

SOUNDING THE ALARM: THE PUBLIC HEALTH THREATS OF E-CIGARETTES

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

SEPTEMBER 25, 2019

Serial No. 116-65



Printed for the use of the Committee on Energy and Commerce
govinfo.gov/committee/house-energy
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

47-351 PDF

WASHINGTON : 2022

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SOUNDING THE ALARM: THE PUBLIC HEALTH THREATS OF E-CIGARETTES

WEDNESDAY, SEPTEMBER 25, 2019

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:01 a.m., in the John D. Dingell Room 2123, Rayburn House Office Building, Hon. Diana DeGette (chair of the subcommittee) presiding.

Members present: Representatives DeGette, Schakowsky, Kennedy, Ruiz, Kuster, Castor, Sarbanes, Tonko, Clarke, Pallone (ex officio), Guthrie (subcommittee ranking member), Burgess, McKinley, Griffith, Brooks, Duncan, and Walden (ex officio).

Staff present: Kevin Barstow, Chief Oversight Counsel; Jesseca Boyer, Professional Staff Member; Jeffrey C. Carroll, Staff Director; Manmeet Dhindsa, Counsel; Evan Gilbert, Deputy Press Secretary; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Judy Harvey, Counsel; Stephen Holland, Health Counsel; Chris Knauer, Oversight Staff Director; Jourdan Lewis, Policy Analyst; Alivia Roberts, Press Assistant; Andrew Souvall, Director of Communications, Outreach and Member Services; Benjamin Tabor, Staff Assistant; Kimberlee Trzeciak, Chief Health Advisor; Jennifer Barblan, Minority Chief Counsel, Oversight and Investigations; Mike Bloomquist, Minority Staff Director; S. K. Bowen, Minority Press Assistant; Diane Cutler, Minority Detailee, Oversight and Investigations; Jordan Davis, Minority Senior Advisor; Margaret Tucker Fogarty, Minority Legislative Clerk/Press Assistant; Brittany Havens, Minority Professional Staff, Oversight and Investigations; Peter Kielty, Minority General Counsel; Bijan Koohmaraie, Minority Deputy Chief Counsel, Consumer Protection and Commerce; Ryan Long, Minority Deputy Staff Director; Brannon Rains, Minority Legislative Clerk; Kristen Seum, Minority Counsel, Health; and Alan Slobodin, Minority Chief Investigative Counsel, Oversight and Investigations.

Ms. DEGETTE. The Subcommittee on Oversight and Investigations hearing will now come to order. Today, the Committee is holding a hearing entitled, "Sounding the Alarm: The Public Health Threats of E-Cigarettes." The purpose of today's hearing is to examine the public health impacts and regulatory authorities related to e-cigarette manufacturing, sales, and use.

The Chair now recognizes herself for purposes of an opening statement.

OPENING STATEMENT OF HON. DIANA DeGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Our country is facing a serious public-health epidemic, one that is causing severe harm. This hearing will examine the cause of that epidemic, the uncontrolled and rising use of e-cigarettes. As life-threatening illnesses sweep the country and the use of e-cigarette products by young people soars, we must act to protect the American people from the myths and the misunderstanding about these products.

First, the data is now clear. Over the past several years, we have seen an acceptably high proportion of young people facing nicotine addiction. This year alone, more than 27 percent of high schoolers report they are using e-cigarettes or vaping, as it is also known. From 2011 to 2015, there was a 900 percent increase, a 900 percent increase in youth vaping, and from 2017 to today, the use, the rate of high school use doubled.

The vaping epidemic and its impact are personal to me. My home state of Colorado has the unfortunate distinction of leading the country in teen vaping. A major factor contributing to the continued dramatic rise of e-cigarette use among teens is the inundation of flavored products. Recent data from the Centers for Disease Control and Prevention indicate that 60 percent of students using e-cigarettes within the last month cited using popular fruit, menthol, or mint flavors.

Young people turning to e-cigarettes also may have the false assumption that these products are safe or relatively harmless. But contrary to many manufacturers' claims, e-cigarettes pose risks to young people and can lead to addiction, harm brain development, affect respiratory health, and can lead to heart disease. Additionally, e-cigarette use increases the risk of youth turning to conventional cigarettes.

As much as we do know, the more troubling concern maybe how much we don't know about these products. For example, in some cases, we don't even know what chemicals and toxins are being inhaled when vaping. In a very real sense, the e-cigarette industry has launched a massive public health experiment in our country, of which its outcomes and consequences remain unknown.

A recent spate of serious vaping illnesses epitomizes just how much we are in the dark about these products. These illnesses, numbering 530 so far and increasing daily, have led to hospitalizations, potential long-term health complications, and several deaths.

While CDC and FDA are here today; I want to thank both witnesses and they will provide more information about the status of the investigation and what products may be the culprit; no specific causes of the illnesses have yet been determined. With these agencies engaged and in collaboration with state partners, I have confidence that the root cause of this outbreak will eventually be identified.

But, even if the cause is isolated to a product sold on the streets or the use of THC, we must keep in mind that branded e-cigarettes sold in stores are not harmless. This brings me to my next concern. Given the potential risks associated with these products, it would be reasonable to assume that the e-cigarettes have been closely re-

viewed and approved by the FDA. But they haven't. E-cigarette products are only on the market today because FDA is temporarily giving them a pass by exercising its enforcement discretion.

Let me be clear, no e-cigarette currently on the market in the United States today has been fully reviewed by FDA for its impact on public health. FDA needs to do its job, examine these products, and tell the public what the risks are. Can they even be legally sold? If so, how? In other words, FDA must go forward with conducting its repeatedly delayed premarket reviews for all e-cigarette products and determine whether the sale of the product is "appropriate for the protection of public health."

Now, after years of the delays around the regulation of e-cigarettes, the administration recently announced that the FDA would prioritize enforcement and clear the shelves of non-tobacco flavored e-cigarette products pending review. I am encouraged by this recent action, but FDA needs to provide additional details and a timeline for action. We have to ensure that this policy will be implemented and enforced in a reasonable way. In the meantime, nothing is stopping manufacturers from submitting their applications to FDA today. The burden is on the cigarette companies to demonstrate that these products meet the FDA's health standards.

And regardless of the administration's recent announcement, legislation action is not off the table. I and others have introduced bills to tackle this public health priority, including Chairman Pallone, who has been a steadfast leader on these issues. States on the front lines of the youth epidemic have also been taking action on e-cigarettes. We are going to hear some of their plans today.

Now, the industry has been swift to rail against efforts to restrict the products, claiming they assist adult smokers in quitting traditional cigarettes. That evidence, however, is far from conclusive, and FDA has not approved e-cigarettes for cessation purposes. Any benefit to adult smokers has to be weighed against the generation of young people for which vaping represents an on-ramp to use.

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE

Our country is facing a serious public health epidemic, one that is causing severe harm. Today's hearing will examine the cause of that epidemic—the uncontrolled and rising use of e-cigarettes.

As life-threatening illnesses sweep the country and the use of e-cigarette products by young people soar, we must act to protect the American people from the myths and misunderstandings about these products.

First, the data is now clear. Over the past several years, we've seen an unacceptably high proportion of young people facing nicotine addiction.

This year, more than 27 percent of high schoolers report they are currently using e-cigarettes, or "vaping," as it's also known.

From 2011 to 2015, there was a 900 percent increase in youth vaping, and from 2017 to today, the rate of high school use doubled.

The vaping epidemic and its impact is personal to me: my home state of Colorado has the unfortunate distinction of leading the nation in the rate of teen vaping.

A major factor contributing to the continued dramatic rise of e-cigarette use among teens is the inundation of flavored products. Recent data from the Centers for Disease Control and Prevention indicate that 60 percent of students using e-cigarettes within the past month cited using popular fruit, menthol, or mint flavors.

Young people turning to e-cigarettes also may have the false assumption that these products are safe or relatively harmless.

But, contrary to many manufacturers' claims, e-cigarettes pose risks to young people and can lead to addiction, harm brain development, affect respiratory health,

and can lead to heart disease. Additionally, e-cigarette use increases the risk of youth turning to conventional cigarettes.

As much as we do know, the more troubling concern may be how much we don't know about these products. For example, in some cases, we don't even know what chemicals and toxins are being inhaled when vaping.

In a very real sense, the e-cigarette industry has launched a massive public-health experiment in our country, of which its outcomes and consequences remain unknown.

A recent spate of serious vaping illnesses epitomizes just how much we are in the dark about these products. These illnesses, numbering 530 so far, and increasing daily, have led to hospitalizations, potential long-term health complications, and several deaths.

While CDC and FDA are here today and will provide more information about the status of the investigation and what products may be the culprit, no specific cause of the illnesses has been determined yet.

With these agencies engaged and in collaboration with state partners, I have confidence that the root cause of this outbreak eventually will be identified.

But, even if the cause is isolated to a product sold on the streets or use of THC, we must keep in mind that branded e-cigarettes sold in stores are not harmless.

This brings me to my next concern—given the potential risks associated with these products; it would be reasonable to assume that e-cigarettes have been closely reviewed and approved by FDA.

But they haven't been. E-cigarette products are only on the market today because FDA is temporarily giving them a pass by exercising its enforcement discretion.

Let me be clear, no e-cigarette currently on the market in the United States has been fully reviewed by FDA for its impact on public health.

FDA needs to do its job, examine these products, and tell the public what the risks are and how—or if—they can be legally sold.

In other words, FDA must go forward with conducting its repeatedly delayed pre-market reviews for all e-cigarettes products and determine whether the sale of the product is [quote] “appropriate for the protection of public health.”

After years of dithering and delays around the regulation of e-cigarettes, the Administration recently announced that FDA would prioritize enforcement and clear the shelves of non-tobacco flavored e-cigarette products pending review.

This recent action is an encouraging first step. But FDA has yet to provide additional details or a timeline for action. We must ensure this policy will be implemented and enforced in a timely and effective manner.

In the meantime, nothing is stopping manufacturers from submitting their applications to FDA today. The burden is on e-cigarette companies to demonstrate that these products meet FDA's health standards.

And regardless of the Administration's recent announcement, legislative action is not off the table. I and others have introduced bills to tackle this public health priority, including Chairman Pallone, who has been a steadfast leader on these issues.

States on the front lines of the youth epidemic have also been stepping up to take action on e-cigarettes. We'll hear some of their plans and ongoing efforts on today's second panel.

The industry has been swift to rail against efforts to restrict their products, claiming that they assist adult smokers in quitting traditional cigarettes. The evidence, however, is far from conclusive and FDA has not approved e-cigarettes for cessation purposes.

Any potential benefit to adult smokers must be weighed against the generation of young people for which vaping represents today's “on-ramp” to tobacco use.

We can, and we must do more to ensure we are not sacrificing today's young people to a lifetime of nicotine addiction.

I thank the witnesses for their service and look forward to hearing about how we can work together to address this critical public health issue.

MS. DEGETTE. I want to thank the witnesses for being here today for their service, and I look forward to hearing how we can work together to address this very serious public health issue. And I will yield to Mr. Guthrie from Kentucky.

OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. GUTHRIE. Thank you, Chair DeGette, for holding this hearing. And before I get started on my opening statement, I want to say I know a lot of our members are going to have to be going back and forth. For whatever reason, this Committee scheduled two important subcommittee hearings at the same time.

And so, we have drug pricing upstairs; I think everybody agrees it is an important issue for the country, and this is an important issue for the country as well, and a lot of members here are membership of that subcommittee. So, I apologize that we are going to be in and out; that is where we are.

And I want to say that I am deeply concerned about the growing outbreak of lung illness associated with vaping and e-cigarette use, as well as the marketing of e-cigarettes to kids. We need to understand the causes of this vaping illness and ensure that e-cigarettes are not marketed to kids. It is also important that we understand the health implications of vaping and e-cigarette use more broadly, whether an adult is vaping THC derived from marijuana, nicotine, or another substance.

So far, the available evidence of the 553 reported cases of lung illness and eight deaths does not point to a conclusive cause. But the test samples overwhelmingly suggest an involvement of illicit e-cigarette devices, the psychoactive ingredient in marijuana called THC, and other black market products. For example, according to the Centers for Disease Control, most patients who have experienced these lung illnesses have reported a history of using e-cigarettes products containing marijuana or THC. However, some have reported using products that contain THC marijuana with nicotine, while others have reported only using products with nicotine.

Separate from the outbreak of lung illnesses, according to the U.S. Food and Drug Administration, the United States has a youth e-cigarette epidemic. The most recent data from the National Youth Tobacco Survey show that 27-1/2 percent of youths reported using e-cigarettes compared with 20.8 in 2018. The rate was only 11.3 percent just three years ago.

These trends are unacceptable. The marketing of e-cigarette products to children must be stopped, and youth access to e-cigarette products must be blocked more effectively. This epidemic is already driving legislation and regulatory responses.

Last September, the FDA issued more than 1,300 warning letters and fines to brick and mortar retailers who illegally sold e-cigarette products to minors, and five warning letters to e-cigarette manufacturers about their plans to address youth access of their products. Eighteen states have increased the legal age to purchase tobacco products to 21. Michigan, New York, and the District of Columbia have issued a proposed regulation to ban flavored e-cigarettes.

On September 11th, 2019, the Trump administration announced that the FDA would finalize a compliance policy to prioritize enforcement against the marketing of unauthorized non-tobacco flavored e-cigarettes, including mint and menthol e-cigarettes. While these responses are aimed at reducing the attraction of e-cigarettes to youth, wide bans will almost certainly create black markets. In

that vein, we will also need a response to an increased black market demand for flavored pods and to address the growing trade in illicit cannabis marijuana vaping products.

A New York Times article reported that a recent bust of a THC oil operation in Wisconsin revealed a very advanced, immature illicit market for marijuana vape cartridges and distribution of contaminated marijuana-based vape carts. I am told these illicit operations are using a tactic in other illegal drug operations. They are cutting their product with other substances, including some that could be dangerous.

Public health advocates, for example, said a particular cutting agent, vitamin E acetate, is an oil that could cause breathing problems and lung inflammation if not heated fully during the vaping process. By using smaller amounts of the expensive THC, or marijuana, and diluting it with oils that cost much less, one can increase their profit by selling the product. For example, medium-grade THC can cost \$4,000 a kilogram, but additives may cost pennies on the dollar. These operations rely on pen factories that buy empty vape cartridges and counterfeit packaging from Chinese factories and then fill them with THC liquid that they purchased from the United States market. Empty cartridges and packaging are also available to purchase on the internet.

While federal and state authorities are working on an effective response against teen e-cigarette use; we must ensure that our youth is educated on the dangers of using e-cigarettes. For example, in Massachusetts, Governor Baker's administration launched a campaign to combat teen vaping and e-cigarette use in April 2019. The Massachusetts Department of Public Health launched a campaign to highlight the use of vape pens and e-cigarettes in July 2018. These actions are commendable, and I look forward to seeing the results of these campaigns.

With regard to adults trying to quit smoking, some studies suggest that e-cigarettes are less harmful than traditional cigarettes. According to the CDC, e-cigarettes have the potential benefit, cessation, from combustible cigarettes for adult smokers, but CDC cautions that e-cigarettes are not safe for youth, young adults, pregnant women, or adults who are not currently using tobacco products. Additional research should occur to look at the effectiveness.

I want to thank our witnesses for being here on both panels today, and I really look forward to this important discussion. So, I will be back and forth between hearings, but that is where we are, and I yield back.

[The prepared statement of Mr. Guthrie follows:]

PREPARED STATEMENT OF HON. BRETT GUTHRIE

Chair DeGette, thank you for holding this hearing. I am deeply concerned about the ongoing outbreak of lung illness associated with vaping and e-cigarette use, as well as the marketing of e-cigarettes to kids. We need to understand the causes of this "vaping illness," and ensure that e-cigarettes are not being marketed to kids. It is also important that we understand the health implications of vaping and e-cigarette use more broadly, whether an adult is vaping THC derived from marijuana, nicotine, or another substance.

So far, the available evidence from the 530 reported cases of lung illness and eight deaths does not point to a conclusive cause, but the test samples overwhelmingly

suggest the involvement of illicit e-cigarette devices, the psychoactive ingredient in marijuana called THC, and/or other black-market products. For example, according to the Centers for Disease Control, most patients who have experienced these lung illnesses have reported a history of using e-cigarette products containing THC. However, some have reported using products that contain THC and nicotine, while others have reported only using products with nicotine.

Separate from the outbreak of lung illness, according to the U.S. Food and Drug Administration, the United States has a youth e-cigarette epidemic. The most recent data from the National Youth Tobacco Survey showed that 27.5 percent of youths reported using e-cigarettes, compared with 20.8 percent in 2018. The rate was only 11.3 percent just three years ago. These trends are unacceptable. The marketing of e-cigarette products to children must be stopped, and youth access to e-cigarette products must be blocked more effectively.

This epidemic is already driving legislative and regulatory responses. Last September, the FDA issued more than 1,300 warning letters and fines to brick-and-mortar retailers who illegally sold e-cigarette products to minors and five warning letters to e-cigarette manufacturers about their plans to address youth access use of their products. Eighteen states have increased the legal age to purchase tobacco products to 21. Michigan, New York, and the District of Columbia have issued or proposed regulations to ban flavored e-cigarettes. On September 11, 2019, the Trump Administration announced that the FDA would finalize a compliance policy to prioritize enforcement against the marketing of unauthorized non-tobacco flavored e-cigarettes, including mint and menthol e-cigarettes.

While these responses are aimed at reducing the attraction of e-cigarettes to youth; wide bans will almost certainly create black markets. In that vein, we will also need a response to an increased black market demand for flavored pods; and to address the growing trade in illicit cannabis vaping products. A New York Times article reported that a recent bust of a THC-oil operation in Wisconsin revealed a very advanced and mature illicit market for THC vape cartridges and distribution of contaminated THC-based vape carts.

I am told that these illicit operations are using a tactic seen in other illegal drug operations: cutting their product with other substances, including some that could be dangerous. Public health advocates, for example, said a particular cutting agent, vitamin E acetate, is an oil that could cause breathing problems and lung inflammation if not heated fully during the vaping process.

By using smaller amounts of the expensive THC and diluting it with oils that cost much less, one can increase their profit from selling the product. For example, medium-grade THC can cost \$4,000 a kilogram, but additives may cost pennies on the dollar. These operations rely on “pen factories” that buy empty vape cartridges and counterfeit packaging from Chinese factories, then fill them with THC liquid that they purchase from the United States market. Empty cartridges and packaging are also available to purchase on the internet.

While federal and state authorities are working on an effective response against teen e-cigarette use; we must ensure that our youth is educated on the dangers of using e-cigarettes. For example, in Massachusetts, Governor Baker’s administration launched a campaign to combat teen vaping and e-cigarette use in April 2019. The Massachusetts Department of Public Health launched a campaign to highlight the dangers of vape pens and e-cigarettes in July 2018. These actions are commendable, and I look forward to seeing the results of these campaigns.

With regard to adults trying to quit smoking, some studies suggest e-cigarettes are less harmful than traditional cigarettes. According to the CDC, e-cigarettes have the potential to benefit cessation from combustible cigarettes for adult smokers, but the CDC cautions that e-cigarettes are not safe for youth, young adults, pregnant women, or adults who do not currently use tobacco products. Additional research should be continued into the effectiveness of e-cigarettes for smoking cessation and to understand long-term health effects.

I thank our witnesses on both panels for being here today and being part of this important discussion. I yield back.

Ms. DEGETTE. I thank the gentleman. The Chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes for purposes of an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you. I want to thank Chairwoman DeGette for having this very important hearing today. We are examining the growing public health crisis involving e-cigarettes and the proliferation of these products amongst kids and teens. I am deeply concerned about the recent outbreak of lung illnesses that have killed eight people and sickened more than 530 here in the U.S.

I am also very frustrated by the fact that e-cigarette usage has reached epidemic proportions in recent years among kids. If you talk to any parent of a high school student, you know that our nation's e-cigarette problem is real and it is getting worse, and it is long past time for public health agencies to address vaping and e-cigarette usage in a meaningful way. I look forward to hearing about what the FDA and the CDC can tell us about how they are addressing these tragic mystery illnesses and their recent actions to combat youth e-cigarette use.

But make no mistake, I firmly believe that many aspects of the youth vaping epidemic could have been addressed if the FDA had moved forward with reviewing all e-cigarettes on the market when it first had the chance two years ago. Instead, in July 2017, FDA announced that it would delay the implementation of key provisions of the agency's final deeming rule, which ensured the agency would review all e-cigarette products on the market. That same day, I issued a statement expressing deep concerns that these delays would mean that e-cigarette products would continue to lack needed public health oversight for several years and risk continued exposure to a new generation.

And here we are over two years later, and unfortunately, my concerns have come to fruition. Since that decision, youth e-cigarette usage has skyrocketed. More than one in four high school students say they have used e-cigarettes in the past 30 days. These products have been marketed and targeted to kids without our knowledge of the full public health consequences, and as a result, we could lose an entirely new generation to a lifetime of nicotine addiction.

At the same time, hundreds of people throughout the country have developed unknown lung illnesses following the usage of vape products. In many instances, these products were manipulated beyond the product's intended use, but it still remains unclear what these products contain and how exactly they were manipulated.

The lack of certainty on the root cause of these illnesses speaks to a larger problem. We do not know the full spectrum of health consequences associated with the use of e-cigarettes. Ten years ago, the Family Smoking Prevention and Tobacco Control Act was signed into law after coming out of this Committee. This law gave FDA the tools that it needed to effectively regulate all tobacco products. But, unfortunately, that is not happening. Therefore, it is critical that FDA and CDC explain today what actions they are taking and what more we can be doing to protect consumers.

And I also look forward to hearing from states that have forged their own responses in the wake of an action at the federal level. The wide availability of flavored e-cigarette products clearly designed for kids' consumption are putting the interests of industry

above the health of our kids. While I am pleased by the Administration's announcement that it plans to pull all flavored e-cigarette products from the market until they undergo full FDA review, I believe that ban should occur immediately. Above all else, we must get to the bottom of what is causing these lung illnesses, and we must ensure that vape products are kept out of the hands of our kids.

At the same time, it has become clear to me that we must enact new comprehensive legislation; to fully address this growing youth epidemic. We must eliminate flavors, prohibit online sales that make it easy for kids to buy e-cigarettes, and ensure that these products are not being marketed to anyone underage. My legislation, the Reversing Youth Tobacco Epidemic Act, does each of these things while also raising the age to 21 to buy tobacco products. It is my intention to move this critical legislation forward, and I hope that it will receive the strong bipartisan support that it deserves. It is long past time to address the public health risks associated with e-cigarette use. We have to use every tool at our disposal to solve this crisis.

And if I could just say, Madam Chair, although it is true as you mentioned that we do want to move legislation. I also think that it is very important for the Oversight and Investigations Subcommittee to find out what is happening, you know, what the agencies are doing, what is actually causing this epidemic, so I really appreciate the fact that you are having this hearing. I think we need to have this hearing. As much as I want to move forward with the legislation; we need to have this hearing first to get to the bottom of this. So thank you again. I yield back.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

We are here today to examine the growing public health crisis involving e-cigarettes, and the proliferation of these products among kids and teens.

I am deeply concerned about the recent outbreak of lung illnesses that have killed eight people and sickened more than 530 here in the United States. I am also exceedingly frustrated by the fact that e-cigarette usage has reached epidemic proportions in recent years among kids. If you talk to any parent of a high school student, you know that our nation's e-cigarette problem is real—and getting worse. It is long past time for the public health agencies to address vaping and e-cigarette usage in a meaningful way.

I look forward to hearing about what the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) can tell us about how they are addressing these tragic mystery illnesses and their recent actions to combat youth e-cigarette use. But make no mistake—I firmly believe that many aspects of the youth vaping epidemic could have been addressed if the FDA had moved forward with reviewing all e-cigarettes on the market when it first had the chance two years ago.

Instead, in July 2017, FDA announced that it would delay the implementation of key provisions of the agency's final deeming rule, which ensured the agency would review all e-cigarette products on the market. That same day I issued a statement expressing deep concerns that these delays would mean that e-cigarette products would continue to lack needed public health oversight for several years and risk continued exposure to a new generation. Here we are over two years later, and unfortunately, my concerns have come to fruition.

Since that decision, youth e-cigarette usage has skyrocketed—more than one in four high school students say they have used e-cigarettes in the past 30 days. These products have been marketed and targeted to kids without our knowledge of the full public health consequences. As a result, we could lose an entirely new generation to a lifetime of nicotine addiction.

At the same time, hundreds of people throughout the country have developed unknown lung illnesses following the usage of vape products. In many instances, these products were manipulated beyond the product's intended use, but it still remains unclear what these products contained and how exactly they were manipulated. The lack of certainty on the root cause of these illnesses speaks to a larger problem—we do not know the full spectrum of health consequences associated with the use of e-cigarettes.

Ten years ago, the Family Smoking Prevention and Tobacco Control Act was signed into law after coming out of this Committee. This law gave FDA the tools that it needed to effectively regulate all tobacco products. Unfortunately, that is not happening. Therefore, it is critical FDA and CDC explain today what actions they are taking, and what more we can be doing to protect consumers. I also look forward to hearing from states that have forged their own responses in the wake of inaction at the federal level.

The wide availability of flavored e-cigarette products, clearly designed for kids' consumption, is putting the interest of industry above the health of our kids. While I am pleased by the Administration's announcement that it plans to pull all flavored e-cigarette products from the market until they undergo full FDA review, I believe that ban should occur immediately.

Above all else, we must get to the bottom of what is causing these lung illnesses, and we must ensure that vape products are kept out of the hands of our kids. At the same time, it has become clear to me that we must enact new, comprehensive legislation to fully address this growing youth epidemic. We must eliminate flavors, prohibit online sales that make it easy for kids to buy e-cigarettes, and ensure that these products are not being marketed to anyone underage. My legislation, the Reversing the Youth Tobacco Epidemic Act, does each of these things while also raising the age to 21 to buy tobacco products.

It is my intention to move this critical legislation forward, and I hope that it will receive the strong, bipartisan support that it deserves.

It is long past time to address the public health risks associated with e-cigarette use. We must be using every tool at our disposal to solve this crisis.

Thank you to the witnesses for being here today, and I yield back.

Ms.DEGETTE. The Chairman yields back. The Chair now recognizes the ranking member of the full committee, Mr. Walden, for 5 minutes.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr.WALDEN. Thank you, Madam Chair, and thanks for holding this hearing.

Electronic cigarettes or e-cigarettes, the current outbreak of lung illnesses associated with e-cigarettes, and the youth vaping epidemic are a front and center health concern in the United States and particularly in my state of Oregon. In recent weeks, an as yet unidentified illness has killed seven people; sickened more than 500 across 38 states. As we will hear from Dr. Sharpless and Dr. Schuchat today, the investigation of the cause or causes of the illnesses is ongoing, but it appears to be vaping-related. Many of the individuals who have gotten sick seem to have used black market products that contain THC.

Earlier this month, public health officials in Oregon announced a person who died of severe respiratory illness in July had used an e-cigarette containing marijuana oil purchased from a licensed dispensary, meaning that the product sold in the store should have gone through a testing process regulated by the State of Oregon. It was the first death in the U.S. tied to a vaping product bought in a marijuana shop. Much is still unknown, however, which dispensary sold the product and whether it was contaminated or whether something was added into the liquid into the device after the purchase.

In July, an 18-year-old young man went to a hospital complaining of breathing problems. Within 48 hours, he was sent to the intensive care unit and diagnosed with acute respiratory distress syndrome, a condition associated with acute lung injury. He was connected to a breathing tube and placed in a medically-induced coma for a week. Later, the patient's mother found an e-cigarette cartridge with the label of a licensed company based in California that sells THC products. However, the cartridge later was found to be a counterfeit of that company's product.

In North Carolina, five individuals, bought the marijuana oils that made them sick, on the street, from unlicensed and likely illegal dealers. All five were hospitalized, three in intensive care. It took a battery of tests to figure out that all five had acute exogenous lipoid pneumonia, that is, lung inflammation caused by breathing oil. Luckily, the individuals in New York and North Carolina survived, but not all have been so lucky, including the individual from Oregon who died.

These cases of young, seemingly healthy young adults getting sick after vaping are piling up far too quickly. These cases are shining a light on the youth vaping epidemic in the United States. The most recent data from the National Youth Tobacco Survey is very troubling. About 27-1/2 percent of youth reported using e-cigarettes in 2019 compared to 20.8 percent in 2018. That is an 11.3 percent jump in just three years.

Given these trends in the administration, the Trump administration, the states, and this Committee are right to look for solutions to curtail youth access to e-cigarettes. So, I appreciate the Trump administration's pursuit of an effective solution to the problem of youth access as well as the partnership between the administration and the states to investigate these outbreaks of lung illnesses.

However, there is another overlay to the e-cigarette problem, and that is counterfeit products, including counterfeit THC products. Bootleg THC cartridges are becoming too common on the market, with vendors advertising counterfeit and bootleg products on social media platforms such as Snapchat and Instagram. And according to press reports, the states that appear to be most inundated with counterfeit THC products are states where recreational marijuana is legal.

According to the California Department of Public Health, there were 28 potential cases of acute lung disease among people who had recently vaped cannabis products. In August, the California Department of Public Health reported a cluster of at least seven healthy kids in Kings County, California, all admitted to hospitals with symptoms of severe lung disease and all seven were linked to THC vapes that had been purchased from the black market. Lab tests conducted by a third-party testing company showed common contaminants in the counterfeit vapes, including pesticides, a fungicide that, when vaporized, converts into a substance used as a chemical weapon by the French during the first war, World War I.

In addition to the ongoing work, we need a full investigation into counterfeit THC cartridges, Madam Chair, as well as the vaping and cannabis black markets. That needs to be part of this investigation. So, let's get a full set of facts to ensure we get it right when we move forward on policy solutions. I appreciate the wit-

nesses who are going to testify today and others who have weighed in and echo the comments of the top Republican on the subcommittee, Mr. Guthrie.

Unfortunately, we have two very important subcommittees that the majority decided to schedule, one on top of the other, one on prescription drugs that begins in about eight minutes upstairs on a very partisan bill, and this one. So, sorry, but we will be going back and forth as we work on both of these issues, and I yield back.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Chair DeGette, thank you for holding this hearing. Electronic cigarettes, or e-cigarettes, the current outbreak of lung illnesses associated with e-cigarettes, and the youth vaping epidemic are a front-and-center health concern in the United States and particularly my home state of Oregon.

In recent weeks, an as-yet-unidentified lung illness has killed seven people and sickened more than 500 across at least 38 states. As we will hear from Dr. Sharpless and Dr. Schuchat today, the investigation into the cause or causes of this illness is ongoing, but it appears to be vaping-related. Many of the individuals who have gotten sick seem to have used black-market products containing THC.

Earlier this month, public health officials in Oregon announced that a person who died in July of a severe respiratory illness had used an e-cigarette containing marijuana oil purchased from a licensed dispensary, meaning that the products sold in the store should have gone through a testing process regulated by the state. It was the first death in the U.S. tied to a vaping product bought at a marijuana shop. Much is still unknown, however, including which dispensary sold the product and whether it was contaminated or whether something was added into the liquid in the device after purchase.

In July, an 18-year-old male went to the hospital complaining of breathing problems. Within 48 hours, he was sent to the Intensive Care Unit and diagnosed with acute respiratory distress syndrome, a condition associated with acute lung injury. He was connected to a breathing tube and placed in a medically induced coma for one week. Later, the patient's mother found an e-cigarette cartridge with the label of a licensed company based in California that sells THC products. The cartridge was later found to be a counterfeit of the company's product.

In North Carolina, five individuals, bought the marijuana oils that made them sick "on the street" from unlicensed and likely illegal dealers. All five were hospitalized, three in intensive care. It took a battery of tests to figure out that all five had acute exogenous lipid pneumonia—lung inflammation caused by breathing oil.

Luckily, the individuals in New York and North Carolina survived, but not all have been so lucky, including the individual who died in Oregon. These cases of young, seemingly healthy young adults getting sick after vaping are piling up too quickly.

These cases are shining a light on the youth vaping epidemic in the United States. The most recent data from the National Youth Tobacco Survey is very troubling. About 27.5 percent of youth reported using e-cigarettes in 2019, compared with 20.8 percent in 2018. This is a big jump from 11.3 percent just three years ago.

Given these trends, the Administration, the states, and this Committee are right to look for solutions to curtail youth access to e-cigarettes. I appreciate the Trump Administration's pursuit of an effective solution to the problem of youth access, as well as the partnership between the Administration and the states to investigate this outbreak of lung illnesses.

However, there is another overlay to the e-cigarette problem: counterfeit products, including counterfeit THC products. Bootleg THC cartridges are becoming more common on the market, with vendors advertising counterfeit and bootleg products on social media platforms, such as Snapchat and Instagram. According to press reports, the states that appear to be the most inundated with counterfeit THC products are in states where recreational marijuana is legal.

According to the California Department of Public Health, there have been 28 potential cases of acute lung disease among people who had recently vaped cannabis products. In August, the California Department of Public Health reported a "cluster" of at least seven healthy adults in Kings County, California, all admitted to hospitals with symptoms of severe lung disease. All seven of these cases were linked

to THC vapes that had been purchased from the black market. Lab tests conducted by a third-party testing company showed common contaminants in counterfeit vapes, including pesticides, and a fungicide when vaporized that converts into a substance used as a chemical weapon by the French army during World War I.

In addition to the ongoing work, we need a full investigation into counterfeit THC cartridges, as well as the vaping and cannabis black markets. Let's get a full set of facts to ensure we get it right on the policy solutions.

I look forward to listening to the testimony of the witnesses and working in a bipartisan fashion on solving this problem.

Ms.DEGETTE. The gentleman yields back. The Chair now asks unanimous consent that Members' written opening statements be made a part of the record. Without objection, so ordered.

I would now like to introduce our first panel of witnesses for today's hearing, Dr. Norman E. Sharpless, M.D., Acting Commissioner of the Food and Drug Administration, and Dr. Anne Schuchat, M.D., the Principal Deputy Director, Centers for Disease Control and Prevention. I want to thank both of you for appearing before the subcommittee today. I know you have both appeared before this Committee before, and it is great to see you. You are aware, I know, that this Committee holds an investigative hearing, and when it does so, it has the practice of taking testimony under oath. Do you have any objections to testifying under oath?

Let the record reflect the witnesses have responded no.

The Chair then advises that under the rules of the House and the rules of the Committee, you are entitled to be accompanied by counsel. Do either of you desire to be accompanied by counsel?

Let the record reflect the witnesses have responded no.

So if you would, please rise and raise your right hands so you may be sworn in.

[Witnesses sworn.]

Ms.DEGETTE. You may be seated.

Let the record reflect that the witnesses have responded affirmatively, and you are now under oath and subject to the penalties set forth in Title 18 Section 1001 of the United States Code.

The Chair now will recognize our witnesses for a 5-minute summary of their written statements. In front of each of you is a microphone and a series of lights. The light will turn yellow when you have a minute left and red to indicate your time has come to an end.

Dr. Sharpless, you are now recognized for 5 minutes.

STATEMENT OF NORMAN E. SHARPLESS, M.D.

Dr.SHARPLESS. Good morning, Chairwoman DeGette, Ranking Member Guthrie, and members of the subcommittee. Thank you for the opportunity to be here today to discuss the regulation of electronic nicotine delivery systems or ENDS, and the agency's role in the ongoing investigation into lung injuries experienced by individuals who use vaping products.

As you know, prior to coming to the FDA, I was director of the National Cancer Institute, and I'm a longtime cancer doctor. My experience treating patients has informed all of my work at the agency, including the issues before the Committee today. We are here to discuss two top priority issues. First, the ongoing investigation into the cause of the lung injury associated with the use of vaping products, and second, the FDA's ongoing efforts to address

an epidemic of youth use of ENDS products, including the administration's recent announcement about our intention to issue a policy that would address ongoing marketing of flavored ENDS products.

Let me start by discussing the vaping illness outbreak. Working with state partners, CDC and FDA have been investigating an outbreak of severe lung injury associated with the use of vaping products. Most cases have reported the recent use of vaping products containing THC, the psychoactive ingredient in marijuana. Although these cases seem similar, it is not clear if they have a common cause or if they have different pathogenesis with similar presentations. The investigation has not identified any specific substance or product that is linked to all cases.

Let me outline the main components of our investigation. FDA's Office of Emergency Operations has activated an Incident Management Group to coordinate across the agency and work alongside CDC's Incident Management System. FDA's regulatory field force is playing a critical role in the fact-gathering analysis. With state health departments, we are collecting samples for analysis at our Forensic Chemistry Center. The FCC is using state-of-the-art methods to assess the presence of a broad range of chemicals in these products, including nicotine, THC, and other cannabinoids, opioids, cutting agents, and other additives, pesticides, and toxins.

Additionally, we are working with Customs and Border Protection to identify illicit vaping products at the international mail facilities. FDA's Office of Criminal Investigations is focused on identifying the products that are making people ill and following the supply chain to the source. FDA is not pursuing actions associated with personal use of any vaping products; our interest is in the suppliers. But to be clear, if we determine that someone is manufacturing or distributing illicit adulterated vaping products that caused illness or death for personal profit, we would consider that to be a criminal act. Because many of the products associated with the cases contain THC oils, we have engaged the DEA to help with our investigation.

Now, let me turn to the FDA's efforts to address the disturbing rate of ENDS use by children. This summer, working with CDC, the agency received preliminary data from the 2019 National Youth Tobacco Survey, or NYTS. Despite strong compliance and education strategies, the 2019 data indicate another alarming increase in youth use of ENDS products.

FDA's response to the 2018 NYTS data was aggressive and multipronged. We stepped up compliance and enforcement efforts by issuing warning letters and civil money penalties for retailers for sales of ENDS to minors. We collaborated with the Federal Trade Commission to remove kid-appealing products from the market and pursued ENDS manufacturers employing unlawful online posts by social media influencers. Most recently, earlier this month, we issued a warning letter to Juul Labs, Incorporated, for marketing unauthorized modified-risk tobacco products, including at a presentation to children given at a school.

We also expanded our efforts to educate youth about the dangers of e-cigarette use. Our youth e-cigarette prevention campaign, the Real Cost campaign, is a comprehensive effort targeting nearly 10.7 million youth aged 12 to 17. Despite these significant efforts,

the 2019 NYTS preliminary data, as well as another study supported by NIDA demonstrate a continued rise in the disturbing rate of youth e-cigarette, use especially through the use of non-tobacco flavors. In particular, these data show that more than a quarter of high school students were current e-cigarette users in 2019, and youth e-cigarette users cited fruit and menthol/mint flavors as being the most popular.

In short, these data indicate that the FDA must do more. That's why the President announced his support for the FDA's intention to soon finalize a compliance policy related to flavored ENDS. This policy would prioritize FDA's enforcement of premarket authorization requirements for non-tobacco flavors. FDA is not banning flavors as it has been described in some news outlets. Rather, FDA intends to enforce existing law that limits the marketing of such products.

This policy would not mean that flavored e-cigarettes could never be marketed. If a company can show through an application to FDA that a specific product meets the standards set forth by Congress, then the FDA would authorize that ENDS product for sale. FDA intends to prioritize enforcement actions such that flavored e-cigarette products will be expected to exit the market unless and until manufacturers of these products provide scientific evidence demonstrating that marketing their products is appropriate for the protection of the public health.

I want to assure the subcommittee that I am firmly committed to employing all the tools at FDA's disposal to tackle these important problems. We will not rest until we have answers to the questions in the investigation and until we've dramatically reduced the access and appeal of e-cigarettes to children. Thank you.

[The prepared statement of Dr. Sharpless follows:]

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TESTIMONY

OF

NORMAN E. SHARPLESS, M.D.
ACTING COMMISSIONER OF FOOD AND DRUGS
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

“FDA REGULATION OF ELECTRONIC NICOTINE DELIVERY SYSTEMS
AND INVESTIGATION OF VAPING ILLNESSES”

SEPTEMBER 25, 2019

RELEASE ONLY UPON DELIVERY

Introduction

Good morning, Chairwoman DeGette, Ranking Member Guthrie, and Members of the subcommittee. Thank you for the opportunity to be here today to discuss the Food and Drug Administration's (FDA or the Agency) regulation of electronic nicotine delivery systems, or ENDS, which include e-cigarettes, and the Agency's role in the ongoing investigation into severe respiratory lung injury associated with e-cigarette use or vaping. I am Ned Sharpless, Acting Commissioner of the U.S. Food and Drug Administration, which is part of the Department of Health and Human Services (HHS).

FDA is deeply concerned by the severe respiratory lung injuries and reported deaths associated with e-cigarette use or vaping, and the Agency is working very closely with the Centers for Disease Control and Prevention (CDC) and state officials to investigate these incidents. FDA is committed to taking appropriate actions to protect the public as the facts emerge. To date, most patients have reported a history of using vaping products containing tetrahydrocannabinol (THC). Many patients have reported using products containing THC and products containing nicotine. Some have reported the use of e-cigarette products containing only nicotine.

I appreciate the opportunity to be here today to provide an update on FDA's regulation of ENDS, including the Administration's recent announcement to finalize a compliance policy that would prioritize enforcement against flavored ENDS to clear the market of those products, unless and until their marketing has been shown to be appropriate for the protection of the public health, as Congress required, and to provide an update on FDA's efforts to investigate the illnesses associated with the use of vaping products.

Background

Let me start with some basic background on our tobacco regulatory authorities.

Tobacco use is the single largest preventable cause of disease and death in the United States. Each year, more than 480,000 people in the United States die prematurely from diseases caused by cigarette smoking and exposure to tobacco smoke. In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to oversee the manufacture, marketing, distribution, and sale of tobacco products and protect the public from the harmful effects of tobacco product use. This authority gave FDA comprehensive tools to protect the public from the harmful effects of tobacco use through science-based tobacco product regulation.

With limited exceptions, FDA evaluates new tobacco products based on a public health standard that considers the risks and benefits of the tobacco product to the population as a whole, including users and non-users. Similarly, when developing regulations, the law generally requires FDA to apply a public health approach that considers the effect of the regulatory action on the population as a whole, not just on individual users, taking into account initiation and cessation of tobacco use.

Under the statute, FDA had immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Tobacco Control Act also authorized FDA to “deem” other “tobacco products” (which include “any product made or derived from tobacco that is intended for human consumption” that is not a drug, device, or combination product under the FD&C Act, “including any component, part, or accessory” of that product) to be subject to the Agency’s regulatory authority in Chapter IX of the FD&C Act.

On May 10, 2016, FDA issued a final rule (the “deeming rule”) to deem additional products that meet the statutory definition of a “tobacco product,” except for accessories, to be subject to FDA’s regulatory authority. Deemed products include ENDS, cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and any future tobacco products. The deeming rule, and FDA’s regulation of these products, took effect on August 8, 2016.

Regulatory Requirements for ENDS Products

When the deeming rule took effect in August 2016, many of the regulatory and legal requirements that had been in place for manufacturers of cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own tobacco since 2009, as well as several new requirements specific to deemed products, became applicable to makers of e-cigarettes and other ENDS products. These include:

- Registering domestic establishments and submitting lists of products manufactured at those establishments, including all labeling and representative samples of advertisements;
- Submitting tobacco health documents;
- Submitting ingredient listings;
- Marketing new tobacco products only after FDA review; and
- Marketing products with direct or implied claims of reduced risk only if FDA confirms that scientific evidence supports the claim and determines that providing a marketing authorization for the product will benefit the health of the population as a whole.

In addition, the following regulatory provisions also apply to deemed tobacco products, including ENDS products:

- Minimum age restriction and identification requirement to prevent sales to underage youth;
- Requirements to bear certain health warnings on packages and advertisements (including certain ENDS components, such as e-liquids) such as, “WARNING: This product contains nicotine. Nicotine is an addictive chemical” and
- Prohibition of vending machine sales, unless in a facility that never admits youth.

FDA recognized that industry would need time to comply with some of the new regulatory requirements triggered by the final deeming rule and announced a compliance policy with staggered timeframes for compliance. Some of the requirements, such as the Federal minimum

age of purchase, took effect immediately when the deeming rule took effect on August 8, 2016, while, as an exercise of enforcement discretion, FDA provided industry with additional time to comply with other requirements, such as premarket review of “new” tobacco products.

Premarket Review of ENDS

All deemed products, including ENDS products, became subject to the premarket authorization requirements in the Tobacco Control Act on August 8, 2016. All “new” tobacco products are required to obtain authorization from FDA before they can be legally marketed. Pursuant to the Tobacco Control Act, a “new” tobacco product is one that was not commercially marketed as of February 15, 2007, or that was modified after February 15, 2007.

FDA’s initial compliance policy for premarket review stated that the Agency did not intend to enforce the requirements of premarket review against manufacturers of newly-regulated new tobacco products that were on the market as of August 8, 2016, as long as they submitted applications seeking marketing authorization within specific timeframes. As a result, FDA anticipated that many ENDS products would remain on the market without premarket authorization for up to three years.

In July 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation that would serve as a multi-year roadmap in an effort to significantly reduce tobacco-related disease and death. The comprehensive plan was, in part, announced to afford the Agency time to explore clear and meaningful measures outside of premarket review to make combustible tobacco products less toxic, less appealing, and less addictive. One aspect of the plan involved striking a balance between regulation and encouraging development of innovative tobacco products that may be less harmful than cigarettes. The Agency announced that it planned to issue an updated compliance policy further deferring some enforcement timelines described in the final deeming rule.

The July 2017 announcement led to publication of the August 2017 Compliance Policy, which was later the subject of litigation. In May 2019, a U.S. District Court in Maryland vacated FDA’s 2017 Compliance Policy. In July 2019, the court ordered that applications for deemed “new” tobacco products such as e-cigarettes, cigars, pipe tobacco, and hookah tobacco, that were

on the market as of August 8, 2016, must be filed with FDA no later than May 12, 2020. The court order also provided for a one-year period during which products with timely filed applications might remain on the market pending FDA review, but subsequently clarified that its order does not restrict the agency's authority to enforce the premarket review provisions against deemed products prior to May 12, 2020, or during the one-year review period.

No ENDS product in the United States is on the market legally. To be legally marketed as a tobacco product, the product would need to undergo FDA scientific review and the Agency would have to find that the marketing of the product is appropriate for the protection of the public health. Alternatively, an ENDS product that is marketed for therapeutic purposes as a drug would need to be reviewed under FDA's drug authorities, and approved for such marketing. There is no FDA-authorized or FDA-approved ENDS product currently on the market.

FDA's Aggressive Actions to Address the Youth Epidemic of ENDS Product Use

At the time FDA issued the August 2017 Compliance Policy to modify the enforcement discretion policies regarding premarket authorization, nationally representative data suggested that youth use of e-cigarettes had declined.¹ While no level of youth use is acceptable, FDA took this directional data into consideration, along with the potential for some such products to offer a public health benefit to some individual addicted adult smokers. In the context of these uncertainties and this evidence, and with the potential for FDA to pursue other bold measures, in part by reducing the addictiveness of combustible cigarettes while temporarily delaying the immediate market exit of innovative, potentially less harmful tobacco products, FDA determined that the balancing of public health considerations argued in favor of a different comprehensive approach. However, the NYTS 2018 data showed a significant increase in youth use of e-cigarettes. Data from the NYTS showed that, between 2017 and 2018, current e-cigarette use among high school students increased 78 percent, from 11.7 percent to 20.8 percent.² Current e-

¹ Jamal A, Gentzke A, Hu SS, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2016. *MMWR Morb Mortal Wkly Rep* 2017;66:597–603. https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm?s_cid=mm6623a1_w The NYTS defines e-cigarettes as “battery-powered devices that provide nicotine and other additives to the user in the form of an aerosol.”

² *Id.*

cigarette use among middle school students also increased by 48 percent over the same time period, from 3.3 percent to 4.9 percent.³

Moreover, evidence demonstrates that youth are especially attracted to flavored ENDS products. Data from the 2018 NYTS showed that current (past 30-day) use of any flavored e-cigarette increased substantially among high school students who reported current e-cigarette use (60.9 percent to 67.8 percent) in just one year.⁴

Preliminary data from the 2019 NYTS show a continued rise and disturbing rate of youth e-cigarette use, especially through the use of non-tobacco flavors that appeal to kids. In particular, the preliminary data show that more than a quarter of high school students were current e-cigarette users in 2019, and the majority of youth e-cigarette users cited the use of popular fruit and menthol/mint flavors.

FDA must act to try to reverse these trends. We are committed to keeping tobacco products out of the hands of youth and will not stand idly by as a new generation becomes addicted to nicotine and tobacco products. I am committed to tackling the epidemic of youth e-cigarette use using the regulatory tools at the Agency's disposal. We are taking a number of actions to help address the epidemic:

- Earlier this month, the President announced that as part of the Administration's ongoing work to tackle the epidemic of youth e-cigarette use, FDA intends to finalize a compliance policy in the coming weeks that would prioritize the Agency's enforcement of the premarket authorization requirements for non-tobacco-flavored e-cigarettes, including mint- and menthol-flavored products. It is important to note that this does not mean flavored e-cigarettes can never be marketed—if companies think they can show that specific products meet the standards established by Congress, then they can submit that evidence to FDA through a product application, which FDA will then evaluate. It

³ *Id.*

⁴ Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018," *Morbidity and Mortality Weekly*, 67(45):1276-1277 (2018).

does mean that FDA intends to prioritize enforcement action such that, unless and until the manufacturers of these products meet their burden under the Tobacco Control Act to show that scientific evidence demonstrates that their marketing is appropriate for the protection of the public health, these products will be expected to exit the market.

- FDA has been holding retailers and manufacturers accountable for marketing and sales practices that have led to increased youth accessibility and appeal of e-cigarettes. For example, FDA has issued more than 10,000 warning letters and more than 1,400 civil money penalties to retailers, both online and in brick-and-mortar retail stores, for sales of ENDS and their components to youth.
- FDA has sent letters to about 90 companies seeking information on over 110 brands, including ENDS products, to determine whether those products were not marketed as of August 8, 2016, and therefore not subject to any previous FDA compliance policy. To date, FDA has issued warning letters to five ENDS companies notifying them of the need to remove a combined total of more than 40 products from the market.
- The Agency has issued warning letters, many in collaboration with the Federal Trade Commission (FTC), that resulted in the removal of dozens of e-liquid products resembling kid-friendly foods, such as juice boxes, cereal, and candy.
- FDA and FTC sent warning letters to firms that make and sell flavored e-liquids for violations related to online posts by social media influencers on their behalf that lacked the required nicotine addiction warnings.
- On September 9, 2019, FDA issued a warning letter⁵ to JUUL Labs Inc. for marketing unauthorized modified risk tobacco products by engaging in labeling, advertising, and/or other activities directed to consumers, including a presentation given to youth at a school, by marketing it for reduced risk or harm from using the product compared to cigarette smoking. Concurrently, the Agency issued a second letter expressing its concern and requesting additional information about several issues raised by Congress regarding JUUL's outreach and marketing practices, including those targeted at students, tribes, health insurers and employers.

⁵ The warning letter is available at: <https://www.fda.gov/news-events/press-announcements/fda-warns-juul-labs-marketing-unauthorized-modified-risk-tobacco-products-including-outreach-youth>.

- The Administration has also continued to invest in campaigns to educate youth about the dangers of e-cigarette use. Last year, FDA launched “The Real Cost” Youth E-Cigarette Prevention Campaign⁶— a comprehensive effort targeting nearly 10.7 million youth, aged 12-17, who have used e-cigarettes or are open to trying them. The campaign features hard-hitting advertising on TV, digital and social media sites popular among teens, as well as posters with e-cigarette prevention messages in high schools across the nation.
- FDA joined forces with Scholastic to develop educational resources for high school teachers and administrators. These materials have been distributed to over 700,000 high school educators. Our work with Scholastic continues, and we are currently developing additional resources, including lesson plans, for both middle and high school educators throughout this school year.
- The Agency also developed posters and resources for doctors, youth groups, churches, state and local public health agencies, and others on the dangers of youth e-cigarette use and has worked to advance discussion and understanding around how to help those kids who are already addicted to e-cigarettes quit.

We will continue to take vigorous actions aimed at ensuring e-cigarettes and other tobacco products are not being marketed or sold to kids. In addition, we will continue and expand our public education efforts to get the word out to youth about the harms of e-cigarettes.

Investing in Research to Learn More About the Health Impacts of ENDS Products

FDA is funding several research projects assessing the health impact of e-cigarettes, including the FDA and NIH Population Assessment of Tobacco and Health (PATH) Study. The PATH Study is a national, longitudinal cohort study of almost 46,000 youth and adults in the United States that collected its first wave of data in 2013 and is following study participants over time to learn how and why people start using tobacco products, quit using them, and start using them again after they have quit, as well as how different tobacco products affect health (such as cardiovascular and respiratory health) over time. The PATH Study is tracking potential

⁶ More information is available at: <https://www.fda.gov/tobacco-products/real-cost-campaign>.

behavioral and health impacts, including collecting biospecimens to analyze for biomarkers of exposure and harm.⁷

In 2016, FDA awarded a contract to National Academy of Sciences, Engineering and Medicine (NASEM) to “conduct an in-depth evaluation of the available evidence of health effects from electronic nicotine delivery systems (ENDS) and make recommendations for future federally funded research.” This work included convening a multi-disciplinary committee of 13 members that met several times and holding an open meeting in order to obtain input from a wide range of stakeholders. The committee’s methodology included a comprehensive literature search, literature review and quality assessment, evidence synthesis to assess causality for health effects, and application of a framework for levels of evidence. Over 800 peer-reviewed scientific studies were evaluated and the consensus report, “Public Health Consequences of E-Cigarettes,” was released by NASEM in January 2018.⁸ Among the conclusions in the NASEM report is that teens who experiment with an e-cigarette are more likely to try conventional cigarettes compared to teens who never used an e-cigarette.

As noted in the NASEM report, assessing the long-term health effects of e-cigarettes is challenging given the range of devices and constituents. For example, products can vary widely in terms of device type, mechanism, ingredients and the characteristics of aerosol generation. Variables of ENDS that could affect health impact include factors such as: exposure to metals (including heavy metals), heating capacity, e-liquid substrates, nicotine concentration, flavors and flavoring ingredients, and use of other ingredients or contaminants with unknown inhalation effects. A specific ENDS product’s health impact is also likely to be significantly affected by user behaviors (and we know that many ENDS users also use other tobacco products in addition to e-cigarettes). Assessing the short-term health effects is also challenging for these same reasons. To help understand the individual and population impact of ENDS, FDA is funding studies assessing the short- and long-term health effects of e-cigarettes including nicotine

⁷ More information on the PATH Study can be found at <https://www.fda.gov/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health>.

⁸ More information can be found at <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.

dependence, cardiovascular and pulmonary toxicity, potential carcinogenesis, effects of maternal use during pregnancy, and effects in the oral cavity.⁹

Investigation of Severe Respiratory Illnesses Associated with Vaping Products

In recent weeks, an outbreak of severe respiratory lung injury associated with the use of vaping products has possibly sickened over 530 people from 38 states and one U.S. Territory. Sadly, seven deaths have been confirmed in California, Illinois, Indiana, Kansas, Minnesota, and Oregon. These illnesses do not appear to be due to infectious diseases but rather appear to be associated with a chemical exposure from vaping products. Patients report a gradual start of symptoms including breathing difficulty, shortness of breath, and/or chest pain before hospitalization. Many patients have reported recent use of vaping products containing THC. Although these cases seem similar, it is not clear if they have a common cause, or if they involve different diseases with similar presentations. The investigation has not identified any specific product or substance or vaping product that is linked to all cases.

FDA is working closely with CDC and the affected states to investigate these cases. FDA's Office of Emergency Operations has activated an Incident Management Group (IMG) and is working alongside CDC's Incident Management System. The IMG serves as FDA's focal point for emergency management and is staffed by experts from across FDA.

FDA's work to investigate the illnesses includes field sample collections in coordination with states, sample analysis, criminal and civil investigations, and coordination with state and Federal partners.

FDA is also assisting states by collecting and analyzing samples. FDA's Forensic Chemistry Center (FCC) is an accredited laboratory in the field of forensic science testing and has experience in rapid response and specialized analytical services. FDA is analyzing samples for the presence of a broad range of chemicals, including nicotine, THC and other cannabinoids

⁹ More information can be found on the FDA website at <https://www.fda.gov/tobacco-products/research/ctp-supported-tobacco-regulatory-research-projects>.

along with cutting agents/diluents and other additives, pesticides, opioids, poisons, and toxins. Many samples received have contained little to no liquid, which limits the amount of testing our laboratory is able to conduct. In most cases, patients have acknowledged recent use of THC-containing vaping products. Many patients have reported using products containing THC and products containing nicotine. Some have reported the use of e-cigarette products containing only nicotine. Similarly, the samples we are continuing to evaluate show a mix of results and no single substance, including Vitamin E acetate, has been identified in all of the samples tested. Importantly, identifying any compounds that are present in the samples will be one piece of the puzzle but will not necessarily answer questions about causality, which makes our ongoing work critical.

Investigating this crisis is FDA's Office of Criminal Investigations' top priority. Our agents are following every possible lead, which includes traveling throughout the country and attempting to gather any available evidence, including devices, pods/cartridges, diluting agents, etc.

FDA is working with our other Federal partners to investigate the illnesses. For example, we are working with Customs and Border Protection to identify potential illicit FDA-regulated products at the border.

It is critical that FDA communicate with the public when we have information to share, and we work to do that as frequently and openly as possible. For example, earlier this month, FDA issued a warning to consumers to avoid THC-containing vaping products. While the investigation is ongoing, we strongly encourage consumers to help protect themselves and avoid buying vaping products of any kind on the street, and to refrain from using THC oil or modifying/adding any substances to products purchased in stores. FDA also encourages the public to submit detailed reports of any unexpected tobacco- or vaping-related product issues to FDA via the online Safety Reporting Portal, which can be found on our website (or at www.safetyreporting.hhs.gov).

Conclusion

Thank you for the opportunity to testify today about FDA's work to investigate the severe respiratory illnesses associated with vaping and our efforts to regulate ENDS products. It is an ever-changing landscape that FDA is committed to navigating with the goal of vigorously protecting and improving the public health.

I am happy to answer any questions you may have.

Ms.DEGETTE. Thank you, Dr. Sharpless.
 Dr. Schuchat, you are now recognized for 5 minutes.

STATEMENT OF ANNE SCHUCHAT, M.D.

Dr.SCHUCHAT. Thank you, Chairwoman DeGette and Ranking Member Guthrie, and members of the subcommittee. I'm happy to have the chance to update you about our ongoing investigation of lung injury as well as what we're doing related to the youth epidemic of e-cigarette use. I want to tell you what we know and what we don't know, what we're doing about the lack of knowledge, and also what we're doing about the youth e-cigarette problem.

I want to make four key points. First, since the first time we learned of these cases of lung injury, CDC has been working 24/7, hand in hand with the state and local public health as well as the FDA, to get to the bottom of it. Secondly, our ability to do this type of investigation relies on a critical underlying public health infrastructure, including data systems that need modernization, and a trained public health workforce, including a data-savvy public health workforce.

Third, CDC has made important recommendations to the public already, including the comment that while this investigation is ongoing, people who are concerned about health risks should consider refraining from using e-cigarette products or vaping. People should not acquire products off the street and should not modify these further beyond what was intended by the manufacturers. Adults who use e-cigarettes or vaping products because they have quit cigarette smoking should not return to smoking cigarettes.

And, fourthly, this outbreak reinforces the need to address the broader epidemic of cigarette use among youth. What we know so far is that this epidemic is striking young people. Half of the cases are under 25. About three in four are male, but those numbers are changing as we get more data. We are getting new cases reported every day, and I expect this week's numbers to be hundreds higher than what we reported last week.

What we don't know unfortunately, is the cause. We know that most of the reported cases with information available so far describe e-cigarette use containing THC or THC and nicotine e-cigarette use. But no single product, brand, substance, or additive has been identified with all cases at this point. It may be that there is one cause or that there are many causes, and there may be complex root causes.

CDC is working vigorously together with the states to respond. We've dispatched our disease detectives to assist some of the state and local public health. We've been coordinating case definition, data collection, and analysis. We've issued clinical guidance, and we're working with the clinical community to update that as new information becomes available. We activated Our Emergency Operations Center as we do for various public health emergencies, and we are coordinating and convening the public health and clinical community as well as doing frequent media telebriefs to keep the public informed as well. We're working closely with the FDA on the traceback of products that people have used.

And while our laboratory is not testing the patient products that are collected—that's, the FDA's role at this, point—our tobacco lab

is working to develop assays to test the aerosols produced from some of the products. There are challenges with this response. The investigation includes trying to gather information about exposures to potentially illicit products and so some respondents may not be totally forthcoming. State laws vary regarding THC and cannabis use, that can also complicate the data collection challenges.

E-cigarettes or vaping are part of a marketplace that is very wide and diverse. As you've heard, a multitude of product varieties and different substances can be used with the devices. There is also the issue of counterfeiting or black market products. Public health data collection for its response is relying on antiquated and fragmented systems that need modernization. The disease, unfortunately, is moving faster than our data systems at this point and that is a barrier to our getting to quick answers.

Let me turn briefly to what we're doing about the youth vaping issue or the youth e-cigarette use. We know that youth are much more likely than adults to use e-cigarettes. CDC has been messaging about our concerns with youth e-cigarette use since 2013, when we got the initial data about the alarming increase from 2011 to 2012 in youth use of e-cigarettes, so we have been at this, and we continue to be at this in terms of our concerns.

Finally, CDC is dedicated to working around the clock together with FDA and state and local health officials to identify the cause or causes of this outbreak, and we will continue to keep Congress updated. Thank you.

[The prepared statement of Dr. Schuchat follows:]



Written Testimony
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

September 25th, 2019

Statement of
Anne Schuchat, M.D. (RADM, USPHS, RET)
Principal Deputy Director

Centers for Disease Control and Prevention
Department of Health and Human Services

For Release on Delivery
Expected at 10:00 am
On Wednesday, September 25, 2019

Good morning, Chairwoman DeGette, Ranking Member Guthrie, and members of the Subcommittee. I am Dr. Anne Schuchat, the Principal Deputy Director of the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to testify before you regarding CDC's investigation into lung disease associated with using e-cigarette or vaping products, and for your continued commitment to supporting CDC's work in protecting public health.

Introduction

On August 1, 2019, Wisconsin first alerted CDC to a cluster of pulmonary illness among young adults that began in July 2019. As of September 18, 2019, 38 states and one territory have reported 530 confirmed and probable cases of lung disease associated with e-cigarette use or vaping. Six states (California, Illinois, Indiana, Kansas, Minnesota, and Oregon) have reported the death of a patient who had been hospitalized with lung disease with a history of recent e-cigarette or other vaping product use. As of September 18, there have been seven reported deaths. These tragic deaths reinforce the urgency of efforts by CDC, in coordination with the U.S. Food and Drug Administration (FDA), to identify the cause of this illness and to equip states with the necessary resources to address this emerging public health issue.

As you know, CDC's mission is to protect America from health, safety and security threats. CDC leverages cutting edge science and experience in preparedness and response to effectively protect Americans from public health threats. Consistent with what we do for other emergency investigations, CDC implemented an incident command structure in August and, on September 16, activated its Emergency Operations Center to enable it to dedicate more resources to this investigation. CDC works directly with state and local health departments as they identify cases, better describe illnesses, and search for causes and risk factors. CDC facilitates information sharing between state health departments and clinicians, analyzes data and conducts investigations, coordinates national communication activities such as updates on the status of the investigation, and provides health messaging tools for states.

Epidemiology Summary

The ongoing investigation into the cause of lung injury associated with e-cigarette or vaping product use

is challenging for a variety of reasons. First, the investigation covers a large number of states. Second, the investigation is complicated by the diversity of the e-cigarette or vaping product marketplace, with a multitude of products, a wide array of ingredients, and the intersection with potentially illicit substances such as marijuana. Users do not know what is in their e-cigarette or vape solutions. Moreover, many of the products and substances themselves can be modified by the user. They can be obtained from brick and mortar stores, online retailers, on the street, or through social sources. Our preliminary results are from data collected from dozens of states. In addition, data collection on the products used relies on self-reporting, and interviewees may be hesitant to share information about their use of illicit substances such as marijuana. According to data collected in two states and recently published in the New England Journal of Medicine, most patients (around 80 percent) reported using e-cigarette or vaping product liquids containing tetrahydrocannabinol, or THC (a psychoactive compound of marijuana), and more than half (around 60%) reported using liquids with nicotine, while around 10-20 percent reported using products with nicotine only. No single e-cigarette or vaping product, brand or specific substance has been definitively linked to the outbreak.

CDC has received complete sex and age data on 373 of 530 cases. Nearly three-fourths of cases are male. Two-thirds of cases are 18 to 34 years old. Sixteen percent of cases are under 18 years and 17 percent are 35 years or older. Patients reported use of e-cigarette or other vaping products which could include devices, liquids, refill pods, and/or cartridges. The lung injuries observed in this outbreak does not appear to be due to infection. The pathologic appearance and absence of infectious diagnoses suggests chemical exposure(s). Patients first experienced their symptoms from a few days to several weeks after they most recently used e-cigarette or vaping products. Most patients reported a gradual onset of difficulty breathing, shortness of breath, or chest pain before hospitalization. Some patients reported mild to moderate gastrointestinal illness, sometimes preceding respiratory symptoms. Some patients have reported other symptoms, such as fatigue, fever, and weight loss. Investigators have not identified any specific product or compound that is linked to all cases thus far.

CDC's Collaboration with States

CDC and FDA are working closely with and providing a coordinating function to state and local health officials to investigate these incidents as quickly as possible and aggregate information across states. CDC activated its Emergency Operations Center on September 16. CDC's incident command structure comprises more than 80 staff from across the agency to coordinate activities, develop investigation tools and guidance, and provide assistance to states, public health partners, and clinicians around the nation.

Shortly after Wisconsin first alerted CDC on August 1, 2019, to a cluster of pulmonary illness among young adults that began in July 2019, CDC learned that there also were possible similar cases in Illinois. Wisconsin and Illinois state health departments requested an "Epi Aid," a formal assistance mechanism, from CDC on August 14, and August 16 respectively. Four CDC staff, including two Epidemic Intelligence Service Officers, were deployed to Illinois and Wisconsin on August 20, 2019, to assist with their respective state investigations. Building on the tools that were developed in Wisconsin and Illinois, CDC staff worked with all the states and the Council of State and Territorial Epidemiologists to help develop a standardized surveillance case definition and medical data collection tools to allow for more consistency across the states as they complete their own investigations and verify and classify their cases.

When state investigators learn of suspected cases, they examine the medical records and consult with the clinical care team for each case. Using the standard case definition that has been developed, the state investigators then determine which cases are confirmed and which are probable. In both confirmed and probable cases, the patient recently used an e-cigarette product or vaped, developed a breathing illness, and other common causes of illness were ruled out as the primary cause of the illness. Confirmed and probable cases differ in the certainty with which an infectious cause is ruled out. But because the differences between these definitions are subtle, CDC reports confirmed and probable cases together for simplicity. In addition to approaching the investigation from this clinical perspective, clinicians and public health departments are also interviewing patients to gather more information about the devices and substances used as well as individual

behaviors.

CDC has established a data reporting system which has been made available for states to enter data or to send data to CDC in an effort to describe the outbreak and define causes. CDC also reaches out to state health departments when it receives anecdotal reports of possible cases from clinicians and other sources. The reported information will allow CDC to aggregate and analyze the data across states to provide a better national picture of this emerging health issue.

CDC is coordinating regular multi-state conference calls with health officials, laboratory personnel, and others to exchange information and is leading outreach to state health departments and clinicians, as well as coordinating efforts with FDA to gather information on devices or substances used, to help build a more comprehensive picture of these incidents. CDC is gathering reports of the types and brands of e-cigarette or vaping products used, the substances used, any modifications of the products, and where the products and liquids were obtained. This information will be shared with FDA to help FDA assess which of the products fall within FDA's regulatory authority. CDC also developed interim guidance for clinicians and the public in support of the investigation.

Based on CDC's expertise in evaluation of e-cigarette or vaping devices and solutions, additional investigations are in development to help identify the potential chemical cause or causes of lung disease associated with use of e-cigarettes and vaping products. Because of the variety of chemicals that are present in e-cigarettes or vaping liquids and that may be added to e-cigarette or vaping liquids, as well as the diversity of products in circulation, laboratory analyses may be complex. In addition, users can modify the products, and the heating process can also influence the types and amounts of chemicals a user is exposed to. Thus, the identification of the cause or causes for the outbreak may take substantial time and continuing effort.

CDC's Outreach

CDC is the source of public health information on this investigation and ensures that the findings from the investigation, as well as evidence-based interim recommendations, are provided to the public, health care providers, and others as soon as possible. CDC has communicated to consumers, clinicians, and public health

professionals through scientific publications, web products, social media, traditional media, and other channels.

On August 16, 2019, CDC released a Clinician Outreach and Communication Activity (COCA) Clinical Action Alert describing this investigation and asking providers to report possible cases to their state health departments. CDC released a Health Alert Network (HAN) Health Advisory on August 30, 2019, with specific recommendations for clinicians, health officials, and the public. On September 6, 2019, CDC released additional information through the Morbidity and Mortality Weekly Reports (MMWRs), a summary from clinicians in North Carolina of clinical characteristics and e-cigarette or vaping product use exposures among five identified cases in that state, as well as CDC guidance for public health officials, clinical providers, and the public about prevention, case identification, and reporting.

The New England Journal of Medicine article by authors from the Illinois and Wisconsin health departments in collaboration with CDC authors was also published on September 6. The article summarized the clinical characteristics and e-cigarette or vaping product use exposures among 53 Wisconsin and Illinois cases. Many of the patients, but not all, reported recent use of products containing THC, and some reported using both THC- and nicotine-containing products. Around 10-20 percent of cases report using nicotine-containing products only.

CDC and FDA are working tirelessly to investigate whether the disease may be linked to specific ingredients or contaminants in the devices or substances associated with e-cigarette or vaping product use.

Challenges

This investigation has posed a number of challenges. First, most public health data collection and reporting systems are antiquated and fragmented, making it challenging to assure timely, actionable information while continuing to safeguard patient privacy. This investigation is emblematic of a challenge to all our work that requires rapid collection and analysis of public health data but is often reliant on paper-based systems and fax machines rather than electronic reporting and systems that are not interoperable. Second, the nature of the investigation includes inherent challenges, as reports of use of illicit drugs may complicate data collection from patients. State laws vary regarding THC and cannabis use, which may make standardized and

consistent data collection challenging. Finally, the e-cigarette and vaping marketplace is wide and diverse, with a multitude of substances that can be used with the devices. This can complicate toxicology testing (when there are a limited number of samples) and the interpretation of results (when there are many chemicals and substances that may be found across a wide variety of products).

Despite these challenges, CDC has released interim recommendations for healthcare providers, health departments, and the public, and CDC will continue to provide evidence-based recommendations as we learn more.

CDC's Efforts to Address the Epidemic of E-cigarettes

This outbreak comes in the middle of epidemic-level use of e-cigarettes by young people in the United States and reinforces the need to address the broader e-cigarette epidemic in the United States. Youth are much more likely than adults to use e-cigarettes. In fact, e-cigarettes are the most commonly used tobacco product among youth and their increased use has erased recent progress in reducing overall use of tobacco among youth. Preliminary data from the 2019 National Youth Tobacco Survey show a continued rise in rates of youth e-cigarette use. The data show that in 2019, more than a quarter of high school students were current (past 30 day) e-cigarette users, a substantial increase in e-cigarette use among youth since 2017. E-cigarette use among high school students increased by 77.8 percent from 2017 to 2018, and more than one in four high school students reported current use of any tobacco product. As a result, the U.S. Surgeon General in December 2018 called the use of e-cigarettes among youth an epidemic in the United States.

CDC is engaged in multifaceted efforts to prevent and reduce use of all tobacco products, including e-cigarettes, among young people. In collaboration with our partners and other Federal agencies, CDC collects data and conducts research on youth use of tobacco products, including e-cigarettes. CDC and FDA jointly administer the National Youth Tobacco Survey (NYTS), an annual survey to monitor trends in the use of tobacco products among U.S. students in grades 6 through 12. CDC complements its routine surveillance efforts with novel, rapid response monitoring that captures emerging trends concerning e-cigarettes, such as the rise of e-cigarette sales from 2013 to 2017. In addition, the Tobacco Laboratory in CDC's Environmental Health

Laboratory provides critical laboratory science, including measuring harmful and addictive constituents in e-cigarette solutions and aerosol, and measuring chemicals in the blood and urine of people who use e-cigarettes or are exposed to secondhand aerosol.

CDC also educates the public about the harms of tobacco products, including e-cigarettes. For example, in 2016, CDC collaborated with the Surgeon General to release a Surgeon General's Report entitled *"E-Cigarette Use Among Youth and Young Adults."* This was the first comprehensive report on e-cigarettes among young people released by the U.S. government. Since, then, CDC has continued to promote the findings of the Report to educate parents, influencers of youth, and youth themselves. In response to compelling data about the sales and increased market share of JUUL, reports of widespread teen use of this and similar products, and mounting public concerns, CDC launched a partner initiative to expand the reach of CDC public health warnings. CDC developed plain-language infographics and social media posts for public health organizations and consumer audiences about e-cigarettes and has conducted back-to-school social media campaigns. CDC was the primary federal agency that assisted the Office of the Surgeon General in writing and launching a December 2018 e-cigarette advisory to bring awareness to relevant audiences (teachers, parents, clinicians) about e-cigarette use by young people. CDC also developed promotional materials to support the release of the advisory, which was the first such advisory on a tobacco related topic released by the Office of the Surgeon General.

Through the National Tobacco Control Program, CDC provides funding and technical support to all 50 states, the District of Columbia, 8 U.S. territories, 12 tribal support organizations, and 8 national networks representing priority populations, which are essential for coordinating the public health response to prevent tobacco initiation among youth and young adults, promote quitting among youth and adults, eliminate secondhand exposure to smoke and e-cigarette emissions, and identify and eliminate tobacco-related disparities. With funding from CDC, state and territorial health departments have taken a number of approaches to reduce youth access and exposure to e-cigarettes, including preparing nicotine health advisories and tobacco-free school toolkits, conducting surveillance of tobacco product use among youth, and creating and disseminating evidence-based educational materials to the public through social media and other mechanisms.

CDC's Efforts to Understand the Harms Associated with Marijuana Use

CDC is working to monitor cannabis use, identify associated health effects, and increase the surveillance capacity of CDC and state/local jurisdictions. The exposure to e-cigarettes or vaping products containing THC in many patients in this outbreak suggests the need to understand the health effects of increasing marijuana use in the United States and the changing marketplace as states continue to pursue legalization of marijuana for medical or recreational use. In 2018, an estimated 16 percent of the population age 12 and older reported using marijuana in the past year. The potency of THC in marijuana and the different products available have significantly increased over the last two decades.

CDC Interim Outbreak Recommendations for Providers, States and the Public

CDC has released interim recommendations for healthcare providers, health departments, and the public to supplement its existing e-cigarette and vaping product messaging. As we learn more about this outbreak, CDC will continue to provide evidence-based recommendations. While this investigation is ongoing, CDC recommends that individuals who are concerned about lung disease associated with e-cigarette use or vaping consider refraining from vaping or using e-cigarette products. CDC recommends that, regardless of the ongoing investigation, anyone who uses an e-cigarette or vaping products should not buy these products (such as e-cigarettes or vaping products with THC or other cannabinoids) off the street and should not modify or add any substances to these products that are not intended by the manufacturer. In addition, regardless of the ongoing investigation, e-cigarette products should not be used by youth, young adults, pregnant women, or adults who do not currently use tobacco products.

CDC recommends adults who use e-cigarette products or vape because they have quit cigarette smoking should not return to smoking cigarettes. Those who need help quitting tobacco products, including e-cigarettes, should contact their doctor. Adult smokers who are attempting to quit should use evidence-based treatments, including counseling and FDA-approved medications. People who have recently used e-cigarette or vaping products should seek medical attention if they experience symptoms associated with this outbreak, such as cough, shortness of breath, or chest pain.

CDC will share more information as it becomes available. Updated information related to this investigation is available at <https://www.cdc.gov/lunginjury>.

Conclusion

CDC's foundation of public health work, including direct relations to state and local governments is essential to the nation's ability to respond to expected, unexpected, and unimaginable threats. CDC prioritizes sharing information with clinical providers, public health departments, toxicologists and laboratories, and the public, to help prevent additional cases and to rapidly identify and treat affected individuals. CDC is working around the clock, together with state and local health officials and FDA to identify the cause or causes of this outbreak and will continue to keep Congress up to date on our progress in this rapidly evolving investigation.

Ms.DEGETTE. Thank you so much, Doctor. It is now time for members of the Committee to ask questions, and the Chair will recognize herself for 5 minutes.

So, in 2015, the CDC stated, “Youth, young adults, pregnant women, as well as adults who do not currently use tobacco products should not use e-cigarettes.” I think that was also echoed by you, Dr. Sharpless.

So my question is, Dr. Schuchat, does the CDC believe that e-cigarette products are safe?

Dr.SCHUCHAT. We are really concerned about the use of e-cigarette products among youth, pregnant women, young adults, and those who are not using tobacco products.

Ms.DEGETTE. I mean, even somebody who is not using, who is not smoking or using e-cigarettes now, it is not like they are safe for people to use; isn’t that right?

Dr.SCHUCHAT. The aerosol that e-cigarettes produce can have a lot of potentially harmful substances. We have a lot to learn about both short-term and long-term effects.

Ms.DEGETTE. So your answer is yes, it is not; or no, it is not safe; yes, it is safe?

Dr.SCHUCHAT. Right.

Ms.DEGETTE. What is it?

Dr.SCHUCHAT. It is they are not safe for——

Ms.DEGETTE. For those categories.

Dr.SCHUCHAT. For those categories.

Ms.DEGETTE. Are they safe for other people?

Dr.SCHUCHAT. We are focused on those categories because there are the most data about them and particularly for those with the developing brain.

Ms.DEGETTE. So we don’t know if they are safe for the other people?

Dr.SCHUCHAT. Right.

Ms.DEGETTE. OK.

Dr.SCHUCHAT. But we also are quite concerned about people going back to smoking cigarettes——

Ms.DEGETTE. Right.

Dr.SCHUCHAT [continuing]. And we don’t want them to do that.

Ms.DEGETTE. OK. Is it true that youth are more likely than adults to use these unsafe products?

Dr.SCHUCHAT. That’s correct.

Ms.DEGETTE. Now, Dr. Sharpless, the 2009 Tobacco Control Act gave the FDA the authority to put e-cigarettes under its regulatory authority, which the FDA did in the 2016 deeming rule; is that right?

Dr.SHARPLESS. That’s correct.

Ms.DEGETTE. In 2017, the administration extended the compliance deadline by four years for companies to submit materials to the FDA for review of the public health risks of e-cigarette products; is that right?

Dr.SHARPLESS. That’s correct.

Ms.DEGETTE. And is it accurate to say that e-cigarette products are only on the market because the FDA has exercised its enforcement discretion to allow them to remain on the market and not because the products have been reviewed by the FDA?

Dr.SHARPLESS. All ENDS products currently on the market are illegal. They have not been reviewed by the FDA.

Ms.DEGETTE. OK. And in fact, your testimony says, “No ENDS product in the United States is on the market legally,” right?

Dr.SHARPLESS. Correct.

Ms.DEGETTE. OK. And so, you also agree with the CDC that e-cigarette products are not safe; is that right?

Dr.SHARPLESS. E-cigarette products are not safe. They are not without harm.

Ms.DEGETTE. OK, so here is my concern. Both FDA and CDC say e-cigarettes are not safe. We are seeing an explosion of young people using the products, and now we are seeing serious illnesses around the country, but FDA still allows these products to stay on the market even though they haven’t undergone a full market review. So I think time is of the essence, and I would like to ask you, Dr. Sharpless, when does the FDA intend to use its regulatory authority to assess the health impact of these products?

Dr.SHARPLESS. I agree with you; I think time is of the essence. I think the context of the history is perhaps important. In 2017, when that light regulatory touch was taken, the data at that time showed that youth use of those products was sort of leveling off or going down. Therefore, I think the FDA being a science-driven organization, opted for that policy at the time. Then what happened, as you’ve described, is this epidemic of youth use.

Ms.DEGETTE. Right.

Dr.SHARPLESS. And now we’ve accelerated our timeline. We’ve stepped up enforcement. We’ve stepped up education. And I can tell you; we are on this problem——

Ms.DEGETTE. So, what is your timeline?

Dr.SHARPLESS. The next major development will be the finalizing of its compliance guidance, which will have the effect of removing non-tobacco flavors from the market and we expect that to be weeks.

Ms.DEGETTE. OK. And then what are you going to do after that?

Dr.SHARPLESS. So typically, when a guidance is finalized it has 30 days to go into effect or some period along those lines, and then we apply an enforcement strategy which we have——

Ms.DEGETTE. So, is the flavor strategy the only thing the FDA intends to do?

Dr.SHARPLESS. I can’t speak to, you know, a guidance in the process, but it is certainly the major target of that effort.

Ms.DEGETTE. And why is that? Do you think that that is going to solve the youth vaping epidemic?

Dr.SHARPLESS. No, we do not believe that any single policy or process will solve the vaping epidemic. It’s a combination of enforcement and education and multiple policy things that we’re doing.

Ms.DEGETTE. Are you continuing to review these products to see if they are inherently safe or unsafe?

Dr.SHARPLESS. So all products, ENDS products, will have to submit an application to the FDA by May 2020.

Ms.DEGETTE. OK.

Dr.SHARPLESS. And so very soon, everything should be coming in, but flavors would be removed from the market sooner than that because of our concerns about the youth epidemic of use.

Ms.DEGETTE. OK, just one last question. How far is the FDA prepared to go to protect the health and well-being of young people if it determines that these are unsafe?

Dr.SHARPLESS. The FDA is a science-driven organization. If the data support more aggressive measures, then we will take those.

Ms.DEGETTE. How far?

Dr.SHARPLESS. We could ban all flavors, for example.

Ms.DEGETTE. Thank you. I now recognize the ranking member for 5 minutes.

Mr.GUTHRIE. Thank you very much. I thank you both for being here; we appreciate it; your testimony is informative.

Dr. Schuchat, you said that in all the 530 cases, or all the cases you have data for, there is no consistent; you haven't found like this is the cause; these are the things that we found or the thing that we found. Is there a trend line that is developing in what you are seeing?

Dr.SCHUCHAT. The data are coming in, really, literally, as we speak. We believe that most people who have exposure histories that we've gathered describe using either THC e-cigarettes or THC e-cigarettes and nicotine e-cigarettes. There are very few that used only nicotine e-cigarettes.

But I think it's important to say that what people say they used may not be fully descriptive of what the problem is. It may be, as you heard, a cutting agent. It may be something together, something related to the device and how the device changed whatever product they used, and they may not really know what was in the product they got.

Mr.GUTHRIE. It has been reported over 80, or 80 percent of the cases, the person reported they used THC.

Dr.SCHUCHAT. That's right. That was in the report from Illinois and Wisconsin about the first 53 cases, and those numbers are from about 40 people. But that trend is continuing as we get additional data. I think it's also important to recognize that there may be a particular problematic source in the Midwest and a different one in California, and I think we really need to be on top of this investigation.

Mr.GUTHRIE. Absolutely.

Dr.SCHUCHAT. And make sure that we understand all of the causes.

Mr.GUTHRIE. When you say people are doing THC and nicotine is that they have nicotine e-cigarettes and THC, or they're not combining THC and nicotine?

Dr.SCHUCHAT. Right, separate products.

Mr.GUTHRIE. Two separate products, OK.

Dr.SCHUCHAT. But one individual might have many different products that are being tested. So it's a very complex investigation, and understanding exposure versus causality is something that we're really trying to get to.

Mr.GUTHRIE. And I think we are looking at—we have the specific lung injuries we are looking at in this hearing. I know a lot of people are talking about the flavored and just the general growth in

e-cigarettes which we need to address, but also the THC or the marijuana that we are needing to addressing.

Some states have made it illegal. I think Massachusetts just said they are going to pull back the flavors, but I don't know if they announced they are going to undo their marijuana policies and move them forward. And in your written testimony, you said that e-cigarettes or vaping products containing THC—and many patients in this outbreak suggest the need to understand the health effects of increasing marijuana use in the U.S. That was in your testimony.

What concerns does the CDC have about the effects of brains on teenagers who vape products containing THC?

Dr.SCHUCHAT. You know, the adolescent brain is still developing. In fact, brains develop all the way through about age 25. So whether it's nicotine or marijuana, I think we really want to know the effects that occur. There are animal data to suggest some concerns, and there's behavioral data. But this is one of the reasons that there's a focus on the e-cigarette issue on avoiding use in adolescents and young adults. We don't know as much as we need to know about both short-and long-term effects, and there are harms associated with nicotine in the adolescent brain, as well as marijuana.

Mr.GUTHRIE. Dr. Sharpless, what does FDA think of the effect of the brain and THC and vaping?

Dr.SHARPLESS. We, as Dr. Schuchat said, there is animal data and some human data to suggest that the developing brain is sensitive to these kinds of chemicals, and there are large ongoing prospective trials that the NIH is funding to address these questions, so I think we'll know more. But our current recommendation is that children should not be exposed to high doses of nicotine or THC for a long period of time. It's a bad thing.

Mr.GUTHRIE. Thank you. And, Dr. Sharpless, CDC's written testimony states that product information from the outbreak cases will be shared with the FDA to help FDA assess which of the products fall within FDA's regulatory authority. Has CDC shared such product information with the FDA?

Dr.SHARPLESS. We are sharing information continuously both with CDC and states and also now with the DEA. I think, you know, one of the things that we're doing that is important is we are getting these samples from the states that are linked to the cases and taking them to our lab and testing them directly to see what they contain.

Mr.GUTHRIE. Are you seeing a trend? I know there has not been a consistent——

Dr.SHARPLESS. We've received about 300 samples. We've tested about 150. I would say the answer's about 70 percent are THC products. The rests are nicotine products or something else. A significant fraction of the THC products, like maybe half of them, are contaminated with a vitamin E acetate, as you mentioned, which is a skin oil that has no business being in a pulmonary product. We believe is added as a cutting agent as you mentioned.

Mr.GUTHRIE. Can you know if, or can you tell if the 150 you have tested were secondhand or bootlegged or were they actual commercially purchased; can you tell that?

Dr.SHARPLESS. That's difficult to ascertain. Some of the products, particularly the nicotine products, are things you could buy at a store and appear to be manufactured products, but many of them are clearly illicit products.

Mr.GUTHRIE. Thank you. Well, my time has expired, and I will yield back.

Ms.DEGETTE. Dr. Sharpless, you said those oils don't have any place in people's lungs. Can you explain why you said that?

Dr.SHARPLESS. Sure. Vitamin E acetate is a skin oil. It's used for a sort of, you know, wound healing in the skin. It's an oily goo. And it is—we have looked. There is virtually no pulmonary toxicologic literature on the use of this product as an inhaled substance. You know, an oily thing, the lung is not the gut. An oily substance in the lung is not going to be easily cleared and could cause a thing like lipoid pneumonia which has been seen in some of the cases.

Ms.DEGETTE. I had a—I am sorry to say this.

Mr.GUTHRIE. Go ahead.

Ms.DEGETTE. But I had a pediatric pulmonologist in Denver tell me that what happens with this oil is it settles in kids' lungs, and it impairs the development of their lungs, and she has even seen kids whose lungs are like the lungs of 80-year-olds and that is never going to resolve itself. That is going to be what happens. That is why we are so worried.

The Chair now recognizes the gentleman from Massachusetts, the vice chair of this subcommittee, for 5 minutes.

Mr.KENNEDY. Thank you, Madam Chair. And I want to thank you for calling this important hearing. Thank our witnesses for being here.

Yesterday, Massachusetts Governor Charlie Baker announced a public health emergency in a 4-month ban on the sale of all vaping products. To date, we know that at least nine people have died, and 530 have been diagnosed nationwide. Back home in Massachusetts, there are at least 61 possible cases, and yet we don't know concretely why. We don't know whether it is the nicotine products or the THC products. We don't know if there are additives that are responsible or if it is parts of the device that are causing the illness. We don't know if the products can be traced back to black market sales or over-the-counter purchases.

So building off of what the chair just asked, Dr. Sharpless, help me answer some of those questions. How is it—what do we know, and how is it that we don't know more?

Dr.SHARPLESS. Regarding the vaping lung injury?

Mr.KENNEDY. I am sorry?

Dr.SHARPLESS. Regarding the vaping lung injury?

Mr.KENNEDY. Yes.

Dr.SHARPLESS. Yes. I think, you know, the first cases were really appreciated in July, so it's still a relatively new entity. I think the progress and the federal cooperation have been pretty good. We now have a rigorous case definition. We've begun to test a lot of the products both and interview the cases. And as I said, we've started a criminal investigation for to learn more and, I think we will gather more information quickly. I don't know if Dr. Schuchat wants to comment as well?

Mr.KENNEDY. So how did we get to the point where we are backtracking on this rather than actually putting in place the right consumer protections from the front end if you are telling me that vitamin E shouldn't be an inhalant and is costing people's lungs to the extent that children's lungs look like the lungs of an 80-year-old? Where was the regulatory failure to allow that to happen in the first place?

Dr.SHARPLESS. We believe that adulterating a THC product would be an illicit activity. It would be illegal and tough to regulate, you know, illicit drug dealers effectively. I mean that is people who are cutting their product to sell it for greater profit.

Mr.KENNEDY. And so you are saying that with regards to those specific cases with vitamin E acetate or an oil in it that you have no evidence that any of that is actually an approved commercial sale?

Dr.SHARPLESS. No. Vitamin E acetate is not approved for inhaled use. I should be clear, though that it's only present in about half of the THC products. We have a lot of cases that are not associated with vitamin E acetate.

Mr.KENNEDY. Right.

Dr.SHARPLESS. We don't know if it causes anything or is just a marker for adulteration or, you know, is sort of a marker for a bad product.

Mr.KENNEDY. And so how, to both of you, how do we get to a point where we have got now a widely used consumer, series of consumer products that are getting 530 people sick, and understanding that it is somewhat new here, but there was clearly a massive regulatory failure that allowed for this to happen was there not?

Dr.SHARPLESS. I believe, speaking about not to conflate the two issues, but speaking about the epidemic of youth use of e-cigarettes, in retrospect, the FDA should have acted sooner. We should have been regulating these devices sooner. Since I've been at the agency, we've greatly accelerated the date. We've put out a bunch of education campaigns. We've announced new policies like the PMTA guidance that will help people submit these applications, and now we are open for business to receive these applications. But we're going to catch up.

Mr.KENNEDY. Doctor?

Dr.SCHUCHAT. I would just say I'm extremely frustrated with the pace of our investigation. I wish we had answers already. I'm concerned that we may—

Mr.KENNEDY. So, if you are frustrated with the pace of the investigation, what can speed up the pace of that investigation?

Dr.SCHUCHAT. Well, I think we have more than a hundred people working on this and the states are also making this a top priority. I think the FDA and DEA doing product sourcing can help. But I actually think there may be a very complex set of root causes here that are going to be difficult for us to address as a nation and we need to take it very seriously.

Mr.KENNEDY. Like what?

Dr.SCHUCHAT. Well, I think if there's a set of supply chains that are completely underground that are adulterating products that in ways that are just experimental and are building on top of a popu-

lation that is addicted to e-cigarette use as young people through the past few years, that we have a very vulnerable population and very challenging supply chain to address.

Mr.KENNEDY. And we're none of those questions posed throughout any aspect of the regulatory process before these products were approved?

Dr.SCHUCHAT. I don't—

Mr.KENNEDY. Nobody thought that there would be a possibility of diversion or illicit use or that there could be implications here that we are going to have adverse health impacts?

Dr.SCHUCHAT. So, as you know, the THC containing issues are really regulated at the state level, not at the federal level, and I guess I would let the FDA describe that. CDC's not a regulatory agency.

Mr.KENNEDY. Understood.

Dr.SCHUCHAT. But we have been raising the alarm about e-cigarettes and youth since 2013, when we first saw the rise. We also support state and local health departments to exert tobacco control comprehensive approaches.

Mr.KENNEDY. Dr. Sharpless, I will let you finish.

Dr.SHARPLESS. Yes, so I think, as Dr. Schuchat said, THC is a Schedule I drug. It's illegal by federal law but is being tolerated in some of the states. There's a state sovereignty issue. To the extent those products are reviewed and regulated, it generally occurs at the state level now.

Mr.KENNEDY. Right. And just very briefly though, it is not, as you said, not all of these illnesses and death are linked squarely to THC; there are other issues here as well. And my concern is that if there is a failure in the regulatory and approval process on the front, it should have been easily foreseeable that some aspect of these would have been illicitly used or cut or otherwise.

And so I want to understand where that process broke down so that we can make sure it doesn't happen again. I yield back. Thank you.

Ms.DEGETTE. The Chair now recognizes the gentleman from West Virginia, Mr. McKinley, for 5 minutes.

Mr.McKINLEY. Thank you, Madam Chair, and thank your panel. But I missed the earlier, your remarks, your earlier, because we do have another meeting going upstairs on prescription drugs. So you can see what has happened, the back and forth of this, so I apologize. That maybe your testimony might explain some of this, but I am trying to follow the chronology of this because from what I can gather from on the internet is that these cigarettes were introduced to the market around 2003; some said 2006. Can one of you confirm when these things came on?

Dr.SCHUCHAT. Yes, the e-cigarettes began to be marketed in 2007, to my knowledge.

Mr.McKINLEY. So back to you now, Doctor. If they have been—2007, again, I will accept your 2007. I have got 2003. But why has the FDA not come up with a final? Because I heard the chairman's remarks that, I can't agree more with her concerns. I mean there, is no light between the two of us on this. Why has the FDA not finalized some kind of determination that allows these things be-

cause they are still out there on a generally approved, or how do you describe their permitted use?

Dr.SHARPLESS. Sure. No ENDS products currently on the market are there legally. They are illegal. They——

Mr.McKINLEY. I am sorry. I couldn't hear.

Dr.SHARPLESS. They're illegal. They are not authorized to be sold. They're on the market through a policy of enforcement discretion where the FDA can prioritize the enforcement of its authorities. The history is, you know, e-cigarettes became deemed products subject to tobacco control like in 2016.

Mr.McKINLEY. Well, you missed my point. I am sorry.

Dr.SHARPLESS. Oh, I'm sorry.

Mr.McKINLEY. If one of the byproducts of these is fine particles getting into people's lungs, we have had number of debates in this Committee over the last eight or ten years about what is happening with the coal combustion of particulate matter at 2.5 microns, but yet from what I understand, my research on this is that these e-cigarettes are introducing not only 2.5 microns but even less, smaller, and getting down in the lungs.

So if we take action that is affecting and impacting the fossil fuel industry across America, why are we not finalizing and saying until we know more about the carcinogens, the heavy metals, and other things, cutting fluids or whatever its additives, why aren't we stopping this until your final determination? Why are these things still on the market if they are causing this kind of health risk——

Dr.SHARPLESS. Sure.

Mr.McKINLEY [continuing]. Twelve years after they were introduced?

Doctor?

Dr.SHARPLESS. I think the—we don't consider these products safe. They are harmful.

Mr.McKINLEY. Excuse me?

Dr.SHARPLESS. We do not consider these products safe. We think they have harmed. We do not think; really, anyone should be using them other than people who are using them in place of combustible tobacco. I think it has to be said that combustible cigarettes are very——

Mr.McKINLEY. But you know that it is naive to think that that is what happening—children. Why aren't they just off the market until you make a final determination?

Dr.SHARPLESS. So, the drive at the FDA is to be guided by the science and what's good for the public health. We think that some small offramp to allow addicted adult smokers off of it to transition from combustible cigarettes to another product is a public health value. But we really want to limit the ability of youth and children to get access to these products because of the epidemic of youth use.

Mr.McKINLEY. OK. Well, let me go up to the CDC. Would it be more beneficial to our youth and others if these cigarettes were taken off the market?

Dr.SCHUCHAT. We would like to make——

Mr.McKINLEY. Now watch what I said. Should we take it off the market?

Dr.SCHUCHAT. We would like to make it possible for no youth to be——

Mr.McKINLEY. I am sorry?

Dr.SCHUCHAT. We would like no youth to be using these products.

Mr.McKINLEY. So why hasn't Congress worked on that?

Dr.SCHUCHAT. I'm sorry. Did you say why it isn't Congress?

Mr.McKINLEY. Yes. Why haven't——

Dr.SCHUCHAT. Well, we——

Mr.McKINLEY. Why aren't they off the market? If you are saying they got a problem, you are thinking they should be better; why are they still out there? What is your opinion of why they are still out there if they are causing this kind of problem? If they are introducing particulate matter into our lungs that we are having such devastation with the coal industry and all fossil fuels, but yet we are allowing children to inhale it at a higher concentration level, let alone something that is up the stack a thousand feet up in the air, we are putting it directly into someone's lungs, and we are saying that is OK.

Dr.SHARPLESS. To be clear, Congressman, our plan is now to clear the market abruptly of characterizing flavors so that these kid-appealing products will be off the market as we finalize this guidance and implement this new policy.

Mr.McKINLEY. I have run out of time. I yield back.

Ms.DEGETTE. And don't worry; you can co-sponsor my bill to raise the smoking age to 21 if you haven't already.

The Chair now will recognize Mr. Ruiz for 5 minutes for questioning.

Mr.RUIZ. Thank you, Chair. There is a misleading notion when people say that it is safer than tobacco cigarettes that somehow it is safe. You said, and I believe you agree, and I wholeheartedly agree that vaping and e-cigarettes are not safe. In fact, there have been numerous scientific studies by different medical schools that have tried to elucidate whether or not vaping has any net public health benefit. And so far, the vast majority of researchers have concluded that they believe that there is more population-level harm than benefit with e-cigarettes.

So on one hand, you both know that e-cigarettes have a very narrow benefit in that it helps tobacco smokers of cigarettes quit smoking, period. Not just to convert the market from tobacco to vaping for an industry's benefit, but it is to quit smoking and inhaling nicotine. There is no benefit to nicotine, period, but that is very narrow.

Then the harm, the biggest harm here is that youth and young adult never-smokers, nonsmokers, and people who have never touched a cigarette are starting to smoke nicotine through e-cigarettes. These are new users. And there is even suspicion that there are more new users than there are those who are actually using e-cigarettes to stop smoking in general.

So the benefit-harm, you can see, clearly the—in addition, there is a study from Pittsburgh that shows that those who are never-smokers who are now smoking and vaping, 47.7 percent of those youth and young adult smokers start smoking tobacco. Tobacco cigarettes. So you count those with never-smokers, compare those

to those who are stopping to smoke, then that is why they are saying there is a net public health harm with this industry, to begin with.

Then, there are other studies showing that vaping those e-cigarettes still have volatile organic compounds that are still carcinogenic and cancerous. And if you get a young adult who are more, have more propensity to be addicted, they have more propensity to stay smokers for a longer period of time, therefore inhale benzene for a longer period of time, you can start to see that they can also acquire lung cancer and other types of cancers.

And that is not to mention that the concentration of these pods, cute little pods that they do in USB cords, et cetera, have higher nicotine than tobacco, and you are starting to see reports in the emergency department of teenagers coming in with cardiac arrest and cardiac arrhythmias. I know; I am an emergency medicine physician.

So where is the benefit of this industry to our nation's health except for that very small, narrow, tobacco smokers to get them to stop using tobacco and stop using e-cigarettes? So the best case scenario was that. The worst-case scenario is that new smokers, non-smokers, and lifetime e-cigarette smokers, which the e-cigarette industry and vaping industry would love to take tobacco smokers since they are large around the world and just simply buy our products because it is "safer," i.e., the misnomer that it is safe.

So we need to prevent the youth from getting their hands on there, and I am introducing legislation that will just do that to help increase the fines for first-time penalties for selling these to the youth. I am also introducing legislation to do more research, more research on the long-term effects. So, I would like to ask you, Dr. Schuchat, what are the secondhand smoke effects of vaping?

Dr.SCHUCHAT. You know, you've raised really critical issues that the aerosol that e-cigarettes can produce includes many toxic things; the direct and indirect effects are not fully understood, so the issue of additional research to really get at those long-term effects makes sense. And we absolutely share the concern about youth that no youth should be using e-cigarettes and that it can open the door for many problems.

Mr.RUIZ. I ran out of time.

Ms.DEGETTE. The Chair now recognizes the gentleman from Virginia for 5 minutes.

Mr.GRIFFITH. Thank you, Madam Chairman. I appreciate it.

Dr. Schuchat, you said earlier that there were a lot of different issues going on here, and so I am going to touch on a couple of different issues, and I am going to jump around. So it may not always; one question may not lead to the next question. Let me start by just saying that there is an agency that is not here that I think has some issues that we need to look at and that is the DEA. Because for 20 years, I have been for medicinal marijuana, but we have not been able to do adequate studies to find out what the benefits are. And if you can't find out the benefits, you don't have any data on the harm.

And so we really don't know, when you start adding THC into these vape products, we don't really know the long-term consequences of THC, particularly when you start as a youth. We

know it is not good because the brain is developing as you said, Dr. Schuchat, until 25. As a part of that, the Virginia legislature this last year raised the age for all tobacco products to 21. So, you know, obviously, the states can lead on that and Ms. DeGette mentioned that she has a bill that would do that at the federal level, and that seems to be a proper step for youth.

And in reality, Dr. Schuchat, I think you may have mentioned this yesterday as well. Don't we really have two problems? We have these mysterious lung diseases, and then we have the whole youth and flavor issues. And I bring that up in particular because my wife is a juvenile domestic relation district court judge and they are seeing all kinds of problems in the schools because, unlike a regular cigarette where the teacher can immediately identify what part of the classroom it is coming from, they are not getting that with the vaping cigarette. They are just putting it in their pockets or whipping it out real quick when the teacher's back is turned. And they have no idea that vaping is going on in the classroom unless they actually catch them, which sometimes does happen. But am I correct? We are really talking about two different issues here today.

Dr.SCHUCHAT. Yes, there are two extremely important critical issues; where they overlap we don't know yet.

Mr.GRIFFITH. Right. Now one question that my colleague from West Virginia brought up and that is that e-cigarettes have been on the market for quite some time, 12 years at least, but the vaping illnesses seem to be new. So here is the question, and I would like a quick answer if I can get it because I have other things I want to ask about.

Does the CDC or the FDA know if the current outbreak is a new phenomenon, or is it just that there is a new awareness and people have started looking for these lung disorders from people who may have been vaping?

Dr.SCHUCHAT. Increasingly, the data suggests it is a new outbreak. There have been individual cases in the past, but nothing like what we have seen now.

Mr.GRIFFITH. And am I correct that the knockoffs, the illegal, imported many times pods is a relatively new development as well?

Dr.SCHUCHAT. Well, even the mod pods, are relatively new, so knockoffs of mod pods would be new as well.

Mr.GRIFFITH. OK. And so previously, we may not have had as much of the various chemicals being added in to dilute or have we?

Dr.SCHUCHAT. I don't actually know. I'm not—

Mr.GRIFFITH. Do you know, Dr. Sharpless?

Dr.SCHUCHAT. I don't have that knowledge.

Dr.SHARPLESS. We are—we don't really know what the practices of adulterating these products have become. Other than that, we know that when we test them we find signs of adulteration. That appears to be occurring, but whether that's new or an older practice, we can't say.

Mr.GRIFFITH. All right.

Now, Dr. Sharpless, I'm aware that there are a number of vape products, or vapor products for sale in the U.S. that came onto the market after the FDA's August 8, 2016 deadline. That means they are already being sold illegally. What is the FDA doing right now

to get those illegal products, many of which are compatible for use with legally sold products, off the market?

Dr.SHARPLESS. When we identify products that are on the market after the period that you alluded, we act to remove them from the market by sending warning letters and other notifications. We've done that in a handful of instances or a significant number of instances. It can be difficult to ascertain when something came on the market, so that makes it a little more tedious than you would have expected.

Mr.GRIFFITH. All right. Now I mean this as a friendly question. We can't control all the importation of illegal substances coming across our borders, currently. Do you have much hope that we are going to have much success with keeping imported, possibly tainted mods, pods, whatever the right terminology would be, coming across the border?

And what I am trying to say is somebody else earlier said that you know, how come you all haven't stopped this? If we can't stop fentanyl, how are we going to stop pods for vaping?

Dr.SHARPLESS. Congressman, I agree it's a very challenging issue. We have engaged the DEA to help, to discuss these topics and rely on their expertise. Our international mail facilities work with Customs and Border Protection to see what's coming in, and we are doing fact-finding presently in the IMFs to find what vaping products are being sent to the United States and what are the characteristics.

Mr.GRIFFITH. All right. I think we will probably have more hearings. I appreciate your time. This is a serious issue. We are all very concerned about it, and I yield back.

Ms.DEGETTE. The Chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Madam Chair.

Earlier in September, the President announced that FDA intends to finalize the policy in the coming weeks to clear the market of flavored e-cigarettes until products undergo full premarket review. And while I certainly agree with the statement Dr. Sharpless made that we must act swiftly against flavored e-cigarette products, I am disappointed that it has taken so long to get to this point.

E-cigarettes have been available for purchase for over a decade and it has been over three years since they were brought under the regulatory authority of the FDA. And during this time, the e-cigarette market has dramatically expanded and has become more attractive and accessible to children and teens.

E-cigarette use amongst middle and high school students has risen sharply, with preliminary data released last week demonstrating that a third of twelfth graders are e-cigarette users.

And I agree that the clearing the market of flavors could help reduce youth utilization of e-cigarettes and raising the minimum purchase age of tobacco to 21 could also help reduce youth access, but these steps in isolation aren't enough. It is my strong belief that Congress must take comprehensive action, and I now have some questions about FDA's guidance and our need to do more.

So, first, let me start with Dr. Sharpless. It is my understanding that FDA intends to outline the Administration's policy to prohibit

the sale of non-tobacco flavored products through guidance; is that correct? Yes or no.

Dr.SHARPLESS. That is correct.

Mr. PALLONE. Dr. Sharpless, FDA guidance, in my opinion, lacks the permanence and legal force of a statute or a formal rule issued by the agency; is that correct?

Dr.SHARPLESS. To be clear, we will—the guidance will just allow us will describe how we're going to enforce existing law. So these products are illegal, and we're just announcing how we're going to prioritize enforcement of existing law.

Mr. PALLONE. So, but do you disagree that the guidance lacks the permanence and legal force of a statute or a formal rule issued by the agency?

Dr.SHARPLESS. Well, the products are illegal by the act of Congress, so guidance is merely to—

Mr. PALLONE. So you are saying that with the guidance you will now enforce the underlying law?

Dr.SHARPLESS. Right. The guidance will describe our enforcement policies.

Mr. PALLONE. Well, what kind of steps can the FDA take to ensure that the industry is complying with this flavored tobacco prohibition, given what you just said?

Dr.SHARPLESS. Sure. The FDA has experience with this kind of problem. Generally, we send warning letters to the legitimate retailers and manufacturers. They will come into compliance, usually, and then that will have a dramatic effect to the products on the market.

Mr. PALLONE. Well, I still don't understand how you force them to comply with the guidance.

Dr.SHARPLESS. The way it works is we send a warning letter. It says that your product is no longer, you know, subject to enforcement discretion and at that time, we expect it to be removed from the market, any flavored products.

Mr. PALLONE. And if they don't?

Dr.SHARPLESS. Then we have a number of other activities that escalate, you know, further warning letters, civil money penalties we actually, and manufacturers we can seize through injunctions.

Mr. PALLONE. And you intend to impose those enforcement measures?

Dr.SHARPLESS. What's that? I'm sorry.

Mr. PALLONE. You would impose those fines and those other enforcement measures?

Dr.SHARPLESS. For manufacturers, it's usually an injunction. Yes, but we would impose those, if needed.

Mr. PALLONE. OK. Let me—as the proposed flavored ban includes mint and menthol flavored products. Can you commit that these flavors will remain part of the compliance guidance when it is finalized?

Dr.SHARPLESS. You know, I can't describe what's going to come out in the future, in a guidance we're working on, with certainty. I can tell you that the data suggests that mint and menthol are very popular with children and if the intent of the policy is to—

Mr. PALLONE. But I mean you are not committed if that is going to be a part of the compliance when it is finalized?

Dr.SHARPLESS. Well, the compliance guidance will be out in weeks and, you know, I think we will——

Mr. PALLONE. Well, it sounds like you are saying you are not committed to it, unfortunately. I just think the only way we can realistically verify that tobacco products, both flavored and non-flavored, don't flow to children is through direct, you know, this question is about face-to-face sales. I think the only way that you can verify that tobacco products, whether they are flavored or non-flavored, don't flow to kids is through direct face-to-face sales. And my bill would ban the sale to online, and other would ban online and other remote sales.

So, can you commit that any guidance banning the sale of the flavored e-cigarettes would extend to online and other remote sales?

Dr.SHARPLESS. The guidance we envision would extend to all retail channels, so online and in-person sales.

Mr. PALLONE. OK. Now, as I understand it, there are reports of as many as three million distinct e-cigarette products currently available for sale in the U.S. Does the FDA face any resource or capacity challenges in monitoring the e-cigarette market to be able to enforce the agency's existing authorities?

Dr.SHARPLESS. So, as you know, the Center for Tobacco Products at FDA is entirely funded off user fees. E-cigarette products do not pay a user fee, as I think contra distinction of other tobacco products. I think a user fee program for e-cigarettes would be helpful to the FDA to enforce these activities that you described.

Mr. PALLONE. Are those user fees that you are receiving now available for monitoring e-cigarettes?

Dr.SHARPLESS. We are using the appropriate monies for our activities related to tobacco products.

Mr. PALLONE. What about the user fees?

Dr.SHARPLESS. I'm sorry, sir?

Mr. PALLONE. What I am trying to find out is if the money you are getting from user fees is available for monitoring e-cigarettes, or are you just using the money from appropriate sources?

Dr.SHARPLESS. The money we're getting for user fees is available for the use of monitoring e-cigarettes.

Mr. PALLONE. All right. Thank you.

Thank you, Madam Chair. Sorry to go over, but I, you know, this is such an important issue. I apologize for going over.

Ms.DEGETTE. You are the Chairman. The Chair now recognizes the gentlelady from Indiana, Mrs. Brooks, for 5 minutes.

Mrs.BROOKS. Thank you, Madam Chairwoman. And thank you for hosting this incredibly important hearing.

According to the Indiana State Department of Health and in a recent publication, as Dr. Kris Box, the commissioner, stated, the numbers are staggering in Indiana as well. Nearly one in five high school students and one in twelve middle schoolers say they use e-cigarettes, according to the 2018 Indiana Youth Tobacco Survey, and it is a 350 percent increase since 2012. She also writes that one e-cigarette can contain the same amount of nicotine as an entire pack of cigarettes? I think there is so much that is not known about e-cigarettes.

And so my question for both of you, given how little we know about e-cigarettes and the long-term effects of e-cigarettes, what research or studies are currently underway to help educate everybody about the e-cigarettes? Dr. Sharpless, when do we expect the studies to be complete, what studies are underway, and the same to you, Dr. Schuchat.

Dr.SHARPLESS. Sure. There are a number of studies by a variety of federal agencies looking at the kind of composition of e-cigarettes and their use as a switcher cessation device type approaches from both NIH and FDA and other agencies. But, you know, these are still relatively new products, and we don't have the long-term experience with them that we would like. The FDA has launched very vigorous education campaigns, particularly targeting youth about the dangers of e-cigarettes, including recent online, you know, ads and TV ads.

Mrs.BROOKS. My concern—and, Dr. Schuchat, is anything else you would like to share about studies and research?

Dr.SCHUCHAT. Yes, CDC's just doing surveillance and monitoring. We're not doing research. We do test the aerosols, and we're really, really focused right now on the lung injury outbreak and studies related to that.

Mrs.BROOKS. Well, in fact, right after Dr. Box issued this report and indicated that our Governor Holcomb at one of my high schools announced a two million dollar campaign to curb youth vaping at Fishers High School, talked about this, announced it at Fishers High School, a lung injury death happened to a young Hoosier within the week of this incident. And this has impacted 50 others in our state, nationwide over 400 cases.

My concern is, is that all of the research, if we wait—the, research being done on marijuana still isn't conclusive. We are still waiting on the federal government to really come up with conclusive studies to be finished on marijuana decades after we started it. Why do we think that this is going to be any different than that? Dr. Sharpless, why do we think the research is going to be any different, and it is going to be done any faster because more people are dying?

Dr.SHARPLESS. No, I think I agree with you that this is going to be a tough topic to study. It's going to require a long-term effort. I think some data will be more easy to glean forthcoming, but the answer to the questions that we really want to know, like what's the safety of these products over years and decades, is going to take a while. In the interim, I think the FDA's charged with using existing science to come up with a regulatory framework that is best for the public good.

Mrs.BROOKS. So, whether it is a surveillance or the investigations being done, is there a consistent substance, brand, or product identified in the cases so far?

Dr. Schuchat?

Dr.SCHUCHAT. There's not yet a consistent one. And one of the reasons that we took action of making broad recommendations right now is it may take a while to get answers and we wanted to warn the public in the meantime.

Mrs.BROOKS. Dr. Sharpless, anything that you are, any different statement on that?

Dr.SHARPLESS. I would agree that the majority of products as I mentioned are THC, but there are certainly some that are nicotine only; and there's no particular brand or product or contaminant that we've identified in all cases.

Mrs.BROOKS. And in the studies that you are doing, how many, do we know if the individuals are reporting buying them at the vaping products at stores versus online, or are they getting counterfeit or black market products on the street?

Dr.SCHUCHAT. I think anecdotally we see a lot of social sources, you know, not retail purchase but more, you know, from someone they know. So I think we're concerned about that in terms of what the ultimate supply chain may be.

Mrs.BROOKS. And do we know, have there been questions from them by those that are asking the questions whether or not they have modified after purchasing either the device or the product?

Dr.SCHUCHAT. They're a set of questions and I don't have yet the results of the interviews. The states on the next panel may have more information because they are actually doing the interviews with their patients.

Mrs.BROOKS. OK, thank you. I yield back.

Ms.DEGETTE. The gentlelady yields back. The Chair now recognizes the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes.

Ms.SCHAKOWSKY. Thank you. I understand that you are saying that we don't have any evidence or that the evidence is that this might help some smokers. But on the website smokefree.gov, which is part of the Department of Health and Human Services, it says, "E-cigarettes are not approved by the FDA as a quit-smoking aid. So far, the research shows there is limited evidence that e-cigarettes are effective in helping smokers quit. There are other proven safe and effective methods for quitting smoking." So that is the quote.

So, clearly, e-cigarettes are not proving to provide smokers with smoking cessation and it seems to me that, you know, if we are unable to limit cigarette use to existing smokers that we should just ban it. I don't understand why the default position right now should be to allow it continue in any shape or form. Dr. Schuchat, who I barely remember out of uniform, that we should be saying no right now, and then if there is a way to phase in some of it, OK.

But meantime, people are dying, including a person in my state. How many children are we going to allow to die before this is considered the emergency it is, and we just say no? So I would like to hear from both of you.

Dr.SHARPLESS. Sure. I'll start if you—mind. I agree with what you said. These are not approved cessation devices. The FDA does have other cessation approaches that are approved. The FDA is driven in its decision-making by science for what's good for the public health. The argument against banning all e-cigarettes is that we think in that instance, there are people, millions of Americans using e-cigarettes today, who may find no other source of nicotine that's gratifying, satisfying to them other than moving back to—

Ms.SCHAKOWSKY. OK.

But, Dr. Schuchat, you said that the aerosols have toxins in it. I mean, I understand what you are saying and maybe that is true. But in the meantime, we have an epidemic of people ending up in the hospital and eight people who are dead. Let me ask Dr. Schuchat to——

Dr.SCHUCHAT. Yes, what I would say, of course, CDC doesn't have the regulatory authority; but we have aggressively announced warnings and we want parents, teachers, state health departments, and clinicians to know about the dangers that this outbreak is associated with. Our recommendations say that if you have concerns about health risks, we suggest you not use vaping or e-cigarettes at this time.

Ms.SCHAKOWSKY. That is nice. That is nice, but—so, I want to ask another question. I understand, and we have heard from several media outlets, and I want to put some articles into the record that report that the White House is still planning to hold a listening session with several conservative think tanks and industry groups that are concerned that eliminating or banning any part of this would hurt the President's reelection. And so, it seems that no other, no public health groups are on the list and you were not invited, as I understand.

Do you think that it is appropriate that industry groups and organizations that support the President and support vaping should be in a meeting?

Dr.SHARPLESS. I can't really comment on meetings the White House plans to take. I——

Dr.SCHUCHAT. Yes, CDC's a data-driven organization and we're gathering the data and alerting people about risks.

Ms.SCHAKOWSKY. Well, I do want to ask that we put into the record some articles about this potential meeting. And let's hope that the whole idea——

Ms.DEGETTE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Ms.SCHAKOWSKY. Thank you. And let's just hope that all of this is data-driven. But do you have any metrics at what point we say we are going to address this, not just by education? Are we going to see an implementation of taking this away? Did you send the letter yet that you said is going out and what have the responses been? I don't feel a sense of urgency. I just don't feel a sense of urgency here.

Dr.SHARPLESS. Congressman, we are very, have a strong sense of urgency at the FDA on this topic. We sent the letter to the manufacturer I mentioned, to Juul Labs, regarding their marketing practices. We also, this compliance guidance, as we finalize it in a few weeks, will have a dramatic effect on the marketing of flavored products and what's available to the American consumer today and I think will be really good for kids because we know flavors are particularly attractive to the young people.

Ms.SCHAKOWSKY. OK, and they will be banned in a few weeks?

Dr.SHARPLESS. They will be withdrawn from the market because we will exercise our, we will stop exercising enforcement discretion over those products.

Ms.SCHAKOWSKY. And they will be banned?

Dr.SHARPLESS. That will have the effect of removing them from the market. Yes, ma'am.

Ms.SCHAKOWSKY. OK, I yield back. Thank you.

Ms.DEGETTE. The Chair now recognizes the gentleman from South Carolina, Mr. Duncan, for 5 minutes.

Mr.DUNCAN. Thank you, Madam Chair. You know, the use of e-cigarettes is common among our youth and the reported deaths and illnesses that have been associated with that are incredibly worrisome. The issue as I see it, isn't necessarily about vape or vaping products as much it is about how these devices are abused.

I thank the witnesses for being here to help us understand the issue better so that we can hopefully find appropriate solutions, but I believe the immediate answer is for our youth to stop buying black market pods and stop trying to get high by lacing these pods with THC. That seems to be the common thread. I believe it is crucial though, that we look further into the THC counterfeit, black market products that people are buying and vaping. I understand these products have a short history, but we need to have all the facts before we can fully remedy the situation.

So I am going to ask both witnesses here today, I understand that patients with reported lung illnesses have admitted to using e-cigarettes containing just THC, THC and nicotine, and just nicotine. But does CDC and/or the FDA believe that THC counterfeit, black market vaping products pose a higher risk than legally sold, unadulterated nicotine cartridges used in e-cigarettes? Both witnesses.

Dr.SCHUCHAT. We're concerned about both right now and we're—it's an ongoing investigation about the lung injury outbreak. We're very concerned about e-cigarettes and youth on an ongoing basis because the trends are increasing.

Mr.DUNCAN. OK.

Dr. Sharpless?

Dr.SHARPLESS. I agree with Dr. Schuchat's remarks. I think no single product has been linked to all the cases. When we test cases, products that are actually linked to cases in our lab, we find the majority are THC products but not all of them. There are certainly nicotine-only products as well.

Mr.DUNCAN. Thank you for that. Are there any enforcement actions that CDC and FDA believe we should be taking against counterfeit manufacturers?

Dr.SHARPLESS. A challenging issue for the FDA, particularly around THC, which provides some jurisdictional challenges; I think we can certainly try and enforce what comes in at the borders through the international mail facilities. When it is an FDA-regulated tobacco product, we certainly have significant enforcement authorities. And as I said, we've engaged the DEA for their help on products that are more challenging for us jurisdictionally.

Mr.DUNCAN. Yes. Dr. Schuchat?

Dr.SCHUCHAT. I really think this is an extremely challenging issue. I don't have the tools, and I'm not sure what the tools are, but I think counterfeiting, and there clearly are a lot of dangerous products out there.

Mr.DUNCAN. Yes. Given what little we know about these counterfeit products, what research or studies are currently underway to

help us understand more? What are you all doing to help us understand more?

Dr.SCHUCHAT. Just briefly, the state and local public health are interviewing patients associated with the lung injury outbreak and identifying what they used, where they got it, how they used it, and providing that product information to FDA or as appropriate to DEA.

Dr.SHARPLESS. We're taking the data we're getting from CDC and other datasets and integrating that and we have, you know, and across the agency effort involving all our scientists to think about, you know, what's the cause of this outbreak and what we could do to prevent further cases. And then, I mentioned the extensive testing that we are doing in our criminal lab to, in our forensic chemistry lab, to identify the components in the possible contaminants.

Mr.DUNCAN. I think there needs to be a strong public service announcement, a marketing effort targeting the age groups of middle school and high school that are using these, even college and even young adults. Two weeks ago, the CDC put out a statement regarding whether users should consider not using e-cigarette products at all while the investigation is ongoing. Conversely, the FDA put out a statement urging consumers to avoid buying vaping products from the street and to refrain from using THC oil or modifying using any substance, adding any substance products purchased in the stores.

Why have the CDC and FDA been putting out conflicting warnings and recommendations to the public?

Dr.SCHUCHAT. You know, I would say there's no light between the recommendations that the two agencies have been putting out and if it's interpreted as different, we want to correct that.

Dr.SCHUCHAT. Yes, I would agree. I think we're in lockstep on this about the public health emergency here and the avoidance of these products by all parties except for those people who may be using them to not use combustible cigarettes. I think, you know, we do look at slightly different datasets and we, as data emerge in real time, we want to make it available to the public as quickly as possible because of the public of import of this information.

But I agree, we're in substantial agreement on——

Mr.DUNCAN. Does it concern you at all that the federal health officials, and public health officials are putting out conflicting statements and there will be confusion among those who are using e-cigarettes legally? Not the ones who are buying the black market, not the ones that are adding things to it, you know, the confusion over those that are legally using vaping products? Does that concern you at all?

Dr.SCHUCHAT. We strive for clear communication and want to do better.

Dr.SHARPLESS. I would agree. We have constant communication, and I think we will strive for very coordinated communication.

Mr.DUNCAN. I think the message here today is to stop putting THC products in legally purchased pods and stop buying black market pods. There is a health risk and is coating the lungs of our children, keeping the oxygen from making it into the system to pro-

vide oxygen to the brain. It is damaging the health of our kids and that is the message today. Stop doing this. I yield back.

Ms.DEGETTE. The gentleman's time has expired. The Chair now recognizes the gentlelady from New Hampshire, Ms. Kuster, for 5 minutes.

Ms.KUSTER. Thank you, Chairwoman DeGette, for holding this critical hearing, and thank you to our witnesses for joining our committee while we seek answers from the public about this public health emergency. And I think you are hearing in a bipartisan way the research is really important, communication and transparency of the data to the American people. I can certainly say as a parent, this is a very scary time in terms of; I personally don't think we should be holding out any of these products as "safe" to the public because we haven't had the research and we have not thoroughly tested them.

Based on the data, just as we were on the precipice of minimizing tobacco's hold on our nation's youth, the tobacco industry has devised a new way to place our children once again in the crosshairs. As a result, e-cigarettes are now the most commonly used tobacco product among youth, surpassing the rate of youth use of conventional cigarettes five years ago in 2014. In fact, e-cigarette use among youth doubled from 2017 to 2019—doubled—demonstrating this problem is only getting significantly worse.

In my own home state of New Hampshire, the Department of Health and Human Services estimates that at least one-quarter of all high school students uses vaping products, and that number is on the rise. Now you may know that our state is still in the throes of an opioid epidemic that began with misleading marketing and a lack of regulatory oversight. My fear is that we are repeating those same mistakes and making way for a new generation grappling with addiction. And that is why I am proud to cosponsor the Reversing Youth Tobacco Epidemic Act of 2019, which includes numerous important provisions to curb the rise of youth tobacco use.

And with that, I want to ask a few questions. Dr. Schuchat, based on CDC's surveillance and research, what do you believe are the reasons that young people are smoking e-cigarettes at such alarming rates?

Dr.SCHUCHAT. We know that flavors are a principal attractant to young people. The latest generation of e-cigarettes also is extremely high in nicotine content. They often include nicotine salts which are a little bit more palatable or less bitter, and the flavors are, you know, really targeted at youth. So we think the addictiveness of the high nicotine level and the appeal of the flavors are key. We also think some of the companies have had youth-targeting ads.

Ms.KUSTER. And the marketing. According to the National Institute of Health, 81 percent of adolescents who have ever used tobacco products began with a flavored product. Dr. Schuchat, what more can you tell us about the contribution of flavors to this dramatic rise? And you have mentioned this, anything more to add?

Dr.SCHUCHAT. Yes, I think that we have seen a little bit of a shift in the most recent preliminary data with an increase in the menthol and mint flavors among what youth are using. So we do think flavors are a critical beginning to youth use, and then the

nicotine provides that addictive substance that keeps them going back.

Ms.KUSTER. Thank you.

Dr. Sharpless, will you ensure that the newly announced federal policy to clear the shelves of flavored e-cigarette products will be effective?

Dr.SHARPLESS. We believe this policy will have dramatic effects on the flavored products sold in the market today.

Ms.KUSTER. And does that include menthol and mint cigarettes will be cleared from the shelves?

Dr.SHARPLESS. We are finalizing the policy, and I don't want to prejudge the policy under preparation, but I can say that the data support mint and menthol being a significant problem, as Dr. Schuchat alluded that it's been very popular with children.

Ms.KUSTER. Thank you. Last year as part of the FDA's comprehensive plan for tobacco and nicotine regulation, the agency launched the Youth Tobacco Prevention Plan. Dr. Sharpless, what are the goals of this youth-focused plan, and can you discuss the status of some of the efforts like the Real Cost campaign that the FDA has or plans to implement?

Dr.SHARPLESS. Thank you for the question. The FDA has a long-standing anti-tobacco campaign, educational campaign. Initially, we focused around combustible cigarettes, getting youth not to use that. We believe it's very successful in that regard that the campaign reaches 11 million kids, age 12 to 17, who are users of tobacco products or are open to using tobacco products. In the last year or so we have really shifted that focus to e-cigarettes to catch up with this epidemic. This includes some new TV ads that are very; they really tested off the charts with the youth markets. They're strong ads to discourage youth use of e-cigarettes, to make sure kids are aware. You know, sometimes kids aren't even aware that some of these products contain nicotine, for example, so juuling has become verb in high school that is not really understood to be a dangerous product, necessarily. So there's really a lot of education effort devoted by the FDA towards this topic.

Ms.KUSTER. Well, in my view, manufacturers and retailers are creating a new generation of nicotine-addicted consumers at a time when our nation's youth face unique obstacles, now more than ever. So it is important we take action to constrain further reversals and protect our youth. And with that I yield back.

Ms.DEGETTE. The Chair now recognizes the gentlelady from Florida, Ms. Castor, for 5 minutes.

Ms.CASTOR. Well, thank you, Chairwoman DeGette. This is a very important hearing and thanks to our witnesses for being here.

America has a serious and growing vaping problem. I have seen it firsthand. My two daughters are just a couple of years out of high school, and I noticed a sea change in behavior among high school kids, and middle school kids, over the past decade, and it reflects the research the yearly Florida Youth Tobacco Survey that is run by our Department of Health found that from 2012 to 2018 there was a 361 percent increase of kids aged 11 to 17 who had tried electronic vaping. Even worse, there has been a 582 percent increase in kids that currently use electronic vapes and a 651 percent increase when the survey focused only on high school stu-

dents. And on top of that, the survey also found that e-cigarettes are by far and away from the most common form of youth smoking.

So, clearly, this is a very serious public health problem. Do you determine an epidemic or an emergency, Dr. Schuchat?

Dr.SCHUCHAT. Yes, we are calling the youth use of e-cigarettes an epidemic.

Dr.SHARPLESS. As are we.

Ms.CASTOR. OK. Dr. Sharpless, on September 10th in a post titled, "How FDA is Regulating E-Cigarettes," you wrote that clearly some of the rapid rise in youth use of these products, meaning e-cigarettes, has resulted from irresponsible practices of the manufacturers who have targeted children in particular. Give us some examples of these insidious practices by Juul and other manufacturers.

Dr.SHARPLESS. So on September 9th, we sent a letter to Juul Labs, Incorporated detailing their use of unauthorized marketing claims, the so-called modified risk tobacco product claims, so things like saying their product is essentially safe or much safer or 99 percent safer. Some of these were made in presentations to children and they——

Ms.CASTOR. So, they are just outright saying things that are untrue.

Dr.SHARPLESS. There is no data to support those claims. There are no data to support those claims that I am aware of.

Ms.CASTOR. So that is untrue.

Dr. Schuchat? Yes.

How are these manufacturers specifically targeting kids? What type of marketing are they using that really alarms you?

Dr.SCHUCHAT. Yes, we're aware of a lot of presence on social media and recruiting youth social influencers, you know, influential people, celebrities and so forth, to make this look cool or fun. And certainly, as Dr. Sharpless mentions, a lot of youth aren't aware there's even nicotine in e-cigarettes, you know, flavor and water, that's what I thought I was getting.

So I think we're seeing the kind of tactics that were used with cigarettes being used again. And we think we need to take really aggressive action to protect the young——

Ms.CASTOR. Yes.

So, Dr. Sharpless, you said in the—we need all the regulatory tools that have been mentioned here, but you said in your public relations campaign you are going to use TV ads. That is not going to do it. You know, you have heard, you know what they are using.

Dr.SHARPLESS. Yes.

Ms.CASTOR. They are on Instagram. They are on Snapchat. They are using these influencers. Don't you have plans for a more modern type of education campaign to really get to young people?

Dr.SHARPLESS. I totally agree there's; this is a market that requires a lot of different channels to reach. We have done some of this, so with the Federal Trade Commission; for example, we took down some sites that were using these social media influencers that were sort of hyping e-liquid products without disclosing they contained nicotine, which is a violation.

Ms.CASTOR. Who were the public health influencers that you all are going to bring to bear, because these products, you are right,

young people, they think they are cool. They think they are not so harmful. They think, oh, that has happened somewhere else. It is not happening in my friend groups.

Dr.SCHUCHAT. In terms of public health, of course the Surgeon General's really been out there and our partners at state and local public health. I think there's a lot of kids behind me who might be influential as well.

Ms.CASTOR. Really. You have got to get with the program here. This is, you are not going to be able to combat this with the same old ways to communicate to young people these days. You have got to get—you have got to bring the most modern techniques to bear. I don't think the Congress has all the answers in that either, so I really encourage you and I encourage the Committee to move aggressively on this, otherwise other people are going to die, and other young people are going to get hooked that they don't even—they think it is cool, they think it is not harmful, and now all of your, the evidence we have so far that is just not the case.

So I will yield back my time and encourage you to be more hip. Thanks.

Ms.DEGETTE. The gentlelady now—well, let's see—now, recognizes the gentleman from Maryland, Mr. Sarbanes, for 5 minutes.

Mr.SARBANES. Thank you, Madam Chair. I want to thank the witnesses for being here today.

I would like you to speak, both of you, but maybe Dr. Schuchat to begin, on—map out for me, because I think this is horrifying what is happening. It is sort of we are playing the same reel over again that we saw with, you know, cigarettes before the tobacco settlement, with opioids before, now the heightened scrutiny that it is receiving and all the litigation that has ensued and presumably some kind of compensation that will come too late for many families and many communities.

But even as we are dealing with those things, the after-effects of those crises, those public health crises, we have a new one unfolding before our eyes. And you can just predict that we are going to be having hearings ten years from now, looking back and picking up the pieces of a terrible public health crisis with incredible impacts on communities across the country. The fact that it is starting, its breeding ground is among children is what makes it even more horrifying, so there is a lot of discussion about how we need to better regulate this and addressing the industry's practices and marketing and all the rest of it, which is important.

But maybe you can map out the scenario of what the public health crisis could look like ten years out, five years out, ten years out if we don't take really dramatic steps now to address this on what arguably is still kind of the front end of it, although we are kind of getting into the thing. Map that out for me because, in a way, what I am asking you to do is put on the record a scenario that we can come back to. I don't want to have to do that, but that sadly, we may find ourselves coming back to later and saying this was all predictable. So talk about that.

Dr.SCHUCHAT. We've been warning about e-cigarettes and youth since 2013, when we first saw the increase in our data from 2011 to 2012. But the industry has changed substantially since then and the products in this fourth generation of e-cigarettes are much

more risky even than the earlier ones in terms of nicotine level, flavors, the nicotine, salts and the concealable product that make it really hard to know that anybody's using in class and so forth.

So if these trends continue and we don't turn this tide, we have a generation addicted to nicotine with potentially the impacts on the adolescent brain or the developing brain that last for life in terms of memory, attention difficulties, learning problems, and the implications of that as adult workers. We have the potential to progression to cigarette smoking which we know is incredibly lethal in people who smoke, and we have all the signs of that happening in terms of the last few years of data.

The issue right now with the lung injury outbreak has people dying. It's not a question of 20 years from now. It's a question of now and the forces that have led to that we don't fully understand. Just as with the opioid epidemic, we didn't understand prescription drugs to heroin to fentanyl to analogs to stimulants. And so I think we have a lot of people getting addicted—

Mr.SARBANES. But one thing we have come to understand and we probably could have understood in the moment with the opioid crisis if we hadn't, in effect, had the wool pulled over our eyes by an industry with very effective marketing techniques, is how a whole industry can either affirmatively be trying to encourage dependency on their product or at a minimum turn a blind eye to alarming trends that are happening that they know are happening and look for sort of plausible deniability about their own responsibility. And I think we are seeing it all play again, the same movie.

So anyway, we are going to keep our focus on this. Thank you very much, Madam Chair, for convening the hearing. I yield back my time.

Ms.DEGETTE. The Chair now recognizes the very patient, gentlelady from New York, Ms. Clarke, for 5 minutes.

Ms.CLARKE. I thank you, Madam Chair, and I thank Ranking Member Guthrie, for convening this subcommittee hearing today on the threats of e-cigarettes. I would also like to welcome and thank our panelists for their expert testimony here today and for attending as we fight to protect the American people from the harmful effects of smoking, but more specifically e-cigarettes and vaping.

And I would like to jump right into my line of questioning. Dr. Schuchat, according to your testimony, as of September 19, 2019, there were 530 confirmed cases of lung disease associated with e-cigarette use in 38 states and one territory. So far, at least nine people have died as a result and the overwhelming majority of these cases, 83 percent, of which the CDC has complete data are under the age of 35. These are young people. It is devastating that this disease has already taken nine lives that we know of and it is an obvious tragedy. I have also seen reports, however, of individuals currently still on life support or on respirators for days on end.

So, Dr. Schuchat, what do you know about the potential long-term health effects about this pulmonary illness associated with e-cigarettes?

Dr.SCHUCHAT. We fear there may be long-term illness in a number of individuals. We're recommending individualized care for clinicians to follow patients after they're discharged and check pul-

monary function tests and so forth. It's so new that the clinical course is probably variable, and some improvement is being noted in a number of individuals when they get steroid treatment. But, you know, the issue of long-term effects is very serious because these are young people who were pretty much fine and may have a life that's quite altered if they recover.

Ms.CLARKE. Is it possible that there are cases that we have missed prior to the outbreak?

Dr.SCHUCHAT. Yes. We know there have been individual reports of serious lung injury following vaping or e-cigarette use in the past. We believe that something new is happening to cause these many cases that we're seeing now and we know that the states and clinicians are really looking backward and getting all the cases reviewed that they can.

But new cases continue to occur, and that's one of the reasons we feel this sense of urgency to get the public health messages out so that we can prevent further cases.

Ms.CLARKE. Dr. Schuchat and Dr. Sharpless, you have both said that no single product, device, or component has been identified as the specific cause of these illnesses, but you have reported at least some of the illnesses have been traced to "street" products not sold by legitimate retailers. Dr. Sharpless, what authority does FDA have to take action against counterfeit or unregistered e-cigarette products?

Dr.SHARPLESS. So, for counterfeit tobacco products, we have a range of authorities when we're able to identify them. This includes testing.

Ms.CLARKE. No, no, no. I mean the e-cigarettes.

Dr.SHARPLESS. Yes. Well, so for when the products involve THC not a tobacco product, this is—

Ms.CLARKE. Generally speaking, e-cigarettes.

Dr.SHARPLESS. So e-cigarettes as the FDA uses the term or FDA-regulated tobacco product and there we have—

Ms.CLARKE. OK.

Dr.SHARPLESS [continuing]. The same authorities we have with other tobacco products.

Ms.CLARKE. OK. And so you do have the ability to take action against this?

Dr.SHARPLESS. If it is a tobacco product, we have significant authorities, yes.

Ms.CLARKE. I am sorry. You are parsing words here. We are here specifically about these e-cigarettes, right.

Dr.SHARPLESS. I apologize for the lack of clarity. The FDA has significant authorities around tobacco products, including e-cigarette nicotine delivery and the nicotine is a tobacco-derived substance, so those products we have great, you know, strong authorities from the 2009 Tobacco Control Act as well as the deeming rule.

THC and other, you know, things that might be vaped that are not nicotine are jurisdictionally more challenging. A substance like THC that is a Schedule I drug is some shared regulation between the FDA and the DEA, which is why we have been working with them on those sorts of products.

Ms.CLARKE. OK. Dr. Sharpless, to the extent that some of these products contributing to the illnesses may have been sold by reg-

istered retailers, what ability does the FDA have to order or recall or get these dangerous products off the shelves?

Dr.SHARPLESS. So, we can identify a manufacturer source. We can send warning letters and other measures, civil money penalties and that like, and even no tobacco sale order if we can identify a retailer that's selling a product that shouldn't be on the market.

Ms.CLARKE. And so have you already begun that process?

Dr.SHARPLESS. Early days in this investigation; as I said right now, our main focus is on testing the products, finding what they are and where they seem to come from, and then in many cases, engage our—

Ms.CLARKE. But if people are losing their lives right now, wouldn't it be prudent to do a recall too, you know, a moratorium on sales, something that stops this until your testing is done?

Dr.SHARPLESS. Well, let me—so that sounds a bit like a food outbreak, like what we would do if there were a bad food. But this is different in this way.

Ms.CLARKE. How is it different? People are dying.

Dr.SHARPLESS. Well, many of these products are illicit so people are not forthcoming to—

Ms.CLARKE. Yes, but you know what you can do a process of elimination, right?

Dr.SHARPLESS. We have better authorities about the illicit products that are sold through legitimate retailers, but many of these products are not that.

Ms.CLARKE. Thank you very much, Madam Chair. I yield back.

Ms.DEGETTE. The Chair now recognizes the gentleman from New York, Mr. Tonko, for 5 minutes.

Mr.TONKO. Thank you, Madam Chair, for the subcommittee hearing and thank you to our witnesses for appearing before the subcommittee.

The 2016 final deeming rule issued by FDA brought e-cigarettes within FDA's regulatory authority under the Tobacco Control Act, but FDA is not exercising that authority to its fullest extent and e-cigarettes only remain on the market today due to FDA's enforcement discretion. As has been well established this morning, teen use of e-cigarettes has skyrocketed over the past several years. In fact, the youth use rate of e-cigarettes surpassed conventional cigarette use some five years ago.

So, Dr. Sharpless, can you explain why FDA decided in 2017 to extend the compliance deadlines for FDA review of the public health risks of these products?

Dr.SHARPLESS. Sure. As part of a broader comprehensive strategy regarding tobacco in general, the FDA at that time looked at the data—we're a science-driven organization—and concluded that e-cigarette use among children from 2015 to 2017 was going down or leveling off. That was before this explosion of youth use that we've now seen in the last two years. When the FDA began to appreciate this sort of rocket was taking off, and we needed to be more engaged, we stepped up our enforcement education activities and now very broad policy activities that would have a major effect on the market.

Mr.TONKO. Well, in retrospect, should the FDA have had acted more urgently?

Dr.SHARPLESS. I believe in retrospect we should have acted more urgently.

Mr.TONKO. OK. So if I understand you correctly, FDA decided to delay the compliance deadlines in 2017 because it was a brief decline in youth use rates in 2015 and there was a potential health benefit to some individual addicted adult smokers. So my question to you then is, now that we have a fuller understanding of the terrible epidemic that youth in this country are facing, have these considerations changed?

Dr.SHARPLESS. The FDA has always been very clear that as new facts emerge and we get new data, we will change our regulatory posture and I would argue have done so starting with the 2018 NYTS data, which was very concerning, and then the preliminary data we've seen from 2019 has really sounded the alarms for—

Mr.TONKO. So, if that is true then, how will FDA account for them in their eventual reviews of these products?

Dr.SHARPLESS. Right. So we have moved up the date for PMTA submission, these premarket tobacco applications, so now to May 2020. So all products on the market today are illegal. To be legally marketed, they will have to come to the FDA and have a PMTA approved. In addition, our compliance policy that we announced, the President, you know, announced his support for recently, would have the effect of moving flavored products, which are particularly appealing to children, from the market very soon.

Mr.TONKO. Well, Dr. Sharpless, we will hear on the second panel that Michigan has temporarily banned flavored products while Massachusetts has banned all vaping products for four months. There seems to be the recognition that we have a public health epidemic requiring some urgency from our regulatory agencies. So why has it taken a multistate outbreak of severe pulmonary illnesses and several deaths for this administration to take action to protect young people's health?

Dr.SHARPLESS. Congressman, I would say the major point of data that is driving our compliance policy is the Youth Tobacco Survey, the NYTS, so this epidemic of youth use that we've identified for multiple datasets, not just the NYTS, shows youth use. And that is, I think, the sense of urgency is further injected by this other problem, the vaping lung injuries, but I think that, you know, the administration considers its duty to protect children a top priority and is really acting in response to the NYTS data.

Mr.TONKO. Well, when FDA finally reviews these products, it must assess whether they are "appropriate for the protection of public health." So, Dr. Sharpless, will the FDA ban them if it ultimately determines that the dangers of youth use outweigh any potential benefits to adult smokers?

Dr.SHARPLESS. Certainly. We have issued guidances, or a guidance to industry about what the information is to be included in a PMTA. I think we've been very clear, and we've already approved products through the PMTA process. And that's the sort of thing we consider is the benefit—the standard is what you mentioned. This product has to be good for the public health, and if it's not, it won't be authorized.

Mr.TONKO. Well, I thank you for your responses. With all these new tobacco products flooding the market over the past few years,

without a full understanding of the public health risks, it is not surprising that we are in such a crisis situation today. And I have to echo my concerns over and over again how this administration has rejected science in many formats and ways and that is troublesome to me.

So I would hope again that we approach this issue with all the science-based, evidence-based data at our fingertips, and those data speak to us boldly, and we should respond in public policy format so as to protect the lives of young people and all people across the board by sound policies. So with that, I yield back, Madam Chair.

Ms.DEGETTE. I thank the gentleman. The ranking member and I now will just ask a few closing questions.

Mr. Guthrie, recognized.

Mr.GUTHRIE. Thank you. Thanks, Chair, for doing a second round really quick.

And based on something I heard earlier, and I saw this yesterday; I think I saw it. I don't remember if I heard it or read it, but somebody says if this were lettuce, it would be off the market tomorrow. So, if you want to look at the equivalent, if somebody bought tainted lettuce at a grocery store, you would trace back to where that came from, and you would shut that whole supply line down.

But if somebody bought tainted lettuce at a corner store, or if you drive through Kentucky, people are on the side of the road selling their vegetables in the summertime, which is fantastic to get fresh vegetables, but if somebody is just out selling, you wouldn't go shut down all the supply line in the grocery stores because somebody bought tainted lettuce from somewhere that you can't trace, you can't figure exactly where it comes from. I think that would be more of the clue and I think if you could trace that you would shut it down; just is my guess on that.

Dr.SHARPLESS. No, I agree with that characterization, Congressman Guthrie. I think the problem here is that we don't believe that the cases are being totally forthcoming with us in all instances of what they've been using and they're not eager to identify what products they've been using, and certainly a manufacturer is not eager to identify, to be known.

In a food outbreak, the manufacturer has an interest in getting that food off the market. They don't want their product to get a bad reputation. But with an illicit substance, it's very different from a food borne.

Mr.GUTHRIE. It is a lot easier when it comes to a corporate chain because you can trace it as opposed to somebody's farm that just sold it to someone—it is hard to find. It is just harder to find that way.

Dr.SHARPLESS. Correct.

Mr.GUTHRIE. So, you said the National Youth Tobacco Survey is what you used to make some decision. And I have noticed it has increased greatly, but that information is relatively new, is it? Maybe it came out in September or so? So you are using it to react to, and I think what you said given where we are now, we should have reacted three years ago, but you are reacting to it now—now that you know, you are knowing the information today.

Dr.SHARPLESS. Right. I think as new facts have emerged, the FDA has changed its posture, so, you know, we're very clear that as we would continue to monitor the science and gather new data. The NYTS data from 2019 is still preliminary. We're working to get that data out with the CDC as quickly as possible, but I would say it's not the sole data source.

So there's a study from NIDA and these state studies that have been referenced. And the fact that there's a striking epidemic of youth using e-cigarettes is, I think, noncontroversial.

Mr.GUTHRIE. Absolutely.

Dr.SHARPLESS. It's supported by many datasets.

Mr.GUTHRIE. Good. And then one final thing, I was going to ask this in my previous questions. I was talking about THC previously in my questions. So, is the FDA involved in any federal investigation of vaping products containing THC, and/or has the FDA declined to be involved in any federal investigation of vaping products with THC?

Dr.SHARPLESS. So we have engaged heavily with the DEA, so we've had numerous joint calls and set up communication between our chemists and their chemists, our enforcement people and their enforcement people, our cybercrimes people, and their cybercrimes people. They have a number of ongoing investigations related to THC vaping products, and they're sharing data on those with us. Our question is, where are these products coming from and are they adulterated and of that nature. So I think there's good co-operation between the federal agencies related to THC.

Mr.GUTHRIE. OK. I am going to use all my time, but I will finish with this. I was in your mail facility, the mail facility, our mail facility as Americans, at JFK Airport and your FDA group was there. It is amazing the things they are finding illicit. They were showing different tablets that were brand—that we would consider brand-name drugs today and how they copied the logos and the logos are off-center and things like that.

So when you stand there and see the volume that your people, your brave people there going through some, dealing with fentanyl where they have to wear protective gear to find what is going through, they are there working, but it is an enormous task. We ask a lot of them, but we appreciate the effort that you guys do and what the CDC is doing as well and just all the work that you guys are doing.

Dr.SHARPLESS. Thank you very much. But I'd like to say that's a real pride of the FDA, the IMFs, and have substantially increased their capacity thanks to the generous support of Congress in recent years.

Mr.GUTHRIE. Thank you very much. I appreciate that and I yield back.

Ms.DEGETTE. I thank the gentleman.

Dr. Sharpless, I just want to clarify how this compliance policy of the FDA on the flavors is going to work, which I understand is the same way it would work under the legislation that I have introduced. And that is you send out your order; then the companies are required to withdraw the flavored products. And then they can come and make an application with the FDA to try to show why they think that it is safe to market them; is that right?

Dr.SHARPLESS. That's correct. Upon finalization, the guidance would then go into effect some period later. We would send out warning letters and other sorts of enforcement activity; pull the flavored products from the market. Anyone who thought that their product was good for the public health that could meet the standard can file a PMTA application at any time before May 2020, but at least by May 2020, and if the product can demonstrate a public health use, then it would be authorized for sale.

Ms.DEGETTE. And what would the criteria that would be used to allow that to happen?

Dr.SHARPLESS. So the PMTA application, we've provided extensive guidance about what we expect industry to include on those. It's things like how it is manufactured, what are its components, nicotine levels, appeal to children, and use by specific populations, risks for addictions and diversions, and things like that.

Ms.DEGETTE. But the reason why you are withdrawing it now is because there is substantial evidence that these flavors are appealing to teenagers and youths and getting them hooked on nicotine; is that right?

Dr.SHARPLESS. That's correct. The data suggests that kids really like flavors. Nicotine is somewhat harsh straight and so flavors can mask that and make it more appealing to new users.

Ms.DEGETTE. OK, so that is the evidence that would be used to counterweight any of the arguments.

Dr.SHARPLESS. Right. And the evidence that's emerged from the NYTS studies and other studies is very strong that flavors drive a child to use.

Ms.DEGETTE. OK. So I have got to say I haven't heard anything today to show why these products should be marketed. There is some anecdotal evidence that maybe it can help some existing adult smokers not smoke cigarettes, but other than that I haven't heard any reason why we shouldn't ban these flavors, why we shouldn't ban them, ban kids from being able to get this, and why we shouldn't aggressively pursue this from a public health perspective.

But I think there has been some confusing questioning to both of our witnesses today, implying maybe it is just illicit drugs or maybe it is just off-market vaping devices or whatever, so I, you know, you guys have the forum right now.

I would like to ask each one of you to tell us what your is message to the parents of America regarding whether their kids should be using any form of e-cigarettes.

Dr. Schuchat, we can start with you.

Dr.SCHUCHAT. We want parents to talk to their kids. They should not be using these products, e-cigarettes with nicotine or vaping products with other substances. We're very concerned. We have tip sheets for parents on how to talk to their kids about this. These are dangerous products for youth.

Ms.DEGETTE. Dr. Sharpless?

Dr.SHARPLESS. I think our message always, largely, agrees. We think that these products are unsafe for children, whether they contain THC or nicotine and would not recommend their use. We really don't think anyone should be using e-cigarettes except for perhaps the person who's using it instead of a combustible ciga-

rette because combustible cigarettes are really bad. We want to minimize their use as well.

Ms.DEGETTE. Thank you. I want to thank both of our witnesses for participating today. You know the drill. Members will submit questions for the record, and I would ask each of the witnesses to agree to respond promptly to any of those questions should you receive any.

With that, the subcommittee will dismiss Panel I. And after the second panel has been set, we will invite our witnesses to come. Thanks to both of you for coming today.

[Whereupon, at 12:04 p.m., the subcommittee recessed to reconvene at 12:10 p.m., the same day.]

Ms.DEGETTE. I am now delighted to introduce our second panel of witnesses for today's hearing.

Dr. Joneigh Khaldun, who is a doctor, Chief Deputy Director for Health and Chief Medical Executive, Michigan Department of Health and Human Services; Dr. Elizabeth Cuervo Tilson, State Health Director and Chief Medical Officer of North Carolina Department of Health and Human Services; Dr. Lee Norman, Secretary of the Kansas Department of Health and Environment; and Dr. Monica Bharel. And Dr. Bharel is the Commissioner of the Massachusetts Department of Public Health.

I want to thank all of you for appearing before the Committee today. Now you are aware the Committee is holding an investigative hearing and when we do so, we have the practice of taking our testimony under oath. Do you have any objections to testifying under oath today?

No. I will let the record reflect that the witnesses have responded no.

The Chair then advises you that under the rules of the House and the rules of the Committee, you are entitled to be accompanied by counsel. Do any of you request to be accompanied by counsel today?

No. Let the record reflect that the witnesses have stated no.

If you would then, please rise and raise your right hand so you may be sworn in.

[Witnesses sworn.]

Ms.DEGETTE. Let the record reflect that the witnesses have responded in the affirmative and you are already seated. You are now under oath and subject to the penalties set forth in Title 18 Section 1001 of the United States Code.

The Chair will now recognize our witnesses for a 5-minutes summary of their written statement. In front of you is the microphone and a series of lights. The light will turn yellow when you have 1-minute left, and red to indicate when your time has come to an end.

And so let me, please start with you, Dr. Khaldun. Welcome, and you are recognized for 5 minutes.

STATEMENT OF JONEIGH S. KHALDUN, M.D., CHIEF DEPUTY DIRECTOR FOR HEALTH AND CHIEF MEDICAL EXECUTIVE, MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES; ELIZABETH CUERVO TILSON, M.D., STATE HEALTH DIRECTOR AND CHIEF MEDICAL OFFICER, NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES; LEE NORMAN, M.D., SECRETARY, KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT; AND, MONICA BHAREL, M.D., COMMISSIONER, MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF JONEIGH KHALDUN, M.D.

Dr. KHALDUN. Chair DeGette, Ranking Member Guthrie, and members of the subcommittee, thank you for the opportunity to speak with you today regarding the public health crisis of youth e-cigarette use.

As the mother of three children, a practicing emergency medicine physician, and a state public health official, there's nothing more astounding than the fact that we have let an entirely new generation of youth start using nicotine products. As a society, we let these e-cigarettes sneak onto the market without proper oversight or understanding of their health impacts. We can no longer stand idly by while this public health crisis ravages our communities.

Nationwide, e-cigarette use among middle and high school students increased 900 percent between 2011 and 2015. The total number of children who are currently using e-cigarettes rose to an astonishing 3.6 million in 2018, 1.5 million more than the previous year. In some counties in Michigan, more than a third of high school students are using e-cigarettes. This epidemic can be attributed in large part to the appeal of flavored vapor products to youth as well as the advertising and promotional activities by companies that glamorize the use of nicotine products nationwide.

Flavors such as strawberry milk, banana split, cotton candy, and gummy bear clearly target children. Advertisements for vaping products are often visually appealing to children with pictures of candy on the packaging. Studies show that flavors are a major reason that youth start vaping. And even scarier, many young people use these products without understanding their contents or the fact that they have nicotine in them. I recently spoke with the parent of one of my children's friends, who were devastated that they found these products in their child's bedroom, and they're now desperately trying to find resources for support for their child's addiction.

Earlier this month, under the leadership of Governor Gretchen Whitmer, Michigan became the first state to announce a ban on the sale of all flavored nicotine vaping products. Our emergency rules also ban fraudulent or misleading advertising and disallow marketing of these products at the point of sale. This strong leadership is necessary given the significant toll this epidemic has taken on our society and particularly our youth. And I'm pleased that other states are taking similar action.

In addition to this public health crisis of youth e-cigarette use, as of September 20th, we had 530 confirmed or probable cases of vaping-associated lung injury across the country and nine deaths.

In Michigan, we know of 15 confirmed or probable cases of this illness and are investigating several more. During our investigation into these vaping illnesses, it's been heartbreaking to speak to families of young people who were otherwise healthy and are now barely clinging to life.

There are key things we must do to fight this epidemic. First, we need strong, regulatory oversight over e-cigarettes. E-cigarettes should not be allowed on the market unless they are proven to be safe, and companies selling these products should not be allowed to market to youth or fraudulently market their products as safe.

Second, more research is needed to understand the long-term health effects of e-cigarette use. Assertions that e-cigarette use is effective for smoking cessation are not scientifically proven and the FDA has not approved e-cigarettes as part of a smoking cessation program. E-cigarettes also can contain cancer-causing toxins. We need to make sure we fully understand the health impacts of these products before we allow them to be on the market.

And, finally, we need to make sure there is sustained and increased funding for tobacco prevention education as well as funding for tobacco cessation efforts for youth and adults. Prevention efforts are a critical part of putting an end to this epidemic. The data around the epidemic of youth vaping is very clear and we must do more to properly regulate these products so no one, youth or adult, is harmed.

Thank you for allowing me to participate in this subcommittee hearing today, and I look forward to working with you.

[The prepared statement of Dr. Khaldun follows:]



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

ROBERT GORDON
DIRECTOR

TESTIMONY OF

Joneigh S. Khaldun, MD, MPH, FACEP
Chief Medical Executive, State of Michigan
Chief Deputy Director for Health, Michigan Department of Health and Human Services

HEARING ON

“Sounding the Alarm: The Public Health Threats of E-Cigarettes.”

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives
September 25, 2019

Chair DeGette, Ranking Member Guthrie, and members of the Subcommittee, thank you for the opportunity to speak with you today regarding the public health crisis of youth e-cigarette use.

Earlier this month, Michigan became the first state to announce it was banning the sale of all flavored nicotine vaping products, a move that was necessary given the significant toll this epidemic has taken on our society, and particularly our youth. Youth vaping is a public health emergency, and measures such as the flavor ban are necessary to protect public health. It is important that our local, state, and federal health officials not stand idly by while an entire generation of youth becomes newly addicted to nicotine.

Unfortunately, our country is moving backwards when it comes to use of tobacco products among youth. Nationwide, e-cigarette use among middle and high school students increased 900% from 2011-2015.¹ The total number of children who are currently using e-cigarettes rose to an astonishing 3.6 million in 2018, 1.5 million more than the previous year.² Since 2014, e-cigarettes have been the most commonly used tobacco product among youth in the U.S.³ Preliminary data from the 2019 National Youth Tobacco Survey show that youth use of e-cigarettes continues to increase, with over 27% of high school students reporting current (past 30 day) e-cigarette use in 2019. The overwhelming majority of youth e-cigarette users cited the use of popular fruit and menthol or mint flavors.⁴ Between the years 2015-2016 and 2017-2018,

¹ Surgeon General’s Advisory see footnote 1; citing Wang TW, Gentzke A, Sharapova S, et al. Tobacco Use Among Middle and High School Students – United States, 2011-2017. MMWR Morbidity and Mortality Weekly Report. 2018;67(22):629-633.

² See Footnote 3.

³ U.S. Surgeon General’s Advisory on E-Cigarette Use among Youth, available at <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

⁴ U.S. Food and Drug Administration news release. Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products. September

counties across Michigan witnessed between a 30% and 118% increase in use among high school students who used an e-cigarette during the past month. In several Michigan counties, more than a third of high school students use e-cigarettes.⁵

This epidemic can be attributed in large part to the appeal of flavored vapor products to youth, as well as the advertising and promotional activities by companies that glamorize use of nicotine products nationwide. Flavors such as “strawberry milk”, “banana split”, “cotton candy”, and “gummy bear” clearly target children, and advertisements for vaping products are often visually appealing to children with pictures of candy on the packaging. According to a recent study, 81% of youth e-cigarette users reported using a flavored e-cigarette at first use.⁶ Earlier this month, the Tobacco Center for Regulatory Science of the American Heart Association published results of a study that found that flavor was a common reason for vaping initiation and that young adults aged 18-24 were nearly twice as likely as people aged 35-44 to identify flavors as the major reason they took up e-cigarette use.⁷ We now have a new generation who are addicted to nicotine, unmistakably because of insidious and fraudulent marketing of these products towards youth and lack of sufficient regulatory oversight.

The Centers for Disease Control and Prevention (CDC) has concluded that the use of e-cigarettes is unsafe for kids, teens, young adults, pregnant women, and adults who do not currently use tobacco products. The nicotine in e-cigarettes is harmful to young people’s developing brains, and young people who use e-cigarettes are more likely to smoke cigarettes in the future.⁸ The FDA has determined that youth who experiment with e-cigarettes are 7.7 times more likely to become established smokers than those who do not experiment.⁹ E-cigarette aerosol that users breathe and exhale can contain harmful substances including nicotine, ultrafine particles, flavoring such as diacetyl, which is a chemical linked to a serious lung disease, volatile organic compounds, cancer-causing chemicals, and heavy metals such as nickel, tin, and lead.¹⁰ Recent research has demonstrated that acute exposure to flavored e-liquids or e-cigarette use can exacerbate endothelial dysfunction, which often precedes cardiovascular diseases.¹¹

11, 2019. <https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey>.

⁵ Michigan Profile for Healthy Youth Survey by MDE & MDHHS, 39 County Data from 2015-2016 and 2017-2018 for e-cigarette usage among high schoolers.

⁶ Villanti AC, Johnson AL, Ambrose BK, et al. Flavored Tobacco Product Use in Youth and Adults: Findings from the First Wave of the PATH Study (2013-2014). *Am J Prev Med.* 2017;53(2):139–151.

doi:10.1016/j.amepre.2017.01.026. <https://www.ncbi.nlm.nih.gov/pubmed/28318902>.

⁷ Landry R, Groom A, Vu T, Stokes A, Berry K, Kesh A, Hart J, Walker K, Giachello A, Sears C, McGlasson K, Tompkins L, Mattingly D, Robertson R, and Payne T. The role of flavors in vaping initiation and satisfaction among U.S. adults. *Addictive Behaviors.* Volume 99, December 2019, 106077. Available online at

<https://www.sciencedirect.com/science/article/abs/pii/S0306460318311821?via%3Dihub>; see also <https://newsroom.heart.org/news/study-finds-flavors-play-a-role-in-initiation-addiction-to-e-cigarette-use>.

⁸ Centers for Disease Control and Prevention, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html, March 11, 2019.

⁹ <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the-p-761>

¹⁰ U.S. Department of Health and Human Services. E-cigarette use among youth and young adults: a report of the Surgeon General. https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf. Atlanta, GA: US Department of Health and Human Services, CDC; 2016.

¹¹ Hee Lee W, Ong S, Zhou Y, Tian L, Bae H, Baker N, Whitlatch A, Mohammadi L, Guo H, Nadeau K, Springer M, Schick S, Bhatnagar A, and Wu J. Modeling Cardiovascular Risks of E-Cigarettes With Human-Induced Pluripotent

E-cigarettes have not been validated or approved by the Food and Drug Administration (FDA) as a smoking cessation strategy. In one study of adult smokers, those who used e-cigarettes were less likely to have stopped smoking combustible cigarettes, and also smoked more cigarettes than those who did not use e-cigarettes.¹² The long-term health effects or efficacy of e-cigarettes for smoking cessation have not been properly evaluated, so any assertions that these products are safe, healthy, or part of a smoking cessation program are not scientifically confirmed.

Lack of sufficient regulatory oversight of these vaping products has contributed to the over 500 confirmed or probable cases of severe lung injury associated with vaping across the country, including 8 deaths.¹³ While we thankfully have not experienced any known deaths in Michigan, as of September 20, 2019 the State of Michigan has 13 confirmed or probable cases, and is currently investigating several more. The vaping-associated lung injuries we know about in Michigan have afflicted younger people, with an age range of 16 to 31 years and a median age of 21 years. The Michigan Department of Health and Human Services is working diligently with the CDC, FDA, our local health departments, and healthcare providers to identify potential cases. We also collect product samples and send them to the FDA laboratory for testing. At this time, we have not identified any specific substance, brand, or product as the cause of this illness. While many cases have reported using tetrahydrocannabinol (THC), some have used both THC and nicotine, and some only nicotine. In light of this current outbreak of vaping associated lung injuries, and the very strong body of evidence linking vaping with future combustible cigarette use, we recommend much stronger oversight of all vaping products. We support the FDA's current proposal to not allow these products on the market unless their safety has been proven. Given the overwhelming data that show the epidemic of youth vaping in Michigan, the Michigan Department of Health and Human Services declared young vaping to be a public health emergency on September 4, 2019. This allowed Michigan to move forward with implementing emergency rules, which were signed by Governor Whitmer and went into effect on September 18, 2019. Michigan's emergency rules make it illegal to sell or distribute any flavored nicotine vaping product, ban fraudulent advertising, and disallow marketing of these products at the point of sale of purchase.

When Governor Whitmer announced the emergency finding by the Department of Health and Human Services and the fact that emergency rules would be forthcoming, leading health care organizations, including the American Academy of Pediatrics, American Academy of Pediatrics Michigan Chapter, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative issued a joint statement in support of these actions. These organizations called the action "necessary and appropriate" and called for the FDA to immediately remove all flavored e-cigarettes from the market nationwide. In addition, in response to the alarming levels of e-cigarette use among youth in the United States, on September 10th, 2019, Bloomberg Philanthropies announced the creation of a new \$160 million initiative, which will be led by the Campaign for Tobacco-Free Kids, to end the youth e-cigarette epidemic. Walmart also

Stem Cell-Derived Endothelial Cells. *Journal of the American College of Cardiology*. Volume 73, Issue 21, June 2019. <http://www.onlinejacc.org/content/73/21/2722>.

¹² Kulik MC, Lisha NE, Glantz SA. E-cigarettes Associated With Depressed Smoking Cessation: A Cross-sectional Study of 28 European Union Countries. *Am J Prev Med*. 2018;54(4):603-609. doi:10.1016/j.amepre.2017.12.017

¹³ Centers for Disease Control and Prevention. Outbreak of Lung Disease Associated with E-Cigarette Use, or Vaping online factsheet. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html. Posted September 12, 2019 at 6:15pm ET.

announced this month that they will no longer sell e-cigarettes. On September 11, 2019, the White House announced plans to move forward to ban flavored e-cigarettes. The State of Michigan supports efforts to keep these products out of the hands of youth and properly regulate them.

The data regarding the epidemic of youth vaping is clear. We must do more to properly regulate these products so that no one, youth or adult, is harmed. Thank you for allowing me to participate in this subcommittee hearing today, and I look forward to working with you as we tackle this public health crisis.

Ms.DEGETTE. Thank you, Doctor.
 Dr. Tilson, you are now recognized for 5 minutes.

STATEMENT OF ELIZABETH TILSON, M.D.

Dr.TILSON. Chairman Pallone, Chair DeGette and Ranking Member Guthrie, and members of the subcommittee, thank you for the opportunity to testify today on the public health threats that e-cigarettes pose to our youth. My name is Dr. Elizabeth Cuervo Tilson and I serve as the state health director and chief medical officer for the North Carolina Department of Health and Human Services.

As you know, in December of 2018, the U.S. Surgeon General called e-cigarette use among youth an epidemic. As a public health official, a pediatrician, and a preventive medicine physician, I see this epidemic playing out across our schools and our communities in North Carolina. Our most recent North Carolina Youth Tobacco Survey found that although combustible cigarette smoking was at a lowest ever recorded amongst high school students at 8.9 percent, e-cigarettes use increased 894 percent since 2011. E-cigarettes have become the most commonly used tobacco product amongst youth in North Carolina, and further concerns have now risen with the multistate investigation of severe lung illness associated with e-cigarettes and vaping.

But before I go on, let me put a face onto this epidemic. Luka is a teenager from High Point, North Carolina. As a high school freshman, Luka started using Juul as a way to fit in with his upperclassmen on football Friday nights. He quickly became addicted to the nicotine in the product, even to the point of selling his clothes and other items to raise the \$150 a week he needed to support his nicotine addiction.

Once a Boy Scout, an athlete, and an A-student, Luka let his grades fall and dropped out of extracurricular activities. Usually a well-behaved 15-year-old, Luka became irritable and angry, even throwing violent outbursts of rage. Finally, a nicotine-related seizure ended him up in the emergency department. At that point, Luka and his parents knew they had to do everything they could to get Luka the treatment he needed for his nicotine addiction. Luka participated in a nearly 40-day substance use treatment program in California twice. Thankfully, he is now living substance-free.

But Luka is not alone, and we've heard similar stories from across our state and our nation and we must act to protect our children. And let me be clear, e-cigarettes are not safe. Nicotine is the major psychoactive substance found in e-cigarette solutions and is highly addictive. Youth and young adults are particularly at risk for the long-term effects due to the exposure of nicotine on their developing brains. Nicotine is related to seizures. Nicotine can cause harm to developing fetuses. And there's emerging data that nicotine use through e-cigarettes can, may increase their risk of emphysema, a form of long-term lung disease.

Further, as the acute outbreak of severe lung illness associated with e-cigarette products, 36 cases have been reported in North Carolina, almost all requiring hospitalizations, more than half requiring intensive care—thankfully, we've had no deaths to date in

North Carolina—and, currently; we have not identified the exact cause of this illness in our state.

Some key factors identified that may be driving e-cigarette use among our youth include marketing strategies that appeal to youth; the delivery systems like the USB-like systems that are easy to conceal, used discreetly, and not recognized as adults as e-cigarettes; the use of flavors that attract youth to the products; and then the highly addictive nicotine which keeps them coming back.

Youth use of e-cigarettes has challenged the resources of our state to address. Despite our 100 percent tobacco-free school policy, our school staff are finding e-cigarettes on school grounds, report that students' e-cigarette use is problematic, contributing to learning disruptions and do not think they have the resources to sufficiently address this new wave of tobacco products. We have insufficient resources to do evidence-based mass health promotion and media campaigns to compete with the e-cigarette and vaping messages. Our quit line, which is our telephone and web-based tobacco treatment program, is only resourced to serve about one-eighth of the number of our state tobacco users recommended by CDC best practices, and our local health departments are not structured or resourced to sustain a long-term response to this new outbreak.

The e-cigarette epidemic among youth and young adults is a public health threat that will not be solved by one strategy, one policy, or a single federal agency or state. We'll need a comprehensive approach and utilize best practices and lessons learned from our success in combustible tobacco. Federal and state policies to consider include curbing advertising and marketing to youth, limiting youth access to e-cigarettes in retail and internet settings, reducing access to flavored tobacco products by youth, implementing price policies, and adding e-cigarettes to smoke-free indoor air policies.

Increased funding should be allocated to further adopt and expand on CDC-recommended evidence-based state and local tobacco use prevention and cessation interventions, including community interventions; mass reaches health communications in mass media, evidence-based treatment and cessation interventions, surveillance, and intervention, infrastructure, administration, and management. Thank you for the opportunity to share some of our experiences with you, and I applaud the subcommittee's work to help address this urgent public health issue.

[The prepared statement of Dr. Tilson follows:]



STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

ELIZABETH C. TILSON, MD, MPH
STATE HEALTH DIRECTOR
CHIEF MEDICAL OFFICER

United States House Energy and Commerce Oversight and Investigations Subcommittee

“Sounding the Alarm: The Public Health Threats of E-cigarettes”

September 25, 2019

Testimony of

Elizabeth Cuervo Tilson, MD, MPH
State Health Director and Chief Medical Officer
North Carolina Department of Health and Human Services

Chairman Pallone, Chairwoman DeGette, Ranking Member Guthrie and Members of the Subcommittee, thank you for the opportunity to testify today on the public health threats that e-cigarettes pose, especially to our youth and young people.

In December 2018, the U.S. Surgeon General Dr. Jerome Adams called e-cigarette use among youth an “epidemic”. As a public health official, a pediatrician, and a preventive medicine physician, I see this epidemic in our schools and communities across North Carolina. In our state, we’ve seen a dramatic increase in e-cigarette usage among youth, which has rapidly reversed our earlier progress towards reducing overall youth tobacco use in North Carolina. These products are available in thousands of kid-friendly flavors including candy, fruit, bubble gum, cotton candy, graham cracker, mint and menthol and some have packaging that mimic kid-friendly products like Lucky Charms cereal. Of major concern are the newest models of e-cigarettes that look like USB drives or other ordinary items. Pods of e-liquids can contain nicotine levels that are equivalent to a pack or more of cigarettes. Further concerns have now risen with the multistate investigation of severe lung illness associated with e-cigarettes and vaping.

Data Trends

The data trends in North Carolina delineate the challenges we face as public health officials in addressing the alarming trends of youth vaping. The 2017 North Carolina Youth Tobacco Survey

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LOCATION: 101 BLAIR DRIVE • ADAMS BUILDING • RALEIGH, NC 27603
MAILING ADDRESS: 2001 MAIL SERVICE CENTER • RALEIGH, NC 27699-2001
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(NCYTS) found that although combustible cigarette smoking was the lowest ever recorded among high school students at 8.9%, e-cigarette use increased 894% since 2011. E-cigarettes have become the most commonly used tobacco product among youth in North Carolina, with 16.9% of high school students currently using them, and with even more (23.3%) saying they plan to use them in the next year. Further, adolescents and young adults who have used e-cigarettes are more likely to report using traditional cigarettes at follow-up compared with those who had not.

Like in North Carolina, youth e-cigarette use is increasing across the country. The 2018 National Youth Tobacco Survey saw a 78% increase in high school e-cigarette use between 2017 and 2018. The 2019 Monitoring the Future survey revealed similar results, with youth e-cigarette use more than doubling between 2017 and 2019 among 8th, 10th and 12th grade students nationwide. The increase from 2017-2018 was the largest ever recorded in the survey's 43-year history for any single substance.

Based on this data, we believe that the 2017 NC Youth Tobacco Survey data underrepresents the scale of the youth e-cigarette use epidemic in North Carolina. Currently, our Division of Public Health is working with the NC Department of Public Instruction and randomly selected schools across the state to conduct the 2019 NC Youth Tobacco Survey. We expect to have the survey results in early 2020. Ninety percent of adults that report using tobacco products reported starting before the age of 18. That is why this trend in youth use is incredibly concerning.

The tobacco prevention and control experts in our Division of Public Health identify key reasons why the use of e-cigarettes among youth is continuing to grow. Chief among those reasons are marketing strategies that appeal to youth and have been found to be successful in marketing combustible tobacco products to youth, delivery systems (e.g., USB like systems) that are easy to conceal and not recognized by adults as e-cigarettes, and the use of flavors that attract young people to the products, as well as, highly addictive nicotine, which keeps them coming back. Per the North Carolina Youth Tobacco Survey (NCYTS), the main reasons NC students report using e-cigarettes are because a friend or family member uses them and because they were available in flavors. The 2018 National Youth Tobacco Survey reports 68% of high school students currently use e-cigarettes of any flavor and 51% currently use menthol or mint flavored cigarettes. A 2016-2017 FDA study showed nearly all (97%) current youth e-cigarette users had used a flavored e-cigarette in the past month and that 70% of youth users do so "because they come in flavors I like." In order to better understand the consumption of flavored e-cigarettes among the North Carolina youth population, we have added a question for the 2019 NCYTS that asks students what types of flavors they have used in the past 30 days. We will also ask students what specific brands they have used in the past 30 days.

Health Impacts

Nicotine is the major psychoactive substance found in e-cigarette solutions. Nicotine is highly addictive and youth and young adults are particularly at risk for long-term, long-lasting effects of exposing their developing brains to nicotine. These risks include nicotine addiction, mood disorders, permanent lowering of impulse control, attention and learning difficulties, and increasing the risk of use of combustible tobacco products. High levels of nicotine delivered by some e-cigarette products may be linked to seizures among teens and young adults. Nicotine has

also been linked to adverse health outcomes for the developing fetus including prematurity and stillbirth.

One North Carolina teen, Luka Kinard of High Point, has been willing to share the story of his addiction to Juul e-cigarettes, but his story is not unique. We have heard similar stories from across our state and nation. As a high school freshman, Luka started using Juul as a way to “fit in” with the upperclassmen on football Friday nights. He quickly became very addicted to the nicotine in the product, even to the point of selling his clothes and other items to raise the \$150 a week he needed to support his nicotine addiction. Once a Boy Scout, an athlete and an A-student, Luka let his grades fall and dropped out of his extracurricular activities. Usually a well-behaved 15-year-old, Luka became irritable, angry – even throwing violent fits of rage. Finally, a nicotine-related seizure sent him to the emergency room and convinced his parents to do everything they could to get him off Juul. Luka participated in a nearly 40-day substance use treatment program in California twice and now lives substance-free. Now 16 years old, Luka has visited dozens of middle and high schools nationwide to talk to other youth about managing teen stress without substance use – including nicotine.

High levels of nicotine can also result in nicotine poisoning. The NC Poison Control recently published the numbers of people being poisoned from direct exposure to e-cigarette liquid. In 2019 to-date, 162 people have been reported as becoming ill from exposure to nicotine in e-cigarette products; 72 of the people treated for poisoning related to vaping products were children under the age of 5, with exposure routes including oral, eyes, and skin. There is also emerging research on the risk of chronic lung disease associated with e-cigarette use. Published in the [American Journal of Respiratory Critical Care Medicine in 2018](#), University of North Carolina researchers found that sputum from vapers and smokers contained elevated levels of enzymes and proteins associated with emphysema, a type of chronic obstructive pulmonary disease (COPD). Last month, a different team of researchers at UNC School of Medicine released additional research that suggests the use of e-cigarettes may lead to a higher risk of emphysema. Published in the [American Journal of Respiratory and Critical Care Medicine](#), the study examined lung fluid samples from smokers, e-cigarette users and non-smokers. Researchers found that e-cigarette users, like smokers, had higher levels of protease enzymes than non-smokers. They also found that higher levels of those enzymes were induced by nicotine exposure. Elevated protease enzymes are associated with the process that causes damage to lung tissue seen in emphysema. The researchers concluded that individuals who use e-cigarettes long term may be at higher risk than nonusers for emphysema.

Investigation of Severe Lung Illness

The NC Department of Health and Human Services, Division of Public Health and our 85 local Health Departments are participating in the multistate investigation of severe lung illness associated with e-cigarette use. As of September 18, 2019, 33 cases of lung illness associated with the use of e-cigarette products have been reported in North Carolina; almost all have been hospitalized and more than half required intensive care. To date, there have been no deaths in North Carolina. Currently, we have not identified the exact cause of these illnesses -- whether they're caused by a substance, contaminant, additive, ingredient in the liquid or the actual device. Most (but not all) cases in North Carolina reported vaping products containing THC – the majority of patients interviewed in North Carolina used products containing both THC and

nicotine. North Carolina has been, and will continue to, collaborate with our federal partners at the CDC and FDA, as well as other states as part of this investigation. We submit case-patient data to CDC weekly and submit samples for product testing to the FDA.

While this investigation is ongoing, consistent with CDC guidance, we are recommending that all members of the public consider not using e-cigarette products. We are also advising individuals who continue using e-cigarette products and experience symptoms such as those reported in this outbreak to seek medical care promptly. In addition, we are reinforcing our routine recommendations that:

- Youth and young adults should not use e-cigarette products.
- Women who are pregnant should not use e-cigarette products.
- Adults who do not currently use tobacco products should not start using e-cigarette products.
- If you do use e-cigarette products, you should not buy these products off the street (for example, e-cigarette products with THC or other cannabinoids).
- You should not modify e-cigarette products or add any substances to these products that are not intended by the manufacturer.
- Adult smokers who are attempting to quit should use proven treatments, including counseling, FDA-approved medications, contacting their health professional, or utilizing our North Carolina Quitline.

Work with NC Schools

We hear a common misconception among both youth and adults that these e-cigarette products contain little or no nicotine and e-cigarettes deliver only “flavored water vapor”. That misperception prompted our Tobacco Prevention and Control program to partner with the NC Department of Public Instruction and the State Laboratory for Public Health to conduct a small study in 2018 to analyze the nicotine content for a sample of e-cigarettes confiscated from students in schools. Exhibit 1. Our final analysis concluded that nearly all e-cigarettes from across seven schools contained nicotine, and of those that contained nicotine, 20 percent contained high levels of nicotine (about 40mg/ml or above).

North Carolina General Statute 115C-407 requires that every North Carolina school district have a written 100% tobacco free school policy that prohibits the use of any tobacco products, including e-cigarettes, on campus and at school-related events for students, staff, and visitors. Due to e-cigarettes, schools are newly challenged to enforce this policy.

In May 2019, our Department furthered our work with schools and partnered with the CDC to conduct a Rapid Response Assessment of school staff knowledge of high school students’ e-cigarette use and school policy. School staff were invited to participate in a survey. Investigators also collected e-cigarette products confiscated from students during the 2018–19 academic year and determined e-cigarette retailer density within 5 miles of schools.

Among 599 staff members who completed the survey, 52 percent observed e-cigarettes on school grounds in the past year, 88 percent believe students' e-cigarette use is somewhat or very problematic and 84 percent believe that e-cigarettes contribute to learning disruptions. Most all respondents know their school's tobacco-free policy prohibits possession, use, and sale of e-cigarettes on school grounds. Nearly 32 percent of school staff were not confident that their school has the resources to prevent student e-cigarette use and 55 percent are not confident their school has resources to help students quit using e-cigarettes. From 35 interviews, emerging themes included concern that their school's tobacco-free policy is currently not effective in deterring students from using e-cigarettes on school grounds, and that additional resources and education are needed, such as peer to peer education, on e-cigarette harms. Investigators also collected 263 products from 9 schools, including 144 e-cigarettes and 81 pods. Exhibit 2. Eighty-nine (89) e-cigarette retailers were identified ≤ 5 miles of participating schools.

Our conclusions are that school staff believe e-cigarette use is a problem among students, but our state needs resources to address it. These conclusions are supported by our statewide and regional work in North Carolina, as we are continually contacted by school personnel with requests for presentations, educational resources and technical assistance on dealing with e-cigarette use among students in schools.

Our Department, through the Division of Public Health, continues to work with schools statewide to:

- educate staff, parents, and youth on e-cigarette harms
- assist schools with obtaining compliance with their tobacco-free school policy
- provide evidence-based tobacco use prevention curriculum and alternatives to out-of-school suspension programs
- recommend, consistent with CDC guidance, to not implement tobacco industry-sponsored school-based tobacco prevention programs which have been found to be ineffective and may promote tobacco use among youth and
- help youth quit using e-cigarettes

Other efforts in North Carolina to address e-cigarette use

The Division of Public Health has also been working since 2011 to reach out and educate adult influencers of young people, such as pediatricians, dentists, teachers, school health nurses and other school personnel on the use of and risk of e-cigarettes. When we began, many adults who work with children were unaware of e-cigarettes that are often designed to mimic other products that kids may have, like USB-drives, highlighters, or lipstick. This work has increased awareness among parents, pediatricians, and school personnel about these products and how they harm the developing brains of young people.

Federal funds through the CDC support our North Carolina Tobacco Prevention and Control infrastructure and staff at the state and regional level. It does not, however, provide adequate funds for evidence-based mass media campaigns to reach young people. North Carolina has used limited one-time state funds of \$194,000 for evidence-based tobacco prevention messages – that include e-cigarette prevention – on social media to reach one high risk youth peer group statewide. Effective mass media campaigns are expensive to carry out and it is a challenge to compete with the pro-vaping messages that are continuing to go viral on social media every day.

The desire to stop using tobacco products is high, especially among our youth, with 73.7% of high school students and 58.2% of middle school students who currently use tobacco attempting to quit in the past year. Evidence-based tobacco treatment is a combination of counseling and FDA approved medications, provided with easy access. North Carolina provides a telephone and web-based tobacco treatment program ([QuitlineNC](#)) free to our state's residents who need help quitting tobacco use. Quit Coaching is available in different forms, for different populations, which can be used separately or together, to help any tobacco user give up tobacco. There is a special five-call program for teens who are addicted to tobacco products, including e-cigarettes. Teens who call receive coaching from a dedicated Quit Coach, specially trained to work with adolescents. The QuitlineNC could be more effective with more funding. For example, QuitlineNC is currently funded 24 hours a day/7 days a week with a combination of federal and state funds to serve only about 1-1.4% of North Carolinians who smoke or vape. CDC Best Practices recommends that state Quitlines should have funding to reach 8% of their state's tobacco users annually.

The Tobacco Prevention and Control Branch has also been working with local health departments across the state as they work with their respective Boards of Health, County Commissioners and municipalities to adopt new regulations that prohibit the use of e-cigarettes in local government buildings, government vehicles, government grounds and enclosed public places. To date, a total of 41 counties and 52 municipalities have adopted electronic cigarette regulations in North Carolina.

Due to concern of unintentional poisoning by exposure to e-cigarette liquid, the North Carolina General Assembly passed a law in 2015 requiring child-resistant packaging for any e-liquid container.

Recommendations

The e-cigarette epidemic among youth and young adults is a public health threat that will not be solved by one strategy or policy or a single federal agency or state. Much like the response to the opioid epidemic, federal, state and local agencies, along with many partners, need a coordinated, sustained, and sufficiently resourced effort to implement population-based public health interventions and policies that work to prevent the use of e-cigarettes among our youth and promote effective cessation for people currently using tobacco products. Lessons learned from tobacco control of combustible cigarettes along with available e-cigarette research can be used to build science-based regulations and interventions. A combination of federal and state policies may decrease access to and demand for e-cigarettes for youth. Increase funding can promote adoption of evidence-based state and local tobacco use prevention and cessation interventions.

The Office of the Surgeon General, the American Academy of Pediatrics, and the Association of State and Territorial Health Officers (ASTHO) have released recommendations for federal and state policies to consider that may decrease youth access to and demand for e-cigarettes. There is overall consensus to consider some type of policies within the following domains:

1) **Curb advertising and marketing to youth:** for example, regulate e-cigarette advertising and marketing that are appealing to young people, consistent with regulation of advertising of combustible cigarettes

2) **Limit youth access to e-cigarettes:** for example, restrict young peoples' access to e-cigarettes in retail and internet settings, license tobacco retailers, implement point-of-sale restrictions, increase the legal age of retailer and internet tobacco sales to persons aged 21 and over, and/or restrict all internet sales of e-cigarettes and e-cigarette solution.

3) **Reduce access to flavored tobacco products by youth:** for example, consistent with regulations of flavors for combustible cigarettes pursuant to the Family Smoking Prevention and Tobacco Control Act of 2009, regulate flavors for e-cigarettes. The federal government can regulate manufacturing of flavored e-cigarettes, while states can regulate sales and use. Consider including menthol and mint in flavor regulations, as more than half of current high school students who currently use e-cigarettes report using menthol or mint (2018 National Youth Tobacco Survey).

4) **Implement price policies:** for example, prohibiting the distribution and sampling of e-cigarettes and related products for free or at a nominal cost, prohibiting the use of coupons, rebates, and other discounting practices, imposing excise tax on e-cigarettes and related products comparable rates to those of conventional cigarettes.

The Surgeon General and ASTHO also recommend to:

5) **Add e-cigarettes in smoke-free indoor air policies** which can: reduce exposure to secondhand smoke and aerosol, reduce the prevalence of tobacco use, increase the number of tobacco product users who quit; reduce the initiation of tobacco use among young people; and reduce tobacco-related morbidity and mortality, including acute cardiovascular events.

To effectively address this epidemic, Congress and states should allocate more funding for states to further adopt and expand on CDC recommended evidence-based state and local tobacco use prevention and cessation interventions which include:

- 1) **Community interventions:** adoption and support of tobacco-free policies, partnerships with traditional and non-traditional organizations, youth empowerment and engagement, community education and engagement, evidenced based tobacco use prevention educational programs, alternative programs to suspension for students who violate tobacco-free policy, enforcement and compliance checks to prevent and reduce retailer tobacco sales to youth
- 2) **Mass-reach health communication interventions:** mass media campaigns, especially social media, to reach youth and youth people, counter-marketing ads and health promotion ads for cessation support.
- 3) **Evidence-based treatment and cessation interventions:** expand capacity of evidenced based cessation services, for example QuitlineNC, and local or regional cessation services and resources to community members;
- 4) **Surveillance and evaluation:** enhance states' statewide and local data collection, for example, the NC Behavioral Risk Factor Surveillance System (BRFSS), NC Youth Tobacco Survey (NC YTS), NC Youth Risk Behavior Surveillance System (YRBSS), Pregnancy Risk Assessment Monitoring System (PRAMS). Conduct process, outcome, and impact evaluations to make modifications to the program and measure the achievement of

objectives. Conduct surveillance to measure over time and to inform program and policy directions.

- 5) **Infrastructure, administration, and management:** conduct strategic planning; recruit and develop staff; provide technical assistance and training to local health departments, coalition members and other partners; develop and maintain needed websites and media resources.

I applaud the Subcommittee's work and help to address this urgent public health issue.

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Exhibit 1: E-cigarettes collected from 7 North Carolina High Schools, tested for nicotine content by the State



Exhibit 2: E-cigarettes collected from 10 North Carolina High Schools in collaboration with CDC

Ms.DEGETTE. Thank you, Dr. Tilson. Thank you for putting a human face on this too.

Dr. Norman, you are now recognized for 5 minutes.

STATEMENT OF LEE NORMAN, M.D.

Dr.NORMAN. Good afternoon, Chair DeGette, Ranking Member Guthrie, and subcommittee members, and thank you for the opportunity to speak with you today. My name is Dr. Lee Norman and I am the Kansas Secretary of the Department of Health and Environment. I'm also the state health official and I'm an Army lieutenant colonel and the Army state surgeon of Kansas.

I want to first give you a brief update as what we're seeing in Kansas. We now have ten hospitalizations confirmed from vaping and e-cigarette-related illnesses, including two deaths in adults. That's an increase over the numbers that were quoted by the CDC from last week, and that was just a new adult added this week to that list. We have the same vaping patterns as seen around the country with these lung diseases and illnesses from the vaping solutions. Some have been nicotine only, some have been THC only, and some have been a combination of both, including CBD oil.

The final analysis is pending the return of the test results from the FDA, and what I just told you is of what we took by way of history from the deceased family members. Similar demographics as U.S. vaping patterns, two-thirds are 18 to 34-year-olds in Kansas, 16 percent are under the age of 18, seventeen percent of users are under age 35, and three-fourths of the users are male. In Kansas and nationwide, over one-half of all e-cigarette users also smoke combustible cigarettes while, of note, 80 percent of youths' first contact with nicotine is through vaping.

What we are doing in Kansas, similar to my colleagues' intensive public health information campaign, we are working closely with the Department of Education on school programs for vape-free tool-kits; intensive medical professional education and alerts; we are working with the FDA and CDC, of course, and our local municipalities to incorporate e-cigarettes into the state Indoor Clean Air Act.

I want to comment briefly on the military because there's an ominous trend going on in smoking and e-cigarette use in the military. The military, in aggregate, right now is at its lowest rate of combustible cigarette use in modern history. But the new trend line, especially due to vaping, shows it to be on the rise. Now, alarmingly, e-cigarette users outnumber combustible cigarette smokers in military service members.

In my 2017 to 2018 deployment in the Middle East, I saw vaping-related lung injury firsthand. This is an emerging military health protection issue. The hard-earned anti-tobacco gains are being quickly swept away by vaping and e-cigarettes. We need help at the state level regulating marketing. The flavors attract the youth, no question about it. Ninety-six percent of the youth who end up using tobacco started with flavored products. Joe Camel and the Marlboro Man taught us valuable lessons about the effectiveness of marketing to youth.

We must together counter the effective industry marketing efforts. We must regulate sales. We shouldn't sell tobacco products

to those less than 21 years of age. No internet sales of nicotine products. Regulating the contents of vaping and e-cigarette products is important. There is no consistent labeling of the products; there should be. We don't know what the offending substances are. We need to know what those are. We need time for the science to catch up with the epidemic of illnesses and death. We need to broaden the anti-smoking laws to include e-cigarettes. We need to support tobacco control and prevention funding.

In summary, e-cigarettes are wildly efficient nicotine delivery systems designed to expose and addict youth to nicotine. Currently approved smoking cessation methods are not approved for those under 18. We must prevent addiction to nicotine. Vaping is effectively showing them the way to nicotine use and addiction. The U.S. Preventive Services Task Force and other professional research organizations say "insufficient evidence to support e-cigarettes as an effective tobacco cessation intervention." Other proven methods of cessation do exist.

Given that we don't fully know the health effects of vaping solutions or oftentimes even the contents, we must apply consumer protection fundamentals to protect our citizens much as we would tainted meats or malfunctioning automobile airbags. I will welcome your questions, of course, later, and thank you very much for this opportunity.

[The prepared statement of Dr. Norman follows:]

United States House Energy and Commerce Oversight and Investigations Subcommittee
Sounding the Alarm: The Public Health Threats of E-Cigarettes
September 25, 2019

Testimony of

LTC Lee Norman, MD, MHS, MBA
Secretary, Kansas Department of Health and Environment (KDHE)
Senior Medical Officer and State Surgeon
Kansas Army National Guard
Assistant Professor, Kansas University School of Medicine

Chair DeGette, Ranking Member Guthrie, and distinguished subcommittee members thank you for the opportunity to appear before the House Energy and Commerce Oversight and Investigations Subcommittee today to discuss the need to the public health emergency regarding e-cigarettes, or as the industry has termed it, vaping. We greatly appreciate your attention to this issue of critical importance to the health of the population. As the State Health Officer of Kansas, a US Army Lieutenant Colonel and the State Surgeon of Kansas, and as a recently-deployed 35th Infantry theater medical commander in the Middle East, I have personally witnessed the deleterious impact addiction to any substance, whether it be nicotine, alcohol or illicit substances has on the citizens of Kansas and the economic costs to our entire health care system.

I am now witnessing an outbreak of lung diseases impacting our state and recently claim the life of one Kansan. Our youth were poised to be the generation that ended smoking. That legacy is now in jeopardy. Youth usage of e-cigarettes, along with outbreak of lung diseases that continue to be investigated, is alarming. As a physician, public servant, military serviceman, father and grandfather, I owe it to the troops I work with, the staff I support and the Kansans I serve, to do what I can to win this battle for our youth.

In Kansas, we currently have eight probable/confirmed vaping related cases with one of those being a death. Of the cases, four are male and four are female and range in age from 17-57 years old. All were hospitalized, five have been released from the hospital and two remain hospitalized. Regarding the types of vaping products used, three of the patients reported using only nicotine, two reported only THC, one reported using CBD, and two reported using both THC and nicotine.

According to the Centers for Disease Control and Prevention (CDC) e-cigarettes typically contain nicotine, most also contain flavorings and other chemicals, and some may contain marijuana or other substances. They are known by many different names and come in many shapes, sizes and device types. E-cigarettes can contain harmful or potentially harmful substances, including nicotine, heavy metals (e.g., lead), volatile organic compounds, and cancer-causing chemicals. Additionally, some e-cigarette products are used to deliver illicit substances; may be acquired from unknown or unauthorized (i.e., "street") sources; and may be modified for uses that could increase their potential for harm to the user. Youth, young adults, pregnant women, as well as adults who do not currently use tobacco products should not use e-cigarettes. E-cigarettes containing nicotine have the potential to help some individual adult smokers reduce their use of and transition away from cigarettes. However, e-cigarettes are not

currently approved by the Food and Drug Administration (FDA) as a quit smoking aid, and the available science is inconclusive on whether e-cigarettes are effective for quitting smoking.¹

E-cigarettes are the most commonly used tobacco product among youth. Forty-four percent of Kansas high school youth who use e-cigarettes also currently use conventional cigarettes. Nationally, 96.1 percent of youth who initiated e-cigarette use between 2016 and 2017 did so with a flavored e-cigarette product. Preliminary findings from the 2019 National Youth Tobacco Survey (NYTS) were reported. They found over one quarter of U.S. high school students report using an e-cigarette product in the past 30 days, an increase from 2018 when the rate of past 30-day use was 20.8 percent. Most teens who are vaping never smoked cigarettes. Vaping is how they are initiating inhaling substances into their lungs. In Kansas, the top reasons why youth report using e-cigarettes include: a friend or family member uses, its availability in different flavors; and they perceive it as being less harmful than other forms of tobacco. We must work diligently to stop youth from acquiring and using e-cigarettes or vaping devices.

States are taking a leading role in implementing strong action to protect consumers from the harms of e-cigarette product use. New York has also banned most flavored vaping products but will allow mint and menthol flavorings to remain on the shelves. California announced a crackdown on illegal and counterfeit vaping products and allocated funds into a public awareness campaign on vaping harms.

Kansas is committed to combating the issue. We are actively reviewing policy options to address this epidemic, which includes options to ban of flavored e-cigarette products through executive action or passing of legislation as the federal government moves ahead with its own regulatory plan. To increase education regarding e-cigarettes and what the tobacco industry has termed as “vaping,” KDHE and the Kansas Department of Education partnered to develop a Vape-Free Schools kit. Schools are urged to adopt the kit and parents and caretakers are encouraged to have conversations with their children.

I recognize this to be a public health emergency of considerable importance. As Chief Medical Officer of large health systems for over 25 years, I have served as incident commander for H1N1 pandemic influenza, Ebola, the ongoing opioid epidemic, and now this. We are currently losing the battle against e-cigarettes and vaping, and we do not even understand the cause. We need a diligent and consistent approach to solving this, including thoughtful policy-making and regulatory changes, in the name of consumer protection and the public’s health. I am happy to participate in the effort.

¹ <https://emergency.cdc.gov/han/han00421.asp>

Ms. DEGETTE. Thank you, Dr. Norman.

And now, Dr. Bharel, I am pleased to recognize you for 5 minutes.

STATEMENT OF MONICA BHAREL, M.D.

Dr. BHAREL. Thank you very much. Good afternoon, Chair DeGette, Ranking Member Guthrie, and members of the subcommittee. Thank you for the opportunity to provide testimony on this pressing issue today.

As the Massachusetts Commissioner of Public Health, as a physician, and as a community member, I am extremely concerned about vaping, especially among our youth. So thank you for—I commend you for shining a light on this crisis today.

I'd like to take a few minutes to share with you today what we are seeing and what we are doing about this critical public health issue in Massachusetts. I'm proud that Massachusetts has a long history of being at the forefront of public health, and with the current vaping epidemic, we're continuing to be proactive in our response based on evidence-based tobacco cessation and education programming. Last year, Massachusetts raised the minimum age to purchase tobacco products, including e-cigarettes, to 21. We also prohibited vaping, where it's illegal to smoke and became the first state in the nation to ban the sale of all tobacco products in pharmacies.

Massachusetts has made significant progress in curbing both youth and adult tobacco use over the last few decades. Looking back to 1996, our youth smoking rate in 1996 was 38 percent. Now that rate today is 6.4 percent, and our adult smoking rate is one of the lowest in the nation at less than 14 percent. The cornerstone of our work has always been prevention. We have a strong cessation and prevention infrastructure and a network of community partners and dedicated advocates to help educate our communities on what we know. Unfortunately, this progress is now at risk. The industries are using the same old techniques to bring new products: cheap, sweet, and attractive to youth. And it's working in Massachusetts and across the country.

We hear time and time again horror stories from children who are talking about the vaping in their bathrooms at school, who are too short of breath to participate in their sports activities, and children 11 and 12 years old who have to sleep with these devices underneath their pillows because they're so addicted they're waking up in the middle of night to use them. We know that in Massachusetts, from our 2017 data that 40 percent of high schoolers have tried these products, and one in five, 20 percent, are using them regularly. And now we're confronted with the emergence of this serious vaping-related lung disease being seen across the country.

Two weeks ago, I exercised my authority as Public Health Commissioner to mandate that physicians immediately begin reporting any unexplained vaping-associated pulmonary disease to us at the Department of Public Health. We immediately started to hear about cases, ten cases or more a day, as we began to ask for this reporting. We are now looking at 66 reported cases to us and have already reported to the CDC three confirmed cases and two probable ones.

What this tells me and what I'm afraid of is that this is just the tip of the iceberg in what we will see related to these e-cigarettes. We don't know what is causing these illnesses yet, but we want to act now to protect our children. And yesterday in Massachusetts we took a landmark step. Our governor, Governor Charlie Baker, declared a public health emergency in the commonwealth and put in place an immediate 4-month ban on the sale of all vaping products, both nicotine and THC, both in retail and online.

This ban on vaping product sales will enable our state to take a much-needed pause, to take a pause and gather more information and data to inform our next steps to protect our public's health. We can't stand by and watch the industry hook another generation on these deadly products. It's up to us to confront the facts, sound the alarm, and protect public health particularly, in our youth. Our goal is simple. We do not want another generation of children to become addicted to nicotine. Thank you for your commitment to your issue and I look forward to working with you. Thank you.

[The prepared statement of Dr. Bharel follows:]



The Commonwealth of Massachusetts
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER
Governor
KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary
MONICA BHAREL, MD, MPH
Commissioner
Tel: 617-624-6000

United States House Energy and Commerce Oversight and Investigations
Subcommittee

"Sounding the Alarm: The Public Health Threats of E-cigarettes"

September 25, 2019

Testimony of
Commissioner Monica Bharel, MD, MPH
Massachusetts Department of Public Health

Chair DeGette, Ranking Member Guthrie, and members of the subcommittee, thank you for the opportunity to provide testimony on this pressing issue today. The Massachusetts Department of Public (DPH) is one of the nation's oldest public health departments and one that has been at the forefront of public health across the country. In fact, this year we are marking our 150th anniversary. The mission of DPH is to keep people healthy and communities strong. Our dedicated employees work to prevent illness, injury, and premature death; ensure access to high quality public health and health care services; and promote wellness and health equity for *all* people in Massachusetts.

In my role as the Commissioner of Public Health and as the state's chief physician, I am often asked about vaping among youth, a rising epidemic around the country and in Massachusetts. I commend you all for shining a light on this crisis among our nation's youth, and am pleased to be here today to tell you about what we are seeing in Massachusetts and what we are doing about the issue across the Commonwealth.

Massachusetts made significant progress in curbing youth and adult tobacco use over the past two decades. In 1996, the youth smoking rate was 36.7%. Today, the youth smoking rate is 6.4%.¹ Our adult smoking rate is also low, with just under 14% of adults using combustible tobacco products.²

Our low smoking rates are a result of years of hard work. In Massachusetts, we have a strong tobacco cessation and prevention infrastructure that assists local health departments with tobacco control policies and enforcement, as well as a network of community partnerships

and dedicated advocates including parents, school leaders, and physician groups that educate the community about tobacco-related issues, resources, activities, and policies.

In fact, we recently translated the commitment of these partners and long-standing prevention efforts at the Department into legislative action, with Governor Baker signing into law a 21+ age restriction in Massachusetts to purchase any tobacco product – including e-cigarettes. The law also incorporates e-cigarettes into the definition of tobacco, thereby making it illegal to vape where it is illegal to smoke per our Smoke-Free Workplace Law. The law also banned sales of tobacco products in pharmacies, making Massachusetts the first state to do so.

But even with the strong laws and policies we have on tobacco products, all of this progress is now at risk. The tobacco and vaping industries are using tobacco's old playbook – developing new products that are cheap, sweet and easy to get to attract young users. And it's working.

In 2017, 20.1% of high school students reported vaping in the past month and 41.1% have tried it.¹ This means that more Massachusetts high school youth used e-cigarettes than all other tobacco products combined. And nearly 10% of **middle school** students reported trying e-cigarettes.¹ We haven't had rates this high for cigarettes since 2003 – 16 years ago. Current use of e-cigarettes among high school students is 6 times higher than that for adults (3.3% of adults reported using e-cigarettes in the past 30 day).^{1,2}

Despite daily headlines and news coverage about the harmful effects of vaping, there is a lack of information – or misinformation – about vaping. Young people may be unaware that e-cigarettes and e-juices and e-liquids contain nicotine. In fact, some vape pods can contain as much nicotine as a pack of cigarettes. And flavors such as fruit medley or bubble gum make these products seem harmless.

We know that nearly all e-cigarettes contain nicotine and that nicotine is an addictive chemical. Adolescents are particularly vulnerable to developing addiction because of how the brain develops³. The parts of the brain associated with "executive functions" such as impulse control, self-monitoring and error correction are the last to develop. During this developmental phase, teens are driven towards behaviors that produce large rewards - accounting for the risk taking often associated with this developmental phase. Substance use, while both unnatural and unhealthy, is one of the most efficient ways to deliver large rewards. Indeed adolescents and young adulthood is the age range when individuals are most interested and most likely to initiate substance use. At the same time, the pre-frontal cortex appears to be protective against developing the brain changes associated with addiction, and the relatively immature prefrontal cortex in adolescents leaves them especially vulnerable.

We know that nicotine can damage the developing brain of teens and young adults, impacting memory, learning ability, and other areas of the brain.³ And we know the aerosol created by vaping contains potentially harmful chemicals.³

Yet there is a lot we don't know. Our lack of information is highlighted by the emergence of serious vaping-related lung disease being seen around the country.

Earlier this month, I used my authority as Commissioner of Public Health to declare any suspected cases of vaping-associated pulmonary disease to be immediately reportable to the Department for the next 12 months. During the first two weeks of this mandated reporting, clinicians reported 46 suspected cases. We are receiving up to 10 suspected cases a day.

I have been reflecting on how we, as a Commonwealth, and as a country, got here. One reason is flavors, including mint and menthol. But when flavored cigarettes were banned by the FDA in 2009, menthol was excluded, leaving these widely used products on the shelves. Why is this so significant?

- Data show us that 80% of current youth tobacco users nationally report using a flavored product.¹
- Flavors make a product more appealing. Data from the 2013-2014 Population Assessment of Tobacco and Health (PATH) study found that more than 80 percent of 12-17 year olds who had ever used a tobacco product started with a flavored product. Moreover, for each tobacco product, at least two-thirds of youth reported using these products "because they come in flavors I like."⁴

In Massachusetts, our daily work includes efforts to prevent youth initiation. We do this by supporting our local health departments –those on the front lines when it comes to passing and enforcing tobacco regulations. These regulations include capping the number of tobacco retail licenses in a community; regulating a minimum distance from a school for tobacco retailers; and restricting the sale of flavored tobacco products to adult-only retail establishments. Massachusetts has a strong enforcement infrastructure. Our local health departments educate retailers and conduct regular compliance checks and our FDA inspectors conduct retail inspections to enforce federal tobacco regulations statewide; combined, there are close to 15,000 inspections each year.

I am proud to say that 161 cities and towns in Massachusetts have a flavored product restriction in place, covering approximately 67 % of the population.⁵ While this is a strong way to protect our youth from exposure and access to these products, we have also realized a flavored product restriction that excludes mint, menthol and wintergreen products, leaves many people behind – people who historically have been targeted by the tobacco industry with these products.⁶ We are working to correct this and to date, 13 municipalities have included mint, menthol and wintergreen in their flavored tobacco product restrictions.

A 2019 study on the impact of flavored tobacco product restrictions in Massachusetts found that the use of both flavored and non-flavored tobacco products decreased in a community with a flavor restriction compared to a community with no restriction. In fact, the community with no restriction saw youth usage rates **increase**. This is evidence that policies can make a difference when it comes to protecting our youth.⁷

One of the most important aspects of our tobacco prevention work is engaging youth. In Massachusetts, we have a powerful resource – they’re called the 84 Movement. This is a statewide movement of youth fighting tobacco in Massachusetts. “The 84” represents the 84% of Massachusetts youth who did NOT smoke when the movement began – and importantly that percentage has now increased to 92%. The 84 Movement aims to empower high school youth to make change in their communities. With chapters in schools and community-based organizations across the state, these incredible young people educate their peers and communities about the influence of the tobacco and vaping industries. Each year, Massachusetts hosts Kick Butts Day, and the youth march to our State House and meet with their legislators to impress upon them the importance of protecting youth from the dangers of a lifetime addicted to nicotine. One of our former 84 members, Sarah Ryan, joined Surgeon General Adams at his news conference declaring vaping an epidemic among youth. Sarah was also named the 2019 Barrie Fiske National Youth Advocate of the Year by the Campaign for Tobacco Free Kids.

Despite all of our great work, when youth rates of e-cigarette use began to skyrocket, we knew that the public needed up to date, factual information.

In July 2018 we started by launching a campaign aimed at educating parents, school staff, and other youth influencers about vaping products – what they are, that they contain nicotine, and can damage the developing adolescent brain. We created ads on social media, billboards, busses and other public transit. We created a website with a toolkit for schools consisting of resources and materials, and tips for parents to talk with their kids about vaping – all available free of charge through our Health Promotion Clearinghouse.

In April of this year, we launched an information campaign for youth, a campaign created with youth input and feedback. What our youth focus groups told us is that young people want the facts. They know smoking is harmful to their health. But they don’t connect those same harms with vaping. Many youth have told us that they consider e-cigarettes the “safe cigarette”. So that’s what the youth campaign does: it compares vapes with cigarettes and clearly shows both contain nicotine, both are addictive, and both contain harmful chemicals.

We know our education is reaching people. For our adult campaign, we have distributed over 60,000 materials to date and had over 1,250 downloads from our toolkit. In the short time since we launched the youth campaign, over 20,000 campaign materials were ordered from our Clearinghouse. We have also received requests from across the country --and even from other countries --to use and adapt information from our campaigns.

Prevention is, of course, important. But we are also all hearing about young people struggling with addiction. I am pleased to tell you that we offer a Smokers’ Helpline (a partnership with National Jewish Health) and work with the Truth Initiative to offer Massachusetts youth who are addicted to nicotine valuable and much needed resources to help them quit.

I am proud of what we are doing in Massachusetts to combat the youth vaping epidemic. But we recognize that there is more to be done. Under current law, vape products are not taxed, making it hard to determine who is really selling these products in our communities. These are topics and tools for preventing youth tobacco initiation that we will continue to discuss as a state.

As I've discussed, much is being done at the state level, but working in tandem with the federal government is critical to combatting this epidemic. For example, states are not able to regulate the manufacturing or labeling of e-cigarettes and other tobacco products, but that can be done by the FDA. We don't know what's in these products; if we don't know, how can youth know what they are putting in their bodies and what short and long term effects it may have on their health, in addition to very real health concerns over nicotine and addiction?

The FDA is currently looking into reducing the level of nicotine in combustible cigarettes, why not extend that to regulating the amount and type of nicotine contained in e-cigarettes? And a federal ban of all flavored cigarettes that includes menthol would be a strong step in reducing youth use; it is that same reason – protecting our youth – that flavored cigarettes were banned in 2009. The same logic can and should be applied to e-cigarettes and other tobacco products.

In 1971, the Public Health Cigarette Smoking Act banned the advertising of cigarettes on television and radio. Yet, e-cigarettes have no advertising restrictions. The vaping industry has used all of the same tactics the tobacco industry used for years. Curbing cigarette advertisement was a strong factor in reducing smoking among youth and adults.

We also need more data. Support from the federal government in funding research on the ingredients in e-cigarettes and their possible health effects will go a long way to helping the states and localities make more informed decisions and regulations about these products.

And finally, the problem in front of us is vaping – but what is coming at us next? Unlike many other public health issues, we are facing an opponent – one that has money, has a powerful lobby, and is nimble to counter our actions. I urge us to consider solutions to the vaping epidemic quickly and seriously – yet with thought about how regulations or actions put in place today also apply to products that the industry may develop in the future.

We can't stand by and watch as another generation becomes hooked on deadly products. We have to be out in front. We have to be bold in our actions. It is about the health of our youth.

Thank you for your dedication to this issue. I look forward to working together with our federal partners to build a solution to tackle this epidemic and protect the health of our young people – now and into the future.

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Ms.DEGETTE. Thank you so much, Doctor, and thanks to the entire panel. The Chair will now recognize herself for 5 minutes for questioning.

Last year, the Surgeon General declared the youth use of e-cigarettes as an epidemic. Now you are from all around the country, I would guess you probably would agree with the Surgeon General. I think you can all answer.

Dr. KHALDUN?

Dr.KHALDUN. Yes, I would agree.

Ms.DEGETTE. Dr. Tilson?

Dr.TILSON. Yes, ma'am.

Ms.DEGETTE. Dr. Norman?

Dr.NORMAN. Agree.

Ms.DEGETTE. Dr. Bharel?

Dr.BHAREL. Agree.

Ms.DEGETTE. And, Dr. Norman, you said in your testimony, in your written testimony, our youth were poised to be the generation that ended smoking. That legacy is now in jeopardy. What do you think needs to be done to reverse this tide and the epidemic? Dr. Norman?

Dr.NORMAN. Well, number one is that we are focusing today mostly on youth use of e-cigarettes. But one of the things that I think we cannot lose sight of is that these are so addictive that we have to also think about smoking in general because this is an on-ramp to the use of e-cigarettes.

Ms.DEGETTE. That is exactly right. That is right.

Now I—so you might have heard me say to the previous panel I have sponsored legislation to increase the age to 21 for all of these products. And I was telling Mr. Guthrie that I have been—it is a bipartisan bill. We have bipartisan sponsorship. And in the Senate, the Senate Majority Leader, Mr. McConnell has a companion bill.

But, nonetheless, as I have been talking to people on both sides of the aisle and trying to get cosponsorship for my bill, people are reticent to cosponsor my bill because they say that if somebody is serving in the military, they should be able to smoke and people over 18 can serve in the military. When I was listening to your testimony, Dr. Norman, I thought you would be the perfect person to give the answer to that. So what is the answer to that?

Dr.NORMAN. I don't think we should allow smoking anywhere, but that's a public health expert talking.

Ms.DEGETTE. Right.

Dr.NORMAN. The military has a long history of even supporting smoking, to be honest, way back to the days when it was in C-rations, and they're available, nicotine and all products are available at very low cost. And I think that we need to accelerate smoking cessation and vape protection.

Ms.DEGETTE. Do you think that is a good idea that we are making that available to the military?

Dr.NORMAN. No, I don't. There's nothing that would support that from a public health perspective.

Ms.DEGETTE. And do you, and you said you think it is a good idea to raise the smoking age to 21.

Dr.NORMAN. Yes, ma'am.

Ms.DEGETTE. Do you think that even includes the military?

Dr.NORMAN. Yes, ma'am.

Ms.DEGETTE. And that is because of the risk to public health; is that right?

Dr.NORMAN. Yes.

Ms.DEGETTE. Now, so I want to ask each of you, I guess starting with you, Dr. Khaldun, what do you think the federal government could be doing more to protect children from e-cigarettes?

Dr.KHALDUN. I think we really need to make sure that we don't allow this fraudulent marketing, this marketing to children saying that these products are safe. I think we need more evidence and data that they're actually, one, safe, and two, even effective for smoking cessation because that is not scientifically proven.

Ms.DEGETTE. OK, thank you.

Dr.KHALDUN. So that is what I believe.

Ms.DEGETTE. Yes, that is important.

Dr. Tilson?

Dr.TILSON. Yes, ma'am. As I mentioned in my comments, I think that we need to think about a comprehensive approach to tobacco control, same like we did with combustible. So combinations of a policy around marketing, around regulation, around limiting access to youth, around price policies, as well as we need to increase resources for states to be able to implement CDC's best practice recommendations for prevention and cessation.

Ms.DEGETTE. Dr. Norman?

Dr.NORMAN. I think it should—it hovers a lot around marketing. I think we need to make it less appealing. I think we need to regulate the availability of an older population, and I think that we need to control what's the labeling of the products so people know what is actually in there.

Ms.DEGETTE. Dr. Bharel?

Dr.BHAREL. When we passed Tobacco 21 in Massachusetts last year, it was based on the science of the developing brain. So whether someone can serve in the military at age 18 is a different question than whether or not someone should be using a tobacco product, because the brain continues to develop up to age 25 and we know that there can be damage to that and that's how we support tobacco being raised to 21 for all.

Ms.DEGETTE. Oh, go ahead.

Dr.BHAREL. And I was just going to add that I support what the other panelists said around the restriction of flavors, also restriction of nicotine content, and ad restrictions for it.

Ms.DEGETTE. I just want to ask you one more question. You said that after you used your authority to require reporting, reports skyrocketed. Do you think that is going to happen in other states around the country as we get more and more reporting?

Dr.BHAREL. Yes, I do. And I think the reason for that is several. One is that clinicians have not been asking about vaping; teens have not been disclosing the use of these products. So as we increase awareness and we begin to ask and come forward, we'll see those cases. And also, there seems to be something going on in this current environment and that's why I said I'm worried that this is the tip of the iceberg and we'll see more, not just acute things but chronic conditions as well.

Ms.DEGETTE. Thank you very much. And I am now pleased to recognize the Ranking Member Mr. Guthrie for 5 minutes.

Mr.GUTHRIE. Thank you very much. I am not here going to argue on the military. I agree that people 18 should not be smoking. But the principle, kind of, is if somebody is going to be old enough to wear the uniform, are they not allowed to make other decisions about that? And I think it is debatable. I am open to looking at it at your bill as well.

And also, it was mentioned, I won't say who mentioned it, but I mentioned that I was talking a lot about THC here. But it seems like there is a big move to ban nicotine, which we need to prevent nicotine, but there is other states all across the country and whatever giving more opportunities—I know they are not focusing on young people, but if you give opportunities for people to have access to marijuana, it is going to get into the hands of younger people. And glad to see that you banned, Dr. Bharel, all forms of vaping, even THC.

But I have a question and for all the witnesses but, Dr. Norman, you kind of answered this in your statement, so you don't really have to since you answered it. But in your state, you reported cases of vaping associated with pulmonary illness and for each of you, how many cases have been reported in your state and can you provide a breakdown of how many of those cases involved E, but nicotine, THC, or both, and if it had THC, did it also have E acetate?

Dr.KHALDUN. Yes, so we in Michigan have had over 44 cases that have been reported to the Health Department. Fifteen of those are confirmed or probable cases. We have seen a mix, and again this is family members or patients who are self-reporting, so we have some questions about what the actual truth may be, but this is self-reported. It's been THC, it's been nicotine, it's been both for some of them, so we don't again know what the exact substance is.

Mr.GUTHRIE. OK.

Dr.KHALDUN. We have not in Michigan; we don't test the products ourselves, we send it to the FDA lab for testing. And so, at this point, we do not know what other substances may be involved.

Mr.GUTHRIE. OK.

Dr.TILSON. Yes, sir. I'll share some of the data we have from North Carolina. So we have 36 cases reported so far. We're in the midst of investigating those cases, so for the 27 that we have the medical record information from, 75 percent of them have reported THC use, 17 percent have reported CBD, 45 percent have reported nicotine in flavors, and 37 percent have reported both THC and nicotine. Of the 16 that we've had the actual interviews for 94 percent have revealed the use of THC and 56 percent have reported vaping nicotine.

And we have been doing testing in our state lab as well as sending our samples to the FDA. We don't have our FDA reports back, same as the other states, but of what we found in our lab of the 41 that we have results from, 71 percent have had evidence of THC, half have had evidence of vitamin E, so only half and the other half haven't. As well as we found terpenes, nicotine, menthol, and glycerol as well in some of the other samples. So, a mixed bag of different findings.

Mr.GUTHRIE. OK. You have already kind of talked about it, Dr. Norman.

Dr. Bharel?

Dr.BHAREL. We've had, in Massachusetts, we've had 66 cases that have been reported to us. Three have been confirmed by the CDC definition and two are probable. The rest are currently under investigation. However, we do know that so far, the majority of them are under the age of 30 in terms of the suspects, and we also know that it is a mix. Some are THC only, some are nicotine only, and some are both THC and nicotine.

Mr.GUTHRIE. And do you know if there are other oils if—do you know if there are other oils in that?

Dr.BHAREL. No, we're not doing our investigation of the actual materials. This is survey-based from both clinicians and individuals, so we aren't doing the actual testing in our lab.

Mr.GUTHRIE. OK. Well, thanks a lot. And then all of you said that you were using the FDA; you are waiting on FDA results. How long does it take to get the results from the FDA and has the FDA told your state about the information they will share about your state's results and how do your results compare to the overall results they uncover?

Dr.KHALDUN. In Michigan, I'm not actually aware of how long it will take the FDA to get those results back to us. We do have regular communications with the FDA and the CDC, but I am not aware of how long it will take to get those results back.

Mr.GUTHRIE. OK.

Dr.TILSON. Yes, sir. And I think this is a relatively new outbreak.

Mr.GUTHRIE. Are you starting to get results back, I guess; have you got some results back, so you know how long it is taking or you still waiting for—OK.

Dr.KHALDUN. I'm still waiting.

Dr.TILSON. Yes, we have not gotten specific results back, but we have gotten communication from the FDA talking about what they have been finding and, again, haven't found in one specific additive. They have been telling us they've been finding a broad range of additives; not one substance seems to be identified. So we've been getting qualitative reports back from the FDA, but not the specific quantitative reports back.

Mr.GUTHRIE. OK, thank you.

Dr. Norman?

Dr.NORMAN. Our first sample was sent in, in mid-August, and we haven't received any of the results back yet.

Mr.GUTHRIE. Oh, OK.

Dr.BHAREL. Our information at this point is qualitative as well.

Mr.GUTHRIE. OK. Well, thanks.

So, getting back to the other. If you do just a search on the web, as a matter of fact, Chair DeGette was showing me a picture of a hoodie that, actually the cord of the hoodie is a vaping device. It just seems there is a lot of—I don't know if that is even legal. I don't know if that was an illicit side or what you can move forward, but obviously is marketing towards children, it appears, unless somebody who is an adult wants to do it at work and nobody knows they are doing it.

People that I know that are going from cigarettes to vaping don't hide that they are vaping because they didn't hide that they were smoking, so moving forward. But there are a lot of illicit products. I would say more, and I am out of time, so I will turn it over to my friend from Massachusetts. But I was going to say what are your states are doing to move forward, but I will yield back to my friend.

Mr.KENNEDY [presiding]. The acting Chair thanks the gentleman and—yes, right—and recognizes the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes.

Ms.SCHAKOWSKY. Thank you. On August 23rd of this year, we learned that an Illinois resident died from the current outbreak of lung illness linked to e-cigarettes. The death is tragic, but the more I listen to what is the testimony I have heard today, it also seems to be preventable.

And, Dr. Norman, your state has also suffered two deaths in recent weeks due to this illness. Do you believe, and anyone else can weigh in on this, do you believe that we could have prevented these deaths in this outbreak if the FDA had not delayed the Obama administration final rule that would have started e-cigarette regulation in 2018? And then that was postponed by this current administration.

Ms.SCHAKOWSKY. And who was that question poised to?

Ms.SCHAKOWSKY. And you, but anyone who wants to answer.

Dr.NORMAN. OK. Well.

Ms.SCHAKOWSKY. As well.

Dr.NORMAN. We've been doing public health messaging for a long time, and I really feel that in the state of Kansas, people and the potential users and users know it is not healthy to vape or to use e-cigarettes, so it's not out of lack of knowledge that people are starting and using e-cigarettes. And I do believe that whatever regulations can be propagated that would push towards restriction and less easy access to products and unregulated products, I think that's where the holy grail is.

Ms.SCHAKOWSKY. So as my question was that actually it could have started in 2018. Would that have been effective? Regulation could have started. Wondered if anyone else wanted to weigh in.

Yes, Doctor?

Dr.KHALDUN. I mean, we saw across the country a 900 percent increase in students who were using vaping products between 2011 and 2015, so it started a little bit earlier. I do know that there are youths in the state of Michigan who don't even know what's in these products they've been marketed to, so it is a possibility that that could have potentially prevented some of this, but I don't think we know for sure. Again, we don't know what the exact cause of these vaping-related illnesses are.

Ms.SCHAKOWSKY. So we heard from Dr. Schuchat that the—not the accelerator, what do you call the—the what? Yes, the aerosol has toxic chemicals in it that we apparently know that. So do we, are we aware of everything that is in these? Have we done good research to know even how things like the aerosol could affect the health, anybody? Do we know?

Dr.NORMAN. We learned last week on an FDA call that we have more information about what is in the vaping solution that goes in

that end of the e-cigarette than what comes out in the aerosol, because there's certainly are changed by the process of the vaping.

Ms.SCHAKOWSKY. So were you all here for the last panel?

Dr.NORMAN. Yes.

Ms.SCHAKOWSKY. OK, yes. So did you hear enough in terms of what is being done? Do you feel satisfied that going forward that we are going to make progress as fast as we could, as effectively as we could, from what you heard both from the FDA and the CDC? Let's start at that end.

Dr.KHALDUN. I think it's a complex investigation. I'm pleased that the FDA and CDC are providing support to our state and local governments, but I think collectively, as a society, we probably could have done more sooner. But I am pleased that the CDC and FDA are looking at this closely.

Ms.SCHAKOWSKY. OK.

Dr.TILSON. I would agree. I'm pleased with the proactive approach that CDC and FDA is taking, but I think we all acknowledge and I think the prior panel acknowledged, that there's a lot more that we need to do and this is really an urgent public health crisis that we need to do a lot more and we need to do it quickly.

Ms.SCHAKOWSKY. OK.

Dr.NORMAN. Agree.

Ms.SCHAKOWSKY. OK.

Dr.BHAREL. What I know is that we are seeing an alarming increase, as you mentioned earlier, in these vaping-associated pulmonary diseases, and in Massachusetts, we put the temporary ban of all vaping products in place in order to take a pause, prevent further illness and death from this lung-associated disease, and be able to gather more data and information because there is so much that's unknown in this area.

Ms.SCHAKOWSKY. So we are going to see an increase in the number of people, we are, that are addicted to nicotine right now. Is this something that is going to be alleviated even at this point? Are we going to see this increase going on as we go forward? Just yes or no.

Dr.KHALDUN. Yes. We do currently have youth who are addicted to nicotine and we need to help them address their addiction.

Dr.TILSON. Yes, and we need a comprehensive, full steam ahead approach to address this.

Dr.NORMAN. Yes, I think we're going to see a marked uptick.

Dr.BHAREL. Nicotine is highly addictive to youth and the way it's currently being marketed with the flavors and access, we're going to see the problem continue to get worse.

Ms.SCHAKOWSKY. Thank you. I yield back.

Ms.DEGETTE. Thank you. The Chair now yields to Mr. Griffith from Virginia, 5 minutes.

Mr.GRIFFITH. Thank you very much, Madam Chair. Appreciate all of you all being here today; the information is very important to us.

Dr. Tilson and Dr. Norman, because marijuana is not legalized in your states, do you believe youth are accurately reporting their use of products containing THC when they become sick?

Dr.TILSON. Well, it's always hard to know exactly if people are being completely accurate. However, in both our medical records

and our interviews, people are reporting that they are using THC up to 75 percent. So it's hard to know that everybody's reporting accurately, but a certain, a large percentage are reporting.

Mr.GRIFFITH. And the same question to you, Dr. Norman.

Dr.NORMAN. I feel pretty certain that we don't always get the straight story and that's why we really do need to know the chemical analysis. I don't think that people are always honest with their medical history taken.

Mr.GRIFFITH. Yes. And are there—I understand the chemical analysis, but are there any other alternatives that you might use to increase the accuracy of the reporting?

Either of you.

Dr.TILSON. Well, we are testing their devices and what the solution is in the devices. So it's a combination of medical reports, interview, and then the testing of the actual liquid in the devices that we're using.

Dr.NORMAN. Yes. I think that's the key piece that's missing. Our medical evaluations are pretty straightforward. The clinical care that's being provided is well understood. Our data gathering that we forward along to the CDC and the FDA is, I think, traditional of what we do in medicine and in public health, but we do need more of the analytics.

Mr.GRIFFITH. And just curious because I know when we are doing polling data, we ask the same question sometimes in two or three different ways so that we are trying to elicit a more accurate response. Do you all do that for this information as well, figure out different ways to ask something similar so that you can elicit a better response?

Go ahead, Dr. Tilson.

Dr.TILSON. Well, one, we're using the CDC reporting, making sure we're reporting the data elements of CDC so we can have a consistent reporting of different elements across the state and that our interviewers are pretty experienced in doing interviews with patients; so it is hard to know exactly that they're 100 percent accurate, but our interviewers are pretty experienced in doing interviews with people.

Mr.GRIFFITH. I will take that as a yes. You are doing some interesting things, but each interviewer does it with their own style. You know, we talked about the street products and so forth. And in knowing that street products are contributing to the outbreak, what are your states' enforcement authorities and jurisdictions doing to crack down on the illicit street products that aren't from your commercial sellers? And anybody can answer that.

Dr.TILSON. Yes, so a couple. So, one, within North Carolina tobacco sales are not licensed, so it's a little bit hard for us to really use that licensing data and to track within our license. And then with, our illicit and unlicensed dealers and vendors, as was talked about earlier in this panel, it's hard to track those down.

The investigation authority sits within our state bureau of investigation, our alcohol and law enforcement, so we've been starting to have conversations with them. If there was a complaint or us to be able to figure a signal, looks like it's coming from this geographic area or this store, then they can then go and then inves-

tigate that complaint. But right now, we don't have enough localizing data to really direct them.

Mr.GRIFFITH. Let me ask this and I'm going to start with you. And I'm sorry I was not here earlier. I was in another hearing. Dr. Bharel?

Dr.BHAREL. Yes, that's right.

Mr.GRIFFITH. Did I get that right? OK, thank you. I apologize.

Dr.BHAREL. No problem.

Mr.GRIFFITH. Do you all have a possession, is it illegal to possess a vaping device under the age of 18 in your state?

Dr.BHAREL. No. So the temporary ban that we put in place yesterday is around the sale.

Mr.GRIFFITH. OK.

Dr.BHAREL. So the temporary ban for four months is sale.

Mr.GUTHRIE. Do any of you have a possession statute?

Dr.KHALDUN. Yes, in the state of Michigan, in June, we actually passed a law and updated the Youth Tobacco Act, so now it prohibits a minor from possessing or using a vapor or alternative nicotine product.

Mr.GRIFFITH. All right, I appreciate that.

Let me ask Dr. Norman. You raised an issue earlier when you were talking about the FDA and they are testing what is going in, but you don't know if they are testing what is coming out. Is that correct?

Dr.NORMAN. That's what we heard on the call with the FDA last week.

Mr.GRIFFITH. And you think it would be important, and I would agree with that, but I don't want to put words in your mouth that we test the smoke that is coming out as well because the process is while the vaping is taking place could actually change some of those chemicals. And it could be that—

Dr.NORMAN. Yes. I'm not an expert on the engineering that goes into the vaping devices and there are many different ones, but I think there's plenty of reason to believe that the ingredients that go in are not necessarily identical to the ingredients that come out.

Mr.GRIFFITH. And so the lung problems could actually be either or both. What is in it to begin with, what is coming out is the smoke, or a little combination of the two; is that correct?

Dr.NORMAN. I don't know. I mean I really don't know the answer to that until we find out.

Mr.GRIFFITH. It is a reasonable guess, though.

Dr.NORMAN. A reasonable guess would be—

Mr.GRIFFITH. That it is some combination thereof and we need to know all the answers and not just half of them; is that what you are saying?

Dr.NORMAN. Yes.

Mr.GRIFFITH. I appreciate it very much and I yield back.

Ms.DEGETTE. I thank the gentleman. The Chair now recognizes the gentleman from Massachusetts for 5 minutes.

Mr.KENNEDY. Thank you, Madam Chair. Thank you to our witnesses. Thank you for your patience and your extensive testimony today. Dr. Bharel, wonderful to see you again and thank you for your leadership at the helm of our healthcare system in Massachusetts. Grateful that you are here.

Yesterday, our governor, Governor Charlie Baker, declared a public health emergency and implemented an immediate ban on the sale of vaping products in Massachusetts. As patients sit in hospital rooms with a mysterious vaping-related illness and now businesses across our commonwealth shutter, this has clearly been, at least in my mind, a catastrophic regulatory failure.

Dr. Bharel, to start with you, what should the FDA be doing immediately to support state efforts to contain this outbreak?

Dr.BHAREL. So, there are several things that our federal partners could do. We could look at in Massachusetts; we went to Tobacco 21, that would decrease access for young people. Flavor restrictions would also decrease access as well as understanding what is the content of these products, just like we do with tobacco products and testing the nicotine levels, as well as allowing us to limit advertising and put warnings on the products as well as in stores.

Mr.KENNEDY. And I wanted to see if you can clarify and walk me through this a bit, any of the witnesses here. Looking at the Acting Commissioner's testimony, he said that "No ENDS product in the United States is on the market legally." For somebody that doesn't quite understand perhaps the term of the art there, it certainly seems like there is a legal market for these products; is there not?

Doctor?

Dr.BHAREL. You know, and I can't speak to that specific thing.

Mr.KENNEDY. Yes.

Dr.BHAREL. What I do understand is that there are FDA nicotine replacement, FDA-approved nicotine replacement therapies available. And as a clinician, that is what I would advise individuals to use, the FDA-approved such as the patches, the gums and the lozenges. And—

Mr.KENNEDY. Do you think the public is aware that there are products, that there are some of these products that does not, do not actually have FDA approval that are on the market?

Dr.BHAREL. I think that part of our education has to be around what approved cessation tools they are. And actually, as part of our temporary ban in Massachusetts we're doing an effort around enhanced education and access for these FDA-approved nicotine replacement products.

Mr.KENNEDY. To any of our witnesses, do you have suggestions as to what the FDA should have done? We heard the Acting Commissioner acknowledge that in retrospect, they should have been more active on the regulatory side for their upstream what should have been done to avoid where we are at the moment for people that are obviously patients that are sick, for businesses that are now shuttering or employees that might lose their jobs, for folks that are addicted to be forced into a black market for it, there is no part of the solution that is good at the moment.

So how do we make sure we avoid this in the next round of whatever that might be? Doctor?

Dr.KHALDUN. Yes, as my colleagues have said, it's unfortunate that we don't exactly know what the substance or device is that's causing these vaping illnesses, so when you don't know, it's kind of hard to say what you could have done to prevent it. But at the same time, I think their fraudulent marketing, the fact that a lot of adults and youth think that these products are effective, or don't

know what's in the products, or that they're effective for smoking cessation is a problem. So I——

Mr.KENNEDY. Was it wise for the FDA to essentially allow for these products to hit the market without knowing the consequences of these products?

Dr.KHALDUN. I think that we could have potentially had stronger regulations sooner.

Mr.KENNEDY. Dr. Tilson?

Dr.TILSON. I think these two issues too are related but somewhat conflated. So we have the problem with nicotine which we know is in there, and then we have the problem with what is in these substances with the vaping illness. I think we've known forever nicotine—not forever, but that nicotine is highly addictive. And I think the lessons learned in our combustible cigarette tobacco we should think about and be sure we're proactively applying those same lessons learned in a comprehensive approach when we're thinking about a product that has nicotine.

Mr.KENNEDY. Dr. Norman?

Dr.NORMAN. About six years ago, when I was the chief medical officer at the University of Kansas Health System, I outlawed vaping on our healthcare campus because it was that we had a no-tobacco policy. I got a certain amount of pushback for that because of the ostensible benefit for tobacco cessation. I didn't believe it then, and I don't believe it now.

I think looking in our rearview mirror; we would have benefited by having much tighter regulatory controls on the products that are the vaping devices and the vaping solutions. I think we deluded ourselves early on to think that this would maybe be a flash in the pan, a fad that would pass. But nicotine doesn't act that way. It's too addictive.

Mr.KENNEDY. Thank you all. I appreciate your testimony and I will yield back the final 5 seconds.

Ms.DEGETTE. I thank the gentleman. I would advise the panel that there are some other members who would like to ask questions. They are upstairs at this other hearing and they can't get down.

And so under the committee rules, members do have ten additional business days to submit questions, and I suspect several members, including Dr. Ruiz, who is a medical doctor and cares a lot about these issues, they will want to ask you questions in writing. And if you don't mind, if you could please respond to those because this is an important public health issue.

And I so appreciate all of you coming today. Your perspective from around the country being on the ground, and what we can do it is really vital to our consideration. And I hope you don't mind, I have decided to deputize all of you as our experts in assisting as we develop these policies. And with that, again, Members will have ten additional days to ask questions. And I want to thank everybody and we probably will be having some more hearings, certainly some more investigation. With that the Committee is adjourned.

[Whereupon, at 12:59 p.m., the subcommittee was adjourned.]

GOP allies warn vaping ban will sink Trump in 2020



[Alayna Treene](#), author of [Axios Sneak Peek](#)



Illustration: Lazaro Gamio/Axios

Conservative leaders are circulating data to White House staff that claims adults who vape will turn on President Trump if he follows through with his planned ban on [flavored e-cigarettes](#), Axios has learned.

Between the lines: The data (shown below) reveals that the number of adult vapers in key battleground states greatly outweighs the margins by which Trump won those states in 2016 — and they argue it could cost him reelection.

What we're hearing: "While parents may be concerned about e-cigarettes, the people who genuinely care about vaping as a voting issue so far outweighs the number of people Trump needs to win in 2020 that they are royally screwing themselves by doing this," Paul Blair, the director of strategic initiatives at Americans for Tax Reform, tells me.

- Suburban moms concerned about vaping "don't have the same voter intensity on this as adult vapers do," an industry lobbyist said.
- Florida, which Trump won by 113,000 voters, had about 873,000 adult vapers in 2016. They reason that if 1 in 8 vapers turn against Trump in 2020 because he foreclosed their vaping options, it could jeopardize the election.

Why it matters: If Trump backs away from proposed enforcement policy, it would be the second time in recent weeks that political concerns prompted him to dial back government regulations.

- Trump's openness this summer to expanded background checks cooled after the gun lobby and campaign advisers warned about bad internal polling.

Our thought bubble: There are four unsubstantiated assumptions about adult vapers in the case being presented to Trump:

1. They start out as Trump voters.
2. They wouldn't vape anymore if they couldn't get the flavors.
3. They are single-issue voters around vaping rights.
4. The eventual Democratic nominee would be more vape-friendly.

Still, the math can't be totally ignored, especially in places like Michigan, Pennsylvania and Wisconsin where Trump's 2016 win margins were so narrow and the number of adult vapers is relatively high.

By the numbers: More than 4 million people in swing states regularly used e-cigarettes in 2016, [according to FDA-funded survey data](#) published last year in the Annals of Internal Medicine.

- Industry experts say that number has increased significantly in recent years.

Data: Mirboulouk, et. al, 2016, "[Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System, 2016](#)", Census Bureau, [Atlas of U.S. Presidential Elections](#); Chart: Andrew Witherspoon/Axios

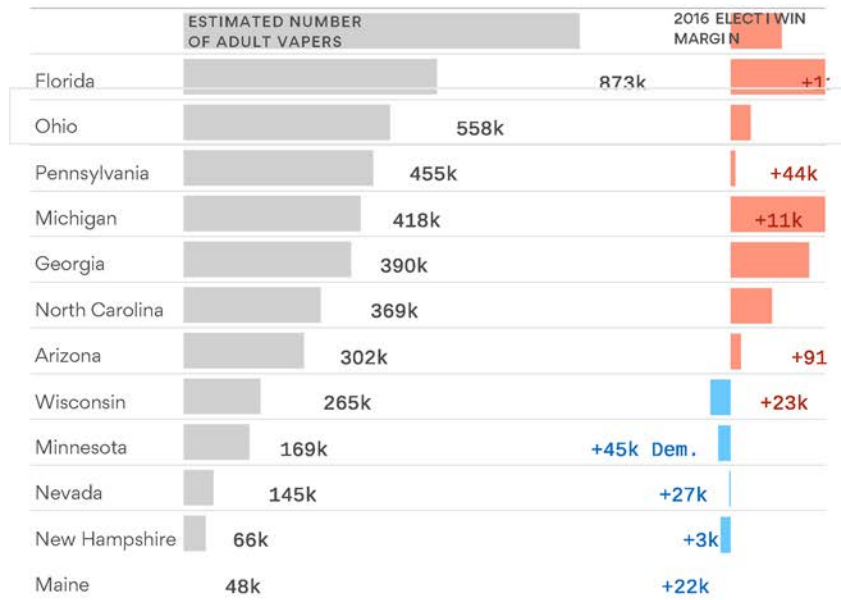
Behind the scenes: The White House scheduled a listening session with conservative groups last Thursday after receiving intense backlash from GOP leaders and industry execs following the announcement of the ban.

- **Among the invitees:** The Competitive Enterprise Institute, the Goldwater Institute, AFT and the Vapor Technology Association.
- But roughly 24 hours after invitations went out, the meeting was canceled.
- "They're in chaos mode on this stuff because the backlash has been so resoundingly overpowering," one invitee said.
- A White House official says the meeting is expected to be rescheduled.

The bottom line: The political pressure points regarding the ban have gotten Trump's attention.

- Shortly after the proposed ban was announced, [Trump tweeted](#) that he still likes vaping as an alternative to cigarettes.
- Trump's 2020 campaign manager [Brad Parscale also hit back](#) at a Trump follower who tweeted that banning vaping products is "not on brand with MAGA."
- One administration official said the tweets were prompted by a flood of criticism from conservative leaders.

Comparing adult vapers and 2016 presidential
election win margins in battleground states



POLITICO



President Donald Trump. | Mark Wilson/Getty Images

By [DANIEL LIPPMAN](#) and [DAN DIAMOND](#)

09/19/2019 04:11 PM EDT

Updated: 09/19/2019 06:07 PM EDT

[HEALTH CARE](#)

White House abruptly cancels meeting with vaping advocates

The White House abruptly organized — and then quickly canceled — a meeting Thursday with frustrated conservative policy leaders, to try to tamp down anger about a sweeping vaping ban that's inflamed the Trump administration's traditional allies, four individuals with knowledge of the meeting told POLITICO.

President Donald Trump last week [announced a ban](#) on flavored e-cigarettes, a policy that officials portrayed as a response to an epidemic of teen vaping amid a potentially unrelated outbreak of a mysterious vaping-related disease that's stricken 530 and killed seven people.

Politics

White House Cancels Pro-Vaping Meeting as Illness Cases Rise

By [Jennifer Jacobs](#)

September 19, 2019 2:52 PM EDT

-
- U.S. says 530 people are ill from vaping-related lung ailment
 - Official says meeting is postponed due to scheduling conflict
-

Can We Actually Ban Vaping?

The White House called off a meeting with supporters of vaping as federal health officials said 530 people have fallen ill from a mysterious lung ailment related to use of e-cigarettes.

The meeting, originally set for 10 a.m. on Thursday, was billed as “a conversation with the Senior White House Officials on Electronic Cigarettes,” according to an invitation. A White House official who asked not to be identified said the meeting was postponed due to a conflict and would be rescheduled.

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While public health officials largely cheered Trump's crackdown, conservatives have sought to convince the White House that the president's ban is a federal overreach that will anger millions of adult vapers, including as many as 2.55 million in 12 swing states. In the past week, the Wall Street Journal editorial board [has blasted](#) "the frenzy against e-cigarettes" and multiple conservatives have taken aim at Trump's ban in high-profile op-eds.

"A ban on flavored e-cigarettes could cost Trump a second term," Paul Blair of Americans for Tax Reform [argued](#) in a Washington Examiner op-ed last week. The "well-organized vaping constituency could swing the outcome of the Electoral College one way or the other."

The Trump administration on Wednesday morning invited outside conservatives to a meeting with senior officials, framed to hear out their concerns. But by Thursday morning, the meeting with conservative groups was called off, and invitees told POLITICO that they've felt sidelined through a rapidly evolving debate — and that it's misrepresented their position.

"I think that the White House didn't necessarily have an accurate feel for where conservative groups were at on this," said Blair, who was invited to the meeting and has shared concerns about the vaping strategy with administration officials. "I think there's a little bit of chaos over at the White House given how strong the pushback has been."

"They should do research before implementing nationwide policies," said Michelle Minton, a senior fellow at the Competitive Enterprise Institute, who was also invited. "I would encourage them to continue this outreach and continue to look into this issue before they do anything."

A White House official said the meeting was canceled due to a scheduling conflict and is expected to be rescheduled. The official noted that Trump has directed the FDA to take action to protect the public health of children. [Trump tweeted last week](#), "While I like the Vaping alternative to Cigarettes, we need to make sure this alternative is SAFE for ALL! Let's get counterfeits off the market, and keep young children from Vaping!"

Bloomberg first [reported the meeting's cancellation](#).

Beyond Thursday's canceled meeting, the Trump administration has sought to reassure vaping advocates and other potential critics by deploying top health officials — including Surgeon General Jerome Adams — to listen to their concerns over the past week, said two individuals with knowledge of the strategy. An HHS spokesperson said Adams had a number of calls with interested parties, as is common with policy rollouts. "Those calls have been with leading health care organizations and associations that seek to advance public health and highlight the dangers tobacco products pose for our youth," the spokesperson said.

The vaping ban has increasingly pitted Trump's advisers in the White House — worried about alienating activists and allies who are mobilizing around the issue — against public health officials like Adams and former FDA Commissioner Scott Gottlieb, who took a hard line against teen use of e-cigarettes before stepping down in April, according to three people with knowledge of the disputes.

That fight accelerated earlier this year as health officials sought new restrictions on vaping. A [February letter](#) — signed by prominent conservatives like Grover Norquist and Ken Cuccinelli, who was [subsequently tapped](#) to serve as a top immigration adviser to the president — warned that any

crackdown on e-cigarettes would hurt small businesses and hinder adults' efforts to quit traditional cigarettes. Adams also has [clashed online](#) with conservatives who say Trump's e-cigarette strategy goes too far.

Meanwhile, vaping advocates and lobbyists, led by the Vapor Technology Association, swarmed Capitol Hill on Wednesday to push back against Trump's ban and [possible congressional legislation](#). The group's representatives also met with White House officials, said one individual with knowledge of the meeting. The association didn't respond to questions about the meeting.

The shared goal of conservatives and vaping advocates: To weaken or reverse Trump's broad ban, which still needs to navigate a regulatory thicket ahead of the 2020 election.

"I think if the proposal goes out, and flavors are pulled from the market, you would see a dramatic adverse economic impact," said Tony Abboud, the head of the Vapor Technology Association. "I certainly hope that will be taken into account when you have 14,000 small business owners who would be virtually eliminated overnight."

Juul, the dominant e-cigarette manufacturer, has avoided directly lobbying the White House since Trump's ban was announced, said an official with knowledge of the company's strategy, as it weighs short-term trade-offs versus long-term strategy.

"The company fully supports the flavor part of the ban," said the official, adding that the rise in teen vaping has created public health concerns and puts the entire industry at risk. But Juul is still deciding its position on Trump's call to limit menthol e-cigarettes, because menthol is available in combustible cigarettes, the official added.

Sarah Owerhohle contributed to this report.



December 31, 2020

The Honorable Frank Pallone, Jr.
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Pallone:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the September 25, 2019, hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, entitled "Sounding the Alarm: The Public Health Threats of E-Cigarettes." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

/s

Andrew Tantillo
Acting Associate Commissioner for
Legislative Affairs

cc: Hon. Greg Walden, Ranking Member, Committee on Energy and Commerce
Hon. Diana DeGette, Chair, Subcommittee on Oversight and Investigations
Hon. Brett Guthrie, Ranking Member, Subcommittee on Oversight and Investigations

The Honorable Frank Pallone (D-NJ)

- 1. In your testimony before the Subcommittee, you stated that despite the Administration’s announcement that FDA intends to finalize a compliance policy that would prioritize enforcement of the pre-authorization requirements for non-tobacco-flavored e-cigarettes, including mint- and menthol-flavored products, this does not mean that [quote] “flavored e-cigarettes can never be marketed.” What kind of evidence will have to be provided for the manufacturers in their PMTA submissions to convince FDA that flavored products should be legally marketed?**

Ensuring new tobacco products undergo a robust premarket evaluation by FDA is a critical part of our mission to protect the public health, particularly among youth, and to reduce tobacco-related disease and death. While the authorization of new tobacco products doesn’t mean they are safe, the review process under the PMTA pathway requires FDA to determine that permitting the marketing of the product is appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole. This includes consideration of the increased or decreased likelihood that users of tobacco products will stop using such products and the increased or decreased likelihood that nonusers will start using tobacco products. For example, FDA will consider whether marketing of a tobacco product would increase the likelihood of youth use of the product, and the potential for the product to move adult smokers away from use of combustible cigarettes. As part of a marketing granted order for a new tobacco product, FDA may also put in place post-marketing requirements if needed to enable it to determine whether there is or may be grounds for withdrawing or temporarily suspending an order, which could include, among other things, requirements for monitoring market dynamics such as potential youth uptake. FDA must also withdraw a PMTA marketing order if FDA determines that the continued marketing of a product is no longer appropriate for the protection of the public health (e.g., if there is an uptake of the product by youth).

Issues related to the manufacturing and marketing of electronic nicotine delivery systems (ENDS) products, including e-cigarettes, from the use of flavors and nicotine salts, to the levels of nicotine in the finished product, and the manner in which the product is marketed and sold, are all factors FDA will consider as part of our review of marketing applications for these products.

With respect to PMTA submissions for flavored ENDS products, FDA will assess, among other things, potential health risks to determine if permitting the marketing of a new tobacco product would meet the statutory standard of “appropriate for the protection of the public health” for marketing. As explained in FDA’s June 2019 guidance regarding PMTAs for ENDS products,¹ because of the potential impact of flavors on product toxicity and appeal to youth and young adults, scientific reviews of flavors (e.g., toxicological analyses of flavor additives, chemistry analyses, clinical studies, literature reviews), should be included in a PMTA for an e-liquid. There may be significant differences in the health risk of flavors depending on their route of exposure as well as the formation of additional chemicals due to heating or burning of the flavored e-liquid.

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends>

FDA considers the appeal and use of ENDS product flavors important in ascertaining the health risks of these products. In this regard, FDA recommends that PMTA applicants describe research on flavor development including, but not limited to, market segmentation analysis or sensory testing. Applicants should describe consumer perceptions among current ENDS users and other tobacco product users for appeal and use intentions, based on labeling and actual use of flavors, as well as product design. It is also important that PMTAs for flavored products examine the impact of the flavoring on consumer perception, especially given the attractiveness of flavors to youth and young adults. Additionally, to provide a better understanding of the appeal of flavors to adults, FDA recommends that PMTA applicants provide information examining adult appeal of such flavors in their decisions to initiate use, cease use of more harmful products, or engage in dual use.

2. **Despite FDA's 2016 deeming rule making it illegal to sell e-cigarettes to individuals under age 18, some underage young people have turned to the internet to purchase e-cigarettes online. One study found as many as 97 percent of online purchase attempts by those under the age of 18 were successful.²**

- a. **What are the challenges of regulating internet sales of e-cigarettes to youth?**

FDA conducts routine surveillance of sales, distribution, marketing, labeling, and advertising activities related to regulated tobacco products on the internet, including in social media; in publications; at promotional events; and through other compliance and enforcement activities. Through its activities including online surveillance, FDA has observed that online tobacco retailers utilize a variety of age verification methods, with varying levels of sophistication. FDA has taken action against hundreds of websites and other online media sites for violations such as sales of tobacco products to minors. The enormous volume and everchanging nature of these websites, however, can present challenges to enforcement.

- b. **What more, if anything, should FDA be doing to ensure that sellers are not able to get e-cigarettes into the hands of underage young people through the internet?**

FDA remains committed to tackling the troubling epidemic of e-cigarette use among kids. Preventing youth access to and use of ENDS remains one of FDA's top priorities. Our plan includes compliance and enforcement activities and high-profile, impactful public education efforts designed to reach nearly 10.7 million youth at risk of starting or continuing to use e-cigarettes.

On December 20, 2019, the President signed legislation to amend the Federal Food, Drug, and Cosmetic Act, raising the Federal minimum age of sale of tobacco products from 18 to 21 years. It is now illegal for a retailer to sell tobacco products—including cigarettes, cigars and e-cigarettes—to anyone under 21.

² Nikitin, D., et al., "Is the E-Liquid Industry Regulating Itself? A Look at E-Liquid Internet Vendors in the United States," *Nicotine & Tobacco Research* (Mar. 19, 2016).

FDA has taken swift action aimed at the manufacturers of youth-appealing ENDS products and continues to take action to stop sales to minors. FDA has also taken a number of actions to remove tobacco products that lack FDA premarket authorization, including ENDS, from the market. These include:

- issuing warning letters to companies for illegally marketing backpacks and sweatshirts designed with stealth pockets to hold and conceal ENDS products that resemble smartwatches, or devices appearing as children’s toys;
- issuing warning letters to companies marketing e-liquids that imitate packaging for food products such as candy, or feature cartoon characters like SpongeBob SquarePants;
- conducting investigations of more than 115 companies that may be illegally marketing more than 150 unauthorized tobacco products, including ENDS, to youth; and
- issuing seven warning letters to companies for illegally marketing over 170 unauthorized tobacco products, prior to the 2020 compliance policy, that includes a warning letter issued in October 2019 to a company for illegally marketing nearly 100 unauthorized ENDS products.

In March 2020, in line with the Agency’s actions to protect the health and well-being of staff during the COVID-19 outbreak, FDA issued a partial stop work order to the entities the Agency contracts with at the state level for activities such as compliance checks and vape shop inspections. The Agency continues to evaluate the effect of COVID-19 on its programmatic activities and will continue to communicate any changes as they occur. Guided by health and safety considerations, FDA will continue taking appropriate actions, as outlined by its priorities, on a rolling basis. Certain enforcement efforts, such as monitoring the online marketing and sale of regulated tobacco products and issuing import alerts for unauthorized tobacco products, remain uninterrupted by COVID-19.

3. Section 904(a)(4) of Food, Drug, and Cosmetic Act requires tobacco manufacturers, importers or agents to submit to FDA documents that relate to “health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.”

a. What of this information has FDA required or requested from e-cigarette manufacturers under this provision?

FDA has required ENDS manufacturers to preserve all documents relating to health, toxicological, behavioral, or physiologic effects of finished tobacco products (“health documents”). This should include, for example, cell-based, tissue-based, animal, or human studies, computational toxicology models, information on addiction, intentions to use, and other behavioral effects such as abuse liability. FDA is taking an incremental approach to enforcing this provision with respect to the timeframe that documents were developed and the date that documents must be submitted. The compliance deadline for submitting certain documents (i.e., health documents developed between June 23, 2009

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and December 31, 2009), was February 8, 2017, or in the case of small-scale tobacco product manufacturers, November 8, 2017. FDA generally does not intend to enforce the requirement with respect to health documents developed after December 31, 2009, at this time. However, tobacco manufacturers and importers are still to preserve all health documents developed after December 31, 2009 for future submission to FDA.

In addition to the authority in Section 904(a)(4), FDA may request health-related and other information under Section 904(b) at any time. Based on the growing concerns about the popularity of their products among youth, in April and May 2018, FDA requested that Juul Labs, Inc. and several other e-cigarette manufacturers submit additional research documents in accordance with section 904(b) of the FD&C Act. With the goal of understanding youth use of the products and what aspects could be driving their youth appeal, these requests³ sought information including marketing practices and research on marketing, adverse experiences and product complaints, effects of product design, and public health impact.

- b. In light of the outbreak of vaping lung illnesses and increasing evidence of a youth epidemic of e-cigarette use, has FDA considered revising its compliance guidelines for Section 904 of the FDCA to start requiring e-cigarette manufacturers to submit more information, particularly health studies, related to their products as such studies are developed? If not, why?**

Premarket applications for all currently marketed e-cigarettes were required to be submitted to FDA by September 9, 2020. FDA expects to receive extensive information including health studies in Premarket Tobacco Product Applications (PMTAs) submitted under Section 910(b) for e-cigarettes. FDA has published a guidance for industry on Premarket Tobacco Product Applications for ENDS,⁴ which includes detailed recommendations on the scientific studies and data to be submitted by industry in PMTAs for e-cigarettes. In addition, FDA intends to continue requiring that manufacturers submit other documents under the provisions of 904(a)(4) and 904(b) as appropriate.

The Honorable Diana DeGette (D-CO)

- 1. In 2018, a report by the National Academies of Sciences, Engineering, and Medicine found that there is “conclusive evidence that in addition to nicotine, most e-cigarette products contain and emit numerous potentially toxic substances.” In that same report, the National Academies also reported that the long-term health effects of e-cigarettes are not yet clear.**

³ These letters are posted at: <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/ctp-letters-industry>

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends>

a. Do you anticipate that long-term public health studies will be available for FDA as a part of its application review process, either from the manufacturers, federally funded studies, or elsewhere?

E-cigarettes are presently too new a technology for there to be long-term studies in existence that follow morbidity and mortality over a long period of time (e.g., decades). There are a number of national public health surveys that may yield so-called surrogate data on long-term health effects of ENDS: The Population Assessment of Tobacco and Health (PATH) study, the National Health Interview Survey (NHIS) and the Tobacco Use Supplement to the Current Population Survey (TUS-CPS) have been linked to mortality data from the National Death Index (NDI).

The PATH Study is an on-going national, longitudinal, cohort study of users of tobacco products and those at risk for tobacco use ages 12 and older and how use affects the health of people in the United States. Research topics in the PATH study include evaluating patterns of tobacco use such as switching products and using multiple products, as well as seeking to understand perceptions, knowledge, attitudes and use of tobacco products. CTP is also funding biospecimen analyses via a research contract and is working with the Division of Laboratory Science within CDC's National Center for Environmental Health and other laboratories to support analyses of biomarkers of tobacco exposure and potential harm. CTP is exploring additional short and long-term measures for PATH that capture potential health effects of e-cigarette and other tobacco use.

It may take several to many years to make definitive statements about e-cigarette use and long-term disease risk. In the meantime, we are looking at how often current e-cigarette users report certain illnesses and at differences in chemical exposures and other health measures taken at the time of the survey compared with other types of tobacco product users and non-users. Since long-term studies presently are limited, applicants may submit studies, published reports, or data on relevant biomarkers of harm or exposure such as cotinine, NNAL, and N-Nitrosonornicotine which may have a longer history of research and data.

We will also learn about any studies from manufacturers as we review premarket applications. It is likely that applicants will conduct certain investigations themselves and submit their own research findings as a part of their PMTA.

b. How will FDA weigh potential long-term public health impacts in the possible absence of such studies?

FDA uses long-term studies to examine trends of concern and develop strategies to mitigate those concerns. Without these studies we will rely on reviewing current and available evidence (such as shorter-term biomarker studies, and nonclinical studies) that may be extrapolated to long term health impacts. While long-term studies are most useful for identifying chronic effects associated with use of a product, such studies are not

routinely expected to be submitted as part of a premarket application. In general, FDA does not expect that applicants will need to conduct long-term studies to support an application; in some cases, it may be possible to support a marketing order for an ENDS product without conducting new nonclinical or clinical studies. Some applicants may be able to use published literature reviews to help support a PMTA, reference Tobacco Master Files (TPMFs) submitted by other manufacturers, or bridge to other studies. “Bridging” allows a PMTA applicant to refer to other research studies if there is applicable data or findings from those studies previously conducted by themselves or another party. For example, if there is an established body of evidence regarding the health impact (individual or population) of the product or a similar product that can be adequately bridged to the product in question, such as data from the published literature or government-sponsored databases, these data may be sufficient to demonstrate that the marketing of a product would be appropriate for the protection of the public health and support a PMTA.

Additionally, postmarket surveillance and reporting may help to ensure anticipated health impacts based on premarket information continued to be applicable.

Information about the use of bridging studies in PMTAs is publicly available in the PMTA ENDS guidance,⁵ CTP websites,⁶ and CTP presentations available online.⁷

The Honorable Brett Guthrie (R-KY)

1. Once a provider or state collects a sample, where are the samples that are collected sent for testing?

Initially, most samples were submitted to FDA’s Forensic Chemistry Center (August–October 2019). In late October 2019, sample triaging based on testing requirements began, with CDC’s laboratory focused on aerosol testing, and FDA’s Irvine, San Juan, and Detroit Medical Products Laboratories performing liquid testing. As of February 3, 2020, CDC and FDA are no longer accepting clinical or product samples related to EVALI cases.

Please refer to CDC’s response to this question for additional details.

a. How many samples have been received for testing to date?

As of October 9, 2020, FDA laboratories had received a total of over 1,600 product samples from 31 states and the U.S. Virgin Islands. Of these, 1,238 samples were specifically connected to an EVALI patient.

Please refer to CDC’s response to this question for additional details.

⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends>

⁶ “Marketing ENDS as New Tobacco Products: A Guide for Manufacturers.” <https://www.fda.gov/tobacco-products/manufacturing/marketing-ends-new-tobacco-products-guide-manufacturers>

⁷ <https://www.fda.gov/media/117507/download>

b. How many of those samples have been tested and what are they being tested for?

FDA analyzed e-liquids for the presence of a broad range of chemicals to provide insight into the nature of the chemical exposure(s) contributing to the EVALI outbreak. As of October 9, 2020, testing had been completed on 1,015 of 1,238 product samples specifically connected to an EVALI patient. The remaining samples include devices and empty packaging with no product available for testing.

Laboratory analyses have included testing the samples for nicotine, substances such as tetrahydrocannabinol (THC) or other cannabinoids, and other chemicals and ingredients such as cutting agents/diluents, additives, pesticides, opioids, and toxins.

c. Has the CDC or FDA requested samples from commercial e-cigarette manufacturers to compare to those collected in the investigation?

FDA has tested devices and e-liquids from some commercial e-cigarette manufacturers, however most products involved in the investigation are illicit products and not commercialized e-cigarettes.

Please refer to CDC's response to this question for additional details.

d. How do the samples compare? Are you finding that the samples are the same, or are commercial samples being modified after purchase?

Results of testing of products associated with illnesses and deaths have shifted the focus from e-cigarettes and associated nicotine containing fluids, to vaping cartridges containing fluids comprised of tetrahydrocannabinol (THC) and associated diluents.

Please refer to CDC's response to this question for additional details.

e. Can you determine from the samples provided how many are counterfeit products?

This issue is not related to counterfeit products but to the availability and use by consumers of products containing unknown materials of unknown origin. National and state data from patient reports and product sample testing suggest THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most EVALI cases and play a major role in the outbreak.

Please refer to CDC's response to this question for additional details.

f. What additional information or samples would you need to determine whether the samples involved in the investigation are counterfeit?

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Investigations of counterfeit products require authentic samples for comparison. In these cases, this would involve authentic samples of any associated marketing materials and packaging, devices, cartridges and liquid contents. As previously discussed, the current issue is not related to counterfeit products but to the availability and use by consumers of products containing unknown materials of unknown origin.

2. In addition to analyzing the vaping liquid, do CDC and FDA investigators also receive and examine the vaping or e-cigarette device itself?

As part of the investigation, FDA received various products and substances to analyze, including products containing varied levels of liquid as well as packaging and other documentation. However, relatively few vaping devices were received.

Please refer to CDC's response to this question for additional details.

a. Have investigators found modified e-cigarette or vaping devices in any of the outbreak cases? If so, how many cases?

The devices have not been the focus of this investigation. Preliminary data suggested that the liquids contained in the devices were the most likely cause of the illnesses. In November 2019, CDC published a study report noting that products containing THC, particularly those obtained off the street or from other informal sources (e.g., friends, family members, illicit dealers), were linked to most of the EVALI cases and played an important role in the EVALI outbreak.⁸

Please refer to CDC's response to this question for additional details.

b. Are most of the devices closed system products or open system products?

As mentioned previously, FDA received various products and substances to analyze. While a variety of products are involved in the investigation, the cause is strongly linked to the liquid and not the device used. To date, this type of information (open or cartridge-based systems) is not reflected in the samples packages or data received by the ORA Laboratories and is not being tracked or generated.

Please refer to CDC's response to this question for additional details.

c. Are you at least receiving the devices? Why not also collect and examine the devices themselves to look for commonalities?

As stated previously, the cause is strongly linked to the liquid and not the device used and relatively few vaping devices have been received.

⁸ https://www.cdc.gov/mmwr/volumes/68/wr/mm6843e1.htm?s_cid=mm6843e1_e&deliveryName=USCDC_921-DM11790

3. How many different chemicals is FDA testing for? What criteria did FDA use to select the chemicals for screening?

Laboratory analyses have included testing the samples for nicotine, substances such as tetrahydrocannabinol (THC) or other cannabinoids, and other chemicals and ingredients such as cutting agents/diluents, additives, pesticides, opioids, and toxins.

a. How is FDA conducting the testing? Are the samples being tested as if it they are coming out of a vaping device?

FDA testing has focused on liquid product testing rather than testing the aerosol that is formed when the liquid is vaped. CDC conducted aerosol emissions of case-associated e-cigarette, or vaping, products in order to replicate patients' exposure to aerosols produced by these products and to identify constituents associated with health risk.

4. What does scientific research show about the effects of nicotine on the adolescent brain? What is the effect of nicotine delivered by e-cigarettes as compared to combustible cigarettes?

Studies of the effects of nicotine exposure in the adolescent brain find that it is uniquely vulnerable to nicotine compared to the adult brain. Repeated exposure to nicotine during adolescence induces long-lasting structural and functional changes in brain regions involved in addiction, attention, learning, and memory. These changes in the brain can persist after nicotine exposure has ended and prime the adolescent brain for addiction to nicotine and other drugs, such as cocaine and methamphetamine. Studies further suggest that nicotine-induced changes in the adolescent brain can lead to long-lasting effects on cognitive function, such as cognitive deficits following nicotine abstinence, and may contribute to the risk for mood and anxiety disorders.

Nicotine is the primary addictive substance in tobacco products, including e-cigarettes and combustible cigarettes. The rate and extent of nicotine delivery significantly impacts product abuse liability. Higher nicotine content and faster rates of nicotine delivery increase products' abuse liability due to the rapid absorption of nicotine into the brain. The e-cigarette product category includes a range of product types and features. Some e-cigarettes can achieve similar or greater rates of nicotine delivery as cigarettes.

Nicotine delivery by e-cigarettes is influenced by nicotine yield (the amount of nicotine heated and released) in e-cigarette aerosol. Nicotine yield is impacted by e-liquid nicotine concentration and several product characteristics, including battery power/wattage. Nicotine exposure (the amount of nicotine absorbed by the body) from e-cigarettes is influenced by e-liquid composition (e.g., propylene glycol to vegetable glycerin ratio, pH, presence of nicotine salts) and user behavior (e.g., puff volume/duration, number of puffs per use session, length of use session). Emerging evidence on nicotine salt formulations suggests that these e-liquids may result in greater nicotine exposure and faster nicotine absorption than freebase nicotine e-liquids with the same nicotine concentration. Notably, e-cigarette use behavior is not self-limiting due to a large

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e-liquid volume capacity (i.e., one tank/pod may deliver as much nicotine as one pack of cigarettes) and the ability to use the product for a longer duration than a cigarette. As a result, nicotine exposure from an e-cigarette can vary in rate and magnitude to a greater degree compared to a cigarette.

5. What is the FDA's plan for increasing enforcement of non-FDA regulated products, such as THC vaping e-liquids, or CBD oils?

FDA has been actively monitoring the CBD market and seeking to remove violative products that pose a risk to consumers. For example, we have seen many CBD products being marketed with claims of therapeutic benefit, or other drug claims, without having gone through the drug approval process. Some of these products are marketed for serious diseases and conditions like cancer, Alzheimer's disease, and opioid use disorder. Selling products with unsubstantiated therapeutic claims can put consumers at risk by influencing them not to use proven, approved therapies to treat serious and even fatal diseases. These products are unapproved drugs, and their sale and distribution are illegal. FDA has sent warning letters to companies marketing such unlawful products, and we will continue to monitor the marketplace and take action, as needed, when we encounter violations that deceive consumers and put them at risk.

We also have serious concerns about CBD products that put the public at risk in other ways. For example, we are acutely aware of the risks posed by product contaminants (e.g., heavy metals, toxic minerals, or other potentially harmful substances). We also have significant concerns about products marketed with false claims or statements (e.g., omitted ingredients, incorrect statements about the amount of CBD), products marketed for use by vulnerable populations (e.g., children or infants), and products that otherwise put the public health at risk.

The Joint Explanatory Statement that accompanied the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) directed FDA to provide a report regarding the Agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which CBD meeting the definition of hemp will be evaluated for use in FDA-regulated products within 60 days of enactment. We provided this report, and an additional report with a sampling study of the current CBD marketplace, to Congress.

It is possible that some individual products containing CBD fall outside of FDA's jurisdiction. Specifically, a product containing CBD falls outside FDA's jurisdiction if it is not intended for use as a human or animal drug; is not a human or animal food; and is not a cosmetic, medical device, biological product, tobacco product, or combination product. FDA does not have authority to exercise regulatory oversight over such products, even to address potentially serious matters of public health and safety.

FDA continues to review information received following the 2019 public hearing and has more information on these products on FDA's website: <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>

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Further, FDA enforces the FD&C Act. The FD&C Act gives FDA jurisdiction over foods (including dietary supplements), drugs, cosmetics, and tobacco products among other products. In some situations, the use of cannabis and its derivatives (including THC and CBD) is a violation of the FD&C Act, regardless of whether it is also a violation of the Federal Controlled Substances Act (CSA). Whether a product containing cannabis is subject to FDA regulation – and, if so, whether it violates the FD&C Act – is determined by a fact-specific inquiry. FDA inspects manufacturing facilities, conducts investigations and responds to consumer complaints in all states including those where local laws have lifted restrictions on cannabis. These actions by state and local governments have increased situations where FDA may encounter products containing cannabis while performing routine activities, and prompt questions as to the regulatory status of these products under the FD&C Act.

6. According to your testimony, FDA has issued more than 1,400 civil money penalties to retailers for sales of ENDS and their components to youth. How much money has been fined in Civil Monetary Penalties generated to date?

If FDA finds subsequent violations at a retail establishment after the issuance of a warning letter, it generally seeks a Civil Money Penalty (CMP) in accordance with the penalty schedule published in the Tobacco Control Act (TCA) and adjusted for inflation. A CMP is an administrative enforcement action and retailers are entitled to a hearing in front of a U.S. Health and Human Services Departmental Appeals Board (DAB) Administrative Law Judge (ALJ) to contest some or all the allegations, and the amount of the penalty.

Since FDA began issuing CMPs in 2011, the Agency has collected more than \$17 million as a result of CMPs issued to tobacco retailers for repeated violations (largely due to the sale of tobacco products to minors) since the retail compliance check inspection program began.

a. How much is outstanding and how much has been collected?

As noted above, since FDA began issuing CMPs in 2011, the Agency has collected more than \$17 million. Please note that FDA does not disclose the status of CMP cases until they are closed, including the amount sought. This protects the integrity of the process.

b. What has been done with that money?

All CMP payments are deposited in the U.S. Treasury as miscellaneous receipts, not allocated to FDA or FDA's Center for Tobacco Products (CTP).

7. Did the FDA use research from the United Kingdom when deciding to postpone the PMTA deadline and if so, what evaluations or studies did the FDA conduct in the difference between UK regulations from the FDA regulations before using the UK research as a basis for policy decision-making? Explain the difference in the United Kingdom's regulation of e-cigarettes versus the FDA's.

In July 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation that would serve as a multi-year roadmap to significantly reduce tobacco-related disease and death.

Prior to this announcement, nationally representative data suggested that youth use of e-cigarettes had declined.⁹ The comprehensive plan was announced in part to afford the Agency time to explore clear and meaningful measures to make combustible tobacco products less toxic, less appealing, and less addictive. In accordance with this plan, in August 2017, FDA extended timelines to submit tobacco product review applications for newly-regulated products that were on the market as of August 8, 2016.¹⁰ This extension of time was intended to enable FDA to strike a balance between regulation and encouraging development of innovative tobacco products that may be less harmful than cigarettes. FDA did not rely on research from the United Kingdom (UK), including work produced by Public Health England, when it set out this extension.

FDA notes that we monitor relevant global e-cigarettes studies. of the rules governing e-cigarettes in the UK differ from those in the U.S. The UK Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority for the notification scheme for e-cigarettes and refill containers in the UK and is responsible for implementing many of the provisions under Article 20 of the Tobacco Products Directive 2014/14/EU (TPD). Example provisions include:

- Restricting the maximum volume of nicotine-containing e-liquid for sale in one refill container to 10ml;
- Requiring nicotine-containing products or their packaging to be child-resistant;
- Banning certain ingredients such as colorings, caffeine and taurine;
- Including new labelling requirements and warnings; and
- Requiring all e-cigarettes and e-liquids be notified to MHRA before they can be sold.¹¹

In the U.S., FDA has had authority over all tobacco products, including ENDS, since the final deeming rule went into effect in 2016. As a result of the final deeming rule, manufacturers, importers and retailers of newly-regulated tobacco products are subject to applicable provisions related to tobacco products in the FD&C Act and FDA regulations. This brings them in line with other tobacco products FDA has regulated under the TCA in 2009. For example, requirements include:

- Registering manufacturing establishments and providing product listings to FDA;
- Reporting ingredients, and harmful and potentially harmful constituents;
- Premarket review and authorization of new tobacco products by FDA;
- Placing health warnings on product packages and advertisements; and
- Not selling modified risk tobacco products (including those described as “light,” “low,” or “mild”) unless authorized by FDA.

⁹ Jamal A, Gentzke A, Hu SS, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2016. *MMWR Morb Mortal Wkly Rep* 2017;66:597–603. DOI: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm>.

¹⁰ FDA notes that as a result of a court order, premarket submissions became due to FDA on September 9, 2020, for all new deemed tobacco products currently on the market.

¹¹ <https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products>

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FDA's premarket review process is unique to the U.S. In the UK, in contrast, manufacturers of new e-cigarette products only must submit notification to MHRA six months before they intend to put their product on the UK market, and can begin marketing their product as soon as their notification is published on the MHRA website.

a. Has the FDA evaluated research results of e-cigarette use presented in support of, and research results following the implementation of the UK and EU e-cigarette regulations to study the effectiveness of the UK and EU regulations?

FDA regularly looks to regulatory and scientific counterparts, both domestically and internationally, to inform our regulatory actions to the extent feasible and appropriate given distinctions in respective authorities, tobacco product marketplaces, and populations. This includes the treatment of ENDS under the EU Tobacco Products Directive (TPD). In 2018, the US National Academy of Sciences released a CTP-commissioned report on the Public Health Consequences of ENDS.¹² This report built upon 2014 and 2015 reports commissioned by Public Health England on the cumulative evidence of potential public health benefits and harms related to ENDS in the UK.

Policy impact analysis is among CTP's research priorities. CTP's Office of Science (OS) conducts targeted evaluations of domestic and international policies of interest that are relevant to our regulatory authorities. We have funded and are currently funding evaluations of policies to inform future regulatory actions (e.g., impact of sales restrictions on flavored tobacco products).

Specific examples of areas in which OS is monitoring the EU and UK ENDS experience to inform tobacco regulatory science include but are not limited to, TPD restrictions on e-liquid volume and constituents; tobacco product labeling; post market and adverse event reporting; and child-resistant packaging.

Please note, however, that while global experience may inform FDA regulatory authority, FDA regulations must reflect U.S. consumer use and unique U.S. marketing. E-cigarette use in the UK differs from that in the U.S., as the UK has not experienced the same youth use epidemic. Public Health England found that, while youth experimentation with e-cigarettes has steadily increased in recent years, regular use remains low. In 2018, 1.7 percent of 11-18 year old youth in Great Britain reported at least weekly use. Adult e-cigarette prevalence has remained stable since 2015. In 2017-2018, an estimated 5.4 percent to 6.2 percent of all adults in Great Britain used e-cigarettes.¹³

¹²National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems; Eaton DL, Kwan LY, Stratton K, editors. Public Health Consequences of E-Cigarettes. Washington (DC): National Academies Press (US); 2018 Jan 23. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK507171/> doi: 10.17226/24952

¹³Vaping in England: evidence update summary February 2019.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/821179/Vaping_in_England_an_evidence_update_February_2019.pdf

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8. Will the FDA plan to add questions to the National Youth Tobacco Survey asking which substances youth are smoking in e-cigarettes other than nicotine?

The 2020 National Youth Tobacco Survey (NYTS) included a question asking whether youth have ever used marijuana or cannabis (including concentrates, waxes, or hash oils) in an e-cigarette. Questions for the 2021 NYTS are not finalized; should there be changes to this newly added question about marijuana or cannabis use, we will inform the Committee.

The Population Assessment of Tobacco and Health (PATH) Study is a national longitudinal study of tobacco use and how it affects the health of people in the United States. PATH annually collects a comprehensive set of measures concerning ENDS use among youth and adults, and over time improvements have and are being made to the survey design to disentangle use of ENDS for vaping nicotine as well as other substances.

The Honorable Michael C. Burgess (R-TX)

1. We know that teen use of e-cigarettes has rapidly and steadily increased in recent years. What has the FDA been doing to study this steep increase in youth vaping?

On September 9, 2020, FDA, in partnership with the Centers for Disease Control and Prevention (CDC), released new data from the 2020 National Youth Tobacco Survey (NYTS), which show 1.8 million fewer U.S. youth are currently using e-cigarettes compared to 2019. After two years of disturbing increases in youth e-cigarette use, we are encouraged by the overall significant decline reported in 2020. This is good news; however, FDA remains very concerned about the 3.6 million U.S. youth who currently use e-cigarettes and we acknowledge there is work that still needs to be done to curb youth use. Youth use of e-cigarettes remains a public health crisis that is affecting children, families, schools and communities, and we will do everything possible to stop it.

FDA has taken a multi-pronged approach to study youth vaping. We are analyzing data from well-established studies such as the NYTS and Population Assessment on Tobacco and Health (PATH) Study to understand e-cigarette (or ENDS, electronic nicotine delivery systems) use by youth. In addition, FDA is collaborating with NIH to fund tobacco regulatory science grants; with nearly 20 active grants focusing on behaviors associated with youth use of ENDS.

FDA has also conducted research using a method known as social media listening, which monitors social media platforms to help identify emerging products used by youth as well as trending topics. Retail sales data are also used to provide near real-time information on tobacco product sales and to assess overall tobacco marketplace trends in the U.S.

Lastly, FDA participates in a cross-agency tobacco-focused work group along with CDC and NIH that meets routinely to enhance our understanding of the troubling epidemic of e-cigarette use among kids.

2. What conversations has the FDA had with e-cigarette manufacturers about curbing teen vape use?

In late 2017, FDA started to see a marked increase in complaints about ENDS products. FDA initiated an investigation of these complaints, the majority of which pertained to minors' access to and use of these products. This new information indicated an alarming increase in the use of ENDS products by middle and high school students. As part of FDA's response to the increasing use of ENDS products by youth, FDA contacted manufacturers directly to hold them accountable, and to solicit their input in combating youth use of these products. Some examples of FDA interactions with e-cigarette manufacturers about curbing teen vape use include:

- In April and May of 2018, FDA sought information from manufacturers of certain ENDS products commonly used by minors requiring them to submit documents to inform the Agency's understanding of the reported high rates of youth use and the particular youth appeal of these products.
- On September 12, 2018, FDA issued letters to manufacturers of five of the top-selling ENDS brands (JUUL, Vuse, MarkTen XL, blu e-cigs, and Logic), requesting each company to submit a plan describing how it would address minors' access to and use of its products. At the time, these products made up most products illegally sold to minors as part of an FDA enforcement blitz. In response to the September 12th letters to industry, manufacturers described safeguards that they could implement to help to restrict minors' access to ENDS products sold at brick and mortar retailers and online.
- FDA leadership met numerous times with e-cigarette manufacturer with a call to action for the five largest to specifically address the issue of youth use.
- CTP Director, Mitch Zeller, continues to meet with manufacturers as well as various trade associations for both large and small vaping companies and vape shops. Agency representatives also speak frequently at trade associations and host industry listening sessions where the issue of curbing teen e-cigarette use is directly addressed.

3. I believe a critical part of this conversation should be the health concerns associated with counterfeit products. What has the FDA done in recent years to deal with counterfeit products?

U.S. Customs and Border Protection (CBP) allows brand owners to record their registered trademarks and copyrights with the Intellectual Property Rights (IPR) Branch within the Regulations and Rulings Directorate of CBP's Office of Trade. CBP then uses this registration information to help detect counterfeit goods at ports of entry, including at international mail facilities (IMFs) and express courier locations.

In addition to using our regulatory authorities to combat counterfeit e-cigarettes, where appropriate, the Office of Criminal Investigations (OCI) may investigate and refer criminal violations to the Department of Justice for prosecution. Prosecutorial thresholds and criteria vary depending upon the particular U.S. Attorney's Office receiving the referral. OCI also works with closely other Federal, state and international law enforcement agencies to combat the manufacture and sale of any counterfeit FDA-regulated product.

4. Is the FDA prepared to monitor and combat a potential surge in counterfeit or black market products following the flavor ban?

FDA has regulatory tools and enforcement authorities to address ENDS and other tobacco products that are marketed without authorization, that are counterfeit, and/or that are otherwise involved in illicit trade. FDA uses its resources to inspect, detect, and prevent products that violate the FD&C Act, including counterfeit or other illicit products, from entering the U.S. market. FDA has a comprehensive tobacco compliance and enforcement program, which is overseen by CTP and in some areas utilizes FDA's Office of Regulatory Affairs (ORA) staff. Enforcement activities include tobacco retail compliance check inspections, inspections of domestic manufacturers and imported tobacco products, and surveillance and review of tobacco promotions, advertising, and labeling. FDA also has eight import alerts in place to ensure that products presented for entry into the U.S. meet the requirements set forth by the FD&C Act. FDA's import alerts are intended to prevent products that are in violation of certain provisions of the Act from entering the country.

FDA could utilize its advisory, administrative, and judicial enforcement tools against illicit trade in tobacco products. For example, adulterated or misbranded products might be seized at any time. Entities involved in initiating and taking a seizure action include CTP, ORA, FDA's Office of Chief Counsel, the U.S. Attorney's Office, and the U.S. Marshal's Service. FDA also might seek to enjoin any company or person from engaging in a prohibited act. If a firm had a history of violations and had promised correction in the past, but had not made the corrections, an injunction might be pursued. In considering an injunction, FDA evaluates the seriousness of the offense, the actual or potential impact of the offense on the public, whether other possible actions could be as effective or more effective, the need for prompt judicial action, and whether FDA will be able to demonstrate the likelihood of the continuance of the violation in the absence of a court order. Finally, FDA might refer a criminal enforcement action to the U.S. Department of Justice through FDA's OCI.

FDA also receives reports about potential violative tobacco products. FDA evaluates all reports submitted to determine if the activity is a violation of the FD&C Act or related regulations. Before deciding what follow-up action, if any, is necessary, the Agency will check to see if the product named in the complaint is regulated by FDA. If the product is regulated by a different Federal or state agency, or different part of FDA, we will forward the complaint to the applicable entity for review. FDA does not rely solely on what was submitted to take enforcement action. After reviewing a complaint, FDA's investigation may include:

- performing an inspection of a tobacco product manufacturer, distributor, or importer;
- conducting a compliance check inspection of a tobacco retailer; or
- initiating monitoring and surveillance of a tobacco product manufacturer's or retailer's website.

FDA may determine that there is no evidence of a violation or may find evidence of the reported violation or of other potential violations that requires additional surveillance, monitoring, and/or inspections.

Lastly, OCI conducts criminal investigations of illegal activities involving FDA-regulated products and referring them to the Department of Justice for prosecution. OCI utilizes FDA's Forensic Chemistry Center, which provides forensic laboratory support by performing many different tests on products that are the subject of investigations. CTP refers potential criminal activity, which would include potential counterfeit or other illicit tobacco products, to OCI to investigate.

From FY 2019 to mid-year of FY 2020, OCI's investigations involving counterfeit, adulterated and misbranded tobacco products have resulted in 13 arrests, 5 convictions, and over \$700,000 in court ordered fines and restitution. In FY 2020 alone, OCI's Tobacco Enforcement Program has initiated over 15 criminal investigations. These cases are based upon a combination of referrals from CTP, complaints from the general public and Center-initiated inspections, as well as information provided by sources within regulated industry. In a recent OCI-led investigation, a defendant was charged in Federal court for trafficking in a counterfeit electronic nicotine delivery system. Thus far, the investigation has led to the seizure of thousands of illicit nicotine delivery devices.

5. Under the new proposed rule requiring manufacturers to submit premarket tobacco product applications, how will the FDA weigh factors such as the product components, ingredients, additives, constituents, toxicological profile and health impact in determining whether a manufacturer has demonstrated appropriate protection of public health?

The Premarket Tobacco Product Applications and Recordkeeping Requirements proposed rule, if finalized, would explain what information applicants would need to include in their applications in order for FDA to find that the marketing of a new tobacco product is appropriate for the protection of public health. The proposed rule does not provide a calculus as to how the Agency will weigh various factors in determining whether the marketing of the new tobacco product would be appropriate for the protection of public health; how all the many factors are weighed to make this determination will vary depending on the tobacco product being evaluated. The proposed rule's preamble does provide some examples of how an applicant could help show that permitting the marketing of its new tobacco product would meet the statutory standard of appropriate for the protection of the public health.

In accordance with section 910(c)(5) of the FD&C Act, FDA will base its determination of whether permitting the marketing of a product would be appropriate for the protection of public health on well-controlled investigations, where appropriate, and other valid scientific evidence that it finds sufficient to evaluate the product, which could include literature reviews and nonclinical studies. In addition to the proposed rule, in June 2019, FDA published a guidance¹⁴ to provide recommendations on some appropriate means of addressing the premarket authorization requirements for deemed ENDS products. CTP will consider the totality of the evidence, as well as the strengths and limitations of each information source and study in the review of a PMTA to determine whether the marketing of the proposed new product is appropriate for the protection of public health.

¹⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends>

6. Will the health impact analysis include things such as adult versus teen use and preferences, flavors, marketing of products, and potential for e-cigarette users to return to traditional cigarettes?

Yes, FDA's premarket review of new tobacco products includes an evaluation of a number of health impacts. FDA's finding that permitting a new tobacco product to be marketed through the PMTA pathway would be appropriate for the protection of the public health must be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products, including youth, will start using such products.

For example, FDA's consideration of the likelihood that nonusers, including youth, will start using an e-cigarette product could involve consideration of youth flavor preferences, how the product will be marketed, and the extent to which youth will be exposed to the marketing. Youth appeal and use behaviors are an important aspect for applicants to include in a premarket tobacco product application.

The Honorable Markwayne Mullin (R-OK)

- 1. During last week's Senate Ag Appropriations mark up, the Committee added report language that "commended" the Administration's actions to confront underage nicotine vaping, but also described the Committees "deep concern about a separate public health crisis involving vapor products ... likely caused by low quality or adulterated vaping products that contain THC."**

The newly added bill language requires FDA to determine how product design requirements could help prevent consumers from modifying or adding any substances to these products not intended by the manufacturer.

Is this the real root of the lung illness outbreak issue?

FDA, CDC, and state health authorities have made progress in identifying substances of concern in the e-cigarette, or vaping, product use-associated lung injury (EVALI) outbreak. National emergency department data and active case reporting from state health departments around the country show a sharp rise in symptoms or cases of EVALI in June 2019, a peak in September 2019, and a gradual, but persistent decline since then.

National and state data from patient reports and product sample testing suggest THC-containing vaping products, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most EVALI cases and played a major role in the outbreak.

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Vitamin E acetate is strongly linked to the EVALI outbreak. Vitamin E acetate has been found in product samples tested by FDA and state laboratories and in patient lung fluid samples tested by CDC from geographically diverse states. Vitamin E acetate has not been found in the lung fluid of people that do not have EVALI. However, there is not sufficient evidence to rule out the contribution of other chemicals of concern, including chemicals in either THC or non-THC products, in some of the reported EVALI cases.

On February 18, 2020, in accordance with the “Further Consolidated Appropriations Act, 2020,” FDA published a Request for Information (RFI) in the *Federal Register* to solicit information regarding EVALI. The Agency specifically sought information related to the use of vaping products that are associated with EVALI, including comment on product design and ways to prevent the public from modifying or adding substances to these products that are not intended by the manufacturer. FDA is reviewing the information submitted to the RFI.

2. **Vapor products started being sold in the U.S. around 2007 – and began to be regulated by the FDA in 2016. We are more than a decade into vapor use in American – but these cases are just now appearing. Legal vapor sellers have had to register with the FDA, list product ingredient with the FDA, and open their facilities up to FDA inspections.**

Is there a recent change in what is being put into products before being sold on the black market that is responsible for these newly and rapidly occurring illnesses?

As mentioned above, national and state data from patient reports and product sample testing suggest THC-containing vaping products, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most EVALI cases and played a major role in the outbreak.

Vitamin E acetate is strongly linked to the EVALI outbreak. Vitamin E acetate has been found in product samples tested by FDA and state laboratory and in-patient lung fluid samples tested by CDC from geographically diverse states. Vitamin E acetate has not been found in the lung fluid of people that do not have EVALI. However, there is not sufficient evidence to rule out the contribution of other chemicals of concern, including chemicals in either THC or non-THC products, in some of the reported EVALI cases.

With respect to distribution, FDA is investigating the supply chains related to the products these patients used.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
“Sounding the Alarm: The Public Health Threats of E-Cigarettes”

September 25, 2019

Dr. Anne Schuchat (RADM, USPHS, RET), Principal Deputy Director, Centers for Disease Control and Prevention

The Honorable Frank Pallone (D-NJ)

1. Over 3.6 million middle and high school students reported using e-cigarettes in 2018. This figure is beyond alarming, and represents a preventable public health failure, the likes of which we haven’t seen since the height of youth smoking in the mid-1990s. We are now going to have to confront the fact that millions of young people in America will likely need help if they are going to quit using these products.

- a. As we try to combat youth use of e-cigarettes, what have we learned regarding youth smoking in the past that might be helpful in our current efforts—are there similarities to smoking cessation efforts among young people that can be applied to vaping cessation interventions?

Response: Population-based interventions that have been shown to prevent cigarette use; reduce smoking in youth and young adults; and support tobacco users trying to quit are expected to have similar impact when modified to address all tobacco products, including e-cigarettes.

The following are examples of evidence-based interventions at the national, state, and local levels that reduce and prevent smoking:

- Tobacco taxes and other strategies that increase the retail price of products
- Mass-media, counter-marketing campaigns
- Adoption of comprehensive smoke-free laws (that also prohibit e-cigarette use)
- Availability of accessible, affordable tobacco cessation options
- Restricting youth-appealing advertising and promotion (including online and in popular media)
- Prohibiting flavors, including mint and menthol
- Increasing the minimum age of sale

- b. Does preventing youth use of e-cigarettes and developing cessation interventions for young people already addicted to e-cigarettes pose unique challenges that differ from traditional cigarettes?

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Response: In 2019, of the high school and middle school students who reported current (past 30-day) use of tobacco products, 57.8% reported that they are seriously thinking about quitting, and 57.5% reported that they stopped using tobacco products for at least one day in the past year because they were trying to quit. However, there are special challenges in engaging youth in cessation interventions regardless of whether they use conventional cigarettes, e-cigarettes or other tobacco products. Much less information on effective tobacco cessation approaches is available for youth than for adults. This is an area in which the [U.S. Preventative Services Task Force](#) has called for more research. In addition, engaging and retaining youth in cessation treatment is more challenging than for adults because of youth attitudes, schedules, and competing demands on their time. Youth tobacco users may also not consider themselves to be tobacco users or to be addicted and may be ambivalent about quitting or seeking cessation help. Youth may be reluctant to seek help quitting because they don't want their parents to know that they are using tobacco products, and because they don't want their peers to know that they are planning to quit.

There are additional challenges specific to helping youth quit e-cigarettes, which are relatively new products that have evolved rapidly since their introduction. Notably, e-cigarettes are a large and diverse class of tobacco products, with significant variation between products in terms of nicotine concentration, device delivery mechanisms, and e-liquid ingredients. The recent addition of nicotine salts to e-cigarettes has further complicated this picture by making it possible to deliver higher concentrations of nicotine in a palatable form. Additionally, variations in user behavior, including device modification and frequency and intensity of use, have implications for cessation strategies that are unique to this product class. Further, other substances, such as tetrahydrocannabinol (THC), are being mixed with nicotine or being used exclusively in devices which further complicates cessation efforts. These variations in product characteristics and user behaviors make understanding even the basics of nicotine dependency significantly more complex for e-cigarettes than for conventional cigarettes and pose further challenges for the development of cessation interventions for all populations, including youth. Additionally, because flavors are driving youth initiation of e-cigarettes, the continued availability of flavors has the potential to complicate cessation efforts.

c. What research and other activities is ongoing or planned to develop evidence-based interventions to help young people avoid nicotine addiction, not transition to combustible cigarettes, and ultimately quit e-cigarette use?

Response: CDC is working on addressing the gaps in knowledge on effective youth tobacco cessation approaches, including approaches to help youth quit e-cigarette use. For example, CDC works with FDA and NCI as part of a tri-agency cessation workgroup to ensure coordination of agencies' efforts to build the evidence base of tobacco cessation, including e-cigarette cessation, among both youth and adults.

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In addition to FDA and NCI, CDC collaborates with state health departments, universities, tobacco quitline providers, and other partners to conduct ongoing research of youth tobacco use, including youth e-cigarette use, using large, nationally representative surveys. This research is complemented with other data sources, such as retail scanner data and web-based surveys that allow more rapid examination of evolving behaviors, trends and issues related to tobacco use.

CDC makes recommendations based on data. Our traditional tobacco-related data systems provide limited insight of the specifics of the problem with e-cigarette use. During the EVALI outbreak, we worked with state public health authorities to pull together several data sources and put in place additional data collection.

2. You stated in your testimony that our public health collection and reporting systems are [quote] “antiquated and fragmented.”

a. How does this concern and other technological or infrastructure concerns affect the ongoing vaping lung illness outbreak investigation efforts?

Response: Public health runs on data. Protecting America’s health requires reliable and up-to-date information to help prevent, detect, and respond to health threats. Public health data collection and reporting systems are often antiquated and fragmented. In FY 2020, CDC began a multi-year effort to modernize public health data collection to assure timely, actionable information while continuing to safeguard patient privacy.

CDC’s data modernization initiative will improve efficiency, effectiveness, and responsiveness to the threats facing America’s health. Data currently moves slower than disease. A modernized electronic means of sharing data among CDC, states, local jurisdictions, and healthcare professionals will promote the seamless reporting of data from the point of care to state health departments (using electronic health records) while simultaneously notifying federal health officials of potential health threats.

The investigation of injury and death from e-cigarette, or vaping, product use associated lung injury (EVALI) is emblematic of a challenge to all our work that requires rapid collection and analysis of public health data but, in reality, is still more reliant on paper-based systems and fax machines than electronic reporting and interoperable systems.

Timely surveillance, including surveillance concerning the use of newly emerging and rapidly evolving tobacco products (e.g., e-cigarettes) and cannabis in forms other than smoking (e.g., vaping, dabbing, edibles) as well as surveillance concerning youth cessation, in the United States is nascent. Although there have been efforts to improve cross-cutting mortality, laboratory and emergency department surveillance in recent years, this outbreak and the lack of estimates of background rates of use and use

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behaviors related to THC use in e-cigarette, or vaping, products highlights that data collection efforts have not kept up with the rapidly changing landscape.

States, in particular state health departments, which are increasingly charged with tracking trends in cannabis use and many other emerging health threats, often lack state funding and have restricted data collection and analytic capacity, limiting their ability to track and respond to these threats. Specifically for cannabis use, succinct, valid, and reliable measures are not available for several important indicators, such as the amount and types of products consumed (including THC and Cannabidiol (CBD)), populations using THC and CBD products (youth versus adults), mode of use (e.g., vaping, smoking, dabbing), reasons for use (medical/nonmedical, and associated behaviors) and health-related harms such as lung injury, cannabis-impaired driving, and cannabis use disorder. In addition, limited data and policy surveillance presents challenges for state health departments and state regulatory agencies that are responsible for providing oversight of medical and nonmedical cannabis markets. Such data and infrastructure concerns constrain states' ability to make evidence-based policy and public health decisions.

More broadly, CDC's data modernization initiative will benefit many public health areas, such as the opioid crisis, HIV elimination, and vector-borne diseases in addition to being able to respond to a new previously unanticipated threat. There is a need for augmented workforce development, data systems modernization, and increased innovation. These efforts will improve interoperability and analytic capacity, bringing health record data to public health, merging different types of health data for greater insight, and tapping into non-health data to deliver on greater situational awareness.

b. What types of investments would aid in expediting this and similar public health investigations?

Response: CDC's public health data modernization initiative, which began in FY 2020, will improve detection, automation, and streamline information sharing. We have progressively learned the criticality of this need from Ebola and Zika in both the international and domestic context. Increased interoperability and analytic capacity will provide new insights previously unrecognized, enabling swifter more effective intervention. Critically, data systems modernization goes hand in hand with increased public health workforce capacity.

Speed matters in public health. Rapid response prevents deaths and the spread of disease. The sooner CDC has access to up-to-date data, the sooner we can respond effectively and stop outbreaks and public health threats.

In FY 2020, Congress appropriated \$50 million for CDC to begin their multi-year data modernization efforts. In addition, the CARES Act provided \$500 million for public health data modernization. These funds will be used to transform the current

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siloes data systems to common platforms that enable rapid, bi-directional flows of data and information between CDC and state health departments and to train and build a data-savvy public health workforce. These funds will also support state and local public health departments to make catalytic investments in data science, and to access technical support in this transition from other partners, academic institutions and industry. Finally, these funds will support continued innovation in developing and evaluating next generation public health data tools, modeling and predictive analysis, artificial intelligence applications for public health, and machine learning approaches.

The Honorable Diana DeGette (D-CO)

1. **A 2016 Surgeon General report stated that young people may be trying e-cigarette products based on the belief that e-cigarettes are less harmful than other tobacco products. However, a single e-cigarette pod is comparable to a pack of combustible cigarettes. What are some potential health consequences of higher concentrations of nicotine that are present in some e-cigarette products?**

Response: Nicotine is a highly addictive drug and individuals who use tobacco products often can develop nicotine dependence and tobacco use disorder. Increased nicotine consumption has the potential to result in greater nicotine dependency, which can lead to increased use, worsened withdrawal, and greater difficulty in quitting using tobacco. It is also known that nicotine is harmful to the developing brain and that use in adolescence can harm the parts of the brain that control attention, learning, mood, and impulse control. The brain's prefrontal cortex is not fully developed until the age of 25.

In addition, nicotine is acutely toxic at high doses. The high concentrations of nicotine in e-cigarette liquids has potential to result in nicotine toxicity or poisoning, particularly in young children who require less nicotine to experience toxic effects. Symptoms of acute nicotine toxicity include gastrointestinal and cardiovascular effects (e.g., nausea, vomiting, diarrhea, rapid heart rate), seizure, and, in rare cases with very high nicotine doses, death.

The newer types of e-cigarettes contain nicotine salts as opposed to the freebased nicotine found in combustible cigarettes and in earlier designs of e-cigarettes. This new nicotine formulation allows particularly high levels of nicotine to be used with less irritation. This changing product landscape can increase risks for adverse outcomes as high levels of nicotine are delivered more efficiently.

In addition, risks of secondhand exposure to e-cigarette vapor by bystanders could be higher with new products. Studies done several years ago with products with lower concentration of nicotine already showed adverse effects among bystanders who were exposed.

2. **We know without question that long-term use of conventional cigarettes is extremely dangerous and has serious adverse medical risks. Decades of prevention efforts have**

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been devoted to driving the smoking rate down among youth to current day historic lows.

- a. In addition to a quarter of youth risking nicotine addiction due to their use of e-cigarettes, is there evidence pointing to reasons to be concerned about vaping being an on-ramp for young people to transition to conventional cigarette use?**

Response: Dozens of studies have found some evidence that e-cigarette use increases the frequency and amount of cigarette smoking in the future. The 2018 National Academy of Sciences report, which summarized the body of evidence, concluded: “Among youth and young adult e-cigarette users who ever use combustible tobacco cigarettes, there is moderate evidence that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking.” However, a definitive causal link of e-cigarettes serving as an “on-ramp” to conventional cigarette smoking effects has not been proven.

The limited studies on youth transition from e-cigarettes to combustible cigarettes were conducted before the current generation of e-cigarettes (e.g., pod mod e-cigarettes that have higher levels of nicotine) were widely available. However, any youth use of e-cigarettes is unsafe, irrespective of whether they transition to cigarette smoking.

- b. Are the youth who are using e-cigarettes ones that would have started smoking regardless?**

Response: Based on the available evidence on youth susceptibility, some youth who are using e-cigarettes today are not otherwise susceptible to cigarette smoking. In 2019, over 60% of high school and middle school students who reported using e-cigarettes used e-cigarettes exclusively.

The Honorable Brett Guthrie (R-KY)

- 1. Once a provider or state collects a sample, where are the samples that are collected sent for testing?**

Response: As of February 3, 2020, CDC is no longer accepting clinical or product samples related to EVALI cases. State health departments, usually their state public health laboratories, handled the submission of e-cigarette, or vaping, products associated with the national outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI). States that wanted to submit case-associated patients’ e-cigarette, or vaping, products could contact either CDC or FDA, who used information from the states to triage samples (e.g., volume of liquid) and tell states where to send the samples. Case-associated patients’ products were sent to FDA for testing the e-liquid itself and, when sufficient e-liquid volume is available, CDC also received patients’ products for aerosol emissions testing.

CDC entered data from their testing in a secure repository to link epidemiologic, clinical, and product sample information to cases and FDA sent the lab results to CDC. The agencies also reported data to states. CDC and FDA developed a visual schematic that illustrated this process, which can be found at: <https://www.fda.gov/news-events/public-health-focus/lung-injuries-associated-use-vaping-products>. This approach built on previous data exchange and partnership with FDA. CDC's investments in data modernization and related workforce development will enable CDC and partners to detect and respond to emerging problems more quickly and effectively.

a. How many samples have been received for testing to date?

Response: With respect to case-associated products for aerosol testing, CDC began receiving product samples the week of October 22, 2019. CDC successfully performed aerosol testing on 174 of the 278 case-associated products received since October 2019. CDC was not able to test products that were empty, defective, or otherwise did not generate adequate aerosol.

Due to the subsequent identification of the primary cause of EVALI, and the continued decline in EVALI cases and deaths since a peak in September 2019, CDC stopped collecting clinical and lab samples related to EVALI cases as of February 2020. However, CDC continues to monitor EVALI cases and conducts activities with existing data sources.

More information about FDA's lab analyses can be found at: <https://www.fda.gov/news-events/public-health-focus/lung-injuries-associated-use-vaping-products>.

b. How many of those samples have been tested and what are they being tested for?

Response: CDC tested case-associated e-cigarette, or vaping, product aerosol emissions for diluents/additives, active ingredients, and breakdown products. Because the process of heating and vaporization of an e-liquid can change its chemical makeup, it was important for CDC to test the aerosol emitted from the e-liquid (if there is sufficient volume), as a complement to FDA's testing of the e-liquid itself. FDA analyzed e-liquids for the presence of a broad range of chemicals to provide insight into the nature of the chemical exposure(s) contributing to the EVALI outbreak.

c. Has the CDC or FDA requested samples from commercial e-cigarette manufacturers to compare to those collected in the investigation?

Response: CDC's Tobacco Lab has studied the aerosol of commercially-obtained, nicotine-containing e-cigarette, or vaping, products for over a decade. CDC's

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attempts to purchase a wider range of products has been complicated by the varying legal landscape related to cannabinoids and THC. CDC compared the information it had about the aerosol of the products it previously studied to the aerosol data it collected as part of this investigation. FDA's labs also obtained commercially-obtained products before and during this investigation and analyzed them.

d. How do the samples compare? Are you finding that the samples are the same, or are commercial samples being modified after purchase?

Response: The focus of CDC's laboratory investigation was not to identify specific product modifications. However, CDC has over a decade of experience analyzing nicotine-containing e-cigarettes and did not notice any obvious or widespread differences between the commercially-obtained products that we have tested in the past and the EVALI-associated nicotine-containing products received since October 2019. We did note that some products contained more than one active ingredient (usually at low concentrations), which could have resulted from users refilling and reusing cartridges with different vaping liquids. The EVALI-associated CBD and THC products had minimal data against which they could be compared because of a lack of surveillance of these emerging product marketplaces.

Laboratory analyses were nearly complete in March 2020 when COVID-19 significantly disrupted laboratory activities, including aerosol testing. Analyses have now restarted, but staffing constraints continue to affect laboratory operations. We do not yet have a defined timeline for completion.

e. Can you determine from the samples provided how many are counterfeit products?

Response: This issue falls outside the scope of our analysis of constituents. There are a variety of factors used to determine whether a product is counterfeit, including product packaging, access source, etc. As the nation's health protection agency, CDC's analysis of aerosol emissions is specifically intended to identify constituents associated with health risk. We therefore defer assessment of the potential counterfeit nature of sample products to enforcement entities.

However, some self-reported data from EVALI cases are available on this issue. On December 6, 2019, CDC published a MMWR report that analyzed national data on specific THC-containing product use reported by EVALI patients. Overall, more than 130 different THC-containing products were reported by EVALI patients. Dank Vapes were the most commonly reported THC-containing product used by EVALI patients nationwide, followed by TKO, Smart Cart, and Rove. Dank Vapes are a class of largely counterfeit THC-containing product of unknown origin. These products do not have a single source of production or distribution even though they are referred to with names that might suggest otherwise.

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Although Dank Vapes were the most frequently reported THC-containing product used by patients in all four regions of the country, regional differences were seen in reports of other THC-containing products and brands. The data in the report further supports that EVALI is associated with THC-containing products and that it is not likely associated with a single brand of THC-containing product. More information can be found at:

https://www.cdc.gov/mmwr/volumes/68/wr/mm6849e1.htm?s_cid=mm6849e1_w.

f. What additional information or samples would you need to determine whether the samples involved in the investigation are counterfeit?

Response: This issue is outside the scope of our analysis of constituents. We again would defer to the appropriate enforcement entities to address this issue.

2. In addition to analyzing the vaping liquid, do CDC and FDA investigators also receive and examine the vaping or e-cigarette device itself?

Response: Please see above for FDA's and CDC's coordination on testing product samples. When CDC received samples of case-associated e-cigarette, or vaping, products from patients for aerosol testing and also received patients' devices, CDC attempted to replicate the patients' exposure by testing aerosol emissions produced using those patients' personal devices. Many of the patients' product samples submitted by state health departments consisted of liquid that was not accompanied by a device. However, as a result of CDC's previous research on e-cigarette, or vaping, product aerosol, CDC has multiple clean and fully-charged devices that interface with all of the typical cartridges in use today. CDC used those devices when testing samples of case-associated products from patients who did not also provide their personal devices.

a. Have investigators found modified e-cigarette or vaping devices in any of the outbreak cases? If so, how many cases?

Response: Several published reports assessed the e-cigarette, or vaping, products that EVALI patients reported using. They can be found at the bottom of this page: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease/resources/index.html. The studies focused on where products were obtained and the substances used in the products, rather than on whether patients modified their e-cigarette, or vaping, product devices.

b. Are most of the devices closed system products or open system products?

Response: The October 4, 2019 MMWR report from Illinois and Wisconsin (<https://www.cdc.gov/mmwr/volumes/68/wr/mm6839e2.htm>) provides detailed data regarding e-cigarette, or vaping, products used among EVALI patients in those two states. Most were universal 'vape pens' that are adaptable to the prefilled THC

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cartridges reported by many patients. A December 13, 2019 MMWR report (https://www.cdc.gov/mmwr/volumes/68/wr/mm6849e1.htm?s_cid=mm6849e1_w) provides data regarding e-cigarette, or vaping, products used among EVALI patients throughout the U.S. Overall, 80% of hospitalized EVALI patients reported using THC-containing e-cigarette, or vaping, products. Many of the products that patients reported using that were sold under a brand name were cartridge-based systems.

c. Are you at least receiving the devices? Why not also collect and examine the devices themselves to look for commonalities?

Response: As noted above, when CDC received samples of case-associated e-cigarette, or vaping, products from patients for aerosol testing and also received patients' devices, CDC attempted to replicate the patients' exposure by testing aerosol emissions produced using those patients' personal devices.

3. What does scientific research show about the effects of nicotine on the adolescent brain? What is the effect of nicotine delivered by e-cigarettes as compared to combustible cigarettes?

Response: Compared with older adults, the brain of youth and young adults is more vulnerable to the negative consequences of nicotine exposure. The Surgeon General has concluded that nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain. The effects include addiction, priming for use of other addictive substances, reduced impulse control, deficits in attention and cognition, and mood disorders.

Also of concern is that newer types of e-cigarettes contain nicotine salts as opposed to the freebased nicotine found in combustible cigarettes and in earlier designs of e-cigarettes. This new nicotine formulation allows particularly high levels of nicotine to be used with less irritation, potentially increasing the likelihood and ease with which young people can initiate the use of these products and may increase levels of addiction.

The brain's prefrontal cortex is not fully developed until the age of 25.

The Honorable Michael C. Burgess (R-TX)

1. The CDC has recommended that the public consider refraining from using e-cigarette or vaping products until more is known about the health risks and causes. What is the CDC doing to ensure that the states are properly reporting lung illness associated with the use of e-cigarette products so that it can advise the public?

Response: Beginning in August 2019, CDC worked with FDA, state and local health departments, and public health and clinical stakeholders to get at the root cause or causes of these lung injuries. As mentioned above, the investigation has shown that THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online dealers, are linked to most EVALI cases and play a major role in the outbreak. Vitamin E acetate is strongly linked to the EVALI outbreak. However, the

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evidence is not sufficient to rule out the contribution of other chemicals of concern, including chemicals in either THC or non-THC products, in some of the reported EVALI cases. CDC and FDA recommend that people not use THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online dealers. Vitamin E acetate should not be added to any e-cigarette, or vaping, products. Additionally, people should not add any other substances not intended by the manufacturer to products, including products purchased through retail establishments.

Throughout the investigation, CDC provided technical assistance as well as tools and resources to states to assist with data collection. This included:

- Development and dissemination of data collection, exchange, and analysis tools and provision of data science and epidemiological expertise, in related areas, including case definitions and interview questionnaires to state health departments
- Development of guidance documents to assist public health laboratories, healthcare providers, pulmonologists, pathologists, and others with specimen collection, storage, and submission
- Individual consultation with states, including on: case definitions, data collection and analytic tools, investigation tools, autopsies
- Individual consultation with states on communications, health alerts, and public outreach
- Provision of multi-state weekly updates to facilitate information-sharing across state health departments, labs, and partners
- Hosting calls with health departments and clinicians to learn about and offer a forum for sharing current experiences in evaluation, management, and clinical course of patients suspected of having lung injury associated with use of e-cigarette, or vaping products
- Activation of the Laboratory Response Network for Chemical Threats, a network of CDC, state, and local public health labs that provide critical laboratory testing support to the programs and providers who are responding to this outbreak
- Engagement with a multi-state collaborative on cannabis representatives from health departments and public health, including and state regulatory agencies, which allowed for information sharing across states.

CDC activated its Emergency Operations Center (EOC) on September 16, 2019, to enhance the inter-agency response to this investigation, which allowed the agency to provide increased operational support for the response to meet the outbreak's evolving challenges. Since that time, hundreds of staff from across CDC assisted with the investigation from multiple disciplines, including surveillance/epidemiology, clinical, policy, communications, laboratory, and others. Due to the identification of the primary cause of EVALI and the continued decline in EVALI cases and deaths since a peak in September 2019, CDC transitioned its coordination of activities related to the EVALI outbreak from a centralized emergency operations center back to individual CDC programs in January 2020. CDC continues to work alongside FDA and state health

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departments to protect the nation from this public health threat. Ongoing activities have included conducting EVALI-related surveillance and evaluation, examining product and biological samples, and providing guidance to state and local health departments, healthcare providers, and the public. CDC has also continued to ensure prompt communication of any new information as it becomes available.

- 2. In light of the fact that some of the causes of these lung illnesses associated with the use of e-cigarettes has yet to be fully understood, can you explain how the CDC will evaluate topics such as the type of products are causing harm and where those products are being purchased?**

Response: CDC put its scientific expertise to use across epidemiologic, laboratory, and clinical realms to gain a more comprehensive understanding of outbreak-associated lung injuries and the potential cause or causes. With regard to the collection and analysis of data about the products, ingredients, and compounds that may be responsible for the outbreak, CDC took multiple approaches to bring together different sources of data. For example, CDC developed a uniform survey for states to use to collect their data and worked with states to compile data across states. CDC's National Syndromic Surveillance System was modified to capture events passing through our nation's emergency rooms. CDC reported data, including data related to products, sources, and risk behaviors, and other relevant factors, on patients with EVALI. As discussed above, CDC transitioned its response activities from a centralized emergency operations center back to individual CDC programs in early 2020.

CDC continues to monitor EVALI cases and continues to conduct case-finding activities through its National Syndromic Surveillance System, which collects EVALI-related symptom data from throughout the U.S. Critically, CDC's investments in data modernization and related workforce development will enable CDC and partners to detect and respond to emerging problems, like EVALI, more quickly and effectively.

CDC continues to partner with states to explore additional quantitative and qualitative studies to increase our understanding of the outbreak and product use behaviors among EVALI patients and individuals engaging in the use of e-cigarette, or vaping, products. For example, the 174 products that CDC successfully analyzed were associated with approximately 71 EVALI cases. Most cases sent us multiple products. Future merging of the CDC laboratory data with epidemiological data on these cases will allow us to further explore the data and better characterize exposures related to EVALI.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
“Sounding the Alarm: The Public Health Threats of E-Cigarettes”

September 25, 2019

**Dr. Joneigh Khaldun, Chief Deputy Director for Health and Chief Medical Executive,
Michigan Department of Health and Human Services**

The Honorable Frank Pallone (D-NJ)

1. States, including yours as the first, have attempted to address youth e-cigarette use by, among other efforts, banning certain flavored e-cigarette products.

- a. Why is addressing access to flavors so important in addressing the youth epidemic of e-cigarette use?

There is overwhelming evidence that youth initiate use of e-cigarettes because of flavors. Data from recent studies such as the CDC’s population assessment of tobacco and health (PATH) study found that 96.1% of 12-17 year olds who initiated e-cigarette use since the last survey started with a flavored product,¹ 97% of current youth e-cigarette users used a flavored e-cigarette in the past month, and 70.3% say they use e-cigarettes because “they come in flavors I like.”²

- b. Do you believe there should be a nationwide ban on non-tobacco e-cigarette flavors, including mint and menthol?

Youth vaping is a public health emergency and measures such as a flavor ban are necessary to protect the public health. As Chief Medical Executive for the State of Michigan, I found that a public health emergency exists in the State of Michigan regarding youth use of e-cigarettes. That finding formed the basis for emergency rules that prohibited the sale, transport, or distribution of flavored nicotine vapor products in Michigan. Including mint and menthol is important as the CDC National Youth Tobacco 2018 data indicates that menthol or mint was popular among 75.5% of High Schooler e-cigarette users in 2018 and 65.9% in 2019.³

¹ <https://www.fda.gov/media/121384/download> fn. 14-15.

² *Id.* at fn. 17.

³ Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products. September 11, 2019. <https://www.fda.gov/tobacco-products/youth-and-tobacco/youth-tobacco-use-results-national-youth-tobacco-survey>.

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- c. Do you think the measures contained in the emergency rules will do enough to help reverse the trend of youth use rates, or do you need FDA to do more?

Despite the FDA's August 2016 deeming rule, the state of Michigan and other states across the United States have seen a marked increase in youth usage of e-cigarettes. After that rule went into effect, the numbers of high schoolers using e-cigarettes continued to rise significantly, more than doubling from 2016 to 2019. The US Surgeon General identified strategies to combat the epidemic of youth use of e-cigarettes to include removing access to flavors and restricting marketing and advertising for youth. While states are working to reduce youth access to flavored e-cigarettes, FDA action to prohibit flavors would assist and streamline nationwide efforts to reduce the national rates of youth addiction to nicotine through the use of e-cigarettes.⁴

- d. What types of resources has your department had to marshal to respond to both the vaping lung illness investigations as well as in response to youth vaping use?

The Michigan Department of Health and Human Services (MDHHS) Tobacco Section has shifted full time staff from their regular assignments in order to address the youth e-cigarette epidemic. These staff members have committed significant time to reaching out to state level partners to educate them on the youth e-cigarette epidemic. The Tobacco Section team spent many hours vetting existing e-cigarette resources and creating new ones, which were then used to publish a dedicated e-cigarette webpage. This webpage contains sections to educate and assist school staff and administrators, parents, and healthcare professionals. In addition, there has been increased collaboration within the Department in order to maximize efficacy and resources while addressing the e-cigarette epidemic. Numerous staff and managers throughout MDHHS have dedicated considerable time and resources to assist in addressing the e-cigarette epidemic as it relates to their service populations. Additional resources that are necessary for continued response include funding for media campaigns to raise awareness and education and additional staffing to handle statewide education and prevention efforts.

With regard to the response to the outbreak of severe lung injury associated with vaping or e-cigarette use, MDHHS first became aware of the outbreak in early August when it was reported in Wisconsin and Illinois. In anticipation that this outbreak would reach Michigan, MDHHS assigned a masters level epidemiologist and a medical epidemiologist to develop a plan to identify possible injury cases and conduct investigation. The first patient suspected of having this disease was reported in mid-August, and reporting has steadily increased since then with no signs of abatement. (As of 10/24/2019 80 cases have been reported and 43 have met the CDC case definition for "confirmed" or "probable" injury case, including one death). MDHHS

⁴ <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

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has engaged significant resources since mid-August to develop and maintain the public health surveillance system; review medical records and interviews; ensure communications with the public, local health departments, medical associations, other states agencies, CDC and FDA; and utilize the MDHHS laboratory in processing and shipping of vaping products and clinical specimens to the FDA and CDC. Local health department staff already experienced with infectious disease outbreaks have been trained to collect medical records and conduct interviews of reported patients. The MDHHS epidemiologist and medical epidemiologist have worked almost full time on the investigation most weeks, taking away from other work responsibilities. A senior level public health consultant was brought on to coordinate the response and public communications. This response team has worked closely with the MDHHS Tobacco Control Program to ensure consistent messaging regarding this outbreak. Senior management in MDHHS has been deeply engaged in policy decisions using the surveillance data provided by the outbreak response team and nationally by CDC, aided by the communications, public health administration, legal affairs, and the office of the Director.

- e. To what extent does this youth vaping crisis require additional resources or the development of new approaches to address nicotine addiction among young people?

The Michigan Department of Health and Human Services has responded to the increase in demand for youth vaping resources by partnering with National Jewish Health, one of the nation's largest quitline providers. Funding was provided to develop a new program designed for teens and with teen input. The program is called My Life My Quit (MLMQ) and relies heavily on interactive text and online coaching and uses promising practices. In the four years prior to launch of MLMQ, an average of 23 new youth (under 18) participants were enrolled across the 16 states National Jewish Health serves. Since launch of the MLMQ dedicated youth program there have been an average 81 new participants enrolled per month, mainly related to having a dedicated program that could be promoted directly to youth.

Additional funding is needed to help states and national partners to develop and test youth vaping cessation strategies such as MLMQ in order to move from promising practices to an evidence-based approach. Other points to consider include:

- Raising the minimum legal age of sale of tobacco products, including e-cigarettes, to 21 years of age will help to reduce youth use of tobacco products, prevent youth initiation, and reduce the morbidity and mortality caused by tobacco use.
- Dedicating a portion of each state's Master Settlement Agreement revenue to state tobacco prevention and control programming, including funding to assist youth to quit e-cigarette/tobacco use, will help states to address youth use of tobacco products including e-cigarettes.

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The Honorable Diana DeGette (D-CO)

1. According to your testimony, between the years of 2015–2016 and 2017–2018, counties across Michigan witnessed between a 30 percent to 118 percent increase in e-cigarette use among high school students who used an e-cigarette in the past month. What are some of the concerns you have regarding the potential long-term public health consequences of this marked increase in use?

The tobacco industry knows that the younger children are when they first experiment with or begin using tobacco, the more likely they are to become addicted, life-long tobacco users. This early use, which often leads to addiction, can lead to tremendous health implications for these people.⁵

According to the CDC, most e-cigarettes contain nicotine—the addictive drug in regular cigarettes, cigars, and other tobacco products. Nicotine can harm the developing adolescent brain, which continues to develop until about age 25. Using nicotine in adolescence can harm the parts of the brain that control attention, learning, mood, and impulse control, and may increase risk for future addiction to other drugs.⁶

The long term health consequences of the epidemic are still being determined, but are likely to be serious. Young adults who use e-cigarettes are more than four times as likely to begin smoking tobacco cigarettes within 18 months as their peers who do not vape.⁷ As they shift to become users of combustible cigarette, there is a greater potential for increased health consequences ranging from heart disease, stroke, cancer, and asthma among others. Studies of health impact of e-cigarettes have begun to find health consequences of e-cigarettes to include oral, lung, cardiovascular and dermatologic health.⁸ Current adult asthma

⁵ <https://www.tobaccofreekids.org/what-we-do/us/sale-age-21>

⁶ https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html.

⁷ Initiation of Traditional Cigarette Smoking after Electronic Cigarette Use Among Tobacco-Naïve US Young Adults. The American Journal of Medicine. April 2018, Volume 131, Issue 4, Pages 443.e1–443.e9.

⁸ It's Worse Than You Think (Advisory article). January 10, 2019. Scott Froum, DDS, and Alisa Neymark, DDS <https://www.perioimplantadvisory.com/articles/2019/01/vaping-and-oral-health-it-s-worse-than-you-think.html>

⁸ Inflammatory Response and Barrier Dysfunction by Different e-Cigarette Flavoring Chemicals Identified by Gas Chromatography-Mass Spectrometry in e-Liquids and e-Vapors on Human Lung Epithelial Cells and Fibroblasts. Appl In Vitro Toxicol 2017;3:28–40. doi:10.1089/aivt.2016.0030

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prevalence is nearly twice as high in e-cig smokers (18.4%) as in non-smokers (10.6%).⁹ Studies have also shown acute effects of e-cigarette use to vasculature and airways.¹⁰

2. Your state was the first to implement a flavored e-cigarette product ban in the country. Why do you believe this and other actions are critical to act swiftly to address the youth epidemic of e-cigarette use?

Michigan was the first state to announce a flavored nicotine vapor ban in the country, but the United States still has a long way to go to protect our children from the dangers associated with vaping and nicotine addiction. E-cigarettes are a much newer product than cigarettes, though they have been around in the United States since approximately 2007. Since the deeming rule went into effect in 2016, the number of high schoolers using e-cigarettes has continued to rise significantly, more than doubling from 2016 to 2019. It is clear that children still have access to e-cigarettes at an alarming rate. According to the U.S. Surgeon General, it is flavors that have fueled the epidemic rise in youth use of e-cigarettes. The Surgeon General identifies removing youth access to flavors and restricting advertising and marketing are effective strategies to address the youth epidemic of e-cigarette use.¹¹ A ban on flavored nicotine vapor products is therefore necessary to protect the public health, safety, and welfare.

The Honorable Brett Guthrie (R-KY)

1. What are your states seeing in terms of data and trends with respect to youth use of e-cigarettes over the past few years?
 - a. For the data that is included in these statistics, how often or how recently does an individual have to have used an e-cigarette to be captured in the data (e.g. in the last 30 days, single-use versus chronic use)?

The National Youth Tobacco Survey reports data from past 30-day use of e-cigarette use as well as use over lifetime.

⁹ Barth O, Anderson B. Michigan Adults with Current Asthma: Symptoms, Management, and Productivity. Michigan BRFSS Surveillance Brief. Vol. 11, No. 2. Lansing, MI: Michigan Department of Health and Human Services, Lifecourse Epidemiology and Genomics Division, December 2018.

¹⁰ Acute Effects of Electronic Cigarette Inhalation on the Vasculature and the Conducting Airways. Cardiovascular Toxicology, pp 1–10. First Online: 08 April 2019. Lukasz Antoniewicz, Amelie Brynedal, Linnea Hedman, Magnus Lundbäck, Jenny A. Bosson
<https://link.springer.com/article/10.1007%2Fs12012-019-09516-x>

¹¹ <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

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- b. Does the data break out how many are using e-cigarettes for tobacco products (e.g. nicotine) or for THC products?

No. The National Youth Tobacco Survey questions asks whether the electronic cigarettes that were used in the past 30 days consists of flavors such as menthol, mint, clove, spice, candy, fruit, chocolate, or other sweets. It does not directly ask about THC products.

2. How does that data compare to trends regarding youth use of combustible cigarettes?

According to data obtained from the Youth Risk Behavior Survey (1999-2017), the trend of current cigarette smoking among youth had been decreasing from 1999 until 2017 (the last year data is available for Michigan). For tobacco use in general, a decreasing trend was seen over the same period of time until 2015 when it started to trend up again due to e-cigarette use.

The Honorable Michael C. Burgess (R-TX)

1. The state of Michigan has banned the sale of flavored e-cigarettes, Dr. Khaldun, how will the Michigan Department of Health and Human Services regulate and enforce the ban?

The emergency rules are enforced by both state and local law enforcement. Local law enforcement may also get assistance from the Michigan Department of Health and Human Services Tobacco Section.

A person who violates any provision of the rules is guilty of a misdemeanor, punishable by imprisonment for not more than six months, or a fine of not more than \$200, or both, as set forth by MCL [333.2261](#). Fines for selling flavored nicotine vapor products are calculated on a per-item per transaction basis. Retailers, including online retailers, and resellers are subject to the emergency rules.

2. Following the ban in your state, what will Michigan do to monitor the impact a ban could have on smoking cessation for those who utilize e-cigarettes to quit smoking?

The Tobacco Control Program has developed an evaluation plan to monitor and assess the e-cigarette use rate among youth before and after the ban including the youth quit attempts through the My Life My Quit program.

E-cigarette has not been approved by the FDA as a tobacco cessation method therefore cannot be evaluated as such.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
“Sounding the Alarm: The Public Health Threats of E-Cigarettes”

September 25, 2019

Dr. Elizabeth Cuervo Tilson, State Health Director and Chief Medical Officer, North Carolina Department of Human and Health Services

The Honorable Frank Pallone (D-NJ)

1. Your testimony mentioned a range of recommendations to address youth vaping use, including curbing marketing to youth, increasing the legal age of tobacco sales to persons aged 21 and over, and reducing youth access to flavored tobacco products. Why isn't one approach—such raising the age of sale to 21—enough to address the youth e-cigarette epidemic?

Lessons learned from the comprehensive approach to tobacco control of combustible cigarettes can be applied to the approach to e-cigarette use. Comprehensive strategies that combine policies to **decrease access to** (e.g., raise the age of sale to 21, price increases) with those that **reduce demand and appeal for** (e.g., curbing marketing to youth) and **acceptability of** (e.g., smoke free policies, social messaging) e-cigarettes, as well as with those to **promote effective cessation** for people currently using tobacco products, when implemented with robust enforcement and adequate funding, have been found to be most effective.

The CDC Best Practices for Comprehensive Tobacco Control Programs (https://www.cdc.gov/tobacco/stateandcommunity/best_practices/index.htm) state “individual components are most effective when they work together to produce the synergistic effects of a comprehensive tobacco control program.” Similarly, the [Community Preventive Services Task Force \(CPSTF\)](#) recommend comprehensive tobacco control programs based on strong evidence of effectiveness in reducing tobacco use and secondhand smoke exposure. Further, the Office of the Surgeon General, the American Academy of Pediatrics, and the Association of State and Territorial Health Officers (ASTHO) have released recommendations for federal and state policies to decrease both youth demand for and access to e-cigarettes and promote effective cessation for people currently using tobacco products. There is overall consensus to consider some type of policies within each recommended domain described in the written testimony.

In addition, [according to FDA](#), 96.1 percent of youth who initiated e-cigarette use did so with a flavored e-cigarette product. Therefore, restricting the sale of flavored e-cigarette products

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would be a particularly key component of a comprehensive policy strategy to reduce youth e-cigarette use.

Specific to consideration of raising the age of sale of tobacco products to 21, the American Heart Association, American Cancer Society Cancer Action Network and the American Lung Association agree that a strong tobacco minimum legal sales age of 21 policy (Tobacco 21) should include the following robust provisions:

- Define tobacco products to include current and future tobacco products, including e-cigarettes;
- Prohibit the sale of tobacco products to persons under the age of 21;
- Require the tobacco retailer or their employee to verify the age of the purchaser prior to the sale;
- Require tobacco retailers to post signs stating that sales to persons under the age of 21 are prohibited;
- Designate an enforcement agency and establish a clear enforcement protocol;
- Create a tobacco retail licensing program if the jurisdiction has the authority to do so under state law,
- Dedicate funding to fully cover enforcement costs, either through licensing fees or as a provision in a state statute or local ordinance;
- Provide authority for the state, county, or municipality to inspect tobacco retailers for compliance with Tobacco 21 and a mandated minimum number of annual compliance checks for every tobacco retail establishment;
- Provide penalties focused on the tobacco retailer or licensee rather than the youth purchaser or non-management employee. This would mean eliminating Purchase, Use, and Possession penalties where they exist in current tobacco sales laws or policies;
- Establish a civil penalty structure for violations rather than a criminal penalty structure to avoid unintended consequences that disproportionately impact marginalized communities and undermine the public health benefits of the policy, and
- Where state legislation is pursued, ensure that local jurisdictions have the authority to enact more stringent regulations for tobacco products than state or federal law.
- No exemption for military

Restriction to internet sales would complement the protective effects of restrictions on sales to youth in retail settings.

2. Your testimony highlighted emerging research from the University of North Carolina that suggests the use of e-cigarettes may lead to higher risks of emphysema, a form of chronic lung disease.

a. What are some of the gaps in research that we still have regarding the long-term use of e-cigarettes?

As the Honorable Congressman Pallone points out, unregulated e-cigarette use, products and ingredients have been rapidly evolving since introduction to the market and little is known about

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long-term use. In addition, because tobacco-related disease often presents itself decades after initiation, we will not fully understand the health consequences of e-cigarette use for some time.

In preparing our response to your follow up questions, we consulted our research colleagues at the University of North Carolina in Chapel Hill (UNC). Their input is included below as well as recommendations from our public health content experts. Areas of future research could include:

Larger population-based studies

The published studies from UNC were based on a limited sample of participants and are cross-sectional (i.e., at one point in time). The UNC researchers recommend repeating them on a larger scale that fully reflects the ethnic diversity of North Carolina and other states. The researchers also recommend additional longitudinal studies that follow cohorts of e-cigarette users over time to understand the longer term effects on exposure to e-cigarettes and ensure the findings are consistent and reproducible. Further, the researchers recommend studies to understand whether and to what extent vaping/e-cig induced health effects are reversible. These additional studies are feasible. For example, the links between elevated proteases and emphysema, bronchiectasis and lung cancer metastasis are well-established and measuring lung protease levels is fairly easy to do. Therefore, studies can be designed and implemented to assess the impact of vaping on protease levels in the population at large.

Investigating effects on organs other than lungs

In addition to lung effects, people may be experiencing vaping-associated health manifestations in other organs that need further exploration. For example, many patients are presenting with gastrointestinal symptoms prior to showing lung effects as part of the outbreak of the acute pulmonary illness. It is unknown if this has been happening in the past or is now just being uncovered as part of the outbreak and warrants further research.

Acute Outbreak of E-cigarette or vaping product use-associating lung injury (EVALI)

The CDC, FDA and state departments of health have mobilized to monitor and investigate the cases associated with acute outbreak of e-cigarette or vaping product use-associating lung injury (EVALI). CDC is tracking relapse and readmissions to the hospital and expanding the scope of its investigation to include lab tests of the heated vapor emitted from e-cigarettes, lung cells, and other substances—such as vitamin E acetate—found in e-cigarettes. They also have examined autopsy specimens, blood, lung biopsies, and urine. While we have learned a great deal to-date, CDC and FDA report that they “have not identified the cause or causes of the lung injuries in these cases, and the only commonality among all cases is that patients report the use of e-cigarette, or vaping, products. No one compound or ingredient has emerged as the cause of these illnesses to date; and it may be that there is more than one cause of this outbreak. Many different substances and product sources are still under investigation.” While, THC does seem to play a role in the majority of cases of EVALI, more research needs to be done to further identify the cause or causes of the pulmonary injury.

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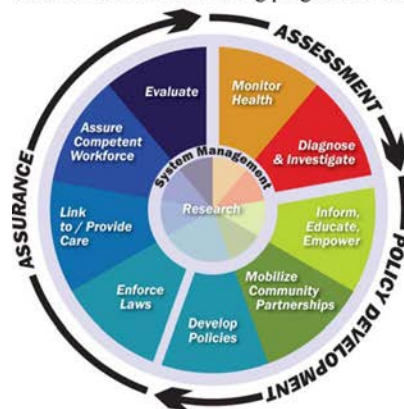
Further, as EVALI symptoms are beginning to be characterized, investigations should not be focusing solely on cases that require hospitalizations or intensive care treatment, but should also examine what symptoms of health problems may be occurring in individuals without hospitalizations. This would give us information on the extent of risk or harm to the population.

Cessation

Further research is needed on if e-cigarettes are an effective smoking cessation modality and on effective youth cessation programs and treatments.

Applied Public Health Research

One of the core functions of public health is Assessment, including collecting and analyzing information about health problems. This in turn informs Policy Development which, when enforced and linked to strong program services helps to Assure population health.



Tobacco use patterns and other drug use patterns are in a time of rapid transition in North Carolina and the U.S. as new and emerging products reach the marketplaces, which include both brick and mortar and digital marketplaces, and as new and emerging forms of social media promote use of these products.

Further study, including public health monitoring and tracking can inform policy development and strategies that minimize or eliminate harms. Systems such as the Youth Risk Behavior Survey, the more in-depth Youth Tobacco Survey, the Behavioral Risk Factor Surveillance System are critical resources for

monitoring and tracking state and national trends in tobacco use, perceptions and knowledge. These systems have suffered, and new investments are needed such that state and local public health can more rapidly adjust and monitor health trends for the purpose of preventing population health problems through evidence-based policy development and implementation

Other applied research that could be helpful include:

Content of e-cigarettes: Currently, e-cigarette products do not have consistent labels with ingredients, including nicotine levels. Evidence-based methods to assess content of e-cigarettes including nicotine levels would be helpful to inform research on health effects of chemicals in e-cigarette vapor as well as guiding proper dosing for nicotine replacement therapy for tobacco use treatment.

Pricing interventions: There is robust data from health economists for pricing strategies that are effective in preventing combustible tobacco use among young people and helping people who

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smoke combustibles to quit. There is a need for evidence for pricing interventions to deter young people from starting to use e-cigarettes.

Mass Media: NC is impressed with the [Rescue Agency's peer crowd mass media approach](#) in effectively preventing combustible tobacco initiation. It would be helpful to have community-level research to find evidence to determine if their newest "peer crowd" approach to e-cigarette prevention using mass media is also effective in preventing e-cigarette use or vaping among teens.

b. What role do you believe the federal government should play in supporting such research?

The federal government should have a role in funding, supporting, and understanding the long-term impact of e-cigarettes on the lung and other organs of the body at various levels ranging from epidemiological to biochemical.

The EVALI outbreak indicates that THC use (either by itself or as dual use) contributes to this disease. However, because of the classification of THC as a class 1 controlled substance, the ability to systematically study the toxicity and health effect of THC products in the lab is severely limiting. The federal government could facilitate research related to THC.

Epidemiological services have historically invested time and resources in the diagnosis and investigation of communicable disease outbreaks and the health impacts of acute environmental hazards and events. More investment is needed for diagnosing and investigating tobacco use and other substance use and the relation to chronic disease conditions in order to inform policy and program development. Further, more investment in monitoring systems, such as the Youth Risk Behavior Survey, is needed.

A new code within the 10th version of the International Statistical Classification of Diseases and Related Health Problems version (ICD-10) for vaping/e-cigarette would allow health care providers to document vaping/e-cigarette use in medical history, which could be crucial to understanding health effects about which we currently do not know. The new ICD-10 could also be used for tracking data on use of e-cigarettes/vaping devices.

The Honorable Diana DeGette (D-CO)

- 1. In your testimony, you noted that e-cigarette products "are available in thousands of kid-friendly flavors including candy, fruit, bubble gum, cotton candy, graham cracker, mint and menthol and some have packaging that mimic kid-friendly products like Lucky Charms cereal." Are young people using e-cigarettes today likely to be the young people who would have smoked traditional cigarettes regardless of the availability of e-cigarettes?**

It is difficult to say definitively and there are many factors that would have to be considered that are not included in the population-level data we have. However, we have indications that youth

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who are using e-cigarettes may not have used combustible cigarettes, if e-cigarettes were not available.

In North Carolina, we observed more than a decade of decline of combustible cigarette use among teens before introduction of e-cigarettes to the market. Once e-cigarettes became available, however, we saw a rapid change in the prevalence of use. From 1999-2017, we have seen a decline in the use of combustibles tobacco use in high schoolers from 31% to historic low of 8.9%, but e-cigarette use increased 894% since 2011. If e-cigarettes were just a replacement for youth who would ordinarily be using combustible cigarettes, we would not have expected to see such a dramatic change in our prevalence rates of youth use of tobacco products.

In addition, we have questions to gauge susceptibility and intention to use in our North Carolina Youth Tobacco Survey (NCYTS). More teens are susceptible or considering e-cigarettes than combustible. In addition, adolescents who use e-cigarettes appear to have fewer social and behavioral risk factors than conventional cigarette users. Further, according to a 2015 report from the National Health Interview Survey, 40 percent of young adults who use e-cigarettes every day or some days were never smokers before trying e-cigarettes.

Further, flavors that appeal to youth are playing a role in youth initiation of e-cigarettes. For the most part, these flavors are not available in combustible cigarettes. Per the North Carolina Youth Tobacco Survey (NCYTS) the main reasons NC students report using e-cigarettes are because a friend or family member uses them and because they were available in flavors. [According to the FDA, 96.1 percent of youth who initiated e-cigarette use](#) did so with a flavored e-cigarette product. A 2016-2017 FDA study showed nearly all (97%) current youth e-cigarette users had used a flavored e-cigarette in the past month and that 70% of youth users do so "because they come in flavors I like." The 2018 National Youth Tobacco Survey reports 68% of high school students currently use e-cigarettes of any flavor and 51% currently use menthol or mint flavored cigarettes.

For combustible cigarettes, the only flavor legally available is menthol. In addition, JUUL, the most widely sold e-cigarette product in the United States, contains nicotine salts, which [CDC has found](#) allows high nicotine levels to be inhaled more easily and with less irritation than other tobacco products. For these reasons, e-cigarette use may be more appealing to youth than combustible cigarettes, as evidenced by recent increasing youth rates of overall tobacco product use following years of decline.

Further concerning is the data from the Surgeon General's Report 2016 that youth initiation of e-cigarettes can often lead to using traditional tobacco products in the future.

The Honorable Brett Guthrie (R-KY)

1. What are your states seeing in terms of data and trends with respect to youth use of e-cigarettes over the past few years?

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The data trends in North Carolina delineate the challenges we face as public health officials in addressing the alarming trends of youth vaping. The 2017 North Carolina Youth Tobacco Survey (NCYTS) found that although combustible cigarette smoking was the lowest ever recorded among high school students at 8.9%, e-cigarette use increased 894% since 2011. E-cigarettes have become the most commonly used tobacco product among youth in North Carolina, with 16.9% of high school students currently using them, and with even more (23.3%) saying they plan to use them in the next year. Further, adolescents and young adults who have used e-cigarettes are more likely to report using traditional cigarettes at follow-up compared with those who had not.

Like in North Carolina, youth e-cigarette use is increasing across the country. The 2018 National Youth Tobacco Survey saw a 78% increase in high school e-cigarette use between 2017 and 2018. The 2019 Monitoring the Future survey revealed similar results, with youth e-cigarette use more than doubling between 2017 and 2019 among 8th, 10th and 12th grade students nationwide. The increase from 2017-2018 was the largest ever recorded in the survey's 43-year history for any single substance.

Based on this data, we believe that the 2017 NC Youth Tobacco Survey data underrepresents the scale of the youth e-cigarette use epidemic in North Carolina. Currently, our Division of Public Health is working with the NC Department of Public Instruction and randomly selected schools across the state to conduct the 2019 NC Youth Tobacco Survey. We expect to have the survey results in early 2020. Ninety percent of adults that report using tobacco products reported starting before the age of 18. That is why this trend in youth use is incredibly concerning.

- a. For the data that is included in these statistics, how often or how recently does an individual have to have used an e-cigarette to be captured in the data (e.g. in the last 30 days, single-use versus chronic use)?**

The prevalence data that was presented from the National Youth Tobacco Survey and the North Carolina Youth Tobacco Survey was current use, meaning use in the past 30 days. This is a standard measure of regular youth use used by CDC and other national youth tobacco surveys.

- b. Does the data break out how many are using e-cigarettes for tobacco products (e.g. nicotine) or for THC products?**

In North Carolina 9.6% of all high school students had ever vaped cannabis in 2017. This increased by grade, ranging from 4.7% of all 9th grade students to 15.5% of all 12th grade students. Among all high students who had used an e-cigarette in the past 30 days, 29.3% had ever vaped cannabis. Among all high school students who had smoked a cigarette in the past 30 days, 32.2% had ever vaped cannabis.

- c. How does that data compare to trends regarding youth use of combustible cigarettes?**

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Cigarette smoking has been consistently decreasing in North Carolina since the North Carolina Youth Tobacco Survey began in 1999. Between 1999 and 2017 high school cigarette use decreased 71%, from 31.6% to 8.9%, and middle school cigarette use decreased 83%, from 15% to 2.5%.

While the 2017 North Carolina Youth Tobacco Survey (NCYTS) found that although combustible cigarette smoking was the lowest ever recorded among high school students at 8.9%, e-cigarette use increased 894% since 2011. E-cigarettes have become the most commonly used tobacco product among youth in North Carolina, with 16.9% of high school students currently using them, and with even more (23.3%) saying they plan to use them in the next year. Further, adolescents and young adults who have used e-cigarettes are more likely to report using traditional cigarettes at follow-up compared with those who had not.

This survey also asks some evidence-based questions that gauge susceptibility – intention to use. More teens are susceptible or considering e-cigarettes than combustible cigarettes.

**Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

**Hearing on
“Sounding the Alarm: The Public Health Threats of E-Cigarettes”**

September 25, 2019

Dr. Lee Norman, Secretary, Kansas Department of Health and Environment

The Honorable Frank Pallone (D-NJ)

1. In your testimony you stated that “we could have benefited by having much tighter regulatory controls on [vaping devices] and the vaping solutions.” What more could the FDA do to protect the public from the public health harms of e-cigarettes?

FDA needs to execute their authority to regulate vaping and e-cigarette products and prioritize the enforcement of those products that do not have FDA authorization for marketing. FDA should also provide clarification to the public that just because an ingredient is FDA approved for human ingestion, does not mean the product has been approved for human inhalation. The FDA needs to act quickly. They originally planned to require premarket tobacco product applications from all e-cigarette manufacturers by 2018, but that deadline got [pushed back](#) to as late as 2022 before the federal court ruling that brought it back up to May 2020.

2. You also stated in your testimony that we know very little about the contents of the aerosolized vaping solution. Why is it important to understand the potential health effects of the contents of these aerosolized solutions used in vaping?

It is essential to understand the potential health effects of the contents in vape solutions because as of October 29, 2019 they have been related to over 1,600 cases of lung injury and illness, including 34 deaths in 24 states. In addition to the potential risk to the user, there has been limited research on the effects of secondhand aerosol to non-users who happen to be nearby someone using an Electronic Nicotine Delivery System device.

The Honorable Diana DeGette (D-CO)

1. You noted in your testimony the Kansas Department of Health and Environment is working closely with the Kansas Department of Education on school programs for vape-free toolkits. What lessons have you learned from that collaboration, and to what extent does the youth vaping crisis require the development of new approaches?

We learned that collaboration is key to addressing this epidemic. Working with schools has been crucial to reaching our target audience, young people. We heard from school

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teachers and administration that student use of e-cigarettes in class has become severely disruptive to learning. Schools have been burdened by the need to provide staff and student training and resources to address this issue among their students. In addition, building relationships with other community members has been necessary to reaching audiences such as parents, school nurses, medical providers, and state legislators.

Development of new approaches is important to reaching all youth in a way that will get their attention and potentially get them help for their nicotine addiction. While e-cigarette companies have used tactics historically used by the tobacco industry to entice young people to use their products, they have been able to reach young people that would not have traditionally been tempted to try conventional tobacco products.

2. Your testimony discussed the addictive nature of nicotine:

- a. Do you think the average consumer knows enough about the potential dangers of e-cigarette use?

No, but the perception of the risk of the potential dangers from e-cigarette use has increased in recent years. The proportion of adults who perceive e-cigarettes as less harmful than combustible cigarettes decreased from 2012 to 2017 (-5.5% TPRPS study; -16.2% HINTS study).

Among adolescents, e-cigarettes have one of the lowest levels of perceived risk for regular use of all drugs, including alcohol. The percentage of youth who perceive e-cigarette use as a risk to health increased from 14.5% in 2015 to 20.3% in 2017 among 8th graders, from 14.1% to 19.4% among 10th graders, and from 14.2% to 16.1% (a non-significant increase) among 12th graders. Perceived risk of vaping nicotine on a regular basis declines at higher grade levels, which is opposite of the pattern seen for perceived risk of combustible cigarette smoking.¹

- b. What more can be done to share this information?

Clarity of messaging from FDA and CDC that these products are not safe and are not approved as tobacco cessation devices. Additional funding and resources for statewide tobacco control programs to conduct mass media campaigns in order to educate the public. We have been sending e-cigarette, or vaping, products associated with lung illness to the FDA for analysis. KDHE has not seen any results from the FDA. Sharing these results with states would be very helpful.

¹ Johnston LD, Miech RA, O'Malley PM, Bachman JG, Schulenberg JE, Patrick ME. (2018). Monitoring the Future National Survey Results on Drug Use: 1975-2017: Overview, Key Findings on Adolescent Drug Use. Ann Arbor, MI: Institute for Social Research, The University of Michigan.

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The Honorable Brett Guthrie (R-KY)

1. What are your states seeing in terms of data and trends with respect to youth use of e-cigarettes over the past few years?

- a. For the data that is included in these statistics, how often or how recently does an individual have to have used an e-cigarette to be captured in the data (e.g. in the last 30 days, single-use versus chronic use)?

Current e-cigarette use is defined as use at least one time in the last 30 days.

- b. Does the data break out how many are using e-cigarettes for tobacco products (e.g. nicotine) or for THC products?

Kansas data defines how many high school students are using e-cigarettes for tobacco products; however, Kansas does not currently have data available on the prevalence of vaping THC products.

CDC researchers estimated that about 1 in 11 US students between 6th and 12th grades had consumed THC through vaping in 2016. This is approximately 1.7 million high-schoolers and 425,000 middle-schoolers, nationwide.²

Data from the 2017 North Carolina Youth Tobacco Survey indicate approximately 1 in 10 high school students reported ever vaping cannabis (9.6%).³

- c. How does that data compare to trends regarding youth use of combustible cigarettes?

The Kansas Youth Risk Behavior Survey (KS YRBS) shows that the percentage of high school students who currently smoked combustible cigarettes has significantly declined from 20.6% (95% CI: 18.2% - 23.2%) in 2007 to 7.2% (95% CI: 5.6% - 9.1%) in 2017. The 2017 KS YRBS also shows that 10.6% (95% CI: 8.7% - 12.9%) of Kansas high school students currently use e-cigarettes. Unfortunately, KS YRBS only has one data point for e-cigarettes so to examine trends we must look at another data source. The Kansas Communities That Care (KCTC) data show that the prevalence of e-cigarettes has more than doubled since 2016.

² Trivers KF, Phillips E, Gentzke AS, Tynan MA, Neff LJ. Prevalence of Cannabis Use in Electronic Cigarettes Among US Youth. *JAMA Pediatr.* 2018 Nov 1;172(11):1097-1099. doi: 10.1001/jamapediatrics.2018.1920.

³ Kowitz SD, et al. Vaping cannabis among adolescents: prevalence and associations with tobacco use from a cross-sectional study in the USA. *BMJ Open.* 2019 Jun 13;9(6): e028535. doi: 10.1136/bmjopen-2018-028535.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
“Sounding the Alarm: The Public Health Threats of E-Cigarettes”

September 25, 2019

Dr. Monica Bharel, Commissioner, Massachusetts Department of Public Health

The Honorable Frank Pallone (D-NJ)

1. Earlier this month, you mandated that possible cases of unexplained, vaping-associated pulmonary disease be reported to the Massachusetts Department of Public Health. What have been some of the challenges in identifying confirmed and probable cases of lung illnesses associated with vaping in your state?

On September 11, as more cases of vaping-related pulmonary disease were being seen nationwide, I used my authority under state regulations to require reporting of this emergent condition. We thought it was very important to establish the legal framework for healthcare providers to report cases and suspected cases so that we could get a better sense of the overall burden of disease in Massachusetts.

While we are seeing high levels of compliance among clinicians, there are significant challenges to obtaining the data we need to identify cases. There are multiple steps and each is dependent on the participation of several partners.

First, patients with symptoms consistent with vaping-associated injury must present for medical care and be evaluated. The range of symptoms is wide and may not be considered severe enough (or may be confused with pre-existing conditions) by a given individual to warrant medical care. Clinicians in turn need to have a high degree of suspicion and investigate respiratory illnesses in the context of asking patients questions about vape product use.

Second, to meet the case definitions, clinicians must order the appropriate tests (blood oxygen levels, chest X-ray, CT scan, infectious disease panels). Clinicians also must observe the current reporting regulations and fax an intake form to DPH with basic information about a suspected case. Next, DPH reviews these forms, excludes those that do not meet the case definition, and refers the remainder for follow-up. Follow-up entails requesting and reviewing the patient’s medical record and determining whether to assign a case to the probable or confirmed categories or deciding to exclude a case. In some instances, further information may be sought from the reporting provider, including clinical specimens for possible testing by the CDC.

Each confirmed and probable case is then contacted by DPH epidemiologists and asked if they would agree to an interview. While an interview is not necessary to determine if they are a case, in some instances information from the patient will result in the exclusion of a report from the case group (e.g.,

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if a patient indicates no recent vape product use). The primary goal of the interview is to gain additional information about the products and devices used and how recently and frequently they were used. Patients are also asked to hold any remaining product for possible submission to the FDA for testing.

We rely on clinicians to suspect a vaping-associated case, collect sufficient information about the suspect case, and make an initial report. Since we do not know yet the total number of these injuries we are unable to determine at this time the completeness of this reporting, though it is required under public health regulations. We rely on the clinician's health care institution to submit requested medical records, and while this may take some time, DPH has seen a high level of compliance with these requests. Review of medical records is conducted by multiple clinical staff at DPH resulting in new case determinations on a weekly basis. We rely on patients to respond to our interview requests and agree to provide information over the phone. Again, we are seeing a high level of compliance and DPH is not wholly dependent on these interviews to make case determinations.

2. Vaping products were also recently banned in Massachusetts for all ages.

a) Is this an indication that raising the minimum age is not enough to combat rising rates of youth use?

The purpose of the temporary ban is to take a pause on sales so that we can learn what is making people sick and figure out how to regulate these products to protect the health of all of our residents. Increasing the minimum age is an important and effective part of reducing youth exposure to vaping by restricting their access. Policies that raise the minimum age to 21 reduce youth access to these products, but as with every other public health intervention, raising the age is most effective when complemented by other supportive policies, such as flavor restrictions, pricing strategies, and careful permitting to moderate density. This ban gives us a pause while we learn more about how to keep both Massachusetts youth and adults safe from harm.

b) In addition to the temporary ban, what other recommendation has Massachusetts considered or implemented?

Prevention: Massachusetts has 161 cities and towns with a flavored product restriction in place, covering approximately 67% of the population, to help reduce both exposure and addiction. A growing number of communities are expanding restrictions to include mint and menthol, and many others are working to cap permits to reduce density and limit youth exposure. Our award-winning statewide vaping education campaign helps parents identify vaping products and dangers, and provides guidance for speaking with their children around this topic. Another vaping prevention campaign created with youth speaks directly to young people about how nicotine harms the adolescent body, and offers ways to take local action in fighting industry influence in their communities. Massachusetts has also included vaping in our smoke-free workplace laws, and is the first state to have banned the sale of tobacco products in pharmacies.

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Youth Cessation: Our state has worked with the Truth Initiative and our Massachusetts Smokers' Helpline vendor, National Jewish Health, to provide resources to support youth with cessation. In addition, we have plans to work with school nurses to increase referrals to both of these programs. Adult Cessation: In addition to creating a standing order for FDA-approved, over-the-counter nicotine replacement therapy (NRT) products such as gum, lozenges, and patches, Massachusetts has also increased support to the Massachusetts Smokers' Helpline, and the amount of available NRT from four weeks to eight weeks. There are no co-pays for nicotine replacement therapies for Medicaid and the state's employees and retirees and their dependents and survivors and participating municipalities, known as the Group Insurance Commission (GIC).

The Honorable Diana DeGette (D-CO)

1. In your testimony you state that "working in tandem with the federal government is critical to combatting this epidemic." What successes have you had in working with the federal government to address e-cigarette use, and where is there room for improvement?

Successes: We cannot combat this epidemic on our own and we welcome the support of our federal partners, with whom we already work closely. For example, in collaboration with the FDA, our local health departments educate retailers and conduct regular compliance checks. Our FDA inspectors conduct retail inspections to enforce federal tobacco regulations statewide and combined, there are close to 15,000 inspections each year. We successfully collaborate with national efforts around cessation through the CDC's Tips from Former Smokers campaign. Massachusetts regularly works to complement this campaign by running it locally, and we see the results from this effort with increased calls to our Smokers' Helpline from many adults in our state seeking support to quit using nicotine.

I would also mention that Massachusetts follows the Synar Amendment, enacting and enforcing federal and state laws that prohibit the sale or distribution of tobacco products to individuals under the age of 18, conducting random, unannounced inspections to ensure compliance with the federal law. We consider this a shared success, because it represents federal commitment for creating policies that create healthy conditions, thereby empowering Massachusetts to implement this policy locally, resulting in lower sales violation rates in our state.

Where we could use some assistance: We look to our federal partners for help when it comes to advertising, regulating, funding, and enforcement. One way to ensure that we are identifying risks on e-cigarettes and any potential new nicotine products, is to strengthen the collaboration and resources around funding research on the ingredients in e-cigarettes and how this influences health outcomes, so that people can make informed choices, and states can implement stronger laws and regulations based on additional evidence.

Massachusetts encourages our federal partners to create restrictions for advertising around e-cigarettes, at a minimum, mirroring what exists now for combustible cigarettes. Massachusetts

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encourages the U.S. Food and Drug Administration (FDA) to ban flavored e-cigarettes, including mint and menthol. Massachusetts also request that the FDA be assertive in holding retailers and manufacturers for sales and marketing efforts that target youth.

2. Public health officials have worked to develop effective strategies for combatting youth use of traditional combustible cigarettes. Your state of Massachusetts has led successful campaigns to reduce youth tobacco use, such as the 84 Movement. To what extent does this youth vaping crisis require additional resources or the development of new approaches?

We know that changing the conditions in which people live is one of the most impactful ways we can help people make healthy choices. One of the reasons the 84 Movement is so successful is that the youth involved educate their peers and adults on the dangers of the tobacco industry and they work to create change locally and statewide.

Additional resources would allow the Commonwealth to continue our youth education campaign, and increase partnerships with our local coalitions, local boards of health, and schools to specifically target the youth population.

On a federal level, increased funding for research on these products, their ingredients, and the links between ingredients and health outcomes would provide all public health departments with the tools and data needed to regulate and provide appropriate resources.

The Honorable Brett Guthrie (R-KY)

What are your states seeing in terms of data and trends with respect to youth use of e-cigarettes over the past few years?

First, I'm proud that Massachusetts has made significant progress in curbing youth and adult tobacco use over the past two decades. In 1996, the youth smoking rate was 36.7%. Today, the youth smoking rate is 6.4%. Our adult smoking rate is also low, with just under 14% of adults using combustible tobacco products. Our low smoking rates are a result of years of hard work with many local and regional partners.

In terms of the data, based on 2017 Youth Risk Behavior Survey (YRBS) data, Massachusetts has one of the lowest youth smoking rates, and yet highest youth vaping rates in the country. 2017 data show that 20% of high school youth vaped in the past 30 days, and one in 10 middle school youth tried vaping.

While 2019 statewide data is not yet available, school surveys conducted by local schools and districts across the state show youth vaping rates as high as 33% for current use and over 50% for ever use. These data were collected before the emergence of JUUL, so it is possible that newer data will show a greater increase in youth vaping due to JUUL's recent rise in popularity.

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In addition, current use of e-cigarettes is higher among students in grade 12 (25.9%) than any other age group. Current e-cigarette use among grade 12 students is more than triple the rate of e-cigarette use among 18-24 year olds (7.8%), who have the highest e-cigarette use rate of all adult age groups (ages 18+) (*adult data from 2017 MA Behavioral Risk Factor Surveillance System (BRFSS), youth data from 2017 MA YRBS*).

- a. For the data that is included in these statistics, how often or how recently does an individual have to have used an e-cigarette to be captured in the data (e.g. in the last 30 days, single-use versus chronic use)?

Data collected in Massachusetts captures “ever users” (youth who have ever tried an e-cigarette), as well as “current users” (youth who have used an e-cigarette in the past 30 days).

- b. Does the data break out how many are using e-cigarettes for tobacco products (e.g. nicotine) or for THC products?

This state-level data will be available when the 2019 Youth Health Survey results are released. Once the 2019 data are released, we can report the prevalence of youth who currently use marijuana in a vape product. That said, we know that dual use of vape products and marijuana is high. In 2017, among high school students who used vape products in the past 30 days, 2 in 3 (64.1%) reported also using marijuana in the past 30 days (MA YRBS).

- c. How does that data compare to trends regarding youth use of combustible cigarettes?

In 2017, use of e-cigarettes was three times higher than use of cigarettes (20.1% vs 6.4%) (MA YRBS).

The Honorable Michael C. Burgess (R-TX)

1. The state of Massachusetts Department of Public Health has engaged in a public information campaign about youth use of e-cigarettes, what is the state doing to expand on the research of youth vaping?

When youth rates of e-cigarette use began to skyrocket, we knew public information campaigns would be absolutely critical to increasing both general awareness and to alerting youth – and adults – to the dangers. In July 2018 we started by launching a campaign aimed at educating parents, school staff, and other youth influencers about vaping products and more recently launched a youth campaign, directly informed by youth input and feedback.

Massachusetts is seeking to fill gaps in the data, which includes supplementing existing surveillance systems with additional primary data collection efforts in youth and adults as well as leveraging clinical systems as a means of monitoring vaping use and related adverse events. These new means of data collection are either in the exploratory phases or already being developed, and we will continue to explore feasibility in the coming months.

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The Massachusetts Tobacco Cessation and Prevention Program (MTCP) is engaged in research to evaluate the impact of point-of-sale tobacco control policies which aim to protect youth from the tobacco and vaping industries.

In fact, we published our most recent study this month. DPH evaluated the short-term impact of a partial flavor restriction policy and found that in one Massachusetts community, within six months, both flavored and non-flavored tobacco use decreased among high school youth. In comparison, flavored and non-flavored tobacco use *increased* among high school youth in a similar Massachusetts community without the policy during the same time period (*Kingsley M, Setodji CM, Pane JD, Shadel WG, Song G, Robertson J, Kephart L, Henley P, Ursprung S. American Journal of Preventive Medicine. Short-Term Impact of a Flavored Tobacco Restriction: Changes in Youth Tobacco Use in a Massachusetts Community*).

We are also currently examining the additive impact of passing multiple point-of-sale tobacco control policies on youth tobacco use and other tobacco-related behaviors.

2. How is your state addressing the differences between nicotine and THC e-cigarettes?

Our Massachusetts Tobacco Control Program is solely focused on tobacco and nicotine. Since the legalization of marijuana for consumers in Massachusetts, THC e-cigarettes have been under the purview of an independent state Cannabis Control Commission, which is overseen by 5 Commissioners, consisting of one appointee each from the Governor, Treasurer and Attorney General, and two members agreed upon by the majority of those three constitutional officers. Our roles converge when it comes to underage prevention and we work together to ensure the safety and health of young people – whether we are restricting access to combustible cigarettes or THC e-cigarettes.

In addition, The Massachusetts Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences interviews patients who present with vaping-related pulmonary illnesses and collects data around THC use for the CDC. Our Bureau of Substance Addiction Services also champions primary prevention efforts around marijuana.