The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123 Rayburn House Office Building, Hon. Diana DeGette [chairwoman of the subcommittee] presiding.

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

Staff present: Kevin Barstow, Chief Oversight Counsel; Jesseca Boyer, Professional Staff Member; Jeff Carroll, Staff
Director; Manmoot Dhindsa; Evan Gilbert, Deputy Press Secretary; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Stephen Holland, Health Counsel; Chris Knauer, Oversight Staff Director; Jourdan Lewis, Policy Analyst; Joe Orlando, Staff Assistant; Alivia Roberts, Press Assistant; Andrew Souvall, Director of Communications, Outreach and Member Services; Benjamin Tabor; Kimberlee Trzeciak, Senior Health Policy Advisor; Jennifer Barblan, Minority Chief Counsel, O&I; Mike Bloomquist, Minority Staff Director; S.K. Bowen, Minority Press Assistant; Diane Cutler, Minority Detailee, O&I; Jordan Davis, Minority Senior Advisor; Margaret Tucker Fogarty, Minority Legislative Clerk/Press Assistant; Brittany Havens, Minority Professional Staff, O&I; Peter Kielty, Minority General Counsel; Bijan Koohmaraie, Minority Deputy Chief Counsel, CPAC; Ryan Long, Minority Deputy Staff Director; Brannon Rains, Minority Legislative Clerk; Kristen Seum, Minority Counsel, Health; and Alan Slobodin, Minority Chief Investigative Counsel, O&I.
Ms. DeGette. The Subcommittee on Oversight and Investigations hearing will now to 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.

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.

Now, 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 on 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 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 eventually will 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 reviewed 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, tell the public what the risks are,
and how or even if they can legally be sold. 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 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 standard.

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.

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.

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, but 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 do not point to a conclusive cause. But the test samples overwhelmingly suggest 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 3 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 vapes 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 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 and 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 be 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.

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.

The Chairman. 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 and I 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 2 years ago. Instead, in July 2017, FDA announced that it would delay 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 2 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 entire 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. 10 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.

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

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 in July of severe respiratory illness had used an e-cigarette containing marijuana oil purchased from a licensed dispensary, meaning that 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, including 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 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 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, it 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 3 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 with 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 witnesses 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 8
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.

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 like to now 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 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
Dr. Sharpless, you are now recognized for 5 minutes.
STATEMENT OF NORMAN E. SHARPLESS, M.D., ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION; AND, ANNE SCHUCHAT, M.D., PRINCIPAL DEPUTY DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION

STATEMENT OF NORMAN 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, 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 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 presentation. 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 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 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:]

**********INSERT 1**********
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 are 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:]

**********INSERT 2**********
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's 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. Okay.

Dr. Schuchat. But we also are quite concerned about people going back to smoking cigarettes --

Ms. DeGette. Right.

Dr. Schuchat. -- and we don't want them to do that.

Ms. DeGette. Okay. 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. And in 2017, the administration extended the compliance deadline by 4 years for companies to submit materials to the FDA for review of the public health risks of
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. Okay. And in fact your testimony says, "No ENDS product in the United States is on the market legally," right?

Dr. Sharpless. Correct.

Ms. DeGette. Okay. 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. Okay, so here is my concern. Both FDA and CDC says 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 and,
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. Okay. 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 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 enforcements and education and multiple policy things that we're doing.

Ms. DeGette. And 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. Okay.

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. Okay, 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 and 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 one 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 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, okay.

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 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's animal data to suggest some concerns and there's behavioral data. But this is one of the reasons that there's a focus for 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, does the FDA have -- 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 rest 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 and 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 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 is 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. Yeah. 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 has 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 coating 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 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 population 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 were 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. Yeah, 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 is 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.
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. Yeah, 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 because 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 are fine particles getting into people's lungs, we have had numbers of debates in this committee over the last 8 or 10 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 are 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. -- 12 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 harm. 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 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 off ramp 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 the epidemic of youth use.

Mr. McKinley. Okay. 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 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 okay.

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 is not safe. In fact, there has 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 has 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, 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 cancer. 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, nonsmokers, 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. And 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 and 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 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 relations 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 vape 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's 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 phenomena or is it just that there is a new awareness and people 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. Okay. 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 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.

The Chairman. Thank you, Madam Chair.

Earlier in September, the President announced that FDA
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within may be inaccurate, incomplete, or misattributed to the
speaker. A link to the final, official transcript will be
posted on the Committee’s website as soon as it is available.

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 3 years since they were brought
under the regulatory authority of 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.

The Chairman. 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.

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

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

The Chairman. 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.

The Chairman. 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.

The Chairman. 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.

The Chairman. 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.

The Chairman. And you intend to impose those enforcement measures?

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

The Chairman. 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.

The Chairman. Okay. Let me -- as the proposed flavored
ban included 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 a 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 --

The Chairman. 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 --

The Chairman. 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.

The Chairman. Okay. 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.

The Chairman. 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.

The Chairman. What about the user fees?

Dr. Sharpless. I'm sorry, sir?

The Chairman. 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
appropriated sources?

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

The Chairman. 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 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 same to you, Dr. Schuchat.

Dr. Sharpless. Sure. There's 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, anything
else you would like to share about studies and research?

Dr. Schuchat. Yeah, 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's 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. Okay, 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 for
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 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, okay.

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. Okay.

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. Yeah, 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 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 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 follows:]

**********COMMITTEE INSERT**********
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. You know, 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. Okay, 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. Okay, 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. Okay.

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
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, an 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. 2 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. Yeah, 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 emerges in real time, we want to make it available to the public as quickly as possible because 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, 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 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 provide 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 5 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 use 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 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 are 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
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.

And, Dr. Sharpless, will you ensure that the newly announced federal policy to clear the shelves of flavored e-cigarettes 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 FDA has or plans to implement?

Dr. Sharpless. Thank you for the question. The FDA has a longstanding 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 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, 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 651 percent increase when the survey focused only on high school students. And on top of that, the survey also found that e-cigarettes are by far and away 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. Okay. 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. Yeah, 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. Yeah.

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 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 and 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 10 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 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 10 years out, 5 years out, 10 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 analogues 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, 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 pulmonary 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. Yeah. Well, so for when the products involve THC not a tobacco product, this is --


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

Ms. Clarke. Okay.

Dr. Sharpless. -- the same authorities we have with other tobacco products.

Ms. Clarke. Okay. 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. Okay. Dr. Sharpless, to the extent that some of these products contributing to the illnesses may have been sold by registered 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 to, 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. Yeah, 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 5 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 2 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. Okay. 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 4 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,
showing 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 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 real 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 was lettuce it would be off the market tomorrow. And 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 food, 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 some -- 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 3 years ago, but you are reacting to it now that you -- 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 use 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 didn't go -- 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 cooperation between the federal agencies related to THC.

Mr. Guthrie. Okay. 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 we do -- it is just, 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 is I understand it 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 is it 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. Okay, 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. Okay. 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 is your 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 cigarette because combustible cigarettes are really bad and 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 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-minute 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 a 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 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 BHADEL, 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 entire 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 and 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 my children's friends who was 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
d 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:]

**********INSERT 3**********
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 brain. Nicotine is related to seizures. Nicotine can cause harm to developing fetus. 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 reach 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 experience with you and I
applaud the subcommittee's work to help address this urgent
public health issue.

[The prepared statement of Dr. Tilson follows:]

**********INSERT 4**********
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 in 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 toolkits; 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 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:]

**********INSERT 5**********
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. Look 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.

2 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 begin 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 commitment to your issue and I look

forward to working with you. Thank you.

[The prepared statement of Dr. Bharel follows:]

[The prepared statement of Dr. Bharel follows:]

**********INSERT 6**********
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 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 is available in very low cost. And I think that we need to accelerate the 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. Okay, thank you.
Dr. Khaldun. So that is what I believe.

Ms. DeGette. Yeah, 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 to 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 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 skyrocket. 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 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. Okay.

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. Okay.

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 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. Okay. 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 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. Okay. 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. Okay.

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 -- okay.

Dr. Khaldun. I'm still waiting.

Dr. Tilson. Yeah, 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. 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. Okay, 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, okay.

Dr. Bharel. Our information at this point is qualitative as well.

Mr. Guthrie. Okay. Well, thanks.

So getting back on the other. If you do just a search on the web -- 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 -- so 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 -- yeah, 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. Okay. 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 youth 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?
Yeah, 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. Okay, 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. Okay.

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. Okay.

Dr. Norman. Agree.

Ms. Schakowsky. Okay.

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. Yeah. 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. Yeah. 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 interviews 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. Yeah, 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 investigate 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? Okay, 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. Okay.

Dr. Bharel. So the temporary ban for 4 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's 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. Yeah.

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 is 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 6 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 10 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 10 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.]