

**U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
National Center for Chronic Disease and Health Promotion
Office on Smoking and Health**



**Public Committee Meeting of the
Interagency Committee on Smoking and Health**

**Empowering Youth and Youth Influencers
to Prevent the Use of Emerging Tobacco Products**

**U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave SW
Washington, DC 20201**

September 9, 2019, 9:00 a.m. – 4:00 p.m.

Record of the Meeting

**Opening announcements/welcome by
Simon McNabb, Designated Federal Official
Office on Smoking and Health (OSH)
Centers for Disease Control and Prevention (CDC)**

Simon McNabb: This meeting is being recorded. This is a public meeting and people are listening in on the phone. The conversation will mostly be from the Committee members and presenters. Please hold questions until the discussion time. There will be an opportunity for public comment at 3:15 p.m. We welcome the comments, but we will not be responding or answering questions. Please sign up for a public comment with the operator for those on the phone or with Monica Swann for folks in the room. Please sign up before we break for lunch. Please identify yourself and your organization when you are speaking. If you are unable to make a public comment today, you may submit a written comment to Monica.

We will now introduce the committee members and presenters. I ask the committee's public members to please disclose if you have any conflicts of interest.

Our first speaker is Vice Admiral Jerome Adams, U.S. Surgeon General. Dr. Jerome Adams is the 20th Surgeon General of the United States. His mission as the "Nation's Doctor" is to advance the health of the American people. Dr. Adams' motto as Surgeon General is "better health through better partnerships." He is committed to strengthening relationships with all members of the health community, and forging new partnerships with members from the business, faith, education and public safety and national security communities.

**Opening statement by
Vice Admiral Jerome M. Adams, MD, MPH
U.S. Surgeon General U.S. Department of Health and Human Services**

Vice Admiral Jerome Adams: We have a quorum and are officially calling this meeting to order. As for the charge to the committee, I want to start off by reading the objective because we go to so many of these meetings and sometimes lose sight of what the goal of the meeting is.

Our objective today is to identify federal actions to empower youth, parents, educators, health care professionals, and others who influence youth and young adults to prevent the initiation and use of e-cigarettes and other emerging tobacco products.

I want to thank the members of the Interagency Committee on Smoking and Health for your commitment; we know folks have traveled from all over the country. I especially want to thank our public members: Dennis Henigan, Patricia Nez Henderson, Jasjit Ahluwalia, and Lisa Henriksen. This is Dr. Ahluwalia's and Dr. Henriksen's first meeting, so welcome to the Interagency Committee. I think it's important that we recognize this is also Patricia's final meeting. Please give her a round of applause. Her voice has been critical because we know one of the groups most disproportionately affected is the tribal communities. Thank you very much for your contributions. Even though you're rotating off the Committee, know we'll still be tapping into you for your expertise.

We made great strides in reducing cigarette smoking in the U.S., but tobacco smoking still remains the leading cause of preventable disease, disability, and death in the United States. As a result of this decline that we've seen thanks to help of many of you all in the room, we're a healthier, stronger, and more nation and we should be proud of that. Fewer folks are dying from all illnesses when Americans are not smoking, and it's why the Office of the Surgeon General has long embraced tobacco cessation and prevention as a top priority. Whatever you can think of that's bad, it's worse when you smoke. If you can prevent people from smoking, we're going to mitigate that harm.

We've made strides in reducing second-hand smoking exposure. We just celebrated the one-year anniversary of the HUD Smoke-free Public Housing rule, which protects non-smokers from second-hand smoke, and which also makes it easier for people to quit smoking. That's critical here, and one of the things I hope we get a chance to talk about today, the different policies people are enacting. We don't want to be overly punitive; we want to give people a glide path to quit. It's one thing to say I'm going to charge you a higher deductible if you smoke, for instance, and it's another thing to say I'm going help you quit. Versus charging you a higher deductible and saying it's your fault because you can't quit this highly addictive substance with zero help and zero environmental support.

My motto is better health through better partnerships. I want to recognize HUD in their contributions to the success we've had. They've educated residents about how they can quit using tobacco, which has been integral to that policy's success. I am very, very appreciative of HUD partnering with us.

I'm happy to see we have representation from DOD and VA at the table. As many of you hopefully know, we are working to address tobacco use in the military. A large percentage – too large of a percentage – of folks in the military still smoke. For some branches, it's above the national average. Shockingly, the majority of those who smoke in the military didn't come into the military as smokers. So why do we have an environment where we're putting people onto the leading preventable cause of disease and disability? I've been partnering with the DOD and VA, and they're equally concerned about these new and emerging tobacco products because it's hurting their readiness, it's hurting their ability to recruit people. Folks are now coming into the military addicted to nicotine because of e-cigarettes. That makes us a less-safe nation.

Many of you have heard me say this several times, but it still is a shocking stat that bears repeating. Seven out of ten 18 – 24-year-olds in this country are unable to join the military because they can't pass the physical fitness test, don't meet the education requirements, or have a criminal background record. While these new and emerging products are making it such that people can't pass the physical, it's putting people onto pathways to other addictions because we know in far too many cases early exposure to nicotine primes your brain for addiction to other substances. In short, it contributes to the seven in ten young people who are ineligible for military service. What we're doing is important not just for health, but for our national security. It's why I collaborated with the Surgeons General of the Air Force, the Army, and the Navy in writing an open letter that we recently published in *Stars and Stripes* urging people to take actions that will help service members quit all forms of tobacco product use.

And mind you, in that letter in *Stars and Stripes*, we talked about service members and what the military can do. But seven out of ten of our 18 – 24-year-olds are ineligible for military service and another seven out of ten active duty members live off-base. We're not going to solve this problem solely by focusing on what happens while people are on-base and on the clock. We need a community effort to protect our national security.

Everyone who is here today, Committee members, presenters, and even the public that's in attendance, plays a key role in continuing to reduce the use of all tobacco products, especially by youth and young adults. I value your continued commitment to keeping young people from starting to use tobacco products and to helping people quit, particularly given the unique challenges posed by emerging tobacco products.

We're here today because our work is not done. Declines in tobacco use have been erased. You've been working, in many cases for most or all of your professional lives, to help us drive down youth tobacco use rates. But we've seen those gains erased among youth as the result of an introduction of new tobacco products into the marketplace, most notably, e-cigarettes. There's been an alarming increase in the use of

e-cigarettes by our young people. That's why I declared this an epidemic among our nation's youth just last December. And things move very, very, very quickly.

My predecessor put out a Surgeon General's Report on e-cigarettes and got ripped to shreds for it. A few years later, I put out an advisory, and I got ripped to shreds for it. We're now a year later and folks are going "oh my gosh, what's going on?" Far too often in public health, we're playing catch up. We're being reactive instead of proactive. We've still got a chance here. We're still at the beginning of this new trend, I think. And I think it's important we have this conversation today so that we can try to be proactive in our communities. So we can try to evaluate some of the policies being put in place throughout our country critically, so that people can make more informed decisions.

Given the epidemic of e-cigarette use among our nation's youth, we're meeting to discuss what the federal government can do to empower youth, parents, educators, health professionals, and others who influence youth to address this key issue. More than 3.6 million U.S. youth including one in five high school students and one in 20 middle school students currently use e-cigarettes. And, as you all know, one of the challenges in public health is we're often driving by looking in the rearview mirror. Those facts I gave you are already outdated, and we know this simply from talking to people in the communities that we exist in. We know those numbers are far worse right now. The recent surge in the last year is largely due to the use of Juul, a USB-shaped e-cigarette with high levels of nicotine that now command the majority of US e-cigarette marketplace.

I've got a 15-, a 13-, and a 9-year-old, who all know about the dangers of cigarettes, and who've all been offered e-cigarettes in their schools. As you know, the CDC, the FDA, NIDA, state and local health departments, and other clinical and public health partners are investigating a multi-state outbreak of severe pulmonary disease associated with e-cigarettes use. I want to thank the people who have been working on this. These folks have been working around the clock, they're busting their tails. Anyone who's been in public health knows how hard it is to do an outbreak investigation, whether it's a food-borne illness or a new infectious disease, they are trying to figure out what's in common among all these cases. And right now, there is no single substance that's been found to be in common amongst all these cases. The only thing is common is a history of vaping or e-cigarette use. This outbreak is just another reminder of the risk that these products present and how much we still don't know. That is a danger in and of itself. Folks want to say, "Wait until we know more before we take regulatory action or before we take policy action." The fact is, what we don't know continues to be a danger. We're seeing this play out right now with vaping-related lung illness that's occurring across the country.

We know, and we should say clearly: Youth and young adults should not use e-cigarette products. If you do use e-cigarette products, you should not buy them off the street. You should not modify e-cigarette products or add any substances to them that are not intended by the manufacturer. Those are the messages that my office has been pushing out. We're also pushing for providers to report, because you can't do an outbreak investigation without the data. It's important that we all tell folks to report when they have any suspicious cases and support your federal partners who are working hard to make this happen.

I want to close by setting a charge to the Committee: My charge to you is to commit to a day of rich dialogue aimed toward lasting solutions for tomorrow's generation. It's critical that we continue to adapt to the changing landscape that exists to ensure that tobacco-free future, and that we identify opportunities to build on what we know works and adapt these strategies to address current challenges.

I want to make a plug because I just said, "current challenges." Hopefully you all saw that just a few weeks ago, I put out an advisory raising the alarm about youth and pregnant women using marijuana. We know a third of young people who say they are vaping are vaping marijuana. This is another new twist that we have to take into account with these new and emerging tobacco products. We don't know, but

there's good reason to suspect that people will start using one product and switch to the other, whether it's nicotine to marijuana or vice versa. Folks are consuming both in these delivery devices. In many cases, kids don't always know what they're getting when they use these devices. These advisories are out there to help you all, so that in your communities you can say, "the Surgeon General says this is a problem, and this is why we need to address it in our schools, in our hospitals, in our clinics, and in our communities."

I want to close by saying that every one of you in this room is a leader in your community. In your communities, you're a bigger leader than the Surgeon General is. I go out there and I speak, but I'm trying to create space for you all. I often say when someone calls 911 in their community, it doesn't ring to my office in Washington, D.C. And quite frankly, I'm glad it doesn't because I'd be a whole lot busier than I am. When there's a problem in your communities, you all are the ones who have to deal with it. That's what today is all about. It's about having a conversation, it's about taking this back to your communities, it's about taking advantage of the opportunity to converse with other experts around the table. It's about us leading by example. It's within our power to restore the downward trend in youth tobacco use. As you're tweeting, as you're telling folks about today, I think one of the important thing is that as experts, you help people understand that we have seen a reversal in that trend in downward tobacco use that we've fought for over the last few decades, but it's within our power to restore the downward trends, and we can prevent a new generation of kids from getting addicted to new and emerging products. So let's make use of cigarettes and other tobacco products a thing of the past. Because tomorrow's generation – my kids, your kids, and the kids in your communities – is depending on it. Quite frankly, there is no time to waste.

Thank you, Simon, for allowing me to give that charge to the Committee. I'm looking forward to the conversation.

Simon McNabb: Thank you, Dr. Adams. Now let me introduce our first formal speaker. Dr. Brian King is the Deputy Director for Research Translation at the Office on Smoking and Health within the National Center for Chronic Disease Prevention and Health Promotion at the Centers for Disease Control and Prevention. In this capacity, he is responsible for providing scientific leadership and technical expertise to CDC/OSH, the lead federal agency for comprehensive tobacco prevention and control. Welcome, Brian.

Brian King, PhD, MPH
Deputy Director for Research Translation, Office on Smoking and Health
Centers for Disease Control and Prevention

Dr. Brian King: Thank you, Simon. I'm thrilled to be here. I adore this meeting; I consider it the Game of Thrones of the federal service. We have all the houses aligned and we don't get to meet that often. And I hope the ending will be better than that series finale. But I'm very hopeful. I appreciate the charge from the Surgeon General and I hope this will be a fruitful day. I've been tasked with kicking us off, providing an overview of the emerging tobacco products landscape, and setting the scene for the subsequent discourse for the various speakers you're going to hear from today.

I'm going to frame my remarks today around four commonly asked questions around the emerging tobacco products landscape. I am primarily going to focus on e-cigarettes, though the landscape continues to diversify. We don't want to play a game of public health whack-a-mole with new products. When it comes to youth, there's no redeeming aspect to any tobacco products. We want all use of youth tobacco rates to go down.

I'm going to touch on what are e-cigarettes, who is using them, what are the health effects, and most importantly, what we can do about it? Talking about what we can do is the most critical for us as the federal government. We have to tell people what we want them to do about it. The Surgeon General's

advisory in December outlined the different entities that can take action. And it's no coincidence that our agenda today outlines those specific entities that the Surgeon General did call to action. So let's get started.

When we talk about tobacco product use, there are a variety of products. This includes combustible, non-combustible, and electronic. We'll be focusing heavily on the electronic product landscape today, particularly e-cigarettes. It's important to note e-cigarettes were not the first novel products and they won't be the last. Other products such as IQOS are a good example of that.

E-cigarettes have four generations of products. They entered the US marketplace in 2007. They were disposable and looked like conventional cigarettes. Then the second-generation products gave the user the ability to modify the products to accommodate cartridges with different flavorings and nicotine concentrations. Then they evolved even further into third generation products with tanks or mods that allowed users to modify the voltage. They could still modify the flavor and nicotine concentrations. More recently in 2015, we saw the 4th generation e-cigarettes, commonly called pod mods. The most notable is Juul, but the landscape continues to change. Other pod mod products are out there like Swarm, which is another product that gives the user more latitude to put in as much flavoring or nicotine as they want.

Retail sales data from e-cigarettes sold in the US starting from back in 2013 show that Juul sales surpassed all other manufacturers by the end of December 2018. They have dominated the market with 75% of the market share. These are in the market for direct or indirect access by youth. Now everyone is mirroring Juul's science and technology.

E-cigarettes are starting to be sleeker; they're looking like flash drives. Many come in flavors. We're also seeing new types of nicotine, called nicotine salts. This has potential to facilitate cessation for adults but has strong likelihood to promote initiation among youth and young adults.

Patterns of use show this is an epidemic, per the Surgeon General's advisory in December. There were unprecedented increases in use in the last year. We saw a 900% increase through 2015, but then we saw a decline in 2016 because we started public health messaging about the risks for youth and young adults, and we started implementing new policies at the national, state, and local level. We started to see results. But then the product landscape changed with the release of pod mods, including Juul. The sales of these products corresponded with the increase we saw in the last year. A 78% increase among high school students and a 50% increase among middle school students was simply unprecedented. The NIDA Monitoring the Future study found it was the single greatest year over year increase for any substance ever measured. They've been monitoring that for several decades.

We also know there is some variability in use, but it's primarily ubiquitous. We looked at sex differences among youth. It wasn't as marginal around 2013 to 2015, but the variation has started to attenuate. There is not a lot of variability. There is a high rate of use irrespective of sex. There is some variation by race and ethnicity, but again, all populations have an increase, irrespective of race or ethnicity.

This doesn't follow conventional tobacco trends. One of these factors is there's a price point for everyone. Youth are saying, "If you give me \$1, I'll give you a hit of my Juul." This was similar to cigarettes in the past. You don't necessarily need to buy a \$35 starter pack. Also, they aren't taxed as much as cigarettes. Increasing price has been one of our single most effective strategies for reducing consumption, especially among young people.

When it comes to current use among states, it is not the same as conventional smoking, which has the tobacco belt. Some of the states that have low conventional smoking rates have high e-cigarettes usage

rates (e.g., California and Utah). We do not encourage e-cigarette use instead of conventional cigarette use among youth.

We need to get better at measuring data in a timely way. Web panels by the Truth Initiative have helped us collect rates of use. We also know youth are using other substances beyond nicotine. CDC found that 99% of e-cigarettes on the market contain nicotine. One third of youth who use e-cigarettes report using cannabis and THC in these devices. Beyond our concern for nicotine, we are concerned about this. We also know that 25% of middle schoolers using e-cigarettes report using them for marijuana.

We know that if you lead a horse to water, it will drink. In this case, the advertising will lead a horse to water, the flavors will get it to drink, and the nicotine will keep it coming back. This is the trifecta.

- Advertising: 80% of kids in this country are exposed to e-cigarette advertising. These ads use the same themes and tactics as conventional ads. We've seen an increase in these ads over time. The primary channel is retail stores.
- Flavors: Two-thirds of youth using e-cigarettes are using flavored products. This is the first product they use, and a prominent reason they start. 50% are youth are using menthol varieties.
- Nicotine: Nicotine is highly addictive and can harm the developing brain. There is a new type of nicotine in e-cigarettes that can increase the likelihood of addiction and initiation among kids. Free-base nicotine was in regular cigarettes. Most free-base nicotine is a chemical base and is harsh on the throat. In 2015, Juul lowered the Ph in the product to make the nicotine more acidic. This created nicotine salts, which allow a lot more nicotine to go down a lot smoother. This could be a benefit for adult cessation but also makes it easier to initiate youth and young adults.

Youth use is going up; 21% of US high school students use e-cigarettes, and just 3% of adults. There's a downward trend among adults since 2018. There is a higher rate of use among young adults (7% of 18-24-year-olds), which consists of primarily current and former cigarette users. There's also dual use; 60% of adults who use e-cigarettes are also smoking cigarettes. This is not a public health benefit. They have to quit regular cigarettes and quit completely. There are also 10% of adults who have never used cigarettes but use e-cigarettes. It's 40% among young adults. It reinforces the concern of this as an on-ramp. We have to remain focused on our messaging for youth and young adults, since the brain continues to develop until age 25. There are a variety of strategies under consideration to help address this issue, including limiting the sale of these products until age 21.

Vice Admiral Jerome Adams: Brian, you hit on this, but what is the single strongest statement you'd make when people come back with the retort, "it's a good thing these people aren't smoking cigarettes because otherwise they would be, and these are safer"?

Dr. Brian King: The single strongest statement you can make is: The youth who are using e-cigarettes are not otherwise already susceptible to use conventional cigarettes. These youth weren't otherwise at risk for addiction to tobacco products. The bottom line is any form of e-cigarette use among youth is unsafe. Even infrequent use is problematic. Their susceptibility is concerning. We need to prevent their use to begin with.

In terms of health effects, there are potential benefits and potential risks to e-cigarette use. CDC always acknowledges that there could be a net benefit for adults who use these to quit. We have to base these recommendations on the science. Right now, the science is mixed. There might be certain benefits to these products, but that can't outweigh the risks. There is limited evidence that e-cigarettes help with cessation; this was based on the older products. The science has to guide the decision-making. There was a *NEJM* article that showed they might help adults quit. We continue to monitor the science, but we need to reinforce that there the seven FDA-approved medications that we know work. Companies can submit their products to the FDA for approval for cessation. There are concerns about e-cigarettes being

gateways, concerns about relapse among former smokers, and concerns about exposure second-hand aerosol (we know it's not a harmless water vapor, it might be safer, but it's not safe). There are also concerns about advertising/promotion, concerns about poisoning related to e-cigarette exposure (especially for children), and concerns about product explosions. These products are not harmless.

I also want to reiterate what the Surgeon General said earlier about the multi-state investigation. I can assure you that CDC and others are working night and day on the outbreak. There have been 5 deaths and 450 cases around the country to date. We are extremely concerned but we have to let the science lead the discussion. It takes time to do that. We know enough to know the common denominator is e-cigarettes. We have urged the public to consider not using e-cigarettes while the investigation is ongoing. We have to give the public recommendations based on the science we have. We will continue to update people on the progress. For more information, we have released the public advisory notice at www.cdc.gov/e-cigarettes (with or without the hyphen in e-cigarettes).

The Surgeon General's advisory in December was a critical call to action for the American people. He was the first Surgeon General to call this an epidemic. He called for various entities (parents, educators, health care providers (HCPs)) to take action, and you'll hear from them today.

Vice Admiral Jerome Adams: We're the choir here, and we know that advisory came out. I've been to several communities and schools where people were concerned about vaping and didn't know about the advisory. We can help re-lift the advisory again. I cowrote a letter with the military in *Stars and Stripes*, and people don't know about that. I also cowrote a letter with the head of the FDA for schools. We just got a request from Congress to work with schools to help them teach about the dangers of e-cigarettes. Don't assume your communities know about these products that are already out there that we have made available. A real call to action for you today is to go back to your communities and lift these up.

Dr. Brian King: I absolutely agree. You can go to the advisory webpage to see the calls to action. They are tangible and clear-cut. We don't need to reinvent the wheel. We need to modernize it. We need to pursue new interventions. We need to reduce access to flavored tobacco products. There's been great momentum at the state and local level on this issue. We need to cut this off. We need to address the diversity of flavors.

And to recap:

- E-cigarettes are a tobacco product that produce an aerosol. New products continue to enter the horizon.
- E-cigarette use is higher among youth (21% high schoolers) than among adults (3% adults). When it comes to youth, use of any tobacco product is unsafe. There could be potential benefits for adults, but we are continuing to monitor the science.
- When it comes to interventions, it's going to take all of us from multiple sectors of society to do this. We don't have to reinvent the wheel; we must modernize. We must be nimble. The landscape is changing and so must we.

Here is my contact information and our websites. Thank you very much.

Vice Admiral Jerome Adams: I also want to take a moment to welcome Luka and Meredith. To all our advocates and groups on this side of the table, thank you for the work you do every day. We appreciate you being here.

Simon McNabb: Thank you, sir. Our next speaker is Dr. Donna Vallone. Dr. Vallone serves as the chief research officer at the Truth Initiative Schroeder Institute® and holds an associate professor appointment at the New York University College for Global Public Health. Dr. Vallone leads a multidisciplinary team

of more than 30 research staff focused on examining the influence of health communication and tobacco policy initiatives to reduce tobacco use among youth and young adults. Thanks, Donna.

Donna Vallone, PhD, MPH
Chief Research Officer, Truth Initiative®

Dr. Donna Vallone: It's a pleasure to be here. This is a wonderful opportunity for us to share key findings about e-cigarette use among youth and young adults. I have a really hard act to follow. Please indulge me. But I will share some interesting information. Today my talk is going to focus on studies from the Schroeder Institute at Truth Initiative. First, I'm going to share some prevalence data from our first nationally representative longitudinal cohort of youth and young adults. Second, a review of studies looking at e-cigarette knowledge and perceptions among teachers, administrators, and parents. I'll highlight some results from our recent publication on Juul promotion through Instagram. And lastly, I'm going to share some insights from our consumer research and how we're using that data to develop effective messaging to prevent e-cigarette use.

We published one of the first studies on the prevalence of Juul use among youth and young adults from our longitudinal cohort last year. This is a probability-based sample of respondents age 15-24. You can see there was significant Juul popularity among 15-21-year-olds compared to 21-34-year-olds. The findings also indicate that among those using the device within the past 30 days, one quarter used the device on 10 or more days of the past month. This indicates established rather than experimental use. Unfortunately, our most recent data collection from this spring indicates another significant increase in both e-cigarette and Juul use among youth across age groups. We're working on this data for publication. As a result, we see no decline in this epidemic.

We also conducted two national surveys in the fall of 2018, one with teachers and school administrators and one with parents. We wanted to explore knowledge, attitudes, and beliefs about e-cigarettes and Juul use. Despite the popularity of e-cigarettes and Juul among youth and young adults, teachers, administrators, and parents are less aware of the products. When we showed them photos without the name, a little less than half knew what it was. Similarly, when we showed parents a photo of the Juul device, only 44% identified it as a vaping device and 35% didn't know what the device was. There is a serious opportunity to inform teachers and parents across the nation about this epidemic.

When we asked teachers and administrators if their school had a policy against e-cigarettes, an overwhelming 83% said yes. Of those with a policy, only 44% of teachers and administrators reported that Juul was included in their policy. This lack of including specificity in product names is problematic. It creates gaps for implementing policy. Youth typically say they don't vape, they Juul. Youth often consider e-cigarette and JUULing different behaviors. Policies need to change to reflect the specific language used if we are to curb this epidemic. We also found 66% of teachers/administrators reported that their school has communicated to parents about e-cigarette use. Yet 74% of parents reported that they had not received any communication about e-cigarettes from their child's schools. Here is another opportunity. Though e-cigarette use among high school and middle school youth has increased rapidly, only slightly more than half of parents with children in high school report talking to their children about e-cigarette use. And only 40% of parents with middle schoolers report talking to their children. There is a clear and consistent need for relevant education and guidance for parents and teachers.

Now let me talk about a recent study that characterizes Juul-related content or posts within Instagram. This is an extremely popular social media platform among youth and young adults. We worked with colleagues from the NORC Social media Data Collaboratory to describe the major themes of Juul-related content on Instagram during a three-month period in the spring of 2018. Keyword queries captured close to 15,000 Juul-relevant posts by more than 5,000 unique users. Content fell into four categories: lifestyle

and social norms, youth-related content, promotional content, and nicotine and addiction. Over half of the posts referenced online and offline communities or peer groups (e.g., “Juul gang is the cool gang”). Posts referenced Juul use during social activities and events. There were numerous references to Juul as part of people’s cultural or social identity. Over half of all the content used memes and cartoon imagery. Posts referenced musicians or other celebrities. Posts showed schools and other youth contexts as places where Juul was used. Overall, we found that one-third of the Juul-relevant posts contained overt promotional content. This took the shape of direct user engagement strategies, such as incentivized friend-tagging and giveaways to promote the products (e.g., tag your friends, tag your Juul partner). These themes overlap. They reinforce Juul as part of the culture. It’s people’s social currency.

In November 2018, six months after this study, Juul removed its own Instagram account. However, more than 5,000 vendors and users continue to maintain a presence of Juul use within Instagram. Only 11% of the content referenced anything related to nicotine or addiction. Those categories were minimized. Instead, they refer to the taste and the effects of nicotine to the “Juul buzz.” Posts compared nicotine addiction to a chocolate addiction or Netflix addiction. The online context is a critical influence for youth and young adults given the significant amount of time youth and young adults spend within these platforms. Strong, regulatory action is needed to reduce exposure to this type of content to youth and young adults.

Now I want to talk about how we at Truth, have been working for the last two years on the best messaging strategies to reduce e-cigarette use among youth and young adults. We’ve been in the field for more than two years conducting a set of comprehensive formative studies to understand the role of e-cigarettes among our target audience and then develop effective messages that serve as a deterrent for this audience. We conducted qualitative and quantitative studies across the nation including focus groups and online discussion boards. We conducted in-depth interviews with youth and young adults, many of which were conducted with their homes and with their friends, to understand the role of this device and behavior, as we’ve done with cigarettes in decades past. We also used quantitative studies to assess the links between messages and behavioral outcomes. Each message execution is tested rigorously to understand and maximize its effectiveness. Here’s what we learned:

- Vaping is a social currency. It is extremely popular.
- It’s important that we provide credible information in a non-directive manner. As soon as you say, “don’t do X,” one can prompt their curiosity.
- Given this generation’s ability to fact-check information, we need to maintain credibility with this audience.
- We need to identify their passion points and use issues they’re already interested in to help deliver this message.
- A variety of messaging strategies is needed to maintain interest and attention. We need a consistent discussion over time with the target audience about the harms of vaping, its role within their lives, and how best to avoid initiation.
- Lastly, we developed an anti-vaping scale focused on assessing knowledge of vaping harms, the appeal of these products, social unacceptability of use, and anti-tobacco industry sentiment.

Let me give you an example of how this all comes to life. This is from our newest campaign that launched several weeks ago. [Dr. Vallone played the Truth Initiative’s newest video called “Tested on Humans” featuring animals protesting about lack of evidence related to the long-term effects of Juul.] So there’s a little humor, and we plan that this will be followed by future messages to help turn the tide of this epidemic. Thank you.

Simon McNabb: Alright, moving along. Bonnie Halpern-Felsher, PhD, is a Professor in the Division of Adolescent Medicine, Department of Pediatrics, Stanford University. She is also the founder and executive director of the Stanford Tobacco Prevention Toolkit and the Cannabis Awareness and Prevention Toolkit. As a developmental psychologist with additional training in adolescent and young adult health, her research has focused on social, environmental, cognitive and psychosocial factors involved in health-related decision-making, perceptions of risk and vulnerability, health communication, and risk behavior. Welcome, Bonnie.

Bonnie Halpern-Felsher, PhD, FSAHM
Professor of Pediatrics, Stanford University

Dr. Bonnie Halpern-Felsher: Thank you. Thank you for inviting me. This is a privilege to speak among this esteemed group and hopefully I can add to the conversation. I want to acknowledge my funders at NIH, some of whom are here today. I am going to discuss marketing to youth, some of which has been covered but we'll go a little bit deeper. I'm going to discuss flavors and flavor ads and the importance of that. We'll talk about addiction perceptions and cessation ads, as well as packaging perceptions and high costs.

Let's start with marketing to youth. [An ad is shown with some bright colors and geometric shapes, with a photo of a model using a Juul.] When you show youth these ads even without any words, they know what they're for. It's like the McDonald's sign, they know the arches are there. They aren't in use anymore, but youth know what they are. They know these ads are for Juul even without it being explicitly named. There are also ads from other brands like Blu that target youth. [An ad is showing with a young woman.] They use models that look like the Parkland shooting young lady. It's disgusting. They are using these images to attract youth. Adults may not recognize this young lady, but youth do. She's a powerful force for them.

We see other memes that look like high school bathrooms. [A meme is showing of people vaping in the bathroom.] We've heard this time and time again – are you going to the bathroom to go to the bathroom or are you going to Juul? I travel around the country talking to educators and youth about e-cigarettes. I hear that no it's not in 1 in 20 high school students, it's more like 50% vapes. They run to the bathroom every 15-20 minutes to take a hit. They're not able to sit still.

We're seeing memes of someone who's so stressed out over losing a pod or their Juul that they're going to great lengths to find it. They're comparing losing a Juul to failing an exam or getting rejected or their dog dying. This is a sad state but those are the memes going around.

Let's talk about flavors and flavor ads. There are 15,000 e-cigarette flavors on the market right now. Vapers say, "We need these flavors to quit as an adult." That can't be true with these – some of them have names like booger sugar, banana butt, honey doo doo, barney pebbles, dragon's blood. These are clearly designed toward youth. This makes research very difficult – what category does honey doo doo go into? One positive thing is Juul doesn't have 15,000 flavors. But they do have the most important flavors to attract youth. After Juul was put under the microscope, they changed the name of their flavors (e.g., Cool Mint became Mint, Crème Brulee became Crème, Cool Cucumber became Cucumber, etc.). However, they still have fruit, mint, and menthol. Those are the most important flavors.

We published a *JAMA Network* paper recently where we asked youth to name the first flavor they tried. 26% said mint or menthol and 26% used fruit. The most common flavors are fruit and mint. We're seeing this across the board all the time. A lot of people said, "don't know" or "not sure." They could be switching – sharing the pods and sharing the products. They may not know what they're actually using, especially if it's called something like Dragon's Blood. It's hard to get good data. The majority of youth

are using mint and fruit. We need to stop perpetuating the myth that youth don't use mint or menthol – they do.

We need to look at ads for flavors. We don't talk about this enough. When you ask the industry whether the ads attract youth, they say no. The science says otherwise. We published a study a few months ago where we showed adolescents between the ages of 15-20 real ads (not for Juul, but for other e-cigarettes) in a randomized fashion, counter-balanced, and asked who they think is the target audience. We asked if it was someone their age, younger, a little older, or a lot older. The majority did not say they were targeting someone much older. They said someone slightly older, their age, or younger. Particularly something like the cupcake man with pink colors and flavors, they clearly know that's targeting youth.

The data around flavors and flavor ads shows youth and young adults are using flavors. They're unlikely to use e-cigarettes without flavors. They use the mint and menthol. They're very susceptible to flavored ads. We have to eliminate flavors, including mint and menthol, if we're going to do an appropriate job to limit their use of these products.

When it comes to cessation and cessation ads, youth do not understand addiction and they don't understand addiction messaging. They don't recognize that addiction means that it will be difficult to stop using. When you ask if they could become addicted, they say yes. They know this from our messaging. But when you ask if they can quit tomorrow, they say of course I can. When you ask if they'll be vaping in five years, they say no way. They perceive Juul to be less harmful and less addictive, but those who are using Juul reported them to be more addictive and have higher nicotine dependence than those who used other forms of e-cigarettes or cigarettes. There's a disconnect between their understanding of addiction.

When we have warning signs on products saying that they contain nicotine, it's better than nothing. But it's not getting far enough. This message is not understood. We need to change the warning message. We need better words, better messages, better pictures.

Then we did a study where we looked at cessation ads. This was all pre-Juul. Our data have not caught up to Juul or pods yet. We gave youth randomized cessation ads and asked them what they mean. There are ads that use explicit language like "never going back". There were also more implicit ads using language like "paper or plastic" and "Blu works for you." We asked them what these ads mean. They know the ads with the explicit language are for cessation. For the implicit, the majority still new they were for cessation. When we're thinking about our policies for advertising, we need to take a better look at the ads with cessation claims.

In terms of packaging, we need to follow the lessons learned from cigarette packaging. With the 2009 Tobacco Control Act we were no longer allowed to have words like light, low tar, etc. Instead, Marlboro used different colors. We did a study where we asked youth to tell us the attributes, flavors, and characteristics of the packaging. Youth interpreted these packages exactly as the industry intended them to. They perceived black as harsh, the white packages as light or less harmful. They are aware of the messaging. We need to take these lessons and apply them to e-cigarette packaging.

We asked youth how much nicotine they think a Juul pod has. They are confused. They don't know if it's the same, a little more, or a little less than a cigarette. Then we asked them to list a specific amount. Only 12% thought it was 59 mg/ml, which was correct. Almost 25% thought it was 5 mg/ml, which is much less. They don't know how much nicotine is in these. The Juul packaging says 5%. When you ask youth or parents what 5% means, they have no idea. This is on all kinds of e-cigarettes packaging. It's very vague.

Another product, IQOS, was approved by the FDA to come onto the market. Rather than wait for post-market surveillance, we need to get better at enforcing and regulating these products before they go on the market. The packaging is beautiful. It's similar to an iPhone box. Similar to Juul. It shows fun, sexy, appealing images. According to Phillip Morris, they are not considered "tobacco products" so they don't need a warning label. They don't need to be regulated as tobacco products. Nicotine is not derived from potatoes as people tweet me, it comes from tobacco. Their application is still in review by FDA. We asked youth if they understand these marketing claims, "these can reduce the risk of tobacco-related disease." When we ask youth about this claim, they misunderstand and think these products aren't as risky. We cannot keep making these mistakes. We cannot allow these new products on the market to have these claims (e.g., claims saying they are harm-reduction products). Young people think this must mean it's ok to use. Young people don't see it as relative to cigarettes. They aren't using cigarettes. We need to take a much closer look at the data and not allow these claims to move forward.

Conclusions:

- Youth are being targeted by tobacco marketing, especially e-cigarettes and Juul
- Youth are susceptible to the ads and the packaging
- We need to eliminate all marketing to youth
- Mint, menthol, and fruit flavors need to be part of the conversation
- We have to be better about our addiction messaging to youth
- Youth are recognizing cessation claims and thinking that means these products are ok to use
- We must apply the same research and standards to any new product. We shouldn't rely on post-market surveillance. We don't want an entire generation addicted.

Thank you.

Simon McNabb: Thank you very much, Bonnie. We introduce our next speaker, Gem Benozza. Gem currently serves as the Director of the Division of Public Health & Education at the Center for Tobacco Products at FDA where she leads the strategic planning and implementation of all of FDA's public education campaigns. Welcome, Gem.

Gem Benozza
Director of Public Health & Education
Center for Tobacco Products, U.S. Food and Drug Administration

Gem Benozza: Good morning. Thank you, and I'm very happy to be here today to share information about our public education campaigns and some of our research on youth and what they think about e-cigarettes. As many people here know, public education campaigns are a proven strategy that has been successful in reducing and preventing tobacco use. Currently, FDA has multiple public education campaigns targeting specific discreet audiences who remain open to cigarette smoking. Today I want to talk more about the Real Cost campaign, which is where we're running our e-cigarette prevention messages. It was launched in 2014. Two years later we added specific smokeless tobacco messages in rural communities. Last year we expanded it to include ENDS prevention.

The basic foundation of the campaign is to use facts and science as the main focus of our messaging. With cigarettes, we had decades of research on how dangerous they were. We needed new and innovative messaging. For e-cigarettes, we don't have that available. For this campaign, we know youth are worried about how they look so we focused on appearances, such as premature wrinkles and tooth loss. We reframed addiction to be a loss of control (e.g., we used metaphors like bully). It was very effective. After 15 months, we saw significant changes in youth and young adults' knowledge, attitudes, and beliefs.

We wanted to leverage the strength of that brand and put it toward e-cigarettes. Teens had a cost-free mentality around ENDS. When we looked at developing a campaign, we needed to understand who was using the products, who the target audience is. What were their psychographics? For smokers it was more of outsiders or people with coping difficulties. These people likely didn't have a positive relationship with institutions like schools. These kids using e-cigarettes were very different – they were the traditional popular kids. They were very social, and many of the settings where they vape were social (e.g., parties). These teens have plans – they join groups and are athletes. Teens who are at risk for cigarettes are at risk for ENDS, but we had to broaden the target. The 2017 *Monitoring the Future* study showed that 80% of teens did not see great risk from regular e-cigarette use.

Through focus groups in the winter of 2018, we found out that teens have limited knowledge of e-cigarette risks and need more information. They were looking for information. On top of that, this is a generation that grew up with a cell phone. They believe they are smart enough to understand and make good decisions. They think that of all the available substances, these have the lowest risk. Some of the testimonials they heard through focus groups were:

- “I heard [vapes were] really not that bad. There weren't any studies that showed otherwise. At least yet. A lot of people say that it's a lot better than smoking.”
 - This was their free pass, it allowed them to do something edgy and cool.
- “If this was bad for us, we would know.”
 - They are used to getting public health messages.
- “It's a healthier alternative. It's cool. It's supposedly better.”
 - They think it's cool. It's their social currency.
- “I feel like that's what sets them apart from cigarettes. That's what makes them more compelling than cigarettes. Cigarettes are like, ‘Ooh that's gross,’ and then vapes are like, it makes them seem harmless.”
 - These teens don't want to be seen as cigarette smokers. That has negative connotations and stigma. You get in trouble for smoking. It's not socially acceptable. Vaping isn't like that.
- “Cigarettes – like how they give you cancer because they have all the chemicals and stuff. Vapes don't have any of that.”
 - They didn't see any negative consequences with vaping.

Then we started drafting ad concepts. We tested a series of messages that talked about flavors. They didn't work well because we didn't crack the issue. The concepts were a little too confusing. Teens don't think the reason they use ENDS is because of flavors. It gets handed to them; they don't think they're making that choice.

Teens want clear and concrete information. If you say it causes harm, they want citations. They don't like words like “may” and “can.” The introduction of those words gave them an option to opt out of your message. They think it's not that clear and not that serious. Messaging that nicotine is addicting and it affects your brain isn't enough. Kids understand that, but they equate it to being addicted to their cell phone, chocolate, pizza. In the middle of focus groups, we added specific negative health consequences to the nicotine addiction messages (harm the body, toxic metal particles, dangerous chemicals, known to cause cancer). That helped. It was powerful. The message around “metal particles” was strong. That brings up a lot of concern for them and they find it very convincing.

[Gem shared three of their Real Cost video ads.]

We are seeing a lot of engagement in the ads. There was a void in information. There are 31,000 comments from teens on the videos. 50% of the comments were from people who don't believe vapes are

harmful. 20% of teens who commented think that non-nicotine vapes are safe. 20% of teens who commented think vapes are safer than smoking. 10% of teens asked for help in quitting. We're not seeing those as public comments on the posts, but they're direct-messaged FDA Real Cost's social media platforms saying they are looking for help quitting.

Some of the messages say that they're addicted to Juul, they're stealing money from siblings, they're dizzy from vaping too much, and they're searching for help to quit. We worked with our partners at NCI to update our cessation materials to include new teen-focused e-cigarette cessation web pages. We had more than 7,500 pageviews in the first three weeks. The Real Cost drove 1,000 referrals. We saw a lot of time spent on the sections about how to quit vaping and nicotine withdrawal.

We just did some more focus groups – clearly teens see people who are addicted. That's changed in the last 12 months. They are also talking about new products that are cheaper (\$1 disposable compared to a \$40 Juul). This is all changing very quickly.

Thank you very much.

Simon McNabb: Thank you, Gem. That was a great segue to our last speaker of the morning, I'd like to introduce Dr. Susanne Tanski. Dr. Tanski is an Associate Professor of Pediatrics at the Geisel School of Medicine at Dartmouth (formerly Dartmouth Medical School), a practicing primary care pediatrician, Section Chief and Vice Chair of General Pediatrics at the Children's Hospital at Dartmouth of Dartmouth-Hitchcock Medical Center. And Dr. Tanski is the Project Director in the American Academy of Pediatrics Julius B. Richmond Center of Excellence. We'll switch our focus now to the clinical perspective and talk about what pediatricians are doing. Thank you, Susanne, and go ahead.

Susanne Tanski, MD, MPH, FAAP
Associate Professor of Pediatrics, Geisel School of Medicine at Dartmouth

Dr. Susanne Tanski: Thank you all for this opportunity. It's a privilege to be here with you all. It's a lot of pressure to speak on behalf of all healthcare providers. I have talked to my colleagues around the country to try to get more of a sense of what's going on. I'm a pediatrician practicing in the small state of New Hampshire. The American Academy of Pediatrics is an organization that has 67,000 pediatricians who believe children should grow up tobacco-free and free from the harms of second-hand smoke and second-hand vapor. I'm also directing my remarks on behalf of that body of people. As described so carefully by Dr. Brian King, we've seen a dramatic increase in e-cigarette use among our patients. I see this in my pediatrician offices every day. This is truly an epidemic and it's getting bigger and bigger. This is of great concern among clinicians as we see this epidemic take hold of our patients.

While many of us in tobacco control who specifically work with adolescents have been raising the alarm for many years now, unfortunately there's been insufficient action. We've seen an uptick in e-cigarette use with the effects of long-term nicotine dependence, increased likelihood of transitioning to cannabis and combustible tobacco, and negative health consequences for a new generation. We've also been aware of the intense investigation among CDC, FDA, state health departments, and many other partners about the cases of severe pulmonary disease. There have been five deaths and more than 450 cases across the nation under the investigation linked to vaping. These facts demand urgent action to work together with adolescents, with our teachers, with our coaches, clergy, media, and every other influencer and organization. Cessation is of particular concern; people turn to us to say how do we help our kids quit. We need additional research so we know what the answers are.

In talking with clinicians, we notice adolescent patients are taking to vaping very differently from cigarettes. The tempo for escalation of use is much faster. Twenty years ago, they found it took two

months to go from puffing to inhaling cigarettes, and nine months before they were using monthly. It was 19 months before they were using weekly. It's not like that anymore. Now they go from taking a hit from their friend to vaping weekly in a matter of weeks to months. This is really fast and really scary. The kids don't see it as a big deal.

One of the problems with vaping is that there's no cue to tell them they've had enough. They vape until they get buzzed and they may have had half a pack of nicotine. There's no dose to know, no unit. These are easier to use. It's easier to vape more than smoke more. In many peer groups, vaping is seen as normative. Our kids are using the vape lounge, which previously was the lavatory. In my kid's bathroom at school, they took the doors off because kids were vaping in there so much. Vaping happens everywhere where kids are congregating. I can't drive from my hospital without seeing kids in front of the high school vaping and vaping in their cars. Kids are using it everywhere. Pod use is dramatically on the rise.

From observations in clinical practice, pediatricians are really taking an interest in this. One of my colleagues Dr. Rachel Boykan from SUNY Stoney Brook from New York saw this happening in her community and decided to do an observational study. I'll show you her preliminary data, which is still under review. It was a small pilot study of 506 adolescents and young adults between 12 and 21 years old. The study assesses their use of pods and other kinds of e-cigarettes. Investigators asked them what they were using and then determined if it was a pod-based system or another type of e-cigarette. They also collected their urine to assess cotinine levels, a compound in nicotine. You can see that the numbers are really small, but you can see an interesting relationship. Cotinine levels within pod users was significantly higher than those using other kinds of e-cigarettes. They were comparable to cotinine levels in the exclusive smoker group. Looking at pod users, daily users had far higher levels of nicotine than non-daily users. These higher levels of cotinine were associated with self-reported symptoms of nicotine dependence. Specifically, the researchers used questions from the Hooked on Nicotine Checklist (HONC). An example of one of the questions included in that checklist is, "If I go too long without vaping, it interrupts my thinking." Another example is, "If I go too long without vaping, I become angry or irritable." The HONC scale is independently validated and any positive answer is associated with nicotine dependence. Of the 42 respondents who had vaped in the past week, a total of 12 responded positively to the HONC questions. A total of nine out of the 20 pod users responded yes, and three of 22 other e-cigarette users responded yes. That number is statistically significant. This is six respondents from this very small study who are potentially addicted. We need to replicate this study with a larger sample, but it's still worrying to clinicians. The people who said yes to the HONC questions also had more cotinine in their urine. High nicotine exposure was linked to addiction symptoms.

What we're seeing is nicotine dependence in our practice. Here are two examples of teens who ended up coming in for treatment. We're going to use these stories in an upcoming study.

The first is Austin. Austin is 16 years old and was highly functioning through 8th grade. Then he started vaping in high school. His personality changed and his mom came in and said, "I want my son back." His behavior changed, he quit his sports teams, he was irritable, and he reported daily use (one pod per week of his own plus hits from his friends' pods). His parents discovered he was Juuling and insisted he quit. They started drug testing him at home. He had withdrawal symptoms after two weeks. He said she thought he had ADHD and needed help. His symptoms aligned with severe nicotine use disorder. The doctor did a substance-abuse test and confirmed he was not using any other substances. He didn't meet any mental health disorder criteria. His parents moved him to a private school. His entire life was changed to try to fix this issue. Is his situation going to be any better at private school? Probably not. And indeed, he continues to vape.

The second kid we're going to talk about is Jack. Jack is 14, and he started to vape at age 13. He was caught by his parents after about nine months of use, and they made him quit over the summer. He started

vaping again when school started. He went to the doctor for treatment and he said all he could think about was nicotine. He would take hits before practice. He had to quit his team because he couldn't concentrate on his sports. He had withdrawal symptoms when he quit. He said, "I don't feel right when I quit." He zoned out too much. He quit his sports teams. His parents also said his personality had changed.

From my own community, I had a similar conversation just last week. One of the kids on my son's soccer team is not on the soccer team anymore. His mother was concerned about her son vaping in the locker room for one of the other teams that he was on and moved him to private school. When they would go to away games or when they were getting ready for a game in the locker room they were not necessarily observed. The kids would vape there. She decided to move him.

In all of these examples, parents and kids are being upended. This is entirely because of vaping. And so far, we've talked about the dangers of nicotine only. This doesn't even cover the other health consequences of THC, which we'll talk about in a moment.

So, Brian presented this slide and I've added two more things to the left here: seizures and severe lung disease. There is concern of seizures related to e-cigarettes. It's currently under investigation. I look forward to seeing more from CDC and FDA about that. Also, the severe lung diseases that were mentioned earlier. There have been five deaths. I've had the opportunity to speak with pediatricians who treated teens with the severe lung disease. I also talked to a mom of one of those kids. When I spoke to the mom, she was crying. She was so afraid that her son was going to die. But she was also angry; she had noticed how much she noticed his personality changing. They found out he was vaping, they got him into treatment, they got him to go to a therapist to see if they could get him to quit vaping or quit using THC. Instead, he got sick. He landed in the hospital, in the intensive care unit. He was one of the first cases. The internists had no idea what they were dealing with. It was a pulmonologist who found a case report. The kid and the mom said he was vaping. They put two and two together and the kid got better and he's currently going off to college. But this is an important, life-altering event that affected their entire summer. They continue to live in fear about what's going to happen next. In speaking with the pulmonologist, he actually made the comment that many parents have a passive acceptance of vaping. It's not hard drugs, it's not smoking. They've been lulled by the marketing that this is harmless. Of course, now we know that it's what we all feared, it's not harmless.

I've looked at the literature to see if there were any case reports of deaths from just a few months of smoking cigarettes – there weren't any. This is something new. This lipid pneumonitis is something that we've not seen before. There's a type of cell in the lungs called macrophage. It's important for the way the lung functions. One thought is that the macrophages have lipids in them because you're inhaling something from the outside that gets into the body. Another theory found that chronic exposure to vaping liquid with or without nicotine caused changes in mouse lung cells such as the macrophages themselves, which then produced this lipid. We have a long way to go to figure this out. We had a lot of basic science studies that warned us of likely lung injury, and now we have real cases.

Another colleague I spoke with told me about a 17-year-old girl who was also hospitalized after experiencing respiratory difficulties. She was hospitalized for a week. She gave all of her vapes over to CDC and she was really angry. But it wasn't because she wanted to vape again. It's because she wanted to drive over them with her car and destroy them. Perhaps she is less likely to relapse than others, but what's ahead for her? What's ahead for users? Are these just the sickest people, and are there others who are harming their lungs that we don't know about yet? It certainly seems likely. What's the second-hand exposure risk from these products? What comes next for these patients? Will they have ongoing lung issues? What has been allowed to happen with insufficient regulation of these products?

Right now, we have a large population of adolescents and young adults who are vaping. Many will have difficulty with cessation. We don't know what effective cessation looks like for e-cigarettes since it hasn't been studied yet. The body of evidence is limited. Research for combustible tobacco suggests behavioral and social interventions will work, but we don't know if that would work for e-cigarettes. Studies indicate that nicotine replacement therapies are not particularly effective for youth.

Adolescents do not respond well to blanket statements of risk. They're smart, savvy, and they know how to look things up. We know we need to be accurate and truthful. We can't lose their trust by not telling them the whole story. Trust is difficult to recover. We need to conduct the science and be able to understand the risks very quickly. We need to understand levels of dependence among adolescents so we can customize options for cessation based on severity of dependence. We need to understand the trajectory of nicotine dependence among teens who use e-cigarettes compared to those who use traditional combustible products. We need to know how best to translate this information. I love FDA's new campaign – it's edgy, it's cool. Hopefully that can be our avenue to getting the word out. We need to identify effective interventions. We need to take into account developmental stages; we know 14-year-olds are different from 19-year-olds. And by the way, 14-year-olds and 19-year-olds are all in my wheelhouse. I treat patients all the way up to age 26-years-old. So pretty much all of our young adult users are all in the pediatric healthcare system.

Now for my recommendations:

- We need to know if there is efficacy to use nicotine replacement therapies approved for adults to treat adolescents who want to quit vaping, or are there potential modifications for these products that would make them appropriate for adolescent use?
- We must urgently fund studies on the short and long-term harms of vaping; patterns and trajectories of dependence among different product types of e-cigarettes; as well as behavioral and pharmacological interventions that worked for combustible cigarettes that can be modified and tested in real time.
- We need to support strong regulation aimed at eliminating youth access to e-cigarettes and vaping products with enticing flavors and high nicotine content. This is critical to prevention as well as cessation.

We must prevent youth use of vaping products and nicotine addiction before it starts, while also helping youth who have already fallen victim. We've got a long way to go. We've got a good group of partners here. I look forward to taking the next steps to support our kids. Thank you.

Simon McNabb: Thanks very much, Sue. We are on time and we have gone through our morning set of presentations. Now we are going to move into question and answer and discussion from everything we've heard. Thank you, Dr. Tanski, for cuing up that last part with recommendations. Because as we've discussed, the purpose of this meeting is to look at what we all can do to empower youth and youth influencers to help prevent and help e-cigarette users to quit. This Committee's mandate is the federal government. We're eager to hear from the experts, hear what you think. What Dr. Tanski said is a good start. We will take the next 30 minutes to discuss. Everything is fair game. I am going to turn to our public members and see if they have anything to say to kick us off.

Q&A and Discussion

Dennis Henigan: Thank you, Simon. I'm Dennis Henigan with the Campaign for Tobacco Free Kids. I also want to compliment our presenters this morning. These were absolutely terrific presentations. I know I have a number of questions. I learned a lot. I do want to start with a comment. I want to reemphasize something on the last slide presented by Dr. Tanski on what needs to happen. There was a theme just under the surface of a number of the presentations. We need some context as to what has happened here.

One of the reasons that we are in the crisis situation we are in is not only because we had a predatory industry preying on our kids for all these years, but also, quite frankly, because it's a story of federal regulatory failure. That needs to be recognized at the outset. The federal government had the authority to prevent this epidemic and refused and failed to use that authority. The FDA failed to regulate these products for years despite the constant urging of the public health community. Once they did regulate them, a year later they de-regulated them and also suspended one of the most important tools the agency has to prevent this type of crisis, which is public health review of individual products. They've suspended this until 2022. They announced a modification to the policy, but that policy has deprived the agency of a tool that, quite frankly, had the original deeming rule been left in effect, could have had Juul off the market by now. I think that provides important context. It's almost a moral imperative for federal agencies to figure out how they can help to get us out of this hole and protect our kids. Quite frankly, the federal government did not protect our kids when they could have. I know I probably haven't made a lot of friends in this room by making that comment, but I do remember Simon saying that everything was open for discussion. Now, I do have a question. Going back to Brian's presentation, I want to make sure I understand the prevalence figures and that I'm not comparing apples to oranges. The way I read the data, it appears that the prevalence rate of e-cigarettes among high school kids is about 20% according to the most recent data, but the prevalence rate among adults using e-cigarettes is only 3%. Is that right? The prevalence rate for kids is six times that of adults? Am I reading that right?

Dr. Brian King: Yes, so the definition for usage are not exactly the same. There's a difference between every day and most days. But yes, the stats are 20.8% among high school kids and 3.2% among adults in the year 2018. It's about a seven-fold higher rate of use among high school students compared to adults.

Dennis Henigan: Thank you, that's helpful.

Dr. Lisa Henriksen: I have a comment and a question, and I want to underscore the importance of what Denny just said. I want to give an example of the failure to regulate packaging. Dr. Halpern-Felsher showed us the front side of the Juul pack with the 5% number. And FDA has nice data from kids showing the gross misrepresentation of the amount of nicotine they think they're using. The actual text was 0.5%. The back of the pack is even worse. It is a doubly equivocal statement that says a Juul pod is approximately equivalent to about one pack of cigarettes. I don't know how we can move forward with tobacco control when we can't hold manufacturers accountable for correctly communicating about nicotine. Adults and influencers who want to help need to understand what the actual equivalent is. My own state health department cannot decide how to message on this. We need help. My question is for Dr. Tanski. Your statement about how there's no cue to dosing is really important. There's also no obstacle to administration. As long as you keep the device charged it will work. My anecdotal evidence comes from two teens at jazz camp over the summer, both of whom talk about roommates grabbing the device with one hand from the nightstand in the middle of the night. My question is, are there measures of addiction like HONC and others sensitive enough for people who aren't even aware they're using before waking? Most of our questions are about using upon awakening.

Dr. Susanne Tanski: That's disturbing. I had not heard of kids using it in the middle of the night like that, but I completely believe you. I've had many conversations with college kids, and many don't even know how much they're using until that pod is spent, especially if they're sharing with friends. I know that Dr. Mayne and others are trying to improve the measures of dependence to study. I'm going to probably defer to her. She's been working with a team of people to try to improve our measures on how we quantify measures of dependence and addiction.

Dr. Rachel Grana Mayne: I appreciate the comment, the question, and also the reference to some of the work that we've been supporting. At the National Cancer Institute, we are working to fund a few grants to help us better understand e-cigarette measurement. We held a measurement workshop last year to bring

together experts to begin to tackle the lack of standardization among measures and the challenges posed. We didn't aim to solve the whole issue in a day and a half, but we encouraged the conversation, we had focused discussions, and we're working on papers that will hopefully help inform the field around better syncing around measurement. It continues to be a challenge and we still need more research. I'm glad we're funding it and we need to continue to do so.

Dr. Bonnie Halpern-Felsher: I have two comments on those points. Lisa, you're right. What you just read is newer. The original packaging didn't have anything on it about nicotine, it just had a percent. Later they added that. And on the website, they also have gone back and forth and changed the numbers. Everyone is wondering about how to message it. Is it a pack, a pack and a half, or two packs? In our toolkit, we say one Juul is equivalent to 1.5 – 2 packs of cigarettes. If you just do the math, 41 mg/ml in a Juul pod is closer to the nicotine found in almost two packs of cigarettes. Some of our partners at the state level have been saying one pack. I talked to them about the discrepancy among the numbers and the messaging. They said they got their numbers from the Juul website. We have data to back it up and show that it's more. It's a huge problem that we have right now. The second item you all were talking about is the amount of use of various products, for example asking how much they are using per day. The number varied but the majority said I don't know. This isn't surprising. They're just holding it all day long. The kids put it in their hoodies or whatever. There are special clothes they can buy to use it and hide it. It's so difficult to get the data because they don't know. They use it all day long and share it.

Dr. Susanne Tanski: Just to build on that, Juul has an electric chip in it that controls how much you puff. That's not present on every device. Depending how much they inhale they could get a different type of hit. That again is something that's completely different by product type. It's maddening.

Dr. Jasjit Ahluwalia: I want to thank the presenters; these were wonderful presentations. I think this situation with youth and young adults is an absolute disaster. So, I do work with adults, so I see a different side of the equation. I will say I have two teenage kids and my wife is a pediatrician, so I am very sensitive to this topic. I was just dropping my son off at college and we went out to lunch and for 45 minutes we talked about vaping, believe it or not. But I am a little concerned about things like banning Juul because it doesn't address the other side of the equation. My work has been with African Americans for the last 25 years, a population that suffers from a very disproportionate rate of lung cancer and mortality that doesn't match their rates of smoking at all. Juul is a product that could potentially benefit this population. We just completed the only randomized trial of Juul. The data is being written up and presented. We found that at six weeks, 25% of smokers completely substituted Juul for combustible cigarettes. That's validated. Even at six weeks, there were very dramatic declines in their cancer biomarkers and carbon monoxide, and moderate decline in their respiratory symptom index score. So we clearly need a lot more work in this area, but to ban what is potentially a harm-reduction product for adults and not ban cigarettes seems very odd to me.

Simon McNabb: Obviously that is a pressing question. Some state and local areas are moving in this direction. It's very much on our minds. The availability of the product is a big influence on youth and young adults using it. We don't want to focus just on regulatory or policy approaches. These things don't exist in a vacuum. It's not a silver bullet, it's a comprehensive program. We want to talk about what we can do to empower youth and those who influence them. The policy and legal landscape plays a part in that. If things are legal or illegal, that changes people's mindsets.

Capt. Kimberly Elenberg: I appreciate your comments, sir, and I think that lends itself to the call to action that you said, and that Simon reiterated. That is to discuss the tools that we have that will generate deeper research on the impacts of the consequences that these products have on public health. And I wanted to know sir, can you clarify, what's the name of the policy that was rolled back to 2022?

Dennis Henigan: This was the FDA's policy toward premarket review of new tobacco products including e-cigarettes. The original deeming rule had set a deadline of applications to stay on market of 2018, and then in 2017 it was extended to 2022. It was a significant policy change. Juul was just beginning to emerge at the time that new policy was announced. A federal judge has found that policy to be illegal. That policy has led to the emergence of the crisis we now face.

Dr. Nez Henderson: Thank you, presenters for all the work that you've done in presenting this data. I think it's very interesting from Brian's presentation that whites surpass all other ethnicities in their use of these products. The Navajo nation actually conducted a survey in 2017 that found that 40% of Navajo youth in high school say they have tried e-cigarettes. This is a population where smoking was still very low. It shows what the industry is doing among American Indian communities. You probably heard about what they did with the Cheyenne River Sioux tribe, that's my husband's tribe. Juul came onto the reservation and tried to set up shop there, and the coalition chased them out. That's just one reservation; there are 570 recognized tribal communities. I suspect that if we don't do anything now, we'll be sitting here five years from now and the rates of e-cigarette youth among American Indians will surpass 50%. I am urging the federal government to do something about it. If we say the brain develops until age 25, why aren't all tobacco products restricted to people until age 25? I'm getting very frustrated. I've been a part of FDA's Tobacco Product Scientific Advisory Committee (TPSAC). We made all these recommendations against mint and menthol. And yet we're hearing that these companies continue to sell those products. I am very, very concerned about youth and adolescents' use. I understand what Jasjit is saying about cessation aids, but that's a different thing. We're talking about youth. We're talking about pregnant mothers who will introduce these products to their infants. Something needs to be done. This is out of hand. Thank you.

Dr. Jasjit Ahluwalia: Can I ask a clarifying question? Are we here to talk about regulation or not?

Simon McNabb: Don't feel bad about the mixed messages. What I'm trying to emphasize is the scope and objective of our meeting. Which is to get a sense of how we help youth and youth influencers prevent e-cigarette use. I'm not saying we can't talk about it, but I'm trying to steer the conversation toward our objective. We don't have to ignore product regulation. But what are the things we can do more toward our objective of empowering youth and young adults and their influencers. Does that help?

Dr. Jasjit Ahluwalia: Yes, but one of the best ways to do that is through policy and regulation.

Simon McNabb: Right, that's what I'm acknowledging. Obviously, we know there are serious questions about policy and regulation. We could spend the rest of the afternoon talking about what the FDA could do or what they should do. That would certainly be a fruitful discussion, but not necessarily help us meet our objective. It's a part of the discussion but shouldn't be the whole discussion.

Dr. Donna Vallone: While I appreciate Dr. Ahluwalia's comment, I also want to make a clear distinction that there are many policies and restrictions that can be implemented that are not a ban, compared to an unfettered environment where there's no knowledge of what's in these products. I take issue with this constant drumbeat of extreme contrasts between banning the product and responsible regulation restricting these products among youth and young adults. We know 18-21-year-olds have the highest level of Juul use, and it continues to increase. I just want to remind everybody that there are many steps at the state and federal level that can be implemented that do not include a ban.

Dr. Bonnie Halpern-Felsher: I want to piggyback on that comment. In San Francisco it wasn't a full ban, it was a ban until the evaluation was done. If we're going to consider some of these products that may have some potential benefit for adults – we don't know yet, it's great that you're getting some early data. We need to hold them to a higher bar. The cessation bar is a different kind of bar. Like you're

saying, we don't want to have an unfettered environment where it's an open market. I don't know if that means it needs to be a prescription or what. The point is that right now there's a blurred line. There's confusion among youth, which we'll get to a little more in a moment. Adults might say these are the products out there for cessation, but we don't have any data yet to confirm that. We're confusing youth with our mixed messages and by not holding regulation of cessation products to a higher standard.

Simon McNabb: That's a good point, we've all experienced this in tobacco control. People want to know about e-cigarettes. They ask if they're safe, safer, etc. I feel frustrated from the lack of a clear message. We've come a long way, but using words like "can" or "may" gets confusing. The way we tend to speak in public health – from a careful scientific point of view – doesn't always translate well to powerful messages. We're not always using clear messages with our target audience. I appreciate the discussions on what we're learning and what works.

Meredith Berkman: Dr. Ahluwalia, I just want to confirm, is your research just with adults?

Dr. Jasjit Ahluwalia: Yes.

Meredith Berkman: I just want to amplify, as a mother of four, that to hear public health officials, not anyone at this table, say that they are weighing known harm to youth with "anecdotal evidence of a potential benefit to adults," is devastating. I'm sure the person who said this in a public setting did not intend for it to be interpreted that way. But to hear that we know we're hurting kids, but it could help adults, that's terrible messaging from the public health community to the public. It's also terrible policy. To your point, a lot of things that have been called bans are really moratoriums until the action that we all know should have been taken but has not yet been taken happens. The message we're hearing is we're hurting kids, but we've got to protect what could maybe be helpful for adults.

Simon McNabb: Thank you, Meredith. That speaks to the challenge that we're up against to send clear messages to our audiences.

Gina Bowler: I work in the indoor environment division at EPA, and we have a second-hand smoke program and also an asthma program. Regarding messages, my question is what are the clear messages and citations regarding the risks and harms of second-hand exposure to e-cigarettes? I want to find them to update our second-hand smoke webpage. I can't find it on Google. There are webpages at the federal level for tobacco, marijuana, and e-cigarettes, but I couldn't find the key messages or sources. Also, as I was listening today, I thought more about the other students. The other kids in the locker room, in the bathroom, who aren't even interested in e-cigarettes but are being exposed. It's helpful to think about the other places.

Dr. Brian King: At CDC, we were among the first to articulate this in a clear way. We reinforced this in the Surgeon General's Report. Our messaging states that e-cigarettes aren't harmless. It can include harmful and potentially harmful ingredients including ultra-fine particles, heavy metals, and cancer-causing chemicals. The best way to preserve clean indoor air standards is to have no tobacco product emissions. That includes e-cigarette aerosol and second-hand smoke. We don't get into the harm-reduction messaging because the standard there is clean air. Even though e-cigarette aerosol may be safer than cigarette smoke, it's not a safe standard. When it comes to clean air standards, all tobacco emissions are problematic for health. The Office of the Surgeon General has supported that in the 2016 Surgeon General's Report, for your request for citations, and also the advisory that was issued in December 2018. The bottom line from CDC is that e-cigarette aerosol is not harmless. Other federal partners can reference other documents as well. The Americans For Non-smokers Rights is a great resource for that.

Gina Bowler: I have looked at the Surgeon General's Report that you're referring to but even on the CDC's website about harms from second-hand smoke, it's not on there. That's just an example.

Dr. Brian King: I encourage you to go to cdc.gov/e-cigarettes. We definitely have content on there. I'm aware because I wrote it myself. But we're happy to push it up on the website so it's more visible. We are happy to consider any recommendations.

Dennis Henigan: Let me make one more comment about what makes this such a difficult public policy issue. Which is that we do have an overwhelming demonstration that the emergence of e-cigarettes has caused a crisis in youth nicotine addiction; but on the other hand, there may be emerging evidence that certain devices can help smokers quit. I think the regulatory point is there is actually a mechanism in the law where FDA can take all of those considerations into account and put the burden on the manufacturer to demonstrate that the product is appropriate for the protection of public health before it reaches the market. That would mean a product that helps smokers quit and doesn't attract kids. You can set up realistic and enforceable criteria for that review. The problem is that FDA has suspended that whole mechanism that would allow us to evaluate the competing data and make product-by-product decisions. Not to continually bring this back to regulation, but we need to get that mechanism operational. Until we do, manufacturers have no incentive to prove they're not doing any harm because they're making gobs of money selling these products as many people as they can, including kids.

Dr. Jasjit Ahluwalia: I'm not an expert on regulatory science, but if you're talking about the FDA requirement of 2022, I thought there was litigation that it moved to 2021. Also, you said they have no incentive to pursue that it's safe, but they do. If they can't show net public health benefit by 2021 or 2022, then technically the product could be removed from the market.

Dennis Henigan: That's correct. The reason that there is a new deadline – which isn't 2021, it's actually May of 2020 – is because our group and other public health groups brought a lawsuit against FDA. If left to its own devices, FDA would have extended it even later. That would extend our lack of knowledge and continue the crisis even further. It's unfortunate that the public health community had to go to these lengths to sue FDA to get that date moved up. Now that we have the situation that we have, it is incumbent on the federal government to figure out how to assist all the segments of society who are facing this crisis. I have a 14-year-old daughter and I'm scared to death of this stuff. I hear so much about e-cigarette use at her high school. It's very scary. The government as a whole needs to recognize a special responsibility to address this.

Dr. Lisa Henriksen: I will keep us off the regulatory issue and back to intervention strategies. Dr. Vallone, I am so thankful for the fantastic work from Truth Initiative and for your presentation today. I'm just curious, anti-industry sentiment was such a successful strategy for smoking prevention. Is there any benefit to communicating to young people about the industry – letting them know that Juul and Marlboro are cousins?

Dr. Donna Vallone: We believe there is. We see evidence that exposing the consumer to industry practices can be effective prevention message within our formative research. The move by Altria to invest in Juul was a gift to us in that we can now help consumers understand e-cigarettes as tobacco products. While young people see these products as much less harmful and very different from a cigarette, an anti-industry message as an avenue that we will pursue heavily. Everyone needs to continue to emphasize to this audience that tobacco products, which include e-cigarettes, are the same in nicotine delivery. Moreover, there are so many of the same behavioral cues but it can be much more addictive given the frequency of use. Anti-industry messages have the ability to take the responsibility off of the user and pull it back to the structural determinant. Users can fall prey to effective industry product promotion of the industry. So yes, we see this as very important.

Simon McNabb: Thank you and with that comment we will now adjourn for lunch. When we return, we'll have some more presentations on what's being done to reach certain segments of the population and some digital tools that are available. We'll have more time to continue this discussion.

Simon McNabb: If everyone could take their seats, we'll begin the afternoon portion. We have some wonderful presenters and then a lot of time for discussion. We're now going to hear about the influencers in the education space. Our first presenter is Dr. Bonnie Halpern-Felsher, who I introduced in the morning. So I will just say take it away, Bonnie.

Bonnie Halpern-Felsher, PhD, FSAHM
Professor of Pediatrics, Stanford University

Dr. Bonnie Halpern-Felsher: Hi everyone. I've been asked to kick us off with two presentations on the role of educators and education in e-cigarette use prevention and interventions. During my talk I'll go over best practices in doing education in the schools, then I'll talk about our tobacco prevention toolkit, and I'll end with what happened when Juul took part of our curriculum.

First to go over best practices in tobacco prevention. A lot of this came from the Truth Initiative's lessons learned. The literature on what works and what doesn't actually comes from smoking, not vaping. That's newer literature. We need to make sure we talk about the role that the industry plays in promoting tobacco use, especially in targeting youth. We need to raise the role that tobacco plays. The best kinds of prevention programs talk about what the industry is doing as far as marketing and counter-marketing. They help youth understand they're being marketed to. More recently, we've found that we need to talk to youth about flavors. We don't want to just show them the cool flavors, but we have to use them to show youth that they're being targeted. We need to explain nicotine addiction. Very few interventions used that message of nicotine addiction, but it is important. Programs that discuss social norms and social influences are also effective. Those tend to be the best practices. Part of why I'm going over these now is because this isn't what Juul did.

We started the Tobacco Prevention Toolkit project almost 10 years ago thanks to some great funding from California's Tobacco-Related Disease Research Program and the California Department of Education. We spent several years doing focus groups and interviews with middle and high-school parents, educators, and students to find out what's happening in schools. We wanted to know what they need, what's going on.

We spent a lot of time developing this, and it's been available for three years. The toolkit is geared toward educators, but we also know there are youth, parents, and HCPs using the materials. The goal is to help middle and high schoolers understand basic information about all tobacco products (hookah, smokeless, e-cigarettes, cigarettes), help increase their awareness of marketing strategies, and help kids develop refusal skills. As an example of a refusal skill, one kid asked if we had any fake Juuls that he could use in social settings. After someone asked me this, we went back to develop more refusal skills.

This is an evidence-informed toolkit based on theory. It's based on research and a lot of partner work within California and across the country. It's community-based, participatory research. My two cofounders are in-class educators. Our advisory board includes parents and educators. It's a completely free, online toolkit. Because it's online, we can update information very quickly as new products come on the market or as new research is available. It has been fact-checked by experts.

The website is tobaccopreventiontoolkit.stanford.edu.

I'm just going to give you a high-level overview of what's available. There are specific units on e-cigarettes, as well as ones on Juuls and pods. There are also units on hookahs, nicotine addiction, and menthol and its social justice issues.

We heard that Juul was creating their own "prevention" curriculum. We were in the process of developing a unit on Juul when we heard about this, so we quickly worked to finish it up and get it posted to the toolkit. Then we added more and more to it. So that's how this unit got developed. You'll notice a disclaimer there that anyone can use this as long as they're not a tobacco company. You'll see why in a minute.

So then you'll see that some of the modules and units include printable posters, PowerPoints with teacher talking points, fact sheets, sample curricula, refusal skills, FAQs, activities, discussion guides for parents, and crash courses (in-depth information for teachers). People wanted a menu of what's available. We've also put together materials based on how much time you have, so if you only have one hour or five one-hour sessions, we've put together our recommendations of what materials you should teach. We also offer free Technical Assistance to help people plan sessions for specific ages (e.g., just for fourth graders). We also have blue-ribbon week ideas with materials for what you should do in every class (activations for writing class, math, history, science). We just worked on a program called Healthy Futures, which is an alternative to suspension. We worked on this for many, many months. It's a one-hour session that schools can use for students who are caught vaping or doing anything to get in trouble. Instead of expelling them, we suggest they use this curriculum and use our sample letter. We also have a "kahoot" – if you've ever played this it's a fun game you can play on your phones or computers. We encourage schools to show the question, and then you can see what percentage of the students got it right or wrong and use it as a springboard for a discussion. Everything on here has been vetted. We tell people they can use one piece or all of it and everything in between (unless you're the industry).

As far as evaluation goes, we have reached more than 700,000 kids in the last two years, so we're really excited about that. Our materials are being used in many states around the country. We train educators and do train the trainer models. Almost 2,000 educators across the country have been trained on how to use it. So that's the toolkit.

So, then we suddenly get wind of the Juul curriculum. We said this is interesting that they have their own. We know that no tobacco company should ever be doing their own prevention work because if you go back to the principles, they're not going to call themselves out regarding the marketing and what the industry is doing. A grad student and I analyzed the curriculum and published our findings which were that it never mentions the word "Juul," though they maybe said e-cigarettes, which young people do not think are the same; it doesn't focus on flavors, marketing, or the industry; it has inappropriate content (e.g., it shows a pendulum swinging idea showing that it helps kids relax); and they appear to be using other curriculums. We left it at that for the publication.

When we did a deeper dive, we saw they had stolen our curriculum. Before we had even seen what they were doing, we got wind that they were going around saying they had materials from Stanford, as if they were working with us. We weren't. We did a cease and desist order through Stanford. Juul pushed back and said there was no proof that they stole our materials.

[Dr. Bonnie Halpern-Felsher showed comparison screenshots of their toolkit and Juul's]

If you look on the far left, you can see their curriculum and ours. If you look at the middle box, they are almost identical. After the cease and desist, all they did was update the colors. But we had some PowerPoint slides in the toolkit that had old comments from reviewers in the PowerPoints. We made a mistake by posting the slides with the comments still there. Juul had slides too, and our comments were

still included in their PowerPoints. When BuzzFeed and CNN exposed them, they couldn't believe the Juul curriculum still contained these comments. They had lesson plans and discussion guides that were verbatim to what we had.

So that's the basic story. I did have somebody say to me, why do you care so much that they took your curriculum, don't you want Juul doing prevention education? No, I don't. Also, they weave in marketing questions into their evaluation. There was a question about why do you think youth your age use Juul, which is clearly a marketing question. That's not an evaluation question. I find it very hard to believe that their intentions were really to prevent use. It's a big issue and I do not want them using our curriculum whether they pretend to do a good job or not.

So in conclusion the tobacco industry should not develop prevention or education curriculum. They should follow best practices. We're proud of the fact that our curriculum has been so far-reaching. This is completely free and we go out and do trainings on it. Thank you.

Simon McNabb: Thank you, Bonnie. Our next presenter is Jim Martin. Jim is the Director of Policy and Programs with the North Carolina Tobacco Prevention and Control Branch, Division of Public Health, North Carolina Department of Health and Human Services. His major responsibilities include providing statewide leadership and expertise on tobacco use prevention and control policy and programmatic solutions. Welcome, Jim.

**Jim Martin, MS,
Director of Policy and Programs, Tobacco Prevention and Control Branch,
Division of Public Health, North Carolina Department of Health and Human Services**

Jim Martin: Thank you, Simon. Good afternoon, everyone. I'm truly honored to be here with you all today to share information on what our efforts have been in North Carolina, specifically on tobacco use prevention and control in schools. As you all know, we've got quite a changing environment in our schools. So I'll share some of the things we've done in our state and some of the areas we're currently working on.

Before I begin, let me attest to the Stanford Toolkit curriculum. It's fantastic. We have promoted it throughout our schools very intensely.

We're not immune to the e-cigarette epidemic in our state. This is data from our youth tobacco survey. Beginning in 2011, we started to collect data on e-cigarette use among high schoolers and middle schoolers. You can see that huge increase that's happened since 2011. And you can also see in 2017 we asked if kids thought they would be using e-cigarettes in the next year, and 23% of high school students said yes. We're currently going into the field with our 2019 youth tobacco survey, and unfortunately we are likely to see even higher levels than our current survey shows.

I want to share with you three studies we recently conducted to provide additional context to school environment. The first was a nicotine analysis of e-cigarettes confiscated from seven geographically dispersed high schools in North Carolina. We teamed up with our Department of Public Instruction to have schools voluntarily send us confiscated e-cigarettes to be part of the study. We wanted to investigate what was actually in those products and share that information with the schools. We teamed up with our public health lab to try to get past the perceptions that this was just water vapor, which is what kids often say. And they often say these e-cigarettes do not contain nicotine. We wanted to prove otherwise. We wanted to examine the contents of the confiscated products.

[Jim Martin shows a photo of a table covered by many e-cigarette devices.]

And you can see all of the products here. This was just from seven schools. When I sat and looked at all of these on the board room table, I thought there's a story in each one of these. How did they actually get the product and how long have they been using the product? What enticed them to bring them to school? How many are addicted? It was overwhelming to see.

So when we worked with our public health lab to conduct the analysis, we found that the average nicotine content of these products was 21 mg/ml or 2.1% nicotine. Of those that contained nicotine, 18% were much higher nicotine levels (40 mg/ml or 4%). The high nicotine samples were mostly all Juul products. And the vast majority of these products contained flavors.

More recently we conducted a second study. This was a rapid assessment of e-cigarette use on high school premises. Our EIS officer in North Carolina was the lead on this study. We broke the study into three components: We sent an online survey to almost 600 school staff across the state, we held 35 interviews with school staff (mainly principals and vice principals), and we conducted an environmental scan of e-cigarettes and where retailers were located near schools. We had 12 schools participate out of the 20 that were randomly selected. The schools were geographically diverse, and they included urban and rural schools. Most school staff (88%) said e-cigarettes were somewhat or very problematic. 95% said they were harmful, 84% said they contributed to learning disruptions, 90% said it was a high-priority issue, and 52% of school staff reported seeing e-cigarettes on their tobacco-free school grounds. When it came to resources, school staff were not confident that they had the resources to prevent e-cigarette use (32%) or help students quit (55%).

[Jim Martin shows a photo of another table covered by many e-cigarette devices.]

These were the e-cigarettes that were confiscated from the 12 participating schools. You can see a lot of Juuls there. Pretty overwhelming all together. Again, I want to acknowledge the folks who worked on this. It provides us a lot of valuable information to help us reach schools more effectively. Thank you to the staff from CDC who participated as well as our staff.

More recently, the N.C. School Resource Officers held their annual conference in our state. We were invited to present our findings and also exhibit, and while we were there, we took the opportunity to conduct a short survey with the School Resource Officers. We found that 80% of School Resource Officers think student e-cigarette use is either a moderate or serious issue on their school campuses. We had less than 20% who were offering tobacco-related education instead of a suspension program. Many schools had increased hallway and bathroom patrols as a preventative measure. 30% of School Resource Officers say schools have not taken the necessary measures to address e-cigarette use. Only 5% think their schools are taking effective measures to reduce e-cigarette use. 95% of School Resource Officers wanted additional information. They said resources were needed for educators and parents.

Turning toward the solutions, one of the illustrations that we often use to look at a comprehensive approach is Dr King's tobacco control "vaccine," which is a multi-part intervention strategy. We've adapted it a bit in our state to focus on tobacco-free policies, easy access to effective treatment, funding for additional efforts, price increases, preventing access to tobacco (an effective Tobacco 21 policy), and hard-hitting media campaigns.

Some of the interventions we have put into place in our state are looking at prevention messages through social media that can reach youth, youth empowerment trainings (engaging students in solutions), education of organizations and adult influencers. I have had an opportunity to speak with health care providers, school nurses, coaches, and other adult influencers to make sure they're educated. It's remarkable because just a year ago we'd conducted trainings and participants couldn't even identify a

Juul e-cigarette. That is changing quite extensively now. The number of tobacco-free environments especially at our local level is increasing. Also, looking at tobacco-free colleges, multi-unit housing, and workplaces. Collaborative efforts to reduce youth access to tobacco products is critical. Tobacco 21 is an up-and-coming, effective strategy. Also compliance to the Tobacco-Free Schools Law in campuses and childcare centers. Specifically looking at the school environment, we need some targeted approaches that are critical to prevent e-cigarette use.

In our schools, we just recently celebrated the 10th anniversary of the Tobacco-Free Schools Law. Between 2000 and 2007, we focused one school district at a time to convince decision-makers that a tobacco-free school campus is a policy they should adopt. We went from zero school districts with a tobacco-free policy to 87 out of 115 districts. By that time, we had legislation passed to cover the remaining school districts. By August 2008 we had all of our schools tobacco-free. Of course, the e-cigarette epidemic has turned this policy upside-down. There was very good compliance with these policies until these new products came on the market. It took a long time before schools even identified this as a tobacco product. We had to work with our state legislature to get this added to our law. We've taken specific efforts to reach our schools with this updated guidance. We updated our website to include more information about e-cigarettes. We sent letters to school districts reminding them that e-cigarettes are included in the policy and are prohibited. Schools are struggling with compliance issues. The devices are so small and easy to hide. Kids are bringing their addiction to school as well. We sent out a letter with the Department of Public Instruction to promote effective resources to educators. That was well-received. They were yearning for information. We developed new and updated tobacco-free school signs. We needed to update them to show e-cigarettes on the signs. We've been putting the signs up and trying to get media attention, so parents and educators see that we're doing this.

We are also working toward effective steps for policy violations. We want to encourage teachers and school administrators to confiscate the products. Right now, they sometimes get returned to students or their parents. We advise against that. Educators should get in touch with the parents or guardian to notify them of the violation and the action taken by the school. We want the schools to support the students – it's not just a behavior issue. Tobacco use is addictive and shouldn't just be treated as a disciplinary issue. Schools should refer students to guidance counselors or school nurses who are trained to handle this issue. We also promote alternatives to suspension programs. I'm excited to hear about the new resources from Stanford University. Suspension should be a last resort. We want to make sure students are offered cessation support. We need to help schools feel equipped. We need to engage students and parents in the solution.

We build off our public health infrastructure in North Carolina. We have strong local health departments across the state. We have 10 public health regions where we have staffed folks who work on the ground with the schools and their advisory committees to get the information out to the schools. I have been in each region conducting trainings through Area Health Education Centers that have been set up to reach adult influencers.

I applaud, again, the work of CDC and the Surgeon General for the information on their websites. We pull this information directly from those websites and, with tremendous credibility, and provide the resources at the state and local level.

Thank you very much.

Simon McNabb: Thank you, Jim. Next I'd like to introduce Amanda Graham. Amanda leads the Innovations Center at Truth Initiative, which develops, evaluates, and markets digital programs for tobacco cessation. Under her leadership, the Innovations team has built a suite of technology solutions for tobacco control, including This is Quitting, the digital quit vaping program for teens and young adults that

she'll be talking about today. So we'll be switching gears now to get to that ever-elusive quitting side of the equation.

Amanda Graham, PhD
Senior Vice President, Innovations, Truth Initiative

Dr. Amanda Graham: Great, thank you, Simon. I'm happy to be here representing the cessation side of the house. It's an honor to be here and I'm excited to talk about the program that we've developed. There's obviously been a lot of focus on prevention, but with 3.6 million young people using e-cigarettes, there has to be a role for cessation. We stepped into this space. I had a meme in previous talks that said Keep Calm and Take Action. That's what we did this year. We wanted to see how we could use our expertise at Truth Initiative in building and deploying digital cessation products to meet the demand we were seeing.

For background, I have a number of research grants funded by different agencies. One of them happens to be a NIDA-funded grant to expand an in-house SMS platform that we built in 2010. It has been run in parallel to a website called becomeanex.org that we ran as an adult cessation platform. The grant was to integrate the text messaging platform with the website to leverage the strengths of both. We were knee-deep in all of this code – this was a complex, five-year grant that was ultimately going to result in a 16-arm factorial design – so all of our software engineers, all of our product leads, all of my co-investigators and I were really well-versed and thinking critically about the design and implementation of the text messaging program. Because of the complexity of that design, we had the ability to do rapid and complex quality assurance and updates. We could also upload different versions for the purposes of this trial.

Around this time, we started seeing pleas for help on social media from young people. There's a Reddit forum with people specifically looking for help on how to quit Juul. This was a while ago and there were 1,100 members posting there. There were posts on Instagram, Facebook, and Twitter. There were videos that we saw. The theme was that people don't know how to quit or how to remove the device from their lives. They were asking for help.

We put our heads together and worked with our partners at the Mayo Clinic – we've had a long-standing partnership with the Nicotine Dependence Center at the Mayo Clinic. We really dove in to take the knowledge that we had from the combustible cessation literature to see what was similar, what would work for a vaping cessation program. What was different or unique? We did a lot of formative research. We talked to a lot of young people across the age spectrum and in a variety of contexts. We got our heads in the space of deploying in response to the Surgeon General's call as this as an epidemic and the need to address the issue quite nimbly and rapidly.

Our program is called "This is Quitting." It's a text-message program that is exclusively dedicated to quitting vaping. There are many good reasons for why we decided to go with a text messaging approach. First, we all know this is how kids communicate. In our formative work, many youth would only communicate through text messaging. There is strong evidence from adult cessation literature that text messaging is an effective strategy. It's capable of delivering proven components of what you'd deliver in a clinical setting, but with much more convenience. Most text messages are read within 90 seconds. The vast majority are replied to. It's a form of push notification that allows us to communicate in a way that we know kids are getting it. It's easy to opt-in. Texting is discreet, anonymous, and it doesn't need to involve parents. No difficult conversation is needed. They can text a short code and immediately start receiving treatment without any of the typical barriers that we see with other treatment modalities. We designed this program to be accessible to young people who may or may not be ready to quit. There are different versions of the program for different age groups. It supports quitters of all ages. We have a slightly different messaging strategy depending on age. It fits the lifestyle of young people.

The main program features were based on clinically sound information about quitting abruptly, cutting down, leaving young people in the driver's seat, behavioral activation, and actionable things people can do. Teens are a tough group, there's not great data available for much of anything on cessation for them. There is some data around young adults, so we've anchored our program around that. One of the things we heard very clearly is how socially isolating quitting e-cigarettes can be. We've heard that from a number of speakers today. These products are everywhere, and you don't have to actually own one to get offered to use it. In the process of quitting, people can feel like they're the only ones not vaping. They want to know how to practice the refusal skills that Bonnie mentioned. So, our program acknowledges the social isolation and social norms around quitting.

In terms of the actual implementation, the text messages are written in the first person. Our product lead at Truth Initiative has done a masterful job at creating messages that don't sound like they've been written by adults, but they also don't sound like they're trying too hard to be a teen. They are designed to be warm and personal. An example of a text that a teen might receive is, "I'm checking in with you." We've also gathered input from other young people who have used the program in the past and who have quit. They could submit messages, tips, and strategies for what they would say to other teens trying to quit. We've populated the program with those messages all throughout. So, for example, a user might get a message saying, "Abigail says it's helpful to keep your main reason for quitting top of mind." What that shows is, 1) there are other young people actually using this program and 2) lots of other young people are quitting. It shows them they're not alone. That's how we infuse the program to address this issue of social isolation.

We launched the program January 18. We launched with a 5-6-minute segment on the TODAY show. That day we didn't know what to expect in terms of our enrollment volume. We had a real-time dashboard set up to monitor the enrollment volume and that day we had more than 2,000 young people enroll in the first 24 hours. As the TODAY show aired across the different time zones, we would see a little spike. Then 12 days later, Mashable, a tech-focused outlet, ran a story on their Snapchat channel with millions of followers. It was a very short video story. Within 24 hours (around January 30) we had more than 22,000 young people enroll.

In your binder you have a copy of our published manuscript, which came out in the June issue of *Nicotine & Tobacco Research*. It shows the results from an initial cohort that had enrolled in the first five weeks. This was about 27,000 young people between 13 and 24 years old. The program includes a number of evaluation questions. We analyzed data at the three-month follow-up (around May 25). Some of the percentage points on my slides have changed a bit from what was published in the report, but this will give you an idea of what's been happening. The data showed that we now have more than 47,000 people fully enrolled to date (roughly 20,000 teens and 26,000 young adults). They text into a short code, give us their age, and then we triage them into the appropriate library. Approximately 100-150 people enroll each day. About a month ago we had 41,000 enrollees. We've had light integrations with the Truth Campaign which has caused some enrollment increases.

We also looked at the ways young people are engaging with this program. They are really taking advantage of our resource. Of these people, 71% set a quit date. The most common quit date is the day they enroll. About half use interactive keywords to allow them to get more out of the program (for example, by texting words like slip, crave, or mood). There is one message a day, but with those words they can get more support. 74% want the program to be longer. When we launched the program, it was 30 days long.

We also asked the users about their behavior change. After two weeks, we asked are you Juuling the same amount, more, less, or not at all anymore. At two weeks, 60% said they had reduced their frequency or

completely quit. Interestingly, the “I don’t Juul at all anymore” percentage points have gone up both for teens and young adults since the last time I presented this. We’re not sure if that means we’re getting more motivated kids, kids who are really ready to take advantage of this program. As we’ve rolled this program out and worked with different partners to help us promote the program, we may be seeing a different audience of users. In terms of abstinence, after three months we asked about seven-day abstinence and 30-day abstinence. 26% had been abstinent for seven days. 16% had been abstinent for 30 days. All of us know tobacco use patterns among young people are variable; sometimes they occur intermittently. The fact that we’re seeing users with 30 days of abstinence under their belts, to me, is quite promising.

Our next step will be to launch a comparative effectiveness trial in October. We’ll start by focusing on young adults. Teens are tricky to navigate some of the research ethics issues. We will get there. But this will give us the ability to make more causal statements about this program.

We also made some recent modifications to our program. It’s sort of a living, breathing, animal we’re tending to. We made some adjustments based on the feedback we’ve gotten in the last seven or eight months.

- We increased the program length, both for those with a quit date and those without it.
- There was a good bit of cheerleading and encouragement in the messages. We heard from young people that that’s great, but they want a thing to do today. They want actionable strategies. We blended those with messages of encouragement and support.
- We offered a keyword for “more” in response to participant feedback that they wanted more information and on-demand support.
- We are seeing around 10-12% who are dual users of e-cigarettes and combustible cigarettes. We added a referral to a smoking cessation text messaging program that we also run at Truth Initiative.
- For ease of evaluation, we informed participants that we’d be assessing their status at various points during the program. One is at sign-up where we let them know we’d be checking in on them in this first-person way about how their quitting is going. And we’ve also started asking about confidence in quitting, both as a measure of change and also as a way of delivering a more tailored experience.

I mentioned we use open-ended questions to encourage active participation. This starts right away on day one. For example, a message might say, “Abigail says having your quit goal front of mind helps you quit. Reply why you’re thinking about quitting.” This message has received 10,000 replies to date. We’re analyzing these, doing some qualitative analysis. That publication will likely be out next month. You have some of that in your book. This is a gold mine of data for us. We’re starting to see the responses morph based on the media coverage on e-cigarettes in the past few weeks. None of this is new, some of these stories have happened across different media channels. But we’re seeing comments that reference the things young people are seeing in the media.

[Dr. Amanda Graham read some of the comments they’ve received.]

The notion that young people are oblivious to what’s happening in the world is not the case. They’re in tune with these media stories; they have heightened awareness of the risks now that this lung disease is in the news.

In terms of what’s coming next, I mentioned that we’re integrating this program into the Truth Campaign. Truth has been focused on prevention messaging for the last two decades, so balancing prevention with cessation has required careful thinking and careful creative work. We had some light integrations with the

piece that Donna showed about testing on humans, as well as a piece with Now This. We started to see an increase in enrollment since those collaborations. The call to action was not central to the piece, the focus was not on cessation, but there was an uptick in enrollment.

Before I get into the support for parents, I want to talk about the massive outreach we've had from youth organizations. We stood up the ability to offer custom versions of the program, including school systems, foster care organizations, states, and local health organizations. The customization is extremely cost-efficient. There are various avenues to get it out as a cessation resource and to get it into school curricula. We work closely with the CVS Health Foundation and the American Heart Association, among others. We can spread the message that there is cessation support available.

I'll end on a note that we didn't want to leave parents out. There are parents who recognize that a kid might be struggling. We stood up a version of the program for parents. They can text into the program. They can also get connected with other parents of vapers at the online community at BecomeAnEX. This has all been earned media at this point. We've had over 5,000 parents subscribe. The feedback has been unanimously positive.

Simon McNabb: Thank you. We're moving into our final presentations. I'm going to introduce our next three speakers because they follow closely upon each other.

First up will be Gustavo Torrez. Gustavo is the Director of Youth Advocacy for the Campaign for Tobacco Free Kids. There he oversees efforts to engage youth leaders in meaningful policy change. He has been involved in the tobacco control movement for the past 20 years. He began his work in tobacco control as a youth advocate in California and continued his career in the field in Boston, where he was a Program Manager with Fenway Community Health and the National Network for LGBT Health Equity, one of the CDC-funded priority population networks.

After that we will hear from Luka Kinard. Luka is a 16-year-old high school student from High Point, North Carolina. In 2018, he spent 39 days at an inpatient treatment center for a severe vaping addiction. In an effort to help other teens, he has chosen to share his story publicly and continues his mission by speaking at schools, community events, and conferences about the dangers of vaping.

Then we'll hear from Meredith Berkman. Meredith is a cofounder of Parents Against Vaping E-Cigarettes (PAVE), a grassroots advocacy group started in 2018 by three moms as a response to the youth vaping epidemic. They discovered not only that their teen sons were Juuling, but also that a Juul rep had come into their kid's school through an outside anti-addiction group without the school's knowledge and told the students that Juuls were totally safe.

Thank you, all, and over to you Gustavo.

Gustavo Torrez
Director, Youth Advocacy, Campaign for Tobacco-Free Kids

Gustavo Torrez: Great, thank you. First, thank you to the Committee for inviting me to be here today. It's a privilege to be in the room with all these folks who are helping to create the first tobacco-free generation. Young people are our present and our future, and we need to invest in them and do better for them. As we're talking about social media and social media influencers, it's important to be reminded that this is something our young people see every day. As we're talking about new and emerging products, we need to remember there are still images being marketed in flavors like Summer Twist on social media.

[Gustavo showed a slide of social media images and ads featuring celebrities.]

This is the Summer Twist yacht party in Miami, Florida. Attendees included DJ Diesel, aka Shaquille O'Neal. Other young personalities popular with young adults were featured like Bella Thorne (former Disney Channel star with 20.3 million Instagram followers), Chanel Westcoat (3.2 million followers), Justina Valentine (4 million followers), Mariyah Lin (1.3 million followers), and other influencers. When we pulled these images, the account wasn't age-verified. The Instagram handle for the cigarillo company was on the back of every package. Consumers are encouraged to follow them and engage with them. It's no coincidence that they are pushing social media on their packaging. As we are looking at our efforts, it's really important to know what we're up against. We need to know how the industry is using influencers to promote their products.

When Juul first came out with their colorful, eye-catching designs and youth-oriented themes, it was no coincidence that the product took off and we saw a huge influence on social media. Advertising was clearly youth focused. It was also promoting a lifestyle. A lot of things that young people relate to and aspire to be were shown in the ads. Youth use rates show these campaigns were successful. Juul did stop posting on Instagram and Facebook in November 2018, but hashtag Juul use continues to rise. From January 2019 when it was around 300,000 instances to now it's over 500,000 instances. Whatever's on social media doesn't just go away even if the industry removes its handle, it's still there.

[Gustavo shows images on Snapchat of high schoolers who buy e-cigarettes in bulk and then post on Snapchat saying that they are "delivering rn, lmk" (delivering right now, let me know).]

What you're seeing in front of you is a Snapchat photo from one of our youth advocates from Miami Dade County. He got this picture from Snapchat from one of his peers. It's a high school senior who would purchase lots of e-cigarette products and then sell and distribute them to his friends. "LMK" means let me know. He is delivering all day. This is a huge problem. People could be selling hits of a Juul or these types of pods.

At the Campaign for Tobacco Free Kids, thanks to the generous support of the CVS Health Foundation, we've created an online training program called Taking Down Tobacco. This helps to train and engage young people to help us with this fight. They are the ones most impacted. They see it through social media, they're being bombarded in schools and in retail setting. We're working to train and partner with them. We have a Taking Down Tobacco 101 skills-based program that teaches young people how they you can use their voice to address this issue. We have some new courses on Juul and e-cigarettes, as well as refusal skills. We have core four direct advocacy skills. We are showing them how to take direct action, influence and inform their peers and communities through local, state, and national action.

Which you've seen here in front of you. Some young people have gone through the program and are on the forefront of this issue. They are bringing forth what they're seeing in their communities. I've had the privilege to travel across the country and speak to young people. I ask what they're seeing. We aren't as connected as our young people are. They're on the forefront addressing tobacco use through policy change. They are impacted directly. We provide a platform for them to have their voice be heard. We're working toward the first tobacco-free generation. With that, I'll pass it over to Luka Kinard who will talk about his story and what he's doing to support young people.

Luka Kinard
Teen Advocate

Luka Kinard: Hi, I'm Luka Kinard. Thank you, Gustavo for introducing me. I'm 16 years old and I was touched by big tobacco, by big vape. My first time using tobacco was when I was 14. I was at boy scouts. I started with chewing tobacco to fit in, then cigarettes, then cigars. It wasn't until my first high school

football game as a freshman in high school that I was introduced to Juuling. I wanted to fit in. I wanted to sit with the seniors and the juniors. I wanted to be with a cooler crowd. That was my token.

It very quickly became a stress-reliever. I was dependent on it. I would stay up and vape if I had a test at school or if I had issues with family or friends. That was my reason to use. Then it became my identity. I quickly began selling. Just as Gustavo pointed out that people deliver, that was me. To support that, I had to sell my clothes, shoes, and belongings so I could fuel my addiction.

In September of 2018 I had a seizure related to vaping. I had never had a seizure ever prior to that. Four weeks prior to my seizure I had intense chest pains, cold sweats, insomnia, and nausea. But, did it take me having a seizure to stop Juuling? No. I thought the seizure was a one-off. I thought, I'm still living. I wanted to keep going. My mom and dad graciously sent me to rehab in October of 2018. It was mind-changing, completely life-altering. It was 180 degrees. I went from the East Coast to the West Coast overnight, and I went from having a phone to having no phone very quickly. As a teenager, I did not like that. I was there for 39 days. For those days, I didn't have anyone say good morning, good night, I love you. I couldn't just talk to whoever I wanted whenever I felt like it. I was allowed five minutes every day to talk to my mom. I earned five more minutes after three weeks. And to be honest she was the last person I wanted to talk to at the time. Sorry, mom.

It was a very heart-breaking and hard thing to go through. But in addiction, the biggest thing you go through is what's going on with your mental health. You're going to feel depressed. You're going to feel a lot of shame, not guilt. The difference is that guilt is when you feel bad for a mistake and you keep dwelling on it. Whereas shame is when you think, I made a mistake so I am the mistake. We go through shame as teenagers but especially as addicts. For 39 days, I had to sit in my own shame. I hated everything about myself and the world. My whole mindset during vaping was, it was me versus the world. Before vaping I was a straight-A student, but I quickly went to failing. Before vaping I played two sports, but I quit them. I was a boy scout. I plateaued in my rank.

After rehab, I had the opportunity to talk to the *Wall Street Journal*. It was my mom's idea and I hated it at the time. But then I got to thinking maybe I'll talk just a little bit. Since then, I've talked to CNN, Good Morning America, *The Washington Post*, and others. I also travel around speaking to educators, school staff, students, school nurses, and now you guys as well. Thank you for the opportunity.

The biggest thing I think we need to do for a call to action in this room is that we need to work on not just the facts – because you know, teenagers don't like numbers. They go in one ear and out the other. When you start to relate to us and ask us about our personal stories, we will all start talking. Teenagers feel alone, they feel their voice is not valid. Ask us how we feel when we use and how we feel when we don't use. That's my call to action for everyone. Thank you.

Vice Admiral Jerome Adams: As Meredith is coming up, I just want to say thank you to Luka and your mom for being here and sharing your story with us. It's incredibly powerful. I know we don't have a lot of time for questions, but as you've done your interviews is there a shocking part of your story that you think adult educators don't know? What's the one thing you would say to educators or parents?

Luka Kinard: I would say, teenagers feel alone. Our mindsets are typically overlooked. People think we just have a bad teenager attitude. We don't want to just be a bad kid. To be understood, you have to understand. There needs to be more communication between educators and teenagers.

Vice Admiral Jerome Adams: Thank you. I have a 15- and a 13-year-old at home and a little bit of shame just came over me now because I know what you mean. That's an important lesson for us. Thank you.

Luka Kinard: Thank you.

Simon McNabb: Welcome, Meredith.

Meredith Berkman
Parents Against Vaping e-cigarettes (PAVe)

Meredith Berkman: I have the very hard job of following Luka. Luka's mom, Kelly Kinard, works with our group too as a parent advocate. I'm incredibly proud of him as I've gotten to know him, and I'm also incredibly proud of Kelly. And I think one of the issues, which you said so powerfully Luka, is that kids feel alone. And sometimes parents feel very alone too.

There are remarkable people around the table today and all of you know more than I could ever know about public health and all of these issues. But we parents feel that no one is paying enough attention to this problem. Obviously the greatest minds on this issue are. But there is a disconnect between the public health community, what it's trying to do and studying, and what we, the parents and the public, feel is being done.

Twice today I heard that the community needs to be nimble. And Amanda, in the innovation unit, mentioned being nimble. And Dr. Adams, you stated correctly when you charged us that there is no time to waste.

Let me tell you my story. I have four kids from the ages of 12 to 19. I have no public health background, no political background. But my son Caleb came home from school last April and said to me and my husband, there was an anti-addiction talk for 9th grade today. When the teacher left, the person came in from an outside group and talked to us. He started telling us not to Juul, but he gave us a really mixed message and it didn't make any sense. Then he began to describe what had happened in that room. For example, the person was saying "Juul is not for kids, but it's totally safe. Juul doesn't want kids as customers, but it's safe. The FDA is about to approve this any day." At the end, my son with another friend, whose mother is my cofounder by the way, went up to the man asked for clarification. They said, we just want to know what you're talking about. And the man took out his Juul, showed the kids how it worked, and referred to it as the iPhone of vapes.

At that point my two friends and I had discovered that our kids were doing something called Juuling, but we didn't really understand what that meant. That was the ah-ha moment for us. When we began to do our research, we saw two things: 1) That there had been a massive shift in teen social norm that appeared to have happened when no adults had any idea. This was because the kids were being targeted by social media and influencers. And I'm a very involved mom, and I consider myself a good mom. But of course, being a good mom means never good enough. And 2) I saw Dr. Bonnie Halpern-Felsher's toolkit and the notice about how it wasn't allowed to be used by the tobacco industry. Then I realized at that moment what had happened and knew that there were predatory practices targeting our kids. This was a massive public health crisis.

That's when we decided to take action. We thought, there must be a Mothers Against Drunk Driving group for this issue. There wasn't a year ago. We were the ones who formed the group that we would have preferred to join. Our motto is creating a motivated army of "mom-vocates." We are across the country in multiple cities and states where we try to empower parents the same way that Luka has found his voice. And how Gustavo is working to help other young adults use their voices. We want parents to know that their voices matter. We are working all across the country with the help of our partners, many of whom are here in the room. We are trying to create infrastructure to empower parents to take action.

We believe being educated is a form of advocacy. There are so few parents even now who don't know what these products look like. They don't know what they do. We also need to educate parents that there should not be a stigma. Addiction carries stigma and, as Luka mentioned, shame. Parents say to me that they're really glad we're doing this but they're really glad their kids aren't doing it. Parents need to understand if it's not their kid, it's their kid's best friend. How a society protects its children tells so much about that society. I know what the values are of the public health community in this room, and I know what our values are. And that is to protect our kids.

I know we're not meant to reference regulatory action, but this has been mentioned already so I will repeat it. There is lots of research out there that the flavors are hooking the kids. I know I'm preaching to the choir. This is a generation of kids that would not have been initiated into tobacco use. We do not want our kids to be guinea pigs.

At the risk of being presumptuous, our call to action is to let us partner with you. Grassroots, on the ground. Why aren't we offering education at the federal level? Why isn't the Department of Education making this a priority? We can't go school to school. Not every state is doing what North Carolina is doing. This has to be from the top down. We parents are working on the ground level. We are advocating frantically in Congress, at the FDA where we've spoken with our children. Also in cities and states. We beg you to put as many resources as you can into this effort. We know the research is important and at the heart of everything. But this is a race against time and our kids will only be kids for a short time. We need to act now.

And let me say one last thing about influencers. There have not yet been celebrities who have either chosen to step forward and speak to kids and parents or who have been invited to step forward. Sports figures in particular reach across ages, across class, across race. We really need to encourage influencers and athletes to come forward and talk to kids. It doesn't have to mean they never do it, but they can speak to kids about why they shouldn't.

We just launched a parent toolkit, Back to School, Not Back to Juul, with our partners. We can't be everywhere. Please consider putting a link to our toolkit on your websites. Parents listen to parents. We don't judge, we get it. We want to tell parents, you're not a bad parent, these products are stealth by design. If they would take flavors off the market yesterday, which should have been done, we will slow the growth. It will still take us years to make sure that people in Luka's age group are not a generation addicted to nicotine.

Thank you.

Simon McNabb: That's a suitable segue into our next discussion. To kick us off, I'm going to turn it over to our Chair, Dr. Adams.

Vice Admiral Jerome Adams: I just want to say thank you again, Meredith, Luka, and everyone who's been doing this work at the grassroots level. That's what today is really about. We want to figure out how we can better synergize between what we're doing at the federal level and what you're doing on the ground.

To follow up on something you said, Meredith, I actually filmed a PSA with Major League Baseball earlier this year regarding dip and chew. There's an opportunity for you to leverage that and talk to your local baseball teams and owners. I couldn't agree more that there are many opportunities to work with athletes and sports teams. It's just a matter of reaching out to them. I used to work with the Colts when I was at the state level. I hope we can get over the hump that a lot of them have in thinking that this isn't a

big enough issue and that they're going to alienate people. That's where you all can give us cover on the grassroots level.

From a national level, we are always trying to strike a balance between communicating that e-cigarettes being helpful for adult cessation and harmful for youth. We always come back to the science. As I mentioned, my predecessor got ripped to shreds for talking about the science in 2016, and I got ripped to shreds for talking about the science in December. Now we've got Congress saying, well what took you so long? Why aren't you doing enough? In many cases that's where you all give us cover – Truth Initiative, Campaign for Tobacco Free Kids – I think that you all have done a lot to help push for the research at a local level. And that's another place we need to talk about. How we can evaluate some of these programs? How can we better assess what works, especially with regard to local programs? A lot of times people throw spaghetti at the wall to see what sticks. We need critical evaluation. That was refreshing today to hear from all of you.

I have another question, and it's a real concern that we have. We know that Juul has lots of money. As you mentioned, you started with \$5,000. There are colleges and schools out there who say this is a problem, we need help. And it's hard for them to say no when Juul says they're going to give them \$50,000 or \$100,000 for an anti-vaping campaign. They know they don't have the resources to otherwise give it to them. Is there a paradigm to accept their money and/or their support to help us achieve our goals? I've met with the NAACP. There are some HBCUs (historically black colleges and universities) who've accepted money from Juul. The schools say to me, are you going to give me money for an anti-vaping campaign? Because Juul will. Is there a framework for us to accept the good without the bad that comes with it?

Dr. Bonnie Halpern-Felsher: Meredith and I have been talking almost daily for the past year about these issues. So there are two different things. First of all, the good thing is in terms of our toolkit, we can offer it for free thanks to CVS funding and other funding. If that's something that can be mandated to schools from the federal level or state level, our curriculum is free. There are a few others that are free as well. But in terms of what you're saying, Juul will give money and if it goes into an NIH fund or to a federal fund and they donate it or do whatever they do, then it can be completely hands-off and whoever gets the money doesn't have to report to them. And that's the problem. They gave \$30 million to I think it was Iowa? Overseen by Tom Miller. And no one knows where that money went. We knew it was reported and reportable to Juul. The same thing with the schools that were being offered money (\$10,000 or \$20,000) to be used in their curriculum. The only way this could work is if some company wants to do that, Juul or otherwise, it is given through or it's flow-through money. They would not have to report back to Juul. And then whoever applies for the money does so through a federal or state agency and not to Juul.

Dr. Jasjit Ahluwalia: I have two comments. There's already a model for that right now. As some of you know, Phillip Morris did create a foundation called the Foundation for a Smoke-free World, which got \$1 billion over 12 years. Derek Yach is the CEO of the Foundation. He's having a very difficult time giving that money away. Many of his friends don't talk to him anymore. He claims and it appears that there's a pretty strong firewall between the Foundation and Phillip Morris. But it hasn't worked well. The idea that Juul might give money to some other party is still going to be seen as problematic by many of the scientists and universities in the community.

Dr. Bonnie Halpern-Felsher: Being a member of the IOM Committee, I have to speak for the Committee, not as individuals. But there was some question about whether that would be the best model. But in our deliberations, that was the only model that we could see. It still has problems.

Dr. Donna Vallone: I just want to respond to that. Unfortunately, the Foundation for a Smoke-Free World (FSFW) funded by Phillip Morris is not really a good example of how this could be done. There's

no transparency. Nobody knows who the Board of Directors are. It's really a shell organization for the industry. If you look at other organizations like Campaign for Tobacco Free Kids and Truth Initiative, we embrace a non-partisan board with public health advocates. There are many credible organizations in the tobacco-control community that could help ensure the funds would be used correctly. There are ways to do this. But I'm skeptical though that that's what Juul really wants i.e. – research or programs to prevent e-cigarette use. From what I've seen, they're ok with research that has some public health benefit, but it's not in any way, shape, or form directed toward preventing e-cigarette use. Even if the funds came from the industry into the FDA and then went to NIDA that could work. There are many mechanisms that could be used for this process. The FSFW is just not one of them.

Dr. Jasjit Ahluwalia: NIAAA took money from the alcohol industry and it was a disaster. That clinical trial was shut down. Clearly, yes, the Foundation for a Smoke-free World is not an ideal model. But I'm not sure if there is one. We just see problem after problem. Would the Truth Initiative accept money from Juul? Is that what you're saying possibly?

Dr. Donna Vallone: Here's what I would say. The mechanisms would have to be very clear and transparent. In fact, there's a peer-reviewed published paper by Cohen and Zeller outlining how industry funding could be used for tobacco control. They have clear criteria of what that organizational processes and procedures are needed to ensure transparency and how they would report to the community. I think there are many organizations that would consider doing that under the right circumstances.

Dr. Wilson Compton: I just want to say we're not in the business at NIDA of soliciting industry funding to support these studies. As a matter of fact, we have very careful rules for examining grantees who have ties to industry, including e-cigarette companies. On the other hand, I wonder if some of the non-government members of this Committee have thought about the potential for including these companies in the industry fees that are used to support the Center for Tobacco Products, the FDA work. Because that would probably require an act of Congress, so it's beyond our current level of federal framework. But it could be considered. That would provide the kind of firewall where it has to go through the treasury before it comes back to the government.

Simon McNabb: I would like to open it up to other questions or comments.

Dr. Amanda Graham: I think it's important to acknowledge that school curricula activities, text messaging programs, and digital activities can be low-cost and scalable. We sometimes receive requests from a county that might not be aware of what's happening at the state level. Or states not realizing what nearby states are doing. There are opportunities to pool resources and leverage economies of scale for efficient, relatively low-cost, high-yield outreach strategies that are ready today.

Capt. Kimberly Elenberg, DNP: First I wanted to thank all the presenters today. The Department of Defense has higher tobacco use rates than the rest of the country. Our prevalence of smoking is going down, but our prevalence of e-cigarettes is exponentially growing, along with dip tobacco. This meeting facilitates the economy of scale concept that was just spoken about. You can see from the number of tweets and emails that have gone out just during this meeting. I did want to bring attention to those youth who are joining the military between the ages of 18-24, which is our highest age group. Juul is targeting them with their marketing. They have service members in their ads. I want to thank you for all the resources. I want to encourage everyone not to forget the young adult audiences.

Simon McNabb: That was a very conscious effort on our part when we put this meeting together. We know it's not just youth, but it's young adults. We know that from the science. We know brains continue to develop until age 25.

Dennis Henigan: Thank you to those of you who brought the voice of youth and parents to the table. I want to commend Gustavo, Meredith, Luka, and your mom. This is the most powerful set of voices we have. It's powerful today, it's powerful on the Hill, it will be powerful in the future. With that in mind, I have a question for Luka. Your story is enormously important. It takes a lot of courage to say it once, and it takes even more courage to say it again and again. So thank you. In the months leading up to the seizure, were you only using Juul? Did you use other products, other substitute pods, or was it only Juul?

Luka Kinard: No, it was not strictly Juul. I was using Juul, Soren, Eonsmoke, Blu, and mod devices. And yes, I did substitute a lot of vape juices. So if I were to buy vape juice for Eonsmoke, a brand that's copied Juul, I would fill that up. Juul pods are not solicited as refillable but you can refill them. So I would fill that up. It was a combination of various vaping devices.

Dennis Henigan: Thank you.

Dr. Nez Henderson: Several years ago, I know that ANR (American Nonsmokers' Rights Foundation) put a lot of focus into putting e-cigarettes into their policies. I would encourage us to make sure that's included in our policies when we go home. Another recommendation that I have is for the states. A lot of times American Indian and Alaska Native communities are not included in the regulation. They're vulnerable and being preyed on by the industry. I looked at a study regarding Navajo Nation and found that 18% of Navajo youth under the age of 18 purchased e-cigarette products on Navajo Nation. There's a lot of work we need to do on Navajo Nation, but it's going to be a huge issue if we don't do anything. It's going to take a lot of work from the federal agencies as well as us at the grassroots level to make a dent in what's happening now.

Gina Bowler: I'm a parent of 8- and 10-year-old daughters. My kids attend a Spanish-immersion school. I'm on the PTA Board. I've never heard anything about e-cigarettes except through my job. I'm wondering if PAVE has partnered with the national PTA, Girl Scouts, Boys and Girls Club of America, or Department of Education? I haven't heard anything through those organizations, the school, or from other parents.

Meredith Berkman: The problem is this is happening so quickly and it's unfolding in real time. We would love to, but we are groups of volunteer moms at a grassroots level across the country. We're a national organization, but we can't keep up with the need. These are all great ideas, but we don't have enough support to do everything else we're trying to do. We go to the head of the PTA per state. We tried to go to the national level. It's a matter of how much time and support we have. We're all volunteers building an organization. We'll talk to anyone if we can.

My question back to all of you is, how can we speed up this process and speed up research? I know that's not how government works. But we know this is an emergency. We know it's an epidemic. Donna's research shows not only that there's no decline, but there's going to be an increase. This story is only going to get uglier. So to the ideas you have, I say yes, yes, yes. But we need more time and more parents. I would actually love to have a PAVE pod in Navajo Nation. So again, how do we speed this up? I know there's not enough evidence about potential help to adults, but there's certainly enough evidence about harm to kids. And I'm not even referring, by the way, to this terrifying outbreak. As horrible as that is, and we pray for all of those families, it only underscores the bigger problem that none of us understand what these kids are pulling deep into their lungs. We all know it, the CEO of Juul knows it. That's the problem. That's why we're all so focused on the flavors. We don't want our kids to be initiated. How can we allow our kids to be guinea pigs? We need to speed it up, everybody. It's an emergency.

Dr. Bonnie Halpern-Felsher: Thank you, this is a great question. From the toolkit perspective, we're trying to get the information out on the state level. We've also been training youth to go and help us do

the work. We go to each school or school district and train educators. Then we try to pair that with an evening with parents in the community as well. We can't fly somewhere just to train parents for an hour, but if we combine it with training educators it's more effective. We go state by state, we share on social media, we're trying, but we could use help at the federal level. If someone could connect us to the national PTA or national Girl Scouts, that would help. We could put resources into national level trainings. We also have to be careful of schools that have good intentions but wind up getting training from Juul or from other organizations that are charging for the curriculum. We want to make sure they know about our free toolkit. We want to encourage them to use that instead. The other thing I wanted to say is you can take a model that works, like our toolkit, and adapt it for Native American materials or military materials. I'd love to partner with you both. We've got the model. We know how to do it. Let's sit down for a day, get some youth involved, we know what the curriculum needs to include, we can nail down the messages. I think we need to leverage what's there instead of creating something that's new.

Vice Admiral Jerome Adams: I'm going to put Brian on the spot a little bit. I ran a state department of health, and as you all know, each state has a tobacco control entity. One of their jobs is to convene players on a state level and bring folks together to have those conversations. They do the local surveillance, they talk to schools, talk to principals, and work on advocacy. All of that is important. We can in fact speed up research. We need to redefine research a bit. There's lab research, and yes that takes time to collect data and determine cause and effect. But a lot of times what CDC pushes for and what's most valuable is local surveillance. We can put you all in the position to do the on-the-ground research, survey, go into schools, talk to principals. Then we can bring you up to the national level to share. We could say, "CDC and North Carolina worked together and brought you this data, and this is likely what's going on in your community too." That's what we want to do. And I know I keep reiterating this, but we're in between a rock and a hard place. Some people don't want to engage with us because there are a lot of people out there who accuse us of fearmongering. And when I say "we" I mean the big "we," not just the government. We've got Public Health England saying that we're fearmongering. Some other traditional health institutions are hesitant to jump in with us. We need a ground-swell of local people helping us prove this case. Your research helps us make the case. We need to share your research at a larger level. Brian, anything you would add about how this happens on a state level?

Dr. Brian King: CDC is distinct in its role as the state conveners, we run the National Tobacco Control Program. We have Program Officers assigned to all the states. We're happy to leverage that and we do that in a lot of ways with our partners and states. 80% of our dollars go out the door to support the states, whether through program and policy or research and surveillance. It's well noted. CDC is committed to doing what we can on this. We just had the National Conference on Tobacco or Health two weeks ago. We're open to opportunities to do that better, particularly given the urgency. We agree on the data front and we've expedited release of the NYTS data by six months this year. We know what gets measured, gets done, whether that's at the state level or the national level. We're open to ideas from folks as to how we could do it better.

Capt. Kimberly Elenberg: Dr. King, one of the things we found in our healthy military pilot is that a lot of times when surveillance is occurring, states and counties are not asking people if they are part of the military. There is an assumption from the states and the counties that if you have a uniform, all of your resources will come from DOD. But just like a regular person in the civilian world, if you work full time you get certain benefits. But if you work part-time, like if you're in the reserves, you won't get the same benefits. We count on the county and state resources. There are also barriers to policy in the county and the state that do not allow service members to access resources. And because addiction is associated with a stigma, they might not seek out DOD resources. Service members in states are not residents of that state with a license, and we can't access those resources. I would charge the counties and the states to 1) collect information by asking people if they are currently serving and 2) waive the military services requirement of residential status to access resources.

Simon McNabb: I'll just say we recently had a meeting with some of the state tobacco control community health programs with DOD health folks to pursue those objectives.

Dr. Jasjit Ahluwalia: There was a lot of discussion about flavors today. Out of all those flavors, we could remove almost all of them and it would still work for adult cessation. You probably could just use tobacco and menthol and it would still work for adults. Until you ban menthol cigarettes, you should not ban menthol e-cigarettes, but we can talk more about that later. But I believe we just need these two flavors. And they might be somewhat attractive to kids, but if you get rid of gummy bears and all those other things completely targeted to kids, that would help. If that's possible for FDA to ban the flavors, then that should happen immediately. If we elect people to government and it's their job to protect people, they should ban those flavors. And then continue the work with adult smokers who are trying to quit.

Dr. Lisa Henriksen: The gap that I heard so eloquently raised was a gap in communication between parents, not so much with educators and students. And I am wondering what can be done to short-circuit communication between parents and principals. Also, the presentation from North Carolina was so provocative. When you gather all the devices and display them like that, there was an audible gasp from my side of the table. I would like to see what the public health community could do to provide principals with a template letter where they can write to parents, drop in a picture of what's happening on their campus, and offer specific recommendations. We can all likely agree on the content, but it's a mechanism that needs to be leveraged.

Dr. Bonnie Halpern-Felsher: We do have those resources in the toolkit. We have the templates. The frameworks are there. It's not just for schools. We also talk about PAVe in every letter.

Dr. Corinne Graffunder: I was not here this morning but I'm the Director of the Office on Smoking and Health at CDC. Just to pick up on what Brian said, the whole point of an Interagency Committee is that CDC can't be the only ones in the federal government doing this work. We certainly have the subject matter expertise, the templates, the language, the tools. We have the partners and can customize materials and use the reach that you all have. I would just ask that none of us leave this meeting today thinking we're going to speed this up just by CDC taking care of all of it. It's not going to happen. CDC can't do it alone.

Public Comments

Simon McNabb: Operator, are there any folks on the phone who would like to make a public comment?

Operator: No.

Simon McNabb: Ok, we will do public comments in the room now. Then we will return to discussion. We have three people signed up in the room. I will call your name and you can come up to the microphone. Thank you for your comments.

Catherine Martin: I'm Dr. Catherine Martin. I'm first a physician but also an educator and a researcher on nicotine. I'm here on behalf of the American Academy of Child and Adolescent Psychiatry (AACAP). What a privilege it's been to be here today. I've learned so much. I'm excited to have a chance to network. Our mission at AACAP is to promote the healthy development of children, adolescents, and families through advocacy, education, and research. As child and adolescent psychiatrists, we look from the broadest perspective, ranging from the neurobiology of the child and adolescent to the impact of family, school, and community. Our concern today is that the vaping epidemic is hitting our most vulnerable population, our youth. Recently I asked a 12-year-old patient whether she was around anyone

who vaped. She looked at me incredulously and said, “Yeah, I’m in middle school and kids vape on campus.” Vaping by adolescence has experienced by far the biggest one-year increase ever seen for any substance in the history of the *Monitoring the Future* survey. Nicotine is engaging the addictive part of the adolescent brain, establishing dependence, increasing risk for life-long use and the risk of other drug use, and detouring neural activity from parts of the brain that lead to engagement in healthy activities at home, school, and community. Youth’s perception of low risk and the targeting of adolescents through flavorings and device designs that encourage covert use, are likely harbingers of increased use. As child and adolescent mental health advocates, AACAP supports increasing awareness of health risks through vigorous education, including social media; messaging to children, adolescents and families; early identification and cessation interventions in clinical and educational settings; and banning of sales of tobacco products and e-cigarettes in stores to youth under 21 and restricting online sales. Strategies that successfully decreased traditional tobacco use should be mobilized, including strict enforcement of FDA regulations and a restriction of advertisements. Thank you very much for the honor of being here and allowing me to hear these exceptional presentations. I and AACAP look forward to learning, engaging in a dialogue, and collaborating with all of you and your agencies to address this critical issue.

Jeffrey Haberman: Good afternoon. My name is Jeff Haberman. I’m an attorney at Schlesinger Law Offices in Ft. Lauderdale, FL. We represent people who have been injured or killed as a result of tobacco-related illnesses. We currently represent hundreds of teenagers and young adults who are addicted to Juul and other e-cigarettes, but mainly Juul. Our clients have pulmonary problems, breathing problems, and some have had seizures. Most of all, they are addicted, and they are crying out for help. We applaud you for having this conference here. It is heartening to see the public health community responding with such great energy to this epidemic, this problem. But we must recognize, we are just catching up. We are a step behind the tobacco industry. We must also recognize that the vaping industry is the tobacco industry. Phillip Morris bought over 30% of Juul. That means Juul has Phillip Morris’ infrastructure and access to their 20-million smoker database. They have access to their lobbyists and lawyers. So when we talk about empowerment, as the Surgeon General did this morning, we need to not only better inform and better educate our kids, but we must use the authority available to act, and to eliminate youth use of e-cigarettes. We need to better protect our kids. We know nicotine is a drug. We know nicotine addiction is just as – if not more – severe than addiction to cocaine and heroin. We know that Juul and e-cigarette use is associated with acute pulmonary events. What we don’t know is whether Juul and other e-cigarettes have any real health benefit for adults. All of the other research to date has shown otherwise. Meredith asked earlier how we can make this go faster. Juul needs to be unreachable to youth. The commercial sale of it should be banned until approved by the FDA. We brought lawsuits in state and federal court throughout the country to reach that end. We encourage the public health community to get on board with that as other Surgeon Generals’ Reports have shown. Litigation is a form of tobacco regulation. If Juul and e-cigarettes really are smoking cessation therapies, they should be available by prescription, just as other nicotine replacement therapies are. Again, thank you for having this meeting. It was extremely informative. Thank you.

Cynthia Hallett: Thank you very much. I’m Cynthia Hallett. I’m the President and CEO of Americans for Nonsmokers Rights and the Americans Nonsmokers Rights Foundation. Thank you to this committee for all the discussion today, and I wanted to add a little bit more. Patricia Nez Henderson, who in full transparency is a member of our Board of Directors, brought up the discussion about including electronic devices in otherwise smoke-free policies. In 2009, we added electronic smoking devices to our model ordinance for smoke-free workplaces, restaurants, and bars. In that year, three municipalities did pass laws that included e-cigarettes. If we look right now at our last quarterly update of our list, 18 states, two territories, and 861 municipalities prohibit the use of e-cigarette devices in their smoke-free workplace, restaurant, and bar laws. We’ve seen phenomenal progress made in that area. In addition, we heard about college policies today. We also collect and analyze the college policies, and three of the five tribal colleges that address smoke or tobacco-free policies include e-cigarettes, along with almost 2,000 of the

other four-year, degree-granting colleges and universities. It is becoming more common to include these devices in smoke-free laws to protect people from exposure to second-hand aerosol. There was a study published in *Tobacco Control Journal* in May 2019 on associations between public e-cigarette use and tobacco-related social norms among youth. In that publication, the researchers found that e-cigarette harm perception was lower among the 6th-12th-grade students in jurisdictions without the inclusion of e-cigarettes in their smoke-free laws. By converse, in those places that had stronger smoke-free laws that included e-cigarettes, there was a greater perception of harm. There is an association between including e-cigarettes in your smoke-free laws and policies, whereby it's not only going to protect people from second-hand exposure, but it's reducing the social norm about the use of e-cigarettes and the perception that everyone's doing it. We do know youth and young adult use is on the rise, but not everybody is using it. I think we need to make sure people see that. There's a carbon copy play in action with what e-cigarette industry are doing in terms of their behavior, their proposed youth prevention programs that is exactly like the programs that we used to see in the 1990s from the tobacco industry (e.g., RJ Reynolds' Right Decisions Right Now, We Card program). These aren't age-verification programs I would say, but more of a way to collect data. We thank you and look forward to working with PAVE and everyone else to make things move faster. Thank you.

Ashley Paleka: Good afternoon. My name is Ashley Paleka. I'm an attorney with a small law firm in DC. We have a lawsuit against Juul. Our suit is more for the consumer claims but it's a nationwide class-action. I've had the opportunity to talk with many of our plaintiffs who are like Luka. Many are under the age of 18 and found themselves severely addicted to these Juul and Eonsmoke products (off-shoots of Juul). I would echo that there are so many youth who truly believe when they start using these products it doesn't contain nicotine, it doesn't look like a cigarette, it doesn't taste like a cigarette. So many think it's just mango water vapor. They don't realize it's so addictive and harmful. Given the purpose of this meeting today, one of the first things parents or teens ask, is what can I do? The Stanford toolkit is a great place to start. But I call upon CDC and other organizations that have the capacity to start to think about the fact that we need more in-person, treatment facilities where teens can go. Because they are severely addicted and it does ravage their lives. It's tragic to hear over and over again. When they live in Colorado or North Dakota and are addicted to Juul, what do you tell them to do? Again, thank you everyone for holding this meeting and working together to combat this terrible youth epidemic. Also think about what we can do to help those teens who are severely addicted and provide them the treatment they will need going forward. Thank you.

Simon McNabb: Thank you very much. Now we will turn it over to the phone. Has anyone indicated their desire to make a public comment?

Operator: No one has indicated that they would like to make a public comment.

Simon McNabb: Thank you. Now it's time to return to discussion. This is the last portion of the afternoon. Let me start by asking my federal colleagues if there's anything you would like to speak to about a program or if you have something to say.

Discussion

Lisa Postow: I am with the division of lung diseases at the National Heart, Lung, and Blood Institute (NHLBI) which is part of NIH. I want to congratulate everyone on excellent presentations. We are supporting a fairly large portfolio of heart and lung research on the health effects of e-cigarettes. Some of that is funded by the FDA through the Tobacco Regulatory Science Program and some is NHLBI funding. In the past few years, an incredibly vibrant research community has formed and it's growing. These researchers are extremely concerned about this severe lung illness. We at NHLBI are eager to work with our federal partners to find out what's happening because this is very much in our wheelhouse

because we house lung diseases at NHLBI. I just wanted to reiterate that we are trying to answer all questions related to pulmonary heart or lung effects of e-cigarettes, particularly in adolescents and young adults. I'd like to remind everyone that in addition to the brain, the lungs are also continuing to develop into young adulthood. We don't know what the effects of e-cigarette use on young lungs are.

Dr. Tina Fan: Hi I'm Tina Fan with the Agency for Healthcare Research Quality (AHRQ). We focus on helping to produce and make sure evidence is used to improve healthcare so it's safer, higher quality, and more equitable. Some of the things we're more actively involved in right now regarding tobacco is there's an evidence initiative now with on heart health and tobacco cessation as one of their aims. There's also a health IT portfolio working to provide grant funding to academic institutions working on implementing more tech-based health IT tobacco cessation. AHRQ is the agency that provides support for the U.S. Preventative Services Task Force. They are funding evidence reviews that will inform the Task Force's recommendations. One of the assets identified in the recommendations – and the public comment period is over, but it's posted on the website if anyone is interested – is that most of the evidence is specifically on tobacco and there's not much research on how to prevent youth from using e-cigarettes. So, my question for the Committee is what should we be tailoring specifically to message this? Is there a similar toolkit that could be used for primary care providers or the military?

Capt. Kimberly Elenberg: We are also making sure our messaging is evidence-based, so I second your call for that kind of a toolkit.

Dr. Bonnie Halpern-Felsher: Two things about that. The first is that we have to be really careful on how we message e-cigarettes and tobacco. E-cigarettes are tobacco. They are regulated under the FDA. I'm constantly getting push-back on that on my messaging online and on Twitter. Where does the juice come from? Of course it's tobacco. When we talk to youth and adults, we have to be careful about that messaging and say they are a form of tobacco. However, there are a lot of messaging differences. Youth are well aware of the harms of cigarettes, but not e-cigarettes. There are things we are doing to message differently. In terms of your other question, we have already been asked by HCPs to take a piece of what we've developed and customize it or use a blurb of it. A lot of people are asking for it, it's just bandwidth. We haven't had time, but we have the capacity in terms of foundational knowledge.

Dr. Wilson Compton: Thanks, this is Wilson Compton from the National Institute of Drug Abuse (NIDA). I was really struck by a number of things today, including the emphasis on youth exposure to nicotine through vaping devices. I was struck by the reminder that it takes us a long time to change public health. Indeed, I'm not sure we've bent the curve yet. It was four years ago that *Monitoring the Future* broke the news that more youth use e-cigarettes than regular cigarettes. For me as a clinician, that really brought this home. I imagined maybe some kids used them who also smoked cigarettes, but the exposure to low-risk youth who otherwise wouldn't be exposed to nicotine is a game-changer and has been now for four or five years. NIDA has made e-cigarettes and vaping and youth exposure to tobacco products one of our three key priorities for emphasis in our programs. Of course, we cover research across the range of addictive conditions and substances. But particularly, vaping, opioids, and marijuana have been the three main foci for developing new research. This includes *Monitoring the Future* and our collaboration with FDA to support the PATH study. I would remind you that PATH includes both the large cohort, which has informed a great deal of our discussions here, as well as ad hoc studies. There was a quick web-based study we did last fall, which has provided new information on vaping and its outcomes. We have new research from funding from both the Tobacco Regulatory Science Program, that's the FDA-supported work at NIH, as well as some work supported by the general NIDA funds. This includes some very interesting work on the mechanism for how flavors produce greater reinforcement. We know they do, but what's going on in the brain that produces that change? Why does a flavor coupled with nicotine make something more addictive than the item on its own? It's pretty interesting and could shed light on many other areas beyond tobacco. That work as part of our basic science program could potentially be

transformative. We remain hopeful that vaping nicotine can be a successful treatment for some, but we need to see some thoughtful, thorough research that provides strong evidence one way or the other to help guide clinical practice. Thank you very much.

Gina Bowler: Thank you. I learned from my colleagues in the indoor environment division that second-hand smoke is a universal trigger for asthma, and some communities, such as African Americans, have disproportionate health impacts from that. EPA does have an asthma program. My question is what's the current research and messaging around second-hand exposure to e-cigarettes and asthma?

Simon McNabb: I don't see Brian in the room. But I would say one of the challenges is that while e-cigarettes are relatively new, until recently if you said, "What's in an e-cigarette," you couldn't get a scientifically accurate answer. It's the wild, wild west. When they did initial testing, you would take 20 products with the same brand name, and you'd find different substances in each item of that product class. We now know Juul is the predominant product out there and they operate with more quality assurance, but we're still learning a lot about what's in them. And as Luka told us, what teens use when they're vaping may be very different than what goes into the product to begin with. I say that because we do not have strong science yet to say that second-hand aerosol has an association to asthma.

Dr. Jasjit Ahluwalia: Brian is not here anymore, but what he said is basically that it's dangerous. I don't think that evidence exists. We need more research from NIH, EPA, and others to better understand this. There's also something called third-hand smoke on objects like the table. We don't know if there are effects for that due to nicotine, carcinogens, or heavy metal.

Simon McNabb: It's an evolving science and an unsatisfactory answer.

Vice Admiral Jerome Adams: I think we have to be careful here. I think a point that Brian made is that safer doesn't mean safe. I don't think we do ourselves any favors by arguing back and forth about whether it's safe or safer. I don't want any kid, asthma or not, exposed to second-hand aerosol. I think the research that has to be done comes down to people who are current smokers and whether or not they lower the risk for themselves or others by using e-cigarettes instead of cigarettes. But too many people will take that and run with it. From a scientific and public health standpoint, I think our message should be that people shouldn't be using either product around kids and we shouldn't encourage people to think they're safe. To go back to Brian's analogy – there's a difference between jumping out of a 10-story window and a five-story window, but you're still jumping out of a window and cause yourself harm. We need to be saying don't jump out of a window at all.

Simon McNabb: A colleague of mine handed me our specific message from OSH, which is that e-cigarette aerosol is not harmless, it can contain potentially harmful substances including nicotine, heavy metals, lead, and cancer-causing agents. That's consistent with what we're saying, but we don't have a specific asthma message for parents. When you're talking to parents about how they can protect their kids with asthma, I would say clean air is clean air. If you keep clean air around the child with asthma, you give them the best chance.

Gustavo Torrez: The National Academy of Sciences, Engineering, and Medicine says that exposure to the ultrafine particles in the aerosol is known to exacerbate respiratory ailments like asthma.

Simon McNabb: Thank you for connecting the dots. We definitely know it's not just water vapor. There are harmful substances in there.

Dr. Rachel Grana Mayne: Thank you everyone for an informative, but also really inspiring day. At NCI, I don't always get to hear from our partners and people in the field. In terms of the National Academy of

Science report, there is some research on primary effects of aerosol. And although it's not isolated to the specific components, there is some evidence that wheezing and asthma symptoms can be exacerbated in youth. There clearly needs to be more research on the exact second-hand effects but there's evidence it's harmful. At NIH and NCI, we collaborate across agencies with CDC and FDA but also across groups at NIH. We get together in working groups to form funding opportunities. We have two funding opportunities relating to e-cigarettes right now with participation from several of my colleagues here at the table. We work together closely to address this issue, it's a high-priority issue. The e-cigarette measurement workshop I mentioned was an interagency workshop across groups. We are committed across agencies to fund this work and we consider it a high priority. Also, the quit vaping resources we developed to support the Real Cost campaign is part of their suite of Smokefree.gov quitting resources. Those are important resources that we invest in and we are committed to collaborating among our partners.

Dr. Rosalind King: Thank you, everyone, for the really interesting and informative day. I've learned so much. There's a report in the back that highlights some of our specific grants, so I will just cut to a general statement. At NICHD, our perspective is the whole child. When thinking about adolescents, we know they are under stress. When people are under stress, they search for coping mechanisms and sometimes resort to self-medication. We don't want to lose that perspective. We don't want to set teens up to quit one vice and pick up another one. It's important to take away e-cigarettes, but we also need components of these programs to show them what to do instead. We can't just say stop doing this, but here are some other ways to cope. That's what my institute's perspective is.

Luka Kinard: The topic that was just brought up about healthy alternatives, that's really key. People will message me or come up to me and say, I quit, what now? As educators, we need to show them the healthier alternatives. Teaching them positive reinforcements can really help.

Meredith Berkman: I've been knitting the whole time, which I know people say is one healthier activity for people who are addicted to something. In terms of all the medical symptoms and research people are talking about – we get hundreds of emails from parents who are describing that their athletes can't run a mile anymore, they have asthma. We have so many first-person stories that are so on-point to the things you're saying. One dad's son was a college baseball player and was vaping. I talked to him on the phone and afterwards realized that what he had said was terrifyingly close to the respiratory disease we heard about on the CDC call. I emailed him after and said I'm not a doctor, but you might want to consider driving up to get your son and getting him checked out. We have our fingers on the pulse and I hope people will use us as a resource. Parents don't go on these websites. Kids don't know about these amazing resources that you have out there. If there was a way to promote one "sexy" place to get all the information instead of in all these different places. That would really help educate and activate people to fight this epidemic.

Simon McNabb: Thank you, Meredith. I think that's a great note to end on. But I will look to my public members – are there any last thoughts or items to end on?

Dennis Henigan: Regarding Meredith's question of how do we make things happen faster? Much of the discussion today had to deal with mobilizing people to tell the truth about these products to the people affected by them. That's important. But the second element is mobilizing the people for public policy advocacy. I don't believe we can beat this emergency without public policy change. We talked about eliminating flavors, we talked about this at the local level and the state level, but ultimately it has to happen at the federal level. There is no public health justification for the flavored e-cigarette products whatsoever. We must mobilize at every level of government to bring about that type of policy change. Ultimately, at the federal level it's all with FDA. They have tools and the authority to do this now. We

must put pressure on FDA at every level – through grassroots, influencers, and any means necessary – to make this happen. I think that’s just as important as the public education that we talked about.

Simon McNabb: And now I will turn it over to our Chair, Dr. Adam, to close our meeting.

Closing Remarks

Vice Admiral Jerome Adams: I want to say a hearty thank you to every one of you again for taking the time and bringing your talent to this meeting. It was exactly the type of discussion that we hope for with these meetings. I had to sneak out earlier to meet with another group, and I told them that I still practice medicine one day a month at Walter Reed. I do that even though it’s hard to fit into my schedule because I’m often shocked at the way that policies are being made about the way the way we practice medicine without the involvement of anyone who actually practices medicine. I’m really proud of the folks we have at the federal level, but it’s important that we get the input from all of you so that we can better inform our policies, and so we aren’t believing something that was true 10 years ago, five years ago, or last year that may no longer still be the reality on the ground.

Thank you so much for being so frank, earnest, and passionate. Know that we have heard you. I know that I’ll take from today that we need to continue to develop resources for parents. That was a key theme I heard. We need to continue to leverage technology to reach young people, in addition to parents and other youth influencers. As Luka said, everyone gets high off of something. We need to give them something positive to get high off of. Some people get high off of sports, knitting, roller coasters, or relationships. When they don’t have those positive things in their lives, they seek out negative things. We must seek out alternatives for folks so that they don’t try these products in the first place. Also, it helps them quit if they know how to fill a void in their lives. We need to develop more resources to help people quit. I’ve heard that over and over again when I talk to people throughout the country. That’s evolved in just the past year. When I put out that advisory encouraging people not to start, the retort I got from so many communities was, “We already started, now what?” We know that’s a place where we need to continue to push.

I encourage everyone to exchange contact information with new friends around the room. One of the most important things we can do as federal partners is to convene these folks around the room. In many cases, the person who is in the best position to help you may not be one of the federal people. Some of the other folks here can share some of their best practices and data with you. Not to say we federal people are shirking our responsibilities, but we can’t always be as nimble. Sometimes the federal government turns like the Titanic, and maybe you all can turn like a jet ski. Continue to push for innovation. Push for local surveillance.

On the flavor debate, I think everyone knows my opinion – I think they’re an on-ramp for kids. It’s not as simple as saying FDA has that authority and they should exercise it. There are Attorney Generals who think we’ve gone too far in limiting access to these products. The FDA has to balance all of this feedback. There needs to be a proven net public health benefit or harm using data. Keep publishing your data, even if it’s a small survey from a local high school. Even if it’s not a large, double-blind, complex study, it adds to the database. Then we can say we feel more confidently that there is a net public health benefit to taking one direction or the other.

You asked about a resource where all these things come together – CDC has a great website. The Surgeon General website has a lot of resources. One of the things we’ll add as a deliverable to this meeting is that we’ll try to beef up and add some of your resources to those sites. We’ll make it more like a traffic light that can connect people to other resources. We encourage you to lift up the Surgeon General’s advisory. Lift up the *Stars and Stripes* letter. Too many people in our community assume everyone knows this is a problem. There are still far too many people who don’t recognize it’s a problem. They aren’t even ready

for resources; they're still in denial that this is a problem that exists. We need to lift up these advisories so people realize it's an effort we need to tackle.

Thanks to everyone, welcome to our new members. To our members who are leaving, thank you for your efforts. We appreciate you. We'll continue to tap into your expertise. Thank you, Simon, and to your team for organizing this. This has been one of the best meetings on this topic. I look forward to continuing this discussion.

Simon McNabb: With that, our meeting is adjourned. Thank you.

CHAIR'S CERTIFICATION

I hereby certify that to the best of my knowledge, the foregoing minutes of the proceedings are accurate and complete.

Date

VADM Jerome M., Adams, M.D., M.P.H.
U.S. Surgeon General
Chair, Interagency Committee on Smoking and
Health



Attachment 1: Participants List

Committee Chair

VADM Jerome M., Adams, M.D., M.P.H.

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U.S. Department of Health and

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Alberta Becenti

Indian Health Service

Gina Bowler

U.S. Environmental Protection Agency

Wilson Compton

National Institute on Drug Abuse

National Institutes of Health

Designated Federal Official

Simon McNabb

Centers for Disease Control and Prevention

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Brown University School of Public Health

Rachel Grana Mayne

National Cancer Institute

Dennis Henigan

Campaign for Tobacco-free Kids

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