# AN EPIDEMIC CONTINUES: YOUTH VAPING IN AMERICA

## HEARING

BEFORE THE

SUBCOMMITTEE ON ECONOMIC AND CONSUMER POLICY

OF THE

COMMITTEE ON OVERSIGHT AND REFORM

HOUSE OF REPRESENTATIVES

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**Wednesday, June 23, 2021**

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND REFORM,
SUBCOMMITTEE ON ECONOMIC AND CONSUMER POLICY,
*Washington, D.C.*

The subcommittee met, pursuant to notice, at 10:01 a.m., 2154 Rayburn House Office Building, Hon. Raja Krishnamoorthi (chairman of the subcommittee) presiding.

Present: Representatives Krishnamoorthi, Porter, Bush, Speier, Johnson, DeSaulnier, Cloud, Keller, and Clyde.

Also present: Representatives Wasserman Schultz, Maloney, and Comer.

Mr. KRISHNAMOORTHI. Thank you so much for joining us this morning. We are starting on time.

So thank you, Mr. Cloud, the ranking member, for making that happen as well. I now recognize myself for an opening statement.

For the last year and a half, the deadly coronavirus pandemic has gripped all aspects of American life. As we see progress against the virus, we emerge with new insights about other threats to public health.

It's time to reevaluate the public health threats that are entirely within our ability to control. There was a youth vaping epidemic in this country before the coronavirus, before this subcommittee was even created, and before Acting Commissioner Woodcock took the helm at FDA.

And the youth vaping epidemic, unfortunately, continues today. More than 20 percent of high schoolers vape and five percent of middle schoolers vape. Those are the same levels that compelled the Surgeon General to first declare a youth vaping epidemic three years ago in 2018.

For as long as this subcommittee has existed, we have been investigating this epidemic. This is our fourth hearing on the matter, and I sincerely hope it is our last because the problems are solvable.

Our first in 2019 involved putting JUUL on trial, and exposing the disturbing scope of the company's behavior, its marketing to children, its attempted use of Native Americans as experimental guinea pigs, and its responsibility for fueling the youth vaping epidemic.

We presented evidence from our investigation to FDA and FDA agreed that JUUL was breaking the law. It sent JUUL a warning letter regarding its marketing practices and declared them illegal.

Now JUUL's fate is, again, in your hands at the FDA. JUUL's products and all e-cigarettes need FDA's approval for their products to stay on the market through what is called the Pre-Market Tobacco Application process, also known as the PMTA process, and FDA's decisions are due by September.

JUUL's marketing to children was simply unacceptable. The attorney general of North Carolina is taking JUUL to trial over that as we speak.

But beyond marketing, JUUL hooked kids for three other reasons. First, kids were attracted to the flavors JUUL cigarettes came in. Second, kids got hooked because JUUL came in nicotine levels much higher than anything else on the market. And third, JUULs were easy to conceal from adults.

Companies copied JUUL's model. When you look at the list of products that are on—that are the subject of PMTA applications, there are many, many even now, in kid-friendly flavors.

There are many that matches—match JUUL's high-nicotine formulation, and many that match JUUL's concealability.

To the FDA, I would say this. No matter what your decision is on JUUL's PMTA, you know that the problem does not end there. To end the youth vaping epidemic, you'll have to deny the applications for all products with the same characteristics that made JUUL so popular with a generation of children.

Because we have watched in real time that whenever a popular flavor is removed from the market, other flavored high-nicotine products take their place.

So I say to Acting Commissioner Woodcock, I believe you want to do the right thing, that you want to keep nicotine out of the hands of children. When you decided to ban menthol cigarettes, you took a strong action to strengthen public health and racial equity.

When this subcommittee exposed the prevalence of toxic heavy metals in baby foods, you made that issue a priority and created the Closer to Zero initiative, and we are appreciative.

However, now FDA has the opportunity to step up and finish the fight against the youth vaping epidemic. Don't let any flavored products from any e-cigarette company stay on the market, not mango and not menthol.

If you leave a single flavor on the market, kids will use it, and that will not be because of the destruction that occurred before you took the helm. It will be because of an affirmative decision that you and the FDA make.

Don't make that decision. Don't let any flavored products on the market. Don't let any high-nicotine products on the market. Other countries cap nicotine at one-third of what is in a JUUL. Those countries do not have anywhere near the youth vaping epidemic problem that we have in this country.

Do these things, and in the next three months we can help stamp out an epidemic. We saw this movie before with Big Tobacco and the opioid epidemic. Let's not let it happen with vapes. Have the courage to say no to Big Tobacco. The health of the Nation depends on it.

Thank you. I now recognize Ranking Member Cloud for your opening statement.

Mr. CLOUD. Thank you, Mr. Chairman.

We have known for decades that cigarette smoking is dangerous and linked to cancer and other illnesses. Smoking causes 480,000 preventable deaths in America each year. That's more than 1,300 deaths a day, and I cannot think of another product on the market where 50 percent of its users want to quit the product.

If you are under 21, you should definitely not use tobacco or begin using vaping products or, for that matter, any other drug or anything else nefarious you should put in your body. It's really important to understand that especially for young teens, if your bodies are still developing these products can have an even outsized greater negative impact on your body as you are—as you are growing and learning and those sort of things.

Unfortunately, as we have covered in past hearings, severely misguided marketing efforts contributed what has become a vaping epidemic among teens in communities across our Nation.

Social sourcing, coupled with nefarious counterfeit and black market products, found their ways in the hands of far too many teens and led to tragic and heartbreaking outcomes for far too many families.

We made some progress with the passage of T–21, but there is still more work to be done. There is some evidence—this is a new industry, and some evidence is coming forth that may lead—that vaping products could help with smoking cessation. If that is true, I hope the FDA will take a good look at the science based on it.

But we need to do everything we can to make sure that our youth do not have access to these products. I share, along with the chairman, our first role before being a Member of Congress is that of a father, and we do not want to see a world where kids have access to these sorts of products.

So, I want to thank you all for being here today. I want to thank you for attending this hearing. I want to thank you also, Dr. Woodcock, for appearing for us today.

I do hope that we will be able to have a good healthy discussion, that we will be able to hear from you, but also make sure we are not unduly influencing improperly a process that is supposed to be evidence based and, hopefully, it will be and that we will be able to do the right kind of—right kind of science of being able to divide how we can protect our kids yet if the science does point out that this is a smoking cessation device that we will be able to have the right adults have access to that product as well.

Thank you, Chairman, for this hearing. Thank you for your passion on this topic, and I yield back.

Mr. KRISHNAMOORTHI. I want to just applaud Mr. Cloud for being part of the bipartisan and bicameral congressional Caucus Against Youth Vaping, which myself, Senator Durbin, and others are chairing. So, thank you so much, Mr. Cloud.

Now, Chairwoman Maloney, thank you for being with us and thank you for your distinguished leadership of our committee. I want to just recognize you for a brief opening statement as well.

Chairwoman MALONEY. Thank you.

Our nation's youth are experiencing a public health crisis. According to data collected by FDA and CDC, more than 3 million high school students and a half a million middle school students use e-cigarettes, and according to the Office of the Surgeon Gen-

eral, an estimated 5.6 million children in this country will die early from a smoking-related illness if cigarettes—could continue to be used at this rate.

That is one in every 13 young people alive today. These numbers are horrifying. They threaten years of progress in reducing youth tobacco use, and the e-cigarette industry is to blame.

Companies like JUUL and Puff Bar knowingly and deliberately pushed tobacco products onto our Nation's youth. They deployed deceptive, dishonest tactics to get our young people hooked on these products.

They even went so far as to promote their products directly, in our Nation's schools. E-cigarette manufacturers have acted with a complete disregard for the health of young people across this country.

Their actions are appalling, and the Federal Government can no longer allow this industry to foster youth addiction as a long-term marketing strategy for its deadly products.

Our nation's regulatory agencies must take immediate action to turn the tide on this crisis. FDA can build on the steps it's taken so far by prohibiting the sale of remaining flavored products, capping nicotine levels in e-cigarettes, and pulling illegal products, like those sold by Puff Bar, off the market.

I strongly urge the agency to take these common sense steps.

Let me conclude by commending the leadership of Chairman Krishnamoorthi and the Subcommittee on Economic and Consumer Policy. The subcommittee's investigation has brought to light the dangerous practices of e-cigarette manufacturers across the country, and it has underscored the urgent need for the Federal Government to act on America's youth vaping epidemic.

Thank you for your leadership, Chairman Krishnamoorthi. I look forward to hearing the testimony and from all of our esteemed witnesses today.

And I yield back. Thank you for allowing me to be with you.

Mr. KRISHNAMOORTHI. Thank you, Chairwoman Maloney. Thank you for your distinguished leadership. Thank you for your opening statement.

Now I would like to begin by introducing our first panelist, someone I know very well, the distinguished senator from my—from my own home state of Illinois.

For decades, Senator Dick Durbin has fought to protect all Americans, including our society's most vulnerable, from the dangers of tobacco and e-cigarettes. His work dates back to leading the congressional effort to have smoking banned on airplanes, a measure that went into full effect in 1990, more than 30 years ago. Today, I am grateful to consider Senator Durbin a champion and a partner in our shared effort to curb youth vaping.

He is the Senate lead of the congressional caucus to end the youth vaping epidemic. He is the Senate lead of our legislation, the Tobacco Tax Equity Act, which will raise taxes on all tobacco products for the first time in over a decade to protect public health.

He is the Senate lead of the Prevent Act, legislation to create youth vaping prevention programs in schools, and this is just a small snippet of the work that Senator Durbin has engaged in, in this space, for decades.

Senator Durbin, in his spare time, is the Majority Whip, the chairman of the Senate Judiciary Committee, and a long-standing dean of the congressional delegation from Illinois. We are so fortunate to have him here today and thank him for his participation.

Senator Durbin?

**STATEMENT OF THE HONORABLE RICHARD J. DURBIN, UNITED STATES SENATOR**

Senator DURBIN. Thanks, Chairman Krishnamoorthi and Ranking Member Cloud, for allowing me to testify today on the youth vaping epidemic and the role of the Food and Drug Administration.

The campaign to reduce tobacco use and prevent our kids from lifetime addiction is personal to me. My father died from lung cancer. He was 53 years old. He smoked two packs of Camels a day.

As a young high school student, I will never forget how he struggled to breathe during my visits to the hospital in his last days. Cigarettes are responsible for 480,000 deaths every year in the United States. My family is, certainly, not the only one who can tell this story.

So, ever since I came to Congress, starting in the House, I have dedicated my career in public service to this fight, holding the tobacco industry accountable for its lies and deception, empowering families, schools, and health care providers to prevent kids from this addiction, and working to build and strengthen a regulatory framework that really does focus on public health.

When last I testified before this subcommittee in July 2019—it seems so long ago—most of our focus was on the skyrocketing rates of youth e-cigarettes, fueled by the kid-friendly flavors, aggressive promotion, and high nicotine concentration of the product.

Since that time, my office, this subcommittee, and the public health community have shone a bright light on the abusive tactics by JUUL that contributed to this foothold with our children.

We now have uncovered the disgusting tactics used by this company to addict our children on these e-cigarette products. I am pleased our public health and antitrust regulators have started to step in.

But what I want to focus today is the record of the FDA over the last several years, and the opportunity that sits before the agency today to correct its missteps in the past and put public health and kids at the forefront of its mission.

Flavored e-cigarette products have exploded in popularity among our kids, nearly 4 million now vaping, a 361 percent increase in just eight years, when only 800,000 kids were vaping.

One in five high school students use e-cigarettes. These alarming trends are erasing the historic progress we have made reducing youth tobacco use.

Who is the cop on the beat to whom we entrust our children? It's the Food and Drug Administration, and this agency has been timid and reluctant for way too long.

For years the FDA delay—delayed implementation of its requirement that companies submit PMTA applications for review.

At the same time, the FDA allowed cigarettes to proliferate essentially unregulated—e-cigarettes to proliferate essentially unregulated—failing to enforce its own Deeming Rule, which required

that all new products entering the market after August 8, 2016, undergo a public health review.

Since my last testimony, we had a glimmer of hope on that day in September 2019 when President Trump promised to ban all e-cigarette flavors.

As part of that, the FDA in January 2020 had a golden opportunity to finally clear the market of these addictive kid-friendly products, the vast majority of which were on the market illegally.

But instead, the Food and Drug Administration took a half measure, only partially clearing the market and leaving major loopholes for this powerful industry.

The result? Kids migrated to these loopholes, to the products that remained unregulated on the market, menthol-flavored e-cigarettes and disposable vaping products. The use of disposable e-cigarettes, one of the loopholes which the FDA lost, which were exempted from the FDA's January 2020 action, increased 1,000 percent last year.

Make no mistake, kids get it. If we don't take this seriously across the board, they will find those loopholes and continue their addiction.

And because the FDA allowed menthol-flavored cartridges from JUUL and others to stay on the market, listen to this, the use of these menthol-flavored JUUL products, cartridges, increased from 11 percent to 62 percent of the market. Another failure by the FDA.

Now we approach one of the biggest milestones in FDA tobacco regulation history, and I worry the agency is going to fail again.

After years of delay by administrations of both parties, the FDA, under court order, under court order, finally required e-cigarette and tobacco manufacturers to submit applications for their vaping products on September 9, 2020.

This is the long awaited opportunity for the FDA to apply a public health standard that Congress passed as long ago as 2009 in the Tobacco Control Act to evaluate whether a product can stay on the market and whether it is, quote, "appropriate for the protection of public health."

That is a high bar. It requires the FDA to balance the risk of youth initiation with potential benefit of adult cessation. And the burden is on the manufacturer. The burden is on the manufacturer to show their products will not lead to youth use, show their products do not harm the user, and to show they actually help adults quit smoking.

Remember that claim made over and over again? Prove it. It can't. They know they can't.

I am deeply troubled with what I have heard from the response of the FDA to my letters. I fear they are going to once again overvalue the unproven potential benefit of cessation for adult smokers, while undervaluing the clear evidence of what is happening to our kids.

Only four percent of adults use e-cigarettes. Twenty percent of high school students. Kids who never would have picked up a tobacco product are vaping.

It is simple. Any product with a history of increasing youth use must be rejected by the Food and Drug Administration, especially flavored products that we know hooks the kids.

This is the Super Bowl for the FDA's tobacco effort. I am afraid they are not ready for prime time. I hope they prove me wrong.

The FDA recently announced plans to ban menthol cigarettes, an important public health action, and I want to commend the acting commissioner who sits behind me on when she called me with the news.

But just like that step, the time is now for FDA to take meaningful action on how it applies public health standards to e-cigarettes. We know FDA's after-the-fact enforcement, warning letters, and perpetual game of whack-a-mole just doesn't work.

To put it bluntly, FDA slow walking and refusal to forcefully act has enabled these e-cigarette companies to addict a new generation of our kids.

It is time for the FDA to be a partner in public health, not a partner to Big Vape, and take these products off the market. As the subcommittee continues to examine the youth e-cigarette epidemic and the role of FDA, I hope we prioritize our kids.

Let me close with a personal note. It has been a few years, but I once served in this House of Representatives, in this building, in the House Appropriations Committee, and one day I decided to offer an amendment on a Transportation Subcommittee bill that I served on to ban smoking on flights of two hours or less.

Why did I pick two hours? Because one of the leaders on the Democratic side in the House Appropriations Committee, Martin Sabo of Minneapolis, was a chain smoker. And I asked him once, Martin, how long could you go without a cigarette? He said two hours, and that is what I put in the first bill. Flights of two hours or less, ban smoking.

What happened afterwards was incredible. Even with the opposition of the House Republican and Democratic leadership, I managed to get this to the floor, thanks to a man by the name of Claude Pepper, who was chairman of the Rules Committee, and basically ignored the Speaker's direction to give me a chance on the floor.

How about that? I had Bill Young of Florida, a Republican, as my co-sponsor. We went to the floor and we won. It shocked everybody that we won.

Why did we win? Because it turned out the House of Representatives was the biggest frequent flyer club in America, and they were sick of smoking on airplanes.

Well, eventually, we banded it on all flights going beyond two hours. I didn't know it at the time. I really didn't know at the time. That was the tipping point.

At that point, people said to themselves, if it is unsafe, if secondhand smoke is dangerous on an airplane, why is it safe on a train, on a bus, in an office, in a restaurant, in a bar, and the dominoes started to fall.

We are at a much different place in America today, because as a junior member of the House of Representatives I tried something that was considered politically impossible and it worked.

You can do the same thing. You have that power at your hands. I hope you will use it.

I know this hearing is an indication of your interest in the subject. Not only give the FDA the tools, but make them use it if they won't. Bring them around to the side of protecting public health. You'll be glad you did.

Thanks for letting me testify today.

Mr. KRISHNAMOORTHI. Thank you, Senator Durbin, for your excellent remarks, and we very much appreciate your second visit on this topic, hopefully your last.

Hopefully, this will be our last hearing, because now we are going to adjourn this panel and invite Commissioner Woodcock to come to the table and tell us how we are going to get the FDA to do the right thing here.

So, thank you. Thank you, Senator.

Clerk, could you please play the video that has been prepared for the public here?

[Video is shown.]

Mr. KRISHNAMOORTHI. Thank you for playing that moving video.

Good morning. We are now introducing panel two. We are joined today by the Honorable Dr. Janet Woodcock.

Dr. Woodcock is the Acting Commissioner of the Food and Drug Administration.

Commissioner, thank you for being with us today. I will begin by swearing in the witness. If you would please rise and raise your right hand.

Do you swear or affirm that the testimony you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

[Witness is sworn.]

Mr. KRISHNAMOORTHI. Thank you. Let the record show that the witness answered in the affirmative. Thank you, and please be seated. The microphones are sensitive, so please speak directly into them. Without objection, your written statement will be made part of the record.

With that, Commissioner Woodcock, you are now recognized to provide your testimony.

**STATEMENT OF DR. JANET WOODCOCK, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION**

Dr. WOODCOCK. Thank you, and good morning, Chairman Krishnamoorthi and Ranking Member Cloud. Thank you for the opportunity to be here today.

This is a very important issue to me. I am here today representing hundreds of staff at the FDA who are working every day to prevent kids from using any tobacco products, including e-cigarettes.

While I have only been in my current position for about six months, I have been with the agency in various capacities for over 30 years. While director of the FDA Center for Drugs, I played a central role in the agency's initial attempts in the early 2000's to regulate e-cigarettes under our drug and device authorities.

Particularly, I was worried that flavors would entice children to use these products and that would cause harm. The issue, ulti-

mately, was adjudicated in the 2010 Sottera court case, where the D.C. District Court ruled that products made or derived from tobacco could only be regulated under our tobacco authorities.

And now, as acting commissioner, I am happy to continue to work closely with my colleagues from the Center for Tobacco Products. It is a new day and we now have a tremendous opportunity and, indeed, a responsibility to keep and elevate kids at the forefront of our efforts to prevent death and disease from tobacco products.

With the September 9, 2020, premarket application deadline behind us, we are taking steps to transform the tobacco marketplace toward one where deemed new tobacco products on the market, like e-cigarettes, will have undergone careful, science-based review and oversight by FDA.

This is truly significant. We have received and initially processed submissions that cover more than 6.5 million products.

Congress granted us a vital public health tool with our premarket review authorities, and I can assure you we intend to use that authority to protect kids, and optimize public health as directed in the statute.

We are working furiously on application review in order to move on from sort of a Wild West, unregulated marketplace. We will complete thorough evaluations to ensure that any products that are granted marketing orders meet the statutory standard of appropriate protection of the public health, as Senator Durbin said, a high bar.

If data for a product do not clearly support that standard, which includes an evaluation of the impact on youth initiation and use, we will not issue a marketing order for that product.

At the end of the day, we are going to do everything we can to end the epidemic of youth use and prevent another generation of kids from becoming addicted to tobacco products.

Importantly, we are going beyond pre-market review. While the 2020 National Youth Tobacco Survey showed an encouraging and significant decline in youth e-cigarette use last year, there are still 3.6 million middle and high schoolers who currently use these products.

The epidemic of youth vaping threatens to undermine decades of progress in reducing the impact of tobacco on public health.

So, we are also focusing our enforcement efforts against any product where the manufacturer fails to take adequate measures to prevent youth access and any product that is targeted to youth, and we have been doing that.

For example, we have issued warning letters to companies for illegally marketing unauthorized and kid-appealing tobacco products, such as a backpack and sweatshirt with hidden pockets to conceal e-cigarettes or those that resemble smart watches or children's toys.

In addition, as of May 31, we have issued over 120 warning letters to firms selling or distributing unauthorized electronic nicotine delivery systems. That includes e-cigarettes that did not submit premarket applications by the September 9 deadline. Collectively, these companies have listed a combined total of over 1.2 million products listed with the FDA.

We are also expanding our critical public education efforts through the Real Cost youth e-cigarette prevention campaign. We are targeting over 10 million teens who have used or may use e-cigarettes.

The most recent impact assessments of the Real Cost are promising, indicating the various elements of the campaign have received over 5 billion views and that 75 percent of youth are aware and receptive to our ads.

Over time, increased exposure to the campaign is expected to increase population level shifts and youth beliefs about e-cigarettes.

As a science-based agency, we now support more than 145 e-cigarette research projects. This research helps us better understand and regulate these products and includes investigation of use behaviors, addiction, and health effects.

We also continue our yearly surveys and studies we undertake with Federal partners at CDC and NIH.

In closing, I give you my commitment and speak on behalf of my colleagues at the agency that we will do all we can to prevent kids from using tobacco products and to address the current youth vaping epidemic.

We will do the hard work, we'll support innovative and informative research, and make science-based data-driven decisions as we follow through on this very important aspect of our public health mission.

Thank you for the opportunity to testify. I appreciate the subcommittee's efforts on support of the agency and your efforts to protect kids, especially from the dangers of tobacco, and I am happy to answer questions.

Thank you.

Mr. KRISHNAMOORTHI. Thank you, Commissioner Woodcock. I now recognize myself for questions. If you could please put the first chart up.

Commissioner, I would like to start by directing you to the NIH Monitoring the Future survey data published in 2019 and 2020.

[Chart.]

This is a chart showing that among a subset of almost 9,000 high schoolers, this NIH study found that the percentage who said they have vaped in the past 30 days equaled 22.5 percent in 2019 and 22 percent in 2020.

Now, back in May 2019, you described youth e-cigarette use as a, quote, "alarming problem." Do you consider—I assume you continue to believe that sentiment, correct?

Can you repeat that? I think your mic is——

Dr. WOODCOCK. Yes, I do.

Mr. KRISHNAMOORTHI. At the same meeting in 2019, you said, quote, "E-cigarette use among youth also increases the risk that they will use combustible cigarettes," closed quote. You still believe that, correct?

Dr. WOODCOCK. I believe that is the case.

Mr. KRISHNAMOORTHI. According to FDA's website, quote, "Nicotine exposure during adolescence can disrupt normal brain development and may have long-lasting effects such as increased impulsivity and mood disorders."

You don't disagree, correct?

Dr. WOODCOCK. I don't disagree with that assessment. It is very concerning.

Mr. KRISHNAMOORTHI. Now, as you mentioned in your opening statement, you have received millions of applications under the PMTA standards, and one of the things that the FDA must assess is, quote, "the increased likelihood that those who do not use tobacco products will start using such products."

When youth who use e-cigarettes that might be subject to the PMTA process have an increased likelihood of using other tobacco products such as combustible cigarettes, that is a problem under the PMTA standard, right?

Dr. WOODCOCK. Yes.

Mr. KRISHNAMOORTHI. The PMTA standard also states that you must consider the, quote/unquote, "risks" to, quote, "people who would use/propose new tobacco products under the PMTA."

We just talked about the health risks to youth. I presume that, again, those health risks, those significant long-term health risks to youth, are, again, a problem under the PMTA standard, right?

Dr. WOODCOCK. Absolutely. That is the harm bar. That is the bar that has to be overcome by benefits in order to have a net benefit in the public health.

Mr. KRISHNAMOORTHI. Very good.

In your June 22 letter, so last night the good folks at FDA sent me a letter late, saying, quote, "The assessment of a new product's likely impact on addiction, especially among youth, is critical to determining whether allowing a new tobacco product would be, quote, 'appropriate for the protection of the public health.'"

And then the letter goes on to state, one of the issues bearing on your assessment of addiction was, quote, "the levels of nicotine in the finished product," close quote.

I would like to now present you with some documents that JUUL produced to our committee during this investigation.

I seek unanimous consent to enter Exhibits A, B, and C. Without objection, so entered.

Mr. KRISHNAMOORTHI. Clerk, can you please display the next slide?

[Slide.]

Dr. WOODCOCK. Thank you.

Mr. KRISHNAMOORTHI. This is a March 2016 JUUL document that was produced as part of their document production to us on this committee. It says, quote—this is an internal document from an employee at JUUL.

It says, quote, "Based on feedback from retailers, customer service, and social media, many consumers feel that five percent nicotine strength is too strong. Our current nicotine level in pods is much higher than other e-cigarettes."

And by the way, as you know, this five percent strength is the strength of current JUUL products. That was in 2016, five years ago.

Now let us go to 2018 when 20 percent of high school students and five percent of middle school students were vaping. Can you please present the next slide, Rich?

[Slide.]

Mr. KRISHNAMOORTHI. JUUL convened something called a Youth Advisory Council to ask why so many children are using its product. This is what Kim said. Kim said, "Very high concentration of nicotine." Then she had some other interesting comments there.

I didn't put this up on a slide but Brett said, quote, "Social acceptance to start addiction to nicotine" keeps them. Noah said, quote, "Social to start, nicotine to stay."

Besides this anecdotal evidence, Commissioner Woodcock, there is objective data that even as late as 2020 the National Youth Tobacco Survey that came out from the FDA shows an increase in nicotine addiction.

According to FDA, almost 40 percent of high school users are using an e-cigarette on 20 or more days out of the month. That is every two of every three days. These numbers are up from 2019 when that number was, roughly, 34 percent.

So, in your assessment of a new product's likely impact on addiction, going back to the standard that you set forth in your letter to me with regard to PMTA, you would be very concerned about youth perceptions, as well as the reality of a product's addictive qualities, correct?

Dr. WOODCOCK. Absolutely. That has to be in the forefront of our assessment of harm—potential harm.

Mr. KRISHNAMOORTHI. You would also be concerned about a company's knowing decision to keep its nicotine levels high, even in the face of internal employee as well as retailer feedback that it is too high?

Dr. WOODCOCK. Obviously, for substances that can cause addiction, exposure is very important, and higher exposure is a problem.

Mr. KRISHNAMOORTHI. And also you would be concerned about youth data showing that it is hooking or addicting kids, right?

Dr. WOODCOCK. Absolutely.

Mr. KRISHNAMOORTHI. When a company has such internal data and continues to keep its nicotine levels high, does that fact present evidence that the company intended to hook kids?

Dr. WOODCOCK. I guess that is—I am not a lawyer. So, that is beyond my area of expertise. I would say that the facts of the case show that this—these products had real dangers to kids.

Mr. KRISHNAMOORTHI. And the companies knew about the dangers?

Dr. WOODCOCK. According to what you show here, absolutely.

Mr. KRISHNAMOORTHI. In February 2020, FDA implemented a new—we call it flavor ban. There is a very much—there is a much longer title. You are familiar with that flavor ban, correct?

Dr. WOODCOCK. Yes.

Mr. KRISHNAMOORTHI. According to the policy, however, it made two exemptions. First, it made an exemption for tobacco and menthol flavors for JUUL and other cartridge-based devices, and then, second, it made an exemption for all disposable e-cigarettes to be in any flavor whatsoever.

Let us talk about menthol for a second, Commissioner. Can you present the next slide?

[Slide.]

Mr. KRISHNAMOORTHI. Forty-four percent of youth in 2019 used mint JUULs, and when mint was banned in February 2020 under

your partial flavor ban, guess what? Forty-four point five percent of youth used menthol JUUL.

So, we went from 44 percent of JUUL users using mint to 44.5 percent of JUUL users using menthol, and as Senator Durbin said in his testimony, 62 percent of all users, regardless of which company, ended up using menthol.

Now, Commissioner, this was before you became commissioner. But I spent an entire hearing in December 2019 with your colleague, Mitch Zeller, telling him that this was such a bad idea to create an exemption for menthol.

I said this is exactly what's going to happen. People are going to migrate from mint to menthol and that is what happened.

Now, I was so pleased that you banned menthol combustible cigarettes, which was the right thing to do. Will you pledge to clear the market of menthol e-cigarettes?

Dr. WOODCOCK. Again, I can't prejudge our decisions. What I can say is that menthol has additional properties, pharmacologic properties, that I believe potentiate the effects of nicotine addiction and make it harder to stop either vaping or smoking. And so it is, to my mind, like actually having a higher concentration of nicotine in your—whatever delivery system.

Mr. KRISHNAMOORTHI. Well, that is enlightening. It, basically, heightens the addictive properties of the e-cigarettes?

Dr. WOODCOCK. That is my belief, based on data. I don't think it is totally settled, but evidence shows it is harder for people who smoke menthol cigarettes to stop smoking, even though they smoke fewer cigarettes. Those facts are compatible with that hypothesis.

Mr. KRISHNAMOORTHI. Let us talk about disposable e-cigarettes.

According to the 2020 NYTS that you folks presented at the FDA, in 2019 only 2.5 percent of high school students—I am sorry, 2.5 percent of high school vapers used disposables.

But after FDA banned most flavors for cartridge devices but allowed all flavors for disposables, guess what? Disposable use surged to almost 27 percent in 2020. You don't dispute that data, correct?

Dr. WOODCOCK. No.

Mr. KRISHNAMOORTHI. The decision to exempt disposables, again, was made before your time as commissioner. Exempting disposable e-cigarettes was a huge mistake. Exempting them from the flavor ban was a huge mistake.

I assume that you consider that problematic. Will you pledge to close the disposables loophole in the flavor ban?

Dr. WOODCOCK. Again, I can't prejudge our decisions, which are coming up very quickly. However, I think this switch to a different alternative method of flavored cigarette rather than staying with the, say, tobacco-flavored JUUL shows—is another piece of evidence that the youth really prefers the flavors, and that that is a really important factor for the youth in sustaining their use of these products.

Mr. KRISHNAMOORTHI. And, in fact, the percentage of youth who use flavored e-cigarettes went up over the last year since the partial flavor ban. Now it is up to 80 percent of youth use flavored products, correct?

Dr. WOODCOCK. I can't remember all these numbers exactly. But it is a very high number. I believe it is 80 percent. Yes.

Mr. KRISHNAMOORTHI. Very good. Let me now recognize Ranking Member Cloud. And I am sorry, I went—I think we forgot to turn on the timer. So, we will give you some extra time here.

Mr. CLOUD. It is a liberal five minutes.

[Laughter.]

Mr. CLOUD. Thank you, again, for being here, and thank you, Chair, for the important discussion on this topic. As we all have agreed we don't want to see these in the hands of our kids and we want to see what we can do to have it.

You mentioned that some progress has been made in 2020 and that there has been some reduction in youth vaping according to the data now, and granted on whatever topic we are talking about, 2020 is a year that it is hard to really put any stock in a lot of definite data.

So, I am curious to know why you think that happened. Did the T–21 legislation that we passed have anything to do with that? Was it some of the administrative actions that were taken?

Also curious to know, as we are looking ahead, like we said, 2020 is kind of a hard year to be definitive about when it comes to data on any topic. But when we can expect to see data that we can kind of see if those trends are moving in the right direction, or if it was a blip because of COVID and all those kinds of things?

What are your thoughts?

Dr. WOODCOCK. Well, the data from surveys should come out. Hopefully, we will have some indication of that later this year to give us another year of data, I think, because the survey has already been conducted. So, the analysis must be done and so forth.

I believe that the apparent decrease last year was probably multi-factorial, and so it is hard to say what the contribution of any given factor was to children. A lot of them were home.

They weren't suffering as much peer pressure. They were very unhappy about not being around their peers. But a lot of them were not in congregate situations. And we heard from the film that you showed—we heard that peer pressure, and in this finder, that peer pressure was a very important factor in some of these kids using vaping products.

So, the ban on the T–21 I think is very helpful. FDA, though, had to stop its compliance checks in the middle of the pandemic because we used under-age children as part of the test subjects along with a trained adult to go in and attempt to purchase, and we couldn't send children into those circumstances with COVID.

But I will say that even before, even when we had the limit at 18, we saw thousands of cases where sales were made to underage, under 18, individuals. So, that's a problem out there that those are—that those retail outlets still will sell to underage individuals.

Mr. CLOUD. There has been a—I am a little concerned about the timing of this hearing. While I think it is a very important topic that we cover and you to be here is great, just because courts have frowned upon in the past Congress weighing in while there is an agency investigating or reviewing a topic. As a matter of fact, Pillsbury Company v. FTC held a congressional investigation cannot be focused on intervening in an agency's adjudicative function.

How are we going to make sure that today's hearing is informative for us, informative for the American people, but that your decisions are going to be evidence based? I noted some of the comments you made talked about what you believed to be the case but you didn't cite any data.

And I realize you have a team and a staff and you can't be expected on every topic you cover to know everything, but how are we going to ensure that as we move forward in this process that it is going to be evidence-based?

Dr. WOODCOCK. Well, as I said, I cannot, in this hearing, prejudge any decisions we will make or commit to any given actions. The Congress has laid out in statute what the statutory bar is for these—for this review program and the—and it is a rather high bar. I don't think that is a matter of dispute.

But, certainly, the agency scientists are hard at work at evaluating these applications against the criteria that are laid out in the statute, and that is the process that we will follow.

Mr. CLOUD. Are you—is there evidence coming to play that shows that there is a use for adults—now, we are talking over 21—to use vaping products as a smoking cessation device? Is there early evidence of that?

Dr. WOODCOCK. I think the studies are somewhat mixed, as far as how effective vaping is.

Mr. CLOUD. It is a new industry. So, I realize it is developing.

Dr. WOODCOCK. No company has come to the FDA Center for Drugs to go through the process of smoking cessation, right, which would be a drug indication and is a different process you would go through as a drug.

We have a number of cessation products on the market. They have all been shown in clinical studies to help people stop smoking, although the adherence to stopping smoking over years may not be that good.

But these, including certain drugs, as well as different nicotine products that people can use as nicotine replacement and help stop smoking.

In all those cases, people are urged to also get counseling or be in a program or something like that. That helps a lot of people with smoking.

So, none of the vaping products have been through that kind of process, which requires clinical trials to prove that you can actually allow—get people to stop smoking. I think most——

Mr. CLOUD. I think you could advertise it as that.

Dr. WOODCOCK. Pardon me?

Mr. CLOUD. That they could advertise it as that kind of product.

Dr. WOODCOCK. They would have claims. Then they would be a drug and they could advertise, absolutely. But they would also have to do toxicological studies on their products, inhaled products, and so forth.

So, in the statute for tobacco products that we are reviewing under says it also has a evidentiary statement in the statute that says, you know, there should be studies that should support the fact—the benefits, and those could be clinical studies or other type of studies.

So the burden, as Senator Durbin said, is on the manufacturer to show that by some studies and data that their product has some public health benefit.

Mr. CLOUD. I don't know if you would have this data handy. If not, it would be—I would be very curious to have your team look into it and see.

But, you know, as we—coming through this year with COVID–19 that is a respiratory illness, and we know that it affected, you know, particularly, seniors and other demographics particularly hard.

But there were some cases where young people were tremendously affected by it. Some died, while that was much more rare than other segments of our population.

Have you all cross referenced that with vaping to see if there was a connection to be susceptible? And then, you know, in the past, we have covered this in a number of hearings so we understood that there is a distinct difference even in the effect of black market products versus others.

Not that you should have any of them. You know, that is well established, I think, at least among us who are talking about this issue.

Have you—have you found any sort of connection?

Dr. WOODCOCK. Yes, I don't think the data are available to link COVID—severity of COVID or catching COVID by youth or having a severe case with vaping practices. I can get back to you.

We can look at what data might be available, but I do not think those data are available. Youth use of COVID usually wouldn't be in a medical record. I mean, the use of, excuse me, of vaping wouldn't be in the medical record. And so that is—then it is hard for people to make that connection.

Mr. CLOUD. Right. OK. Well, thank you. I yield back. Thank you, Chairman.

Mr. KRISHNAMOORTHI. Thank you, Mr. Cloud.

Now I recognize Congresswoman Porter for five minutes.

Ms. PORTER. Thank you very much, Mr. Chair.

Commissioner Woodcock, does the research clearly establish that flavored e-cigarettes appeal to children?

Dr. WOODCOCK. Yes, I believe it does.

Ms. PORTER. And in fact, the FDA banned non-disposable flavored e-cigarettes except menthol in order to, quote, "limit children's access to certain flavored e-cigarette products we know are so appealing to them."

Dr. WOODCOCK. Yes.

Ms. PORTER. But we are having this hearing because disposable flavored e-cigarettes and both disposable and non-disposable menthol products are still on the market, and the inevitable result of this is that e-cigarette use among high school and middle school students is incredibly high, 3.6 million children youth vapers in 2020.

Dr. Woodcock, are—of those middle and high school kids who smoked e-cigarettes, what percentage of them used flavored products?

Dr. WOODCOCK. I believe that eight out of 10 use—e-cigarette users report use of flavored products.

Ms. PORTER. That is what I have, too, right about 80, 83 percent, and that was an all-time high. So, if any flavor other than tobacco flavor of e-cigarette is left on the market, is it likely to encourage youth to start vaping?

Dr. WOODCOCK. The statutory bar that we are talking about is that harm, OK, the harm of——

Ms. PORTER. Oh, reclaiming my time. I am going to get to that balancing out.

Dr. WOODCOCK. OK.

Ms. PORTER. So, I am going to let you do that balancing.

Dr. WOODCOCK. Yes.

Ms. PORTER. So, you are going to have to balance. But what we are balancing on the other side is I want to establish. Any flavor of e-cigarette left on the market is likely to encourage youth to start vaping. And we have to balance that against some other things we are going to get to. Is that correct?

Dr. WOODCOCK. That is correct.

Ms. PORTER. And if the FDA banned all flavored e-cigarettes, would less kids continue to vape among those who have started, in your opinion?

Dr. WOODCOCK. Well, I can't predict the future. I think that might be likely. We also would have to, regardless, limit advertising and sales in targeting children and other practices.

Ms. PORTER. Well, if they are not on the market, it is tough to advertise that, right?

Dr. WOODCOCK. Well, yes.

Ms. PORTER. So, to summarize, if kids have the choices of any tasty flavor, they are going to go for it. And I am speaking to you from experience here as a mom of three school-aged kids.

If there were no watermelon snow cones, my kids are happy with blue raspberry. No blue raspberry, they will take mango. No mango, they will take strawberry. But if their only choice was a brown tobacco-flavored snow cone, they are going to walk away.

So right now, the FDA is analyzing what are called premarket tobacco product applications, and in short, and this is what you were hinting at, you have to decide whether or not an e-cigarette can bring or keep a product on market, and in doing that you have to do that only if it is appropriate for the protection of public health. That is the standard.

And what this means is the FDA is required, as you were saying, to balance youth vaping against any good that e-cigarettes might do in getting adult smokers to quit tobacco products.

Commissioner Woodcock, do you know what percentage of adult smokers use e-cigarettes instead of traditional cigarettes?

Dr. WOODCOCK. No.

Ms. PORTER. It is about 4.5 percent. So, we are talking about a very small fraction of adult smokers, in general, use e-cigarettes. And do you know of that small group of adult e-cigarette smokers, do you know what percentage prefer menthol or mango or if there is a blue raspberry over tobacco flavor?

Dr. WOODCOCK. No.

Ms. PORTER. So, a study in Great Britain—we don't have the study yet in the U.S.—found that 50 percent—56 percent of adult

vapers, people over 55, prefer tobacco. Do you know how many kids like tobacco flavor?

Dr. WOODCOCK. I believe it is a very low percentage, but I don't know the exact amount.

Ms. PORTER. Yes, 1.1 percent of youth vapers. I mean, the number of kids who like broccoli is many, many multiples of that. So, it is really important, I think, that you have that information as you go to do that.

The Surgeon General has said that there is zero real evidence—scientific evidence—that proves e-cigarettes, in general, help adults quit smoking. That is what the Surgeon General has said.

You have testified that kids are drawn to flavored e-cigarettes, based on the evidence, and as a mom of three hopefully non-vaping kids, this is pretty personal for me.

The only way to protect our kids is to deny premarket tobacco product applications for every flavored e-cigarette other than tobacco flavor. Will you commit to doing that?

Dr. WOODCOCK. As I have said already, I can't prejudge the scientific——

Ms. PORTER. Reclaiming my time. Dr. Woodcock, you may not be willing to do it. But I just want to make sure America understands you have the authority to commit today to preventing millions of kids from becoming addicted to vaping by making the decision and the commitment today to us.

And if you don't make that decision today in this oversight hearing, then the alternative is going to be years and years of delay while Congress tries to pass a bill and millions, millions more of kids getting addicted.

So, I appreciate—I hear you. You are not willing to make that commitment to youth today. But I do want the American people to understand you do have that power.

I yield back.

Mr. KRISHNAMOORTHI. Thank you, Congresswoman Porter.

I now recognize Congressman Keller for five minutes.

Mr. KELLER. Thank you, Mr. Chairman.

Youth vaping is an epidemic that puts the health of our children at risk. Even after the Federal minimum age of the sale of tobacco products was raised to 21 years old, and flavor bans were enforced in 2019, in January 2020, the CDC found that almost 20 percent of high school students vaped in the past 30 days. That is unacceptable. We need to focus on getting disposable e-cigarettes out of the hands of our children.

While tobacco itself is not an illegal product, we must ensure that guardrails are set in place for the overall health and benefit of all Americans, especially those too young to understand the danger.

These products are not subject to the same flavor guidance as closed-system electronic nicotine delivery systems. We need smart and targeted solutions for these problems.

So, Dr. Woodcock, I appreciate you being here today. Thank you for that. And I just was wondering, could you give us an update on what actions the FDA plans to take to protect the health and safety of kids, while taking into account the mom and pop or the

small operations around the country that require sensible regulations?

Dr. WOODCOCK. Well, according to the law and the court order that we are under, by September 9 we will come to a decision on these various applications that we have received, and they have to meet the bar that we have been talking about showing that, overall, having the product on the market is appropriate to protect the health of the public, which is a fair—fairly high bar, as we just heard.

So, we are—what we are doing is diligently working to get through—we got applications for 6.5 million products and, of course, some of them were from small businesses.

Now, we have given out a lot of assistance. We have a small business assistance. We have tried to help. But under the statute, these businesses must submit information that shows, among other things, that their products meet this bar and are appropriate for the protection of public health.

Mr. KELLER. Great. And looking at disposable e-cigarettes, you know, it is, clearly, a big part of the problem.

How can Congress and the FDA work together to keep our kids safe? You know, is there something we could do to help collaborate with the FDA? Some tools or things that we could do to help—be helpful and work together?

Dr. WOODCOCK. Well, I think Congress has passed the statute. We need to implement that statute. We are in the process of doing that for the deemed products and, hopefully, that will come to a conclusion very soon.

There are still—there are still problems. There are many problems with addiction. We have the—also we have the group of kids who are now addicted to nicotine that we probably need to think about ways how can we assist them in recovery, getting off of nicotine.

I think as the chairman said, there is evidence that early exposure to various addictive products or drugs will act on the brain in ways that may make it more difficult for these individuals to stop those behaviors.

So, if we—if we can get to the end of this activity, in addition, FDA hopes to get started again as the counties become—you know, the pandemic subsides in the U.S. to rigorously enforce the issues about sales to minors, because we found a large number of retail outlets selling to under-age people, even when that age was 18.

We do need to get our rule out about the T–21 that will change the photo identity standard. So, I think there are many additional things that can be done. But I think recovery is something we should also think about.

Mr. KELLER. Yes, absolutely. And I think we should be very careful as we set policy forward. I know there has been a lot of—a lot of talk across the Nation about recreational cannabis or marijuana. I think we should be careful about that, too.

We are talking about addiction. And while we are talking about making sure that our kids aren't exposed to this, I think some of the policies that are being discussed by policymakers on that front should also be taken into account, as we move forward.

I know that is not what we are here to talk about today. But I wanted to—addiction is a disease. It's not a character flaw like it might have been thought about back in the 1970's, and I think we need to be very serious and careful how we—how we move forward on things that are, clearly, now not legal for recreational use and I, certainly, wouldn't want to expand or I don't think our government should be expanding those things so that they would be available or more readily available to people, then also potentially being able to get into the hands of our kids.

So, I appreciate your time today.

Dr. WOODCOCK. Absolutely. You know, alcohol is probably one of the worst substances and, of course, it is also widely available as far as the toll of addiction on people.

Any substance that causes addiction—exposure is very important, how prevalent it is, how——

Mr. KELLER. I would say caffeine is probably one of the most addictive drugs, isn't it?

Dr. WOODCOCK. They have got nothing on caffeine.

Mr. KRISHNAMOORTHI. Be careful. Be careful, Mr. Keller. Be careful.

[Laughter.]

Dr. WOODCOCK. Yes. They have—epidemiologists have tried and tried, and I follow this and we have nothing on caffeine.

Mr. KELLER. I know. I did read somewhere where that is, like, the most addictive thing there is and because it is in so many things.

But I appreciate your time. Thank you.

Mr. KRISHNAMOORTHI. Congressman Keller, I was going to cut your mic right about there.

[Laughter.]

Mr. KRISHNAMOORTHI. But OK. Mr. Johnson—Congressman Johnson, you are recognized for five minutes.

Mr. JOHNSON. OK. Thank you, Mr. Chairman.

Commissioner, the FDA has received over 6 million premarket tobacco applications—tobacco product applications, or PMTAs. A significant number of those PMTAs were submitted by vape shops, which are required to submit a PMTA for every flavor that they mix.

This means that a single small vape shop might have applications for, say, 30,000 products. The multiplicity of vape shop PMTAs are the overwhelming majority of the 6 million PMTAs. Is that correct?

Dr. WOODCOCK. That is my understanding. Yes.

Mr. JOHNSON. And the FDA recently published the entire list of PMTA applications, and this committee has whittled down that list to the applicants who are most responsible for putting these vaping products into the hands of our children.

And when you do it like that, the list of the PMTA applicants goes down to about 44 companies, which is a much more manageable number, which the committee will share with you those 44 companies.

These are the pods and the disposables that are making their way into high schools and middle schools.

Commissioner, the FDA is under court order to finish ruling on applications by September 9th of 2021 but has signaled that it will likely miss that deadline.

Can you commit today to ruling on all of those applications from the 44 companies that create products that children are most likely to use by that September 9th deadline?

Dr. WOODCOCK. Well, I cannot commit. I have to see the list. I will tell you we have prioritized the—by market share so that we have made sure that we are looking at the companies with large market share that would have the most impact on——

Mr. JOHNSON. And how many of those companies have you identified?

Dr. WOODCOCK. Well, I think there are only about five companies that have the vast majority of the market share, and then there is a very large number of small, as you said, vape shops and other type of enterprises that constitute the rest.

Mr. JOHNSON. And can you name those five?

Dr. WOODCOCK. No. I am sorry. I can get back to you with that information.

Mr. JOHNSON. Well, can you commit to ensuring that their PMTA applications are all processed and ruled upon by the September 9th deadline?

Dr. WOODCOCK. I will commit to do everything I can to make sure that we have reviewed and finished all the high market share company applications, because that will have the most impact on this problem we are all mutually facing.

Mr. JOHNSON. Thank you. I would like to discuss further the details of the PMTA review process. The possibility that a company like Puff Bar might gain months of profit off children because of a backlog at the FDA is troubling and unacceptable.

If you fail to rule on all PMTAs from the five companies and the 44 companies with pod and disposable applications that the committee has identified by the September deadline, will you commit to pulling those products from the market until the applications have been reviewed?

Dr. WOODCOCK. Technically, the products are currently only marketed under enforcement discretion, and after the September 9th deadline, if they don't have an approved marketing authorization, they are, again, only on the market under enforcement discretion by the FDA.

Mr. JOHNSON. Thank you. Thank you.

JUUL dominates the prefilled pod market and its growth and market share has driven the rise in youth vaping rates. And yet, JUUL's PMTA application proposes lifting marketing restrictions after just one year, even though JUUL is currently on trial for marketing addictive and harmful products to children.

JUUL has proven untrustworthy to continue selling its products, and it has greatly contributed to the epidemic that we face today.

So, Madam Secretary, how could—I mean, is the FDA considering allowing JUUL products to be marketed again, or has it already made a decision to ban that practice or to continue to ban that practice?

Dr. WOODCOCK. Those—the products that we are reviewing have to be subject to a marketing application. Something that would be

newly introduced into the market would have to go through the review process, as I understand it.

Mr. JOHNSON. Has that happened yet?

Dr. WOODCOCK. Well, again, I can't discuss any single action that we might take. But——

Mr. JOHNSON. All right. OK. Thank you.

Dr. WOODCOCK. Yes.

Mr. JOHNSON. If an application cannot prove with scientific evidence that the product will not contribute to or increase youth e-cigarette use, will you deny the PMTA application?

Dr. WOODCOCK. That is one bar, and it would have to have—as the other prong of the evidence, it would have to have extremely compelling evidence that it was uniquely positioned to reduce people—to contribute to smoking cessation.

Mr. KRISHNAMOORTHI. The gentleman's time has expired. Thank you, Congressman Johnson.

I now call on Congressman Clyde for five minutes.

Mr. CLYDE. I want to thank Chairman Krishnamoorthi and Ranking Member Cloud for holding this hearing today.

This is my first hearing——

[Technical issue.]

Mr. CLYDE. Are we—are we getting some feedback here?

Mr. KRISHNAMOORTHI. Yes.

Mr. CLYDE. OK. Great. Thank you.

Though this is my first hearing on vaping products, I understand this is probably the fourth or fifth hearing in the last couple of years on this exact same subject, and I think I can speak for my colleagues on both sides of the aisle when I say that no one wants children to have access to tobacco products, including e-cigarettes and I want to thank the FDA for cracking down on enforcement against companies who are targeting children.

Dr. Woodcock, I understand that certain types of tobacco products are inherently less risky than others. For example, smokeless tobacco products are less risky than traditional cigarettes.

Would you agree with that assessment?

Dr. WOODCOCK. That is the likely conclusion of scientific evidence right now. It isn't definitive, but it is very probable.

Mr. CLYDE. OK. All right. Thank you.

Would you agree that marijuana is a more dangerous product than tobacco?

Dr. WOODCOCK. I don't know that a direct comparison has been made. I cannot answer that question.

Mr. CLYDE. OK. Well, marijuana is, certainly, illegal right now at the Federal level and tobacco is not. So, I would assume that, based on that fact alone, that marijuana is a much more dangerous product than tobacco.

Dr. WOODCOCK. Well, it depends on the tobacco. I mean, cigarettes are the number-one cause—preventable cause of death in the United States.

Mr. CLYDE. OK.

Dr. WOODCOCK. So, when you take that figure into account, the fact that marijuana, cannabis, is a Schedule I drug, it is apples and oranges. There is a great deal of mortality and morbidity from cigarette smoking, and that has been well established.

Mr. CLYDE. OK. Thank you.

While the health risks of tobacco is, certainly, a huge concern for my Republican colleagues and I, I find it interesting that all of my Democratic colleagues that were in office last Congress voted in favor of H.R. 3884, the Marijuana Opportunity Reinvestment and Expungement, or MORE Act of 2019, which effectively would legalize marijuana on a Federal level, and I think if my colleagues were truly concerned about the youth smoking epidemic they would not have voted for the MORE Act.

Further, I am concerned that our Chairman Krishnamoorthi recently sent a letter to the FDA to you, Commissioner—Acting Commissioner—asking to act to ban menthol cigarettes and e-cigarettes, and I quote from the letter, "The European Union banned menthol cigarettes a year ago," and the very last line of the letter says, "If you allow menthol-flavored cigarette sales to continue, you fail."

That is really strong language. So, you know, this hearing comes so soon after that letter being sent. That letter was sent on April 21.

But I am concerned that the committee's goal of this hearing is not to address the concern of youth vaping but to strong arm the FDA, you, ma'am, into banning menthol cigarettes and e-cigarettes.

So, Dr. Woodcock, is it true that the FDA is taking steps to prevent children from using e-cigarettes?

Dr. WOODCOCK. Yes.

Mr. CLYDE. Absolutely. Do you think that any of those steps are hampering the adult use of e-cigarettes for those who want to kick the habit of traditional cigarettes?

Dr. WOODCOCK. No.

Mr. CLYDE. No. OK. All right. Great. So, we think e-cigarettes are a safer alternative to traditional combustible cigarettes, at least that is what the science currently says, for those who are trying to quit smoking.

Do you believe that putting limitations on the amount of nicotine in e-cigarette cartridges would hinder adults from switching from the more dangerous combustible cigarettes to e-cigarettes?

Dr. WOODCOCK. I don't think we have concluded our deliberations on that particular factor.

Mr. CLYDE. OK. All right. Then going back to the decriminalizing of marijuana, with many states legalizing or decriminalizing marijuana, what are the FDA's plans to quell youth from participating in smoking marijuana?

Dr. WOODCOCK. I don't think the FDA regulates marijuana.

Mr. CLYDE. So, you are not—there is no—there is no—nothing that the FDA is doing in that regard?

Dr. WOODCOCK. Right now—currently, it is a Schedule I drug.

Mr. CLYDE. Right.

Dr. WOODCOCK. So, we would—we don't regulate it as a medical product. For tobacco Congress passed a special law that caused FDA to regulate tobacco products.

Mr. CLYDE. OK.

Dr. WOODCOCK. So, generally, FDA regulates food and drugs, medical products, devices.

Mr. CLYDE. Does the FDA have any concern with the legalization of marijuana?

Dr. WOODCOCK. Well, I think all in the biomedical community are concerned about availability and managing availability of any drugs that have the potential—you know, psychoactive drugs and so forth. Yes.

Mr. CLYDE. OK. All right.

Dr. WOODCOCK. And the potential impact on youth in particular.

Mr. CLYDE. Mm-hmm. I think it is a very, very dangerous path to go down, the legalization of marijuana. So, thank you very much.

And with that, I yield back.

Mr. KRISHNAMOORTHI. Thank you. Thank you, Congressman Clyde.

Now I recognize Congresswoman Bush for five minutes.

Ms. BUSH. St. Louis and I thank you, Chairman, for convening this critical hearing today. As a nurse, I know just how important health is for our young adults, whose minds and bodies are still growing every single day.

Vaping products by JUUL present an immediate threat to adolescent health. Nearly two-thirds of JUUL users aged 15 to 24 don't even know that JUUL contains nicotine, which can contribute to lung disease, heart disease, and partial brain damage.

The FDA must take drastic steps to ban the uses of—usage of JUUL products and minimize the negative impact on our youth.

Dr. Woodcock, Big Tobacco has a long history of twisting science to meet its needs—its needs. I was dismayed to learn that JUUL bought itself an entire issue of American Journal of Health Behavior to bolster its application for FDA approval. Twelve of the 13 papers in the Journal issue were either written by either JUUL employees or their associates.

So, yes or no, do you agree that the FDA should take into consideration the source of a supposedly scientific study before giving weight to its findings?

Dr. WOODCOCK. FDA always takes into account the source. Obviously, many of the studies of medical products are done by the sponsors of the products, and there are many safeguards that are put into place.

So, we look very carefully at validity of any data that might be published.

Ms. BUSH. So, because it was 12 of the 13 papers in one journal, how can the FDA trust the scientific method and the conclusions of the 12 scientists who were directly funded by JUUL?

Dr. WOODCOCK. Well, I think we have many sources of information, that only being one, and as we have been discussing in this hearing, the statutory bar that the Congress has put into place is a pretty high bar, and we must look at all sources of evidence, and any evidence that is sponsored by the company gets additional scrutiny.

Ms. BUSH. OK. So, will the FDA take into consideration these possible conflicts—like, look at it this way—these conflicts of interest is what I call them—before giving any weight to JUUL's scientific conclusions in their Premarket Tobacco Product Application? Just a yes or no answer for that one.

Dr. WOODCOCK. Yes.

Ms. BUSH. OK. And will you consider Big Tobacco's history of creating junk science to serve its needs while reviewing JUUL's application, yes or no?

Dr. WOODCOCK. Yes.

Ms. BUSH. OK. Thank you for those. Thank you. Thank you. Thank you for that, Dr. Woodcock.

After many years of Big Tobacco lying to people about the safety of its products, I will hope that the FDA will take these—this cautious approach to research bought and paid for by an e-cigarette company.

The U.S. saw a near 30 percent decline in youth vaping rates in 2020. So, Dr. Woodcock, do you believe that additional FDA regulations on vaping products will be effective in curbing youth vaping rates even more?

Dr. WOODCOCK. I believe that we have to do something. I mean, we can't continue with this epidemic. It is very dangerous to children.

Ms. BUSH. Yes. Yes, and that is—that was my next thing, just the—considering the impact that these products have on children, especially middle and high school children. Like, is that a big part of the consideration, like, that group specifically?

Dr. WOODCOCK. Absolutely. That is one of the statutory standards that we have to look at, which is the potential for harm, particularly children, in using these products.

Ms. BUSH. Right. Well, yes, and because we know that—because JUUL is really popular among teens—amongst teens, but that research surveyed—the research only surveyed adult use of its products.

And so, you know, as policymakers we must be equipped with our current—with the current data, the accurate data about vaping products to protect our health and the health and safety of our—of our children.

And let me just ask, despite not having the answer to everything that we want right now at this moment, but JUUL's paid researchers concluded that e-cigarettes would save lives.

So, Commissioner, do you agree that the FDA should closely evaluate these scientific claims from Big Tobacco regarding its impact—its full impact on public health?

Dr. WOODCOCK. Absolutely, and I would reiterate that we have other sources of information, including a lot of studies we have sponsored under our programs.

Ms. BUSH. OK. Thank you.

The information provided by JUUL does not meet the levels of scientific rigor required by actual peer-reviewed studies. So, if we don't know the potential harms of e-cigarettes, there is not enough information available to predict their impact on public health, especially our vulnerable youth.

But what we do know, is that e-cigarettes have hooked a generation of young people on nicotine. The FDA has an obligation to intervene and protect our children.

Thank you, and I yield back.

Mr. KRISHNAMOORTHI. Thank you, Congresswoman Bush.

I would like to recognize our distinguished ranking member of the full committee, Mr. Comer.

Mr. COMER. Thank you, Mr. Chair.

And, Dr. Woodcock, youth smoking cigarettes is at an all-time low and their use of e-cigarettes has significantly declined over the past couple of years as well.

Do you agree that the passage of T–21, which raised the minimum age for tobacco purchases from 18 to 21, has contributed to this downward trend?

Dr. WOODCOCK. I don't know. I would hope so. We have a lot of data that many vape shops and other outlets continued to sell to under-age use, even when it was at 18.

Mr. COMER. While overall youth use has declined for both combustible and e-cigarettes, there has been an increase in youths using flavored disposable e-cigarettes.

Other than sending warning letters to several companies marketing flavored disposables in 2020, what has the FDA done to prioritize clearing the market of these types of flavored products, particularly those who have not submitted their PMTA?

Dr. WOODCOCK. Well, we have further actions that we can take after a warning letter, though, to my knowledge, those have not been taken yet.

Mr. COMER. Have you taken those actions yet?

Dr. WOODCOCK. No, not to my knowledge.

Mr. COMER. Prohibition didn't work for alcohol. Yet, many of my colleagues argue that prohibition is not working for marijuana.

Wouldn't it make more sense for the FDA to achieve the intended health benefit by spending time and effort getting more reduced harm nicotine products to market, and educating smokers about the benefits of switching their nicotine source while continuing to drive down smoking rates with education and efforts to support total cessation?

Dr. WOODCOCK. Well, I believe the FDA is working in all those areas to try and, you know, have campaign—anti-smoking campaigns along with the CDC. Smoking is continuing to decrease, combustible smoking, so that is very good.

We are very interested in additional smoking cessation products, that there are quite a few of those on the market, and other methods for recovering such as digital health methods and so forth are under investigation.

So, hopefully, we can get addicted adult smokers off of combustible cigarettes. That should be a goal.

Mr. COMER. OK. One of the biggest problems we face here is not from the legitimate companies who have filed their PMTAs, but from bad actors who are taking advantage of our current regulations and selling vaping products containing vitamin E acetate, found mostly in THC, not nicotine products in illicit markets.

These illicit products have been known to cause serious illness or death. My question, what steps is the FDA taking to crack down on these kinds of illicit market e-cigarettes and are imports from other countries like China playing a role in these illicit markets?

Dr. WOODCOCK. Yes, and we, certainly, work with Customs and Border Patrol. We have seized fraudulent products coming from China, among other places. We make every attempt to keep these from crossing our border.

We also, of course, do send warning letters, many of the warning letters to companies who failed to submit applications. They did then submit an application in response to that warning letter.

Mr. COMER. That is one thing I want to remind everyone that is paying attention to this hearing, that if they are flavored, like the cotton candy brand and all that that has been banned, if they are still on the market, those are illegal.

Dr. WOODCOCK. The——

Mr. COMER. Pods and stuff that are being sold, right?

Dr. WOODCOCK. Right. Right. The cartridge—the cartridge. Yes.

Mr. COMER. The cartridge. Right.

What is the enforcement action process the FDA takes against companies and individuals that sell illicit e-cigarettes?

Dr. WOODCOCK. Well, our steps would be—these are illegally on the market and so our steps would be a warning letter and then potential other civil actions against them, including injunction.

Mr. COMER. Do you know to date how many companies the FDA has issued warnings to?

Dr. WOODCOCK. Yes, probably somewhere in my facts here. It is quite a—it's a very large number of warning letters.

Mr. COMER. OK. Let me ask you this while you are—you can get that answer to me. How many products has the FDA removed from the market through enforcement action?

Dr. WOODCOCK. That I don't know. I can get back to you an answer to that question.

Mr. COMER. OK. And I am about to run out of time, Mr. Chairman. I have one more question.

I understand that the FDA has a very large number of product reviews and applications which have been filed and are subject to the September 9th deadline.

From a pragmatic standpoint, how and when might the FDA communicate to the public and to the applicants about the status of those products?

Dr. WOODCOCK. So, we have listed all the products that have been submitted and made it through the initial, you know, filing process and those are listed online, and they all have a September 9th deadline under court order to be—for us to make a marketing decision about them. Does that answer your question?

Mr. COMER. Somewhat. I may have a followup or two, if you don't mind, afterwards—after the hearing.

Dr. WOODCOCK. Certainly.

Mr. COMER. But my time has expired.

Mr. Chairman, I yield back.

Mr. KRISHNAMOORTHI. Thank you, Mr. Comer.

And I just want to associate myself with the comments about the enforcement actions. There is a perception and reality that too many warning letters are sent and not enough enforcement action is taken. So, that is something that I hope that you will take under advisement.

Without objection, Congresswoman Wasserman Schultz shall be permitted to join the subcommittee and participate in questioning the witness.

Congresswoman Wasserman Schultz, you are recognized for five minutes.

Ms. WASSERMAN SCHULTZ. Thank you, Mr. Chairman. I appreciate the opportunity to waive onto the committee today.

And Dr. Woodcock, it is a pleasure to be able to talk with you. I know you know that youth e-cigarette usage remains at epidemic levels, and I know I and my colleagues—many of my colleagues here have worked hard through legislation and repeated calls to the FDA for proactivity in science-based policies.

In fact, my colleagues and I wrote to you on March 23 asking that the FDA end its enforcement exemptions for both menthol and disposable e-cigarettes, and clear the market of all flavored e-cigarettes until properly reviewed.

We also asked FDA to deny any premarket tobacco applications for flavored e-cigarettes and deny authorizing the marketing of any e-cigarette that poses an increased risk of youth addiction.

I trust that we will be getting an answer and the responsive actions are forthcoming. I certainly hope so. I look forward to hearing back from you to that letter. I have several questions though, concerning high nicotine content and how this has worsened this crisis for our Nation's youth.

Dr. Woodcock, are you aware that jurisdictions like the European Union, the U.K., and Israel capped the amount of nicotine allowed in an e-cigarette at 20 milligrams per milliliter?

Dr. WOODCOCK. Yes.

Ms. WASSERMAN SCHULTZ. Do you agree that these countries have helped reduce youth e-cigarette use by capping nicotine levels?

Dr. WOODCOCK. It appears that way.

Ms. WASSERMAN SCHULTZ. In the U.K., 94 percent of kids have never vaped and only 1.8 percent of youth are using e-cigarettes more than weekly. Because of the lower nicotine levels, even JUUL isn't popular with kids in the UK.

In the U.S., there is no limit to nicotine levels in e-cigarettes. JUUL has 59 milligrams per milliliter of nicotine, three times the U.K. amount.

Yes or no, would fewer kids become addicted to e-cigarettes if there were no e-cigarettes in the U.S. over 20 milligrams per milliliter of nicotine?

Dr. WOODCOCK. Likely yes.

Ms. WASSERMAN SCHULTZ. Likely yes. In reviewing PMTAs, will you commit to considering how dangerous high-nicotine e-cigarettes are to public health, compared to lower-nicotine e-cigarettes?

Dr. WOODCOCK. That is, certainly, part of the statutory framework. Yes.

Ms. WASSERMAN SCHULTZ. OK. So, you are reviewing that?

Dr. WOODCOCK. Yes.

Ms. WASSERMAN SCHULTZ. And the possibility exists that you would lower the allowable level of nicotine?

Dr. WOODCOCK. Again, I can't comment on what actions we are going to take. That——

Ms. WASSERMAN SCHULTZ. Well, if you are reviewing the possibility exists, presumably. The high nicotine levels in JUUL and other e-cigarettes are leading to not just increased youth vaping, but increased youth addiction.

Does the use of nicotine by adolescents have negative health consequences?

Dr. WOODCOCK. Undoubtedly.

Ms. WASSERMAN SCHULTZ. Over half of 18-to 24-year-olds who vape never smoked cigarettes. Vaping introduced and hooked them on nicotine. That is evidence of the products as an on ramp, not an off ramp, to nicotine use, isn't it?

Dr. WOODCOCK. Yes.

Ms. WASSERMAN SCHULTZ. The only reason to authorize a PMTA for a high-nicotine tobacco product is if there is overwhelming evidence that it is necessary for adult smokers to quit smoking, and the product is not likely to be used by youth.

But that has not been the real-world experience of JUUL on the market. First, adults don't use JUUL. Kids do. JUUL is the preferred brand of just 5.6 percent of adult vapers but 41 percent of youth vapers, and while JUUL was helping to fuel an epidemic of youth e-cigarette use, there was no discernible decline in adult smoking rates.

Second, adult smokers don't need high-nicotine e-cigarette—higher-nicotine e-cigarettes. In one study that JUUL purchased, as Congresswoman Bush mentioned, they purchased it for its PMTA.

Its researchers found that smokers transitioned away from cigarettes to JUUL at the same rates, whether using JUUL's three percent nicotine product or its five percent nicotine product.

So, Dr. Woodcock, if that is true, there would be no reason to approve their five percent product, correct?

Dr. WOODCOCK. The statutory requirement is that—the prong about that it would help in some way protect the public health, right, encouraging smokers to transition. So, there has to be an incremental benefit there, right, in order to outweigh the harms.

Ms. WASSERMAN SCHULTZ. But, again, if researchers found that smokers transitioned away from cigarettes to JUUL at the same rates whether they were at three percent nicotine or five percent nicotine in their products, then that would show that there is no discernible difference and a lesser—a lower nicotine level would be appropriate.

Dr. WOODCOCK. Those are the kind of data that need to be evaluated. Absolutely. Yes.

Ms. WASSERMAN SCHULTZ. OK. But that would seem, based on what you just said, that—what the logical result should be. To be clear, you should reject all of JUUL's products, all of them, given what we know about how JUUL marketed and addicted kids to their product.

And I encourage you to reject every PMT application for products over 20 milligrams per milliliter. It is very clear that there is a direct correlation to a precipitous drop in youth vaping when you have a much lower—not 59 milliliters, but 20, and that there is no discernible difference whether you have a higher-nicotine product in the reduction in smoking by adults.

So, that would seem to me, in the statutory framework that is established by the FDA, to really result in those decisions being made as a result of the evidence.

So, thank you, Mr. Chairman. I appreciate the indulgence. I yield back.

Mr. KRISHNAMOORTHI. Thank you, Congresswoman. I would like to now recognize Congressman DeSaulnier for five minutes.

Mr. DESAULNIER. Thank you, Mr. Chairman, and thank you for your attention to this issue and your passion for it. It is—as you know, I feel very strongly that the actions of JUUL is despicable.

Being from Northern California, I am proud of what we did, both at the state level and local level, to partner with legislators and local government around the country to really make a significant positive impact on the public health issues around smoking, and to see a San Francisco-based, Bay Area-based company whose founders graduated from the School of Design at Stanford, do what they did is, as I say, despicable, and we shouldn't be talking about allowing them, from my view, the ability to continue to market and distribute this product to young people in particular, but we should be personally holding them accountable.

But, Commissioner, in 2018, the Surgeon General declared a youth vaping epidemic, 2018. Youth vaping rates in 2020 were the same as in 2018. As we know—and we know what started it. Between 2017 and 2018, the number of high school vapers doubled from 12 percent to 29 percent. In the same period, JUUL's market share grew from 29 percent to 76 percent.

In November 2018, the Center for Disease Control confirmed the obvious, pointing to JUUL as the cause of this surge. Even after taking away all of its flavors, except menthol and tobacco, over a million children are still using JUUL, still getting addicted to JUUL and a lifetime consequence of that.

It is still the most popular youth vaping brand, used by 40 percent—41 percent of youth vapers, and research shows that many of these young people are unaware of the danger that they are exposing themselves to.

So, Commissioner, do you agree that by the metrics I have just mentioned we are still experiencing a youth vaping epidemic?

Dr. WOODCOCK. Yes.

Mr. DESAULNIER. Do you agree that JUUL is the e-cigarette company most responsible for creating this epidemic?

Dr. WOODCOCK. That is how it would appear.

Mr. DESAULNIER. In ruling on premarket tobacco product applications, will you commit to considering past bad acts in marketing to children and popularity with children when you go through your decisionmaking process?

Dr. WOODCOCK. We have to adhere to the criteria laid out in the legislation that Congress passed and we will do that. If you are talking about the validity of data that is submitted to us, we take a very close look at the validity of the data.

Mr. DESAULNIER. I appreciate that. If there are changes to the statute that you think would help you to enforce the spirit of the legislation, I would—I would greatly appreciate communicating with you.

Do you agree that a nicotine product used by 41 percent of youth vapers is hurting the overall public health for generations to come?

Dr. WOODCOCK. Most likely it is hurting that generation. I can't comment on generations to come, but it is definitely a public health problem of significance.

Mr. DESAULNIER. Thank you, Doctor.

Do you trust the tobacco—the Tobacco Products Scientific Advisory Committee and their advice?

Dr. WOODCOCK. Which—which advisory——

Mr. DESAULNIER. The Tobacco Products Scientific Advisory Committee.

Dr. WOODCOCK. This is the FDA committee or——

Mr. DESAULNIER. Yes.

Dr. WOODCOCK. Likely I do. I am not familiar with this committee. I am sorry. I'm kind of new to my job.

Mr. DESAULNIER. OK. I am happy to provide for the record more information on that.

Dr. WOODCOCK. Certainly.

Mr. DESAULNIER. Madam Commissioner, I appreciate your responsiveness and your succinctness.

JUUL hooked a nation of children in the light of day, but it is asking the FDA to approve its product under shield of darkness. This subcommittee has repeatedly asked JUUL for its PMTA and JUUL has refused to provide it. JUUL knows the junk science it has bought and paid for cannot withstand scrutiny.

If JUUL's PMTA was referred to the Tobacco Products Scientific Advisory Committee, the application would be subject to public scrutiny.

Do you have any comments on this, or on the trial in North Carolina, if you are familiar with it, against JUUL for creating a nicotine product for children?

The judge has already entered in a partial summary judgment against JUUL and is instructing the jury that as a matter of law, all of JUUL's social media posts or youth-oriented, quote/unquote, "evidence from that trial will be relevant to your jury duty."

Will you commit to gathering all documents from that case, including expert reports?

Dr. WOODCOCK. Certainly. I think we should look at all documents. But I can't comment, obviously, on any ongoing case.

Mr. DESAULNIER. Thank you, Commissioner. My time is up. I yield back and I want to thank the chair again.

Mr. KRISHNAMOORTHI. Hey, thank you so much, Congressman.

And now I would like to recognize Congresswoman Speier for five minutes.

Ms. SPEIER. Mr. Chairman, thank you.

And Dr. Woodcock, great to see you, and in your role as Acting Commissioner, you really were not involved in the regulatory process before January 2021. So, I appreciate that.

But I am deeply concerned that this scandal that has been promoted under a previous administration is going to, you know, scar the lives of these children for the rest of their lives, and all you hear about now are these double lung transplants on 13-and 14-year-olds and it's—you know, it takes my breath away.

So, a Federal judge has ordered the FDA to speed up regulations, ruling that the FDA has abdicated its regulatory authority. Would you agree that he—that he was correct in that regard?

Dr. WOODCOCK. As you said, I was not involved in these previous discussions. But, currently, I am committed to getting this done, if possible by the—by the date set by the court.

Ms. SPEIER. So, the previous administration at one point said they were going to ban fruit flavors and then they reversed themselves, and as a result, menthol JUUL pods were increased by, like, a thousand percent among high school students.

Was it a mistake to exempt disposables?

Dr. WOODCOCK. Yes, I wasn't involved in that decision at all. You missed my oral testimony that——

Ms. SPEIER. Yes, I did. I was in a House Armed Services Committee. I apologize.

Dr. WOODCOCK. That is, certainly, important. I was—I was the instigator of the original Sottera lawsuit against the original vapers on drug charges very early in 2000. That was settled that—that we couldn't take drug charges because these are tobacco products.

But so the subsequent actions after that from 2010 on I was not involved in. And so, I mean, certainly, in retrospect it seems, OK, the children switched over to disposables, right, and although youth vaping has decreased in the past year, it might be multi-factorial.

But there was, certainly, continued youth using of these products at really unacceptable levels.

Ms. SPEIER. So, it appears that there are some companies now that are just, basically, ignoring the requirements, Puff Bar being one of them. Are you—based on their prior conduct, are you prepared to reject their application?

Dr. WOODCOCK. Yes, I can't comment on individual——

Ms. SPEIER. How about this? If there are bad actors who have previously shown that their conduct is violative or is thumbing its nose to the government regulation, would that be taken into account with their application?

Dr. WOODCOCK. It would be—it would definitely be taken into account. Yes.

Ms. SPEIER. All right. Thank you.

You know, one of the biggest concerns is that these young people don't appreciate there is nicotine in these e-cigarettes. Do you think we need to improve the labeling requirements for e-cigarettes, or should we just ban them outright?

Dr. WOODCOCK. I think most likely we should make sure that people are aware that—of the nicotine content. That would be an extremely important thing to do.

As we discussed earlier, I really think we are going to have to focus on recovery for teens, too, to get them off their nicotine addiction. I don't know that the healthcare community is well aware of how—what ways might work for youth who are addicted to nicotine but not to cigarettes.

Ms. SPEIER. The amount of nicotine in an e-cigarette is—is it 12 milligrams? Is that what I read somewhere?

Dr. WOODCOCK. There are various—there is various content depending on——

Ms. SPEIER. So, how does that compare to a cigarette in terms of the amount of nicotine?

Dr. WOODCOCK. I think there are some vaping products that have extremely high content within them, up to maybe a whole pack of cigarettes.

They wouldn't get that in one draw, but you—but they are very high and I have heard from families whose children have had very serious experiences after using these very high nicotine products.

Ms. SPEIER. That is alarming. Thank you. I yield back.

Mr. KRISHNAMOORTHI. Thank you. I just have one last question.

Will you admit that the—or acknowledge that the flavor ban exemptions that were created were just a fundamentally flawed policy?

Dr. WOODCOCK. It would appear to have unintended consequences that were very negative. Yes.

Mr. KRISHNAMOORTHI. Negative consequences? So, you admit or acknowledge, I should say—I mean, you were not the Acting Commissioner at that point. But those flavor ban exemptions had very negative consequences.

Dr. WOODCOCK. Correct.

Mr. KRISHNAMOORTHI. Mr. Cloud, do you have one more question?

Mr. CLOUD. I can submit it for the record. Yes.

Mr. KRISHNAMOORTHI. Well, thank you very much for your testimony, and it was a marathon session and I really appreciate your time.

Thank you again.

Dr. WOODCOCK. Thank you.

Mr. KRISHNAMOORTHI. We are adjourned.

[Whereupon, at 10:50 a.m., the subcommittee was adjourned.]

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