

THE FEDERAL RESPONSE TO THE EPIDEMIC
OF E-CIGARETTE USE, ESPECIALLY AMONG
CHILDREN, AND THE FOOD AND DRUG
ADMINISTRATION'S COMPLIANCE POLICY

HEARING

BEFORE THE
SUBCOMMITTEE ON ECONOMIC AND CONSUMER
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OF THE
COMMITTEE ON OVERSIGHT
AND REFORM

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**THE FEDERAL RESPONSE TO THE EPIDEMIC
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ADMINISTRATION'S COMPLIANCE POLICY**

Wednesday, December 4, 2019

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

The subcommittee met, pursuant to notice, at 2:40 p.m., in room 2154, Rayburn House Office Building, Hon. Raja Krishnamoorthi (chairman of the subcommittee) presiding.

Present: Representatives Krishnamoorthi, Maloney, DeSaulnier, Khanna, Pressley, Tlaib, Connolly, Wasserman Schultz, Sarbanes, Cloud, Grothman, Comer, and Miller.

Mr. KRISHNAMOORTHI. The subcommittee will come to order. Without objection, the chair is authorized to declare a recess of the committee at any time.

This hearing is Examining the Federal Response to the Epidemic of Youth E-Cigarette Use and FDA, Food and Drug Administration Compliance Policy.

I now recognize myself for five minutes to give an opening statement.

On September 11 of this year, the Administration released deeply disturbing results from the National Youth Tobacco Survey, otherwise known as the NYTS. The data confirmed our fears that the youth vaping epidemic continues to grow to all-time highs. Today, 5.3 million high school and middle school students use e-cigarette, and the trends are alarming, both among high school students as well as middle school students.

Here I show you two visuals. On your right we see that in 2017, roughly 12 percent of high schoolers were vaping, and in 2019, almost 28 percent of high schoolers are vaping, meaning there is almost a 135 percent increase in vaping among high schoolers.

On your left there is another visual, which is even more disturbing. In 2017, 3.3 percent of middle schoolers were vaping, and today it is almost 11 percent. That is a 218 percent rise in vaping among middle schoolers. As a parent of three children, these statistics are extremely disturbing.

The NYTS data also shows that flavors are driving youth vaping use. Seventy-two percent of youth who vape use flavors, and 64 percent of all kids who vape use mint or menthol, which, by the way, are Juul's most popular flavors. That makes sense, because

NYTS data also confirmed that Juul is the most popular youth brand, with most kids who vape using it.

Armed with this data, the heads of America's public health agencies convinced the President, at least temporarily, to do the right thing. With data linking the alarmingly high youth vaping rates to flavors, the President and the heads of HHS and FDA announced their proposal on September 11 to essentially ban flavored e-cigarettes, with the exception of tobacco-flavored ones.

They put forward a sound and logical response to the problem. As HHS Secretary Alex Azar pledged, quote, "We require that all flavors other than tobacco flavor be removed from the market. This would include mint and menthol flavoring as well as candy flavors, bubble gum flavor, fruit flavor, and alcohol flavor." Secretary Azar explained that "these products are still getting to kids and we cannot let a whole generation get addicted to them through mint and menthol and other flavors," close quote.

During that same announcement, the President committed that this bold flavor ban would be issued within the next, quote, "couple of weeks," close quote. When the President made this exciting announcement on September 11, I, and many members of this committee, led the charge in commending him. A ban of all flavored e-cigarettes would deter new youth users from starting to vape. During a tumultuous time in our politics I frequently referenced the President's announcement as bipartisanship at its best. It was a move to protect and preserve the health of American youth.

But while it is our privilege, or it was our privilege to back the President when he took steps to strengthen public health, it is also our responsibility to hold him and his Administration accountable to their bold promises. Unfortunately, almost three months after the President's initial announcement, the flavor ban has not yet been implemented. Reports illustrate that Big Tobacco lobbyists are working to weaken the ban. There are indications, as well, that the Administration is considering exempting menthol as well as exempting vape shops. We sincerely hope these reports are inaccurate.

In light of these allegations, we tried to find out what was happening. We first wrote the FDA, asking it to finalize and issue the flavor ban without exemptions. FDA did finalize its guidance, but instead of publishing it, the FDA sent it to the Office of Information and Regulatory Affairs, also known as OIRA. That was concerning because OIRA often guts or indefinitely delays agency action. By the way, OIRA is an office within the Office of Management and Budget in the White House, so you will hear that being referred to repeatedly today. In fact, FDA had submitted an e-cigarette flavor ban to OIRA once before, in 2016, and after a flood of industry lobbying, OIRA eliminated that prior flavor ban altogether.

We then wrote OIRA, asking it to quickly complete its review so the flavor ban wouldn't again fall victim to lobbying. OIRA complied, but again, the guidance was not published. Not publishing at that stage is highly unusual, so the subcommittee wrote to both OIRA and the FDA to ascertain which agency currently controlled the guidance. Neither answered. So far neither FDA nor OIRA will clarify if the guidance is with their office. However, we did get an

update on December 3—that would be two days ago—which is that OIRA has said that it has completed its review, so we assume that the guidance is now with the FDA again.

The American people deserve answers. Mr. Zeller, you are the Director of FDA's Center for Tobacco Products. Today parents across the country expect that you will provide them with answers. Once we get those answers, we deserve immediate implementation of a flavor ban with no exemptions.

And with that I now recognize my ranking member, Mr. Cloud, for his opening statement. Thank you.

Mr. CLOUD. Thank you, Mr. Chairman. Thank you, Mr. Zeller, for being here today and participating what might not be the most-watched hearing of the day, but certainly one of the more important ones. Let me say, at the outset, thanks to the chairman for the focus on this issue and the cooperative spirit which, for the most part, we have been able to maintain on this issue, even in today's polarized environment, in having solutions-oriented discussion on this issue.

I know that we are especially united in our goal to end teen vaping. This is an epidemic that is uniquely troubling because it has caused harm in two ways, both fostering nicotine dependency in youth and also the onset of increasingly fatal lung injury. As a father, I can only imagine the agonizing realization of understanding that your child has become addicted to something they had no idea was even harmful, or the pain of the devastating loss of losing a child or a loved one. My sincere condolences to those who have lost loved ones to this illness.

Over the last few months it has become obvious that something is making users of vaping products sick. When we think of the vaping epidemic, it is important to recognize that there are tracks of concern, that each need attention and require a tailored solution. There is the teen vaping epidemic that has enveloped as many as 20 percent of our Nation's teenagers, and then there is the issue of lung damage that, according to the CDC, has tragically led to the deaths, thus far, of 47 people in 25 states and the District of Columbia, as well as 2,290 who have fallen ill to vape-related lung injury.

This aspect of the issue has affected all ages. Of those hospitalized, 15 percent were under age Mr. Cleaver. 38 percent were 18 to 24; 24 percent, 25 to 34; and 23 percent were 35 years and older.

This has been a complex issue, because while it is clear that vaping products are hooking young people on nicotine, it appears that tainted black market products seem likely to be causing much of the lung injury. Some of the challenges in dealing with these issues, of course, have been the rapidly developing nature of this epidemic; the lack of reliable data that definitively points to clear causes; counterfeit products that blur the focus in understanding the origin of tainted products; untraceable supply lines, particularly within the black market; the lack of effective enforcement; and, of course, the challenge we face, as legislators, in protecting the public from harm while protecting their individual liberties.

Thankfully, we have had some breakthrough in findings over the last few weeks that bring some understanding to what is causing lung injury. In the last update from CDC, vitamin E acetate has

been identified as a chemical of concern among people who have gotten sick from vaping. THC has been present in most of the recent samples tested. Vitamin E acetate has been used as an additive, most notably as a thickening agent, in THC e-cigarette products. These findings serve to suggest that THC-containing e-cigarette products from nonregulated sources are the most likely culprit for the recent outbreak of lung injury.

News outlets, including the Associated Press and Wall Street Journal have reported on the availability and pervasive nature of vaping products that are tainted by bad actors. The Wall Street Journal reports that there is a large market for illegal and counterfeit vaping products online. These products are often made by bad actors to resemble those from legitimate manufacturers, but instead contain additives like pesticides.

The CDC has warned users not to buy any vaping products off the street or online, and I am hopeful that the FDA and others in public health entities at the Federal and state levels can continue broadening our understanding of these recent cases of pulmonary illness so they can be addressed appropriately.

Additionally, I would like to spend time today on this hearing discussing on any progress the FDA has made on curbing youth e-cigarette use. I do believe that the focus on this issue in this committee has helped to bring awareness not just to the misconceptions many youth have had toward the health dangers associated with vaping but also to the public safety issues that remain in the quagmire of the vaping product supply chain.

Last, this committee considers solutions to those serious problems I do hope will be appropriately balanced in protecting the public, especially our teens, while protecting the rights of consumers who still may find that vaping is a less-damaging alternative to traditional smoking. And before closing I would like to thank you, Mr. Zeller, for your testimony and being here today, and, as always, I am grateful for the committee and the chair and us being able to work together on this issue.

Thank you, Mr. Chairman. I yield back.

Mr. KRISHNAMOORTHY. Thank you, Congressman Cloud. I now want to recognize our new full committee chairwoman, Carolyn Maloney. Congratulations. I look forward to working with her under her leadership, and I welcome her here today. I know this is an issue that she is very deeply concerned about. And now I would like to recognize the chairwoman to say a few words at this time.

Chairwoman MALONEY. Thank you so much, Chairman Krishnamoorthi, for holding this important hearing, and ranking member for supporting it, and the entire subcommittee for your work on addressing this epidemic.

E-cigarette manufacturers are luring a new generation of Americans into a deadly, life-long addiction. The Centers for Disease Control and Prevention found that tobacco use among high school students has increased by nearly 40 percent in the past year alone. Fueled by e-cigarette use, last year over 20 percent of teenagers reported e-cigarette use, a 78 percent increase from the year before. We are facing a public health crisis.

Thankfully, this subcommittee has stepped in to protect children's health and hold this industry to account. Briefly, it looked like we would have a very important, strong partner in this fight, President Donald Trump. But he has broken his promises, walking back his commitment to take quick, decisive action to address youth vaping by imposing a flavor ban. It looks like, once again, they are going to put profits over people, and we will not allow this to happen.

I look forward to hearing your testimony and the questioning of our witnesses, and I yield back. Thank you.

Mr. KRISHNAMOORTHY. Thank you, Chairwoman. Now I would like to recognize our witness. Today we are joined by Mr. Mitch Zeller, the Director of the Center for Tobacco Products at the Food and Drug Administration.

Sir, if you would please rise and raise your right hand, I will begin by swearing you in.

[Witness sworn.]

Mr. KRISHNAMOORTHY. Let the record show that the witness answered in the affirmative.

Thank you, and I would like to invite you to give us your opening statement. The microphones are sensitive so please speak directly into them. Without objection, your written statement will be made part of the record.

And with that, Director Zeller, you are now recognized for five minutes.

STATEMENT OF MITCH ZELLER, DIRECTOR, CENTER FOR TOBACCO PRODUCTS, FOOD AND DRUG ADMINISTRATION

Mr. ZELLER. Thank you so much, Chairman Krishnamoorthi. Thank you, Chairwoman Maloney. Congratulations on taking over my old committee—I worked on this committee for four and a half years, from the 1980's to the early 1990's, for one of the subcommittees—to Ranking Member Cloud and to members of the subcommittee, and thank you for the opportunity for being here today.

And I want to begin by recognizing the subcommittee for its work to examine the potential causes of the epidemic of youth use of e-cigarettes. I am here today representing hundreds of staff at the Food and Drug Administration who are working tirelessly to prevent kids from starting to use any tobacco product, including e-cigarettes.

I understand that the subcommittee and the public are interested in the Administration's policy with respect to flavored e-cigarettes, and I want to assure the subcommittee that we are committed to doing everything that we can to prevent kids from using tobacco products, and will continue to develop a policy approach that aligns with that concern.

Recently, the Administration held a listening session on the youth e-cigarette epidemic to help inform policy actions going forward, and I will be happy to return to brief members of the subcommittee, the full committee, and staff when updates are available.

I would like to provide some background and an update on FDA's efforts to regulate e-cigarettes. Our initial efforts began more than a decade ago, long before the rise in youth use of e-cigarettes and

the multistate lung injury outbreak. Between 2008 and 2010, FDA attempted to regulate e-cigarettes as unapproved drug device combination products. Our action was challenged and ultimately overturned in court.

In the decade since the Tobacco Control Act was passed, FDA's Center for Tobacco Products, CTP, has established a science-based approach to the regulation of tobacco products, vigorously enforced our authorities to target manufacturers and retailers that violate the law, and designed innovative campaigns to educate kids on the dangers of tobacco use.

CTP has also expanded its focus and authorities to address new challenges by products such as e-cigarettes. The Tobacco Control Act provided FDA the authority to regulate e-cigarettes as tobacco products. Publication of the final deeming rule brought e-cigarettes under FDA's regulatory authority on August 8, 2016.

Protecting our Nation's youth from the dangers of tobacco products is among FDA's most important responsibilities, and we will continue to take aggressive steps to make sure tobacco products are not being marketed or sold to kids.

Let me highlight some of the actions that we have taken to help address the epidemic of youth use of e-cigarettes.

We have issued more than 10,000 warning letters and filed over 1,600 civil money penalty complaints against online and brick-and-mortar retailers for the illegal sale of e-cigarette products to kids. We have issued warning letters that have resulted in the removal of dozens of e-liquid products that resemble kid-friendly foods, like juice boxes, cereal, and candy.

We issued a warning letter to Juul Labs, informed by the work of this subcommittee, for marketing unauthorized, modified-risk tobacco products, including a presentation given to youth at a school marketing Juul products as posing reduced risk or harm compared to cigarette smoking.

We also issued a second letter to Juul expressing our concern and requesting additional information about several issues raised by this subcommittee regarding Juul's outreach and marketing practices, including those targeted at students, tribes, health insurers, and employers. Our letter notes that despite commitments Juul has made to address the youth epidemic, Juul products continue to represent a significant proportion of the overall use of e-cigarettes by children.

Last year, we launched The Real Cost, youth e-cigarette prevention campaign, which features hard-hitting ads on TV and on digital and social media sites popular with teens, as well as posters with e-cigarette prevention messages in every high school across the Nation. And finally, we joined forces with Scholastic to develop educational resources that have been distributed to over a million middle and high school educators.

Yet despite these efforts, the youth vaping epidemic continues to grow, and we know we need to do more.

As the subcommittee considers the issues related to e-cigarette use, it is important to remember that no e-cigarette product is lawfully on the market because none have obtained a marketing authorization from FDA.

When we announced changes to our enforcement discretion policy in August 2017, at the time the nationally representative data suggested that youth use of e-cigarettes had declined. However, as we all know, and as the chairman pointed out in his opening remarks, last year the National Youth Tobacco Survey, or NYTS, showed that from 2017 to 2018, current e-cigarette use among high school students had increased by 78 percent, and by 48 percent among middle school students.

And last month we published the 2019 data, showing that current e-cigarette use had risen to 27.5 percent among high school students and 10.5 percent among middle school students. As in previous years, the 2019 data shows a disturbing rate of youth use of flavored e-cigarettes. Among current exclusive e-cigarette users, nearly three-quarters of those in high school and more than half of those in middle school used flavored e-cigarettes.

We are committed to doing everything we can to prevent kids from using tobacco products, and as I stated at the outset, we will continue to develop a policy approach that aligns with that concern.

I want to thank you for the opportunity to testify today, and I would be happy to answer any questions that you have.

Mr. KRISHNAMOORTHI. Thank you, Mr. Zeller. Thank you for being here today. I would like to recognize myself for five minutes of questions.

Mr. Zeller, you are aware that on September 11, HHS Secretary Azar said the FDA was going to issue guidance clearing the market of, quote, “non-tobacco-flavored e-cigarettes including mint and menthol products.” Right?

Mr. ZELLER. Yes.

Mr. KRISHNAMOORTHI. And you are aware that Secretary Azar announced the ban because, quote, “the numbers from the NYTS show a continued rise in the disturbing rates of youth e-cigarette use, especially through the use of non-tobacco flavors that appeal to kids.” Correct?

Mr. ZELLER. Correct.

Mr. KRISHNAMOORTHI. And Secretary Azar further stated that, quote, “more than a quarter of high school students were current e-cigarette users in 2019, and the overwhelming majority of youth e-cigarette users,” I think you said 75 percent of high schoolers, but “the overwhelming majority of youth e-cigarette users cited the use of popular fruit and menthol or mint flavors.” Right?

Mr. ZELLER. That is correct.

Mr. KRISHNAMOORTHI. The purpose of banning of, as you Secretary Azar said, clearing the marketing of flavored e-cigarettes was to decrease youth vaping. Right?

Mr. ZELLER. That would be consistent with what the secretary said, yes.

Mr. KRISHNAMOORTHI. And there was urgency to this issue. There was urgency. That is why the President said, on September 11, that FDA guidance and action would come in, quote, “a couple of weeks.” Right?

Mr. ZELLER. That is what was said.

Mr. KRISHNAMOORTHI. And there was an urgency that was felt at that time. Right?

Mr. ZELLER. That is correct.

Mr. KRISHNAMOORTHI. And on October 25, you stated that FDA's work on the flavor guidance issue was, quote, "a very, very high priority, and we are trying to complete work on it as quickly as possible." Right?

Mr. ZELLER. I don't remember the date but yes, I said that.

Mr. KRISHNAMOORTHI. Yes. You said that on October 25, to The Hill.

But this guidance, this flavor guidance, has not yet been published yet, has it?

Mr. ZELLER. No.

Mr. KRISHNAMOORTHI. According to a letter sent to me yesterday by FDA and OIRA, FDA drafted guidance and sent it to OIRA, an office within the OMB, as we talked about before, on October 25. Correct?

Mr. ZELLER. Yes, sir.

Mr. KRISHNAMOORTHI. Just to be clear, FDA's guidance document followed through on Secretary Azar's September 11 announcement that the FDA would clear the market of all non-tobacco flavors. Right?

Mr. ZELLER. I am not going to get into the substance of the document that was submitted.

Mr. KRISHNAMOORTHI. Okay. And on what basis are you not getting into the substance?

Mr. ZELLER. Because there has been no final decision made on this policy. Because there are ongoing discussions that are taking place, I am not going to be able to get into the substance of what was in that document.

Mr. KRISHNAMOORTHI. And who instructed you not to get into the substance of it?

Mr. ZELLER. This was based upon discussions internally at the agency and it is standard practice when there is ongoing policy-making that we don't talk publicly about what is under consideration. I would be happy—as I said in my remarks, I would be happy to come back and brief you and your staff when there is a final decision and walk you through everything. But this remains an open, ongoing set of discussions.

Mr. KRISHNAMOORTHI. So according to FDA's letter sent to me yesterday, the FDA OIRA letter sent to me yesterday, OIRA concluded its review on November 4. Right?

Mr. ZELLER. Correct.

Mr. KRISHNAMOORTHI. Now did OIRA make any changes to the initial guidance submitted by the FDA?

Mr. ZELLER. Again, I can't go into the details of what remains ongoing discussions.

Mr. KRISHNAMOORTHI. Now you are familiar with something called Executive Order 12866. Right?

Mr. ZELLER. Yes, sir.

Mr. KRISHNAMOORTHI. According to this catchy phrase, E.O. 12866, the FDA is not allowed to publish in the Federal Register until OIRA has essentially completed its review. Right?

Mr. ZELLER. For things that are subject to the Executive Order.

Mr. KRISHNAMOORTHI. Correct. And this is one of them.

Mr. ZELLER. This was a policy that, because of its significance, we sent to OMB for review, yes.

Mr. KRISHNAMOORTHY. And basically E.O. 12866 would apply. It basically talks about the types of policies that would be submitted to OIRA and then sent back to FDA. Right?

Mr. ZELLER. Correct.

Mr. KRISHNAMOORTHY. Okay. Now OIRA has marked the review, quote/unquote, "completed" on its website. That means, Mr. Zeller, the policy is now back with the FDA. Right?

Mr. ZELLER. They completed their review on November 4, and sent the document back to us, but there were still other ongoing policy-related discussions going in parallel. But OIRA did complete its review, as you stated, and sent it back to us on November 4.

Mr. KRISHNAMOORTHY. When you say there are policy discussions ongoing, between who and who?

Mr. ZELLER. There were parallel policy discussions going on between FDA and the department and the White House.

Mr. KRISHNAMOORTHY. So according to Executive Order 12866, the FDA is not allowed to publish in the Federal Register until OIRA has completed its review. Now that OIRA has completed its review, the FDA can publish the guidance. Right?

Mr. ZELLER. If the complete Executive branch review of the policy was done, but there were still, as I said, in parallel, other ongoing policy-related discussions going on, in addition to the OIRA review of the guidance document that was sent.

Mr. KRISHNAMOORTHY. So these parallel discussions, this sounds like some kind of irregular channel of discussions, independent of the standard submission of the guidance from FDA to OIRA and back from OIRA to FDA. Is there some other review that is happening right now that has nothing to do with OIRA or FDA?

Mr. ZELLER. There are ongoing policy-related discussions between the agency, the department, and the White House about what the policy should be.

Mr. KRISHNAMOORTHY. Okay. So did OIRA really complete its review, if they are still discussing with you this document?

Mr. ZELLER. OIRA completed its review, but at other levels within the department and the White House and the agency, again, in parallel, there were discussions continuing about what the policy should be, even though OIRA had completed its review.

Mr. KRISHNAMOORTHY. And who is part of those discussions at the FDA?

Mr. ZELLER. That would be the leadership of the agency, the leadership of the department, and various parts of the White House.

Mr. KRISHNAMOORTHY. And that leadership includes you?

Mr. ZELLER. I have been involved, I would say, peripherally in those discussions. It has mostly been the leadership of the agency.

Mr. KRISHNAMOORTHY. And at the White House, who has the leadership involved?

Mr. ZELLER. I think it is various offices, from the Domestic Policy Council to the Office of Management and Budget and others. I have not been directly involved in discussions with the White House.

Mr. KRISHNAMOORTHY. So you would agree with me, sir—and the White House Domestic Policy Council is headed by Joe Grogan. Is that right?

Mr. ZELLER. Correct.

Mr. KRISHNAMOORTHY. You would agree with me that the FDA should be regulating tobacco products, don't you?

Mr. ZELLER. That is our job, yes.

Mr. KRISHNAMOORTHY. It is not a waste of time. Right?

Mr. ZELLER. It is one of the most important public health things that a regulatory agency can do. It is something that I have devoted the last 25 years of my life to.

Mr. KRISHNAMOORTHY. That is why I am so concerned by your prior answer that the White House Domestic Council, headed by Joe Grogan, is part of these discussions, when Mr. Grogan said it was, quote, "a huge waste of time," close quote, for FDA to regulate tobacco.

I am going to recognize others for questioning. Mr. Cloud, you are recognized. I took a couple of extra minutes so why don't we put some time on his clock.

Mr. CLOUD. Thank you. Electronic cigarettes have been available in the U.S. for a while now—you mentioned that—for several years. Could you speak to why we are just now seeing cases of this illness?

Mr. ZELLER. I don't think that there is a definitive answer to why only within the last, say, three or four months that we have seen so many cases of pulmonary illness. There is a working hypothesis, and the working hypothesis is that because so many of these cases are associated with the vaping of THC, that there may be something that was added to the product more recently that is associated with the more recent rash and increase in both injuries and deaths.

Mr. CLOUD. Do we have a clear understanding? I mean, this has been a developing issue, a rapidly developing issue, and there are many sources, especially when it comes to teen vaping, many of them getting them from their friends who are old enough, supposedly, to buy them, and such. Do we have a better understanding of the source of the vaping products that are leading to illness yet?

Mr. ZELLER. As you said in your opening remarks, Mr. Cloud, it is important to differentiate between the epidemic levels of kids' use of e-cigarettes where it is just a product that is delivering nicotine versus some kind of vaping device, likely bought off the street, possibly modified by the user, and containing THC and these other compounds that are showing up increasingly in the samples that we and the CDC have analyzed. It is why the advice of the Federal Government is don't vape THC. Don't buy these products. Be careful about what kind of modifications you make to them. That is separate and apart from the focus of your and the chairman's remarks about what to do about kids' use of, I would say, more conventional e-cigarettes.

Mr. CLOUD. Right. And we have had some recent discoveries, I guess, as far as what we think may be causing the illness. Could you speak to that?

Mr. ZELLER. Sure. We are working very closely with CDC using our Forensic Chemistry Center, which is a really sophisticated laboratory that FDA has to support law enforcement action that the agency would take, when we get samples from the states that have collected samples from victims, patients, and forwarded them to us for analysis and to CDC. And it is based upon the analysis of the

samples, at a chemistry level, that we are able to conclude it looks like in roughly 80 percent of the cases that have been linked to patients, THC has been identified. And in about three-quarters of those cases a diluter known as vitamin E acetate, which is an oil, has also been identified.

And because of some analysis of lung tissue, lung fluid that CDC recently did within the last month or so, they were able to conclude that THC and vitamin E acetate may be linked to what is going on here. But both agencies have been very clear to state publicly that there may be more than one cause. But it is looking like some combination of THC with this vitamin E acetate is playing a role in a number of these cases.

Mr. CLOUD. And kind of what I was trying to ask before, but when it comes down to those specific cases that are causing injury, do we have a clear idea of which products and the supply lines for those products yet? Have you been able to trace any of that information back—

Mr. ZELLER. We are using—

Mr. CLOUD [continuing]. where it is most likely coming from?

Mr. ZELLER. I am sorry. We are using the resources of our Office of Criminal Investigations, so we have boots on the ground as we are trying to trace back the supply chain here. We are not using the Office of Criminal Investigations' resources to go after personal use or personal possession of these products. It is who is the responsible party for putting these THC products into the marketplace. And since this is a very sensitive and ongoing investigation, the only thing that I can report to the subcommittee is we are making progress.

But it is not like a romaine lettuce outbreak, where you have responsible, lawful entities that want to get to the bottom of what is causing the outbreak and would work with the regulatory authorities to get to the bottom of it. It is a challenge in doing this investigation. But our Office of Criminal Investigations is making progress.

Mr. CLOUD. Now you did mention some of the stuff the FDA has done recently to help educate kids about the dangers, and I think we have spent, what, \$60 million on The Real Cost campaign? You have highlighted some of those, if you want to touch on those again. And is there anything else the FDA is considering to help mitigate the dangers?

Mr. ZELLER. I think that when it comes to addressing kids' use of e-cigarettes, a comprehensive approach is required. We are using as many of the regulatory, statutory, tools and resources that we have. As you said, we have made a major investment in a public education campaign, because what we have learned from our research—and this is in real contrast to kids' perceptions of the risks of combustible cigarettes. Kids know that combustible cigarettes are dangerous. There are still kids who are at risk of smoking, but they know that it is dangerous.

By contrast, what we have learned from our research is that a lot of kids are walking around thinking that e-cigarettes are harmless. Amazingly, in some surveys, there are kids who don't even know that there is nicotine in e-cigarettes.

So the most important think that we can do in our public education efforts is to communicate to kids, and we know how to do that from the work that we have done in The Real Cost campaign, going back to the last five years, to communicate the health consequences of vaping e-cigarettes, whether it is the risk of becoming addicted to nicotine or the harmful compounds that are present. So public education, compliance and enforcement, the investment in regulatory science to better understand the medium-and longer-term health consequences of e-cigarettes are the tools that we have at our disposal that we are trying to make the best use of.

Mr. CLOUD. Okay. Thank you. I yield back.

Mr. KRISHNAMOORTHY. Thank you, Mr. Cloud. I now recognize Congresswoman Pressley for five minutes of questioning.

Ms. PRESSLEY. Thank you, Mr. Chairman, for your continued commitment to this issue. It is critical that we hold both Big Tobacco and Big Vaping accountable for targeting young people and for knowingly hooking generations of black and brown Americans to nicotine. Our work to end the smoking epidemic is not just simply a matter of public health. This is, and always has been, an issue of racial justice.

Last week, my home state of Massachusetts became the first in the Nation to place a permanent ban on flavored e-cigarette and menthol cigarette products. This is important, because if we are banning flavors we must ban all flavors, which includes mint and menthol. To not do so would be discriminatory, since menthol, in particular, has imposed a unique and deadly burden on the black community.

We must clamp down on the production of menthol products and not the individual possession of it, because there are real intergenerational, traumatic consequences of broken windows policing that has historically over-criminalized black and brown communities, something I called for in my Peoples Justice Guarantee resolution. We must be simultaneously attuned to both public health and public safety to ensure that there are no more Eric Garner's.

For years, Big Tobacco companies disproportionately targeted more tobacco ads and specifically more menthol tobacco ads in black neighborhoods, in some instances, as many as 10 times more ads for menthol products. The CDC reports that nearly nine out of 10 black smokers prefer menthol cigarettes. So I think it is safe to say, Mr. Zeller, that the targeting was effective. Correct?

Mr. ZELLER. I would agree with that.

Ms. PRESSLEY. So today, nearly 45 percent of black menthol smokers say they would quit smoking if menthol cigarettes were banned, and almost two-thirds of black smokers under 24 years of age would do the same. A year ago, the FDA announced plans to ban menthol cigarettes, saying that a ban was necessary because menthol products, quote/unquote, "disproportionately and adversely affect underserved communities."

So a year has passed and the FDA has not followed through on this ban. Why is that, Mr. Zeller?

Mr. ZELLER. As you said, Congresswoman, we went through an advanced notice of proposed rulemaking on a variety of issues related to flavors, including the presence of menthol in cigarettes. And I would add to what you said, that one of the public health

concerns about mentholated cigarettes is not just the disproportionate use of menthol cigarettes by African Americans, but the role that menthol cigarettes plays in attracting kids of any color to experimenting with cigarettes.

And we continue to review the comments and explore what the regulatory options and policies should be, but I absolutely hear you, and as center director share your concern, from a public health perspective.

Ms. PRESSLEY. I am sorry. So just to—reclaiming my time for a moment, just in the interest of time. Just to be clear, on the record, does the FDA plan to follow through with this ban? Yes or no.

Mr. ZELLER. I cannot give you a yes or no answer in an open public hearing. All I can tell you is that we are continuing to review all of the evidence related to flavors in all tobacco products as we try to follow the regulatory science and come up with the right policy.

Ms. PRESSLEY. So previous attempts to ban menthol have been overridden by the Office of Management and Budget. Why is that?

Mr. ZELLER. You need to be more specific. I don't know what you are referring to.

Ms. PRESSLEY. Do you want me to restate the question?

Mr. ZELLER. I don't understand what specific instance you are referring to.

Ms. PRESSLEY. Okay. I will move on. I think the point that I really just reiterating, and I can't underscore enough because we are talking about a life-and-death matter, is that 47,000 black people die every year from smoking-related illness, making this the largest cause of preventable death among black Americans, even more than gun violence or car accidents. So we don't have more time. People are dying.

So in my final second I just want to go to a different line for a moment. So e-cigarettes are not—are e-cigarettes recognized as an effective smoking cessation aid or not?

Mr. ZELLER. They are not approved by FDA as a cessation aid.

Ms. PRESSLEY. Okay. So e-cigarettes are not an effective cessation device. Menthol e-cigarettes are not an offramp for adult menthol smokers. They are an onramp to hooking a new generation of smokers.

Mr. ZELLER. Well, if we can go past the 20 seconds that you have left, there is a public health balancing act that the agency has to do with whatever policy emerges on flavors, and it is balancing, well, are flavors helping adults successfully transition off of cigarettes completely to e-cigarettes? What role are flavors playing in that? And it is part of the balancing that we need to do.

It is an easy call on the negative side of the ledger when it comes to the role that flavors are playing in attracting kids to experiment, especially kids who are walking around thinking that these are harmless products.

But it is a balancing act because we have heard repeatedly from former smokers that it was the presence of certain flavors that helped them successfully transition completely away from cigarettes.

Ms. PRESSLEY. Thank you. I yield back.

Mr. KRISHNAMOORTHY. Thank you, Congresswoman. I now recognize Congressman Comer for five minutes of questions.

Mr. COMER. Thank you, Mr. Chairman. Mr. Zeller, nicotine vaping products must submit pre-tobacco market applications. Those applications must be submitted to the FDA by May 2020. It is my understanding that there are millions of vaping products sold that have registered with the FDA and are currently on the market. It is also my understanding that only a fraction of these products on the market today will have their pre-market tobacco applications filed with the agency by May 2020. Do you agree with that understanding?

Mr. ZELLER. Mr. Comer, our door has been open for those applications to come in ever since we asserted jurisdiction over e-cigarettes three and a half years ago, and precious few applications have come in.

Mr. COMER. Okay. What plans does the FDA have to remove products from the market for which a pre-market tobacco application has not been filed and/or to alert the public and retailers as to which products can continue to be sold?

Mr. ZELLER. If we are in a situation where a deadline has come and gone, and there are currently marketed products that failed to meet the deadline for getting those applications in, then that would be at the top of our priority list for enforcement action. We would monitor the marketplace. It would likely start with a warning letter to the company, telling them to remove the product from the market, and we could take stepped-up enforcement action from them. And then it is up to the manufacturer and the distributor to work with the retailers to get those violative products off of the market.

Mr. COMER. Well, does the FDA plan to post a list in the weeks after May 2020, when the deadline passes, setting forth all those products for which a pre-market tobacco application has been made? Do you plan on making a list?

Mr. ZELLER. I will have to take that back to the center. That is something that could be considered, and I will get back to you as we think about that.

Mr. COMER. Okay. All right. Great. Sounds like a good idea.

So when we talk about all the counterfeit products, which is where a lot of the problems occurred—I could say many of the problems have occurred with the deaths, especially with the THC products, many of which weren't 100 percent THC, many of the products had no THC in it, or had all sorts of counterfeit ingredients in it—what actions does the FDA plan to take against these counterfeit suppliers?

Mr. ZELLER. Let's draw a distinction between counterfeit and illicit. So what we are talking about with whoever the responsible party is for putting these THC products on the market, these are illicit products. And as I said but can't talk publicly about our investigation, we are making progress in working back the supply chain to find the responsible parties. When we find the responsible parties, we have a variety of authorities at our disposal, but we are also working in consultation with the Drug Enforcement Administration, because there could be a role for DEA in this as well. It

starts with finding the responsible parties ,and that is the phase of this investigation that we are in. But we are making progress.

Mr. COMER. That is great. Thank you. I will close by saying this. I think every stakeholder must do their part. Nobody wants to see underaged youth use vaping products. No one wants to see companies marketing to youth. But a lot of the future of this depends on FDA's rules and regulations. When do you think the FDA will finalize and publish the guidance on vaping flavors, when we are talking about regulating the flavors, or a flavor ban, as many have already alluded to up here?

Mr. ZELLER. I can't give a definitive answer, other than to say that the discussions that have been taking place continue and FDA is committed to a policy that aligns with our public health concerns about what is going on with kids and flavored e-cigarettes.

Mr. COMER. Okay. All right. Thank you, Mr. Chairman. I yield the balance of my time back.

Mr. KRISHNAMOORTHY. Thank you. I just going to use the balance of your time to ask another question about these parallel discussions that are happening. You are tangentially—you said you are tangentially related to these discussions. Who at the FDA is part of these discussions directly?

Mr. ZELLER. It is the leadership of the agency and the commissioner's office.

Mr. KRISHNAMOORTHY. So the acting commissioner is part of these discussions?

Mr. ZELLER. Yes, he is.

Mr. KRISHNAMOORTHY. Okay. And then at the White House, who is directing it from their end?

Mr. ZELLER. I don't know.

Mr. KRISHNAMOORTHY. Okay. I would like to recognize Congressman Khanna for his five minutes of questioning.

Mr. KHANNA. Thank you, Mr. Chairman. Mr. Zeller, you have had a long career in regulating tobacco, working with David Kessler in the 1990's, so I want to ask you questions based on your expertise.

The tobacco survey results showed that 27.5 percent of high school kids were using e-cigarettes and 64 percent of kids were using mint or menthol. Do those numbers sound reasonable to you?

Mr. ZELLER. Yes, they do.

Mr. KHANNA. And the data also showed that 72 percent of high school users are using flavors, and most high school users use Juul. Is that correct?

Mr. ZELLER. Yes.

Mr. KHANNA. So based on your entire career of regulating tobacco, going back to your work for David Kessler, who I admire, if you were making a recommendation to the President, do you think that we should ban mint and menthol?

Mr. ZELLER. My recommendation in this process has been to follow the regulatory science and to come up with a policy that most closely aligns with what those numbers show, which is that we have an epidemic use of e-cigarettes by middle school and high school kids. They disproportionately favor flavored products, and the percentage of kids that are using e-cigarettes more frequently is also increasing. I am not going to go into the specifics of the pol-

icy, but I can tell you, speaking on behalf of the Center for Tobacco Products, that our recommendation has been that policy needs to align with that science and that data.

Mr. KHANNA. So do you think that banning mint and menthol would align with that science and data?

Mr. ZELLER. The only thing that I can say publicly is that that is what was said on September 11 by the Administration. I can't go into the specifics of the policy that is still under consideration.

Mr. KHANNA. But you could share your opinion. I mean, what is your opinion. I mean, you have been dealing with the regulation of tobacco for 20 years. If you were talking to David Kessler and he said, "Do you think mint and menthol should be banned?" what would you tell him?

Mr. ZELLER. I will tell you what I would tell him, and that is there was a second reputable national survey that came out within the last month, called the Monitoring the Future Survey. Reputable, been around for years. It measures 8th-, 10th-, and 12th-grade use of all kinds of products, licit and illicit. And the survey instrument in the Monitoring the Future Survey separates mint from menthol. It asks those questions separately. The National Youth Tobacco Survey doesn't. Mint and menthol are included in the same question.

So in the Monitoring the Future results, what we saw, from an analysis that was done of kids who used Juul—but since the majority of kids who use e-cigarettes use Juul, doing a sub-analysis of just kids who use Juul is probably a good indication of what is going on throughout the entire category.

And what that analysis showed, and that was published in the Journal of the American Medical Association within the last month, was that kids who use Juul are way more likely to use the mint product than the menthol product. That was new information, and that was information that has to be accounted for, whether I was having a conversation with the former commissioner, speaking under oath to the subcommittee—

Mr. KHANNA. But we don't know whether, if they don't have the mint option, whether they would just default to the menthol option.

Mr. ZELLER. That is correct, and that would have to be part of the considerations.

Mr. KHANNA. But you are not prepared here to make a recommendation of your opinion, what you would recommend.

Mr. ZELLER. The only thing that I can say publicly is that that new information that came out in that survey had to be—has to be factored into our thinking.

Mr. KHANNA. Do you have any reason to suspect that politics and electoral politics has gone into the decision making, people advising the President that he could lose battleground states if he banned vaping or banned flavors?

Mr. ZELLER. No.

Mr. KHANNA. Would you commit to resigning if you ever had any indication that that was a consideration?

Mr. ZELLER. I would commit to resigning if there was—if we wound up with a fundamentally flawed policy, for whatever reason—

Mr. KHANNA. But if you had heard information that there was political considerations, would you commit to resigning?

Mr. ZELLER. I think it would depend upon what the outcome of the policy was. I am talking about what the final policy is. That is when I would consider a resignation, regardless of what the considerations were that went into that. We have made a recommendation as to what we think the policy should be. No final decision has been made, and I will wait to see what that final decision is.

Mr. KHANNA. I am out of time.

Mr. KRISHNAMOORTHY. Thank you, Congressman. Now I recognize Congresswoman Miller for five minutes of questioning.

Mrs. MILLER. Thank you, Chairman Krishnamoorthi and Ranking Member Cloud, and thank you for being here today.

In our past three hearings, one issue that we all have agreed upon is to keep e-cigarettes and vaping products out of the hands of those who are underaged. I do feel that all of these hearings have also illustrated the important role that e-cigarettes can play in helping people quit smoking cigarettes. It still seems as if it can be a vital tool in reduction and should remain an option for those who do need it.

Can you discuss the proactive steps that both the CDC and FDA have taken to prevent youth from accessing e-cigarettes?

Mr. ZELLER. Yes, and thank you for the question. We are responsible for enforcing the part of the law that establishes a Federal minimum age of sale to all tobacco products, including e-cigarettes, and for enforcing the law about illegal marketing of e-cigarettes to kids.

And so through our Office of Compliance and Enforcement we have issued over 10,000 warning letters and over 1,600 civil money penalty complaints, and that is seeking a financial payment to the Federal Government for repeat illegal sales at the retail level to minors in our, what we call our compliance check program. In addition, we have made a massive investment in public education to complement the ongoing enforcement actions.

I wish I could say that public education and compliance and enforcement alone would be sufficient to reverse the trend that we are seeing in the annual surveys, but it is not. More needs to be done.

Unfortunately, we have had to use our enforcement resources to go after companies that were remarkably selling e-liquids to purposely resemble juice boxes. We did that in a collaboration with the Federal Trade Commission, because those were also violations of the Federal Trade Commission Act.

There is good news and there is bad news, but the good news is when we sent the first 17 of those warning letters, just on the issue of e-liquids that were purposely being marketed to resemble juice boxes, cereal and candy, all 17 manufacturers immediately reformulated their packaging. That was the good news. The bad news is about a month later we were doing the kind of monitoring and surveillance that we do online with the techniques that we had, and we saw that there were a whole bunch of online retailers that were still selling those products. So we had to put out a whole additional batch of warning letters to the online retailers that were

continuing to sell products that manufacturers had agreed to reformulate.

Mrs. MILLER. That sort of leads me to my next question, which is, what is being done? What enforcement efforts are being done to get the illicit and illegal vape products off the market now?

Mr. ZELLER. Well, when are talking about the illicit product, that is taking us into the realm of what is going on with THC vaping, so that is separate.

Mrs. MILLER. Excuse me, but will you please explain what THC is?

Mr. ZELLER. So THC—I can't give you the chemical name but it is a chemical derivative of marijuana.

Mrs. MILLER. So the people do know—

Mr. ZELLER. There are a whole bunch of people who are purchasing this completely illegal product to get high, and what we have seen only in the last three, four, or five months is something changed, something happened in how these products were being manufactured, if you will, and sold, because we weren't seeing the incidence of lung injury and death, even if people had been vaping THC earlier than April or May of this year.

Something changed earlier this year. The working hypothesis is, well, it is a completely illegal enterprise to begin with, and agents are being used to cut the THC to make it go further, and the agents that are being used are oils. And if you inhale oil into your lungs, that is a really bad thing and it can make you very sick. And in all of the cases that the CDC has been able to test lung fluid, they have found this vitamin E acetate, this oil, present in every single sample.

Mrs. MILLER. And that leads to probably my last question, although I have more. Acetate is different than vitamin E oil, so do we have two products being put together to, I mean, to make vitamin E acetate?

Mr. ZELLER. I can't answer that. I will have to get back to you for the record on that. But it is an oil that is being added as a diluter to stretch the THC.

Mrs. MILLER. Okay. Thank you. I yield back.

Mr. KRISHNAMOORTHY. Okay. Without objection, I would like to have Congresswoman Wasserman Schultz and Congressman Sarbanes permitted to join the subcommittee on the dais and be recognized for questioning the witness as well, and I would like, without objection, will enter this response letter from the FDA as well as OIRA to my letter, and copying Mr. Cloud, inquiring about the status of the flavor guidance.

Mr. KRISHNAMOORTHY. With that I will now recognize Congresswoman Tlaib for five minutes of questioning.

Ms. TLAIB. Thank you, Chairman. Thank you so much for being here.

Mr. Zeller, yes or no, does the high nicotine content contribute to youth use?

Mr. ZELLER. I don't know if the high nicotine content contributes to youth use.

Ms. TLAIB. How about nicotine salts?

Mr. ZELLER. Let me elaborate. But the product that seems to be the most popular with kids is very high in nicotine.

Ms. TLAIB. So nicotine salts as well?

Mr. ZELLER. That is different. Nicotine salts may make it easier for the nicotine to go down. It is part of our ongoing investigation of Juul.

Ms. TLAIB. So yes or no. Do you believe that if nicotine levels were capped at non-addictive or minimal-addictive levels that it would help decrease youth use?

Mr. ZELLER. That is something that we are certainly considering for combustible cigarettes, and I will just leave it at that.

Ms. TLAIB. Similarly, if nicotine salts were banned, would that help decrease youth use?

Mr. ZELLER. That I don't know, but we have an active, ongoing investigation into the role of nicotine salts and the nicotine levels.

Ms. TLAIB. And, Mr. Zeller, does FDA have the authority to cap nicotine levels?

Mr. ZELLER. Yes.

Ms. TLAIB. Yes or no. Does the FDA have the authority to ban nicotine salts in e-cigarettes?

Mr. ZELLER. Yes.

Ms. TLAIB. Will FDA commit to bringing these ideas to the table?

Mr. ZELLER. This is part of an ongoing investigation—

Ms. TLAIB. I know. I know.

Mr. ZELLER [continuing]. that starts with gathering facts.

Ms. TLAIB. But those specific bans—

Mr. ZELLER. We would be happy to come back and talk to you when we are further along in the investigation so that we can better understand the science, product design, how these products work, and the public health impacts that they are having.

Ms. TLAIB. Our chairman has taken a lead in—you know, he sent a letter, and I think on September 5, outlining evidence that we uncovered about Juul illegally marketing its products in schools, a number of places that were directly to youth, both as smoking cessation products and by claiming Juul was safer than cigarettes, and so forth. And FDA partly responded by issuing Juul a warning letter, declaring it had broken the law by making modified risk claims.

Briefly, what led you to conclude that Juul had broken the law?

Mr. ZELLER. We had our own ongoing investigation of the marketing practices of Juul. I would say that the information that the subcommittee put on the record at its two-day hearing in July gave us additional information and additional concerns that the very specific examples that you just mentioned crossed the line into what we called illegal modified risk health claims, claims to either reduce exposure to toxins or to reduce risk. And in that area we were able to assemble all the evidence that we had, that you had provided on the public record, and use it as the basis for a warning letter to the company, separate and apart from an additional letter that went to the company on the same day, making a massive request for documents on other things that were being investigated.

Ms. TLAIB. Mr. Zeller, in your letter you all did ask them to respond within 15 days. Did they?

Mr. ZELLER. They responded by the end of the month. If they missed the deadline it was only by a day or two.

Ms. TLAIB. And will you get us that response?

Mr. ZELLER. I can discuss the outcome of that—

Ms. TLAIB. Well, you can't provide the response from Juul to—

Mr. ZELLER. Not while we—it is an ongoing investigation that has not been closed. Were it to be closed, then I could come back and brief you on everything that we have found. The company responded. We are reviewing their response. If we close that warning letter then I can come back and give you more information.

Ms. TLAIB. How long can cases go by? I mean, can it be years?

Mr. ZELLER. It would not be years. Let's just say that a voluminous amount of information was—

Ms. TLAIB. Sorry. I am a mom of two young boys and I am just trying to make sure that we resolve this before, not only juice boxes but we are going to have candy or suckers out there with this stuff.

So FDA can punish companies for making illegal modified risk claims. What are the maximum possible penalties the FDA is permitted to impose, in situations like Juul?

Mr. ZELLER. Let me just talk hypothetically about the authorities that we have at our disposal, and they are both civil and criminal. On the civil side, we can work with our lawyers and the lawyers at the Justice Department, and there can be seizures and injunctions to completely change the behavior of the company that broke the law. There are other instances where there can be massive fines to the Federal Government. And then, working with the Justice Department, if we think that there has been criminal activity then there could be a criminal investigation and prosecution.

Ms. TLAIB. All right. Thank you so much. I yield the rest of my time, Mr. Chair.

Mr. KRISHNAMOORTHY. Thank you, Chair—thank you, Congresswoman. Let me use the remaining time to further explore, why are e-cigarettes so dangerous to youth?

Mr. ZELLER. Two fundamental reasons. Our brains don't fully develop until we are like 25 or 26 years old, and it is clear that any exposure to nicotine in the still-developing adolescent brain is harmful, regardless of what the other hazards, chemicals in the vapor, in the liquid are. Just the nicotine alone is reason enough to be concerned that no kid should be experimenting with this product because of the harmful impact of nicotine.

Then, when you add what is known about some of the harmful compounds in the aerosol, those bring additional risks. When we have the so-called harm reduction debate—is there a role for this product to help addicted cigarette smokers completely switch to e-cigarettes?—that is a completely different and separate question, when we make a relative risk assessment of, well, if you switch to e-cigarettes you will be exposing yourself to fewer toxins. No kid should be initiating on any e-cigarette product, and as I said earlier, kids are walking around with this mindset that it is harmless, that it is water vapor, and some of them don't even know that nicotine is present.

Mr. KRISHNAMOORTHY. I now recognize Congressman Grothman for five minutes of questioning.

Mr. GROTHMAN. Thank you. Maybe we are going to go over some territory you have already covered, but you see the list behind you, the number of middle school kids and high school kids who are using these. Do you know how many of the people are using these

are using what I will call legal products that I could pick up at my local convenience store, and the number that are using illegal products, including THC?

Mr. ZELLER. The data that the chairman has put up is use of lawful e-cigarettes delivering nicotine. That is separate from kids who are vaping and vaping THC.

Mr. GROTHMAN. Okay. So I assume, though, that of, say, the 27 percent, some of those people are using THC.

Mr. ZELLER. They could be, but this is—

Mr. GROTHMAN. Almost always, I would assume. And is it your belief—I mean, this is like the third hearing we have had on this in this building—is it your belief that almost all, or all of the hospitalizations that take place has come from people who are using these THC cartridges?

Mr. ZELLER. In the samples that we have analyzed, that have been sent to us by the states, we are seeing THC in about 80 percent of them.

Mr. GROTHMAN. Okay. I was glad recently to see a high school in my district had some billboard or something or other up, talking about the danger of combining e-cigarettes and THC. As I understand it, when you put, or just these even legal cigarettes, there are different amounts of nicotine from one cigarette to the next. Right? You can buy a 10, you can buy a 50, whatever.

Mr. ZELLER. Are you talking about cigarettes or e-cigarettes?

Mr. GROTHMAN. E-cigarettes. I am sorry.

Mr. ZELLER. Yes. The nicotine content can vary.

Mr. GROTHMAN. Okay. Do we know how many are sold at each of the levels, you know, of 100 percent of the e-cigarettes that are sold, how many are at a 50 or how many are at a 10 or whatever?

Mr. ZELLER. No, but what we do know is that Juul is the highest nicotine product on the market, and kids who use e-cigarettes are most likely to use Juul, and, therefore, they are using the highest nicotine available.

Mr. GROTHMAN. Juul only has high nicotine? I was under the impression, from somebody I know, who stopped smoking, that you can adjust and start at 40 and work to 20 or whatever. But you are saying all Juul cigarettes—

Mr. ZELLER. My understanding is that while there may be a three percent nicotine Juul product out there, that the overwhelming majority of the sales are the five percent, which is an extraordinarily high level of nicotine per pod, per the thing that you insert into the device.

Mr. GROTHMAN. You sure of that?

Mr. ZELLER. Yes.

Mr. GROTHMAN. Okay. I was under the impression that people who stopped smoking, kind of the whole purpose was to work your way down from the top.

Mr. ZELLER. If they are, they are not working their way down with Juul. They could be working their way down to other products that have lower nicotine levels.

Mr. GROTHMAN. Okay. Are you worried that if you ban legal e-cigarettes people will run to the illegal e-cigarettes, just (a) with probably inferior product in there, and (b) with more THC?

Mr. ZELLER. We are not talking about a ban, Congressman. We are talking about a policy to deal with currently marketed e-cigarettes that haven't gotten a marketing authorization from FDA, and what, of the currently marketed products, should basically be put into a category where the only way that they could be sold is if they go through a pre-market evaluation and review process by FDA, because technically, none of these products are lawfully on the market.

Mr. GROTHMAN. Do you know people who have used e-cigarettes and stopped smoking because of it?

Mr. ZELLER. Yes, sir.

Mr. GROTHMAN. Okay. And what is your opinion of that? I mean, is that a good thing? A bad thing? Is it something we should be discouraging? I mean, to me, it seems to me that is a good thing. I mean, my whole life I am told, you know, smoking takes seven years out of your life, blah-blah-blah-blah-blah. All of a sudden we have something that is effective and we are, you know, looking for ways to have less people use it.

Mr. ZELLER. We have heard what I would say are compelling but albeit anecdotal reports from individuals who said, "It was only because of e-cigarettes that I was able to get off of cigarettes." E-cigarettes are not approved by the Food and Drug Administration as a cessation aid. The United States Preventive Services Task Force, Health Services Task Force, has not recommended e-cigarettes as a cessation aid. There is a regulatory pathway for this product to be authorized as a cessation aid, if a company wants to go through the Center for Drugs at FDA. It is why the leadership of the agency and the department have been talking over the last year or more about the onramp and the offramp and the balancing act.

Yes, there are anecdotal reports that some former smokers have successfully transitioned completely to e-cigarettes. But the onramp for kids is getting wider and wider and wider, and our job, as regulators, is to figure out how to balance those two use of the product. And the question for all of us, not just for FDA, is at what price? At what price, as we balance this technology, if e-cigarettes have become more and more of an onramp for kids? And those are the things that we are grappling with internally with the data.

Mr. GROTHMAN. I just have one more question here, and thanks for letting me go over. Is it possible that as less kids, or have you found a way to ban e-cigarettes from kids, what would happen, given that there is a little bit of a natural inclination of kids to rebel, and instead of smoking e-cigarettes they would smoke tobacco cigarettes?

Mr. ZELLER. We have made such progress in reducing the number of kids who smoke cigarettes. The numbers that are coming out will report historically low rates of kids smoking cigarettes. And kids are aware of the hazards of smoking cigarettes.

I guess my concern, just speaking for myself, based upon the data that I have seen, is that the kids who are most at risk when it comes to experimenting with e-cigarettes are kids who would have never thought twice about smoking a cigarette.

Mr. KRISHNAMOORTHY. Thank you, Mr. Zeller. I now recognize Congressman Connolly for five minutes of questioning.

Mr. CONNOLLY. Thank you, Mr. Chairman, but if it is all right I would like to yield to my good friend, Ms. Wasserman Schultz, who was here before me.

Ms. WASSERMAN SCHULTZ. Aw, go ahead.

Mr. CONNOLLY. You sure?

Ms. WASSERMAN SCHULTZ. Yes. I will go next.

Mr. CONNOLLY. I am happy to—all right. Thank you. Give me back my 15 seconds. I was trying to be gracious here, Mr. Chairman.

So Mr. Zeller, welcome. I am going to ask a series of kind of rapid-fire questions to establish just a record, if you don't mind.

Did the compliance policy that FDA sent to OIRA on October 25 exempt vape shops?

Mr. ZELLER. As I said to the chairman earlier, I can't get into the details of the policy that remains under review.

Mr. CONNOLLY. You can't even tell us, as a matter of fact, it either did or did not include vape shops? Your view is that is exempt from congressional scrutiny at a hearing?

Mr. ZELLER. When there has not been a final decision made yet on this policy, and it is clear that a final decision has not yet been made, we don't discuss publicly what the considerations are. I can—it has been accurately reported that the agency submitted the guidance to OIRA. It has been accurately reported, including on the OMB website, that OIRA cleared the guidance. But as I said earlier to the chairman, there are these parallel, ongoing policy-related discussions going on.

Mr. CONNOLLY. Mr. Chairman, I think that answer raises a whole host of other questions about the jurisdiction of this committee. And I would just say to you, Mr. Zeller, I think you are treading on very thin ground with your answer.

Mr. ZELLER. I appreciate that, sir.

Mr. CONNOLLY. And we will revisit that as a committee.

FDA, however, does have the authority to regulate flavors. Is that correct?

Mr. ZELLER. That is correct. FDA has jurisdiction over any device that could be used to deliver tobacco-derived nicotine. Is that correct?

Mr. ZELLER. That is correct. Different types of authorities, but yes.

Mr. CONNOLLY. Yes. FDA has jurisdiction over e-liquids. Is that correct?

Mr. ZELLER. As long as it is part of something that meets the statutory definition of a tobacco product, yes.

Mr. CONNOLLY. Correct. FDA even has jurisdiction over nicotine-free e-liquids as a component or part of a tobacco product if it is reasonably expected to be used for a tobacco product. Is that correct?

Mr. ZELLER. Exactly.

Mr. CONNOLLY. That appears to cover the range of things sold at a vape shop, so FDA certainly has the authority to regulate flavors wherever they are sold, be it a gas station, convenience store, or a vape shop, following that logic.

Mr. ZELLER. Correct.

Mr. CONNOLLY. That is correct. In fact, the Tobacco Control Act prevents FDA from, quote, “prohibiting the sale of any tobacco product in face-to-face transactions by any specific category of retail outlets.” So FDA couldn’t ban gas stations from selling flavors while allowing vape shops to continue. Could it?

Mr. ZELLER. I think that is an accurate reading of the statute.

Mr. CONNOLLY. So I can’t envision any way to exempt vape shops from a flavor ban in light of those previous answers. You are a lawyer, Mr. Zeller. Is there any legal way for a hypothetical flavor ban to conceivably exempt vape shops?

Mr. ZELLER. I think that your reading of an interpretation of the statute is accurate, and I think that under the law we would not be able to differentiate between types of retail outlets.

Mr. CONNOLLY. According to FDA and CDC’s 2018 National Youth Tobacco Survey, almost 15 percent of the kids reported buying e-cigarettes from a vape shop, in the last 30 days, compared to just 8.4 percent who bought them from a gas station or a convenience store. So if the data shows that twice as many underage kids buy e-cigarettes illegally at vape shops compared to convenience stores, how would that support a hypothetical plan that allows flavors in vape shops but bans them in gas stations, when the numbers would suggest exactly the opposite in terms of where the problem is?

Mr. ZELLER. I think you are making a very good point.

Mr. CONNOLLY. I think you are a good lawyer.

Mr. ZELLER. Thank you, sir.

Mr. CONNOLLY. Finally, a California study, published in JAMA, showed that half of the vape shops did not check IDs in youth, and 45 percent of the vape shops sold to youth. The study found vape shops rates of sales to youth significantly higher than other types of stores. If the goal is to keep kids from vaping, how does that data support a hypothetical plan that allows flavors in vape shops but bans them in gas stations and convenience stores?

Mr. ZELLER. As I have said in some of my earlier responses, our job is to follow the regulatory science and to put forward policy recommendations that align with the science, that do the best possible job of protecting kids from the hazards of all tobacco products, including e-cigarettes.

Mr. CONNOLLY. Right. That is a very good, bureaucratic answer, but I prefer it when you wear your lawyer’s hat and answer “that is a very good question.”

Mr. ZELLER. That was a very good question.

Mr. CONNOLLY. Yes, I thought so. All right. Thank you. I mean, we clearly do have a problem here, and we are going to have to take cognizance of the actuality of the problem and where kids are going, so that we can target effective strategies to address it.

Mr. ZELLER. I—Mr. Connolly, I agree, and while we have chuckled in our exchange, that shouldn’t belie the seriousness with which we are taking this issue and trying to do the right thing.

Mr. CONNOLLY. Thank you.

Mr. KRISHNAMOORTHY. Thank you. I now recognize Congresswoman Wasserman Schultz for five minutes of questioning.

Ms. WASSERMAN SCHULTZ. Thank you, Mr. Chairman. When Dr. Ann Schuchat of the CDC testified before this subcommittee on

September 24, I asked her about whether nonsmokers are being drawn to e-cigarettes by their flavors, and she said that among our young people, quote, “flavors are pretty much always what brings youth into starting use of e-cigarettes.” She also testified that for a flavor ban to be effective at keeping kids off cigarettes, all flavors, including menthol, must be included.

Mr. Zeller, do you agree with Dr. Schuchat’s assessment that in order to be effective a flavor ban must include menthol?

Mr. ZELLER. Again, I think much to the consternation of this subcommittee I can’t get into the specifics of the policy that is under consideration. All I can tell you—

Ms. WASSERMAN SCHULTZ. I wasn’t asking about the specifics of the policy under consideration. I am asking your opinion, if you agree with Dr. Schuchat’s assessment that in order to be effective, a flavor ban must include menthol. You are not prohibited in any way, shape, or form from offering your opinion.

Mr. ZELLER. As I said in an earlier response, one of the things that we are trying to account for is the data that came out in the Monitoring the Future Survey. That only came out recently. And I will just repeat it very briefly.

Ms. WASSERMAN SCHULTZ. Please briefly, because I am familiar—I was here when you said it, and I don’t need it repeated.

Mr. ZELLER. Okay. Then I won’t repeat it, and I will just cut to the chase and say we now have data that shows that for kids who use Juul, they are far more likely to use mint than menthol, far more likely. And how do we account for that, as we are trying to make the right policy here to do the best job in protecting kids?

Ms. WASSERMAN SCHULTZ. Okay. So reclaiming my time, does the idea of exempting menthol from a potential ban on e-cigarette flavors originate from the FDA? That is an awfully long pause.

Mr. ZELLER. The issue of what the scope of the policy should be, what it should include, was the subject and remains the subject of ongoing discussions between—

Ms. WASSERMAN SCHULTZ. Did the idea of exempting menthol from a potential ban on e-cigarette flavors originate from the FDA, or did it come from somewhere else?

Mr. ZELLER. FDA put the science forward that I just described to you.

Ms. WASSERMAN SCHULTZ. That is not what I am asking you. The idea to exempt menthol, was it an idea that was generated by the FDA? Yes or no.

Mr. ZELLER. Let me try to answer your question in a more general and hypothetical way.

Ms. WASSERMAN SCHULTZ. I have other questions for you and I want an answer. It is not a trick question. Did the idea—

Mr. ZELLER. The—

Ms. WASSERMAN SCHULTZ.—to exempt menthol from a flavor ban come from the FDA, or did it come from somewhere else?

Mr. ZELLER. There were—there have been a variety of options for the scope of this policy that have been under discussion.

Ms. WASSERMAN SCHULTZ. That—you are talking about options. I am asking, the idea—

Mr. ZELLER. Please let me finish.

Ms. WASSERMAN SCHULTZ. I am trying to get a yes or no question—

Mr. ZELLER. The options—

Ms. WASSERMAN SCHULTZ.—and you are obfuscating.

Mr. ZELLER [continuing]. the options that FDA put on the table for consideration, going to what the scope of this guidance should be, went to the issue of menthol in or menthol out. We put options—

Ms. WASSERMAN SCHULTZ. But is that—did it come—did the idea—

Mr. ZELLER. If the—if—if—

Ms. WASSERMAN SCHULTZ.—to exempt—

Mr. ZELLER [continuing]. if the answer to your question is who put the options on the table, menthol in or menthol out, then the answer is yes, we put it on the table.

Ms. WASSERMAN SCHULTZ. So it didn't come from somewhere else. It wasn't an idea brought to you from the outside. It was generated by the FDA. It was your idea, with no—

Mr. ZELLER. At a point in time when all options were being explored.

Ms. WASSERMAN SCHULTZ. Okay. So there was influence from the outside and it was not—you are not answering that this was an idea that was exclusively generated by the FDA.

Mr. ZELLER. I don't think that is what I said. When we were—

Ms. WASSERMAN SCHULTZ. I want to make sure I understand what you are saying.

Mr. ZELLER [continuing]. when we were identifying options, we put a variety of options on the table for consideration that included menthol in or menthol out.

Ms. WASSERMAN SCHULTZ. Reclaiming my time. Mr. Chairman, we are really going to have to make sure that the FDA understands what they are required to answer when we ask them questions, because Mr. Zeller is not complying with what is required of him.

Do you have any reason to—on November 13, Dr. Schuchat testified that the National Youth Tobacco Survey didn't differentiate between menthol or mint, and we don't even know if kids can differentiate menthol or mint. Do you have any reason to believe that kids can differentiate between menthol and mint flavors?

Mr. ZELLER. I am aware of the literature that says kids may not be able to differentiate between menthol and mint.

Ms. WASSERMAN SCHULTZ. Okay. And menthol and mint e-cigarettes, we know, may carry additional unique harms. Pulegone is a cancer-causing agent present in mint plant oil. Mr. Zeller, the FDA banned it as a food additive last year, didn't it?

Mr. ZELLER. Yes, it did.

Ms. WASSERMAN SCHULTZ. And a recent study from Duke University School of Medicine found extremely high levels of pulegone in both menthol and mint e-liquids. It found a level inhaled by menthol and mint e-cigarette users as much as 1,000 times higher than menthol cigarette users. Shouldn't we be concerned about that?

Mr. ZELLER. We have been looking into that science. We have questions about the study that was done, but we are aware of and we are looking at it.

Ms. WASSERMAN SCHULTZ. You banned it as a food additive last year, so I would think that you already have pretty good science that it is dangerous. Correct?

Mr. ZELLER. We are looking into the methodology and the adequacy of that science.

Ms. WASSERMAN SCHULTZ. Okay. That study came out on September 16. We have heard that a decision to exempt menthol may have been made by October 31. Were you aware of this study on October 31 when you made that decision?

Mr. ZELLER. I am not going to refer to any decision, but we were aware of that study by October 31, yes.

Ms. WASSERMAN SCHULTZ. When you were considering pulling flavors and a revelation comes to light about dramatically high levels of a cancer-causing agent in menthol e-liquids, wouldn't that be a good reason to pull them from the market to determine if they are safe?

Mr. ZELLER. It would be part of the consideration that we would make about what the scope of the guidance should be.

Ms. WASSERMAN SCHULTZ. Okay. I yield back the balance of my time. Thank you for your indulgence, Mr. Chairman.

Mr. KRISHNAMOORTHY. Thank you, Congresswoman. Now I recognize Congressman Sarbanes for five minutes of questioning.

Mr. SARBANES. Thank you, Mr. Chairman and thanks for the opportunity to waive on today. Mr. Zeller, thanks for being here. As we have said now, many times, in September of this year we saw the announcement from the Trump administration that FDA would be releasing a compliance policy to ban all flavored e-cigarette products including mint and menthol products. And this would not be the first time that FDA moved forward with a policy to ban e-cigarette flavors. Correct? Isn't it true that a similar policy was crafted in 2015?

Mr. ZELLER. I wouldn't call it ban, but it is a matter of public record that there was a version of a regulation that would have treated flavored products differently from unflavored products.

Mr. SARBANES. Restrictions would have been put on those. In 2015, when you were director of the FDA Center for Tobacco Products, as you are today, were you involved in that rulemaking process? I assume you were.

Mr. ZELLER. Yes, sir.

Mr. SARBANES. And we know that in October 2015, FDA sent its flavor ban to the Office, to OIRA, for review, and OIRA has an open-door policy, meaning it will meet with any lobbyist as long as the rule is under review. We now know, as a matter of fact, that OIRA met with over 100 industry lobbyists to discuss the 2015 policy, and as a result, or I am not going to say causation, but some correlation, at least, OIRA eliminated the flavor ban policy. Were you satisfied with that result and OIRA's justification back in 2015?

Mr. ZELLER. I was prepared to explain the final policy. It did not square with the policy that we put forward earlier in the process.

Mr. SARBANES. Okay. I am reading between the lines on that answer. That was very diplomatic.

Now let's return to the 2019 flavor ban that was promised in September, which, of course, was accompanied by these startling figures from the National Youth Tobacco Survey, showing that over a quarter of high school students now had used e-cigarettes in 2019. Many had used the popular fruit, mint, or menthol flavors. Despite those trends, the most recent policy now seems doomed to the same fate as the 2015 policy.

Now that the current flavor guidance has left OIRA, the President has taken at least one meeting on the topic. Do we have any way of knowing whether the President or the White House are meeting with industry lobbyists?

Mr. ZELLER. That is a question you need to ask the White House.

Mr. SARBANES. Okay. So you don't know.

Mr. ZELLER. I don't know.

Mr. SARBANES. Of course, the Administration, which is the least transparent in my memory, has eliminated the White House visitor logs, so there is really no way to know who is showing up there for these meetings and lobbying the President.

But even if that was public, that is not really the main problem. The problem, and what I think people are fed up with across the country, is that their government, this government won't tackle important issues without getting permission from special interest. I think that is what is playing out here. I will just be very candid with you. I am not asking you to comment on it.

We are facing a youth tobacco crisis. Two decades of progress in reducing youth smoking is being reversed almost overnight. The President promised to act quickly, promises to do something to protect American kids from these dangerous products, but as soon as he says he will take action, here come the lobbyists, the influencers, and suddenly this particular ban is in purgatory. It is not happening.

And the impression I get, and I think a lot of people in the public, when they read a headline one day and then in 72 hours it is completely flipped around, is that the tobacco industry lobbyists are calling the shots, and it is not public health professionals. Unfortunately, it is not as it should be, an agency like the FDA leaning in to protect consumers and fulfilling its mission in every possible way, because of this influence peddling that goes on.

So it is just another in a long list of examples of what is broken about this place, and the public gets this. They may not understand all of the intricacies of how influence flows through the Executive branch, through Congress, et cetera, but they can feel in their gut that policy is getting made up here for a group of very powerful people and not for them.

We are going to have to fix this, in so many arenas, but certainly when it comes to protecting the health of our kids. And with that, Mr. Chairman, I yield back. Thank you for the opportunity to waive on today.

Mr. KRISHNAMOORTHY. Thank you, Congressman. Thank you all for coming today. I just want to close with a couple of remarks, which is that these figures are alarming, absolutely alarming, and unacceptable. The FDA is charged, by the American people, to stop

this epidemic, and you are failing on the job. We know what will stop it, and that is banning these flavored e-cigarettes. We know it. Those flavored e-cigarettes are what get kids to take up these e-cigarettes, and the nicotine is what gets them hooked, for a life time of nicotine addiction.

And so for you to come in here and tell us you submitted guidance to OIRA, OIRA concluded its review, and then for parallel discussions to be happening, but for us to have zero transparency into who is part of these discussions, how long these discussions are going to happen, when this policy is going to come out, is unacceptable. This is wrong. And the parents of all these kids are still waiting for answers. And the answers you provided today are not going to do.

So I suggest you go back to the FDA and you tell them that the American public is up in arms about this youth e-cigarette epidemic, and you tell the White House and you tell all those who are part of these parallel, irregular, unusual, opaque discussions that time is up. It is time to get their act together and put this flavor ban out, immediately, without delay, before another child gets hooked to these e-cigarettes, before another middle schooler gets hooked to an e-cigarette, and certainly before any high schooler or any child whose brain is still developing to the age of 25 or 26, as you said, gets hooked to an e-cigarette.

Without objection, all members will have five legislative days within which to submit additional written questions for the witnesses to the chair, which will be forwarded to the witnesses for responses. I ask our witnesses to please respond as promptly as you are able.

This hearing is adjourned.

[Whereupon, at 4:09 p.m., the subcommittee was adjourned.]

