement priorities. When potential violations are found, FDA collects and reviews evidence to build a case. Typically, upon finding a violation and gathering the necessary evidence, FDA first issues a warning letter to achieve voluntary compliance. The warning letters describe the violation(s) and give firms the opportunity to take corrective action. FDA follows up on warning letters, prioritizing follow-up inspections, investigations, and surveillance activities for firms that are most likely to continue to violate the law, such as firms that fail to respond to a warning letter or provide an inadequate response. Many recipients of warning letters correct the violative conduct; however, if the company's response is not adequate, the Agency may collect evidence and take escalated actions such as seeking civil money penalties or working with federal partners on judicial actions such as injunctions and seizures.

Manufacturers & Distributors

To date, FDA has conducted over 6,600 inspections of tobacco manufacturers and distributors, including e-cigarette manufacturers and vape shops, resulting in more than 880 warning letters, 57 civil money penalties, six injunctions obtained (with a seventh currently in litigation and an eighth complaint filed), and one seizure. These actions were taken for various violations of the law, but the vast majority were for the manufacture, distribution, and/or sale of unauthorized e-

cigarette products.

In April 2024, FDA and DOJ seized tobacco products in coordination with the U.S. Marshals Service for the first time. More than 45,000 unauthorized e-cigarettes valued at more than \$700,000 were seized at a warehouse in California. The seized products were mostly flavored, disposable youth-appealing e-cigarettes.

Retailers

To date, FDA has issued over 550 warning letters to retailers for selling unauthorized products and taken escalating action by seeking civil money penalties against 140 retailers for continuing to sell unauthorized products. The total collective amount of CMPs sought is more than \$2,600,000.

Moreover, FDA has taken action to address sales of tobacco products to underage purchasers, including conducting nearly 1.5 million inspections of tobacco retailers working with its partners in the states and territories that resulted in FDA issuing more than 138,000 warning letters, 33,000 civil money penalties, and 228 No-Tobacco-Sale Orders.

Importers

FDA works with CBP, and the U.S. Postal Service at the International Mail Facilities, to screen FDA-regulated products at entry for compliance with applicable requirements. Challenges in the import compliance space include manufacturers changing product names to avoid identification at the border as well as fraudulent import declarations.

FDA has two Import Alerts to inform FDA field staff, CBP, and the public about unauthorized tobacco products that can be detained without physical examination. Currently, these Import Alerts address over 40 firms importing e-cigarettes, each of which covers multiple products (e.g., Elf Bar, Esco Bar, and other disposable products from China). FDA regularly updates the Import Alerts, including to account for changes in brand name (e.g., Elf Bar to EB Design). FDA has generally been refusing admission to products listed on these Import Alerts.

Many e-cigarette products offered for import are not properly declared. CBP has authority to administratively seize products that are smuggled or clandestinely imported. The agencies are collaborating to stop the flow of illegal e-cigarettes into the United States. For example, FDA participated in a joint operation with CBP at Los Angeles International Airport that resulted in the administrative seizure of approximately 1.4 million units of unauthorized e-cigarette products, including Elf Bar, with an estimated retail value of more than \$18 million. Most of these products were intentionally mis-declared as various items such as toys or shoes and listed with incorrect values.

Future Actions

In addition to more joint operations and continued escalating actions, FDA is currently working on, and expects to publish later this year, a draft guidance on civil money penalties for violations of the FD&C Act requirements that relate to tobacco products. This guidance intends to describe the Agency's approach to issuing Enhanced Civil Money Penalties (intentional violations), Continuous Enhanced Civil Money Penalties (intentional and other violations that continue after

written notice), and multiple violations in a single complaint (either as a retailer, a manufacturer, or as both). We will continue to engage with our federal government partners to take strong compliance and enforcement actions and with Congress to explore additional strategies for effective enforcement.

FDA's Comprehensive Actions to Prevent Youth Use of E-cigarette Products

Protecting youth from the dangers of tobacco products is among the Agency's most important responsibilities. In addition to our work to protect youth from tobacco products with compliance and enforcement actions as described above, we also conduct premarket review of new products before they may be legally marketed, develop regulations and related guidance documents that protect the public health, and educate the public about the harms of youth tobacco product use.

Premarket Review

Ensuring new tobacco products undergo premarket evaluation by FDA is a critical part of our mission to protect the public health, particularly youth, and to reduce tobacco-related disease and death. To date, FDA has received PMTAs for nearly 27 million e-cigarette products. The PMTAs that FDA has received have included applications for nearly one million non-tobacco nicotine products from more than 200 applicants. This also includes more than 6.5 million products received by September 9, 2020.¹ The volume of tobacco applications received is exponentially greater than submission volume for other regulated products; for example, FDA medical product Centers receive thousands of applications a year.

To date, FDA has resolved more than 26 million of these applications. The Agency has authorized 23 tobacco-flavored e-cigarette products and devices. These products were authorized because the applicant submitted data that demonstrated that the marketing of the products met the applicable public health standard required by law. As part of FDA's evaluation of these products, the Agency determined that the potential for these products to benefit adults who smoke outweighed the risk to youth. In addition, the Agency has resolved marketing applications for millions of products, including through marketing denial orders, because the applicant failed to show that the products meet the public health standard required by the law. FDA is working to complete review of the pending applications as efficiently as possible, consistent with science and the law.

Regulations and Guidances

FDA issues regulations to implement the Tobacco Control Act and guidance documents that explain FDA's approach for implementing statutory or regulatory provisions. This includes a number of rules that outline requirements for e-cigarettes. For example, the Deeming regulation expanded retailer restrictions to include restrictions on sales of e-cigarettes and required a nicotine warning statement for e-cigarettes. More recently, FDA has issued a proposed rule to establish tobacco product manufacturing practice requirements for manufacturers.

¹ Applications for deemed new tobacco products on the market as of August 8, 2016, were required to be submitted to FDA by September 9, 2020, per a federal court order. *American Academy of Pediatrics, et al. v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019).

Public Education

Mass market public education campaigns are a proven strategy to reduce and prevent use of tobacco products, especially among youth, and are another important tool in FDA’s efforts to prevent youth tobacco product use. For example, FDA prioritized public education prevention efforts to address youth tobacco product use. From its launch in February 2014 to November 2016, “The Real Cost” campaign, FDA’s first public education cigarette prevention effort, prevented up to 587,000 youth ages 11 to 19 from initiating smoking, and over time those prevention efforts will save more than \$53 billion in smoking-related costs for youth, their families, and society at large—a cost savings of \$180 for every dollar of the nearly \$250 million invested.² In 2018, FDA launched “The Real Cost” Youth E-Cigarette Prevention Campaign, targeting over 10 million teens who have used e-cigarettes or are susceptible to use, which has successfully reached and engaged teens, generating over 26 billion ad views.

Challenges and Opportunities

The progress described here is just a part of the important work FDA is doing to protect the public health by regulating the manufacture, distribution, marketing, and sale of tobacco products, including e-cigarettes. In addition to the progress we have made, we also face several challenges such as the size and complexity of the tobacco product landscape and resources that have been flat for the last five years.

The sheer volume of premarket applications, receiving applications for millions of products nearly simultaneously, and the rapidly evolving tobacco product landscape have been unprecedented. It is a challenge that no other FDA Center has undergone. FDA is diligently working to complete review of the pending applications as efficiently as possible, consistent with science and the law. Specifically, a substantial proportion of CTP resources have had to be allocated to e-cigarettes—both product reviews and enforcement actions—without receiving any funding from e-cigarette manufacturers, in contrast to most other types of tobacco products.

The additional resources and authorities included in the Agency’s FY 2025 budget request will support CTP’s work in a number of areas, including enforcement and our plans to do more with all of our federal enforcement partners.

First, the FY 2025 budget includes a legislative proposal which seeks to authorize FDA to collect user fees from e-cigarette manufacturers. The statute currently authorizes FDA to assess and collect tobacco user fees from domestic manufacturers and importers of six classes of products: cigars, pipe tobacco, cigarettes, snuff, chewing tobacco, and roll-your-own tobacco, and specifies the total amount of tobacco user fees FDA must assess and collect each year. Since FY2019, this amount has been capped at \$712 million. Because e-cigarettes were a new product category when the Tobacco Control Act was enacted in 2009, the authorized funding did not take into account the resources required for the regulation of e-cigarettes. The FY 2025 proposal seeks to promote a fair distribution of tobacco user fee assessments to all regulated tobacco products, including e-cigarettes; increase the current tobacco user fee collections by \$114 million to account for the workload associated with the additional product categories; and index all future collections to inflation.

² <https://www.fda.gov/tobacco-products/real-cost-campaign/real-cost-cost-effective-approach>

Second, FDA seeks to extend the agile hiring authorities of the 21st Century Cures Act (Cures Act) for CTP to improve its ability to recruit, hire, and retain personnel with the needed skills to effectively meet its public health mandate. CTP is the only FDA Center to which Congress has not granted such Cures Act hiring authority.

Conclusion

FDA's accomplishments in protecting the public from the adverse health impacts of tobacco product use are made possible through our dedicated civil servant staff. Their critical efforts tirelessly support CTP's mission. Guided by our five-year strategic plan, we will continue to collectively take strong actions to protect youth and monitor the effectiveness of our actions.

Thank you again for the opportunity to testify about FDA's comprehensive efforts to regulate e-cigarettes, especially those popular among youth. We stand ready to work with our federal government partners and Congress to meet the shared goal of removing unauthorized e-cigarette products off the market and keeping all tobacco products out of the hands of youth.



Department of Justice

STATEMENT OF

ARUN G. RAO
DEPUTY ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

BEFORE THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

AT A HEARING ENTITLED

“COMBATTING THE YOUTH VAPING EPIDEMIC BY ENHANCING
ENFORCEMENT AGAINST ILLEGAL E-CIGARETTES”

PRESENTED
JUNE 12, 2024

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AGAINST ILLEGAL E-CIGARETTES”**

**PRESENTED
JUNE 12, 2024**

Good morning, Chair Durbin, Ranking Member Graham, and distinguished members of the Committee. My name is Arun Rao, and I am the Deputy Assistant Attorney General for the Consumer Protection Branch, a component of the Civil Division at the U.S. Department of Justice (Department). Thank you for the opportunity to testify today about the important work of the Consumer Protection Branch in combatting the illegal sale of unauthorized electronic nicotine delivery systems (ENDS) products. The sale of illegal ENDS products poses addiction and health risks to Americans, especially youth. The threat is particularly grave for teenagers, at whom these dangerous products are too often targeted. Protecting youth from both physical harm and threats to their online safety and privacy, is a critical part of the mission of the Consumer Protection Branch.

The Department and the Food and Drug Administration (FDA) are committed to enforcing the prohibition on the manufacture and sale of unauthorized ENDS products through all available legal means, including the Family Smoking Prevention and Tobacco Control Act (TCA), the Prevent All Cigarette Trafficking Act of 2009 (PACT Act), and the Federal Food, Drug, and Cosmetic Act (FDCA). In furtherance of that commitment, the Department and FDA recently created a multi-agency ENDS Enforcement Task Force with the sole purpose of addressing the threat posed by the illegal sale of unauthorized ENDS products.

OVERVIEW OF ENDS ENFORCEMENT

The factual and legal issues surrounding ENDS enforcement are complex. In the years since the 2016 FDA rulemaking to bring e-cigarettes under TCA regulation, FDA faced an avalanche of applications for approval to market these products. The market has also since been flooded with e-cigarette products. As FDA has worked to render final decisions on premarket tobacco product applications (PMTAs), manufacturers filed numerous challenges to FDA’s actions in federal court. Additionally, many manufacturers have responded to FDA denial orders with new applications for slightly altered “new” products, which lengthen the regulatory process.

Congress has required that FDA make determinations on new applications within 180 days, but that has proven challenging in many cases given the large volume of applications filed with the FDA. Some overseas manufacturers have also evaded import alerts by mis-declaring shipments at ports of entry. Meanwhile, vape shops across the country have been purchasing ingredients to manufacture their own products in individual stores further complicating the landscape. The scale of the problem means illegal ENDS products remain all too accessible to young people, with illegal ENDS products available in neighborhoods across the country, as well as online.

The Department performs an important role in supporting the FDA's efforts to ensure that illegal ENDS products stay off the market: (1) defending FDA against litigation with manufacturers about marketing applications; (2) filing enforcement actions under the FDCA on FDA's behalf; and (3) coordinating enforcement actions outside the FDCA and TCA.

First, when manufacturers challenge FDA orders denying their marketing authorizations, the Department's Civil Division is responsible for defending FDA's decisions in court. We are deeply committed to defending FDA's denial of marketing authorizations to help ensure that the regulatory process can function as Congress intended. The Department has defended every petition for review that manufacturers have filed in courts of appeals challenging FDA denials of their applications to market ENDS products, which amounts to more than 80 cases and counting. While many of those matters have yet to be decided by the courts, we have prevailed in more than a dozen cases, including in unanimous decisions on the merits in seven courts of appeals. In the one circuit where we have faced a significant loss—the Fifth Circuit—the government is seeking review from the Supreme Court.¹

An effective enforcement tool against companies that sell unapproved ENDS products is an administrative action by FDA to impose civil monetary penalties on manufacturers and retailers. As of May 1, 2024, FDA has issued more than 670 warning letters to manufacturers, importers, and distributors for illegally selling or distributing unauthorized new tobacco products, including e-cigarettes, and more than 550 warning letters to retailers. FDA has brought civil monetary penalty actions against more than 55 manufacturers and 100 retailers. The Department supports FDA's increased enforcement efforts under the FDCA, including by standing ready to assist in collection actions to ensure the civil monetary penalty judgments are not ignored and to seize unauthorized ENDS products. For example, the Department recently partnered with FDA on the first judicial seizure of unauthorized ENDS products under the FDCA, which resulted in the seizure of more than 45,000 unauthorized ENDS products from a warehouse in California.

The Department also has the authority to bring civil injunctive actions referred by FDA. This is an important tool in many contexts, but it can be challenging to deploy where there are a very large number of companies selling unauthorized products. In some circumstances, these injunctive actions can be valuable, and the Department and FDA work closely to pursue these actions where appropriate. The Department has brought a number of civil injunctive actions referred by FDA and stands ready to bring additional actions in coordination with FDA to advance enforcement efforts. Since 2022, we have obtained civil injunctions against six entities to stop them from selling unapproved ENDS products and are litigating against a seventh

¹ *Wages & White Lion Invs., LLC v. FDA*, 41 F.4th 427 (5th Cir. 2022).

defendant. Judicial stays entered by courts in several defensive cases constrain our present ability to bring actions involving certain products, and other products remain under review by FDA or are part of pending administrative appeals. Despite those complicating factors, we stand ready to continue working with FDA to develop cases for enforcement actions of all kinds and to pursue further civil injunction actions.

Lastly, the Department is working with the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and the U.S. Postal Inspection Service (USPIS) on several enforcement activities outside of the TCA and FDCA. In particular, the Department is working closely with ATF and USPIS to identify targets and bring enforcement actions under the PACT Act. The PACT Act prohibits shipment of ENDS products via U.S. mail, requires online sellers of ENDS products to verify the age of purchasers both at the point of sale and the point of delivery, as well as to comply with tax collection provisions and state and local laws, or potentially face felony charges. With our partners at ATF and USPIS, the Department is developing actions for civil penalties and, where appropriate, criminal sanctions under the PACT Act, to help stop sellers who ignore the stringent and clear age verification requirements written into the law.

ENDS ENFORCEMENT TASK FORCE

Consistent with the longstanding mission of the Consumer Protection Branch to protect children from harm online and in the physical world—and in recognition of the urgency of the problem presented by the widespread availability of illegal ENDS products—we are continuing to build on our enforcement approach with our partners in the Executive Branch. To better coordinate these efforts and more effectively combat the public health threat created by the illegal sale of ENDS products, the Department and FDA created a multi-agency ENDS Enforcement Task Force.² The Task Force will bring together market knowledge, enforcement experience, and operational abilities from across the government and consider new avenues for enhanced ENDS enforcement efforts. In particular, the Task Force will meet regularly to address the illegal importation, manufacture, distribution, and sale of ENDS products, the actions being taken by each agency, and ideas for further action and coordination. Members of the Task Force will work together to identify and investigate entities engaged in the manufacture, distribution, or sale of illegal ENDS products, determine appropriate enforcement authorities, and initiate actions under those authorities, when appropriate.

The Task Force will consider and, as appropriate, engage in, a variety of enforcement strategies, including:

- Facilitating the seizure of unlawful products within the United States by FDA and USMS, including by pursuing civil seizure actions in federal court;

² The Task Force includes FDA, primarily the Center for Tobacco Products and the Office of Chief Counsel; the Justice Department's Civil Division, primarily the Consumer Protection Branch, with support from the Appellate Staff and the Federal Programs Branch; ATF; U.S. Marshals Service (USMS), primarily the Asset Forfeiture Division; USPIS; and the Federal Trade Commission (FTC).

- Pursuing administrative actions by FDA against U.S. distributors and retailers leading to civil monetary penalties, as well as taking actions to collect penalties from defendants who refuse to pay penalties they owe;
- Developing administrative and court actions with ATF, USPIS, and the Department to deter the trafficking of ENDS products online and through the mail;
- Developing criminal prosecutions, where appropriate, under available authorities;
- Advancing injunctive actions, the Department can take to halt the illegal distribution and sale of ENDS products; and
- Suggesting legislative measures that would provide Task Force partners with the tools needed to combat the problem, and helping to develop resource requests to better ensure these goals can be achieved.

The Department works closely with investigative and agency partners to develop cases and refer those matters to us. Communication and coordination through the Task Force will allow for more seamless identification of potential targets and collection of relevant evidence. I can assure the members of the Committee that the Department will assign a high priority to enforcement opportunities that build on the work of ENDS Task Force partners. In the near term, we expect the Task Force to consider new strategies to address the illegal importation of unauthorized ENDS products at the border, and even to bring criminal charges against those who flout the law, where the evidence allows.

Coordination between Task Force participants will support actions under the TCA, the PACT Act, and the FDCA, and will provide opportunities to share intelligence about the ENDS marketplace and significant importers and distributors of illegal ENDS products. We expect the Task Force will also gather information from advocates and legitimate industry participants who want to play by the rules but find themselves undercut by less scrupulous actors. We are confident that the Task Force will advance innovative strategies to address the unique and continually evolving problem of illegal ENDS products.

* * *

The Department is committed to using all available tools to protect Americans, especially youth, and to address the threat posed by unauthorized ENDS products. All of us at the Department recognize the trust placed in us to do this work. We are honored to do it, and we are eager to continue our efforts to protect American consumers of all ages.

Thank you for the opportunity to testify. I look forward to your questions.

Statement of Yolonda Richardson
President and CEO, Campaign for Tobacco-Free Kids
Before the
U.S. Senate Committee on the Judiciary
For a Hearing on
Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes
June 12, 2024

Chairman Durbin, Ranking Member Graham, Members of the Committee: Thank you for inviting me to testify today at this hearing on combatting the youth vaping epidemic. Addressing this epidemic can only be achieved by enhancing enforcement to remove unauthorized e-cigarettes that remain on the market illegally.

I am Yolonda Richardson, President and CEO of the Campaign for Tobacco-Free Kids. The Campaign is the leading advocacy organization working to reduce tobacco use and its deadly consequences in the United States and around the world. Through strategic communications and policy advocacy campaigns, we promote the adoption of proven solutions that are most effective at reducing tobacco use and saving the most lives. In addition to our work fighting tobacco use, our Global Health Advocacy Incubator applies our broad range of advocacy experience to supporting organizations working to address other critical public health challenges.

Premarket Review: A Cornerstone for Protecting Public Health

The Campaign has been a strong advocate for the Family Smoking Prevention and Tobacco Control Act, which was landmark legislation enacted in 2009 that gave FDA the authority to oversee tobacco products. Since its enactment, we have urged FDA to aggressively use this authority to protect kids and public health. Through effective regulation, we can reduce the 480,000 deaths and about \$240 billion in health care costs attributable to tobacco use each year in the United States.¹

Congress gave FDA the authority to oversee tobacco products in order to protect the public, and particularly young people, from an industry that aggressively markets harmful and addictive products. Each year, the tobacco industry spends more than \$9.4 billion marketing and promoting products that addict our kids and others. One of the most important tools that Congress gave FDA was the authority to conduct premarket reviews of new tobacco products before they can be legally sold.

Prior to the Tobacco Control Act, when cigarette manufacturers were free to introduce new tobacco products without any oversight by FDA, the public's health suffered enormously. Manufacturers designed cigarettes to deliver precise doses of nicotine that would create and sustain addiction. They added ingredients to mask the harshness of tobacco smoke and make them easier to use, particularly for youth. They added features like filters to provide smokers with a false sense of security that they were reducing their risk of disease.

The Tobacco Control Act was intended to prevent the introduction of new tobacco products that are harmful and increase the possibility of attracting youth. With the Tobacco Control Act in place, decisions about which new tobacco products enter the market would no longer be made solely by tobacco manufacturers, based on economic considerations, such as sales and profits. Instead, these decisions would ultimately be made by FDA, based on a scientific assessment of a product's likely impact on public health that would involve consideration of the risk of the product, how it is likely to be used, and who is likely to use it.

Under the Tobacco Control Act, manufacturers of a new tobacco product must demonstrate that their product is "appropriate for the protection of the public health." This standard is intended to prevent tobacco manufacturers from introducing new products that may increase harm to the public, such as by expanding the number of people who use and become addicted to tobacco or by discouraging people who currently use tobacco products from quitting altogether.

Given the health risks of tobacco products, this is an appropriately high standard, and the burden is on the manufacturer to meet it. In order for a new product to be authorized for sale, manufacturers must demonstrate that the introduction of a new product will measurably enhance public health.

Problems Applying Premarket Review to E-Cigarettes

Unfortunately, premarket review has not been applied in a timely and effective way for e-cigarettes.

By the time FDA first exercised regulatory oversight over e-cigarettes in 2016, a substantial e-cigarette market had already formed, and e-cigarettes had already become the most popular tobacco product among youth. E-cigarettes were available in thousands of different flavors that increased their appeal and use by youth.² And manufacturers were increasing the amount of nicotine that e-cigarettes could deliver, which increased the likelihood that youth who experimented with these products would become long-time addicted e-cigarette users, with a risk that they may move on to smoking conventional cigarettes.³ The e-cigarette market was a "wild, wild West" of unregulated, highly addictive, flavored products marketed to young people.

Not long after FDA finally began to apply its oversight authority to this existing marketplace, it suspended premarket review of e-cigarettes, issuing a guidance in 2017 that sought to extend the deadline for e-cigarette manufacturers to submit premarket applications by four additional years (from 2018 to 2022) and would have allowed those products to remain on the market for as long as it took for FDA to review them. As a result of a lawsuit brought by the Campaign for Tobacco-Free Kids and other public health groups, a Maryland [federal court vacated](#) FDA's guidance, characterizing it as a "holiday from meeting the obligations of the law." The court set September 9, 2020 as the new date by which companies had to file premarket applications and indicated that companies that submitted applications on time could keep those products on the market for only one additional year (until September 9, 2021) without being subject to FDA enforcement.

Because of this court order, FDA began reviewing e-cigarette applications and has completed its review of the vast majority of applications it has received. We commend FDA for appropriately applying the public health standard during its reviews, particularly as to flavored products. The agency has recognized that flavors increase the appeal and use of e-cigarettes by youth and, therefore, is requiring manufacturers to demonstrate that their flavored e-cigarettes provide an

offsetting public health benefit by helping adult smokers to quit. This is the population-wide assessment of public health that the Tobacco Control Act requires of FDA.

But FDA is still far from completing its review of e-cigarettes. Some of the e-cigarettes with the greatest impact on the market, like JUUL, are still under review. While FDA needs to thoroughly review each application it receives, it has had some of these applications for nearly four years. For e-cigarettes that use nicotine derived from tobacco and represent a significant share of the market, FDA must provide a quarterly status report on its progress to a federal court. Initially, FDA projected it would complete those reviews by the end of June 2023. Then it said the end of December 2023. Now FDA is projecting it will complete those reviews by the end of June 2024. Separately, FDA has reported that more than 9,500 synthetic nicotine products are also under review but has not projected when it expects to complete those reviews.

The delay in completing these reviews is particularly problematic because FDA appears to have an unstated policy of not taking enforcement action against products with pending applications. This unstated policy has allowed many unauthorized e-cigarettes to remain on the market, including flavored e-cigarettes that FDA has found present a particular risk to youth. We believe this across-the-board enforcement discretion is contrary to the Tobacco Control Act and the Maryland court decision that established September 9, 2021 as the date by which marketing orders must be issued in order for products to remain on the market without being subject to enforcement action.

E-Cigarette Companies Making a Difficult Situation Worse

FDA's job of implementing premarket review has been made much more difficult because of actions taken by the e-cigarette industry itself. Many e-cigarette companies are simply disregarding FDA requirements. The level of non-compliance for e-cigarettes far exceeds what FDA experiences with other products it regulates such as drugs and medical devices. As the [Reagan-Udall Independent Expert Panel](#) that examined FDA's regulation of tobacco products observed, "there are few incentives for industry to come into compliance and many incentives for industry to delay the process."⁴

E-cigarette companies flooded FDA with premarket applications for millions of products. The vast majority of applications did not contain basic required information and did not represent a serious effort to provide the evidence necessary to meet the public health standard. One company submitted applications for more than 4.5 million products, which FDA refused to file because they failed to meet certain requirements or denied.⁵ In total, FDA received applications for more than 6.5 million products before the September 9, 2020 deadline, which bogged down the premarket review process.⁶

Many other e-cigarette companies sought to evade the premarket review requirement entirely by marketing e-cigarettes with synthetic nicotine rather than nicotine derived from tobacco. Puff Bar, a disposable e-cigarette that appeared on the US market in 2019, quickly became the fourth most popular brand among high school e-cigarette users.⁷ In 2020, FDA issued a warning letter to Puff Bar to stop selling its flavored disposable e-cigarettes without FDA authorization.⁸ In a clear effort to evade the law, in February 2021, Puff Bar announced that it was using synthetic nicotine in its products, and that year, Puff Bar became the most popular e-cigarette brand used by youth.⁹ Many other companies similarly tried to evade premarket review by switching to synthetic nicotine.

Ultimately, Congress enacted legislation in 2022 to clarify FDA's authority to regulate synthetic nicotine products as tobacco products under the Tobacco Control Act.¹⁰

There continues to be widespread disregard for the premarket review requirement today. Some e-cigarette manufacturers are selling unauthorized e-cigarettes for which a premarket application was never submitted. Others are selling unauthorized e-cigarettes that have a pending application at FDA, with the expectation that FDA will not take enforcement action against them. Non-compliance permeates the entire supply chain: manufacturers, importers, distributors, wholesalers, and retailers.

The magnitude of the problem is remarkable. The e-cigarette market in the United States consists almost entirely of unauthorized, illegal products, including a wide variety of flavored products that FDA has found are highly appealing to youth. FDA has authorized 23 e-cigarette products – and no flavored e-cigarettes (only tobacco-flavored e-cigarettes). But thousands of e-cigarettes in a wide array of flavors are available for sale at convenience stores, vape shops, and online. According to retailer scanner data, more than 6,000 e-cigarette products are available for sale in the U.S. – and that does not even include sales at vape shops and online.¹¹

Finding an unauthorized e-cigarette is not like looking for a needle in a haystack. This is not an “underground” illegal market; these illegal products are everywhere and in plain sight. Elf Bar was the most popular e-cigarette brand among youth last year, even though Elf Bar products are not authorized by FDA and are on the market illegally.¹²

This non-compliance with the premarket review requirement necessitates swift and strong enforcement action from FDA, the Department of Justice, and other agencies involved in enforcement.

Unauthorized E-Cigarettes are Creating a Public Health Risk

The large number of unauthorized e-cigarettes on the market present significant risks to public health. These products are highly addictive, can expose users to harmful substances, and have consistently been shown to appeal to youth.

While youth use of e-cigarettes is down from 2019, when it reached an all-time high, e-cigarettes remain the most commonly used tobacco product among middle and high school students in the U.S. In 2023, 2.1 million youth reported currently using e-cigarettes, including 10 percent of high school students.¹³ Each day, more than 4,300 kids (under 18) try an e-cigarette for the first time.¹⁴

Youth are not just experimenting with e-cigarettes but are using them frequently. Last year, nearly 40 percent of high school e-cigarette users reported vaping on 20 or more days during the past month, which is a worrying sign that many are becoming addicted.¹⁵ Because e-cigarettes can be used more discreetly than cigarettes, young people are able to use them easily throughout the day, even during class, exposing themselves to dose after dose of nicotine.

According to an advisory by the Surgeon General, the aerosol produced by an e-cigarette “is not harmless” and that “any e-cigarette use among young people is unsafe.”¹⁶ E-cigarettes expose users to nicotine and other harmful substances, including heavy metals, volatile organic compounds, and ultrafine particles.¹⁷ Nicotine exposure during adolescence can harm the

developing brain and can impact learning, memory and attention.¹⁸ In addition to the risks from e-cigarettes themselves, there is evidence that using e-cigarettes increases the risk that youth and young adults will try cigarette smoking.¹⁹

Adolescence is a particularly important time to prevent the initiation of e-cigarette use. Use of tobacco products almost always begins during adolescence, a time when youth are more vulnerable to nicotine addiction and less aware of the risks of tobacco use. Because nicotine is highly addictive, youth use of e-cigarettes may have lifelong implications. That is why preventing youth tobacco use is a critical consideration in FDA's determination of whether to authorize or deny marketing authorization for an e-cigarette.

Flavors are a key driver of high rates of youth e-cigarette use. E-cigarettes come in thousands of flavors, which make these products more attractive and easier for youth and young adults to use. Last year, nearly 90 percent of youth e-cigarette users used flavored products.²⁰ According to a 2016 Surgeon General report, flavors are among the most commonly cited reasons for using e-cigarettes among youth and young adults.²¹

Flavors are so appealing that young people gravitate to whatever e-cigarette device affords them the flavors they seek. When FDA changed its enforcement priorities in 2020 to prioritize enforcement against most flavored cartridge-based e-cigarettes, which at the time were the most popular e-cigarette products among youth, large numbers of youth switched to disposable e-cigarettes because they continued to be available in a wide variety of flavors.²² It was the flavors that drove appeal and youth use, not the type of e-cigarette device.

Appealing flavors and addictive levels of nicotine is a dangerous combination. That is why FDA has rejected applications for millions of flavored e-cigarettes and has so far not authorized any flavored e-cigarettes, only tobacco-flavored ones.

Yet flavored e-cigarettes remain widely available because of widespread non-compliance with FDA's premarket review requirement. While FDA has not authorized any flavored e-cigarettes, about 80 percent of retail sales of e-cigarettes are for flavored products.²³ Premarket review was supposed to prevent products harmful to public health from being sold. But inadequate enforcement is undermining this important public health protection.

Stronger Enforcement Action is Needed

The Tobacco Control Act provides a number of enforcement tools to address unauthorized e-cigarettes on the market, including civil money penalties (CMPs), product seizures, import restrictions, injunctive actions, and criminal prosecutions. Some enforcement actions FDA can take on its own. For others, it needs to work with the Department of Justice and Customs and Border Protection.

Over the past year, FDA has taken some important enforcement actions. It has increased its use of CMPs, worked with the Department of Justice to seize more than 45,000 unauthorized products at a warehouse in California,²⁴ and worked with Customs and Border Protection to seize 1.4 million unauthorized e-cigarettes at a cargo examination site at Los Angeles International Airport.²⁵

But despite these enforcement actions, unauthorized e-cigarettes continue to dominate the market. The current level of enforcement activity is insufficient to address the large number of unauthorized products on the market effectively.

We welcome the announcement by FDA and DOJ this week about the creation of a multi-agency task force to combat the illegal distribution and sale of e-cigarettes. This could be an important step forward, but it will only have an impact if it is immediately followed with concrete and comprehensive enforcement actions. Federal agencies should also coordinate closely with states and localities enforcing state and local laws against flavored e-cigarettes.

More and stronger enforcement action is needed. Without it, many companies will continue to calculate that the profits that can be made from making and selling unauthorized e-cigarettes are worth the risk.

The Campaign for Tobacco-Free Kids along with 77 other public health, medical, education, and community organizations recently sent a [letter](#) to FDA, DOJ, and CBP, calling on them to use all the enforcement tools at their disposal to clear the market of unauthorized e-cigarettes. In that letter, we urge these agencies to adopt several concrete changes in tobacco enforcement policies and activities to bring this problem under control.²⁶

First, FDA should make more frequent use of the full range of its enforcement tools. While FDA has issued more than 1,100 warning letters to firms for manufacturing or selling unauthorized tobacco products, it has made sparing use of its stronger enforcement tools. For example, FDA has filed CMP complaints against only 55 manufacturers and 140 retailers; injunctions have been sought against only seven manufacturers; and there has been a single seizure pursuant to a civil forfeiture complaint.²⁷ FDA and other federal enforcement agencies should make greater use of its most potent enforcement tools and should consider taking action without first sending a warning letter in appropriate cases.

Second, FDA must seek greater penalties in CMP actions. When FDA has issued a CMP, it has consistently charged companies with only a single violation of the statute and has been only seeking the maximum penalty for a single violation, which currently is only \$20,678.²⁸ FDA is doing this even where a company may be marketing hundreds or thousands of unauthorized products. Such a small penalty cannot provide an effective deterrent to a company making money from illegal sales. The Tobacco Control Act gives FDA the authority to impose much higher penalties, and the agency should use it. FDA can charge a company with multiple violations, up to \$1.2 million in a single proceeding.²⁹ Recently FDA has indicated that it is planning to issue new guidance regarding CMPs. We hope it is implemented quickly and will result in far more severe penalties.

Third, the Department of Justice must seek injunctive relief against retailers to prevent the illegal sale of e-cigarettes. Because FDA does not have its own litigation capability, it must involve the Department of Justice in seeking injunctive relief from courts against the selling of unauthorized products. Yet DOJ has sought injunctions against only seven manufacturers of unauthorized e-cigarettes.³⁰ Moreover, a significant amount of time – between 13 months and more than 19 months – passed between the time FDA first sent the companies a warning letter and the commencement of injunction proceedings. During this time, the companies were able to continue

to profit from the sale of illegal products, which included youth-appealing flavors. FDA and DOJ must find ways to streamline the process for seeking injunctions against unauthorized products.

Fourth, Customs and Border Protection must stop illegal importation of unauthorized products.

Today's market of unauthorized e-cigarettes has been largely supplied by the illegal importation of unauthorized products manufactured in China, particularly flavored disposable e-cigarettes that are appealing to youth.³¹ FDA has stated that it has placed certain e-cigarette companies on its import alert red list, allowing the agency to detain products at the time of entry without a full inspection.³² But FDA and CBP announced the first large-scale seizure of unauthorized products only in December.³³ The detection of authorized products must become a joint priority of FDA and CBP, and the seizure authority must be more aggressively used, particularly for flavored products that appeal to young people.

Fifth, enforcement actions must be brought against all parties in the supply chain. To date, FDA's actions, including warning letters, have mainly been targeted at retailers and manufacturers, with many involving products with minimal market shares. Heightened enforcement actions must also be directed at wholesalers and distributors, particularly those with large-scale operations. As the Reagan-Udall review noted, "high profile [enforcement] actions against wholesalers and distributors who are handling illegally marketed products could help clear the downstream distribution pathways of illegal products and deter those who might bring new products to the market without marketing authorization."³⁴

Sixth, FDA must end the broad exercise of enforcement discretion. FDA has stated that it "has not adopted a broad policy of enforcement discretion regarding tobacco products without marketing authorization" and "[f]or the vast majority of unauthorized e-cigarettes on the market today, the pendency of an application does not create a legal safe harbor to sell that product."³⁵ But we know of no case where FDA or the Department of Justice has brought an enforcement action against – or even sent a warning letter to – a company with a pending application, even though such products are no more legal than products for which no application was ever filed. These products include ones that are popular with youth, such as JUUL. Certainly, as to flavored products with great youth appeal, there should be no across-the-board policy of exercising enforcement discretion.

Lastly, FDA must complete its review of all products, particularly products with large market shares and those used by youth. As noted earlier, thousands of e-cigarettes – products with tobacco-derived nicotine as well as products made with synthetic nicotine – are still under review by FDA. Two years ago, FDA announced a marketing denial order for JUUL, then it stayed its own order and last week it rescinded the order entirely, returning the JUUL application to scientific review.³⁶ This kind of delay and confusion is simply unacceptable, especially as these products stay on the market, particularly for a product with proven appeal to young people.

FDA needs to move as quickly as possible to a true premarket review process – whereby products are reviewed prior to entering the market, as the Tobacco Control Act intended – rather than the current process whereby products are being reviewed when they are already on the market and they stay on the market for years without marketing authorization.

Conclusion

Premarket review is an important requirement of the Tobacco Control Act. It is intended to protect youth and the public from new tobacco products that are harmful to public health. Yet unauthorized e-cigarettes remain widely available, despite the risks they present, especially to young people. Thousands of unauthorized flavored e-cigarettes are being sold despite the evidence that flavors increase the appeal and use of e-cigarettes by youth.

More and stronger enforcement action is needed. Otherwise, companies will continue to flout FDA requirements and put our young people at risk. We need an “all hands on deck” approach to enforcement. We urge FDA, DOJ and other agencies involved in enforcement to work together to address this urgent public health concern.

Premarket review has great potential to reduce youth use of e-cigarettes. We need to make sure that potential is realized and that e-cigarettes do not create a new generation of tobacco users.

Thank you for the opportunity to testify today.

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Testimony of Josephine Shapiro, 18, High School Student from Seattle, Washington
Testimony of Josephine Shapiro, 18, High School Student from Seattle, Washington
U.S. Senate Committee on the Judiciary
June 12, 2024

Testimony:

Hi, my name is Josephine Shapiro. I'm a high school senior from Seattle, Washington, and I'm addicted to nicotine because of e-cigarettes.

I grew up hating cigarettes and other commercial tobacco products. I would cough as I walked by smokers, trying to alert them to the harm that they're doing to their bodies. I never thought I would touch a cigarette or any other tobacco product.

As early as middle school, this started to change. My friends started vaping in seventh grade. They thought vapes were harmless because of the fun flavors and colorful packaging. They wanted to be cool like the pretty girls they saw vaping on social media, but they didn't realize they were becoming addicted.

Vaping soon started to take over their lives. They would leave class early to vape in the bathrooms or anywhere else they could get away with it. It's easy to hide these products in your sock or your bra, which makes it difficult for teachers or parents to know when kids are vaping.

In ninth grade, I began to hang out with a new group, who used all sorts of flavored e-cigarettes. The more I hung out with these people, the more vaping became normal to me, and I had to try it. The first flavor I tried was blueberry ice, but I tried pretty much every flavor my friends had.

I thought I was just enjoying the flavors, but soon my 14-year-old brain craved the nicotine more and more. I promised myself I wouldn't buy my own vape, because I wasn't addicted if I was just hitting it with my friends, right? It wasn't long before I broke that promise to myself. I was already addicted, and little did I know it was about to get worse.

These products are easy to get. You can ask someone older to buy it for you, buy it off a friend or just go to a store where they don't ID.

Once I had my own vape, I would leave class to vape in the bathroom with friends. I would get invited to lunch so people could hit my vape. All of a sudden, my entire circle was centered around vaping.

The hold nicotine had on my young mind was intense and scary. I felt completely out of control, helpless, and alone — even though I know I wasn't alone. Vaping affected my mood, my ability to catch my breath, and even my skin. I couldn't spend quality time with

my friends without thinking about when we were going to get their next hit, and I really miss the times when we could have fun without the presence of nicotine.

One of the saddest things about vaping and nicotine addiction is how it ruins relationships between friends and families. I can't tell you how many ways it's impacted my friends. But let me tell you one example.

One of my friends was so addicted, she would say things like "I'll just die at 20, whatever." I watched her isolate herself from the rest of her life, but as long as she had a vape, she said she was okay. Vaping for her was not just an addiction, it was her lifeline. We would skip class and activities to sit in her car and vape. Then the vapes turned into cigarettes. And then the cigarettes turned into other drugs.

My story is still ongoing today. Our story is still ongoing.

As I look forward to all the wonderful things I have ahead of me, I'm still struggling to get over my nicotine addiction. And I blame it all on the blueberry ice vape.

I've tried to quit vaping over and over again, but it is really, really hard.

Everything in my life is a trigger — hanging out with friends, driving my car, going to the bathroom, going into a convenience store — all of it makes me want to vape.

Honestly, I haven't been able to stay clean for more than two months since I decided to quit. I feel terrible about it. My addiction consumes a lot of my life. It has impacts on my physical and mental health. It makes me feel like I am less than. But the reality is that my ambition and goals have been suppressed by an industry that profits from me and my peers.

That's why I am sharing my story and doing everything I can to prevent young people from ever starting to vape or use any tobacco product. My story is mine, but I also tell it to protect the new generations. I have two younger siblings and imagining them with a blueberry ice vape breaks my heart. There are over 2 million kids who vape in the U.S., and millions more will go through the same thing if we do nothing.

From my perspective, we have to get rid of every single flavored e-cigarette. Until then, kids will continue to use these products and they will continue to get addicted just like me.

Thank you.



June 11, 2024

Chairman Dick Durbin
Members of the Senate Judiciary Committee

Mr. Chairman and members of the Committee, I appreciate the opportunity to join you today. I am David Spross and serve as the Executive Director of the National Association of Tobacco Outlets (NATO), a national retail trade association that represents more than 66,000 retail stores throughout the country. We are very grateful to the Committee for focusing attention on the need to enhance enforcement against illicit vapor products.

At the outset, I want to clearly affirm our strong support for a well-functioning regulatory system in which FDA oversight leads to accelerated reductions in underage use and in tobacco-related harm. NATO and our members are invested in this system and in these goals, which Congress set forth when it enacted the Family Smoking Prevention and Tobacco Control Act of 2009. In short, all tobacco and nicotine products should be made, marketed, and sold in full compliance with FDA laws and regulations. Illicit markets are a major threat to that goal, and thus a threat to the responsible retail community committed to operating within – not outside – the legal system.

NATO members take responsible retailing seriously. Our members include licensed retailers who age-verify their customers to prevent sales to minors. We have partnered with the *We Card* Program, a national non-profit organization providing individual retail establishments as well as large retail chains with educational and training services. We have also been regularly informing our membership of the brands FDA has targeted in its warning letters and other enforcement actions, to ensure our members know in detail what products FDA is taking action against. These services are intended to help our members align their practices with FDA's enforcement priorities, and, most importantly, ensure they are selling only to adult customers twenty-one and older.

Today's hearing addresses a very important topic for the members of NATO as well as for our country. As you have heard today, the legal vapor market is being overrun by illicit and unregulated products—the vast majority of which are flavored vapor products made in China.

In September of last year, we alerted FDA to this illicit market crisis, and I know several NATO members have also independently shared their concerns with FDA. Since then, the crisis has only intensified. By our estimate, flagrantly illicit vapor products – all made, marketed, and sold without any FDA oversight – now make up more than 50% of the market, having grown by double digits since our September letter to FDA. Earlier this year, in a letter to Senator Durbin and others, NATO again shared our concern that the current market is characterized by a large number of illicit products, particularly flavored disposable products from China, and sought greater FDA focus on this burgeoning crisis.

We were heartened by Monday's announcement that the Department of Justice and FDA are creating a federal multi-agency task force that will focus on combatting the illicit distribution and sale of vapor products. To be successful, FDA and the members of the Task Force must use the full range of enforcement tools such as injunctions, civil money penalties, seizures, and import refusals against the largest manufacturers and distributors of these illicit products.

To date, we have seen piecemeal enforcement that often ignores the most egregious actors. When FDA does act, the agency's warning letters often go ignored, and it appears ignoring these letters results in few serious consequences. We need FDA to utilize its injunctive authorities and the enhanced civil penalties that Congress authorized—which can reach in the tens of millions of dollars in fines—to address this issue. Companies in open defiance of the law must be held accountable, and we believe that means FDA must immediately employ its most powerful enforcement tools against the worst offenders. With more aggressive action against these companies that are ignoring FDA requirements altogether, we believe order can be restored to this marketplace.

NATO and our members desire to be part of the solution and want FDA regulation to succeed. To this end, in September of last year, we requested that FDA host a stakeholder meeting to discuss how to enhance enforcement activities. Ideally, this meeting will bring together all stakeholders (*e.g.*, industry, FDA, other state and federal government agencies, and public health organizations) to have an open dialogue to drive solutions on enforcement. The time is now to convene such a meeting.

An effective regulatory system also requires a more coherent compliance framework that clearly communicates FDA's enforcement priorities – what categories of products it wants immediately removed from the marketplace and what categories can remain on the market. That information is critical to helping address the marketplace chaos we see every day.

FDA has been clear that only 23 authorized vapor products are legal. But we also understand that FDA is not currently prioritizing enforcement against vapor products that have fully complied with its 2016 Deeming Rule¹ and that have timely filed PMTAs which remain pending before the agency. FDA has repeatedly acknowledged that the removal of products pending PMTA review would stimulate illicit market activity and take potentially reduced harm products away from smokers. Simply put, NATO members—who are seeking to abide by the law—need greater clarity from FDA.

In addition to enforcement and transparency, we believe FDA should make more progress in reforming its PMTA process. We believe this illicit market has arisen in part because FDA's PMTA process has fallen short of its intended purpose. For example, FDA continues to review applications on products filed in some cases more than four years ago.

To date, FDA has authorized only a small handful of smoke-free products despite millions of adult consumers seeking better alternatives to smoking. This growing adult demand for smoke-free products should be seen as a positive, given the science that such products are substantially less harmful than combustible cigarettes. But with so few FDA-authorized vapor products available to adult smokers, scores of Chinese companies have exploited this vacuum and flooded the market with products that ignore FDA requirements altogether. Authorizing more products will help build a well-regulated market that delivers on harm reduction.

In closing, we believe the solution to the current crisis of illicit products is to urgently address all three needs: enforcement, transparency, and authorizations. NATO and its members support a well-regulated tobacco product market that reduces underage use and delivers on harm reduction for adult smokers. We look forward to working with FDA and the Task Force as it addresses these issues.

Sincerely,

David Spross

NATO Executive Director

ⁱ Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. (81 Fed. Reg. 28974, May 10, 2016).

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

June 12, 2024

Written testimony of
Susan Walley, MD, MHCM, NCNTT, FAAP

On behalf of the
American Academy of Pediatrics

Before the
Senate Judiciary Committee

"Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes"

Chairman Durbin, Ranking Member Graham, and members of the committee:

Good morning and thank you for inviting me to speak today on this critical topic for the health of children. My name is Dr. Susan Walley. I am a pediatrician and chief of the Division of Hospital Medicine at Children's National Hospital here in Washington, D.C. I conduct research on adolescent tobacco use and treat children who are addicted to tobacco products. I am here today representing the American Academy of Pediatrics (AAP), where I recently served as chair of the AAP's Section on Nicotine and Tobacco Prevention and Treatment. The AAP is a non-profit professional medical organization representing over 67,000 pediatricians dedicated to the health and well-being of children and adolescents.

E-cigarettes are addictive and they are dangerous for children. We must do all we can to keep them out of their hands. Unfortunately, we are here today because we're not doing enough to protect our youth from a tobacco industry intent on profiting off selling harmful and addictive products to children.

According to the National Youth Tobacco Survey, over 2 million children currently use e-cigarettes. While this number is down from its peak a few years ago, it is still a shockingly and unacceptably high number. What's more, over a quarter of youth e-cigarette users use them every single day—which indicates that these products are both attractive to children and incredibly addictive.¹

One of the primary reasons children are attracted to e-cigarettes is the sweet fruit, candy, and mint flavors they come in. The flavors smell and taste good and they mask the harshness of tobacco. This makes repeated use more likely, and thereby increases the likelihood of developing nicotine addiction. These products are also often marketed with packaging that can resemble candy, snack food, or even alcohol, are designed to be discrete and easily hidden, and have been routinely pushed by social media influencers.

As a pediatrician, I see all too frequently how nicotine addiction takes hold in my teenage patients who vape e-cigarettes. The brain is more susceptible to nicotine addiction during adolescence. Symptoms of dependence can appear within days to weeks of a teen's first experimentation with e-cigarette use. When the brain does not get the nicotine it craves, teens experience unpleasant withdrawal symptoms such as irritability and anxiety, which leads to continued use. With repeated exposure, tolerance develops quickly, and the user requires more nicotine to just feel normal. For many young people, this is not just sporadic use, but consistent, frequent, and dependent use. Sometimes teens wake in the middle of the night to vape—a sign of intense nicotine dependence. Unfortunately, the trusted adults they usually rely on—parents, teachers, and pediatricians—have limited options to assist in quitting.

I am certified in nicotine and tobacco treatment, which means I have special training on how to help people—including children—quit using tobacco products. But pediatricians like myself have found that helping adolescents stop using e-cigarettes is exceedingly difficult. Many of these children are very addicted and we have limited effective tools in our toolbox to help them because youth tobacco

cessation treatment, particularly for e-cigarettes, is not as well researched as treatment for adults. So the best strategy is to prevent adolescents from using any tobacco products in the first place.

The most effective way to stop youth e-cigarette use is to get the flavored tobacco products off the market. This is where we need the FDA's help. In the Tobacco Control Act, Congress wisely set up a regulatory process at FDA to ensure that dangerous new tobacco products do not enter the market. By law, FDA can only authorize a product for marketing if it is found to be "appropriate for the protection of public health." Central to this determination is analysis to ensure that an authorized product will not be appealing to children. This system of public health review appears, for the most part, to be working as intended. To date, FDA has appropriately determined that no e-cigarettes that are flavored are appropriate for the protection of public health.

This premarket review of e-cigarettes was hard won. The AAP, the Campaign for Tobacco-Free Kids, and other public health partners joined together to sue the FDA in 2018 because—in the middle of a surging epidemic of teen e-cigarette use—the agency was shirking its responsibility under the law to conduct public health reviews of e-cigarettes. At the height of the surge in 2019, one-third of high school students were using e-cigarettes, which has had lasting repercussions on young adult tobacco use today.² Thankfully, a federal court ruled in our favor in 2019 and ordered FDA to do its job and begin premarket review.³

Subsequently, FDA reviewed millions of e-cigarette applications, and has appropriately rejected the vast majority of them. However, five years after that ruling, FDA still has pending applications before the agency, including for JUUL, the product most responsible for the initial surge in youth e-cigarette use. This delay has complicated efforts to get unauthorized products off the market. While FDA says there is no safe harbor for products with pending applications before the agency, FDA has not taken enforcement action against any of these products.

As of today, FDA has authorized only 23 e-cigarette products. These 23 products are sold under only three brands, and none of these products comes in a flavor other than tobacco.⁴ These are the only products that are allowed to be legally sold in the United States. And yet, thousands of illegal flavored e-cigarettes make their way to children every day. Today, 90% of youth e-cigarette users report using a flavored product, despite none of them being authorized by the FDA.⁵ Simply put, this is unacceptable.

The solution should start where the problem starts: with the tobacco industry and its supply chain. Manufacturers should end the production of unauthorized e-cigarettes. Distributors should stop distributing them. Retailers like vape shops and convenience stores should stop selling them to the public, where they ultimately land in the hands of children. But history has taught us that the tobacco industry and its partners are unlikely to do the right thing on its own.

Therefore, the federal government must do more to get these illegal products off the market. We are pleased to see that FDA has stepped up enforcement against illegal e-cigarettes in the past year. We also appreciate that FDA and its law enforcement partners announced this week the creation of a

multi-agency task force to specifically address this issue. It is a good start, but it is not sufficient. FDA should issue steeper fines, seize more illegal products, and criminally prosecute bad actors. But we understand that FDA cannot do this alone. It needs the help of the Department of Justice (DOJ), which must prioritize tobacco enforcement. Customs and Border Protection (CBP) must stop the importation of unauthorized products so that they do not enter the country in the first place. We need an all-of-government effort to keep these illegal products away from children.

We understand that enforcement takes resources and that resources are limited. That is why Congress must provide more funding to support e-cigarette enforcement efforts at FDA, DOJ and CBP. Instituting FDA user fees on e-cigarettes and directing this funding toward enforcement can be part of the solution. And lastly, as the federal government works to remove illegal, flavored e-cigarettes from the market, we need to resume efforts to get other flavored tobacco products that drive youth tobacco initiation off the market as well, including menthol cigarettes and flavored cigars.

And while the federal government must do more, let us not lose sight of the real culprit here: a tobacco industry that puts profits over the health of children and adults alike. Large tobacco companies like R.J. Reynolds and Altria claim to care about ending smoking, but they continue to sell billions of deadly cigarettes (still 60 percent of the tobacco market) each year in the United States.⁶ They continue to market illegal flavored e-cigarette products. They actively fight local efforts to enact common sense tobacco control policies and instead push policies to preserve their market share.

E-cigarette use in children is a solvable problem with solutions that work. We just need the will to implement these solutions. Thank you for the opportunity to be with you here today. America's pediatricians look forward to working with you to ensure that our children grow up without the harms of tobacco products.

¹ Food and Drug Administration. Results from the Annual National Youth Tobacco Survey, <https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey>.

² Centers for Tobacco Control and Prevention. Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019, <https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm>.

³ AAP v. FDA, 399 F. Supp. 3d 479 (D. Md. 2019).

⁴ FDA. Premarket Tobacco Product Marketing Granted Orders. <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>.

⁵ FDA. Results from the Annual National Youth Tobacco Survey, <https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey>.

⁶ Wall Street Journal. America's cigarette market is up for grabs. April 19, 2024.

**Senator Charles E. Grassley Questions for the Record
United States Senate Committee on the Judiciary
Combatting the Youth Vaping Epidemic by Enhancing Enforcement
Against Illegal E-Cigarettes
June 12, 2024**

**Questions for Tony Abboud
Executive Director, Vapor Technology Association**

1. Do any of your association's members sell vapor products that are not authorized for sale by the FDA, and if so, does your organization condone this practice?

**Vapor Technology Association Response to
Question for the Record from Senator Charles E. Grassley
July 5, 2024**

Virtually every company in this country, save one, is presently selling vaping products that are not authorized by the FDA. This includes the biggest companies in the tobacco industry as well as the smaller companies in the independent vaping industry. This fact is not because companies have not sought authorization, but because the FDA for its own political reasons has simply refused to authorize vaping products, has drug its heels for years on product application reviews, has rejected an untold number of applications for both hyper-technical and substantive reasons (only to later withdraw those rejections but still not authorize products), has misled companies as to what is required to obtain market approval, has changed the requirements for the applications *after* the applications were filed, and has not fairly or transparently performed its duties under the Tobacco Control Act and the Administrative Procedures Act. In short, FDA created the situation in which we are in by breaking its own regulatory process and rules.

The FDA's serial malfeasance, which, for example, led to the *en masse* rejection of millions of flavored products, has naturally resulted in 80 appeals to the federal courts (of which FDA has only won 12, per the testimony of the Department of Justice at the hearing). These appeals, many of which are still being adjudicated, cover an untold number of products. In January of this year, the United States Court of Appeals for the Fifth Circuit, in an *en banc* decision, excoriated the FDA's e-cigarette process. The Fifth Circuit opened its opinion with the striking statement, "Over several years, the U.S. Food and Drug Administration sent manufacturers of flavored e-cigarettes on a wild goose chase."¹ The Court later went on to explain, "FDA unquestionably failed to follow § 387g's notice-and-comment obligations before imposing its *de facto* ban on flavored e-cigarettes."² In its holding, the Fifth Circuit made clear:

In sum, FDA's denials of petitioners' PMTAs were arbitrary and capricious. The agency did not give manufacturers fair notice of the rules; the agency did not acknowledge or explain its change in position; the agency ignored reasonable and serious reliance interests that manufacturers had in the pre-MDO guidance; and the agency tried to cover up its mistakes with post hoc justifications at oral argument. The contrary views

¹ *Wages & White Lion, et al v. FDA*, No. 28-60800 (5th Cir. 2024) (*en banc*), p.1.

² *Id.* at 41.

expressed by some of our sister circuits do not address our principal concerns with FDA's decision-making.³ We therefore hold the agency acted unlawfully.⁴

The Fifth Circuit's decision, and its admonishment to the FDA to provide a "full and fair regulatory proceeding on remand, notwithstanding its prior promises to reject their applications no matter what"⁵ was so problematic that FDA was forced to seek review from the Supreme Court. On July 2, 2024, the U.S. Supreme Court granted cert in that case, which means that it will now have the opportunity to review FDA's unlawful conduct as laid bare by the Fifth Circuit's *en banc* ruling.

While VTA does not condone the sale of vapor products not authorized for sale by the FDA, we also do not condone a PMTA process that is so flawed, unfair, and arbitrary and capricious, and we do not condone the FDA's refusal to even review the applications filed by hundreds of companies covering hundreds of thousands of products. We believe FDA's failures have left products, which are appropriate for the protection of the public health, in this bizarre state of regulatory limbo. As a category, vaping products are dramatically less harmful than combustible cigarettes such that leading tobacco control scientists in the U.S. have demanded that the FDA and U.S regulators change their cautious views on e-cigarettes. Dr. Nancy Rigotti of Harvard University, and a member of the National Academies of Science, Engineering and Medicine, in an editorial that she published in the New England Journal of Medicine declared:

"It is now time for the medical community to acknowledge this progress and add e-cigarettes to the smoking-cessation toolkit.... U.S. public health agencies and professional medical societies should reconsider their cautious positions on e-cigarettes for smoking cessation. The evidence has brought e-cigarettes to a tipping point. The burden of tobacco-related disease is too big for potential solutions such as e-cigarettes to be ignored."⁶

For this reason, urgent calls to remove all but a handful of vaping products from the market, because they are not "authorized" by an FDA that is failing both legally and morally in its obligation to protect public health, offers little relief or benefit to the 30 million Americans who remain addicted to smoking combustible cigarettes and the 13-15 million adult Americans who are vaping and do not want to return to smoking. Concern about Americans who smoke must remain at the forefront of the discussion since 480,000 Americans die every year from smoking and another 16 million suffer from smoking related illnesses, costing the U.S. hundreds of billions of dollars in lost GDP and healthcare costs. Therefore, repeated calls to enforce "unauthorized" but less harmful products out of the market simply gives the FDA a pass for its

³ Importantly, those sister-circuits –which upheld the same FDA process about which the Fifth Circuit was so critical – gave the FDA complete deference in how it was interpreting and applying its PMTA rule. In light of the Supreme Court's recent *Loper v. Raimondo* decision, it is possible that the Supreme Court skeptically views the FDA's arbitrary and capricious actions and declares unlawful what the Fifth Circuit called FDA's "de facto ban on flavored e-cigarettes."

⁴ *Wages & White Lion, et al v. FDA*, No. 28-60800 (5th Cir. 2024) (*en banc*), p. 49.

⁵ *Id.* at 4.

⁶ Rigotti, Nancy, M.D., Electronic Cigarettes for Smoking Cessation – Have We Reached a Tipping Point?, *New England Journal of Medicine*, 390:7, February 15, 2024, at https://vaportechnology.org/wp-content/uploads/2024/03/Rigotti-Editorial-on-ECIG-RCT-2_14_2024.pdf.

prior malfeasance that has put us, the U.S. market, and Americans who smoke cigarettes in this current predicament.

VTA believes that all vapor products sold in the U.S. should be subject to a fair and transparent FDA regulatory review and authorization process, and has lodged its criticisms with the FDA, with Congress, and with the Reagan-Udall Foundation for the FDA. In addition to the Fifth Circuit's dismantling of the FDA process, it is important to note that the FDA has been criticized for failing to properly implement its core regulatory function by an independent review group. In 2022, shortly after FDA Commissioner Califf took over at FDA, he asked the Reagan-Udall Foundation to conduct an independent review of the Center for Tobacco Products (CTP) regulatory program. In what the Associated Press called a "blistering report" in December 2022, the Independent Tobacco Expert Panel convened by Reagan-Udall made clear that CTP had failed on the most essential aspect of its job: assessing which products are "appropriate for the protection of the public health" (APPH) – which is the standard set forth in the Tobacco Control Act. Reagan-Udall made clear:

*Applicants, however, will struggle to address the issues necessary to meet the APPH standard unless FDA clearly articulates its expectations. A lack of clarity results in extraneous work on both sides--for applicants and for the Agency. CTP has a responsibility to clearly identify application requirements, if for no other reason than to reduce the burden on the Agency itself and improve efficiency."*⁷

In addition, the report called on FDA "to explain how FDA is interpreting the APPH standard." FDA took one year to respond to the Reagan-Udall report when it issued a thin and highly bureaucratic "five year strategic plan" that stunningly offered no response on what is required to meet the APPH standard or how FDA is interpreting and applying it. Hence, to this day, FDA continues to operate with impunity and continues to deprive American consumers of authorized less harmful flavored vaping products.

While pending and new legal actions might ultimately hold FDA accountable, FDA has yet to answer for the scathing criticisms levelled by its own employees during the Reagan-Udall review. The submissions to the Reagan-Udall Stakeholder Portal by FDA staff articulated VTA's worst fears of what was going on inside FDA: namely, that the process had in fact been subverted to accomplish political objectives not based on science. Some of the most alarming FDA staff comments are quoted here:

- "In cases where reviews are finished and scientific decisions are made they are also overruled by political agendas and *pushed to change* decisions."
- "Politics are being permitted to drive the science and even limit or *alter science-based decisions*."
- "Reviewers in the...Office of Science...lack autonomy to exercise best scientific practices in their application reviews or express differing scientific opinions."

⁷ Reagan-Udall Foundation for the FDA, Operational Evaluation Of Certain Components Of FDA's Tobacco Program, December 2022, p. 20.

- “Scientific disagreement is frowned upon, if not entirely suppressed and punished...”
- “In some divisions ... a ‘gotta get em’ mentality ..., which is unresponsive of a reviewer’s fundamental duty to provide an unbiased review...”
- Need “extra barrier of isolation to prevent such *influence* with the scientists...”
- Need “a culture shift to promote that the scientists follow the science and not be *influenced by non-scientists* especially in terms of application review.”

The full text of these FDA employee submissions are available for your review.⁸ The words from the mouths of FDA employees speak volumes as to the level of political dysfunction in FDA’s tobacco regulatory regime and easily explain why today we only have a handful of vaping products authorized.

VTA is not aware of any member companies that are selling vapor products which are not authorized for sale by the FDA but that have pending PMTAs under review by the FDA. This information is kept strictly confidential by the companies and by the FDA. For example, despite requests made by VTA and other stakeholders, the FDA refuses to publish a list of products that currently have a pending PMTA. Thus, there is no way for any company in the distribution chain to know the precise current or potential future status of any particular product.

Notwithstanding the foregoing, the FDA’s recent prioritization of enforcement of the sale of non-PMTA products is a red herring because if the FDA was following the law and approving products such that there was a diverse marketplace of various ENDS flavored products, retailers would not take the risk of selling non-PMTA products and consumers would not feel the need to purchase same. If and when the FDA approves a diverse, flavored product category, we believe the influx of non-PMTA products would largely abate. Until such time as FDA reverses course and lawfully fulfills its statutory obligation, we believe non-PMTA products will find a way to remain on the market due to the incredible demand for these products, a demand created by more than 13 million adult vaping consumers who have demonstrated their preference for these non-authorized products over the FDA’s authorized products. This means that FDA and DOJ resources are being expended on a problem that could best be resolved by FDA instead applying scientific methods to review and approve a diverse, flavored product category.

We do not believe that outright prohibition of flavored vaping products will work, and we also strongly believe flavored ENDS products are appropriate for the protection of public health and will save lives. The dangers of removing flavored vaping products from the market have been demonstrated scientifically and empirically. Leading tobacco control scientists at Yale, Georgetown and Missouri have demonstrated that in every state and municipality that has restricted flavored vaping products, there was a direct subsequent increase in cigarette sales. They explained, “cigarette sales increase even among brands *disproportionately used by underage youth*. Thus, any public health benefits of reducing ENDS [e-cigarette] use via flavor

⁸ Reagan-Udall Foundation Stakeholder Portal, Comments by CTP Employees to Reagan-Udall, October 2022, captured while publicly available, at <https://vaportechnology.org/wp-content/uploads/2024/03/FDA-Staff-Comments-to-Reagan-Udall.pdf>.

restrictions may be offset by public health costs from increased cigarette sales.”⁹ To be sure, another recent study reported in Newsweek found that flavored e-cigarette bans have led to an increase in youth cigarette smoking.¹⁰ That study concluded that “we also find that ENDS [e-cigarette] flavor restrictions may also have an unintended tobacco-related public health cost. We demonstrate that adoption of a restriction is associated with a one to three percentage-point increase in the probability of combustible cigarette smoking.”¹¹

And, as important as was the discussion about youth vaping at the hearing, it is critical to know that the youth vaping rate in the U.S. plunged a massive 61% since it peaked in 2019, and now only 7.7% of youth report having tried an e-cigarette in the last 30 days, and only 2.5% of youth use them regularly.¹² This was because, instead of banning all flavored vaping products, Congress raised the age to purchase all tobacco products to 21, something VTA championed with Congress and the White House. The result is that today the youth vaping rate now sits at a decade-low, a level not seen since 2013, before e-cigarette products were even regulated by the FDA and before the flavored disposable vaping products came to the market.

Flavored disposable vaping products have received intense focus recently, including at the hearing. But, as VTA shared with the Committee, the dramatic 61% decline in the youth vaping rate since 2019 coincided directly with the dramatic rise in flavored disposable vaping products. This tells us two things: (1) if anything, there is an inverse correlation between flavored disposable vaping products and youth usage; and (2) the dramatic rise in sales of flavored disposable vaping products cannot possibly be attributed to youth, and must be attributed to widespread adult usage. There is no credible argument that increasing sales of flavored disposable vaping products leads to increasing youth use, while youth use is plummeting at the same time.

As important, the National Youth Tobacco Survey year after year confirms that youth are not attracted to vaping on account of flavored products. Youth have consistently reported that flavors are not the reason they first tried an e-cigarette (14.5%) or the reason they currently use e-cigarettes (6.4%).¹³

To further demonstrate that the FDA has lost its way on its mission to end smoking, and has instead created an untenable marketplace, one need only look to its track record since passage of the Tobacco Control Act. Rather than filling the market with a wide variety of less harmful nicotine alternatives to smoking cigarettes under the PMTA process, which was the intent of the Tobacco Control Act, the FDA has done the opposite. FDA has authorized over 16,000

⁹ Friedman, et al., E-cigarette Flavor Restrictions’ Effects on Tobacco Product Sales, 2023, at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4586701.

¹⁰ Mesa, Jesus, Flavored Vape Bans Led to Increase in Teen Smoking: Study, Newsweek, June 10, 2024, <https://www.newsweek.com/flavored-vape-bans-teen-smoking-1910815>.

¹¹ Cotti, Chad, et al., The Effect of E-Cigarette Flavor Bans on Tobacco Use, National Bureau of Economic Research working paper, DOI: 10.3386/w32535, June 2024, <https://www.nber.org/papers/w32535>.

¹² Birdsey, Jan, et al., Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023, MMWR Weekly / November 3, 2023 / 71(44); 1173-1182.

¹³ Park-Lee, Eunice, Ph.D, et al., E-Cigarette Use Among Middle and High School Students, United States, 2022, MMWR Weekly / October 7, 2022 / 71(40);1283-1284.

combustible tobacco products, including more than 3,700 deadly cigarettes.¹⁴ Even more striking is that in the past two years under the current FDA leadership, FDA has accelerated its pace, authorizing 2,000 new combustible products, including 821 new cigarettes, and, only four vaping devices. All told, despite FDA receiving in excess of 20 million PMTAs for vaping products, FDA has only seen fit to authorize a handful (27 in total officially, but only around 10 when one considers what is available on the market) of vaping products, all owned by the three largest cigarette companies. These decisions clearly demonstrate that the current regulatory process in the hands of the FDA is broken.

The FDA is not acting in accordance with the law, not acting based on science – as it repeatedly professes – and is certainly not acting to protect the public health of Americans. Companies deserve a new, transparent, streamlined regulatory process that does not tilt to the whims of political or special interests. Americans deserve access to a wide variety of less harmful vaping products, particularly flavored vaping products that have been shown to help adults quit smoking. To reiterate Dr. Rigotti’s warning, “The burden of tobacco-related disease is too big for potential solutions such as e-cigarettes to be ignored.”

¹⁴ VTA Report, FDA is on Fire, May 2024, at <https://vaportechnology.org/wp-content/uploads/2024/05/VTA-Report-%E2%80%93-FDAs-Tawdry-Record-With-Cigarettes-Final-1.pdf>.



November 12, 2024

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

Dear Chair Durbin:

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

Sincerely,

A handwritten signature in black ink, appearing to read "E O'Q", is positioned below the word "Sincerely,".

Erin O'Quinn
Associate Commissioner for
Legislative Affairs

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

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

Senator Dick Durbin

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 7. FDA has stated that, "For unauthorized tobacco products, the pendency of an application does not create any sort of a safe harbor to sell that product."**
- a. Please list each enforcement action FDA has taken against manufacturers of unauthorized e-cigarettes with pending PMTAs, including—as permissible—a notation of whether such PMTA was timely filed pursuant to court orders or statutory deadlines (for tobacco-derived nicotine products and synthetic nicotine products).**

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

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

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

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

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

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

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

² <https://www.accessdata.fda.gov/scripts/searchtobacco/>

³ <https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-JULY2024.pdf>

⁴ <https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products#Enforcement%20Priorities>

Senator Tom Tillis

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

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

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

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

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

⁵ https://www.nature.com/articles/s41591-024-02926-7.epdf?sharing_token=ETQ3Pkp1wxySB6hBvlyqZNRgN0jAjWel9jnR3ZoTv0P4kOyNQzfYBPc4k1kVmBUHXS Gdi4r5jGtlqGGrr2LUvq3nc1uYYe1eGRY0HFzWsxpAw6VEKuUwyrU2rIEA9i8NcEPSgCHB5M3tluE1e-5ujJePkexBpPqkbXuBzuDUW14%3D

⁶ Section 910(c)(4) of the FD&C Act.

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

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

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

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

The report offered a number of recommendations to improve authorization, enforcement, clarity and transparency at CTP. Among those recommendations, the Regan Udall Foundation specifically called on FDA to “establish an interagency task force to make enforcement of the tobacco laws a government-wide priority, particularly to address the marketing of illegal products and the risks of youth use.”

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

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

a) What took so long? and

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

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

⁹ <https://onlinelibrary.wiley.com/doi/full/10.1111/add.16296>

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Marijuana Vapes

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

- 1. On May 30, 2024, the U.S. Food and Drug Administration (FDA) announced it is seeking civil money penalties to online retailers and brick & mortar stores for unauthorized e-cigarettes/vapes. What type of inspections does FDA conduct for marijuana vapes like the ones sold by Eastern Band of Cherokee Indians and Qualla Enterprise LLC?**
- 2. If you go on Eastern Band of Cherokee Indians and Qualla Enterprise LLC's website, *Great Smoky Cannabis Company*, you can now purchase one of over two dozen marijuana vapes. On these packages, there are no warning labels for children, no description on how the product was tested, and no indication on where the vape pens were manufactured. Can I get FDA's commitment to conduct an inspection to *Great Smoky Cannabis Company* marijuana vapes being sold on their website?**
- 3. The vape pens being sold by the Eastern Band of Cherokee Indians and Qualla Enterprise LLC state that the THC levels range from 65%-79%. Do you agree that these levels of THC are safe?**
- 4. In April, an Associate Judge for the Eastern Band Tribal Court, the Superintendent at Cherokee Central Schools, and tribal health leaders raised their concerns about the marijuana venture's impact on the behavioral health of youth. Do you agree that if a child uses one of the Easter Band's marijuana vape pens or consumes the snickerdoodle cookies—it could have a negative impact to their health?**

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

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

Multi-Agency Taskforce

- 1. Memorandum of understanding (“MOU”) for multi-agency task force. Has FDA, DOJ, and the other agencies that joined the task force executed an MOU that (1) defines lines of authority and responsibility, (2) clarifies processes for coordination, cooperation, and resource allocation, and (3) prevents duplication of effort? If so, please provide us with a copy of the MOU.**
 - a. If not, why is there no MOU in circumstances where FDA has a policy of executing MOUs for agency collaborations and a long history of executing MOUs with agency partners?**
 - b. Given the complexity of the e-vapor crisis – involving multiple federal agencies and multiple federal statutes – will FDA and DOJ commit to finalizing an MOU, and providing a fully executed copy to this Committee, within the next thirty (30) days?**
- 2. Objectives of the multi-agency task force. FDA and DOJ’s announcement on June 10, 2024, clarified that the task force aims not only to bring more civil and criminal enforcement actions, but also to protect the public health by preventing the widespread availability of illegal e-vapor products.**
 - a. Has the task force established key performance indicators, performance metrics, or enforcement action goals to measure its success in preventing the sale and distribution of illicit e-vapor products? If so, please share those metrics with this Committee.**
 - b. Does the task force agree that, more so than the number of enforcement actions it initiates, the most meaningful measure of its success will be a reduction in the actual sale and distribution of illicit e-vapor products in the marketplace? If so, please describe how the task force intends to measure its impact.**
 - c. Does the task force accept that, to meaningfully impact an illicit e-vapor market of this scale and scope, it must bring enforcement actions involving the strongest tools against the largest actors? If so, please explain how the task force will focus its efforts and resources on issuing enhanced civil money penalties, import seizures, injunctions, forfeiture applications, and criminal prosecutions against the leading manufacturers and distributors of illicit products.**
 - d. Is the task force committed to reversing the approach adopted to date by FDA – in which its injunction applications and civil money penalties have been issued only to retailers – and instead pursue the largest manufacturers and distributors of illicit imported disposable products by market share? If so, please explain how the task force will identify the largest manufacturers and distributors of illicit imported disposable e-vapor products by market share.**

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- e. As many of the largest manufacturers of illicit e-vapor products are domiciled in China, and it is difficult to impose judicial orders and administrative penalties against Chinese companies, what strategies is the task force developing to hold such Chinese companies accountable? Please describe the disclosable parts of those strategies and explain how the task force will impose penalties against Chinese companies that bear the greatest responsibility for the relentless growth of the illicit e-vapor market.
 - f. Will the Task Force prioritize preventing the importation of illicit products or shutting the distribution down within the United States? Why is one approach better than the other?
3. Composition of the multi-agency task force. There is some confusion about whether Customs and Border Protection (“CBP”) has joined the task force. FDA and DOJ’s announcement about the task force did not list CBP among the agencies that have joined the task force. However, Deputy Assistant A-G Arun Rao testified as follows to this Committee: “The task force combines the expertise of multiple law enforcement partners, including ATF, the US Postal Inspection Service, the US Marshals Service, US Customs and Border Protection as well as the Federal Trade Commission.”
- a. Has CBP joined the task force? If CBP has not joined the task force:
 - i. The Committee has received reports that CBP field staff may be frustrated by a lack of timely information from FDA’s Center for Tobacco Products (“CTP”) regarding the admissibility or inadmissibility of shipments of e-vapor products. Has this frustration contributed in any way to CBP’s decision not to join the task force, or at least its decision not to join the task force by June 10, 2024? If this was a contributing factor, please explain how the task force intends to remediate the apparently suboptimal working relationship between CBP and CTP field staff.
 - ii. Do you agree with FDA Commissioner Dr. Robert Califf that import prevention and enforcement is likely the most effective way to prevent the flow of illicit products into the U.S. from China, and it is therefore critically important that CBP join the multi-agency task force and take a leading role in preventing the importation of illicit products?
 - iii. Will FDA and DOJ commit to ensuring that CBP joins the task force within the next 30 days and provide written confirmation to this Committee once it has?
 - b. Has the Department of State or any other agencies responsible for national security joined the task force? If not:
 - i. Do FDA and DOJ understand, based on the report “The Global Illicit Trade in Tobacco: A Threat to National Security,” that illicit tobacco markets are a national security threat?

- ii. Do FDA and DOJ understand that illicit tobacco markets operate globally and are major funding sources for international terrorist organizations, including Hamas?
 - iii. Do FDA and DOJ understand that illicit e-vapor products make billions of dollars for the Chinese Tobacco Monopoly and are a key funding source for the Chinese government?
 - iv. Will FDA and DOJ commit to ensuring that the Department of State joins the task force within the next 30 days and provide written confirmation to this Committee once it has?
- c. In addition to federal agencies, state and local agencies are responsible for enforcement of state and local laws that implicate illicit e-vapor products. Does the task force intend to admit state or local law enforcement agencies to its membership or, otherwise, will the task force coordinate with state and local law enforcement, or the National Association of Attorneys General? Please describe how the task force will coordinate its investigations, enforcement decisions, and attorney engagements with state and local agencies.
- d. In testimony before this Committee, Dr. Brian King said that the task force is “multi agency, and that takes time to make sure we get the right folks to the table, and we set the foundation for more programs.” When does the task force expect to finalize its composition? Please explain the process by which agencies join the task force, when that process will be completed, and whether and to what extent the White House is involved in the process.
4. Operation of the multi-agency task force. Please answer the following questions about the task force:
- a. What is the effective date and expiration date for the task force?
 - b. When did the task force first meet and how often does it meet?
 - c. Does the task force have a steering committee, and if so, who are its members?
 - d. Does the task force have liaison officers from each agency, and if so, who are the officers?
 - e. How are personnel, resources, and funds allocated to and within the task force?
 - f. How many staff from each agency, and in total, have been assigned to the task force?

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- g. How will agency staff not assigned to the task force share information with the task force?**
- h. What procedures are in place for the sharing of non-public information within the task force?**
- i. What processes has the task force adopted to ensure efficiency and avoid bureaucracy?**
- j. How are decisions to bring enforcement actions made and how are disagreements resolved?**
- k. Will the task force issue detailed public reports on its progress? If so, how frequently? If not, will FDA and DOJ commit to providing written updates to this Committee at least quarterly?**
- l. How will the task force work with and learn from outside experts? What is the process for interested parties to share information?**

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

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

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

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

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

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

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

FDA’s understanding of the illicit e-vapor market

- 1. What does FDA believe is the size of the illicit Chinese e-vapor market in the U.S. either in terms of total volume or percentage of all nicotine vapor products sold in the U.S.?**
- 2. Does FDA have any data or other information to dispute the assertion that, since 2020, the number of illicit Chinese e-vapor products available in the U.S. market has grown by a rate of 1,500% and that so far there has been no substantial change in this growth trajectory?**
- 3. As FDA, DOJ, and the multi-agency task force should focus on the most impactful enforcement actions, what surveys or other methods does CTP use to measure or monitor the prevalence of illicit tobacco products generally, and illicit e-vapor products in particular, in the U.S.?**

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

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

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

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

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

Senator Charles E. Grassley

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

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

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

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

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

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

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

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

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

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

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

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

¹² <https://datadashboard.fda.gov/ora/cd/impentry.htm>

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

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

¹³ https://www.accessdata.fda.gov/cms_ia/industry_98.html

¹⁴ <https://www.fda.gov/news-events/press-announcements/joint-federal-operation-results-seizure-more-18-million-illegal-e-cigarettes>

Senator Amy Klobuchar

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

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

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

In the past three years, FDA has remained committed to helping manufacturers and importers understand how to prepare applications. For example, FDA published the final PMTA rule that sets forth content and format requirements for PMTAs and issued guidance related to the application process.¹⁷ In addition, FDA developed technical resources for applicants submitting electronic applications,¹⁸ and held multiple meetings and listening sessions with a variety of stakeholders to answer questions about the PMTA process, including a two-day public meeting on the PMTA process hosted on October 23 and 24, 2023.¹⁹

¹⁵ Pub.L. 111–31.

¹⁶ Section 910(c)(4) of the FD&C Act

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

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

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

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

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

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

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

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

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

²⁰ <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders>

²¹ <https://www.accessdata.fda.gov/scripts/searchtobacco/>

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

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

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

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

Senator Richard Blumenthal

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

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

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

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

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

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

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

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

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

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

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

**Written Questions for Arun G. Rao
Deputy Assistant Attorney General
Consumer Protection Branch, Civil Division
U.S. Department of Justice**

Senator Dick Durbin, Chair

1. *The Food and Drug Administration (FDA) does not have independent litigation authority. Rather, the Department of Justice (DOJ) institutes injunction proceedings on behalf of FDA.*
 - a. *What guidance has DOJ provided to FDA regarding the types of cases involving unauthorized e-cigarettes that are appropriate for referral to DOJ?*
 - b. *Please describe each step in DOJ's internal review process upon receiving a referral from FDA regarding an unauthorized e-cigarette?*

The Department is committed to robust enforcement of the Tobacco Control Act (TCA); Federal Food, Drug, and Cosmetic Act (FDCA); and Prevent All Cigarette Trafficking (PACT) Act against any person or company who violates the law. The Department is actively working with the FDA to develop referrals for further enforcement action. As a general matter, the Department stands ready to consider any referral made by FDA where the facts and law support an enforcement action.

Referrals from FDA regarding unauthorized e-cigarettes are generally directed to the Civil Division's Consumer Protection Branch (CPB). As with any agency referral, attorneys with the Branch consider the evidentiary basis for the proposed enforcement action. Consistent with standard Civil Division procedure for moving forward with enforcement actions, if the evidence supports an action Branch attorneys may open an investigation or file suit after receiving appropriate approvals from their Department supervisors.

2. *DOJ has pursued eight injunctions on behalf of FDA.*
 - a. *How many cases in total has FDA referred to DOJ for an injunction since July 1, 2022?*

- b. *For the eight injunctions pursued to date, what is the average time between FDA's referral and DOJ's initiation of the injunction proceeding?*
- c. *How many DOJ attorneys work on FDA cases in general? How many work on e-cigarette-related enforcement cases in particular?*

The FDA has referred a number of injunctive actions, and the Department sought injunctive relief in almost all of them. The Agency decided to pursue other forms of relief in a small number of these referrals.

Department attorneys begin to work with FDA immediately upon referral to obtain underlying evidence and other information regarding a proposed action. Consistent with Department procedures and practice, once approval to file an injunctive action is obtained, attorneys engage with the proposed defendants regarding a potential consent order. All but one of the eight injunctions obtained in ENDS matters to date was obtained via a consent decree. In such cases, the action is initiated in court after the consent decree is signed, and the time prior to filing includes that period of negotiation. In one ENDS injunction matter that did not resolve by consent decree, the United States filed suit and prevailed at the summary judgment stage.

The Civil Division's Consumer Protection Branch is the primary component assigned to handle criminal and civil FDCA matters. Given that attorneys in the Branch and across the Department work on cases involving multiple federal agencies at different times, the number of attorneys pursuing FDA-related or ENDS matters at any one time can vary significantly depending on enforcement needs across the many areas that these components cover. At present, approximately 80 CPB attorneys are handling FDA-related cases, sometimes working with additional attorneys from the Civil Division's Federal Programs Branch and the Civil Division's Appellate staff. Additionally, U.S. Attorney's Offices, in consultation with CPB, also handle a range of FDA cases in their districts.

Senator Thom Tillis

Eastern Band and Marijuana

As you may know, on March 1, 2024, I led a letter to multiple agencies and departments, including the U.S. Department of Justice and regarding the Eastern Band of Cherokee Indians (Eastern Band) and Qualla Enterprise LLC's marijuana business.

In April, the Associate Judge for the Eastern Band Tribal Court, the Superintendent at Cherokee Central Schools, and tribal health leaders raised their concerns about this venture's impact on the behavioral health of youth. Including the negative impact of marijuana vapes.

If you visit Eastern Band's website, Great Smoky Cannabis Company, you can now purchase one of over two dozen marijuana vapes. On these packages, there are no warning labels for children, no description on how the product was tested, and no indication on where the vape pens were manufactured.

- 1. What is the U.S. Department of Justice (DOJ) and U.S. Drug Enforcement Administration (DEA) doing to enforce federal law when it comes to production, cultivation, and sale of marijuana in and around the reservation? Are federally recognized tribes immune from the Controlled Substance Act?*

Although the Department of Justice's (Department's) policies pertaining to the prosecution of marijuana crimes have evolved as states have passed measures to legalize marijuana use, marijuana currently remains a schedule I controlled substance. The Department is committed to enforcing the law—which includes the Controlled Substances Act (CSA)—in a manner that efficiently applies our resources to address the most significant threats to public safety.

The CSA prohibits manufacturing, distributing, and possessing controlled substances with intent to distribute. The CSA also provides for criminal liability for those who distribute controlled substances that result in death or serious bodily injury. As the Attorney General has made clear in prior testimony, personal marijuana use on its own is not currently a top federal law enforcement priority. However, there may be circumstances involving marijuana that merit federal law enforcement action. Several such cases were set forth in 2014 by the Department of the Treasury's Financial Crimes Enforcement Bureau (FinCEN), and include: preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels; preventing the diversion of marijuana from states where it is

legal under state law in some form to other states; and preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity.

Existing Department guidance directs prosecutors to follow well-established principles when addressing crime in their districts. And as a general matter, Main Justice works closely with U.S. Attorney's Offices to determine appropriate law enforcement actions based on the individual circumstances of the drug crisis affecting those communities. This is also true in the context of marijuana-related investigations and prosecutions. Such decisions include considerations regarding the interaction between federal and state or local law, where Congress has explicitly restricted the Department's ability to enforce federal laws in states that have state medical marijuana laws. The Department continues to prosecute drug trafficking organizations that distribute marijuana and other illegal narcotics in the United States.¹ The Department also prosecutes individuals who operate illegal marijuana delivery services or dispensaries.²

While the CSA applies on tribal land and to individual members of federally recognized Tribes, Tribal governments are not subject to federal criminal prosecution.

2. *What action can DOJ take if an individual(s) is harmed using the marijuana vape pens from a tribal reservation? Would Qualla Enterprise LLC as the seller be held liable?*

Marijuana is currently a schedule I controlled substance. The CSA prohibits manufacturing, distributing, and possessing controlled substances with intent to distribute. Where a controlled substance – regardless of whether it is in schedule I or III – is handled without proper authorization, individuals who are legally responsible for those actions can be held liable. DEA personnel in North Carolina routinely conduct investigations and enforcement operations in and around the Qualla Boundary in conjunction with the Bureau of Indian Affairs Office of Justice Services, the Eastern Cherokee Tribal Police Department, and other law

¹ [Office of Public Affairs | Malas Manas Transnational Criminal Organization Leadership Indicted on Charges of Human Smuggling and Drug Trafficking | United States Department of Justice](#)

² [Office of Public Affairs | Massachusetts Woman Pleads Guilty to Tax and Drug Charges Arising from Multimillion-Dollar Marijuana Enterprise | United States Department of Justice](#)

enforcement partners. The CSA applies on tribal land and to individual members of federally recognized Tribes.

3. *At what point is the transportation of marijuana considered trafficking? Are federally recognized tribes immune from state and federal enforcement?*

The CSA prohibits manufacturing, distributing, and possessing controlled substances with intent to distribute. Individuals who transport controlled substances without authorization and with the intent to distribute are frequently prosecuted under the CSA for possession of controlled substances with intent to distribute or other similar offenses. While the CSA applies on tribal land and to individual members of federally recognized Tribes, Tribal governments are not subject to federal criminal prosecution.

4. *What steps does DOJ take to ensure that money from a controlled substance business is not co-mingled with legitimate funds or banking accounts?*

As described above, marijuana remains illegal under federal criminal law. However, certain U.S. states and territories have adopted laws permitting certain types of marijuana sales and other marijuana-related activities. Accordingly, on Feb. 14, 2014, FinCEN issued guidance titled, “BSA Expectations Regarding Marijuana-Related Businesses” (2014 FinCEN Guidance) to clarify Bank Secrecy Act (BSA) expectations for financial institutions seeking to provide services to marijuana-related businesses. Among other things, the BSA and its implementing regulations require financial institutions to maintain records and report certain transactions. Federal financial regulators such as FinCEN supervise financial institutions such as banks. The Department does not supervise or regulate financial institutions but, where appropriate, the Department may pursue enforcement actions against financial institutions that fail to meet BSA requirements.

The 2014 FinCEN Guidance remains in effect and identifies transactions that may trigger federal enforcement priorities, such as: preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels; preventing the diversion of marijuana from states where it is legal under state law in some form to other states; and preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity.

Existing Department guidance directs prosecutors to follow well-established principles when addressing crime in their districts. And as a general matter, Main Justice works closely with U.S. Attorney's Offices to determine appropriate law enforcement actions based on the individual circumstances of the drug crisis affecting those communities. This is also true in the context of marijuana-related investigations and prosecutions; the Department investigates and pursues federal criminal charges as appropriate.³

FDA/DOJ Multi-Agency Taskforce

- 1. Memorandum of understanding ("MOU") for multi-agency task force. Have FDA, DOJ, and the other agencies that joined the task force executed an MOU that (1) defines lines of authority and responsibility, (2) clarifies processes for coordination, cooperation, and resource allocation, and (3) prevents duplication of effort? If so, please provide us with a copy of the MOU.*
 - a. If not, why is there no MOU in circumstances where FDA has a policy of executing MOUs for agency collaborations and a long history of executing MOUs with agency partners?*
 - b. Given the complexity of the e-vapor crisis – involving multiple federal agencies and multiple federal statutes – will FDA and DOJ commit to finalizing an MOU, and providing a fully executed copy to this Committee, within the next thirty (30) days?*

DOJ, FDA, and other task force members work closely together on a range of criminal and civil matters. Though this work predates the task force, the task force has helped centralized that coordination, enhancing information sharing and exploration of new enforcement strategies and targets. We do not believe an MOU is required for this work to continue.

³ See, e.g., [Office of Public Affairs | Manager of Mexico-Based Drug Trafficking Organization Sentenced to More Than 20 Years in Prison for International Methamphetamine Trafficking and Money Laundering | United States Department of Justice](#) (announcing sentencing of a manager of a Mexico-based drug trafficking organization that served as a source of methamphetamine and marijuana supply for a Nebraska-based distribution network).

2. **Objectives of the multi-agency task force.** *FDA and DOJ's announcement on June 10, 2024 clarified that the task force aims not only to bring more civil and criminal enforcement actions, but also to protect the public health by preventing the widespread availability of illegal e-vapor products.*
- a. *Has the task force established key performance indicators, performance metrics, or enforcement action goals to measure its success in preventing the sale and distribution of illicit e-vapor products? If so, please share those metrics with this Committee.*
 - b. *Does the task force agree that, more so than the number of enforcement actions it initiates, the most meaningful measure of its success will be a reduction in the actual sale and distribution of illicit e-vapor products in the marketplace? If so, please describe how the task force intends to measure its impact.*
 - c. *Does the task force accept that, to meaningfully impact an illicit e-vapor market of this scale and scope, it must bring enforcement actions involving the strongest tools against the largest actors? If so, please explain how the task force will focus its efforts and resources on issuing enhanced civil money penalties, import seizures, injunctions, forfeiture applications, and criminal prosecutions against the leading manufacturers and distributors of illicit products.*
 - d. *Is the task force committed to reversing the approach adopted to date by FDA – in which its injunction applications and civil money penalties have been issued only to retailers – and instead pursue the largest manufacturers and distributors of illicit imported disposable products by market share? If so, please explain how the task force will identify the largest manufacturers and distributors of illicit imported disposable e-vapor products by market share.*
 - e. *As many of the largest manufacturers of illicit e-vapor products are domiciled in China, and it is difficult to impose judicial orders and administrative penalties against Chinese companies, what strategies is the task force developing to hold such Chinese companies accountable? Please describe the disclosable parts of those strategies and explain how the task force will impose penalties against Chinese companies that bear the greatest responsibility for the relentless growth of the illicit e-vapor market.*
 - f. *Will the Task Force prioritize preventing the importation of illicit products or shutting the distribution down within the United States? Why is one approach better than the other?*

The purpose of the task force is to coordinate and streamline efforts to bring all available criminal and civil tools to bear against the illegal distribution and sale of e-cigarettes responsible for nicotine addiction among American youth. Its member agencies are working diligently to achieve that goal through enforcement actions using on their existing statutory authorities. The Department is actively working on cases referred by other agencies and working with its Task Force partners to develop further enforcement actions.

Unauthorized e-cigarettes and vaping products continue to jeopardize the health of Americans — particularly children and adolescents — across the country, and, given the current widespread availability of these products, the Department agrees that all available enforcement tools should be brought to bear on the problem. For its part, the Department is committed to robust enforcement of the Tobacco Control Act, the FDCA, and the PACT Act against any person or company who violates those laws. In addition, the Department stands ready to consider any referral made by task force partners, including actions against manufacturers and distributors.

The Department works closely with FDA, U.S. Customs and Border Protection (CBP), Homeland Security Investigations (HSI), and other Task Force members on the interdiction of unauthorized ENDS products from China. Task Force members have been engaged in the seizure of foreign e-cigarettes even before the Task Force was established. Since the establishment of the Task Force, this work has continued, resulting, most recently, in the seizure by CBP of more than \$76 million worth of unauthorized ENDS products as part of “Operation Vapor Caper II” operation. U.S.-based distributors of unauthorized ENDS products imported from China or elsewhere are subject to administrative and judicial penalties under U.S. law.

While the Department is not able to reveal its communications with Task Force partners regarding enforcement strategy or other similarly privileged communications, the Department and the Task Force recognize that effective enforcement against unauthorized products entering the country from abroad requires interdiction at the border, as well as enforcement actions within the United States. CPB and HSI are critical members of the Task Force for this reason.

3. *Composition of the multi-agency task force.* *There is some confusion about whether Customs and Border Protection (“CBP”) has joined the task force.*

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

- a. *Has CBP joined the task force? If CBP has not joined the task force:*
 - i. *The Committee has received reports that CBP field staff may be frustrated by a lack of timely information from FDA's Center for Tobacco Products ("CTP") regarding the admissibility or inadmissibility of shipments of e-vapor products. Has this frustration contributed in any way to CBP's decision not to join the task force, or at least its decision not to join the task force by June 10, 2024? If this was a contributing factor, please explain how the task force intends to remediate the apparently suboptimal working relationship between CBP and CTP field staff.*
 - ii. *Do you agree with FDA Commissioner Dr. Robert Califf that import prevention and enforcement is likely the most effective way to prevent the flow of illicit products into the U.S. from China, and it is therefore critically important that CBP join the multi-agency task force and take a leading role in preventing the importation of illicit products?*
 - iii. *Will FDA and DOJ commit to ensuring that CBP joins the task force within the next 30 days and provide written confirmation to this Committee once it has?*
- b. *Has the Department of State or any other agencies responsible for national security joined the task force? If not:*
 - i. *Do FDA and DOJ understand, based on the report "The Global Illicit Trade in Tobacco: A Threat to National Security," that illicit tobacco markets are a national security threat?*
 - ii. *Do FDA and DOJ understand that illicit tobacco markets operate globally and are major funding sources for international terrorist organizations, including Hamas?*

- iii. Do FDA and DOJ understand that illicit e-vapor products make billions of dollars for the Chinese Tobacco Monopoly and are a key funding source for the Chinese government?*
- iv. Will FDA and DOJ commit to ensuring that the Department of State joins the task force within the next 30 days and provide written confirmation to this Committee once it has?*
- c. In addition to federal agencies, state and local agencies are responsible for enforcement of state and local laws that implicate illicit e-vapor products. Does the task force intend to admit state or local law enforcement agencies to its membership or, otherwise, will the task force coordinate with state and local law enforcement, or the National Association of Attorneys General? Please describe how the task force will coordinate its investigations, enforcement decisions, and attorney engagements with state and local agencies.*
- d. In testimony before this Committee, Dr. Brian King said that the task force is “multi agency, and that takes time to make sure we get the right folks to the table, and we set the foundation for more programs.” When does the task force expect to finalize its composition? Please explain the process by which agencies join the task force, when that process will be completed, and whether and to what extent the White House is involved in the process.*

The Department agrees that effective enforcement against unauthorized products entering the country from abroad requires interdiction at the border, as well as enforcement actions within the United States. CBP and HSI are a critical partners in the federal government’s effort to combat the widespread availability of illegal e-cigarettes. Both agencies are members of, and active participants in, the Task Force. Indeed, CBP and FDA recently announced the seizure of approximately \$76 million worth of illegal ENDS products as part of Operation Vapor Caper II.

The Department agrees that its state and local counterparts are key partners in the fight against unauthorized ENDS products. That is why the Task Force convened a meeting at DOJ in October with the National Association of Attorneys General (NAAG), which included representatives from 15 different states to discuss how the federal government can enhance coordination and collaboration in the fight against the illegal sale and distribution of unauthorized ENDS. During that

meeting, the Task Force, NAAG, and its members committed to work together to curb unauthorized ENDS.

As the work of the Task Force continues, we will consider additional ways to partner with our state and local counterparts and whether additional agencies should join the Task Force. The Task Force's current membership consists of the Department, FDA, ATF, CBP, HSI, the U.S. Postal Inspection Service (USPIS), the U.S. Marshals Service (USMS), and the Federal Trade Commission (FTC).

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

- a. What is the effective date and expiration date for the task force?
- b. When did the task force first meet and how often does it meet?
- c. Does the task force have a steering committee, and if so, who are its members?
- d. Does the task force have liaison officers from each agency, and if so, who are the officers?
- e. How are personnel, resources, and funds allocated to and within the task force?
- f. How many staff from each agency, and in total, have been assigned to the task force?
- g. How will agency staff not assigned to the task force share information with the task force?
- h. What procedures are in place for the sharing of non-public information within the task force?
- i. What processes has the task force adopted to ensure efficiency and avoid bureaucracy?
- j. How are decisions to bring enforcement actions made and how are disagreements resolved?
- k. Will the task force issue detailed public reports on its progress? If so, how frequently? If not, will FDA and DOJ commit to providing written updates to this Committee at least quarterly?
- l. How will the task force work with and learn from outside experts? What is the process for interested parties to share information?

The Task Force was established on June 10, 2024, and will continue to coordinate enforcement actions to curb the illegal sale and distribution of unauthorized ENDS products. The formal Task Force generally meets every other week, but

discussions and cooperation among member agencies on specific matters continues on a daily basis.

The Task Force draws from existing resources and staff from participant agencies to support its efforts. It is intended to coordinate the variety of e-cigarette enforcement actions in which the participants engage, serve as a hub for information-sharing, and encourage sustained action to combat the widespread availability of unauthorized e-cigarettes. In this work, member agencies often share non-public information relevant to the work of the task force. For the Department, no special procedures are necessary for that work to continue.

The Task Force welcomes engagement with outside experts to learn about ongoing trends in the ENDS market.

Senator Amy Klobuchar

In your written testimony you stated the Department of Justice recently worked with its FDA partners “on the first judicial seizure of more than 45,000 unauthorized [e-cigarettes] from a warehouse in California.”

- 1. What barriers do you face to making more judicial seizures of illicit e-cigarettes?*
- 2. Are there other administrative authorities the Justice Department or its partner agencies can rely on to seize illicit e-cigarettes?*
- 3. What other measures has the Justice Department pursued to prevent the distribution of illicit e-cigarettes?*

The Department works closely with CBP, HSI, FDA, ATF, USPIS, and other partners to develop enforcement actions to halt the illegal distribution and sale of unapproved ENDS products. With its investigatory partners, the Department can pursue criminal prosecutions where appropriate. Upon referral from FDA, the Department can advance injunctive actions. Where possible, the Department can support agency administrative actions – for example, by assisting in the collection of judgments. The Department is committed to robust enforcement of all of its existing authorities including under the Tobacco Control Act and the PACT Act.

Senator Charles Grassley

1. *What is the Department of Justice's strategy for removing illegal THC vapor products from the market, and why are these products so readily available, including on the internet?*
2. *During the hearing, you testified that the Justice Department "will use very tool available to bolster our efforts to halt the illegal sale of unauthorized e-cigarettes" and "aggressive enforcement in this space is a priority across the executive branch."*

As you know, I'm a strong supporter of the False Claims Act and the qui tam provision of that law which utilizes whistleblowers to root out fraud against the government. In FY 2023, False Claims Act qui tam whistleblowers were responsible for the recovery of \$2.3 billion out of the total \$2.68 billion recovered through False Claims Act settlements and judgments, as reported by the Justice Department. Further, for a second year in a row, qui tam whistleblowers were responsible for recovering more taxpayer money lost to fraudsters in cases where the government declined to intervene than cases initiated by the government without the help of whistleblowers. Without question, qui tam whistleblowers are a valuable resource to bring strong False Claims Act cases to the Justice Department, yet in some cases the Justice Department has declined to litigate these cases and in others its intervened to dismiss the matter.

Chinese companies are responsible for the majority of illicit disposable vaping products in the United States, yet these products are readily accessible. These companies often avoid seizure and duties at U.S. ports of entry by intentionally mislabeling illicit vaping products as other goods. The False Claims Act has been used to successfully counter customs and duty fraud, including fraud involving the misclassification and mislabeling of goods.

Please explain the current trend over the past two years of the Justice Department declining to intervene in strong False Claims Act cases brought by qui tam whistleblowers even though these cases have recovered more taxpayer money lost to fraud than False Claims Act cases the Justice Department initiated without whistleblowers.

Whistleblowers play an important role in identifying fraud, and the Department's efforts to protect taxpayer dollars benefit greatly from their diligence and courage. When whistleblowers file and pursue qui tam cases under the False Claims Act, their efforts can complement the United States' use of the Act to combat fraud affecting all manner of government programs. Last year, the Department recovered more than \$1.8 billion in qui tam cases pursued by the Department, and whistleblowers recovered an additional approximately \$440 million in declined qui tam matters. Since 1986, when Congress substantially strengthened the Act, total recoveries under the False Claims Act have exceeded \$75 billion. Of that amount, more than \$47 billion have been recovered in qui tam cases pursued by the Department, while whistleblowers have recovered approximately an additional \$5 billion in declined qui tam cases. During that same period, the Department has also recovered an additional \$22 billion in non-qui tam cases. Accordingly, it is clear that the public-private partnership created by the False Claims Act between qui tam whistleblowers and the Department remains invaluable to the success of the Act in rooting out fraud and abuse in federal programs.

3. *Given its success, has the Justice Department considered using the False Claims Act to identify and combat the illegal importation of mislabeled vape products from China and other foreign countries? If not, why not?*

The Department has effectively deployed the False Claims Act to pursue trade related fraud involving the improper evasion, decrease, or concealment of customs duties or other revenue owed to the United States. These civil cases have involved a wide variety of imported products, including wood flooring, graphite electrodes, ultrafine magnesium powder, aluminum extrusions, carbon steel pipe fittings, apparel, jewelry, and furniture. The Department will continue to utilize the False Claims Act, where applicable, to pursue trade related violations, including any potential matters involving vaping products. The Department will also utilize its other civil tools, where appropriate, to pursue trade related violations.

Responses to Senator Grassley's Questions for the Record
Senate Committee on the Judiciary Hearing
Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes
June 12, 2024

Q1: Far too many youths have picked up vaping as a first-time habit. How many youths have picked up vaping in comparison to using traditional cigarettes, and why?

A1: Through implementation of evidence-based policies and programs, youth use of traditional cigarettes has declined substantially, from over 30 percent of high school students in the late 1990s to 1.9 percent of high school students in 2023.¹

But as youth use of cigarettes was declining, e-cigarettes entered the U.S. market and have become popular with youth. Since 2014, e-cigarettes have been the most popular tobacco product among youth, and youth use of e-cigarettes reached an all-time high in 2019.² While youth use of e-cigarettes is down from 2019, more than 2.1 million youth reported currently using e-cigarettes in 2023, including 10 percent of high school students.³

Each day, more than 1,400 youth under age 18 try a cigarette for the first time, but three times as many -- more than 4,300 youth -- try an e-cigarette for the first time.⁴

A major reason why youth are using e-cigarettes is because of the flavors.⁵ The Tobacco Control Act prohibited flavors in cigarettes except for menthol-flavored cigarettes. But e-cigarettes are available in thousands of flavors, including mango, blue razz and pink punch. In 2017, researchers identified more than 15,500 unique e-cigarette flavors available online.⁶ Flavors make e-cigarettes more attractive and easier for youth and young adults to use. FDA has found that "non-tobacco flavored e-cigarettes, including menthol flavored e-cigarettes, have a known and substantial risk with regard to youth appeal, uptake and use."⁷ Last year, nearly 90 percent of youth e-cigarette users used flavored products.⁸

E-cigarettes have also been marketed in ways that appeal to youth. E-cigarette companies have used some of same marketing strategies that tobacco companies used to make cigarettes popular with youth, such as use of celebrity spokespeople and sponsorship of sporting events and music festivals.⁹ E-cigarette companies also have maintained a strong presence on social media. In 2021, 3.1 million youth who used social media reported seeing e-cigarette-related content daily, and 4.5 million reported seeing that type of content weekly.¹⁰

We are concerned that the nation's successful efforts to reduce youth cigarette smoking over the past two decades could be undermined by e-cigarettes. We do not want e-cigarettes to introduce another generation of young people to nicotine addiction and tobacco use.

Q2: What steps must be taken to ensure that vapor products are sold and used for their intended purpose of tobacco cessation, and not as a gateway substance for youth nicotine addiction?

A2: While Congress has enacted legislation to increase the legal age of sale of tobacco products to age 21 and set standards for online sales of e-cigarettes, those actions have not been sufficient to prevent youth use of e-cigarettes. FDA must also address what it is about e-cigarettes that make them so appealing to youth. Flavors increase the appeal and use of e-cigarettes by youth. Using the premarket review process to remove flavored e-cigarettes from the market will reduce the risk that e-cigarettes will become a gateway for youth nicotine addiction.

Specifically, FDA must complete its premarket review of e-cigarettes, deny applications for flavored e-cigarettes, and step up enforcement action (along with the Department of Justice and other enforcement agencies) to remove unauthorized e-cigarettes from the market.

The requirement that e-cigarettes undergo premarket review by FDA is an important tool to protect public health and to reduce youth e-cigarette use. To receive market authorization, a manufacturer must provide strong evidence that its e-cigarette provides a public health benefit by helping adult smokers to quit that exceeds the risks to youth. Given the risks that flavored e-cigarettes present to youth, FDA has so far denied applications for millions of flavored e-cigarettes and authorized just four flavored e-cigarettes.¹¹

But many manufacturers, distributors, and retailers are disregarding the premarket review requirement. The e-cigarette market in the U.S. consists almost entirely of unauthorized, illegal products. FDA has authorized 27 e-cigarette products, but more than 6,000 e-cigarette products are available for sale in the U.S.¹² Swift and strong enforcement action by FDA, DOJ, and other agencies is needed to remove unauthorized e-cigarettes from the market, which will reduce the number of kid-friendly flavored e-cigarettes on the market. While the recent creation of a federal multi-agency task force was welcoming news, this task force will only have an impact if it quickly leads to concrete and comprehensive enforcement actions.

Preventing youth e-cigarette use is necessary because e-cigarettes are highly addictive and expose users to nicotine and other harmful substances. Youth are especially vulnerable to nicotine addiction, and nicotine exposure during adolescence can harm the developing brain, which can impact learning, mood, and attention.¹³ According to an advisory from the U.S. Surgeon General, “any e-cigarette use among young people is unsafe.”¹⁴

Regarding tobacco cessation, it is also important to note that FDA has approved seven tobacco cessation medications (i.e., five types of nicotine replacement therapy, varenicline, and bupropion). But FDA has not approved any e-cigarettes as a tobacco cessation medication. While some smokers have used e-cigarettes to stop smoking cigarettes, leading public health authorities, such as the U.S. Surgeon General and the U.S. Preventive Services Task Force, have found that current evidence is inadequate to conclude that e-cigarettes increase smoking cessation.¹⁵ A majority of adult e-cigarette users continue to smoke cigarettes or never smoked cigarettes.¹⁶

¹ Birdsey, J. et al., “Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023,” *Morbidity and Mortality Weekly Report (MMWR)* 72(44):1173-1182, November 3, 2023, <https://www.cdc.gov/mmwr/volumes/72/wr/mm7244a1.htm>;

University of Michigan, Monitoring the Future: Trends in Last 30 Days Prevalence of Use in 8th, 10th, and 12th Grade, <https://monitoringthefuture.org/data/bx-by/drug-prevalence/#drug=%22Cigarettes%22>, Accessed on June 27th, 2024.

² Wang, T., et al., "Tobacco Product Use and Associated Factors Among U.S. Middle and High School Students – United States, 2019," *Morbidity and Mortality Weekly Report (MMWR) Surveillance Summaries* 68(No. SS-12): 1-22, 2019. https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm#T1_down.

³ Birdsey, J. et al., "Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023," *Morbidity and Mortality Weekly Report (MMWR)* 72(44):1173-1182, November 3, 2023. <https://www.cdc.gov/mmwr/volumes/72/wr/mm7244a1.htm>.

⁴ Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, "Results from the 2022 National Survey on Drug Use and Health." NSDUH: Detailed Tables, Table 4.10A. <https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables>.

⁵ HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016. <https://www.ncbi.nlm.nih.gov/books/NBK538680/>

⁶ Zhu, S-H, et al., "Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites," *Journal of Medical Internet Research*, 20(3), published online March 12, 2018.

⁷ U.S. Food & Drug Administration, "FDA Denies Marketing of Two Vuse Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard," January 24, 2023. <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-menthol-e-cigarette-products-following-determination-they-do-not-meet>.

⁸ Birdsey, J. et al., "Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023," *Morbidity and Mortality Weekly Report (MMWR)* 72(44):1173-1182, November 3, 2023. <https://www.cdc.gov/mmwr/volumes/72/wr/mm7244a1.htm>.

⁹ HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016. <https://www.ncbi.nlm.nih.gov/books/NBK538680/>

¹⁰ Gentzke, A. et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," *Morbidity and Mortality Weekly Report (MMWR)* 71(5):1-29, March 11, 2022. <https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf>.

¹¹ U.S. Food & Drug Administration, "FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review," June 21, 2024. <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-four-menthol-flavored-e-cigarette-products-after-extensive-scientific>.

¹² CDC Foundation & Information Resources, Inc., "Monitoring U.S. E-Cigarette Sales: National Trends," <https://www.cdcfoundation.org/programs/monitoring-e-cigarette-use-among-youth>. Data from Information Resources, Inc. (IRI), which includes e-cigarette sales data from convenience stores, gas stations and other retail store chains. Sales from the internet and tobacco-specialty stores, including vape shops, are not included.

¹³ Centers for Disease Control & Prevention, "E-Cigarette Use Among Youth," May 15, 2024. <https://www.cdc.gov/tobacco/e-cigarettes/youth.html>.

¹⁴ HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

¹⁵ HHS, Office of the Surgeon General, "Smoking Cessation: A Report of the Surgeon General," 2020. <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>; United States Preventive Services Task Force, "Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons, Final Recommendation Statement", 2021. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions>.

¹⁶ QuickStats: Percentage Distribution of Cigarette Smoking Status Among Current Adult E-Cigarette Users, by Age Group – National Health Interview Survey, United States, 2021. *Morbidity and Mortality Weekly Report (MMWR)* 2023; 72:270. DOI: <http://dx.doi.org/10.15585/mmwr.mm7210a7>.



FDA Enforcement Actions Against Tobacco Retailers

This week, FDA issued a new round of civil money penalties (CMPs) to 22 brick and mortar and online retailers for the sale of allegedly violative vapor products. Since May 2023, there has been a significant increase in warning letters and CMPs, with more than 550 warning letters and 170 CMPs issued to retailers for selling allegedly violative flavored disposable products popular with youth. These actions have focused on major brands including Breeze, Elf Bar/EB Design/EB Create, Lost Mary, Funky Republic/Funky Lands, Esco Bars, Lava Plus, Cali Bars, Hyde, and Kangvape.

Warning letters are typically the first step FDA takes before issuing escalating enforcement actions such as injunctions, seizures, or CMPs. Retailers issued warning letters have 15 days to respond to FDA with the actions they will adopt to correct the violation and prevent future violations (or to refute the alleged violations).

FDA has issued substantially more CMPs, or monetary fines, in recent months to retailers that continue selling allegedly violative vapor products. FDA has also started seeking maximum fines of \$20,678 from each retailer for a “single violation.” FDA notes on its website that the agency has the authority to issue even larger fines for “intentional violations,” which could be as high as \$1,378,541 in a single proceeding.

In summary, we emphasize the following recent trends in FDA’s enforcement approach:

1. Increased warning letters to retailers for allegedly violative vapor products;
2. Increased CMPs to retailers that continue selling allegedly violative vapor products; and
3. Increased use of maximum CMPs amounting to \$20,678 for each single violation.

NATO has been tracking FDA’s recent enforcement actions, and below are the disposable vapor brands cited as unauthorized or illegally sold in FDA civil money penalty complaints, import alerts, and warning letters. Please note that just because a brand is identified below does not necessarily mean that all SKUs in that brand family have been cited for enforcement. We strongly recommend that all retailers check with their suppliers to ascertain the status of each individual product. We further note that the fact that a brand is included in the below list does not constitute any commentary on (i) the status of other non-vape categories of tobacco products that may bear the same or similar brand names or (ii) the validity of FDA’s allegations in the civil money penalty complaint, import alert, or warning letter.

Brands Cited in FDA CMP Complaints:

- Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EB Create/ BC5000
- Esco Bar(s)
- Flum Gio
- Lost Mary
- Puff Bar/ Puff Flow/ Puff Max/ Puff Plus/ Puff Xtra/ Puff XXL

Brands cited in FDA Import Alerts:

- Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EB Create/ BC5000
- Esco Bar(s)
- RandM/Fumot

Brands Cited in FDA Warning Letters						
Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EBCreate/ BC5000	Puff Bar/ Puff Flow/Puff Max Puff Plus/ Puff Xtra/ Puff XXL	A+++	Airis	AIS Krim	Aquabar	Bang
BBK-RG	Beco	Blow	Bluum Lab	Boss Bar	Bot-It	Breeze
Cali	DO3	Dotmod	Dragbar	Elf Tank	Esco Bar(s)	Fantasia Vape-PRO Unit
Flair	Fliq	Flum Gio	FOUNS	Friobar	Funky Republic	Game Puff
Gazzbar	Glamee	High Light	HQD Cuvie	Hyde	IJOY Bar	JODK
KangVape	KERG-BBK	Lava	Lavie	Loaded	Loon-300 /Loon Bullet	Lost Mary
Luckee	Mochivap	MOTI	Mr. Fog	Mylé	Oly	Pod Mesh FLO
PURE	Quawins	R&M	RandM/Fum ot	RG Plush	Snowwolf	Space V
STIG	Straw	Super Bucks	VAAL	VapeCa m	VapeTape	Vapin' Donuts
VapMod	Vaporlax	Vaportech	Vpro	Wave	WDG	



FDA & DOJ Seizure of Illicit Vapor Products

The FDA in coordination with the Department of Justice (DOJ) announced that it has seized over 45,000 unauthorized vapor products worth approximately \$700,000 from a warehouse in Alhambra, CA. The seized products were mostly flavored disposable brands including Puff Bar/Puff, Elf Bar/EB Design, Esco Bar, Kuz, Smok and Pixi. This enforcement action is the first time that the FDA and DOJ have seized tobacco products in coordination with the U.S. Marshals Service.

NATO has been tracking FDA's recent enforcement actions, and below are the disposable vapor brands cited as unauthorized or illegally sold in FDA civil money penalty complaints, import alerts, and warning letters. Please note that just because a brand is identified below does not necessarily mean that all SKUs in that brand family have been cited for enforcement. We strongly recommend that all retailers check with their suppliers to ascertain the status of each individual product. We further note that the fact that a brand is included in the below list does not constitute any commentary on (i) the status of other non-vape categories of tobacco products that may bear the same or similar brand names or (ii) the validity of FDA's allegations in the civil money penalty complaint, import alert, or warning letter.

Brands Seized in FDA, DOJ and U.S. Marshals Service Joint Effort:

- Elf Bar/ Elfbar/ EB Design
- Esco Bar(s)
- Puff Barr/ Puff
- Kuz
- Smok
- Pixi

Brands Cited in FDA CMP Complaints:

- Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EB Create/ BC5000
- Esco Bar(s)
- Flum Gio
- Lost Mary
- Puff Bar/ Puff Flow/ Puff Max/ Puff Plus/ Puff Xtra/Puff XXL

Brands cited in FDA Import Alerts:

- Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EB Create/ BC5000

- Esco Bar(s)
- RandM/Fumot

Brands Cited in FDA Warning Letters						
Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EBCreate/ BC5000	Puff Bar/ Puff Flow/Puff Max Puff Plus/ Puff Xtra/ Puff XXL	A+++	Airis	AIS Krim	Aquabar	Bang
BBK-RG	Beco	Blow	Bluum Lab	Boss Bar	Bot-It	Breeze
Cali	DO3	Dotmod	Dragbar	Elf Tank	Esco Bar(s)	Fantasia Vape-PRO Unit
Flair	Fliq	Flum Gio	FOUNS	Friobar	Funky Republic	Game Puff
Gazzbar	Glamee	High Light	HQD Cuvie	Hyde	IJOY Bar	JODK
KangVape	KERG-BBK	Lava	Lavie	Loaded	Loon-300 /Loon Bullet	Lost Mary
Luckee	Mochivap	MOTI	Mr. Fog	Mylé	Oly	Pod Mesh FLO
PURE	Quawins	R&M	RandM/Fum ot	RG Plush	Snowwolf	Space V
STIG	Straw	Super Bucks	VAAL	VapeCa m	VapeTape	Vapin' Donuts
VapMod	Vaporlax	Vaportech	Vpro	Wave	WDG	



FDA Expands Import Alert on Illegal Disposables

Recently, FDA updated its Import Alert 98-06, which includes a “Red List” of manufacturers, distributors, and brands of vapor products that may be detained at the border without physical examination. The list now includes Chinese manufacturers/distributors as well as United States importers and distributors. The products on the Red List are identified below; the full import alert can be found [here](#).

NATO has been tracking FDA’s recent administrative and enforcement actions, and below are the disposable vapor brands cited as unauthorized or illegally sold in FDA civil money penalty complaints, import alerts, and warning letters. Please note that just because a brand is identified below does not necessarily mean that all SKUs in that brand family have been cited in an FDA administrative or enforcement action. We strongly recommend that all retailers check with their suppliers to ascertain the status of each individual product. We further note that the fact that a brand is included in the below list does not constitute any commentary on (i) the status of other non-vape categories of tobacco products that may bear the same or similar brand names or (ii) the validity of FDA’s allegations in the civil money penalty complaint, import alert, or warning letter.

Disposable Vapor Brands cited in FDA Import Alerts:

- Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EB Create/ BC5000/ 6000 PUFFS
- Esco Bar/ Escobar
- RandM/ Fumot
- Juicy Bar Brand
- Mr. Fog Max Pro
- IJOY LIO Stone
- Kangvape Onee Stick
- IPlay Max 2500
- Tyson 2.0 Heavyweight
- St!k (numerous disposable flavors)
- 11 Vape Pen
- Eonsmoke (numerous disposable flavors)

Disposable Vapor Brands Seized in FDA, DOJ and U.S. Marshals Service Joint Effort:

- Elf Bar/ Elfbar/ EB Design
- Esco Bar

- Puff Bar/ Puff
- Kuz
- Smok
- Pixi

Disposable Vapor Brands Cited in FDA CMP Complaints:

- Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EB Create/ BC5000
- Esco Bar
- Flum Gio
- Lost Mary
- Puff Bar/ Puff Flow/ Puff Max/ Puff Plus/ Puff Xtra/Puff XXL

Disposable Vapor Brands Cited in FDA Warning Letters						
Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EBCreate/ BC5000	Puff Bar/ Puff Flow/Puff Max Puff Plus/ Puff Xtra/ Puff XXL	A+++	Airis	AIS Krim	Aquabar	Bang
BBK-RG	Beco	Blow	Bluum Lab	Boss Bar	Bot-It	Breeze
Cali	DO3	Dotmod	Dragbar	Elf Tank	Esco Bar	Fantasia Vape-PRO Unit
Flair	Fliq	Flum Gio	FOUNS	Friobar	Funky Republic	Game Puff
Gazzbar	Glamee	High Light	HQD Cuvie	Hyde	IJOY Bar	JODK
KangVape	KERG-BBK	Lava	Lavie	Loaded	Loon-300 /Loon Bullet	Lost Mary
Luckee	Mochivap	MOTI	Mr. Fog	Mylé	Oly	Pod Mesh FLO
PURE	Quawins	R&M	RandM/Fum ot	RG Plush	Snowwolf	Space V
STIG	Straw	Super Bucks	VAAL	VapeCa m	VapeTape	Vapin' Donuts
VapMod	Vaporlax	Vaportech	Vpro	Wave	WDG	



FDA Issues Marketing Granted Orders to NJOY Menthol Vapor Products

Today, the U.S. Food and Drug Administration authorized its first flavored vapor product with the issuance of marketing granted orders (MGO) for four menthol-flavored e-cigarette products – NJOY ACE Pod Menthol 2.4%, NJOY ACE Pod Menthol 5%, NJOY DAILY Menthol 4.5%, and NJOY DAILY EXTRA Menthol 6%. The two authorized ACE products are sealed, pre-filled, non-refillable pods, and the two authorized DAILY products are disposable e-cigarettes with a prefilled, non-refillable e-liquid reservoir.

A link to the FDA’s press announcement of the MGO is below:

[FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review | FDA](#)



February 27, 2024

FDA Enforcement Actions Against Tobacco Retailers

Yesterday, the FDA filed “Civil Money Penalty (CMP)” complaints against 20 brick and mortar retailers selling Elf Bar cited as the most popular brand among youth according to the 2023 National Youth Tobacco Survey.

A "Civil Money Penalty" is a monetary fine sought by the FDA against a retailer for violating the FDA tobacco regulations. In these cases, the amount being sought against each of the retailers is \$20,678, which is the maximum penalty allowed for a single violation of the FDA tobacco regulations. From the FDA's press release, “We closely monitor the entire supply chain, including retailers, for compliance with the law. This includes follow-up inspections and surveillance of those who have received a warning letter, and taking enforcement actions, including filing civil money penalty complaints and seeking seizures and injunctions, as appropriate.”

This most recent enforcement actions reflect FDA's acceleration of its efforts to address illicit e-cigarette products in the marketplace. Earlier this month, 21 brick and mortar retailers received maximum CMP complaints for selling Esco Bar flavored disposable vapor products, which the FDA noted were the second most commonly used brand among youth e-cigarette users.

NATO has been tracking FDA's recent enforcement actions, and below are the brands FDA has cited as a basis for taking action. We expect this list to expand as FDA continues to ramp up enforcement actions.

Elf Bar / EB Design	Esco Bar	Cali Cali+	Puff Bar	Puff Plus	Funky Republic	Lost Mary	Snowwolf
Ban	A+++	KERG- BBK	Lava	Glamee	Hyde	KangVape	Luckee
BBK- RG	Breeze	FOUNS	Game Puff	JODK	Lavie	Puff Flow	Puff Max
Puff Xtra	PURE	VapeTape	Vpro	Airis	AIS Krim	Aquabar	Beco Pro
Blitz Bot-It	Blow	Bluum Lab	Boss Bar	DO3	Dotmod	Elf Tank	Fantasia
Flair	Fliq	Friobar	Fumot	Gazzbar	Highlight	HQD Cuvie	IJOY Bar
Loaded	Loon	Mochivap	MOTI	Mr. Fog	Myle	Oly	Puff XXL
Quawins	R&M	RandM	RG Plush	Space V	STIG	Straw	Super Bucks
VAAL	VapeCam	Vapin Donuts	VapMod	Vaporlax	Vaportech	WDG	ZOVOO



February 2, 2024

FDA Enforcement Actions Against Tobacco Retailers

This week, the FDA filed “Civil Money Penalty (CMP)” complaints against 21 brick and mortar retailers selling Esco Bar flavored disposable vapor products, which the FDA noted were the second most commonly used brand among youth e-cigarette users according to the 2023 National Youth Tobacco Survey. The FDA also issued warning letters to 14 online retailers for selling unauthorized products such as Elf Bar/EB Design, Lava Plus, Funky Republic/Funky Lands, Lost Mary, Cali Bars, Cali+, and Kangvape.

A "Civil Money Penalty" is a monetary fine sought by the FDA against a retailer for violating the FDA tobacco regulations. In these cases, the amount being sought against each of the retailers is \$20,678, which is the maximum penalty allowed for a single violation of the FDA tobacco regulations. From the FDA's press release, “The FDA will continue to take compliance and enforcement action against those making, distributing, importing, or selling unauthorized e-cigarette products, including seeking CMPs against retailers who violate the law.”

This most recent enforcement actions reflect FDA's acceleration of its efforts to address illicit e-cigarettes products in the marketplace. With these recent FDA enforcement efforts, industry members need to be aware of on-going compliance with the federal law, including FDA regulations and Guidance, since the agency can take enforcement actions against not only retailers, but also wholesalers and manufacturers that sell new tobacco products lacking FDA authorization or otherwise not in compliance with FDA Regulations and Guidance.

NATO has been tracking FDA's recent enforcement actions, and below are the brands FDA has cited as a basis for taking action. We expect this list to expand as FDA continues to ramp up enforcement actions:

Elf Bar / EB Design	Esco Bar	Cali Cali+	Puff Bar	Puff Plus	Funky Republic	Lost Mary	Snowwolf
Ban	A+++	KERG- BBK	Lava	Glamee	Hyde	KangVape	Luckee
BBK- RG	Breeze	FOUNS	Game Puff	JODK	Lavie	Puff Flow	Puff Max
Puff Xtra	PURE	VapeTape	Vpro	Airis	AIS Krim	Aquabar	Beco Pro
Blitz Bot-It	Blow	Bluum Lab	Boss Bar	DO3	Dotmod	Elf Tank	Fantasia
Flair	Fliq	Friobar	Fumot	Gazzbar	Highlight	HQD Cuvie	IJOY Bar
Loaded	Loon	Mochivap	MOTI	Mr. Fog	Myle	Oly	Puff XXL
Quawins	R&M	RandM	RG Plush	Space V	STIG	Straw	Super Bucks
VAAL	VapeCam	Vapin Donuts	VapMod	Vaporlax	Vaportech	WDG	ZOVOO

State Legislative Bill Introductions

State tobacco-related legislative bills that have been introduced in the past week are listed below alphabetically by state:

Hawaii:

- HB1962: Repeals the current ban on remote sales and will allow for deliver sales directly to adult consumers.
- HB2341/ SB3030: Increases the stamp fee from 1.7% to 2.2% of the denominated value of each stamp, with the increase credited to the special fund. It will become effective July 1, 2024.
- HB2441: Bans flavored tobacco products & mislabeled e-liquid products, effective January 1, 2025. Impacts all traditional tobacco, modern oral, and vapor products (including synthetic nicotine and zero nicotine). It will also ban WS3 products.
- HB2442: Repeals statewide preemption and allows local jurisdictions to regulate the sale of tobacco products, alternative nicotine products, and vapor products.
- HB2504/ SB3193/ SB3292: Increases the state excise tax on cigarettes from \$3.20 to \$3.60 effective July 1, 2024 to fund various tobacco cessation programs.

Missouri:

- SB911 provides that the state preempts the field of regulating the sale of tobacco products, alternative nicotine products, and vapor products. Further, the bill provides that no political subdivision shall deny a license to a qualified applicant for a tobacco products license, alternative nicotine products license or a vapor products license if the new license is for the same location that had a license within the previous 24 months.

New York:

- A8912 (same as S4413-A) amends tax law to tax premium cigars at 75% of the wholesale price or \$.50, whichever is less.

Tennessee:

- HB2252 levies a tax on vapor products in a manner similar to the tax levied on tobacco products.
- HB2511 / SB2348 establishes a "nicotine-free generation" by prohibiting the sale of tobacco and vapor products to anyone born on or after or individuals born on or after 1/1/2007.

West Virginia:

- SB545 (same as HB5037) requires vapor product manufacturers to certify with the state that the manufacturer has received marketing authorization from the FDA for a vapor product or the product was marketed in the U.S. as of August 8, 2016, and the manufacturer has submitted a PMTA on or before September 9, 2020, that remains under review or in appeal. Beginning September 1, 2024, the State Tax Commissioner and the Alcohol Beverage Control Commissioner would be required to make the directory publicly available. Starting on that date the sale of any vapor product not listed in the directory would be prohibited in the state.

State Legislative Bill Actions

State tobacco-related legislative bills that have been acted on by a state legislative committee or state legislature are listed below alphabetically by state:

Alaska:

- SB89 (Carryover from 2023 Session), which imposes a tax on electronic smoking products and vapor products at the rate of 25% of the sales price and caps the amount of nicotine in vapor products at 50 milligrams of nicotine per milliliter of vapor product, will be considered in the House Labor and Commerce Committee on February 9, 2024.

Florida:

- HB1007, which requires nicotine products manufacturers to execute and deliver a form, under penalty of perjury, to the Division of Alcoholic Beverages and Tobacco of the Department of Business and Professional Regulation for each product sold within this state which meets certain criteria. Bill also requires the division to develop and maintain a directory listing of certified nicotine products manufacturers and certified nicotine products. This bill was reported favorably in the House Regulatory Reform & Economic Development Subcommittee on January 24, 2024. It is currently in the House Appropriations Committee.
- The Senate version (SB1006) of the above House bill will be considered in the Senate Regulated Industries Committee on February 5, 2024.

Hawaii:

- HB1563, which repeals preemption and explicitly authorizes counties to regulate tobacco and vapor products, will be heard on February 2, 2024 in the House Health and Homelessness Committee.
- HB1778, which includes a statewide flavor ban, will be heard on February 2, 2024 in the House Health and Homelessness Committee. It will only allow tobacco flavor and prohibits labels/packaging containing “chill” “ice” “fresh” “artic” or “frost”. If approved, will become effective on January 1, 2025.

Iowa:

- SF2023, which requires any retailer that holds a permit for the retail sale of tobacco products or vapor products must permit members of the fire, police, and health departments, along with city building inspectors, county sheriffs, members of the department of public safety, and members of the department of revenue to enter the premises without a warrant during business hours to inspect for any violations of provisions of law related to the retail sale of tobacco products, was recommended as “do pass” by the Senate Committee on State Government on February 1, 2024.

Maine:

- LD2028 (SP856), which clarifies the tax law definition of “tobacco product” to include any product that contains nicotine, thereby extending the current excise tax to nicotine pouches, will be heard in the Joint Committee on Taxation on February 8, 2024.
- LD2157 (HP1383), which prohibits the Department of Health and Human Services from issuing a new or renewed retail tobacco license to a retailer operating within 1,000 feet of a school, was heard in the Joint Committee on Health and Human Services on February 1, 2024. No vote was taken. The bill does not grandfather in existing license holders.

New Hampshire:

- HB1591, which provides that a retailer shall only sell alternative nicotine products, e-cigarettes, or e-liquid that have received a marketing authorization order issued by the FDA, or evidence that the premarket tobacco product application was submitted by 9/9/20 and accepted by the FDA and a final authorization or order is pending resolution, will be heard in the House Commerce and Consumer Affairs Committee on February 6, 2024.

Vermont:

- SB18, which bans the retail sale of flavored cigarettes, flavored OTP, e-cigarettes, e-liquids, tobacco substitutes and any menthol flavored tobacco product, was heard in the House Committee on Ways and Means on February 1, 2024.

Virginia:

- HB1036, which allows localities to tax nicotine vapor products--no cap on the rate of tax, was recommended in Subcommittee of the House Finance Committee to be stricken from the docket on January 30, 2024.

West Virginia:

- HB5037 (same as SB545) requires vapor product manufacturers to certify with the state that the manufacturer has received marketing authorization from the FDA for a vapor product or the product was marketed in the U.S. as of August 8, 2016, and the manufacturer has submitted a PMTA on or before September 9, 2020, that remains under review or in appeal. Beginning September 1, 2024, the State Tax Commissioner and the Alcohol Beverage Control Commissioner would be required to make the directory publicly available. Starting on that date the sale of any vapor product not listed in the directory would be prohibited. The bill was heard in the House Committee on Government Organization on January 31, 2024.



July 5, 2024

Delivered Via E-mail to: Record@judiciary-dem.senate.gov

Chairman Dick Durbin
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Durbin and Members of the Committee on the Judiciary:

This letter and attachments respond to a question from the Committee and supplement my testimony on behalf of the National Association of Tobacco Outlets (NATO), a national retail trade association that represents more than 66,000 retail stores throughout the country, at the June 12, 2024, hearing of the Senate Committee on the Judiciary entitled “Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes.”

In particular, on June 24, 2024, U.S. Senator Charles Grassley submitted the following question to NATO:

1. *Do any of your association’s members sell vapor products that are not authorized for sale by the FDA, and if so, does your organization condone this practice?*

NATO understands that some of its members may sell vapor products that are not authorized for sale by the FDA pursuant to a marketing granted order. However, as referenced in NATO’s written testimony, the association also understands that the FDA does not currently prioritize enforcement against vapor products subject to premarket tobacco product applications (PMTAs) that their manufacturers submitted by the applicable deadlines and remain pending before the agency or that is otherwise subject to an applicable court order stay. In some cases, the FDA has not acted on these PMTAs for over four years since their timely submission well beyond the 180-day statutory deadline for the FDA to issue an order from the date of receipt of the application.

As discussed in greater detail in NATO’s written testimony, responsible retailers need greater clarity on this subject from the agency. NATO and its members affirm our support for a well-functioning regulatory system in which FDA oversight leads to accelerated reduction in underage use and tobacco-related harm. An effective regulatory system requires a more coherent compliance framework that clearly communicates the FDA’s enforcement priorities, what categories of products the agency wants immediately removed from the marketplace and what categories can remain on the market pending review of timely filed applications.

The need for clarity is especially high right now, given FDA’s own inconsistent statements over time. The history here is important. Since FDA asserted authority over vapor products in 2016, and per subsequently issued guidance documents and an order from the U.S. District Court for the District of Maryland, certain vapor products have been *specifically allowed* to remain on the market (i) up until

a deadline for filing marketing applications and, thereafter, (ii) during review of timely filed PMTAs for them. The regulated community –manufacturers, wholesalers, and retailers – relied on these policy decisions and continued to make and sell these products within the legal, regulated system, assuming FDA would follow through on its statutory obligation to rule on PMTAs within 180 days of their submission. However, while manufacturers of these products met their obligation under the court’s order, nearly four years since the application deadline, FDA still has not completed reviews of these timely filed applications. It has also not ordered manufacturers of products covered by timely filed PMTAs to remove them from the market pending long-delayed decisions, but of late the agency has contributed to the confusion by pointing to the list of 27 authorized vapor products as the only ones the trade may sell without enforcement risk.

In the meantime, of course, the market has been flooded with new products made by manufacturers in flagrant violation of the Federal Food, Drug, and Cosmetic Act. But rather than say the agency is prioritizing enforcement against these rule-breakers (as it has in the past), FDA now seems reluctant to say one way or the other whether it is actively enforcing the premarket authorization requirements *against products FDA has previously and specifically said could remain on the market pending PMTA review.*

The sensible answer here is for FDA to clearly communicate to regulated industry – the industry members committed to helping federal regulation succeed – that products with timely filed, still-pending PMTAs may continue to be sold. It should focus its enforcement resources on the manufacturers, distributors, and retailers currently building an alternative, illegal, and unregulated marketplace in broad daylight. FDA should stand by the prudent decisions made first in 2016 and again in the years after to allow rule-followers to continue to sell products that met the requirements to remain on the market pending FDA review of timely filed applications – and just say so publicly. Not doing so just adds to the chaos of the current marketplace.

NATO has endeavored to keep its membership informed of FDA statements and actions in this area, and the association unequivocally does not condone the sale of illicit vapor products.

First, NATO has communicated to its members the vapor products that have received marketing authorization from the FDA, which, as of Friday, June 21, 2024, includes 4 menthol flavored vapor products:

- NATO News: “FDA Issues Marketing Granted Orders to NJOY Menthol Vapor Products,” June 21, 2024.

Second, NATO regularly communicates to its members regulatory developments regarding vapor products, including FDA announcements of decisions on PMTAs and government enforcement actions involving illicit vapor products. As requested by U.S. Senator Thom Tillis during the hearing, NATO has enclosed the following examples of “NATO News” communications sent to the association’s membership:

- “FDA Enforcement Actions Against Tobacco Retailers,” February 2, 2024
- “FDA Enforcement Actions Against Tobacco Retailers,” February 27, 2024
- “FDA Enforcement Actions Against Tobacco Retailers,” April 24, 2024
- “FDA & DOJ Seizure of Illicit Vapor Products,” April 30, 2024
- “FDA Expands Import Alert on Illegal Disposables,” May 29, 2024

In these example communications, NATO provided updates on administrative and enforcement actions, and each included a comprehensive list of the vapor brands cited as unauthorized or illegally sold in FDA civil money penalty complaints, import alerts, and warning letters.

Thank you for the opportunity to provide testimony on the importance of effective enforcement, increased FDA transparency, and increased vapor product authorizations. NATO and its members support a well-regulated tobacco product market that prevents underage use and delivers on harm reduction, and we look forward to working with the FDA and the Senate Judiciary Committee to address these issues.

Sincerely,

David Spross

NATO Executive Director
david.spross@natocentral.org
845-430-5471

Attachments (6)

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

Questions for Susan Walley, MD, MHCM, NCNTT, FAAP
Immediate Past Chair, Section on Nicotine and Tobacco Prevention and Treatment,
American Academy of Pediatrics

1. There's an abundance of THC vapor products used by teenagers and children. Can you please elaborate on the negative impacts of THC vapor products on adolescent health?

There are multiple health harms of adolescent e-cigarette/vapor product use that have been documented. Vape products are known to contain many of the same harmful toxins as combusted tobacco products (i.e. cigarettes, cigars); this raises concern that over decades of use, youth that use vape products may suffer the same consequences of combusted tobacco users, which include 12 different cancers, cardiovascular health effects such as heart attacks and strokes, and chronic respiratory issues such as chronic obstructive pulmonary disease (COPD). There is significant co-use of tetrahydrocannabinol (THC) with nicotine, often unknown to the user.¹ This co-use makes it difficult to assess the health harms of THC vapor products independent of nicotine, and thus there is limited data on sole THC vapor product use.

Short and long-term health concerns of vapor product/e-cigarette use on adolescents include:

- a. **Addiction.** Adolescents are uniquely susceptible to nicotine addiction as the brain is not fully mature until age 25 years. In addition, animal models demonstrate that early nicotine exposure can cause permanent brain cell changes.² THC is also well documented to result in addiction.¹
- b. **Progression to combusted tobacco and illicit substance use.** Several longitudinal studies have demonstrated that adolescents that use e-cigarettes are more likely to progress to combusted tobacco use.³ In addition, e-cigarette use is associated with co-use of nicotine with other harmful substances to the developing brain and body including THC.^{4,5} THC has been linked to progression of use to other illegal drug use, including prescription opioid use, cocaine, and injection drugs.¹
- c. **Neurologic health effects.** Adolescents who use e-cigarettes have a higher rate of mental health disorders such as anxiety and depression.⁶ The use of THC at any age is known to result in poor concentration, psychosis, and in adolescence has been associated with lower neurocognitive function, psychosis, and distorted perception. Adolescent use of THC use has been associated with lower neurocognitive function, increased suicide attempts, and development of psychosis.¹
- d. **Respiratory health effects.** In the summer of 2019, the first reports of E-cigarette or Vaping Associated Lung Injury (EVALI) were publicized and ultimately, caused

hundreds of hospitalizations and dozens of deaths.⁷ In addition to EVALI, e-cigarette use is known to cause negative respiratory effects including coughing, wheezing, and worsening of asthma.⁸

- e. **Cardiovascular health effects.** The ultrafine particles present in e-cigarette aerosol (commonly known as vapor) can cause endothelial dysfunction, particularly when used chronically.⁹ This is a similar mechanism of injury that causes heart attacks, strokes, and other vascular disease from combusted tobacco use.¹⁰
- f. **Cancer Risk.** E-cigarette and vapor product use exposes users to carcinogenic substances such as formaldehyde, acrolein, and acetaldehyde that are found in combusted tobacco. There are significant concerns that adolescents who use vapor products are being exposed to these carcinogens.¹¹
- g. **Metal and Other Toxin Exposure.** Many of the e-cigarette and vapor products that are sold and advertised to youth are not authorized by the FDA. Youth that vape have been identified as having higher levels of metal exposure, including lead and uranium.¹²
- h. **Secondhand Aerosol Exposure.** Secondhand aerosol exposes (similar to cigarette secondhand smoke) those who are not vaping to toxins and harmful chemicals. Secondhand aerosol exposure has been associated with shortness of breath and bronchitic symptoms.¹³

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Advancing Convenience & Fuel Retailing | convenience.org

June 11, 2024

Senator Richard Durbin
Chairman
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Senator Lindsey Graham
Ranking Member
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

RE: Hearing on “Combating the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes”

Dear Chairman Durbin and Ranking Member Graham:

Thank you for holding a hearing on “Combating the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes.” Our industry has significant concerns about illegal e-cigarettes that have flooded the U.S. The current market is characterized by a large number of illicit products and a number of actors, from manufacturers to retailers, acting irresponsibly to make and sell products that should not be sold in the United States. In fact, many of these illicit products are coming in from China.

The market for e-cigarettes (also referred to as electronic nicotine delivery systems or “ENDS” products) needs to be cleaned up and needs more enforcement. We and many members of our industry have asked for exactly that. We would like to work with the Committee to achieve this goal.

An important aspect of the current situation is that there is widespread regulatory confusion in this market. Businesses have tremendous difficulty deciphering the regulatory status of ENDS products. The result is that even good actors who expend significant resources attempting to comply with the legal limits on sales of ENDS products may inadvertently sell products that should not be sold.

Many responsible retailers invest significant time and resources in training employees on policies and procedures on the sale of age-restricted programs. They try to fully comply with the law and follow, as best they can, all relevant regulations. But, getting clear information is challenging even for large companies with in-house legal departments, not to mention for the majority of the industry which consists of single-store operators. These businesses need regulators to provide complete information so that everyone knows how to comply.

Background on the Convenience and Fuel Retailing Industry

NACS is an international trade association representing the convenience store industry with more than 1,500 retail and 1,600 supplier companies as members, the majority of whom are based in the United States.¹

The convenience and retail fuels industry employed approximately 2.74 million workers and generated more than \$859.8 billion in total sales in 2023, representing 3.1 percent of U.S. gross domestic product. Of those sales, approximately \$532.2 billion came from fuel sales alone.

¹ Data on the industry comes from the NACS, State of the Industry Annual Report of 2021 Data *available at* <https://nacsannualreport.convenience.org>.

The industry, however, is truly an industry of small business. More than 60 percent of convenience stores are single-store operators. Less than 0.2% of convenience stores that sell gas are owned by a major oil company and about 4% are owned by a refining company. More than 95% of the industry, then, are independent businesses.

Members of the industry process more than 165 million transactions every single day. That means about half the U.S. population visits one of the industry's locations on a daily basis. In fact, 93% percent of Americans live within 10 minutes of one of our industry's locations. These businesses are particularly important in urban and rural areas of the country that might not have as many large businesses. In these locations, the convenience store not only serves as the place to get fuel but is often the grocery store and center of a community.

History on ENDS Market Confusion

To understand the breadth and depth of the challenges presented by the current regulatory regime, it helps to recognize how we got here. Prior to 2016, ENDS products were not regulated by the U.S. Food and Drug Administration's (FDA's) Center for Tobacco Products (CTP). In May 2016, the CTP deemed ENDS products subject to its regulatory authority conferred by the Family Smoking Prevention and Tobacco Control Act.

Given that decision, the CTP could have ordered ENDS products to be swiftly removed from the market because they were not on the market as of February 15, 2007, (and therefore considered "pre-existing tobacco products") and had not received the premarket authorization required under the Federal Food, Drug, and Cosmetic Act before new tobacco products can be introduced to the U.S. market. But the CTP did not order all ENDS products off of the market. Instead, it decided that manufacturers of products on the market at the time the CTP began regulating ENDS products (i.e., August 8, 2016) should submit premarket tobacco product applications (PMTAs) by a certain date and that products for which such applications were timely submitted could continue to be sold while the CTP reviewed those applications.

The CTP, however, was flooded with applications, and the review process has taken much longer than anyone anticipated. In fact, that process continues today. Following multiple extensions of the application filing deadlines, a number of groups sued the FDA in an attempt to speed up the process. The result of the lawsuit was that applications would have to be submitted by May 2020 (later extended to September 2020 due to COVID)² and that products for which an application was submitted by the deadline could remain on the market for up to one year following the date of submission during the CTP's review. The idea was that those applications would be reviewed, and decisions would be made as to whether each of those products could continue to be sold within one year of submission of those applications. That is not what happened.

Prior to that application deadline, the CTP published a [guidance document](#) in April 2020.³ That guidance document made a number of difficult to follow statements. First and foremost, it laid out what the CTP considered as its "enforcement priorities" for ENDS products. The term itself was difficult to

² It is worth noting that final rules specifying the content, format, and review of PMTAs were finalized in October of 2021. See 86 Fed.Reg. 55,300 (October 5, 2021), available at [Federal Register :: Premarket Tobacco Product Applications and Recordkeeping Requirements](#).

³ Food and Drug Administration Center for Tobacco Products, "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*" April 2020 (available at [Enforcement Priorities for Electronic Nicotine Delivery Systems \(ENDS\) and Other Deemed Products on the Market Without Premarket Authorization \(Revised\): Guidance for Industry \(fda.gov\)](#)).

understand. The CTP had for years said that ENDS products could stay on the market based on CTP's exercise of its "enforcement discretion" with respect to ENDS products that were on the market on August 8, 2016. Were "enforcement priorities" the same thing as "enforcement discretion?" The answer appeared to be no, but that was less than fully clear – particularly to regulated businesses, many of them small businesses. If the terms were not the same, how exactly did they differ? That too was less than fully clear.

The April 2020 guidance also provided one year of "enforcement discretion" for the ENDS products for which applications had been filed by the September 2020 deadline and for which the CTP had not reached a decision. Other things were not so clear. For example, the guidance stated that priorities for enforcement would include pod-based ENDS products with flavors other than tobacco and menthol as well as any products for which premarket approval applications were not filed by the deadline. That gave a clear indication of products that should not be sold because they were "enforcement priorities" for the CTP. But it left things somewhat murky regarding the status of products that did not fall within the CTP's "enforcement priorities." Could those continue to be sold? For how long? The basic question of what could and could not be sold was not clearly answered.

The lack of clarity was recognized at the time as a problem. Senator Patty Murray took the lead on a letter from ten senators (including some from this committee) to the FDA in May 2020 seeking more information so that policymakers and the public had the information they needed regarding the status of these products.⁴ Specifically, the letter sought development of a comprehensive list of the products for which applications were submitted by the September 2020 deadline so that everyone would know what products the CTP was allowing to remain on the market. Thanks to these efforts, there are now public lists of products for which applications have been filed, but those lists remain unclear in several respects.⁵

Current Guidance Remains Unclear

The lists of products for which timely applications have been filed are headed by a category that reads "Lists of products for which continued marketing until September 9, 2021 may fall outside of CTP's stated enforcement priorities."⁶ The reference to a date three years ago raises confusing questions including what the status of those products is after September 9, 2021. Is CTP exercising enforcement discretion with respect to those products? Why haven't they clearly stated on the website what the status of those products is today?

This uncertainty is compounded by other information on CTP's website regarding these products. For example, CTP includes in its description of the category of "Tobacco products that cannot be legally marketed and risk enforcement by FDA" the following:

- "In general, a product that is on the market and not the subject of a pending, timely-filed premarket application (excluding pre-existing and previously authorized tobacco products)."⁷

That description seems to imply that a product that is the subject of a timely-filed premarket application is not a product that "cannot be legally marketed" or risks enforcement. Anyone participating in the market would likely conclude from that description that products with timely-filed applications still

⁴ Letter from Ten Senators to FDA Commissioner Stephen Hahn, May 28, 2020 (available at [Letter on Public List of Tobacco Products For Which Applications Submitted_05-20_20_final.pdf \(senate.gov\)](#)).

⁵ See "Deemed New Tobacco Product Applications Lists" (last accessed March 28, 2024; "content current as of 08/09/2021") (available at [Deemed New Tobacco Product Applications Lists | FDA](#)).

⁶ See *Id.*

⁷ *Id.*

under review can be sold. Nothing in the descriptions of the categories of e-cigarette products on the website clearly contradicts that common-sense conclusion.

The category also includes the following reference:

- “Products as described in the guidance on Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization.”

That guidance would appear to allow products with timely-filed applications to be sold as they were not enforcement priorities.

CTP’s website also includes a category of ENDS products described as “Tobacco products that cannot be legally marketed but, consistent with a court order, generally might remain on the market pending FDA premarket review while FDA continues to defer enforcement.” The products in this category, however, are uncertain as the information on these from CTP’s marketing denial order list generally identifies the manufacturer that submitted the application but not the actual products that are the subject of the court order. A list of applications on CTP’s marketing denial order list that have exceptions allowing the products to be sold during the pendency of court or administrative reviews is attached to this testimony. It shows 19 different exceptions but it is unclear how many products can still be sold due to these exceptions because the specific products covered are not identified by CTP.

CTP also provides the following disclaimer on its website: “It is important to keep in mind that the lists are only one source of information. For example, retailers should discuss with their suppliers about the current status of any particular tobacco product’s application or any product’s marketing authorization.” For retailers, however, that disclaimer is not adequate. How are retailers to know which suppliers will provide fully accurate information and which will not do so? Obviously, some suppliers are manufacturers or financially tied to manufacturers who have a vested interest in moving one particular brand or product. It is the responsibility of CTP, as the regulatory agency, to provide this information to retailers. Are retailers supposed to rely on any information they receive from suppliers given the lack of clarity from CTP?

Given the problems getting accurate information from suppliers, retailers need complete and clear information from CTP. We do not have that today.

The ENDS Market Today

In the shadow of this lack of regulatory clarity, bad actors have taken advantage of the situation and flooded the market with new ENDS products. Many of these are single-use products that were not described as enforcement priorities in the April 2020 guidance.⁸ And many of these clearly illegal products are being made and shipped to the U.S. from China. It is estimated that these clearly illegal

⁸ “Once a niche market, cheaper disposables made up 40% of the roughly \$7 billion retail market for e-cigarettes last year, according to data from analytics firm IRI obtained by the AP.” Matthew Perrone, “Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors,” APNEWS.COM (June 26, 2023) (available at <https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f>); “The market share of disposable e-cigarettes increased from 24.7 % to 51.8% during the study period, with disposable brands Elf Bar and Breeze Smoke among the top-selling e-cigarette brands alongside Vuse, JUUL, and NJOY.” Truth Initiative, “E-cigarette market surges amid urgent need for comprehensive regulation and enforcement,” TRUTHINITIATIVE.ORG (July 12, 2023) (available at <https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarette-market-surges-amid-urgent-need>).

products may make up as much as half of the U.S. market for ENDS products today.⁹

While regulated businesses are informed when the CTP announces enforcement actions regarding a particular product and there is a list of the 23 marketing granted orders that the CTP has issued for ENDS products, there are thousands of products with timely-filed applications for which clarity remains lacking.

One thing that the CTP has written, in spite of some statements suggesting the contrary, is that *there are ENDS products that have not received marketing granted orders that can be sold*. We have pressed for, but have not been provided, a listing of the specific products that can be sold. In a letter responding to our requests last year, for example, the CTP wrote:

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

The CTP did not provide any additional information regarding the products that fell into these categories. The marketing denial order list on the CTP's website, for example, does not list the products that are the subject of denial orders. It lists only the companies that submitted the applications that were denied. At least some of the denials cannot cover all of a company's products because many companies are listed more than once on the list. There are notations on the list for at least 18 companies indicating that some or all of the products that are the subject of the denial order might still be able to be sold because part or all of the denial order was rescinded or because it is the subject of further agency review or court challenges. The result is that the status of the ENDS products from those 18 companies cannot be known with any certainty.

The CTP also has not provided clarity regarding the status of ENDS products that were on the market in 2016 and are covered by timely filed PMTAs that remain under review. The one-year timeframe for enforcement discretion following the filing of those applications has ended, but it is not entirely clear what the CTP wants to happen with those products today as they are not part of its "enforcement priorities."¹⁰ Importantly, following the close of the one-year period, CTP leadership never expressly or impliedly communicated an expectation that applicants remove their ENDS products from the market during the pendency of the CTP's evaluation of them.

The situation with JUUL provides one case study of the regulatory confusion. Last year, CTP announced that it was denying applications for all JUUL ENDS products and that those products would need to be removed from the market. While this was momentous, it was at least clear that it applied to all JUUL products. Announcements relating to some other manufacturers were not clear regarding the specific products covered.

Following FDA's denial order, JUUL sued the FDA. Rather than defend its decision in court,

⁹ See *Id.*

¹⁰ Does the CTP, for example, think it makes sense for products that it has denied authorization but which are undergoing additional review to be sold on the market, while products for which CTP has never issued a denial order because it still has not completed its review many years after filing should be removed from the market?

however, FDA quickly asked for a stay of the litigation while it reconsidered its decision.¹¹ That meant the denial order was stayed and JUUL products could continue to be sold. That remained the situation for JUUL products until last week – when FDA announced it was rescinding its denial order for JUUL products entirely. Now, the applications for JUUL products are in the category of the many such applications that were timely filed and remain under review.

Some have advocated that products with pending applications under review should not be able to be sold. But it is very difficult to see that result as coherent. That would mean that JUUL and 18 other categories of products could be sold while they had denial orders from the CTP which were being reviewed but that if CTP decided it was in error in denying those products and rescinded those orders, then the products actually could not be sold. That does not seem to be a reasonable or coherent result.

Clarity and Enforcement

Without regulatory clarity and increased enforcement, we are likely to see bad actors continue to exploit the current state of confusion to grow sales of illicit products. The best way to get that clarity is for CTP to finish reviewing the applications it has and issue decisions. As with JUUL, it may face challenges for products it denies, but it is better to start that process sooner rather than later so that we can all know what can and cannot be sold. The more time that elapses with products in the indeterminate state of being considered by CTP – particularly with the lack of clarity about what can or cannot be done with those products in the meantime – the worse the current situation with large numbers of illegal products on the market will become.

We also need additional enforcement efforts to stop imports of illegal products coming in from China. Of course, that job is more difficult for Customs and Border Protection officials if they do not have a clear picture of which products are and are not legal. The FDA has sent some warning letters and brought some enforcement actions against some of the worst offenders in this market. That is a helpful start, but more of that enforcement activity is needed.

CTP, as the agency with regulatory authority over these products, has the responsibility to provide the clarity that stakeholders and enforcement officials need regarding which products can and cannot be on the market. If the CTP would provide an up-to-date and accurate list of the status of ENDS products (not just manufacturers or applications covering multiple products), the many different aspects of enforcement become much easier to achieve – and voluntary compliance with the law becomes possible. With widespread voluntary compliance, CTP will be able to focus its enforcement efforts on bad actors and can become much more effective clearing the market of illegal products.

Sincerely,



Doug Kantor
NACS General Counsel

¹¹ See Matthew Perrone, “FDA weighs oversight changes after formula, JUUL troubles,” APNEWS.COM (July 19, 2022) (available at <https://apnews.com/article/science-health-tobacco-industry-regulation-robert-califf-bb49dd28719a34872771d82cd60cf02>).

MDO List Exceptions

The list of marketing denial orders (MDOs) issued by the Center for Tobacco Products (CTP) can be found here: [Tobacco Products Marketing Orders | FDA](#). The list generally includes manufacturer names but not product names. As a result, regulated entities cannot know which specific products have been reviewed and cannot be sold. It cannot be assumed that all of a manufacturer's products have received an MDO because many manufacturers are listed more than once.

In addition, the MDO list includes many notations seemingly indicating that those manufacturers' products may be sold either because of ongoing court proceedings or further agency proceedings. Each of those notations are copied below and in total there are such notations for 19 manufacturers. It is not clear how many products those manufacturers have that are subject to the noted exceptions. Only a couple of those entities note the specific products involved.

- Diamond Vapor: "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- Johnny Copper: "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- Bidi Vapor: "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- My Vape Order Inc.: "On October 18, 2021, the Agency issued a stay for this MDO pending its review. On January 19, 2022, FDA partially rescinded this denial with respect to certain products."
- Fumizer LLC: "On October 22, 2021, FDA partially rescinded this denial with respect to certain products."
- ECS Global: "On October 26, 2021, FDA partially rescinded this denial with respect to certain products."
- TPB International LLC: "This order was rescinded on October 7, 2021."
- Wages & White Lion Investments dba Triton Distribution: "On January 3, 2024, the United States Court of Appeals for the Fifth Circuit issued an order setting aside the MDO and remanding to FDA."
- Humble Juice Co., LLC: "This order was rescinded on November 2, 2021."
- Union Street Brand: "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- Vapetasia LLC: "On January 3, 2024, the United States Court of Appeals for the Fifth Circuit issued an order setting aside the MDO and remanding to FDA."
- Pop Vapor Co, LLC: "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."
- Vapornine LLC dba New Leaf Vapor Company: "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA."

- Vapor Unlimited: “On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA.”
- Al Khalifa Group LLC: “This order was rescinded on March 1, 2022.”
- Fontem US LLC: “On Aug. 29, 2023, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in Fontem US, LLC v. FDA, which affirmed in part and vacated and remanded in part MDOs issued on April 8, 2022, for certain myblu products. Specifically, the court’s opinion affirmed the MDOs for new products, including myblu Intense Tobacco Chill 2.5% and myblu Intense Tobacco Chill 4.0%. The court’s order granted Fontem’s petition for review with respect to the myblu Device Kit, myblu Intense Tobacco 2.4%, myblu Intense Tobacco 3.6%, myblu Gold Leaf 1.2%, and myblu Gold Leaf 2.4%, setting aside the MDOs for those products, and remanding those matters to FDA.”
- JUUL Labs, Inc.: “On July 5, 2022, the Agency issued a stay for this MDO pending its review.”
- R.J. Reynolds Vapor Company: “On March 23, 2023, the United States Court of Appeals for the Fifth Circuit granted a stay of the MDO issued to R.J. Reynolds Vapor Company’s Vuse Vibe menthol e-cigarette products pending review.”
- R.J. Reynolds Vapor Company: “On March 29, 2023, the United States Court of Appeals for the Fifth Circuit granted stay of the MDOs issued to R.J. Reynolds Vapor Company’s Vuse Solo menthol e-cigarette products pending review.”
- R.J. Reynolds Vapor Company: “On October 13, 2023, the United States Court of Appeals for the Fifth Circuit granted a temporary administrative stay of the MDOs issued to R.J. Reynolds Vapor Company’s Vuse Alto menthol and mixed-berry e-cigarette products pending review.”
- Fontem US, LLC: “On Oct. 13, 2023, FDA rescinded this denial.”



Paige C. Magness
Senior Vice President
Regulatory Affairs

April 5, 2024

Via CTP Portal

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

Dear Dr. King:

The accelerating growth in unlawful and unregulated e-vapor products is a significant problem that threatens the long-term success of federal tobacco regulation. As we and many other stakeholders have shared over the past year,¹ the illicit e-vapor market has grown rapidly since 2020 to supply more than half of the 17 million adults in the U.S. who are e-vapor consumers.² And illicit e-vapor products are a major contributing factor in underage rates that are significantly higher in this category than any others.³ The problem is now spreading to new product forms such as illicit nicotine pouches and products using “nicotine analogues,”⁴ all from marketplace actors with little interest in FDA regulation succeeding.

For our part, we remain deeply committed to a well-regulated marketplace delivering on harm reduction in the way Congress envisioned when it enacted the Tobacco Control Act in 2009. That means all tobacco products are made, distributed, and sold within an FDA-regulated system that minimizes underage use, provides adult smokers proven lower-risk choices to help them leave cigarettes for good, and ensures all adult consumers benefit from FDA oversight over all the products they buy. None of this can happen if unregulated illicit markets are allowed to displace the legal one.

¹ See Altria’s letters to the CTP Director dated 9/29/23, 11/10/23, and 1/26/24; Altria’s e-Allegation filed with Customs and Border Protection on 12/12/23; and Altria’s Potential Tobacco Products Violation Report filed with CTP’s Office of Compliance and Enforcement on 2/21/24. See also the letter from a coalition of retailers, distributors, and manufacturers to the FDA Commissioner and CTP Director dated 9/25/24.

² See, e.g., Altria, [Presentation at CAGNY 2024 Conference](#) (2/21/24), pp 14-16.

³ According to the 2023 NYTS, 7.7% of middle and high schoolers reported past 30-day use of e-vapor products, of which 60.7% reported using disposable products as their usual device type and 89.4% reported using flavored e-vapor products (none of which are authorized). [By comparison, underage use of cigarettes is at historic lows, with 1.6% of middle and high schoolers reporting past 30-day use of cigarettes in 2023.](#) Source for 2023 NYTS: Jan Birdsey et. al., [Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023. MMWR Morb Mortal Wkly Rep 2023. 72:1173–1182.](#)

⁴ See, e.g., Matthew Perrone, [Elf Bar and other e-cigarette makers dodged US customs and taxes after China’s ban on vaping flavors.](#) Associated Press (12/19/23); Spree Bar, [What is Melatine?](#) (accessed 4/4/24).

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We are encouraged by FDA's increasing recognition that illicit markets are a significant threat to public health and thus a "top priority" for the Agency.⁵ Respectfully, though, FDA's actions so far have had little measurable impact. The illicit market has grown steadily over the past year, even while FDA has announced more frequent enforcement actions. Part of the problem, as we have expressed in other contexts, is a pre-market review process yielding far too few authorized smoke-free options to meet adult consumer demand.⁶

But we also believe FDA's enforcement approach is still not being deployed at the scale or scope needed to bring about fundamental change in the marketplace. That, in short, is the purpose of this letter. We have identified specific steps we believe FDA could take to build a more comprehensive and effective compliance and enforcement program to address the illicit market threat. Among other things, we believe FDA can help reverse the illicit market trend by imposing *direct liability* on the largest manufacturers, importers, and distributors responsible for growing the illicit market, by focusing on import prevention, and by clearing up widespread confusion in the marketplace about FDA's enforcement priorities.

We appreciate the opportunity to share this information with you in writing. As always, we are ready and willing to meet with you or your staff in person and, in the spirit of open dialogue, help develop and drive solutions that can restore order in the marketplace.

Recommendations

Broaden the Scope of Enforcement to Target the Worst Offenders

Recommendation 1: Expand the scope of enforcement actions to include direct penalties on the largest manufacturers and distributors of illicit e-vapor products.

For an enforcement plan to work with an illicit market this large, FDA must focus on the leading manufacturers, importers, and distributors mainly responsible for building and sustaining it. The absence of any direct consequences for these large companies virtually guarantees widespread lawlessness. Indeed, FDA has said that it is committed to "taking action across the supply chain... to remove unauthorized tobacco products from the marketplace" including "continued actions against manufacturers, distributors, importers and retailers."⁷

Yet it appears FDA has so far refrained entirely from holding the largest manufacturers, importers, and distributors directly accountable. Since 2016, it has been plainly illegal to introduce a new tobacco product without prior authorization. While we have obeyed this core element of the Tobacco Control Act, scores of unregistered foreign companies mainly located in China have flouted it, using large U.S.-based allies to distribute flagrantly illegal products in large quantities down the distribution chain to retailers. FDA knows who these manufacturers and distributors are, where they are located, and what products they sell.

While FDA has issued many warning letters citing the *products* these companies make and distribute, it has not imposed any direct liability – civil or criminal – on the companies themselves. None of the top 20 illicit e-vapor companies have been the subject of any civil or criminal actions. While FDA notes that it has sought injunctions against seven "manufacturers," each of these defendants are independent vape

⁵ See, e.g., FDA, Press Release, [FDA Conducts Retailer Inspection Blitz, Cracks Down on Illegal Sales of Popular Disposable E-cigarettes](#) (5/31/23); FDA, Press Release, [FDA Puts Firms Responsible for Esco Bars and Breeze — Two Popular Disposable E-cigarette Brands — on Notice](#) (5/5/23).

⁶ See, e.g., the coalition letter to the FDA Commissioner and CTP Director dated 9/25/24.

⁷ FDA, Press Release, [FDA Warns Online Retailers for Sale of Unauthorized E-cigarettes Resembling Alcohol Bottles](#) (12/20/23).

shops found to be mixing e-liquid for open systems.⁸ And of the 162 Civil Money Penalties (“CMPs”) FDA has issued to date, 54 have been directed to entities FDA also classifies as “manufacturers” – but which are in fact online or brick and mortar retailers mixing e-liquids for open systems.⁹

We agree enforcement should include retailers. But an enforcement plan that *excludes the imposition of liability on manufacturers, importers, and distributors* fails to address the proliferation of illegal products at the source and will just encourage more lawlessness in the market. In fact, the companies at the top of the distribution chain can readily adapt their practices when FDA sends warning letters to individual retailers or singles out individual products for interdiction at the border. Unless and until FDA holds them directly accountable – civilly or criminally – they will keep doing what they are doing.

Civil and Criminal Litigation

Recommendation 2: FDA and the Department of Justice (“DOJ”) should secure injunctions against the largest manufacturers and distributors responsible for the largest share of the illegal e-vapor market in the U.S.

The most powerful tool FDA can use with any entity intentionally violating the Act – whether it is tobacco products, pharmaceuticals, or medical devices – is to seek civil or criminal sanctions in federal court. As mentioned above, FDA has worked with DOJ to seek injunctions against seven vape shops it has characterized as “manufacturers;” yet, six of the seven injunctions were filed in October 2022.¹⁰ Over the past year and a half, FDA and DOJ have filed only one additional injunction action.¹¹

We recognize it is more difficult to bring injunction actions against foreign manufacturers.¹² But we believe most of the leading foreign manufacturers have corporate affiliates, directors, or officers based in the U.S., and many of these foreign manufacturers supply their products through U.S.-based distributors. In addition, several of the leading manufacturers of illicit disposable products – including the largest manufacturer by market share – are domiciled in the U.S. There are thus numerous targets FDA can readily hold accountable in court to deter them and others from further illegal conduct. Indeed, New York City just this week filed civil litigation directly against eleven distributors of illicit e-vapor products, demonstrating a commitment to imposing direct consequences on some of the worst offenders in the marketplace.¹³

Civil Money Penalties (“CMPs”)

Recommendation 3: FDA should impose CMPs at maximum amounts against the largest manufacturers and distributors of illegal e-vapor products.

We are encouraged by FDA’s decision to start issuing CMPs for unauthorized e-vapor products in 2023. But so far, FDA has refrained from using this tool against the largest manufacturers and distributors engaged in the sale of flagrantly illegal e-vapor products. Out of the 162 CMPs it has issued to date, 108 CMPs were imposed on retailers and 54 on entities FDA has classified as “manufacturers.”¹⁴ However, as

⁸ See FDA, [Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products](#) (accessed 4/4/24).

⁹ *Ibid.*

¹⁰ *Ibid.*

¹¹ FDA, Press Release, [FDA, DOJ Seek Permanent Injunction Against E-Cigarette Manufacturer](#) (12/4/23).

¹² See Chris Kirkham and David Kirton, “China e-cigarette titan behind ‘Elf Bar’ floods the US with illegal vapes.” (12/5/23).

(noting that the CTP Director “said in an interview the agency can’t levy penalties or file lawsuits against foreign companies.”)

¹³ NYC Office of the Mayor, Press Release, [Mayor Adams, Corporation Counsel Hinds-Radix Announce Lawsuit Against 11 Companies Illegally Distributing Disposable Flavored E-Cigarettes](#) (4/4/24).

¹⁴ FDA, [Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products](#) (accessed 4/4/24).

noted above, these “manufacturers” are online or brick and mortar specialty tobacco retailers or vape shops – none are manufacturers of the disposable e-vapor products driving illicit markets. We see no reason FDA should refrain from issuing CMPs to the largest foreign and domestic actors most responsible for illicit market growth.¹⁵

FDA is also opting to impose CMPs at far less than the maximum amounts provided by statute for repeat offenders and intentional or continuing violations. FDA has said that it “intends to seek the maximum penalty allowed by law in CMP cases relating to unauthorized tobacco products.”¹⁶ But it has not yet used this tool, much less against the major manufacturers and distributors openly violating the law. FDA has only ever sought CMPs of up to \$20,678 for unauthorized e-vapor products, which is the maximum amount for “single violations.”

FDA should instead issue “enhanced penalties,” as appropriate, under the statute.¹⁷ These penalties may amount to \$344,636 per intentional violation and \$1,378,541 in total.¹⁸ And in the case of continuing violations after FDA issues a warning letter, the penalties may amount to \$1,378,541 for each 30-day period the violations continue and \$13,785,420 in total. These enhanced penalties are more than appropriate in the context of major manufacturers and distributors of these products that are generating enormous revenue streams by avoiding FDA regulation altogether.

Import Prevention

Recommendation 4: FDA should urgently expand the scope of its import alerts to target all leading manufacturers and brands violating the law, including those already cited by FDA in warning letters and other enforcement actions.

Most of the illicit e-vapor market consists of products made by a relatively small number of unregistered foreign manufacturers, almost all located in China. We estimate that illegal disposable products imported into the U.S. generate approximately \$3.5 billion annually for companies that are a part of China’s State Tobacco Monopoly Administration.¹⁹ These companies violate virtually every rule FDA has issued for e-vapor products, are selling products in the U.S. that the Chinese government has banned domestically, and are adapting their operations rapidly to evade FDA enforcement.²⁰ And, given that they avoid all FDA oversight, these illicit imports may also include harmful ingredients and create other safety hazards.²¹

¹⁵ 21 USC § 331(a) prohibits “The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.” Courts have long held that suppliers can be liable under § 331(a) for delivery of a prohibited item for introduction by others into interstate commerce: see, e.g., *Drown v. United States*, 198 F.2d 999, 1004 (1953 9th Cir.); *United States v. Sanders*, 196 F.2d 895, 898 (10th Cir. 1952); *Glaser, Kohn & Co. v. United States*, 224 F. 84 (7th Cir. 1915). FDA issues warning letters to foreign e-vapor manufacturers, which supports the view that it can also issue civil monetary penalties to foreign companies. See, e.g., FDA’s warning letters issued to [Shenzhen Innokin](#), [Shenzhen Fumot](#), and [Shenzhen LUOY](#).

¹⁶ FDA, [Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products](#) (accessed 4/4/24).

¹⁷ See 21 U.S.C. § 333(f)(9)(B).

¹⁸ See FDA, “[Annual Civil Monetary Penalties Inflation Adjustment](#),” 88 Fed. Reg. 69,531, at 69,533-69,534 (10/6/23).

¹⁹ ALCS CMII estimates for FY 2023 theoretical disposable e-vapor volumes and manufacturer’s list price based on estimated trade margins. See also Matthew Perrone, [Elf Bar and other e-cigarette makers dodged US customs and taxes after China’s ban on vaping flavors](#), Associated Press (12/19/23).

²⁰ FDA, Press Release, [Joint Federal Operation Results in Seizure of More Than \\$18 Million in Illegal E-Cigarettes](#) (12/14/23).

²¹ See, e.g., Office of the Indiana Attorney General, Press Release, [Attorney General Todd Rokita lights up Chinese e-cigarette companies](#) (8/29/23) (noting reports that illicit disposable e-vapor products may be laced with fentanyl); Stacy Liberatore, [Moment Chinese-made Elf Bar vape EXPLODES while charging a few feet from a baby is captured by home security camera](#), Daily Mail (3/8/24) (noting reports of illicit Elf Bar disposable products exploding or catching fire in the U.S.).

Last year, FDA issued an Import Alert for illicit disposable e-vapor products, which is a critically important enforcement tool for helping Customs and Border Protection (“CBP”) know which products are illegal and should be denied entry to the U.S. And while FDA has added more products to Import Alert 98-06 over the past month, as of today, the Alert includes only six of the top 20 illicit product manufacturers.²²

FDA should maximize this enforcement tool by including *all* known illicit brands and manufacturers that FDA identifies through other advisory and enforcement actions. At a minimum, it should include all 14 of the 20 largest illicit disposable manufacturers and brands that FDA has identified in warning letters and other actions.²³ Whatever the constraints might be on enforcing CMPs and injunctions against foreign companies, they do not apply to import alerts designed to prevent the entry of illegal imports into the U.S.

Recommendation 5: FDA should work with Customs and Border Protection to adopt a complete import enforcement program directed at manufacturers and importers of illicit e-vapor products.

There has been an encouraging recent increase in import refusals for unauthorized e-vapor products in the first six months of FDA’s 2024 fiscal year.²⁴ However, most leading manufacturers of illicit disposable products are not included on the list of import refusals issued by FDA in FY24 or any fiscal year.

A more complete import prevention program would impose greater constraints on all manufacturers and importers of products that entered the market in violation of the Act following the 2016 Deeming Rule – particularly the flood of disposable products following the 2020 ENDS Guidance. Among other things, FDA could require all importers to enter STN numbers assigned on or before September 9, 2020 as a condition for entry through the ports.

With legal entry no longer permitted for any flagrantly illegal e-vapor product, CBP would need to focus more resources on preventing entry through smuggling, false declarations, and other unlawful methods.²⁵ As such, we recommend that FDA work with CBP to: (1) train additional FDA and CBP field staff on better identifying illegal e-vapor products; (2) increase the number of field examinations at ports of entry with high e-vapor import volume to verify the marketing authorization status of properly declared e-vapor imports; and (3) strengthen the screening systems, including risk-based analytics tools and random joint inspections, to detect, detain, and refuse entry for mis-declared e-vapor imports.

²² The six leading manufacturers and brands added to import alerts comprise: Elf Bar, Esco Bars, Juicy Bar, Mr. Fog Max Pro, Kangvape Onee Stick, and Tyson 2.0 Heavyweight illicit disposable products: see FDA, [Import Alert 98-06](#) (accessed 4/4/24).

²³ FDA has issued warning letters to 10 of the leading 20 illicit disposable manufacturers (or their affiliates) by market share: [Breeze Smoke, LLC](#) (5/25/23); [HQD Tech USA, LLC](#) (7/20/20); [Shenzhen Kanger Technology Co. Ltd.](#) (9/14/23); [Maduro Distributors dba The Loon](#) (8/20/21); [Dongguan Hengtai Biotech. Co., Ltd](#) (8/1/22); [King Distribution, LLC](#) (9/14/23); [Flair Products, LLC](#) (10/15/21); [Shenzhen Innokin Technology Co. Ltd.](#) (5/25/23); [J Vapes, LLC](#) (8/19/22); [Shenzhen Airis Co. Ltd.](#) (12/08/23). FDA has cited illicit disposable brands made by two additional leading manufacturers in warning letters and CMPs issued to retailers – brands made by iMiracle Technology Co., Ltd. (see, e.g., [Elf Bar](#), [EB Design](#), [Lost Mary](#), and [Funky Republic](#)) and Fuma International, LLC (see, e.g., [Posh Plus](#)). FDA has cited products made by another leading manufacturer, Flungio Technology Inc, in a [CMP complaint](#). And FDA has cited an additional leading manufacturer, Dongguan Delin Technology Co. Ltd., in [Import Alert 98-06](#) (accessed 4/4/24). Source for leading 20 manufacturers of flavored disposable products by market share: internal Altria CMI market projections based on scan data, Multi-Outlet & Convenience; 13 weeks ending 12/31/23 (Q4, 2023).

²⁴ See FDA, [Data Dashboard \(Import Refusals\)](#) (accessed 4/4/24).

²⁵ As FDA recently reported as part of its joint operation with CBP resulting in the seizure of 1.4 million units of unlawful e-vapor products, many foreign manufacturers are actively mis-declaring unlawful e-vapor products to avoid detection: FDA, Press Release, [Joint Federal Operation Results in Seizure of More Than \\$18 Million in Illegal E-Cigarettes](#) (12/14/23).

Recommendation 6: FDA should immediately require foreign manufacturers to register with FDA and provide information about the FDA authorization status of e-vapor products presented for import, by way of an Interim Final Rule.

FDA has the authority to issue a rule that would require foreign manufacturers to register with and provide a list of legal products to the Agency. FDA has said it is planning to issue a foreign manufacturer registration rule since 2012,²⁶ yet has still not done so. Foreign manufacturers making and importing illicit e-vapor products are exploiting this major gap in the regulatory system.

FDA should close this loophole promptly, through an Interim Final Rule. We would recommend not only requiring foreign manufacturer registration, but also requiring importers to provide information about the FDA authorization status of e-vapor products presented for import (e.g., whether the products have been authorized by FDA, have FDA marketing denial orders stayed by court order, or have timely-filed applications pending with FDA) – an idea FDA has been considering since 2021.²⁷ With the expansion of import alerts, the adoption of an import prevention program, and the issuance of rules discussed above, FDA and CBP could more effectively and efficiently detect and prevent imports of illicit e-vapor products.

Warning Letters

Recommendation 7: FDA should more closely monitor recipients of warning letters to determine if the violations are continuing and more readily issue penalties when they are.

We support FDA’s progressive approach to enforcement, including its usual practice of sending warning letters before pursuing escalating penalties in response to repeat violations.²⁸ FDA says it is committed to “following up with firms that do not comply with the law and taking escalating actions, as appropriate.”²⁹ However, there is little evidence of ongoing monitoring or progressive enforcement against entities that continue supplying illicit e-vapor products after receiving warning letters. For example, FDA issued 116 warning letters in 2023 to online retailers for the sale of illicit e-vapor products.³⁰ Yet 92 of those 116 online retailers continue to market and sell illicit e-vapor products, and FDA has issued CMPs to only four of the 92 online retailers (4%).³¹ A more robust follow-up plan – including CMPs for continuing violations – would send a much-needed message to take FDA warning letters more seriously.

Establish a Coherent Compliance Framework for Regulated Entities

Recommendation 8: FDA should be clear with regulated industry on what its actual enforcement priorities are.

Regulated industry depends heavily on FDA being clear about its enforcement priorities and expectations. But with e-vapor, FDA is creating confusion with public statements that do not align with FDA’s actual

²⁶ FDA included a proposed rule requiring foreign manufacturer registration in the Fall 2023 [Unified Agenda](#). But FDA first proposed this rule in the 2012 [Unified Agenda](#), and it has appeared in other Unified Agendas every year from 2012 through 2023, including the Fall 2014 [agenda](#), Fall 2016 [agenda](#), Spring 2018 [agenda](#), Fall 2020 [agenda](#), and Spring 2022 [agenda](#).

²⁷ FDA included a proposed rule requiring e-vapor importers to submit PMTA numbers in the Fall 2023 [Unified Agenda](#) (with a January 2024 publication date that has not been met). The rule was first proposed in the Fall 2021 [Unified Agenda](#).

²⁸ See, e.g., FDA, Guidance for Industry, [Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers](#) (8/23), p 7.

²⁹ See CTP, [Strategic Plan](#) (12/23), p 16.

³⁰ To determine whether warning letter recipients voluntarily enter into compliance after the issuance of a warning letter, online retailers are the only recipient category we can reliably assess.

³¹ Altria internal analysis of FDA’s [Warning Letter Database](#) (warning letters issued in 2023 to retailers that cite websites selling e-vapor products that lack premarket authorization) and the websites cited by FDA (as of 3/18/24).

enforcement practices. FDA can clear up this confusion with the publication of a new Guidance for Industry that clearly communicates the Agency's actual hierarchy of enforcement priorities.

When FDA first asserted authority over the category in 2016, all e-vapor products on the market at the time lacked authorization and thus were technically in violation of the Act. But FDA made a critically important policy decision to allow existing e-vapor products to remain on the market as long as manufacturers filed PMTAs within FDA-imposed deadlines. FDA cited to important *public health* reasons for leaving these e-vapor products on the market subject to future review, including concerns that sweeping the market of all e-vapor products could lead to illicit markets and deny adult smoker access to reduced-harm options.³²

In 2020, FDA modified this enforcement policy when it issued a Guidance directing some – but not all – of the 2016 e-vapor products off the market immediately.³³ In particular, FDA directed flavored pod-based products other than menthol off the market *but continued to allow* all other e-vapor products to be sold as long as they had been on the market by August 8, 2016 and filed PMTAs by September 9, 2020. Again, FDA cited the same public health concerns for keeping these products on the market even though they lacked authorization.

FDA is now casting doubt over the compliance status of the products that are fully in compliance with the 2016 Rule and 2020 Guidance. In recent months, FDA has started saying that the 23 FDA authorized e-vapor products “are the only . . . [e-vapor] products that currently may be lawfully sold in the U.S.”³⁴ and that FDA has “not adopted a broad policy of enforcement discretion regarding tobacco products without marketing authorization.”³⁵

These statements simply do not align with what we know to be FDA's actual enforcement practices. We urge the Agency to clear up the confusion. We know that it is legal to sell the 23 e-vapor products FDA has authorized to date. But we also know that FDA is in fact exercising discretion today with respect to e-vapor products in compliance with the FDA's 2016 Deeming Rule and 2020 Guidance that are under PMTA review.³⁶ In this context, given the flood of products that violate virtually all FDA laws, regulations, and guidance, we recommend that FDA issue an updated Guidance clarifying its new hierarchy of enforcement priorities since 2020. That would mean telling regulated industry what FDA's enforcement priorities are *in actual practice*. We believe this level of transparency is not only necessary guidance for a fully functioning regulatory system but also important to demonstrate CTP's credibility as a regulator.

³² [Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products](#), 81 Fed. Reg. 28,974, 28,977-28,978 (May 10, 2016).

³³ FDA, Guidance for Industry, [Enforcement Priorities for Electronic Nicotine Delivery Systems \(ENDS\) and Other Deemed Products on the Market Without Premarket Authorization \(Revised\)](#), pp 10-11 (4/20).

³⁴ See, e.g., FDA, Press Release, [FDA Puts Firms Responsible for Esco Bars and Breeze — Two Popular Disposable E-Cigarette Brands — on Notice \(5/25/23\)](#).

³⁵ FDA, [Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products](#) (accessed 4/4/24).

³⁶ FDA has taken no enforcement action with respect to any product our companies make that are subject to, and in compliance with, the 2016 Deeming Rule and the 2020 ENDS Guidance, nor are we aware of any such action with respect to other companies' products.

Recommendation 9: FDA should re-evaluate its position that it cannot publish a list of e-vapor products commercially launched by August 8, 2016, and for which PMTAs were timely filed by September 9, 2020.

When presented with this proposal, FDA has cited confidentiality concerns in declining to publish a list.³⁷ But this explanation misconstrues the proposal. The e-vapor products that should be included on the list are only those that were commercially launched as of August 8, 2016. FDA’s website rightly confirms that any confidentiality concerns do not apply to products *already on the market*.³⁸ Indeed, we and others³⁹ are simply proposing that FDA update the “Lists of Deemed New Tobacco Products with Timely Applications” it published in May 2021 with current information on which products remain pending under FDA review.⁴⁰ The updated list would enable market actors to identify any currently marketed products that are omitted from the list and then remove those products from the supply chain.

The list would reflect the reality that e-vapor products with pending, timely filed applications are a lower enforcement priority than the droves of youth-appealing and illicit flavored disposable products being imported without any applications submitted to FDA.

Recommendation 10: FDA should more broadly publicize that all synthetic e-vapor products are unlawful under the 2022 statute and subject to immediate FDA enforcement.

There is also widespread confusion about the Agency’s enforcement approach for e-vapor products made with synthetic nicotine. Many of the e-vapor products that flooded the U.S. after 2020 came with labels claiming they were made with synthetic nicotine. The companies responsible for these products argued they could evade FDA regulation altogether. Congress passed legislation in 2022 to shut this loophole down, with the very clear intent to not only sweep these products expressly into FDA regulation, but to remove the products from the market absent FDA authorization by July 14, 2022.⁴¹

Yet most of these products still remain in the marketplace, and regulated entities continue to be confused about the compliance status of synthetic products that filed PMTAs in 2022. The Agency recently clarified, in a March 2024 webinar, that it is illegal for retailers and distributors to sell or distribute all e-vapor products made with synthetic nicotine, because none were authorized by July 2022.⁴² FDA should more broadly publicize this clarifying information along with its active efforts to remove these products from the market.

Conclusion

As we stated at the outset, we are deeply committed to FDA tobacco regulation succeeding. At Altria, we embed FDA regulation throughout our business, to ensure we can reflect FDA requirements and expectations at every stage and in all we do – from product design and manufacturing practices to marketing and sales. We take extensive steps to limit our marketing to minimize exposure to unintended audiences, especially youth, and comply fully with FDA marketing restrictions.⁴³ And we lead the

³⁷ For example, at the Convenience Distribution Association’s meeting on 2/27/24, the CTP Director said FDA will decline to publish a list of e-vapor products that fall within its enforcement prioritization approach for confidentiality reasons.

³⁸ FDA, [Deemed New Tobacco Product Applications Lists](#) (accessed 4/4/24).

³⁹ See, e.g., Energy Marketers of America (EMA), [Citizen’s Petition to FDA](#) (FDA-2023-P-2225) (6/1/23).

⁴⁰ FDA, Press Release, [Update on FDA’s Application Review: PMTA List Posted, Progress Metrics Updated](#) (5/20/21).

⁴¹ See Consolidated Appropriations Act, 2022 [Pub. L. No. 117-103](#), 136 Stat. 790 (2022).

⁴² FDA, Webinar, [Using the ‘Compliance Check Inspections of Brick and Mortar Tobacco Product Retailers’ Database](#) (3/19/24).

⁴³ Altria, [Responsible Marketing](#) (accessed 4/4/24).

industry in efforts to drive underage use down through measures above and beyond compliance to prevent underage access.⁴⁴

The outbreak in illicit market activity over the past three and a half years presents a clear threat to the long-term success of the system. The alternative, illicit market continues to grow and is now substantially larger than the legal, regulated market.

We strongly support the Agency in making the course correction needed to avert this threat. While we have focused in this letter on compliance and enforcement, we believe a complete solution must also include an improved PMTA process that embraces the science on smoke-free products, authorizes many more appropriate smoke-free options for the millions of adults who smoke or who have already moved to smoke-free options, and leverages FDA's powers *within the regulated system* to protect against underage use. Together with a more complete and effective compliance and enforcement plan, we see a future that delivers on the harm reduction promise of federal tobacco regulation.

Thank you for considering our perspective. We welcome the opportunity to answer any questions or further discuss the information and recommendations provided in this letter.

Sincerely,

DocuSigned by:
Paige Magness
Signer Name: Paige Magness
Signing Reason: I approve this document
Signing Time: 4/5/2024 | 4:58:11 PM EDT
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Paige Magness

⁴⁴ Altria, [Underage Access Prevention](#) (accessed 4/4/24).



Paige C. Magness
Senior Vice President
Regulatory Affairs

May 9, 2024

Via CTP Portal and UPS Overnight Delivery

Robert M. Califf M.D., MACC
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Dr. Califf:

We write to share important information related to so-called nicotine analogues that have begun to appear in the U.S. marketplace and which may be evading FDA regulation. As you know, in March 2022, Congress clarified the definition of covered tobacco products to include those using synthetic nicotine, with the intent to establish FDA's clear authority over nicotine-containing products.

The sale of products with an active ingredient designed to imitate nicotine poses a new threat to creation of a fully regulated market. These include "Metatine" (Charlie's Holdings Inc.'s *Spree Bar* product) and "Nixamide" (Outlaw Dip Co's "*Nic-Safe*" product), suggesting these chemicals are "alternative solutions to nicotine" that are not subject to FDA regulation, including tobacco regulatory requirements and that they do not require a Pre-Market Tobacco Product Application (PMTA). Additionally, "Imotine" (from Novel Compounds LLC) is being marketed as a new vapor and pouch product additive that does not require a PMTA.

We believe these companies are intentionally exploiting FDA's regulatory authority because the tobacco and nicotine products regulatory framework is not working as it was envisioned. The Center for Tobacco Products is not making enough science- and evidence-based decisions through the PMTA pathway to authorize less harmful smoke-free products and make them available to adult smokers who can't or won't quit all tobacco use. Rather than go through the established legal regulatory processes for products containing nicotine and wait years for authorization decisions, these companies appear to have determined that it is easier to create new chemical compounds and develop products for sale to U.S. consumers that avoid regulatory oversight and decision-making.

Furthermore, the lack of evidence basis supporting these chemicals is cause for concern. Unlike nicotine which has been studied extensively and is subject to decades-worth of scientific literature, a paucity of evidence supports these newly emerging nicotine analogues. We did identify the attached study published in *Tobacco Control* in March 2024 which focuses on the product *Spree Bar* utilizing "Metatine." As you will see, the authors raise their concerns that the purpose of this and similar chemicals is to evade regulation.

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We encourage FDA to carefully and quickly evaluate these new compounds to determine what regulatory authority it has over these products, and whether manufacturers' public characterizations of the regulatory status of these products are misleading. In particular, we encourage FDA to evaluate the explicit and implicit claims being made about these substances and the products that contain them to assess whether these products fall under the purview of the Center for Tobacco Products as a tobacco product, the Center for Drug Evaluation and Research as an unapproved new drug, or the Center for Food Safety and Applied Nutrition as legally marketed foods or dietary supplements. To that end, we have attached information, including website links and current public statements, to support FDA's fact gathering and analysis.

Additionally, after such a review, we urge FDA to quickly determine and broadly announce its policy on these nicotine analogue substances and take immediate enforcement actions if the Agency determines that the sale and marketing of products containing these substances violate the Federal Food, Drug, and Cosmetic Act and FDA regulations.

It is critically important that FDA move with urgency to assess this situation and exert its regulatory authority where appropriate. FDA's inability to react to an emerging synthetic nicotine market and massive importation of flavored disposable nicotine products has allowed an unregulated market to fester and evade FDA's authorities. If not regulated and subject to timely enforcement action, these so-called nicotine analogue products will only serve to exacerbate the already-existing illicit market, compounding FDA's enforcement challenges and the public's frustrations.

At Altria, we have long-supported a federal regulatory framework designed to ensure that all tobacco and nicotine-containing products are made, distributed, and sold within an FDA-regulated system that minimizes underage use, provides adult smokers who can't or won't quit tobacco use with proven lower-risk choices, and ensures all adult consumers benefit from FDA oversight over all the products they buy.

The introduction and growth of chemicals intended to imitate the effects of nicotine, if left unchecked, could present unknown risks to U.S. consumers and undermine FDA's authority.

Thank you for your interest, and please contact me if you have questions or need more information.

Sincerely,

DocuSigned by:
Paige Magness
 Signer Name: Paige Magness
Signing Reason: I approve this document
Signing Time: 5/9/2024 | 3:28:51 PM EDT
795D387B297646D5B92E1715C2AADA38

cc: Dr. Brian King, Director, Center for Tobacco Products
Dr. Patrizia Cavazzoni, Director – Center for Drug Evaluation and Research
Dr. Donald Prater, Acting Director – Center for Food Safety and Applied Nutrition
Dr. David Strauss, FDA Chief Scientist

Spree Bar, a vaping system delivering a synthetic nicotine analogue, marketed in the USA as 'PMTA exempt'

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BACKGROUND

In February 2021, the popular vaping company, PuffBar, started selling disposable e-cigarettes in the USA containing synthetic nicotine, claiming to be exempt from federal and state laws regulating products containing tobacco-derived nicotine.¹ US lawmakers responded to the emerging synthetic nicotine market by clarifying that synthetic nicotine products are subject to the US Food and Drug Administration's (FDA) regulatory regimen for tobacco products.¹⁻³ As of 14 April 2022, the FDA has been authorised to regulate tobacco products containing nicotine from any source, including laboratory synthesis, requiring manufacturers to submit a premarket tobacco product application (PMTA).³ In October 2022, the FDA sent a warning letter to the company, alerting the owners that its products are 'marketed unlawfully and are subject to enforcement action at FDA's discretion'.^{4,5} Currently, the company appears to be selling PuffBar-branded e-cigarette products without nicotine only.⁶

While many countries have updated their tobacco product laws to cover synthetic nicotine, or are in the process of doing so, a recent WHO report warned that non-nicotine tobacco alkaloids or synthetic nicotine analogues could be used by manufacturers to bypass regulatory schemes focusing on nicotine alone.² Non-nicotine tobacco alkaloids such as anabasin, nornicotine, anatabine and myosmine have well-known addictive and reinforcing effects.⁷⁻¹⁰ Starting in the 1970s, tobacco companies also developed various synthetic nicotine analogues and studied whether they could be used to dissociate nicotine's central and peripheral effects, to create more desirable products, to circumvent regulation or to develop pharmaceuticals.¹¹ The tobacco companies, however, never used these synthetic nicotine analogues in commercial products until now.

products are marketed as containing 'Metatine', a trademarked name for a synthetic nicotine analogue (figure 2).¹³⁻¹⁵ The trademark name owner and wholesaler of Spree Bar, Charlie's Holdings (Costa Mesa, California, USA), states:

'SPREE BAR is pre-filled with flavoured e-liquid containing proprietary Metatine. Metatine is a synthetically derived molecule that is structurally similar to, but chemically different from, other vaping alkaloids. Although Metatine (sic) produces the same sensation as nicotine and may also be addictive, Metatine is not made or derived from tobacco or nicotine, and Metatine does not consist of or contain nicotine from any source.'

SPREE BAR products containing Metatine (and no tobacco-derived materials or nicotine) do not meet the definition of a 'tobacco product' in the Federal Food, Drug and Cosmetic Act (FDCA) and do not require a PMTA to be sold in the USA.¹²

The wholesaler also claims that selling Spree Bar products would allow vendors to keep more profits since they cannot be taxed as tobacco products: 'Metatine products are exempt from nicotine excise taxes in many states, which can result in massive savings for retailers and consumers. Metatine can be combined with many flavours and is legal to sell in nearly all 50 states'.¹⁶

Charlie's Holdings explicitly stated that it was using a synthetic nicotine analogue in Spree Bar, rather than nicotine itself, in order to avoid FDA regulation. The company further explained that it had abandoned its pending PMTA submissions for its nicotine-containing e-cigarette products and was instead focusing on Spree Bar because it was 'frustrated' by the pace of the FDA's PMTA reviews and by the fact that 'no company in the world, to date, has received an FDA marketing order for a flavoured disposable vape product'.¹⁴

'METATINE' (6-METHYL NICOTINE) AS A NICOTINE REPLACEMENT: TOXICOLOGY AND ADDICTIVENESS

'Charlie's Holdings, the supplier of Spree Bar, established a website with the address 'metatine.com' stating that:

The substance Metatine has the International Union of Pure and Applied Chemistry (IUPAC) designation 2-methyl-5-[(2S)-1-methylpyrrolidin-2-yl]pyridine...¹⁷

2-methyl-5-[(2S)-1-methylpyrrolidin-2-yl]pyridine is synonymous with (S)-6-methyl nicotine



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Spree Bar, a 'PMTA exempt' electronic cigarette system

The concern that companies might use synthetic nicotine analogues in order to avoid regulation is no longer hypothetical. As of October 2023, vape stores in the USA had started selling a new electronic cigarette pod system named Spree Bar, advertised as 'PMTA exempt' (figure 1).¹² Spree Bar products are promoted through convenience store advertising and web channels, using youth-appealing and young adult-appealing artificial intelligence-generated characters (figure 1). The

Industry watch

SPREE BAR PRODUCTS SUSTAINABILITY ABOUT METAINE™ CONTACT US WHOLESALE

THE HUMANITY OF ARTIFICIAL INTELLIGENCE

6000 PUFFS PMTA EXEMPT POD DEVICE

NEW

OVER-90% INNOVATIVE POD SYSTEM

Combining award-winning flavors with cutting-edge technology to produce an AMAZING vaping experience! Created by smokers for smokers, SPREE BAR comes in 9 wildly popular flavors... BUT LAST... all day! State-of-the-art rechargeable AND reusable battery flavor pod system is good for the environment... and your wallet!

SEE THE FLAVORS

SOCIALIZE WITH US ON INSTAGRAM FOLLOW US

Figure 1 Screen shot of the Spree Bar website taken on 10 August 2023, with a statement claiming that the products are 'PMTA exempt'.¹⁷ PMTA, premarket tobacco product application.

(Chemical Abstracts Number: CAS 13270-56-9) (figure 3),¹⁸ 6-methyl nicotine is a structural analogue of nicotine (figure 3), with a methyl group substitution at position 6 of nicotine's pyridine ring. Recently awarded patents describe new synthesis protocols to generate 6-methyl nicotine from petrochemical precursors.¹⁹⁻²¹ One such patent was assigned to Shenzhen Zinwi

Biotech, a leading e-liquid company that also sponsored a toxicological study at Guangdong Pharmaceutical University. This study reported that 6-methyl nicotine has increased cytotoxicity compared with nicotine in a permanent human bronchial epithelial cell line (BEAS-2B), but milder effects on the upregulation of lung cancer-related proteins.¹⁹⁻²¹ The authors conclude 'that new

Jordt SE, et al. *Tob Control* 2024;0:1-5. doi:10.1136/tc-2023-058469

Metatine™

A synthetically derived molecule that is structurally similar to, but chemically different from, other vaping alkaloids.

Metatine™ is not made or derived from tobacco or nicotine and does not consist of or contain nicotine from any source. Nevertheless, Metatine™ may be addictive.

Products containing Metatine™ (and no tobacco-derived materials or nicotine) do not meet the definition of 'tobacco product' in the Federal Food, Drug, and Cosmetic Act and do not require a PMTA to be sold in the US.

Figure 2 Section of a screen shot of the Metatine website taken on 23 September 2023, stating that products containing the active ingredient, 6-methyl nicotine, do not meet the definition of 'tobacco product' in the Federal Food, Drug and Cosmetic Act and do not require a PMTA to be sold in the USA.¹⁷ PMTA, premarket tobacco product application.

electronic cigarettes with 6-MN might offer some advantages over conventional electronic cigarettes containing nicotine', providing evidence that the sponsoring company is seeking to encourage use of the compound, 6-methyl nicotine (abbreviated as 6-MN), in e-cigarettes.²² However, no toxicological data in humans are available for 6-methyl nicotine, and in vivo study in rats revealed that the 50% lethal dose for 6-methyl nicotine is at least 1.5–3 fold lower than for nicotine, suggesting that 6-methyl nicotine is more toxic than nicotine.^{23,24}

Another patent, assigned to Shanghai Lingnuo Biotech, includes human studies in which e-cigarette users were asked to rate the 'throat hit' and other psychophysical qualities of e-cigarette aerosol containing 6-methyl nicotine.²⁵ In one of these studies, 1 mg/mL 6-methyl nicotine was found to be as satisfying as 3 mg/mL nicotine and to produce a similar 'throat hit', with the authors concluding that '6-methyl nicotine can be used for replacing nicotine in electronic aerosolisation'.²⁶ Only 10 test subjects participated in this study, with unknown background,

with puffing protocols not mentioned, and with no statistical analysis provided.

While a manufacturer-sponsored study claimed that 6-methyl nicotine may be less addictive than nicotine,²² previous pharmacological studies demonstrated that 6-methyl nicotine is threefold more potent at replacing [³H]nicotine from rat brain membranes and five times more potent at producing prostration behaviour.²⁵ 6-methyl nicotine was found to be twice as potent as nicotine as an analgesic in the tail flick test, and 3.3 times as potent in increasing spontaneous motor activity.²⁶ Since these behaviours are triggered by nicotinic receptor activation, it can be supposed that 6-methyl nicotine is, in fact, more addictive than nicotine.

6-METHYL NICOTINE PRODUCTS IN THE US MARKETPLACE

To our knowledge, Spree Bar is the first and, as of now, only product using 6-methylnicotine marketed in the USA and available for purchase by consumers. Spree Bar products and Metatine are discussed in Reddit posts, including initial user reports, suggesting increasing awareness by e-cigarette users in the USA.^{27,28} The authors of the present study purchased Spree Bar products on 7 October 2023, receiving delivery on 17 October 2023, confirming availability in the USA.²⁹ We identified another company, Novel Compounds (Cheyenne, Wyoming, USA), advertising 6-methylnicotine under the trademark 'Imotine' as a wholesale product to manufacturers.^{30–32} However, we did not identify any US-marketed products yet using this brand name version. An abstract presented by a US-based chemical analytical services company at a recent tobacco industry conference describes a method for the quantification of 6-methyl nicotine and detected its presence in e-liquids, confirming efforts by the industry to market such products.³³ Given the growing activity from several industry groups, we expect that additional 6-methyl nicotine-containing products will be marketed in the USA soon.



Figure 3 Chemical structures of (S)-nicotine (left), the major form of nicotine in tobacco and (S)-6-methyl nicotine (right), trademarked as 'Metatine', with a methyl group substitution (blue) at position 6 of the pyridine ring (positions numbered in green). The red asterisk indicates the chiral centre of nicotine.

Industry watch

6-METHYL NICOTINE: REGULATORY CHALLENGES AND SOLUTIONS

Are products containing 6-methyl nicotine, differing from nicotine by a methyl group, subject to the PMTA requirement and the other provisions of the US Tobacco Control Act (TCA), or are they indeed 'PMTA exempt'? The TCA, as amended in 2022, now covers products 'made or derived from tobacco, or containing nicotine from any source'.¹⁴ The TCA defines 'nicotine' as '1,2. Nicotine. The term "nicotine" means the chemical substance named 3-(1-methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine'.¹⁵ 6-methyl nicotine has a different chemical formula C[11]H[16]N[2] and name. If the FDA concludes that 6-methyl nicotine is a 'complex' of nicotine and takes enforcement action against Spree Bar or other similar products, the manufacturers would likely challenge that determination in court.¹⁶ Other jurisdictions define the term 'nicotine' differently. For example, Article 2 (Definitions) of the European Union's (EU) Tobacco Products Directive (TPD) states: '(19) "nicotine" means nicotinic alkaloids'.¹⁷ The term 'alkaloid' denotes both natural and synthetic nicotinic ligands, thus 6-methyl nicotine would fall within the scope of the EU's TPD.¹⁸

Should the FDA (or a future court decision) conclude that 6-methyl nicotine is not 'nicotine' within the meaning of the TCA, then it does not mean that products containing 6-methyl nicotine are necessarily exempt from all FDA regulation. A federal appeals court ruled in 2010 that 'customarily marketed' nicotine-containing products cannot be regulated as drugs or drug-delivery devices if they are sold 'without claims of therapeutic effect'.¹⁹ However, that decision was based on the premise that these products would be subject to FDA regulation as tobacco products, and the case's reasoning would not apply to products that do not fall within the TCA's definition of a 'tobacco product'.¹⁹ The proclamations on Spree Bar's website that Metatine 'produces the same sensation as nicotine' and 'may also be addictive,' combined with the similarity in chemical form to nicotine and evidence of similar physiological effects, strongly suggest that the FDA could alternatively seek to regulate the 6-methyl nicotine in Spree Bar as a drug under the FDCA.⁴⁰ If the FDA determines that 6-methyl nicotine is being marketed as a drug intended to produce particular physiological effects (the FDCA defines drugs in part as 'articles (other than food) intended to affect the structure or any function of the body'),⁴¹ then it would not be possible for it to be sold legally without the manufacturer first obtaining FDA approval.

When companies market products like Spree Bar as exempt from FDA regulation, it reduces confidence in the FDA's regulatory scheme and undermines the FDA's efforts to protect public health. The FDA should quickly announce its policy with respect to such products and take appropriate enforcement action. Congress might also consider clarifying that products containing non-nicotine tobacco alkaloids or synthetic nicotine analogues are tobacco products under US law, by amending the TCA to expressly say as much. For example, it could follow the EU's approach and define 'nicotine' to more broadly include all nicotinic alkaloids, thus enabling the FDA to regulate e-cigarette products containing 6-methyl nicotine the same way it regulates all other e-cigarette products.^{37,38}

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Contributors SEI and MLB conceptualised and designed the study and wrote the first draft of the paper; SVJ provided advice on product choice and figures design. SVJ and PJZ contributed to revision of the manuscript. All authors critically reviewed, edited and approved the final draft before submission. SEI attests that all listed

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Metatine

Metatine™

Using patented technology and several trade secret processes, Metatine is a synthetically derived molecule that is structurally similar to, but chemically different from, other vaping alkaloids. Notably, even though Metatine is a non-nicotine compound, vape devices that contain Metatine provide adult users with a strong sense of satisfaction, pleasure and enjoyment that is largely indistinguishable from traditional vape products.

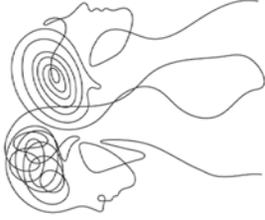


Synthesis and Analysis

Metatine is synthesized using a trade secret process. The starting material is not nicotine and the finished product does not contain nicotine. Metatine has been tested for tobacco-specific nitrosamines (TSNAs) degradation, chemical impurities, and other volatile organic compounds. The results indicate that Metatine poses no additional risk compared to additives found in conventional vape products currently on the market.

Toxicity

Metatine is structurally similar to nicotine. It is expected that Metatine will have a toxicity profile similar to nicotine. Nicotine is considered acutely toxic. It is not mutagenic nor a carcinogen. Metatine is not listed as a carcinogen by IARC, FDA, NIOSH, or NTP. Nicotine is considered to potentially have adverse reproductive effects. Metatine is not listed as a reproductive toxicant by IARC, FDA, NIOSH, or NTP. Pure Metatine is not considered to be irritant to skin or mucous membranes. It is not a skin or eye irritant in rabbits. It is negative in the mouse bone marrow micronucleus genotoxicity test. See Additional Warnings.



Regulatory Status

Since Metatine does not contain nicotine, it is not derived from tobacco, and is not a controlled substance. Metatine does not fall under the regulatory purview of the FDA's Center for Tobacco Products.

Metatine does not meet the definition of nicotine as stated in the Family Smoking Prevention and Tobacco Control Act. It is not a salt or complex of nicotine, and is not itself derived from nicotine or tobacco, accordingly, Metatine is not subject to FDA tobacco regulation. Metatine is not subject to the FDA's Premarket Tobacco Approval (PMTA) authorization (often known as a PMTA) required for new tobacco products, like e-cigarettes.

Metatine is not recognized as a drug in the official United States Pharmacopeia and is not intended for use in the diagnosis, cure, mitigation, prevention, or treatment of disease. It is intended only as a satisfying alternative for adult tobacco users and vapers.

Metatine™
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THE FDA RESPONDS TO NICOTINE ALTERNATIVE NIC-SAFE™ (NIXAMIDE™)

IN A RECENT CONFIDENTIAL LETTER SENT TO OUTLAW DIP CO., THE FDA RESPONDS AND UPDATES THEIR STATUS ON THE USE(S) OF THE ZERO NICOTINE ALTERNATIVE CALLED NIC-SAFE™. WE WOULDN'T LIVE UP TO OUR NAME OF OUTLAW'S IF WE DIDN'T SHARE THESE CONFIDENTIAL RESULTS WITH YOU! (OR AT LEAST WHAT WE CAN!)

NOW, BEFORE WE DIVE IN TO THE MEAT AND POTATOES; WHAT IS NIC-SAFE™ FOR THOSE WHO DON'T ALREADY KNOW?

IN SHORT:

NIC-SAFE™ (NIXAMIDE) IS MADE FROM A PROPRIETARY ALTERNATIVE SOLUTION TO NICOTINE (PATENT PENDING.) MADE FROM NATURAL B3 VITAMINS, NIXAMIDE HAS BEEN SPECIFICALLY FORMULATED TO DELIVER THE SAME SATISFACTION, PLEASURE, AND ENJOYMENT AS TRADITIONAL TOBACCO AND NICOTINE PRODUCTS. GIVING YOU THE BUZZ THAT ALTERNATIVE NICOTINE USERS CRAVE AND TURN TO WHEN THEY NEED TO LAY OFF THE NICOTINE.

READ MORE ABOUT NIC-SAFE AND ITS PROPERTIES, AND HOW IT WORKS [HERE](#).

NOW ON TO THE MAIN POINT: THE RECENT LETTER SENT TO OUTLAW DIP CO. THE FDA OFFICIALLY RESPONDS TO THE USE OF ZERO NICOTINE NIXAMIDE. STATING -

“...WE HAVE NO HESITATION IN PROVIDING OUR OPINION THAT NIXAMIDE™ IS NOT A “TOBACCO PRODUCT” AS DEFINED IN THE FOOD, DRUG AND COSMETIC ACT (“FDCA” OR THE “ACT”), AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009 (“TCA”) AND THE CONSOLIDATED APPROPRIATIONS ACT OF 2022 (“CAA”).”

LET'S TAKE A DEEPER LOOK INTO THE FDCA SECTION 201 FILE SO WE CAN BETTER UNDERSTAND WHAT THIS MEANS...

“In a recent confidential letter to Outlaw Dip Co. —the FDA responds...”

“...we have no hesitation in providing our opinion that Nixamide is not a ‘tobacco product’...”

Imotine

Discover the Future

imotine™ is a new additive that enhances the vape and pouch experience.

▶

- Regulatory Status**
imotine™ is **NOT** considered a "tobacco product" and does not require a PMTA to be sold in the US. This has been confirmed by some of the top law firms and regulatory consulting groups in the tobacco industry.
- Product Safety**
imotine™ has been tested for tobacco specific nitrosamines (TSNA), degradants, chemical impurities, and other volatile organic compounds. The results indicate that imotine™ poses no additional risk than current vape and pouch additives on the market.
- Unique Molecule**
imotine™ is a synthetically derived molecule that is structurally similar to, but chemically different from other vape and pouch additives.

APPLICATIONS

imotine™ is currently being used in a variety of products:

- White Pouches
- Vape Liquid
- Lozenges
- Transdermal Patches



June 12, 2024

The Honorable Dick Durbin
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

RE: June 12, 2024 Hearing: "Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes"

Dear Chairman Durbin and Ranking Member Graham:

The American Lung Association thanks the Committee on the Judiciary for holding this hearing. One of the Lung Association's strategic imperatives is to create a tobacco-free future. The Lung Association has worked for three decades to first, get the U.S. Food and Drug Administration (FDA) authority to regulate tobacco products with the passage of the Family Smoking Prevention and Tobacco Control Act (TCA), and now, for FDA to use its full authority to implement the TCA in order to protect the public health.

As it stands, there are only [23 e-cigarette products authorized and therefore legal to be sold in the United States](#). These products were submitted through the pre-market tobacco applications (PMTA) process and received a marketing grant order (MGO) from the FDA. This means that virtually the entire e-cigarette market consists of unauthorized, illegal products, including many flavored products (largely disposables) that FDA has found to be highly appealing to children. The illegal products on the market tend to fall in two major buckets:

1. Products for which a PMTA has been submitted and a marketing denial order (MDO) was issued; or those applications for which a decision on an application is still pending; and
2. Products that have never submitted a PMTA and are flagrantly disregarding U.S. law.

Even though FDA has denied marketing authorizations for millions of flavored e-cigarette products, several studies indicate that the e-cigarette market has expanded in the U.S. These products are getting larger in volume of liquid they contain, stronger in nicotine strength and cheaper to purchase. None of these products have been authorized to be sold in the U.S. Meanwhile, the prevalence of youth e-cigarette use remains too high, with 2.1 million high school and middle school students currently using e-cigarettes.

The tobacco industry is unlike any other industry FDA oversees, and, consequently, the relationship between FDA's Center for Tobacco Products (CTP) and industry needs to be different than other FDA centers. The tobacco industry does not share CTP's mission of protecting the public health – or the health of any individual. The industry is committed to maintaining sales and addiction to products that are the number one cause of preventable death and disease in this country. They do this in flagrant disregard for federal law.

The proliferation of e-cigarettes and other tobacco products prior to the deeming rule taking effect – and then the failure to stop new products from coming onto the marketplace once it did take effect – make CTP's enforcement of the Tobacco Control Act against an industry that does

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not want to be regulated at all even more difficult. The Lung Association calls on CTP to order all products off the market unless they have been granted a marketing order by the FDA.

However, without more robust enforcement, companies have no reason to do anything other than drag their feet, target kids, rack up profits and continue to defy the law. Now is the time for a comprehensive strategy – including actions that must be taken by FDA, and increased involvement from the U.S. Department of Justice (DOJ) and U.S. Customs and Border Protection (CBP). That is why the Lung Association applauds the announcement on Monday, June 10 from DOJ and FDA for their new multi-agency taskforce to address the illegal distribution and sale of e-cigarettes. We are hopeful that bringing together multiple law enforcement partners, the U.S. Postal Inspection Services and Federal Trade Commission will be a powerful step in combatting the youth vaping epidemic. It will be imperative for the protection for the public health that this taskforce coordinate and streamline efforts to utilize all enforcement tools necessary to remove illegal and addictive tobacco products from the market.

Below, you will find the American Lung Association's recommendations for action.

FDA Must Finish Long Overdue Review of Pre-Market Tobacco Product Applications

A federal court required that all premarket tobacco product applications received by September 9, 2020, be reviewed within one year (by September 9, 2021). Now, more than two years past the deadline, we are still waiting for FDA to complete this work. FDA has made progress in reducing the backlog over the past year, including several decisions on menthol e-cigarette products. There are important decisions on e-cigarette products with high market share remaining.

Last week the FDA rescinded its marketing denial order on JUUL Labs's products. While this rescission is not an authorization – it is deeply concerning that any JUUL product is still available for sale. As you know, JUUL bears the largest responsibility for the youth e-cigarette epidemic from 2017-2019. FDA must swiftly review their applications. FDA must follow the law and not permit any JUUL product or other tobacco product to be sold in the U.S. prior to it receiving a premarket authorization.

It is imperative that CTP not delay beyond the forthcoming June deadline to finish the review of all pending tobacco product applications. The Lung Association continues to recognize that no flavored tobacco product can meet the standard for protecting the public health.

FDA must also finish its long overdue review of PMTA applications for products made with synthetic nicotine. Congress made clear and [FDA has acknowledged](#) that any tobacco product made with synthetic nicotine that had not receive a marketing authorization order by July 13, 2022 must be removed from the marketplace. Greater enforcement against these illegal products is also overdue and greatly needed.

Federal Law Enforcement Must Significantly Increase Their Engagement with FDA Against Illegal Tobacco Products

Despite some actions taken by CTP and DOJ, too many illegal (primarily flavored) e-cigarette products remain on the market. The focus of enforcement must be at the manufacturer, distributor, retailer and importer level. Although we appreciate that FDA has issued over 1100 warning letters to such entities, we urge that FDA make much greater use of its stronger enforcement tools, including civil monetary penalties (CMPs) and no-tobacco-sale orders.



Federal law enforcement must be involved to conduct product seizures, import restrictions, injunctive actions and criminal prosecutions. The Lung Association urges that all these steps be undertaken. It is imperative that the DOJ seek injunctive relief from courts against the marketing of unauthorized products. As it stands, the DOJ has only sought injunctions against seven manufacturers of unauthorized e-cigarettes. Additionally, the first set of these actions were brought between 13 to 18 months after FDA sent a warning letter. Both agencies must work together to bring forward injunctions against more manufacturers of unauthorized e-cigarettes and streamline the process. By waiting between 13 to 18 months, the U.S. government enables and encourages the tobacco industry's profits from the sale of their illegal products. The DOJ must prioritize tobacco product enforcement and protect more children from becoming addicted to these dangerous products.

It is also evident that the illegal importation of unauthorized e-cigarette products manufactured in China, specifically flavored disposable e-cigarettes, has increased in recent years. While FDA has placed certain e-cigarette companies on its import alert red list, FDA and CBP have only recently announced the first large-scale seizure of unauthorized products. The detection and seizure of imported un-authorized e-cigarette products must be a joint priority between FDA and CBP.

Congress Must Pass the Bipartisan Resources to Prevent Youth Vaping Act

The Lung Association also calls on Congress to pass S. 3653, Resources to Prevent Youth Vaping Act, the bipartisan legislation sponsored by Senators Shaheen and Murkowski. While all of CTP's activities are funded by user fees assessed against each class of product, e-cigarette manufacturers are not subject to any use fee – despite the significant amount of resource needed by FDA to enforce the law against them. Congress must take up this legislation to increase the FDA's ability to protect the public health from e-cigarettes.

FDA must act and finalize all pending applications. The FDA also urgently needs greater support and resources for the newly announcement task force plus CBP to protect the next generation of kids from illegal tobacco products. These agencies must use all enforcement tools at their disposal against manufacturers, distributors, importers and retailers to clear the market of unauthorized e-cigarette products, including flavored products that put young people at risk for nicotine addiction and other significant health harms.

The American Lung Association thanks the Committee for discussing this critical public health issue.

Thank you.

Sincerely,



Harold P. Wimmer
President and CEO

Cc: Senate Committee on the Judiciary



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Wednesday, June 12, 2024
Senate Committee on the Judiciary Hearing:
"Combating the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes"
Statement of Congresswoman Sheila Cherfilus-McCormick (FL-20)

Thank you, Chairman Durbin and Ranking Member Graham for holding this important hearing today and allowing me to submit my statement.

Chairman Durbin, your leadership on the issue of unauthorized e-cigarettes is both undeniable and admirable. In Washington D.C., we all too often gravitate from discussing one area of concern to another, being-consumed by multiple issues to be addressed that sometimes, we don't always have enough time to channel our willpower towards finding the much-needed solutions.

I would like to seize this opportunity to express a heartfelt gratitude to you, Chairman Durbin, for continuing to put the interest of our children's health first and for keeping the spotlight on this critical issue.

Early last year, I introduced H.R. 901, The Disposable ENDS Product Enforcement Act of 2023. If enacted, my legislation would help protect our youth from the onslaught of flavored disposable e-cigarettes coming from China by mandating that the FDA remove unauthorized e-cigarettes from store shelves.

Numerous surveys demonstrated that our children are prone to becoming addicted to disposable e-cigarettes from China due to the child friendly flavors and packaging.

Since introducing H.R. 901, I have watched with growing alarm as Chinese manufactures and suppliers of e-cigarettes have continued to flood our market with unregulated, harmful substances that are detrimental to the health and wellbeing of our children.

We have a crisis on our hands that requires swift and decisive action.

That is why I was pleased to hear the Commissioner of the Food and Drug Administration, Dr. Robert M. Califf, recently testify that he believes Congress must act to provide the FDA with the authority it needs to address the issue.

As I have made it clear to the Administration, including Commissioner Califf himself, I stand ready to work with them on my legislation so that it meets their needs and gives the relevant departments and agencies the necessary authority to rid our store shelves of flavored disposable Chinese e-cigarettes.

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I would, of course, welcome the opportunity to work with this Committee so that we can arrive upon a bicameral solution to this epidemic.

There is broad bipartisan support for protecting our children from flavored e-cigarettes coming from China. As the mother of two children and a former healthcare executive, I cannot sit idle and hope this issue will go away. It will not.

We must act and we must act now.

I welcome the U.S. Department of Justice (DOJ) and the U.S. Food and Drug Administration (FDA) creation of a new federal multi-agency task force to combat the illegal distribution and sale of e-cigarettes. This decision **clearly demonstrates that vigorous enforcement of tobacco laws is a government-wide priority. It is the right step in the right direction.**

I look forward to working with the Committee and the Administration on a legislative and enforcement strategy worthy of the challenge we face.

Again, I thank the Committee for affording me the opportunity to have my voice heard on this critical issue.

Sincerely,



Sheila Cherfilus-McCormick
Member of Congress



**STATEMENT FOR THE RECORD
U.S. Senate Committee on the Judiciary**

**A Hearing on “Combating the Youth Vaping Epidemic by Enhancing Enforcement
Against Illegal E-Cigarettes”**

June 18, 2024

Statement By:
Kimberly Bolin
President and CEO
Convenience Distribution Association

My name is Kimberly Bolin, and I write today as President and CEO of the Convenience Distribution Association, the trade organization working on behalf of convenience products distributors in the United States, to share our concern with the growing parallel marketplace of unauthorized, unregulated, illicit, vape products that do not have youth access restrictions that are entering the United States marketplace.

The Convenience Distribution Association (CDA) is the national trade organization working on behalf of convenience products distributors in the United States. Its distributor members employ nearly 59,000 people and represent more than \$102 billion in U.S. convenience product sales, serving a wide variety of small retail formats. Associate members include leading convenience product manufacturers, brokers, suppliers, and others allied to the industry. Typical products sold by broadline convenience distributors include candy, snacks, foodservice, tobacco and tobacco-related products, beverages, beverage programs, groceries, health and beauty care and general merchandise.

Broadline convenience distributors have been deeply engaged in the legal, regulated, age restricted, responsible system for distributing authorized tobacco products for more than a century, and ensure a secure supply chain with licensing, taxing, and revenue compliance. The convenience distribution sector contributes billions in economic and fiscal activity in the U. S. economy including \$2.3 billion in local, state, and federal tax revenue and \$30 billion in tobacco excise taxes.

CDA is a longstanding supporter and member of the board of directors of the “We Card” program that trains and educates retailers to prevent attempts by minors to purchase age restricted products. CDA distributor members have also supported We Card’s new “social source” program to combat the problem of legal age adults serving as a source of tobacco and vaping products for underage youth.

FDA retail compliance check data demonstrates that 87% of retailers do not sell tobacco products to an underage individual.¹ Moreover, studies show that most youth obtain tobacco products from “social sources,” which includes older friends or family members, having an adult buy products for them, asking older individuals for tobacco products, or stealing tobacco products.²

CDA has participated in several meetings with federal agencies, including the U.S. Food and Drug Administration’s Center for Tobacco Products (CTP), the Department of Justice (DOJ), and Customs and Border Protection (CBP), as well as legislators and their staffs regarding the illicit, irresponsible marketing of illicit e-cigarettes in the U.S. marketplace.

During each of these meetings and written submissions, CDA consistently makes the following requests/recommendations to address these problems:

1. Complete the review of Premarket Tobacco Applications (PMTAs).
2. Enforce current laws regarding illicit ENDS products entering the U.S. marketplace and bypassing FDA’s regulatory requirements.
3. Interagency coordination of FDA, DOJ and CBP.

COMPLETE THE REVIEW OF PREMARKET TOBACCO APPLICATIONS (PMTAs)

The **Deeming Rule**, which went into effect in August 2016, granted the **FDA** regulatory authority over **Electronic Nicotine Delivery Systems (ENDS)**, including e-cigarettes, vapes, and other related products. This rule allows the FDA to regulate ENDS in ways similar to how it already regulates traditional cigarettes, smokeless tobacco, and roll-your-own tobacco. Despite the requirement for PMTAs to be submitted by Sept. 2020, a separate final PMTA rule titled “Premarket Tobacco Product Applications and Recordkeeping Requirements” was published in the Federal Register on October 5, 2021 (86 FR 55300) and became effective on **November 4, 2021**. Over the past three and a half years since September of 2020, Pre-Market Tobacco Applications (PMTAs) have been submitted to the FDA by manufacturers covering 26,603,407 electronic nicotine/vapor products.³ To date, the FDA has issued Marketing Granted Orders authorizing the marketing of 23 nicotine vapor products and components manufactured by three companies.⁴

¹ U.S. Food and Drug Administration, “Compliance Check Inspections of Brick and Mortar Tobacco Product Retailers,” <https://timp-ccid.fda.gov/>, (May 31, 2024).

² Susanne Tanski, et al., *Youth Access to Tobacco Products in the United States: Findings from Wave 1 (2013-2014) of the Population Assessment of Tobacco and Health Study*, Nicotine and Tobacco Research, December 2019.

³ U.S. Food and Drug Administration, “Tobacco Product Applications: Metrics and Reporting,” <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting>, May 28, 2024.

⁴ U.S. Food and Drug Administration, “FDA Authorized E-Cigarette Products,” https://digitalmedia.hhs.gov/tobacco/print_materials/CTP-250?locale=en, January 2024.

CTP was ordered by a federal court to finalize the agency's review of all electronic nicotine/vapor product PMTAs which have a 2% or greater retail market share by September 9, 2021, however the FDA has continued to extend the deadline with the latest extension to June 30, 2024.⁵

Besides preventing underage access and use, several key goals of the Family Smoking Prevention and Tobacco Control Act include protecting the public health, reducing the "risks or exposures associated with tobacco products," and "to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products."⁶ This goal of reducing the harm of tobacco products was corroborated in a report compiled by the National Academies of Sciences, Engineering, and Medicine (NASEM), which found conclusive evidence that completely switching from combustible cigarettes to electronic cigarettes reduces an individual user's exposure to numerous toxicants and carcinogens.⁷

ENFORCE CURRENT LAWS REGARDING ILLICIT ENDS PRODUCTS ENTERING THE U.S MARKETPLACE AND BYPASSING FDA'S REGULATORY REQUIREMENTS

This past December there was a seizure of 1.4 million unauthorized electronic cigarettes that were being unlawfully imported through the Los Angeles International Airport (LAX). Also, over the past several months, the FDA has issued a series of import alerts authorizing the detention of unauthorized electronic cigarette products being unlawfully imported into the United States.⁸ Also, from October 2023 through May 2024, the CBP has issued 826 import refusal orders against illicit ENDS products. While these were welcome developments, much more is needed to turn the tide.

The Government Accountability Office (GAO) describes illicit trade this way: "Officials characterized illicit trade in tobacco products similar to a whack-a-mole problem, stating that although illicit trade may decrease immediately following successful law enforcement efforts, these activities usually resume after a period of time. ATF officials also noted that illicit trade in tobacco is often connected to other crime and criminals may use proceeds from illicit trade in tobacco to fund other crimes."

A 2015 report from five federal agencies, including the Department of Justice (DOJ), entitled "The Global Illicit Trade in Tobacco: A Threat to National Security" outlines the issues already present in illicit tobacco product trade.⁹ Among other things, the report highlights the criminal,

⁵ *American Academy of Pediatrics, et al. v. United States Food and Drug Administration, et al.*, U.S. District Court (Maryland), Case No. 8-18-cv-883-DLB, April 19, 2024.

⁶ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 (2009).

⁷ National Academies of Sciences, Engineering, and Medicine, "Public Health Consequences of E-Cigarettes," January 2018.

⁸ United States Food and Drug Administration, "Import Alert 98-06." May 23, 2024.

⁹ U.S. Department of Justice, et al., "The Global Illicit Trade in Tobacco: A Threat to National Security," December 2015.

financial, public health, and even national security issues that are present. The report also describes the current laws and actions available to several agencies, including the DOJ.

Left unchecked, these growing illegal operations solidify into a corrosive mixture of crime, corruption and circumvention of the nation's tobacco-control laws, putting at risk efforts to keep tobacco out of the hands of young people, disrupting legal commerce and putting law-abiding businesses at a disadvantage.

Many of these illicit ENDS products are made by companies outside of the U.S. by manufacturers that have no intention of complying with U.S. tobacco regulations. Rather, they continue to sell illicit products in the U.S. with no concern for abiding by the law, don't pay taxes, may be a cash only business, likely to be short term, so that it's easy to pop up and close down, and are not concerned with prevention of underage access.

On September 25, 2023, CDA along with other industry trade associations and key manufacturers sent a letter to FDA Commissioner Robert Califf and FDA Center for Tobacco Products Director Dr. Brian King outlining the industry's concerns with the marketing of illicit electronic cigarette products in the U.S. This letter included a request for the FDA and the industry members to join in a two-way dialogue to collaborate on the best means to bring regulatory order to the U.S. e-vapor market. Two-way, transparent dialogue is one of the areas of opportunity the Reagan-Udall Foundation identified in its December 2022 report. That letter has gone unanswered.

INTERAGENCY COORDINATION OF FDA, DOJ AND CBP

A clear, coordinated interagency response involving the FDA, U.S. Customs and Border Protection, Department of Justice, and Department of Homeland Security is critical to enforce current laws within their respective departmental authorities with FDA.

CDA is encouraged with the recent announcement of a new collaboration between FDA and DOJ; the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF); the U.S. Marshals Service (USMS); the U.S. Postal Inspection Service (USIPS); and the Federal Trade Commission (FTC). According to the CTP, this new multi-agency task force is being formed "to combat the illegal distribution and sale of e-cigarettes." CDA has long believed a multi-agency approach to enforcement is necessary and will significantly curb the illicit market.

We were encouraged to learn from CBP that they are collaborating with CTP on enforcement issues. However, it was made clear that CBP needs additional information that will help officers identify shipments of illicit products.

To that end, CBP shared information with us regarding their e-Allegations program, which provides an electronic website portal for the trade community and the public to report suspected trade violations. The e-Allegations process enables CBP, in collaboration with its governmental partners, to protect the U.S. economy from the effects of unfair trade practices and guard against the entry of products that could pose a threat to health and safety.

CBP shared the following link that can be used to file an e-Allegation on the CBP website:
<https://www.cbp.gov/trade/e-allegations>.

The continued collaboration of FDA, DOJ, CBP and other governmental agencies is imperative to intercept and seize illicit disposable vapor products, protect public health and safety, and prevent youth access.

Your time and attention to this critical problem are greatly appreciated. CDA stands ready to work with you to combat the illicit e-cigarette market and support legitimate, responsible businesses that are working to uphold the law and prevent youth access.



June 12, 2024

Chairman, Dick Durbin
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Ranking Member, Lindsey Graham
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Durbin and Ranking Member Graham:

On behalf of the Board of Directors of the National Association of Secondary School Principals (NASSP), I write this statement to be submitted to the congressional hearing record regarding the urgent need for stronger enforcement from the Food and Drug Administration (FDA), the Department of Justice (DOJ) and its enforcement partners on combating the youth vaping epidemic by enhancing enforcement against illegal e-cigarettes.

NASSP would like to thank the members of the committee for holding an oversight hearing on the federal jurisdiction against unauthorized and e-cigarette products which has become an unmanageable situation for youth in schools across the country.

I currently serve as the Principal of Huntley High School in Illinois and member and former President of the Illinois Principals Association. NASSP, together with our student programs, the National Honor Society and National Association of Student Councils, represent tens of thousands of educators and over a million students.

As an educator and school leader, I witness firsthand the devastating and often traumatic impact of nicotine addiction, vaping, and vaping of illegal substances on our students' health, mental health, academic performance, and overall well-being. The proliferation of unauthorized and flavored e-cigarette products has fueled an epidemic in our schools, putting our youth at risk for lifelong addiction and other significant health harms. While facing an educator shortage, school administrators are already beyond their capacity while still having to serve as constant vaping monitors, and we are not equipped or trained to serve as drug abuse counselors.

As a building leader, the goal is to help our students become the best versions of themselves and provide them with a top-notch education. However, the job has changed significantly with the need to address students engaging in dangerous addicting activities at school. Whether it's a student experimenting for the first time or one who nearly loses their life due to an e-cigarette filled with THC, these situations have absolutely no place in the hands of youth and in school environments. Responding to near-death incidents is not the role of educators or staff, who are here to educate and support students.

Every child who is affected is only one of the [2.1 million middle and high school students who currently use e-cigarettes](#). This is beyond unacceptable, and we must take decisive action to protect our youth from the dangers of nicotine addiction and the long-term consequences of vaping. My students and millions across the country desperately need strong and coordinated enforcement against unauthorized e-cigarette products by the FDA, DOJ, and U.S. Customs and Border Protection. Despite FDA's efforts to deny marketing authorization for millions of flavored e-cigarette products, virtually the entire e-cigarette market consists of illegal products. And their numbers are only increasing, with larger volumes, higher nicotine strengths, and lower prices.

The marketing of these products faces little to no regulation, allowing businesses to target teens. As a community member and school leader, I've personally had to change barbershops because the vape store next door sells these harmful products to students and minors. Because I am committed to modeling student health and safety in my community, I will make every effort to take a stand against these businesses. I urge the members of this committee to stand up and do the same.

While using these products is a personal choice, it's unacceptable to subject kids to dangerous substances with enticing flavors and attractive packaging. These products are causing serious harm, and it is imperative to protect our youth from such deceptive marketing tactics.

Yet companies targeting students often receive little more than a warning letter. NASSP and educators call on the FDA to aggressively use enforcement tools, including civil monetary penalties (CMP), no-tobacco orders, product seizures, import restrictions, injunctive actions, and criminal prosecutions. Rather than sending a piece of paper companies can ignore with impunity, these powerful measures would clear the market of illegal and youth-appealing products causing the nicotine epidemic.

The FDA can further strengthen penalties by issuing civil monetary penalties commensurate with the harm companies are causing. Consistently issuing a single CMP with a maximum penalty of \$20,678 to a company selling thousands of illegal products does nothing to stop them from breaking the law and harming my kids and our communities.

The FDA is not the only agency that can do more. We urge the Department of Justice to prioritize tobacco product enforcement and streamline the process for seeking injunctions against unauthorized products. [The DOJ has only sought injunctions against seven manufacturers](#), and these few instances came months after warning letters. Every day these companies are allowed to illegally profit means more students fall victim to nicotine addiction.

U.S. Customs and Border Protection can also work with the FDA to stop the illegal importation of nicotine products, prioritizing their detection and seizure for the flavored products imported from overseas.

With its oversight powers, we ask this committee to do what is right for our children, to support policies and initiatives that prioritize the enforcement of existing laws against unauthorized and youth-appealing e-cigarette products. Our students' health and future depend on our collective efforts to address this public health crisis.

Thank you for prioritizing this important issue and for your partnership in providing solutions to protect the health of our students. If you need additional information, please contact Director of External Relations, Jen Silva at silvaj@nassp.org or 904-575-0447.

Sincerely,



Dr. Marcus Belin
Board Member
National Association of Secondary School Principals

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Marijuana and the Pediatric Population

Sadhana Dharmapuri, MD,^{1,3} Kathleen Miller, MD, FAAP,⁴ Jonathan D. Klein, MD, MPH

Cannabinoids, the psychoactive compounds in marijuana, are one of the most commonly used substances in the United States. In this review, we summarize the impact of marijuana on child and adolescent health and discuss the implications of marijuana use for pediatric practice. We review the changing epidemiology of cannabis use and provide an update on medical use, routes of administration, synthetic marijuana and other novel products, the effect of cannabis on the developing brain, other health and social consequences of use, and issues related to marijuana legalization.

abstract

EPIDEMIOLOGY

Cannabis is one of the most commonly used psychoactive substances in the United States.

In recent years, the increase in potency of cannabis (which includes a sixfold to sevenfold increase in tetrahydrocannabinol [THC] content), the proliferation of alternative forms of cannabis for consumption, and electronic vapor device use pose challenges to both public health and clinical practice.¹ In 2017, the Centers for Disease Control and Prevention Youth Risk Behavior Survey found that 19.8% of youth of high school age reported past-month marijuana use, and 35.6% had ever tried marijuana,² down from a peak rate of 47.1% in 1997. Synthetic marijuana use also declined, from 9% in 2015 to 6% in 2017. Although use has declined, youth who use marijuana often engage in other risk-taking behaviors that impact their overall well-being: for example, 13% of youth reported driving after using marijuana.² In 2017, ever use of marijuana among Black or African American (42.8%) and Hispanic (42.2%) students was higher than among white (32.0%) students. The prevalence of current marijuana use was also higher among gay, lesbian, and bisexual (30.6%) students compared with heterosexual (19.1%) and "not

sure" (18.9%) students. Older students had a higher prevalence of current marijuana use, with 13.1% of ninth-grade students, 18.7% of 10th-grade students, 22.6% of 11th-grade students, and 25.7% of 12th-grade students reporting current use. With legalization, marijuana use during pregnancy has become more common, with 7.1% of pregnant women reporting marijuana use in the past month and 3.1% reporting daily use.³

Only one recent study has examined the relationship between the availability of legal medical marijuana and use in adolescents. This cross-sectional survey of students whose school was within a 5-mile radius from a medical dispensary did not find increased use of marijuana among these youth.⁴ More studies are needed to determine the effect of proximity to medical dispensaries on marijuana use.

National surveys have found that youth who engaged in marijuana use in later teen-aged years (>17) were less likely to develop substance use disorders compared with those who started earlier. Positive attitudes toward school, parental monitoring, and strong disapproval of peer's substance abuse were found to be protective factors against substance use disorder.⁵

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Drs Dharmapuri and Klein drafted the initial manuscript and reviewed and revised the manuscript; Dr Miller reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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PHARMACOLOGY

Although a comprehensive review of pharmacokinetics and pharmacodynamics is beyond the scope of this review, it is helpful to summarize the kinetics of cannabis and common cannabis extracts and concentrates to aid clinicians in better understand the effects of various forms of cannabis on youth.

Cannabis occurs naturally as a plant, leading to production of cannabis products made of dried leaves, oils, and concentrates. Many cannabis products contain numerous substances, including terpenes, flavonoids, alkaloids, and >100 cannabinoids. There is no standardized form of cannabis; the presence and relative amount of various substances may differ between cannabis extracts as well as between products designed to be smoked or vaporized.⁵

The endocannabinoid system, composed of endocannabinoids and cannabinoid receptors, is widely distributed in the brain and spinal cord. This system has a regulatory role in many physiologic processes, including inflammation, appetite regulation, immune function, cardiovascular function, neural development, pain, the sleep and wake cycle, psychiatric disease, and others. Endocannabinoids, endogenous lipids with precursors that are present in lipid membranes, interact with endocannabinoid receptors CB1 and CB2.⁶ Being lipophilic, cannabinoids are rapidly absorbed.

Phytocannabinoids, plant-derived cannabinoids, can be categorized into several classes; δ -9 tetrahydrocannabinol (generally known as THC) and cannabidiol (generally known as CBD) are the most abundant and studied forms. THC is considered the main psychoactive component of the plant.

Phytocannabinoids affect users through their interactions with

endocannabinoid receptors CB1 and CB2 and related binding proteins in the nervous system. CB1 receptors are found in the central nervous system on neurons in the prefrontal cortex, basal ganglia, hippocampus, amygdala, hypothalamus, and cerebellum. CB1 receptors are also found in smooth muscle, myocardium, adipocytes, and preganglionic sympathetic neurons. The CB2 receptor is expressed in peripheral blood mononuclear cells as well as in the smooth muscle, myocardium, and vascular endothelium.

THC acts as an agonist at CB1 and CB2 receptor sites. Binding the receptor site reduces neurotransmission, producing effects such as impairments in learning, memory, spatial orientation, and attention and physiologic effects such as tachycardia. THC also has analgesic and antiinflammatory effects.⁷ CBD has weak affinity for CB1 receptors, does not interact directly with CB2 receptors, and does not produce the intoxicating effects of THC ingestion.

There is considerable variation in the pharmacokinetic profiles of THC and CBD between users, by cannabis dosages and forms, with acute and chronic use, and by route of administration. Smoked and/or vaporized cannabis has a rapid onset of action, with peak levels achieved within 10 minutes and greater bioavailability compared with oral ingestion. Bioavailability of THC ranges from 2% to 56% with smoked or vaporized cannabis and from 11% to 45% with smoked CBD. Oral absorption has more variability and lower bioavailability. The acute effects of ingested cannabis may last for several hours, depending on concentration, formulation of the product, and gastrointestinal motility, vascularity, and blood flow.⁵ Distribution of THC is time dependent and is immediate with absorption into fat tissue and highly perfused organs. Elimination half-life also

varies. THC has a fast initial half-life (6 minutes) and a longer terminal half-life (22 hours). Chronic users have longer elimination times, with THC present for >24 hours. CBD has a long terminal half-life, from 33 hours to 5 days, depending on the amount used.

Metabolism of THC occurs mainly in the liver by the cytochrome P450 system. CBD inhibits cytochrome oxidases; thus, it may interfere with other commonly used medications. CBD has a regulatory effect on THC, with the potential to decrease some adverse effects (ie, tachycardia, anxiety, and sedation).⁵

Drug interactions have been noted with the use of cannabis. For example, cannabis containing THC has been associated with increased rates of psychotic relapse and treatment failure.⁸ In an animal study, THC had a negative effect on the efficacy of risperidone.⁹ Drug interactions noted for CBD included increases in serum levels of antiepileptic drugs, resulting in sedation.⁸

Synthetic cannabinoids (SCs) are biochemically similar to THC and are used for both medicinal purposes and recreational purposes. Dronabinol is a schedule III drug and is approved for the treatment of nausea and vomiting associated with chemotherapy and for the treatment of anorexia and weight loss due to AIDS. Dronabinol typically comes in 2.5-, 5-, and 10-mg tablets and is taken 1 or 2 times a day in doses of up to 40 mg/day. Nabilone, a schedule II SC, comes in 0.25-, 0.5-, and 1-mg tablets, is prescribed up to 3 times a day, and is approved for chemotherapy associated nausea and vomiting.⁸

MEDICAL USES OF CANNABIS

The Drug Enforcement Agency has classified cannabis as a schedule I drug. This precludes cannabis being considered for legal medical uses, and therefore it is also not regulated,

except for dronabinol, nabilone, and CBD. Dronabinol and nabilone are SCs. CBD is a plant-derived product approved for use in children as a second-line treatment of 2 conditions: Lennox-Gastaut syndrome and Dravet syndrome.¹⁰

The medical conditions that CBD can be legally used for vary by state. Most studies examining CBD treatment of various conditions (cachexia or wasting, AIDS, cancer pain, etc) have been on adults. According to a National Academy of Sciences review, cannabis and cannabinoids are effective for the treatment of chronic pain in adults, are effective as antiemetics for the treatment of chemotherapy-induced nausea and vomiting, and are effective for improving spasticity in adults with multiple sclerosis.¹¹

Although some benefits of marijuana for treatment of behavioral conditions have been reported in animal studies, there are few studies in humans. In 2 case reports, authors noted benefits from dronabinol in children: one report of a 6-year-old boy with autism and the other of an adolescent with self-injurious behaviors.^{12,13}

The use of medical cannabis for treatment of inflammatory bowel disease (IBD) has increased in recent years. There is some evidence that cannabis may have antiinflammatory properties, improve IBD symptoms, and improve quality of life. However, in adults, CBD did not improve IBD pathology, and use of cannabis in pediatric IBD is not recommended.¹⁴

In a systematic review of cannabis for treatment of seizures, 4 high-quality randomized controlled studies found a reduction in seizures with the use of Epidiolex, a CBD product US Food Drug Administration (FDA) approved for treatment of Dravet syndrome and Lennox-Gastaut syndrome. Outcomes using other cannabis preparations were inconclusive.¹⁵ A few small, nonrandomized studies have suggested benefits from CBD use in

other seizure disorders, including Sturge-Weber epilepsy and febrile infection-related epilepsy; however, there is limited evidence for use in these disorders.^{16,17} Limitations of these studies include the following: use of other CBD products were not compared with use of Epidiolex, treatment time was short, studies had small samples, and CBD was added as an adjunct rather than as a first-line treatment.¹⁵ CBD was noted to provide seizure-free activity in a small proportion of children with Dravet syndrome. However, the authors suggest that a reduction in seizures may be a more realistic expectation with use of CBD rather than seizure-free activity.¹⁵

Parents and providers should be aware that there are limited studies addressing CBD use in children or adolescents and that there often is cross-contamination of CBD products with THC. Thus, CBD products may lead to positive urine drug test results for THC. This is especially important for adolescents required to take drug tests for sports or employment. Additionally, CBD products are unregulated, except for those drugs that are FDA approved.

DUAL USE OF CANNABIS AND TOBACCO

Population-based surveys from the 1990s revealed that most cannabis users were co-users of tobacco. Until the recent electronic cigarette (e-cigarette) or JUUL epidemic, there had been a steady decrease in self-report of tobacco use in youth. However, youth who smoke tobacco remain more likely to report marijuana use.^{18,19} Co-users in this study had lower academic performance compared with cannabis-only users and were more likely to be male than female. In this study, the authors speculated that the increased use of cannabis was associated with normative behavior, whereas tobacco use was perceived as riskier behavior. Another study

examining the co-use of tobacco and marijuana found that marijuana use was associated with greater nicotine addiction among adolescent smokers and that compulsion to smoke and preference to smoke were associated with marijuana use.²⁰ These authors hypothesized that smoking cues for one substance may trigger cravings for the other substance and lead to increased use in adulthood.^{20,21} They suggest that the association of marijuana use with tobacco use should be considered when developing prevention programs for both substances. Alcohol co-use with marijuana has also been identified in several studies. Alcohol has adverse effects on the developing adolescent brain similar to those for marijuana, such as poorer attention and executive functioning, heightened emotional reactivity, and poorer distress tolerance.²² A longitudinal study examining the effect of alcohol use on marijuana use found that alcohol was a significant predictor of cannabis initiation within a year. In their study, Terry-McElrath et al²³ found that co-use of marijuana and alcohol was associated with unsafe driving. They suggested that co-use of alcohol and marijuana in the context of driving should be explored when providing preventive care.

*The Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents, Fourth Edition*²⁴ highlights health issues to be screened for at health maintenance visits. Tobacco, alcohol, and drug risk assessment is recommended throughout the adolescent years.²⁴ The American Academy of Pediatrics (AAP) policy statement on substance abuse and prevention suggests that pediatricians become familiar with substance abuse screening.²⁵ The AAP recommends using short validated screeners to determine youth at risk.²⁵ One validated screener is the CRAFFT (car, relax, alone, forget, family or friends, and trouble), which screens to identify

youth aged 12 to 21 years old at risk for alcohol or substance use, driving or riding risk, and substance use disorder. CRAFFT 2.1 is an updated version of that incorporates opening questions that quantify the amount of use within the past 12 months, and CRAFFT + N includes an opening question on tobacco, including smoking and/or vaping use.²⁶ The tool is scored as low, medium, and high risk. CRAFFT 2.1 includes recommendations on how to discuss risk and how to contract for safe rides, which has been shown to decrease the risk of adolescents riding in a car with someone who has been drinking or using drugs.²⁶

MARIJUANA AND PREGNANCY

Marijuana is one of the most commonly used illicit substances in women, and the estimated prevalence of use among pregnant women in the United States ranges between 3% and 16%.²⁷ From 2002 to 2014 past-month marijuana use among pregnant women increased by 62%.²⁸ Legalization has increased accessibility and strengthened advocacy for its use, which may contribute to the increased use and perceived safety for pregnant women. Pregnant women are using marijuana for several reasons. In a Canadian survey, researchers found that 77% of medicinal cannabis use was for treatment of nausea. Half of the women surveyed reported using marijuana to treat poor appetite, pain, insomnia, or mood disorders (depression and anxiety).²⁸ Use of cannabinoids during pregnancy has led to health concerns related to fetal development because exogenous cannabinoids containing THC cross the fetal-placental barrier in humans.²⁹⁻³¹

The endocannabinoid system plays a major role in fetal development, and the concentration of CB1 receptors is higher in fetal brains than in adults.³² THC binds to the CB1 receptor

instead of endocannabinoids, leading to various neurodevelopmental changes. Animal studies of prenatal THC exposure provide strong evidence for these adverse effects.³³ In a review of several studies on prenatal marijuana use, investigators found a dose-response effect on fetal growth; increased use was associated with decreased growth.³⁴ It was unclear whether prenatal exposure had an effect on preterm births. In a meta-analysis of 31 studies on marijuana use during pregnancy, investigators found that maternal marijuana use and concomitant tobacco exposure contributed to adverse neonatal outcome.³⁴⁻³⁶ Marijuana exposure has also been associated with NICU admissions as well as with increased respiratory and neurologic infections and hematologic morbidity.³⁴

Animal studies revealed that even low levels of exposure to marijuana have adverse neurologic effects.³⁷ In a recent systematic review examining 7 longitudinal studies on the effects of prenatal exposure on neuropsychological function in children, investigators found varied results between the association of prenatal exposure to marijuana and a child's neuropsychological development at ages 1 to 11 years. The majority of studies demonstrated a negative impact of marijuana during pregnancy, including deficits in neuropsychological functioning, decreased attention, memory problems, and poor impulse control.³⁷ However, there were mixed results between studies, and the authors acknowledged that there may be confounding biases.

Another area of interest has been the relationship between breastfeeding and maternal marijuana use. Cannabis concentration in breast milk is related to the maternal dose ingested and frequency of ingestion.³⁸⁻⁴⁰ In 2 studies, authors investigated outcomes for infants exposed to cannabis from

breastfeeding. In 1 study, the authors found an association between marijuana detected in breast milk and decreased motor development at 1 year; however, the authors noted that this result could have been confounded by the use of marijuana during pregnancy. In the other study, authors compared breastfed infants exposed to marijuana and those not exposed to marijuana; these authors noted no differences in motor or cognitive skills at 1 year.^{38,39}

Human studies on maternal marijuana use have been limited, and most have been observational or retrospective, relying on patient self-report. These studies have been confounded by polysubstance abuse and had small sample sizes. At this time, a causal relationship cannot be established. However, because of the paucity of research, it is recommended that women refrain from marijuana use during pregnancy and breastfeeding. The American College of Obstetrics and Gynecology and the AAP recommend that breastfeeding mothers refrain from marijuana use.^{41,42} Standard of care for prenatal and postnatal visits should include screening for drug use, including marijuana use. Clinicians should be aware that women may also seek information on marijuana use in pregnancy and breastfeeding from other sources. Clinicians should try to ensure that patients have access to current evidence-based information about marijuana use.

ADVERSE EFFECTS FROM CANNABIS USE

The adverse effects of cannabis use are well documented. Adverse effects include distorted perception, poor concentration, psychosis, excessive vomiting, and addiction.

Endogenous cannabinoids have an important role in the control of neural circuits and structures in the prefrontal cortex and the hippocampus. During adolescence,

these circuits mature and regulate attention, executive functioning, and memory. Studies have revealed that the development and maturation of these circuits can be affected by cannabis, causing impairment in neurocognitive functioning.^{43,44} THC is a lipophilic substance with a long half-life that becomes distributed in various tissue, including the brain's myelin. It is released back into the bloodstream over the course of 5 to 95 days in individuals with heavy, regular use, meaning that neurodevelopmental changes can continue to occur for weeks to months after consumption.^{45,46} Of note, manufactured and synthetic marijuana products may have higher THC concentrations than naturally occurring products, which can lead to more intense and longer-lasting effects.

In a longitudinal study by Meier et al,⁴⁵ cannabis use >20 years was associated with neuropsychological decline, with worsening effects for long-term users. In another study, authors explored neurocognitive measures in adolescents with recent cannabis use disorder who were now abstaining and also found that younger onset was associated with lower overall neurocognitive function. Similarly, Meier et al⁴⁵ found persistent neurocognitive changes 1 year after cessation of cannabis use.

In a recent longitudinal study on marijuana use and adolescent brain development, researchers found that cannabis use had adverse effects on IQ and executive functioning.⁴⁶ This cross-sectional longitudinal study revealed differences in resting-state networks known to mediate executive functioning (left dorsolateral prefrontal cortex) and regulatory control (anterior cingulate cortex). Marijuana use was associated with declines in neural connectivity over time, especially in adolescents with cannabis use disorder.⁴⁶ In an Australian longitudinal study, authors

found that individuals who used before age 17 years old had a reduced odds of high school graduation and degree completion compared with nonusers. These individuals were more likely to have cannabis use disorder, were more likely to use other illicit substances, and had more suicide attempts.⁴⁷

Animal studies of cannabis use and psychosis have suggested a remodeling of brain structure due to effects on the endocannabinoid system. These changes are similar to changes seen in schizophrenia.⁴⁸ In a recent study by Di Forti et al,⁴⁹ the authors found that daily marijuana use and high-potency marijuana (THC content >10%) are the strongest independent predictors of whether an individual will have a psychotic episode. Initiation of marijuana use by age 15 years slightly increased the odds of having a psychotic episode, but this was not independent of potency and frequency of use. Individuals with daily use had a 3.2 times higher likelihood of developing psychosis compared with nonusers. Individuals who used high-potency marijuana were 1.6 times more likely to develop psychosis compared with nonusers.⁴⁹ Individuals who had both daily use and high-potency use were almost 5 times as likely to develop psychosis compared with nonusers. Further studies exploring frequency and potency of use and gene expression may help elucidate the neurobiology behind the development of psychosis due to cannabis. Physicians should be aware of the increasing potency of legal marijuana products; for example, the average THC content of marijuana sold legally in Colorado is ~18%.

Marijuana use has also been found to be linked to an increase in use of prescription pain medication (opioids). Individuals who used marijuana had a 2.78 increase risk of having an opioid use disorder.⁵⁰ Other

drugs associated with marijuana use include stimulants, cocaine, and injection drugs.⁵¹ In 2018, the Insurance Institute for Highway Safety and the Highway Loss Data Institute reported an increase in motor vehicle crashes in states that had legalized marijuana use. In one study comparing perceptions of impaired driving after alcohol use, young adults felt that marijuana use was safer than alcohol use for driving.⁵² However, study participants did not feel as knowledgeable about the effects of marijuana on driving.

Toxicity from consumption of marijuana has been documented in several case studies. Most individuals who experience toxicity have been exposed to high concentrations of cannabinoids. These individuals can experience adverse health effects, including sedation, respiratory depression, hyperemesis, and cardiotoxicity.

Marijuana use has also been associated with the positive health effect of decreasing nausea. However, chronic use can cause a paradoxical effect, leading to hyperemesis. Patients typically present with cyclic vomiting, nausea, and epigastric pain. Interestingly, these symptoms are often reported to be relieved by hot showers.⁵³⁻⁵⁵ Capsaicin has also been a successful treatment of hyperemesis.⁵⁵

A systematic review of unintentional cannabis ingestion in children and adolescents revealed rates increasing in states that had legalized marijuana.⁵⁶ The most common form of ingestion were cannabis resin, followed by cookies and joints.⁵⁷ Other exposures to cannabis included passive smoke, candies, beverages, and hemp oil. The most common sign of cannabis ingestion was lethargy. Ataxia, mydriasis, hypotonia, and tachycardia were also common presenting signs.⁵⁷

NEW WAYS TO USE

The traditional method of marijuana consumption has been to smoke the dry leaves of the plant. A joint is dried marijuana leaves rolled in cigarette paper. Blunts are marijuana leaves rolled in a hollowed-out cigar. Adolescent users may prefer blunts to joints because blunts hold a larger quantity of marijuana and burn slower. However, use of blunts is a health concern because of the co-use of cannabis and tobacco. In a study by Fairman,⁵⁸ the author found that blunt users had higher severity of current cannabis use-related problems, reporting more tolerance as well as spending more time getting, using, and getting over the effects of cannabis. Because of dual use of tobacco and cannabis in blunts, there is concern that those trying to quit smoking blunts could be at greater risk for relapse because of nicotine withdrawal symptoms.⁵⁸

Other forms of marijuana available for consumption include hashish (a plant extract containing psychoactive resins), hash oil (cannabis concentrate extracted from hashish), and dabs (also cannabis concentrate). THC content varies but is generally much higher than concentrations found in the plant. Typical THC content of the marijuana plant ranges from 12% to 20%. Products produced by using solvents (butane hash oil and dabs) have THC content ranging from 39% to 80%.⁵⁹ Nonsolvent-produced concentrates have THC concentrations between 39% and 60%.

Marijuana is also available as vaporizable cannabis concentrates, as edibles, or as liquids. Vaporizable concentrates include "shatter" (a brittle, translucent material made from marijuana plant materials and solvents), "oil," wax,⁶⁰ and "butane hash." Vaporizable cannabis concentrates contain 60% to 85%

THC, contain higher concentrations (compared with dried-leaf products), and can be consumed through vape pens, e-cigarettes, and dabs.⁶⁰ Dabs are concentrated butane hash oil consumed when the concentrate is heated to high temperatures and the user inhales the resulting vapor. In one study by Loflin and Earleywine,⁶¹ the authors examined why users preferred dabs and examined whether dab use was associated with more problems than traditional cannabis use. Study participants reported that dabs required fewer hits to achieve desired effects. Study participants did not feel that their use was associated with more problems, but dab use was more likely to lead to dependence and withdrawal.⁶¹

E-cigarettes have been advertised as safe and healthier than traditional cigarettes; sales of these devices have targeted adolescents. The 2011–2018 National Youth Tobacco Survey and the Monitoring the Future survey both identified increases in e-cigarette use in middle and high school students compared with other tobacco products.^{62,63} Eggers et al⁶⁴ explored use of cannabis through e-cigarette systems; cannabis use through e-cigarettes was higher among 11th-graders than ninth-graders and among youth with worse grades. In this study, the authors also found that use of cannabis through e-cigarettes (versus smoking blunts) had similar adverse effects on school performance. Both e-cigarette delivery of cannabis and blunt use were associated with greater tobacco use.⁶⁴ Physicians should consider methods of delivery when discussing cannabis use because e-cigarettes are a novel route of administration and appeal to youth who are not otherwise susceptible to cannabis via blunts or joints. The AAP 2015 policy statement on electronic nicotine delivery systems strongly recommends that pediatricians screen for and discourage vaping device use.⁶⁵

SCS

SCs, (eg, Spice and K2) have become popular recreational substances among young adults. These substances are plant-derived material adulterated with substances similar to synthetic THC. These are readily available for purchase online or in shops specializing in marijuana and tobacco paraphernalia. SCs are often marketed as safe, natural, herbal blends not intended for human consumption in attractive packaging. However, these products are not naturally produced. They are typically mass produced outside of the United States. They are typically dissolved and mixed with dried vegetation in an imprecise process. The dosing of one product batch can vary greatly from that of another batch. These products can also be contaminated with heavy metals, bacteria, and chemicals. For example, in 2018, 70 individuals experienced serious drug overdose in Connecticut from using synthetic cannabis that was contaminated with rat poison. Unlike THC, which is a partial agonist at CB1 and CB2 receptors, SCs are full agonists at CB1 and CB2 sites, increasing the potency of SCs.⁶⁶ This may account for the increased morbidity and mortality seen with the use of SCs compared with marijuana.⁶⁷

Serious adverse health effects have been documented with the use of SCs. Adverse effects include cardiac abnormalities, coagulopathies, and neurologic and psychiatric abnormalities.⁶⁸ Cardiac effects include tachycardia and acute myocardial infarction.^{69,70} A cardiac fatality was reported in a young adult after smoking SCs.⁷¹ Hematologic abnormalities due to long-acting vitamin K-dependent antagonist contamination of SCs have been reported.⁷¹ In a review of SC use, reports of acute kidney injury were noted. All individuals required hospitalization, and one individual required dialysis.⁷² Neurologic abnormalities are also well

documented. SCs have been linked to strokes, seizures, and psychiatric effects, including anxiety, agitation, suicidal ideation, and psychosis. The neuropsychologic effects of SCs, compared with marijuana, are enhanced because of the difference in SC action at CB1 and CB2 sites.

There can be significant variation in SC potency, which can lead to serious adverse health events. These compounds can be mixed with other psychoactive substances, (eg, ecstasy, bath salts, and others). SC detection is often difficult in medical settings, and typical drug screening is often not helpful. Providers should be aware of possible adverse side effects of SC and should have a high index of suspicion when patients present with symptoms that could be due to consumption of SCs.

MARIJUANA AND THE MEDIA

In 2019, marijuana was legal in 33 states for medical use and in 11 states for recreational use by adults. As legalization has increased, more and more information has appeared in mainstream press and social media discussing the benefits and risks of marijuana. Reports include discussion of different strains of marijuana plants, health benefit claims, adverse effects, where to purchase marijuana, how to obtain medical certification, where to use marijuana, and other topics. Thus, pediatricians should be aware of the information about marijuana use being disseminated through the media. Marijuana can be obtained through dispensaries for medicinal purposes with appropriate certification. Generally, patients need to consult with a physician and need to have a qualifying condition (which varies in different states). Depending on the state, they may be given an identification card, which allows them to purchase marijuana at a medical dispensary. The amount an individual may possess or purchase also varies by state. Medicaid and Medicare will

not pay for medicinal marijuana because the federal government prohibits the sale of schedule I drugs.

In general, consumers aged 21 years or older can purchase marijuana legally from recreational dispensaries. Although many cannabis purchases occur through traditional illegal face-to-face sales, cannabis products can also be purchased online, both through legal recreational use sales and illegal drug markets on the dark Web. Recreational sales are cash only in most states. Prices vary by product type, weight, and location of the sale. For example, a sativa-hybrid dried plant bought online costs \$60 per 3.5 g, and indica dried leaf bought from a recreational dispensary costs \$18 per gram.

A variety of marijuana products are available in recreational and medical dispensaries. Retail shops may display menus listing THC content, cannabis strain, and the mood or symptom relief it may provide. For example, Afgooey (indica strain), has 22.9% THC and is advertised as "manageable psychoactivity and a wide range of applications, including pain relief and sedation."⁷³ Although different strains may be advertised as sedating or invigorating, there is no scientific evidence to support these claims. These aspects of a product may be due to other components of the plant, such as terpene content.^{74,75} Further research is needed to accurately describe the effects of specific products.

Many people purchase medical and recreational marijuana online. In a 2017 *JAMA* study, authors found that nearly 70% of CBD products sold online contained higher or lower concentrations of the drug than was on their label. Some CBD products contained significant amounts of THC. CBD products sold for vaping were mislabeled 88% of the time, and THC was detected in 18 of 84 samples, some with enough to produce

intoxication.⁷⁶ It is important to counsel patients and parents about the THC content in CBD products and to note that they lack regulation by the FDA. Pediatricians should also refer to individual state laws for further information concerning purchasing, use, and possession of marijuana.

CANNABIS USE DISORDER

Monitoring the Future survey data suggest that most adolescents do not perceive marijuana use as harmful, addictive, or associated with withdrawal.^{77,78} However, 8% to 12% of marijuana users will develop moderate to severe cannabis use disorders. Additionally, animal studies reveal that marijuana can prime the brain to the effects of other illicit substances. Although less clearly delineated in humans, according to the Substance Abuse and Mental Health Services Administration, 4.2 million people in the United States had cannabis use disorder in 2017. The *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* defines cannabis use disorder as use of cannabis for at least 1 year with the presence of 1 or 2 other findings consistent with addiction and significant impairment of functioning and distress.⁷⁹ Although cannabis use can negatively impact the user's health, to date it has not been linked to fatal overdoses.⁸⁰⁻⁸² In addition, individuals can experience cannabis withdrawal. The *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* describes cannabis withdrawal as having ≥ 3 of the following signs and symptoms within the 1 week of discontinuing use: (1) irritability, anger, or aggression; (2) nervousness or anxiety; (3) sleep difficulty or insomnia; (4) decreased appetite or weight loss; (5) restlessness; (6) depressed mood; and (7) at least 1 of the following: abdominal pain, shakiness or tremors, sweating, fever, chills, or headache.⁷⁹

Being young, having a lower socioeconomic status, male sex, and being a minority increases the risk of developing cannabis use disorder.⁸³

Several treatments have been investigated for treatment of cannabis use disorder. In a review by Brezing and Levin,⁸⁴ the authors found several medication treatments that may be of benefit. Only one study was focused on treating adolescents: topiramate reduced marijuana use in adolescents but was not well tolerated.⁸⁵ In adult studies, gabapentin has been found to reduce withdrawal, reduce cravings, and improve cognitive functioning. Dronabinol and nabilone were also found to improve withdrawal symptoms and reduce cannabis use.^{86,87} Nabilone plus zolpidem also improved withdrawal symptoms and reduced cannabis use.⁸⁸ Limitations to the current studies include inclusion of individuals with severe cannabis use disorder and high attrition rates. Brezing and Levin⁸⁴ note that reduction in use, rather than abstinence, may be an appropriate goal for treatment of cannabis use disorder. However, there is no consensus in the literature defining a meaningful reduction in use. Although research on medications for cannabis use disorder continues; motivational and cognitive behavioral therapies continue to be the mainstays of treatment at this time.

CONCLUSIONS

Marijuana is one of the most commonly used psychoactive substances. The literature reveals a number of health concerns associated with marijuana use, from physical health effects to mental health effects, that can occur over the course of development and social consequences associated with use. It is important for providers to be aware of policies and laws around marijuana in their states to provide appropriate and evidenced-based

recommendations and to counsel appropriately to prevent exposure and thus harm to developing brains. The health and well-being of children and adolescents should be prioritized when providing this information. More research is needed on the long-term effects of marijuana and should also be focused on prevention of use in adolescents.

ABBREVIATIONS

AAP: American Academy of Pediatrics
 CBD: cannabidiol
 e-cigarette: electronic cigarette
 FDA: US Food and Drug Administration
 IBD: inflammatory bowel disease
 SC: synthetic cannabinoid
 THC: tetrahydrocannabinol

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2,110,150 is the estimated # of new nicotine vaping initiates in 8th through 12th grade for the 33 month period spanning September 2021 through May 2024.

Details on this estimate below.

Question text:

When (if ever) did you FIRST do each of the following things?

8="Never" 1="Grade 6 or below" 2="Grade 7" 3="Grade 8" 4="Grade 9" 5="Grade 10" 6="Grade 11" 7="Grade 12"

- a. Smoke your first cigarette
- b. Smoke cigarettes on a daily basis
- c. Try smokeless tobacco (snuff, plug, chewing tobacco, snus, dissolvable tobacco)
- d. Vape an e-liquid with nicotine (JUUL, e-cigarette, e-pen, etc.)

Students coded for having started vaping since start of school year if (a) in 12th grade and reported started in 12th grade, or (b) in 10th grade and reported starting in 10th grade, or (c) in 8th grade and reported started in 8th grade.

This question asked of a 5/6 randomly-selected sample in 8th grade and in 10th grade, and of a 2/3 randomly-selected sample in 12th grade.

The question on grade of first nicotine vaping added to the survey in 2020.

Table 1: Percentage of Student Population that Initiated Nicotine Vaping Since Start of School Year, by Time period and Grade

Year	2021	2022	2023	2024 ^a
Grade				
8th grade	5.1	5.1	4.1	2.9
9th grade ^b	4.3	4.9	4.15	2.6
10th grade	3.5	4.7	4.2	2.3
11th grade ^b	3.35	3.95	3.4	2.15
12th grade	3.2	3.2	2.6	2.0

^a Estimates for 2024 based on surveys collected through April 2024 (total n=16,601)

^b Estimate for this grade interpolated as average of estimates from adjoining grades.

Table 2: Number of Students that Initiated Nicotine Vaping Since Start of School Year in the 33 Month Period from September 2021 through May 2024, by Time period and Grade

Time period	9/21 through 12/21	All of 2022	All of 2023	1/24 through 5/24 ^a
Number of months	4	12	12	5
Grade				
8th grade	69180	209635	168530	49668
9th grade	59359	204975	173601	45318
10th grade	49155	200025	178745	40785
11th grade	44185	157875	135893	35805
12th grade	39472	119611	97184	31149

Total = sum of blue cells = 2,110,150

Source: Monitoring The Future

^a Estimates for 2024 based on surveys collected through April 2024 (total n=16,601)

Notes:

- Estimates use sampling weights to take into account complex sampling design of Monitoring the Future.
- Number of new initiates (blue numbers in Table 2) is % new initiates (see Table 1) multiplied by population size. Total # of students in 8th, 10th, and 12th grade are 4,110,489, 4,255,843, and 3,737,846, respectively. Number of students in 9th and 11th grade are interpolated (average of 8th and 10th, and 10th and 12th, respectively) and are 4,183,166 and 3,996,844.
- Analyses use MTF estimates collected from February through the end of May as an estimate for the whole year. This assumes average # of new initiates per month using estimates from February through May is a close approximation for average # of new estimates per month when using all 12 months (Colwell et al. 2006, "Variations in the Initiation of Smoking Among Adolescents" *Nicotine and Tobacco Research* 2006:239-43 doi: 10.1080/14622200600576503").