FOOD AND DRUG ADMINISTRATION

ELIMINATING YOUTH ELECTRONIC CIGARETTE AND OTHER TOBACCO PRODUCT USE: THE ROLE FOR DRUG THERAPIES

PART 15 PUBLIC HEARING

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Great Room, Building 31, Room 1503

10903 New Hampshire Avenue

Silver Spring, MD 20993

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A P P E A R A N C E S

Commissioner Dr. Scott Gottlieb

Dr. Jennifer Rodriguez Pippins, Panelist

Ms. Sarah Seager Stewart, Panelist

Dr. Dionna Green, Panelist

Dr. Terry Michele, Panelist

Dr. Celia Winchell, Panelist

Dr. Iilun Murphy, Panelist

C O N T E N T S

C O N T E N T S (Continued)

C O N T E N T S (Continued)

P R O C E E D I N G S

OPENING REMARKS

DR. PIPPINS: Good morning everyone. And welcome to the public meeting on Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies.

My name is Dr. Jennifer Rodriguez Pippins. I am the Associate Director for Clinical Programs in the Office of Medical Products and Tobacco here at FDA. I'll also be the presiding officer for today's hearing.

This morning it is my great pleasure to introduce FDA Commissioner Dr. Scott Gottlieb who will be providing some opening remarks.

Dr. Gottlieb.

[Applause.]

DR. GOTTLIEB: Thanks a lot and thanks for having me here today and thanks for joining us here at the FDA today for this very important meeting.

I just want to start off with a few thoughts about the challenges we are facing right now. The FDA's work and our staff continue despite the partial lapse in FDA funding. As you know we continue with a lot of our critical health functions, but the current shut down represents one of the most significant operational challenges in this Agency's recent history. But as an Agency we are committed to fulfill our public health mandate to the best of our abilities given the current circumstances.

We've had to make some hard decisions over the last month to preserve key functions and maintain our critical consumer protection role given the current circumstances and as our biggest user fee program the prescription drug user fee program, PDUFA, begins to run out of money we have many more hard decisions ahead of us. And some of you probably read some of the reports in the press today related to that. As the application workload related to PDUFA declines because

we haven't received new applications since the end of last year, we are going to have to be required to furlough some additional staff from that center. We simply won't have enough PDUFA-related work to support all the staff. And the PDUFA fees need to go to PDUFA-related work. It is not like we can take our user fee money and put it to Food Safety or other activities. It has to go towards the work that it was paid in for.

This decision to furlough people is among the hardest and most painful decisions that we have to make in this process, and it is another consequence of the prolonged shutdown.

We'll maintain our critical safety functions across all our programs including our drug program and preserve as much of the review function as possible for as long as we can. But given the fact that the review function itself isn't excepted work under law, it is not necessary for the protection of human life under the way the law reads, that review function can't continue unless it is exempted work, unless it is being supported by user fees. So once the user fees run out that work has to stop.

We are in unfamiliar territory, it is a watershed moment in the life of the Agency, and we will come out of this I think much stronger for having grappled with this challenge together and having prevailed. But the road between now and the end will be marked by continued challenges and hardships for our people and continued impacts to our work as we focus on preserving our functions.

As I said many times through this process, everything we do here at FDA is important. People ask me are there important things not getting done. Everything we do is important. And to the extent that there are things not getting done and people not here who are important to our mission, important things aren't getting done.

But today we are joined by a broad range of stakeholders to discuss a very important issue that we wanted to continue in this environment given when it was scheduled and how important it is to the work that we are doing. And that is approaches to eliminating youth use of e-cigarettes and other tobacco products. And specifically, our focus is the potential role that

drug therapies may play in the broader effort to eliminate e-cigarettes or other tobacco use among young people as well as the appropriate method for evaluating such therapies.

I am deeply troubled by the fact that we find ourselves at this crossroads today. In recent years we've appeared poised to slay one of the most pernicious public health challenges of our times -- the death and disease caused by cigarette smoking. Significant strides had been made to reduce conventional smoking among both youth and adults. In fact, this past November the CDC had reported that smoking rates among adults reached an all-time low in 2017. Fourteen percent of adults reported cigarette smoking every day or some day marking a 67 percent decrease since 1965.

Sadly, this progress is being undercut even eclipsed if you will by the recent and dramatic rise in youth vaping. A few years ago it would have been incredible to me that we'd be here today discussing the potential for drug therapy to help addicted young people quit vaping. Instead in recent years there's

been a reason to hope that e-cigarettes could play a different role in the nicotine product continuum of risk.

When I announced the FDA's comprehensive plan for tobacco and nicotine regulation July 2017 I believed and I still believe that e-cigarettes present an important opportunity for adult smokers to transition off combustible products and onto nicotine delivery products that may not have the same level of risk associated with them. The FDA's plan was founded on the principle that what primarily causes the death and disease from tobacco use isn't the nicotine in these products but rather the harmful chemicals associated with cigarette combustion.

But we also know that nicotine isn't a benign substance. We know that initiation to and addiction to nicotine by never-smokers predominantly youth and young adults raises its own set of public health concerns. Over the past year the FDA's concerns about the public health impacts as well as the very personal impacts of youth use of e-cigarettes and other tobacco products has spiked along with the escalating popularity of

these products.

Although we knew that rates of youth use of e-cigarettes had surpassed use of combustible products a few years ago these rates had recently appeared to level off. Reported e-cigarette use among high school students which peaked at 16 percent in 2015 had decreased to 11 percent in 2016 and held steady in 2017. But in late 2017, early 2018 anecdotes from policy makers, from parents and the press suggested an alarming rise in the youth use of e-cigarettes generally and in particular products made by JUUL Labs. Instead the ubiquity of this one product became so entrenched so quickly that give rise to its own verb, JUULing. And so over the course of 2018 I announced a series of escalating regulatory actions to try to investigate the root cause of this spike in youth e-cigarette use and arrest the momentum of these trends. Unfortunately, the data from the 2018 National Youth Tobacco Survey confirm that youth use of e-cigarettes has become an epidemic. From 2017 to 2018 there was a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among

middle school students. And the total number of middle and high school students currently using e-cigarettes rose to 3.6 million. That's 1.5 million more students using these products than the previous year.

Additionally, more than a quarter, about 27.7 percent of high school student current e-cigarette users are using the products regularly on 20 or more days in the last month. So the old argument that people are just experimenting on weekends doesn't hold true anymore. People are using it regularly and you know it is the fact that addiction starts with occasional use and then it becomes regular use. And more than two-thirds, 67.8 percent, are using flavor products.

The numbers have risen significantly in 2017. Data from the Monitoring the Future study found similar trends. From 2017 to 2018 current past 30-day e-cigarette use reportedly increased from 6.6 percent to 10.4 percent among eighth-graders and 13.1 percent to 21.7 percent among tenth-graders. Finally, 16.6 percent to 26.7 percent among twelfth-grade students. This youth use continues to grow and even if we are

successful at implementing our regulatory steps to address the access and appeal of these products to kids, those actions are going to take time to have their full effect. And meanwhile the appeal to these products to kids and resulting increases in use show no sign of abating.

I fear that the survey data that we'll get next year is going to show continued increases in youth use of e-cigs. We'll be in the field with the National Youth Tobacco Survey from March to May in 2019, I'll tell you this if the youth use continues to rise and we see significant increases in use in 2019 on top of what we found in 2018 I believe this entire category will face an existential threat. I find myself debating with tobacco makers and retailers the merits of selling fruity flavors in ways that remain easily accessible to kids. But if this epidemic continues to mount, I am sure that the debate will change to one where these products should, whether or not questioning whether or not these products should continue to be marketed at all without authorized pre-market tobacco applications. It really could be game over for some of these products

until they have successfully traversed the regulatory process in full.

I think the stakes are quite literally that high. And it would be a blow to all the currently addicted adult smokers who I believe could potentially benefit from these products if this came to pass. But the major marketers of these products don't seem to fully understand the scope of this challenge or they don't seem to fully be committed to their own stated obligations and commitments they made publicly and privately to curtail this youth use to the FDA.

I've met with senior executives from five of the largest manufacturers of e-cigarettes products and I'll be calling some of them back to meet again. The companies give us written commitments about the steps they would take to stop youth use of their products and I have questions whether they are living up to the very modest promises that they made. And we all need to ask ourselves that questions.

It matters if the e-cigarette makers can't honor even modest voluntary commitment they made to the FDA. It is going to inform how we shape our regulatory

policies and it is going to inform how we shape our enforcement activities. Because we are not dependent on their voluntary action the FDA is going to be taking steps on its own. The FDA is committed to reversing youth trends and in November we announced our development of a revised policy framework for certain electronic nicotine delivery systems or END's products, including e-cigarettes. Evidence shows that minors are especially attracted to flavored ENDS products and that youth access to these products from both brick and mortar retailers as well as online is a part of the way by which they get the access to them.

We will be focused on ways to ensure that flavored ENDS products are sold in a fashion that makes them less accessible and less appealing to minors. We also plan to revisit our policy for certain flavored cigars and cigarillos which data shows appeal to minors and continue to be important among first time cigar users. And if data continues to show up where trends in youth use of tobacco products, we'll continue to expand what we do.

But already I've heard too many painful

stories from parents of teenagers and pediatricians and young people themselves, stories make clear that for many young e-cigarette users addiction has already taken hold. Perhaps the kids didn't realize what they were inhaling contained nicotine, a highly addictive chemical, and perhaps they simply thought that e-cigarettes were safer than combustible cigarettes or chewing tobacco or other forms of nicotine delivery about which they'd been warned. And perhaps the cool factor of these products outweighed those concerns. For these addicted young people, the reasons that they try e-cigarettes may not matter anymore. These young people are hooked on vaping and their worried parents, physicians and the public health community are searching for tools to help them quit.

This is why as a public health agency the FDA must examine the problem of underage use of e-cigarettes holistically. When it comes to youth use of tobacco products including e-cigarettes, we recognize that there are many facets to this issue. We must not only seek to develop evidence-based programs to prevent youth use and young people from using tobacco in any

form, we must also explore evidence-based approaches to address the existing youth use of these products and all tobacco products.

Although there is a large body of research on adult smoking cessation the methods to treat adolescents and teens who are addicted to vaping are not well understood. There is little information about how drug or behavioral interventions by support youth e-cigarette cessation as well as tobacco use more generally. And the data and other information presented today, at today's hearing, will be vitally important to helping FDA and other stakeholders begin to address these informational gaps.

And so I want to thank you in advance for your contributions. And I speak for myself and my colleagues on the panels in saying that we look forward to hearing insights that you are going to share today.

I also want to be clear that we are listening closely to all perspectives. Already the issue of how FDA should address underage use of e-cigarettes while preserving the harm reduction potential for adults has sparked powerful commentary from a range of

stakeholders.

We welcome this dialogue and the feedback as we further define our own strategies to address this epidemic. The FDA is committed to addressing this crisis in a comprehensive way to fulfilling our commitment to the public health.

Thanks a lot.

[Applause.]

DR. PIPPINS: Thank you Dr. Gottlieb.

The purpose of this hearing is to provide an opportunity for broad public input on FDA's approach to eliminating youth electronic cigarette or e-cigarette use as well as other tobacco product use with a focus on the potential role of drug therapies to support youth e-cigarette cessation and the issues impacting the development of such therapies.

Before we begin, some housekeeping. First, please silence any cell phones or other mobile devices as they may interfere with the audio in the room today. Second, we ask that all attendees sign in at the registration tables outside if you have not already done so. Third, the restrooms are located in the lobby

past the coffee area to the right and down the hallway. Finally, copies of today's presentations are available upon request. Please just contact those who are staffing the registration table outside.

I would now like to ask the panelists introduce themselves.

MS. SEAGER: My name is Sarah Seager Stewart -- I'm Sarah Seager Stewart. I am with the office of Chief Counsel.

DR. GREEN: Good morning. My name is Dionna Green and I am with the Office of Pediatric Therapeutics.

DR. MICHELE: Hello, I'm Terry Michele. I'm with the Division of Non-Prescription Drug Products in CDER.

DR. WINCHELL: I'm Celia Winchell. I'm with the Division of Anesthesia, Analgesia and Addiction Products in CDER.

DR. MURPHY: Good morning. I'm Iilun Murphy. I'm from the Office of Science and Center for Tobacco Products.

DR. PIPPINS: Thank you. For media inquiries

our press officers today are Michael Felberbaum and Angela Stark. If you both could just stand and identify yourselves. Thank you very much. They are in the back.

If any members of the media are here today, please sign in and if you have any questions or are interested in speaking with the FDA about this hearing please contact them.

I want you to know that the hearing is intended to give FDA the opportunity to listen to the comments from the presenters. So the panelists and other FDA employees are not available to make statements to media.

Although there are no rules of evidence for this particular hearing there are some general procedural rules. They are as follows: No participant may interrupt the presentation of any other participant. And only FDA panel members will be allowed to question the presenters. There will be an open public comment period at the end of the day, once all the presenters have finished.

Public hearings are public administrative

proceedings and are subject to FDA's policy and procedures for electronic media coverage. Representatives of the electronic media are permitted subject to certain limitations to video tape, film or otherwise record FDA's public proceedings including the presentations of the speakers today.

I want you to know that this hearing will also be transcribed, and copies of the transcript can be ordered through the docket or accessed on our website approximately 30 days after the public hearing.

Today we have 16 speakers registered and each of them will have ten minutes to present. After each presentation five minutes are scheduled for the panel members to ask questions.

I want you to note that if a speaker finishes early or if the questions from the panel do not take the full allotted period we intend to move on to the next speaker. This means that speakers may find themselves being called up to give their presentations ahead of the time that is currently listed on the agenda. But importantly, although we may be adjusting the speaker schedule as needed, we do plan to keep to

our scheduled break.

For the speakers we have timer lights to guide you. The light will indicate when to begin speaking and when to stop. You will get a two-minute warning before the red light goes on. If you have not concluded your remarks by the end of your allotted time, I will ask you to do so.

Please remember that the hearing is being transcribed so please be sure to use the microphone when speaking. And I just want to note I've practiced all of your names, but I apologize in advance if I get any wrong.

If you did not register to speak but you would like to present your comments you may be able to do so during the open public hearing which is currently scheduled to begin at 2:05 p.m. Again, that may change depending on how the day proceeds. If you are interested, please sign up at the registration table outside by the meeting room by 11:00 a.m.; that is important you must sign up by 11:00 a.m. for an available three-minute speaker spot.

Also important we strongly encourage you to

submit to the docket any comments you may have by February 1, 2019. You can see the Federal Register Notice for detail on how to submit comments to the docket. And they are extra copies of the notice available at the registration table.

Please note that this hearing is being webcast live. However, this is not an interactive meeting. Again, only the FDA panel members are allowed to ask the presenters questions.

In closing I want to thank everyone including our panelists and speakers for participating today. And I look forward to a productive hearing.

With that so we'll get to the business at hand and I'd like to call up our first presenter, Dr. Halpern-Felsher.

WHAT FDA SHOULD DO TO REDUCE YOUTH ADDICTION TO E-CIGARETTES.

DR. HALPERN-FELSHER: Thank you. Good morning and I'm excited to be here to talk to you about this very important issue that we have going on today.

So I first want to go into looking at pharmacology and pharmacological approaches to youth

cessation. And really, we have no current FDA approved nicotine replacement therapies for youth. There is therefore no evidence of their effectiveness when used off-label. So anybody using a nicotine replacement therapy for any youth person under the age of 18 would be considered to be used off-label. So clearly, we need much more research using randomized control trials to really understand the effects of nicotine replacement therapies on youth underage.

Certainly, lots of pediatricians, other health care providers are using them potentially with some effect which is great, but we need some evidence. So that is the first thing we need to consider.

But there are a lot of non-pharmacological events that we can do and before we do that one of the most important things is to realize that youth don't tend to quit right away. They don't understand that they are addicted which I'm going to talk about in a minute. But when they do tend to plan on quitting it tends to be later. So we need to think of not only pharmacological but non-pharmacological ways to help them quit.

One very effective way that we've learned from the Truth Initiative and other campaigns is to really give adolescents evidence that the industry, the tobacco industry, the e-cigarette industry is really targeting them and manipulating them to want to use their products. And if we can turn that around to say you are being manipulated, you are being targeted, we are doing that in our own prevention work, then you can help motivate a youth to quit.

But those efforts are really thwarted by other efforts that really talk about e-cigarettes as being harm reduction. And that is a problem because when youth hear that message, they think that the industry is trustworthy and therefore they can use their products. So that really is impeding our efforts to help young people stop smoking.

There are other social factors that are important that we need to talk to youth about. When you talk to youth about not using nicotine, any nicotine tobacco product we need to realize that they are more focused on the social effects, like looking cool, the flavors, taste, all those things, than they

are about the health effects. So simply telling young people about lung cancer, heart attacks, things like that, that is not going to help them stop or prevent them from using.

The other thing that we need to think about when we are trying to both help young people quit as well as prevent is that really we, and this is a call to the FDA, need to stop letting e-cigarette companies make cessation claims. These are attractive to youth. And I'm going to show you a little bit of data about that.

So first of all for most adults we heard Commissioner Gottlieb this morning just a few minutes ago talking about the hope that e-cigarettes will have on adults being able to quit. That is a great goal. We all hope it to be true. But the evidence isn't playing out. We most of the time see that adults who are using electronic cigarettes tend to not be able to quit smoking cigarettes and if anything, tend to use both cigarettes and e-cigarettes therefore increasing the amount of nicotine that they are using.

The other thing that we know is that in our

own data that when you see cessation claims they think that therefore it means that it is okay to use these products which just adds into their desire to quit later or not quit at all.

So some data that we recently published asked adolescents to identify what the messages are from four e-cigarette current at the time of the data collection, current ads and really ads that if we look at them are sort of explicit claims like never going back or helping me quit versus things that are more implicit like it works for you or paper or plastic. We see that the overwhelming majority of adolescent recognize that these are cessation claims, these are quit claims particularly the explicit but the implicit as well. So youth are getting that message that these are great for cessation when they aren't necessarily good for cessation for adults and that has given them the idea that they are therefore safe and okay to use.

Further it is really important to understand that youth simply don't understand addiction. So we are going to talk to them about being addicted we really need to realize that that term and those

concepts are difficult for an adolescent to understand. They don't recognize -- in our own research they don't recognize that addiction means that they are going to find it more difficult to stop smoking either immediately or in a few years. And they don't understand that they are very likely going to continue smoking beyond the time that they want.

So those are definitions of smoking -- of addiction and they don’t understand that.

The other thing we just published some very recent data on adolescent's perceptions of JUULs and adolescents see JUULs as less harmful and concerning less addictive which is not true given the high amounts of nicotine that JUULs have. And despite the fact that adolescents including those who use JUULs thought that they were less addictive on our independent scales of dependence it showed that they were actually addicted. So these young people were not recognizing the connection between what they were doing, the amount of nicotine in these products and what they are actually experiencing in terms of addiction.

So an example in terms of messages that we

really need to change that are not going to be effective to young people is something like this on the JUULS saying warning this product contains nicotine, nicotine is an addictive chemical. Given the research that is out there that adolescents, and the FDA has some similar research and we published on this as well, that adolescents simply don't understand these terms of addiction. So these kinds of messages are not going to be very effective in either helping them stop or helping them not start in the first place.

The other really important thing to look at is the packaging on these products and how the packaging conveys the amount of nicotine that is in there. So currently, I'm not sure if you can see this up there but currently what all this JUUL package says is that there is five percent in there. It does not -- and then if you look closer at other parts of the packaging it says .7 milliliters. Youth and adults, I gave a talk to several hundred parents recently about this and asked them to interpret what this five percent means; they have no understanding of how much nicotine is actually in there. And it is 59 milligrams per

milliliter or about 42 milligrams of nicotine within that package. Young people are absolutely not aware of how much nicotine is in there. And that is a big problem because they really do believe that there is no nicotine or very little nicotine and therefore not going to cause addiction for them.

So what should the FDA do? One important thing that the FDA can do is simply eliminate all flavors. And I want to emphasize all flavors. The FDA is currently talking about banning flavors but not mint and menthol. Those flavors also need to be eliminated. There is no evidence that adults need these flavors to quit smoking. There is no evidence that adults need these flavors to use e-cigarettes to quit smoking. But we do have evidence that adolescents are using not only flavors but also using mint and menthol flavors. In the paper that we recently published in JAM online we showed that almost 27 percent of the adolescent in our study who were using JUULs were using mint and menthol and 12 percent who were using other forms of e-cigarettes were also using mint or menthol. So while fruit and dessert flavors are certainly the most

prevalent, mint and menthol are still being used by adolescents and when you talk to adolescents that's the flavor they'll tell you they are using. So all flavors need to be eliminated.

The other thing we need to look at is to eliminate all ads for flavors. We also did a study recently published where we gave adolescent current e-cigarette ads that you can see here, both the bottles as well as the actual ads for e-cigarette flavors. And what we found, and we asked adolescents, are these ads for you, these flavors targeted for somebody younger, these adolescents were between 16 and 19 years old, are the ads targeting you, somebody a little bit older, somebody a little bit younger or much older meaning a bona fide adult? And what we see is very few across the board including by the way for the Appletini and the Coffee flavors very few adolescents really believe that these products, these flavored products in the ads were targeting much older adults. Most of them felt that the ads were targeting people their age and for some of them, like the really dessert fruity kinds, thought that they were actually targeting somebody much

younger than them. So these ads are attracting young people.

So in sum what does the FDA need to do? We need to eliminate all flavors and ads for flavors and again I am going to re-emphasize the importance of including mint and menthol in those bans. We need to stop saying that e-cigarettes are safe or safer. And prohibit the e-cigarette companies from making such unauthorized reduced risk claims. Youth hear these claims. They know what they are for. They think that that means that these products are harmless and therefore okay to use. We need to stop saying that e-cigarettes help adults quit smoking when again there is no clear evidence that that is the case and instead it is just attracting young people. And then we need to stop reinforcing for youth that they think that they can quit later. Youth don't understand addiction. They don't understand that they are addicted, and we need to stop and correct our messages in that vein as well.

Thank you.

[Applause.]

DR. PIPPINS: Thank you for your comments. I'll open up to the panel to see if there are any clarifying questions.

DR. MICHELE: Hi. Terry Michele. Thank you so very much for your presentation. I noted on your slides about youth not understanding addiction. You mention that they don't understand the warnings on the labels. And I wondered if you had any thoughts about what warnings they would understand?

DR. HALPERN-FLESHER: That is a very good question. We are actually going to be tackling that research. We have not done it ourselves. I think other people have. But really my suggestion would be from talking to youth and doing some of our own prevention work not using the word addiction and/or making sure that they hear and see that that means that it will be difficult to quit; that they are not going to be able to quit on their own volition; that it is going to take many years to quit and really defining the characteristics it is going to have psychological and physiological effects on you and that is going to have longer term implications. Because when we in our

own research ask adolescents can you become addicted, they say yes. And then we say does that mean you can quit smoking in a few years? Oh, easy, I can quit tomorrow. So there is a disconnect in the definition. So putting that definition out there is going to be important.

DR. MURPHY: Hi, this is Iilun Murphy. Thank you so much for your presentation. So if you have any study data on how youth and young adults interpret claims, whether they are implicit or explicit, that would be helpful and you can submit those to the docket.

DR. HALPERN-FLESHER: Will do and we actually have new data on ICOS (ph) and actually explicitly on the claims that are being made that we are about to submit so I'll give -- I'll include that in the comment. Thank you.

DR. GREEN: Hi, Dionna Green. You also state in your slides that e-cigarettes ultimately increase nicotine use in adults and you mention that with some data or understanding you've had based on your work and that also would be helpful to --

DR. HALPERN-FELSHER: I'm sorry. I am having a little trouble hearing you.

DR. GREEN: I'm sorry. So for one of your slides you mention that e-cigarettes actually ultimately increased nicotine use in adults. However, you didn't provide a reference for that and I don’t know if that is data that you have based on some of the work that you've done and if so again that would be helpful information to submit to the docket.

DR. HALPERN-FLESHER: Absolutely. It is not work I've done but my colleagues have, and we often cite it so I can submit those as well to the docket. Thank you.

DR. PIPPINS: In the 2018 -- this is Dr. Pippins. In the 2018 study that you describe on the slide that talks about first flavors, it sounds like that is a youth specific study. Could you tell us the ages that you studied and were there any patterns across say young adolescent or older youth.

DR. HALPERN-FLESHER: This is the one recognizing the ads for flavors; sorry?

DR. PIPPINS: No, this is the one reporting

first flavors used by participants --

DR. HALPERN-FLESHER: Oh, absolutely. They were -- let's see the data were collected in 2018, the end of 2018 so they were between the ages of -- I have to think exactly the same ages as my kids, so they were between 17 and 21 at the time of the data collection. So they were adolescents to the young adult transition. But they were the first flavors as well as the continued flavors. And I do have a lot more data on those flavors that we are just now analyzing.

DR. PIPPINS: Thank you very much. We --

DR. HALPERN-FLESHER: Thank you.

DR. PIPPINS: -- will move on to the next presenter.

So next we have Ms. Spike Babaian.

YOUTH VAPING EPIDEMIC? WHAT IS BEST FOR PUBLIC HEALTH?

MS. BABAIAN: My name is Spike Babaian. I am the Technical Analysis Director for New York State Vapor Association.

So I guess that eliminating youth electronic cigarettes and other tobacco product use title for today is concerned about an epidemic. And we've all

heard lots of news about this epidemic. But the general definition of an epidemic is something that insinuates a negative or a harmful consequence. And we understand that youth should not be using nicotine and should not be smoking cigarettes. But we haven't seen a negative consequence to youth vaping yet. And I do use the words yet because we don't have long-term data yet.

So I think to call it an epidemic is a little bit presumptuous because we are not really there yet. We don't know that it is making youth start smoking. We don't know that it is causing harm to anyone yet which we may find out. But I think maybe it is a little bit of an early panic.

Past 30-day use of vapor products does not qualify really as an addiction or a dependence but more of experimentation. And while we do see that youth experimentation of e-cigarettes is at a very high rate, an all-time high. We are also seeing that youth daily use of cigarettes, tobacco cigarette smoking daily, so tobacco cigarette smoking among our youth and young people is at an all-time low. So is that an epidemic

that youth are actually not smoking daily. They are not -- the people that are smoking daily are the ones most likely to go on to continue smoking. And we are at an all-time low with youth daily smoking. And I think that is a really important thing to factor in when we start considering this an epidemic. We can't say necessarily that one is causing the other but it is important to recognize.

Diagnosing dependents, we're assuming that these youth are becoming dependent and you know dependent on nicotine and addicted to nicotine. I think that part of the National Youth Tobacco Survey should consider asking questions that determine whether these youth are actually dependent on nicotine. Experimentation with nicotine does not mean dependence.

The monitoring -- the National Youth Tobacco Survey this was, I apologize but my slides were made before the National Youth Tobacco Survey data came out. I know that we said 2018 showed an increase. Monitoring the Future -- we don’t actually have the National Youth Tobacco Survey data accessible from what I understand. But the Monitoring Future Data is

available. And that shows that youth daily smoking rates are at an all-time low. And I think again that is really important to be aware of.

If youth vaping is at an all-time high is that a bad thing if youth smoking is at an all-time low? If it is better -- as Dr. Gottlieb said if it is better for adults to use e-cigarettes than to smoke, although youth shouldn’t be using nicotine at all, isn't it better for them to use nicotine than to smoke cigarettes. We are here to talk about putting them on NRTs. So we are going to give them nicotine but we are not going to let them use e-cigarettes because that could lead to smoking but using an NRT couldn't? I'm a little confused about that I guess. But I guess we need more research on that.

These are questions for National Youth Tobacco Survey. I'm going to skim through the quickly, but it is going to show you that these are the 2015 questions, these are the 2016 -- this is the same question. I apologize, this is the same question 2015, 2016, you will see that it grows each time and you add a new item each time. I'm going to go back so that we can look at

these items here. But we add a different name for e-cigarettes in each question. And so it makes sense that the youth -- that the number using e-cigarettes has gone up because you are adding a new item every year. So when you add vape-pen, hookah-pen, e-hookah, e-cigar, e-pipe, personal vaporizer, mod, and then you add more examples you are going to have more people say yes. It is like if I said did you have steak tonight, did you have hamburger tonight, did you have coffee today. The more things you add the more people are going to say yes. That is pretty much how it works. That's science as far as I understand.

So increasing the number of items in the question and then saying the number has gone up is not really a valid statement which is really kind of concerning.

The other big concern is you'll notice that in the questions they added items like -- these items actually have been in since 2015, vape-pen, hookah-pen, e-hookah. A vape-pen is not a device that is used to use nicotine. It is not an e-cigarette. It is used for marijuana purposes. In the past two years the

number of additional states that have legalized marijuana and decriminalized marijuana use had grown tremendously. So when we had more states that are allowing legal marijuana use and we add cartridges with marijuana that are used in vape-pens which are marijuana products the number of youth using e-cigarettes and vape-pens and e-hookahs is going to increase because you are adding additional items. So to say that this is a nicotine epidemic when a lot of the products listed in your National Youth Tobacco Survey questions are not nicotine products, that is a concern. And I understand there was a differentiation to ask how many of them used them with nicotine but that was not the numbers that we were given and not the numbers that we're basing this epidemic on. So this is a big concern. Hookah-pens and e-hookahs are used with zero nicotine flavors. They are used with flavored liquid that have no nicotine. So we are talking about marijuana vape-pens and non-nicotine flavored liquids and talking about children being addicted to nicotine. I think there is a big concern here.

These are searches that I did on You-Tube for

a personal vaporizer. The first one here is for personal vaporizer. You'll see that all of them say marijuana. Personal vaporizer if you look it up on You-Tube and Google it it is going to show you marijuana products. Vape-pens, sorry, I skipped one there. Vape-pens also going to show you CBD and marijuana pens. Again this is a marijuana product. Hookah-pens, if you read the descriptions or watch the videos, you'll see that these are zero nicotine products. So they don't contain nicotine. They are flavors. That being said it is also included under e-cigarettes. And we're basing an epidemic on this. E-hookah again zero nicotine.

The questions asked in summary don't really differentiate between e-cigarettes with nicotine, the question asked, there is differentiation between nicotine use and non-nicotine use in some of our surveys, our national surveys. And it is important. The Monitoring the Future data showed that the number of youth using vapor products without nicotine or with marijuana concentrates is likely to be a high proportion of the number of youth using e-cigarettes.

And this is important to factor in.

Saying that youth are addicted to nicotine without knowing whether they are actually using nicotine is just not realistic. You will notice some of my data is missing on the last portion of the past 30-day smoking because we don’t have that number yet. But yes past 30-day vaping did increase. What I don't have on this graph is the youth daily smoking rate which again is at an all-time low.

Correlation between youth vaping increasing and youth smoking decreasing I don't know. None of us do, that is why we are here I think. Clarifying the data it is important to really separate the data and find out whether youth are actually using this product with nicotine or with marijuana or with flavors that don't have nicotine.

The risk and the benefit. I'm going to go through these slides fairly quickly, but you'll see that these are side effects that are listed for Chantix, suicidal behavior and ideations, weakness, tiredness, sleeping problems, unpleasant taste and digestion, constipation. We are talking about giving

this product to youth, our teenagers. They are not tested for teenagers as Bonnie mentioned, this is not something that we tested with youth. Wellbutrin, Bupropion, the same thing. We have things here that are really concerning about giving these medications to our youth. These are NRT side effects, maybe less side effects, maybe less severe side effects, maybe it is safer to give NRTs to youth. Currently most of the side effects from NRTs are caused by nicotine and some of them may be by how the product is administered. These are the side effects that are known from the FDA's adverse events page for e-cigarettes. So I don't have to scroll back and show you but this the smallest list of all of the ones that we've looked at. And it is important to understand that you are talking about getting youth off of a product that has these side effects and putting them on a product that has all those other side effects. Is that the best way to do this? I don't think so.

Therapy and addiction counseling is helpful. We all know that it is not the best option. Keeping them out of the hands of youth is important. That is

going to be the best way to do it.

Benefits to reducing youth vaping, well, I mean it would be great if we could get all of the youth off of nicotine. The problem is if we take away nicotine there is a high likelihood that some of them are going to end up smoking cigarettes. And as Dr. Gottlieb said e-cigarettes we know are not as harmful as smoking cigarettes. So if we take the e-cigarettes away from the youth and they end up smoking is that better or is it worse?

I'm not going to go through a summary because I am a little short on time. I'm going to show my little apple here and give my quick 20 second summary.

If I told you that this apple had a 50/50 chance of killing you, would you eat it? Everyday people go out and they buy cigarettes and these cigarettes say right on the package, they don't just get them, they buy them, they pay money for a product that is very likely to kill them. This is important. There are people's bodies who need nicotine. If you take away the safer form, they will get it however they have to.

Thank you for your time.

DR. PIPPINS: Thank you so much for your presentation.

We'll open it up for clarifying questions from the panel.

I have one question. You spent some time discussing the use of products in the absence of nicotine. Are you aware of any data or any descriptive data that talks about such patterns for say younger adolescents versus older youth? Are there sort of differences based on age and how these products are used with or without nicotine?

MS. BABAIAN: For marijuana products specifically or for non-nicotine e-cigarettes?

DR. PIPPINS: Non-nicotine e-cigarettes.

MS. BABAIAN: I think that there is a difficult communication with youth and I believe that Bonnie is correct and that they don't really understand whether or not there is nicotine in the product. I think that that is a concern so there are -- it is hard to ask a youth are you using nicotine or not and know whether they understand the difference. And I think

that is important also. I think that someone should be doing clinical trial to actually say can I test your e-cigarette to see if there is nicotine in it. I mean obviously there would be concern about them wanting to give it up because they don't want to get in trouble. But I think they don't really understand whether they are using nicotine. And that is an important factor too. But that comes with education. We need to educate them to explain to them that nicotine is in these products and they shouldn't be using them.

DR. PIPPINS: Thank you very much.

With that we'll turn to our next speaker.

And actually our next presentation has two speakers. I'd like to call up Ms. Newman and Ms. Talcherkar.

MS. TALCHERKAR: Hi, my name is Anjali Talcherkar. And I'm an Integrative Addictions Counselor, a SKY Youth teacher and a recovered addict.

I began abusing drugs, alcohol, and nicotine during my adolescence. And that addiction progressed well into my 30s. My story includes trying various approaches, different rehabs, CBT based modalities and

12-step programs. And in my case nothing proved to be completely successful until I was introduced to the SKY breathing practice. And the tools taught in IAHV programs.

While some of the other modalities might have partially worked for me. I wasn't able to achieve complete sustained sobriety until I was practicing these techniques consistently. And I am now recovered for over six years.

So we are here to discuss the mechanisms of action, some of the bio, psycho, social and scientific aspects of what makes these interventions so successful. And here to do that today is Ms. Ronnie Newman. She is our director of research for IAHV. Ronnie Newman has conducted research for at-risk youth jointly funded by the Department of Health and Human Services, the Department of Education and the Department of Criminal Justice so I'll introduce Ronnie now.

MS. NEWMAN: Thank you very much. Let me just see how to advance this before I start. Do I advance this? Ah, very good. But it doesn't seem to be

working. It doesn't seem to be working. Okay. So what do I do?

Okay. Very good. Thank you very much and I am here to provide the understanding for why these programs work. And the answer in a nutshell as most of you will understand is that while drug therapy may certainly be important in targeting the mechanisms of addiction, drug therapy alone is not sufficient to allow our youth to both quit using and to prevent them from using in the first place. And many of the factors that were brought up already; thinking it is cool which is social factors, psychological factors of anxiety all need to be taken into account. And in order for us to effectively produce a program for tobacco cessation or tobacco prevention we need to look at the unique biology, psychology and social factors affecting youth.

And I'm just going to go through these quickly. So we know that youth begin using and continue using for a number of reasons. And that again social and psychological factors are important and when we directly address the biology as well as the psychology and sociology that makes it most effective.

We know that Stanford, for example, has a program for resistance skills for youth, however that is -- and while it is a very valuable program and it is critical that we educate our youth we know that the best strategies can be swept away with strong emotions in our youth. We know that, for example, the withdrawal syndrome is driven by the stress response. And when youth begin the withdrawal process the stress response kicks in which makes it more likely for them, it increases the cravings and makes it more likely for them to continue. And while drugs that we know that some drugs target the nicotine receptors, blunting the craving. We also know that that blunting effect of the pharmacotherapy can routinely be overridden by social and psychological factors. So it is critical that we address the stress response. Otherwise we are only looking at part of the problem.

Now in addition another reason to calm the stress response in adolescents is because as many of us here know first of all the darker area here, the pre-frontal cortex which sits right behind our forehead and is responsible for our sophisticated human intellect is

also the place where effective decision making and resistance skills function. However under stress when the stress response is active in the youth and actually in all of us for that matter we go from the -- what we tell the youth the wizard brain where we execute our higher knowledge and our higher wisdom and preserve ourselves; we go to the reptilian brain or the medulla area of the brain and so the corticolimbic system is not stable in youth especially because their brains are not fully developed in their teens and actually in their early 20s and so they are more susceptible to impulsivity as well. So when the stress response kicks in on top of that and moves us to our lizard brain there is much less chance for them to abstain.

So the question becomes what can we do to calm the stress response so that the biology of the pharmacotherapies and all of the social and psychological therapies, the counseling that we provide has its strongest chance of surviving. And what we do for that is we use techniques that use the breathe which is one of the -- it is the only function of our automatic or autonomic nervous system that is under our

control. So because we know that under stress the sympathetic or the stress response is active because the breath is the only function of the autonomic nervous system that is under the youth's control by teaching them specific breathing practices we actually can physiologically reduce the stress response from the very first session. And there is data which I don't know if I'll have time to show showing, for example, in adults who are in treatment for addiction the cortisol levels which is the major stress hormone dropped twice as much, significantly greater, than during treatment as usual. So we are providing a shield to protect the youth in this most vulnerable time during treatment. And to also give them the resistance skills to resist. I'm just going through this quickly.

So the program that specifically I am -- oh so there was one - all right. I'm just going to have to go past this. So the program that we are talking about in particular is the SKY Youth Program. SKY stands for Sudarshan Kriya Yoga which is a regulated rhythmical controlled breathing practice which has been taught to over 100,000 youth in the United States and over a

million youth worldwide, probably like seven million youth worldwide. And because the breath allows us to calm the stress response when we interweave that with the social/emotional learning and the education we provide a powerful platform that locks these practices into the psychophysiology of the adolescents making it more easy to recall.

And this is exactly what it found. This study which has been conducted at the UCLA Center for Addicted Behavior looked again at the prefrontal cortex in adolescents who were subjected to an effective challenge. And what they found was that the youth's ability to remain in the prefrontal cortex where all of the resistance skills and responsible decision-making take place instead of reverting to the limbic system was significantly increased and increased significantly greater than even just relaxation because when we talk about programs for stress management in youth telling them to just relax is one thing. If somebody says to you, you are really upset and somebody says chill, how effective is that compared to when somebody says take a deep breath bro. [Deep breath.] Right, because when

we take the breath we are actually using the physiology to calm the psychology. And that seems to be the most effective way. And in fact the data here show this study was also done at UCLA on high school students who are at risk and it showed significantly greater reductions in impulsivity.

We also found in the study which Anjali mentioned that was jointly funded that I'm working on which is now under review for publication we found that all of -- we looked at seven risk factors. And all seven risk factors significantly reduced using these breathing practices.

So and again one of the things we looked at was self-esteem which we all know is highly correlated with nicotine use and increased emotion regulation. Now one of the most important things here is that the youth actually use these programs because we can develop anything we think here. But it is just like the ad for you know this product can cause addiction. It doesn’t register to the kids. And in this study which is the study under review right now what we found is that 90 percent of the students actually reported using

the breathing practices when they felt stressed or upset. So it wasn't just some class that they had to take in school. It was actually an elective. But the following year the results were so strong that the school administration made it an elective for the entire school.

And we also see -- okay I mentioned about the stress hormone. We've got 21 seconds left. This is a study of individuals who are in a recovery program for alcohol dependence and what was found was that when we added the SKY breathing practices to treatment as usual which was pharmacotherapy and counseling that the anxiety rates were significantly greater, the reduction in anxiety.

And to conclude you know when the -- what does it say when the tires hit the road this was a report from the principal of that school. In the last two weeks we've had more problems with violent episode and substance use than the rest of the year combined probably due to state testing pressure. There were a lot of problem students in the SKY program but not one of them got involved in this.

So our take home points are.

DR. PIPPINS: Thank you very much. We'll have to conclude.

MS. NEWMAN: 20 seconds on there it says.

DR. PIPPINS: Okay. You may wrap up.

MS. NEWMAN: So to conclude to successfully address youth nicotine we need a multi-pronged approach and medication alone is insufficient and bio-psycho social programs like the SKY youth program that I mentioned can fill this therapeutic gap by addressing the biologic, psychological and social risk factors associated with addition. It is evidence-based, cost effective and sustainable.

Thank you.

DR. PIPPINS: Thank you very much. Sorry I interrupted you.

With that we will turn to any clarifying questions from the committee.

UNIDENTIFIED: Hi, Ms. Newman, thank you for your presentation. I just had a couple clarifying questions. So you mentioned some of the results from some of the work you've done looking at the SKY

technique. Have you done any work that looked at outcomes in adults as compared to young adults or youth and have you done any look at older youth as compared to younger adolescents?

MS. NEWMAN: We have that data and we're working on submitting it for publication now. Most of the data because these practices have been, there are 30 million people in the world to do these practices so most of the published data in peer review journals is from adults. However the data, most of the data I showed is on younger adults. We do not have the comparison although what I can say is that when we look at the data for youth it seems to pretty much parallel what we see in the older adults. And I'm very happy about the pre-frontal cortex -- the data from the Neuro Imaging Center at UCLA because it shows that even in youth with incomplete brain development because these were kids like 15 and 16 that there is stabilization of the corticolimbic system in the youth. And we definitely need to look more into this, and we can add into the docket what we have.

DR. PIPPINS: Any other questions from the

panel?

I have one. When schools are utilizing these programs, are they doing it in a setting to specifically address say other alcohol dependence or other behaviors or tobacco or e-cigarette use or are schools utilizing these programs to generally deal with the issues of stress among youth?

MS. NEWMAN: That is a very good question. That is why our research was jointly funded by the three agencies because it is used -- the programs are used both for prevention of risk and so it is risk for tobacco, alcohol, and opioids as well. And we have some programs going on right now for opioid use. But it also used because academic failure -- it turns out that you know youth are youth. They are one unit and the same risk factors for academic failure, violence, all of these things have the same risk factors for tobacco use. And so some schools bring it in for developing leadership and some schools bring it in for risk prevention because the program is the same because the risk factors and the protective factors are the same.

DR. PIPPINS: Thank you very much for your comments.

With that we will turn to our next Mr. Bill Godshall.

STILL NO EVIDENCE OF A YOUTH NICOTINE VAPING EPIDEMIC

MR. GODSHALL: My name is Bill Godshall. I'm founder and executive director of Smoke-Free Pennsylvania. My title, my presentation is Still No Evidence of a Youth Nicotine Vaping Epidemic. For several disclosures. I started smoking cigarettes when I was about eight years old. By the time I was 13 I was a daily smoker and by the time I was 17 I was a three-pack-a-day smoker. I finally quit when I was 21. But then I went to graduate school for public health and I started my first campaign against smoking was in 1981, my first day of graduate school when I told the dean that smoking in the foyer and throughout the building was totally unacceptable. And he agreed and we got it banned that year.

Several disclosures. Neither I nor Smoke-Free Pennsylvania has ever received any funding from any tobacco company, from any drug company, from any e-

cigarette company. And we haven't received any money from the FDA or NIH. So we have no financial conflicts.

This presentation will document that according to Department of Health and Human Service data and scientific evidence many or most youth who vape are not vaping nicotine. Many high school students who vape are 18-year-old adults. Very few never-smoking youth vape daily or frequently. Youth-smoking has dropped sharply as youth-vaping increased. Vaping is far less harmful than cigarettes smoking. No evidence that daily nicotine use increases human disease risk therefore it is not an addiction. Nicotine is very similar to caffeine. Chantix and Zyban pose more risk than nicotine. And youth engage in many far more harmful behaviors than nicotine use.

According to the 2017 NYTS, that is a CDC survey that Dr. Gottlieb has relied upon completely for this epidemic declaration, but the 2017 NYTS found that 50 percent of all the sixth through twelfth-graders who ever used an e-cigarette used an e-cigarette containing THC marijuana, wax or hash oil, up from 38 percent in 2016. We haven't seen the 2018 data because it hasn't

been released. Unfortunately, since 2014 CDC and FDA have categorized all vaping by youth as tobacco use and called them all tobacco users. Teens also vape caffeine, vitamins and melatonin. And these products are all sold legally to children at most convenience stores in America. And they also do CBD too.

The 2016 National Youth Tobacco Survey found that 46 percent of sixth through twelfth-graders who ever used an e-cigarette reported using any substance other than nicotine, vaping them. And that was up from 35 percent in 2015. Unfortunately, in 2017 CDC dropped this question from the survey. So here they are finding that the kids aren't vaping nicotine and they are reporting that they are vaping nicotine to the public and so does FDA.

NIDA’s Monitoring the Future, also -- that is funded by NIDA, conducted by the University of Michigan, found that more eighth through twelfth-graders percentage wise vape just flavoring or marijuana than vape nicotine. And these are the last two years data and yet they've been asking -- they ask a similar question slightly different in 2015 and 2016

that also found the same thing.

But, of course, FDA and CDC call all of them tobacco users.

2017 Youth Risk Behaviors survey, this another survey conducted by CDC found that nine out of the ten states with the highest e-cigarette use just happened to be states that legalized marijuana. And nine out of the ten states that had the lowest e-cigarette use among teens or high school students were -- did not legalize marijuana and Pennsylvania, the only one that did, didn't implement it until 2018. Now the survey data doesn't show that kids are increasing marijuana use, it is just as they -- instead of smoking it they are vaping it. It is like instead of smoking cigarettes they are now vaping.

So an analysis of the 2016 Monitoring the Future survey found that twelfth-grade smokers were far more likely to vape nicotine, 61 percent, than non-smokers, 18 percent and never-smokers. And that same survey found that never-smokers were far more likely than smokers to vape just flavoring.

And while CDC and FDA repeatedly referred to

high school students as youth in virtually every publication on this for the last five years many ninth through twelfth-graders who vape are 18-year-old adults. The 2017 Youth Risk Behavior survey found 34 percent of ninth through twelfth-graders who used a vapor product in the past 30 days were 18-year adults. And the NYTS in 2017 found that 18 and a half percent of the high school e-cigarette users past 30 days were adults. But CDC and FDA continually refer to these people as youth, always.

Oh, and by the way it is illegal for the FDA to ban the sale of any tobacco product to anybody over the age of 18. That as in the Tobacco Control Act of 2009 which was one of the reasons why I opposed it.

Daily, this is a very important slide, daily and frequent e-cigarette use one percent and one and a half percent used by sixth to twelfth-graders. It was very similar from 2014 to 2017. While experimental use declined. And the problem is that CDC and FDA only publish the one plus, the column -- the roadrunner cross of did you vape even one day in the past month and they ignore the frequency showing that very few

people vape frequently that are vaping in the past 30 days.

And daily and frequent e-cigarette use by sixth through twelfth-graders who have ever used an e-cigarette has changed very little from 2014 to 2017 while experimental use declined. Has a rate of about five percent of all ever vapors who were teens using daily and about seven percent using frequently 20 or more days in the past 30 days.

In 2017 twelfth-graders comprised 45 percent of ninth through twelfth-graders who frequently used e-cigarettes. And most twelfth-graders as reported earlier were 18 plus years old when they took the survey. And the only thing we have new from the 2018 data, that 2.3 percent of ninth through twelfth-graders vaped frequently, that is now at about five -- 5.7 percent, so that is a concern. And we need to know about who are these frequent vapors and who are these daily vapors among youth. But only a small percentage of the past 30-day vapors according to this survey too are frequent.

YRBS also found the past 30-day e-cigarette

use of e-cigarette products by ninth through twelfth grades declined by 45 percent from 2015 to 2017, from 24.1 percent down to 13.2 percent. So basically, one CDC survey in 2015 found a 24 percent past 30-day use of vapor products among youth but that wasn't an epidemic. Now that it is 20.8 percent it is an epidemic. It's just something wrong with these numbers here, analysis of them.

The 2017 Youth Risk Behavior survey also found that 2.4 percent of ninth through twelfth-graders vaped daily and 3.3 percent vape frequently, similar that the NYTS and the twelfth-graders were far more likely to use vapor products daily, frequently and in the past 30 days than were ninth through eleventh-graders. And remember many of these twelfth-graders were adults.

Now this is a very important slide in 2015 National Youth Tobacco Survey found that smokers in Grade 6 through 12 were exponentially more likely to use e-cigarettes and never-smokers. And that just 0.3 percent of never-smoking youth were frequent e-cigarette users, it is not youth, these were students, many of these were adults. And that is well -- and it

is probably still below one percent. We don't know. The 2018 data hasn't been released on that yet.

Just frequent smokers were 84 and 73 times more likely than never-smokers to vape frequently. And frequent smokers were 14 times more like than never-smokers to vape in the past 30 days. And in fact for five years straight CDC's NYTS found that exponentially more smokers reported vaping in the past 30 days than never-smokers, so it is mathematically impossible for those years for vaping to lead to smoking. It was the exact opposite what they found. But they reported differently.

Valenti, Andrea Valenti, et al. revealed that in the 2014 NYTS found that only 0.1 percent of never-tobacco-users in sixth through twelfth-graders reported vaping in ten plus of the past 30 days. And oh, by the way that 2014 NYTS also found the largest single year decline ever in teen smoking. Unfortunately, the CDC's press release for that revealing that data said e-cigarette use triples among middle and high school students in just one year and Mitch Zeller was quoted that day in that press release saying the progress we

have made in reducing youth cigarette smoking rates is being threatened. And yet the survey found a huge reduction in smoking and at that very few never-smokers were vaping. And Tom Friedland (ph) even made more inflammatory comments that were totally contradicted by the survey data that he was citing.

NYTS found clear declines in cigarette smoking by sixth through twelfth-graders 50 percent decline, 64 percent in daily smoking, frequent smoking down 63 percent, past 30-day smoking down 52 percent and 43 percent decline in ever smoking.

And similarly, the NHIS young adults 18 to 24 years cut down smoking 48 percent in that same time period, very similar to the high school data showing that vaping has prevented millions of future cigarette deaths.

DR. PIPPINS: Thank you so much. We are -- I am being told we are at time; is that correct.

MR. GODSHALL: Okay. I'll go through these quickly.

DR. PIPPINS: Thank you very much for your comments and presentation. And again, should anyone

ever run out of time there is also opportunity to submit to the docket as well, if you do want to hear comments.

With that I'll ask the panel if there are any clarifying questions.

Not seeing any we'll move on to the next presentation.

MR. GODSHALL: No questions. We need more transparency and truthfulness out of FDA. They need to stop protecting cigarettes and start protecting public health.

DR. PIPPINS: Our next speaker is Dr. Susanne Tanski.

TOBACCO CESSATION FOR ADOLESCENTS

DR. TANSKI: Good morning. My name is Dr. Susanne Tanski. And I am a pediatrician and a tobacco control expert with about 17 years of experience researching tobacco and counseling youth about tobacco cessation and their tobacco product use.

I'm here today representing the American Academy of Pediatrics, a non-profit professional organization representing over 67,000 primary care

pediatricians, pediatric medical sub-specialists and pediatric surgical sub-specialists. The Academy believes that all children should lead tobacco-free lives free from the use of all tobacco products and free from exposure to second hand smoke and vapor.

As the FDA is well aware and Dr. Gottlieb said recent trends in use of e-cigarettes by adolescents are quite concerning. According to data from the National Youth Tobacco Survey current e-cigarette use among high school students increased by 78 percent as mentioned. That is one in five high school students in a total of 3.7 million middle and high school current users. These youth are using e-cigarettes frequently with 27 percent saying they are vaping 20 or more days in the last month.

These dramatic increases in e-cigarette use among adolescents are of grave concern and the AAP appreciates Commissioner Gottlieb's recognition of these epidemic levels in youth e-cigarette use.

Pediatricians have seen the growing threat in e-cigarette use among our patients. The rise of a new generation of products like JUUL that are sleek,

discrete and available in appealing flavors has enticed our teens to try these products. What's more these products deliver very high levels of nicotine meaning that even brief experimentation is likely to put adolescents at risk for long term dependence.

For those teens already dependent on e-cigarettes clinicians urgently require new solutions to safely and effectively help stop them using these and all tobacco products for good.

Reversing these trends and ultimately eliminating youth e-cigarette use will require a multi-faceted approach. And strong tobacco control policies must play the primary role.

Let me say at the outset that while it is important to discuss how drug therapies can help adolescents who already are dependent on tobacco products, preventing youth use in the first place should be FDA's primary goal. We must all recognize that if an adolescent has developed a nicotine addiction as a result of vaping we've already failed.

FDA's recently announced regulatory actions regarding e-cigarettes do not go far enough and we urge

much stronger action regarding e-cigarettes.

Strong tobacco control policy aimed at keeping these products away from adolescents may be more effective in achieving adolescent cessation than medical interventions. Indeed, it is likely that nothing FDA does to advance tobacco dependence treatment for adolescents will be as powerful or effective as addressing the availability of flavored e-cigarette products that are attracting and sustaining youth use.

We must prevent youth nicotine addiction before it starts.

There is unfortunately no data on how to treat an adolescent for e-cigarette addiction and there is significant need for research in this area. We simply do not yet know if our traditional approach for cigarette cessation will apply to e-cigarettes. And in the absence of this data we must be informed by the evidence-based strategies for helping teens quit traditional tobacco products.

Most teen cigarette smokers want to quit although most struggle to do so and relapse rates are

very high. While the evidence base is limited research suggests that behavioral and psychological interventions delivered in schools, community settings and medical visits are at last somewhat effective in helping youth stop smoking.

Research from the APP's Julius B. Richmond Center of Excellence tested use of one of the five A's intervention which is Ask, Advise, Assess, Assist and Arrange by pediatricians in the primary care setting. While this intervention increased teens likely to have a quit attempt, at follow up most teens had relapsed and there was not a significant impact on cessation at six months.

Outside of the medical setting a school nurse delivered cessation program was found to be effective for abstinence and short-term smoker reduction in adolescents meeting teen's needs in a location where they spend a great deal of time. Other techniques that focus on motivational interviewing and face-to-face cessation counseling have been found to increase quit attempts and aid in cessation.

Overall however a 2015 state of the art

literature review by the AAP Tobacco Consortium found that while evidence for youth tobacco cessation is increasing few results are generalizable. Beyond behavior interventions little research has been conducted assessing the effectiveness of pharmacological interventions such as nicotine replacement therapy, varenicline and bupropion for smoking cessation in adolescents. And what has been done to date has been disappointing.

While bupropion and NRTs seem to increase quit attempts and decrease daily intake of cigarettes in youth they have not been shown to have a long-term increase in cessation. Crucially adolescent adherence to treatment protocols for pharmacotherapy is very low which may impact the efficacy of these drugs. Due to insufficient evidence of efficacy NRT for adolescent cessation is not recommended in the most recent guidelines and NRT has not been approved for use for youth under the age of 18.

Studies have found that some adolescent tobacco users do elect to use NRT without physician guidance indicating at least some interest in

pharmacotherapy from adolescents. This is an important area for further investigation.

Such research to conclusively identify the most effective tobacco cessation modalities for adolescents addicted to e-cigarettes is an urgent need. In particular we need the FDA to help identify how best to treat young people who are already addicted and dependent on high delivery nicotine delivery products like JUUL.

In order to better understand how to help adolescents quit e-cigarette use we must understand the specific trajectories of e-cigarette use and related nicotine dependence in this age group. Our current understanding of nicotine dependence trajectories is based on experience with traditional tobacco products and largely combusted cigarettes. We recognize that it is plausible that the dependence trajectory for young cigarette users may differ from that of e-cigarette users and in particular users of JUUL and other similar pod-based devices due to higher nicotine delivery levels.

Recently published research has documented

high exposure to nicotine among users who use JUUL and other pod-based systems. One study published in September looked at urinary cotinine concentrations in teen users of pod-based systems and found that the concentration of urinary cotinine was higher in users of pod-based systems as compared to teens using traditional combusted cigarettes.

In a study currently in press at pediatrics pod-based e-cigarette users had median cotinine levels significantly higher than non-pod users and daily e-cigarette users had significantly higher median cotinine concentrations than non-daily users. That higher cotinine levels correlated with higher nicotine intake and more frequent use corroborate teens self-described addiction to these new products. These early and limited data suggest that adolescent users of JUUL and other similar e-cigarettes may require unique cessation techniques.

We strongly urge the FDA to funds studies to better understand adolescent e-cigarettes addiction while also quickly identifying effective interventions for this population of e-cigarette users whether they

be drug therapies, behavioral interventions or most likely regiments that combine the two.

We must also explore whether these interventions should be the same for adolescents at different points in the nicotine dependence trajectory. And whether they should differ depending on the severity of dependence. Indeed, the very issue of measuring a nicotine dependence in adolescent e-cigarette users is also likely to be a challenge and researchers may need support in measuring dependence in a consistent way.

Expanded research of nicotine replacement therapies and other drug therapies for e-cigarette cessation is needed. There have not been any trials for e-cigarette cessation with NRT. A randomized control trial of NRT in adolescence could be a useful line of study. It is also possible that modifications to the characteristics of currently available NRT products such as changes to flavor to make them more palatable to adolescents may help improve regimen compliance and improve effectiveness. They should be explored as we look for treatment solutions to e-

cigarette dependence among adolescents.

We are very aware that pharmacological studies in pediatric populations can be difficult and drug company often have little financial incentive to pursue drug development in children. Two pediatric drug laws, the Best Pharmaceuticals for Children Act, BPCA, and the Pediatric Research Equity Act, PREA, have been successful in greatly increasing the number of drugs with data on pediatric dosing, safety and efficacy.

We've learned a great deal about how to better study drugs in children and we need to apply these lessons to treatment for nicotine dependence. For example, we know that while recruiting patients into pediatric drug trials isn't easy. With the appropriate expertise, protocols and use of networks and multi-site trials sufficient numbers can be enrolled to make meaningful progress.

We urge the FDA to apply the lessons it has learned to drug therapies for nicotine dependence and we also urge FDA to utilize the incentives and requirements provided by BPCA and PREA whenever appropriate to encourage additional drug study in this

area.

As industry interest in adolescent nicotine dependence has not been robust, we recommend that the FDA take the first steps and fund large, well-powered, multi-site clinical trials. The design of any such trials and future label changes if justified by the evidence must also recognize that teens have unique access issues that are different from adults. Some teens use tobacco products without their parents' knowledge and accessing treatment may out them to their parents. As such a teen's ability to confidentially access drug therapies may be critical to the ability to scale and disseminate any successful research interventions that do not involve pharmacotherapy.

FDA will need to consider how to encourage safe and confidential access points for teens to obtain any evidence-based pharmacotherapies and treatment for nicotine cessation.

As these changes are explored, we also urge FDA to ensure that any novel drug therapies or modifications to existing therapies address the needs of young e-cigarette users, also taking into account

the potential risks to nicotine-naïve adolescents and young adults. Currently approved NRT products are absorbed very slowly and therefore have a low abuse potential even in adolescents making them generally quite safe. However, as FDA contemplates new formulations and novel products that could be useful in helping e-cigarette dependent adolescents, we encourage caution so accessible NRT products do not become attractive to those who've not already been exposed to nicotine.

DR. PIPPINS: Thanks --

DR. TANSKI: Seeing my time is wrapping up. E-cigarette use among adolescents is a significant public health crisis and we can and must use --

DR. PIPPINS: I'm sorry, we are out of time. I'm going to have to close it but --

DR. TANSKI: Thank you.

DR. PIPPINS: -- I encourage any final comments to be submitted to the docket. Thank you for your presentation.

DR. TANSKI: Thank you very much. Any questions.

DR. PIPPINS: Are there any clarifying questions from the panel?

DR. MICHELE: Hi, I have one. You mentioned level of dependence among adolescents. Are you aware of any validated measures to determine this?

DR. TANSKI: There are no validated measures to assess adolescent e-cigarette addiction. However, there are a number of tools that have been used in the adolescent population. One is called the Hooked-on Nicotine Checklist and that has been validated in a number of populations both here in the U.S. and in Canada for nicotine dependence in general; most used extensively with cigarette use. So that is a possibility that could be validated but again those studies will need to be done to confirm that that is actually valid in this population. Thanks for the question.

DR. PIPPINS: I have one question. Are there any particular lessons learned from trials of combustible cigarettes in this population that you think apply potentially to development of trials for e-cigarettes?

DR. TANSKI: There have been a number of studies that have been conducted with traditional combustible tobacco cigarettes but until we really understand how e-cigarettes and particularly some of these high nicotine delivery devices like the JUULs and the other pod-based systems until we really understand how the kids are addicted to these we don't know if they are going to apply. So this may be really a different animal than combusted tobacco cigarettes. With combusted tobacco a cigarette is pretty much a cigarette. And with these vaping products each of them is so different, the characteristics of the electronics, the nicotine solutions that are used in them are so different that we are really talking about a wide array of product types that each may require a different approach.

DR. PIPPINS: Thank you very much.

DR. TANSKI: Thank you.

DR. PIPPINS: With that we're actually going to call up the next presenter, Ms. McCormack.

ROCKVILLE CENTER COALITION FOR YOUTH

MS. McCORMACK: Hello everyone. My name is

Ruthanne McCormack. I'm the project coordinator for a drug-free community coalition located in Nassau County, Long Island. We are an incorporated small village. We received a grant in 2015 and we've had it - we are in our fourth year of funding right now.

So as a drug-free community coalition there are certain guidelines that we need to adhere to to sustain our grant regulations. And that includes having all sectors of our community involved. And as you can see from this schematic that many of the sectors have more than one representation.

We have fake ID flyers that we encourage the parents to be aware about in our community. Social hosts law, we have our own law, 16 years or older serving alcohol are subject to a fine and a summons. We have a permanent drop box in our community. We educate teens about the dangers of alcohol. We have sticker shock that we use. In fact, we used a vaping sticker shock this past year that is very effective with our youth.

JUULs started in 2015. Our kids have been vaping for three years. They start as young as fourth

grade. They have easy accessibility. Even though JUULs said they would remove the fruit flavors and the dessert flavors in our brick and mortar stores they are still available. And the stores that sell them do not ask for ID.

The had a kick-off party in New York City and they targeted our youth through Instagram and Snap Chat and as you can see these are young youth. These are not 18 or 21-year-olds. So the e-cigs are very easy. The parents did not know what the kids were using. They thought they were flash drives.

In 2016 parents started finding them in the laundry, in their kids' laundry and they would show them to other friends or even ask the kids and the kids would say oh, I don't really know what this is, but kids are using it and it’s cool, you plug it into your computer. So those were the little kids in third and fourth grades.

Then the older kids started giving -- selling them the vaping. And that is when the younger kids started using it. We have a high incidence of fourth-graders vaping in our middle schools. They are vaping

Commented [TD1]: Most middle school starts at either 6th or 7th grade. Just checking to ensure this is what the speaker stated.

three cartridges a day. Now most adults that I know that are using JUUL to stop smoking they tell me a cartridge lasts maybe three or four days. So our youth are vaping a huge amount of cartridges in Rockville Center.

So this is how they are using them in the library. Now the library, you know, the librarians know what to look for. So we had a vaping billboard that was up from June through September and then our local papers in all of our towns on Long Island ran this PSA for us for free. So we really had a far reach.

So this is statistics that we all know about what high school kids are doing. It is no surprise. We see it in our schools. We've had kids come to our health teachers and say to them I need help I want to stop. And they have used the Nicorette. But a lot of kids use it and then they go back to it.

So in our town this past week we've had an 18-year-old who was an athlete, he was using vaping, he was vaping marijuana and he decided to lay on the Long Island Railroad tracks and commit suicide. So that was

Friday. And then on Sunday we had a youth who also started vaping in middle school then went on to use alcohol and other drugs and he overdosed in his home on Sunday, 24 years old. So this has really impacted our community. And I like what you said about the breathing and the -- we actually do that in school, but I think what you do we need to really implement where our kids are. The pressures they are under. Having their friends die from starting with vaping, moving on to marijuana, overdosing on other drugs doesn't seem to get through to them. They are not afraid of it.

I'll say to them your friend died and he was vaping, he was vaping since middle school, moved on to marijuana, moved on to heroin. And it doesn't really get through to them. Their sensitivity to this kind of loss it seems like they are very stoic about it, it doesn't mean anything.

So what I suggest is we get some tools for these kids to really realize how dangerous this vaping is for them. And I know they are giving them the gum when they ask for it, but we don't know what it does to them. So I think we need more studies about this. And

I think parents need to really watch what their kids are doing and to get help for them.

I've had kids come to me that have been caught with vape materials in school. We have a zero tolerance. They also have marijuana in school. So then you know they do not call the authorities because we are an incorporated village. Instead they get them into counseling. And the kids say to me I'm not addicted. And I -- you know they've been vaping for maybe five or six years. And I say to them how do you feel when you don't vape. And they get agitated, they get anxious, they get nervous, they can't sleep. So then you know I kind of say to them well, what do you think that is? Do you think that is normal behavior? And then when you go through it with them, they kind of understand it.

But I think these kids are addicted, they need help and we need to stop it because all the teens that we know they are vaping marijuana, so they are moving on to the marijuana from the JUUL. And marijuana is going to be legalized in New York State and the reduction of youth marijuana is just not going to

happen because the perception of risk is very low. And the availability will be increased in New York. So that is one thing we are working on.

So anything that the FDA can do to help us. We are starting education, prevention in the primary grades. We start in kindergarten and hopefully those kids when they get to middle school, they will make more wiser decision about their health and not continue to engage in this risky behavior.

So thank you to the FDA and thank you for listening to what our youth are doing in Rockville Center. I don't know what other people are seeing but where we are it is huge, and they are addicted. We are number four in the state for overdoses. And they do start with alcohol and vaping marijuana.

Thank you.

DR. PIPPINS: Thank you very much for your presentation.

Any clarifying questions from the committee?

DR. GREEN: Thank you for your presentation. Can you give us a little more information on what has been your experience with the various modalities you've

used for education that you find have been most effective in educating youth about the potential for addiction related to nicotine?

MS. McCORMACK: Well, we had all the athletes have to sign an agreement that they are not going to vape, but they do anyway. They only get penalized if they are caught in school with the vaping paraphernalia. So they are still vaping but it is a matter if they are going to get caught. And the one athlete that just died on Friday, he was all county -- Nassau County basketball player and I don't know why they are so conscious about health these athletes, but they don't think that vaping is unhealthy for some reason. And they are all doing it. So that is another thing it is the social pressure, the peer pressure. So the health teachers go over it in their health classes, the athletic coaches go over it. I have an evidence-based program that I do called Teen Intervene that I -- the school asked me to do when kids are caught in school with it. And parents actually have called me and asked me could I do it with their own kids, just because they are worried about what their kids are

doing. They are worried, they know the kids are doing risky behavior. They found the vaping devices.

And also if a kid is caught in Rockville Center with alcohol possession they are referred to our village court and then the judge refers them to the coalition. And they have to actually partake in all the prevention messages that we relay to our community. And they like it. I've had great feedback from the parents. You know it is great our kids get to know firsthand, they listen to young people in recovery, young addicts in recovery about how they started, and it scares them. You know they don't want -- not every heroin addict started with marijuana. Not every marijuana user said I'm going to go right to heroin, but every heroin addict started with marijuana. And the vaping of the marijuana I mean -- I've heard it from kids if I'm vaping, I'm vaping marijuana.

So we need more help.

You know they don't get scared; their friends die, and they don’t get scared. I think they think it is not going to be me. Oh, he -- it happened to him. You know why was he so depressed that he decided to lay

on the railroad track. You know so that is what we need, we need some social emotional learning, we need coping skills, we need refusal skills, we need the SKY program in our school.

So that is what we need.

And kids need to value their health more. For some reason they don't.

DR. PIPPINS: Any further questions from the panel?

DR. MICHELE: Just wanted to mention that certainly our sorrow and appreciation for the parents and all of the other students in all of the communities across the nation who for whatever reason have had early deaths from overdoses of whatever products and whatever other types of things are leading into this regardless of whether it is vaping or other ideas and I'm not drawing any conclusions here but just expressing our sympathy and concern.

MS. McCORMACK: Thank you.

DR. PIPPINS: Thank you, Dr. Michele and thank you very much for your presentation. Appreciate your comments.

With that we will turn to the break. We will be back 10:42. It is ten minutes. 10:42.

BREAK

DR. PIPPINS: Thank you. Our next presenter is Dr. Daniel Hussar.

REDUCING ADDICTION TO NICOTINE: STRATEGIES HIDDEN IN PLAIN SIGHT

DR. HUSSAR: Thank you. I'm a pharmacist and Dean Emeritus at the Philadelphia College of Pharmacy at University of the Sciences. I have no financial disclosures or any working relationships with the nicotine industry.

Last Friday, January 11 marked the 55th anniversary of then Surgeon General Luther Terry's report: Smoking and Health. How far have we come in the last 55 years? The estimated number of deaths to tobacco-related causes is 480,000 each year and there are millions of additional individuals who are addicted to nicotine either through cigarette consumption or through other nicotine containing products.

Embarrassment is too soft a word to describe that. That is a tragedy that as a society we can no

longer tolerate.

Nicotine is a drug. The FDA recognizes that. It has approved nicotine replacement therapies that underwent extensive study, clinical trials by pharmaceutical companies and a comprehensive review process in reviewing those products before they were approved for marketing. Two of those products a nicotine replacement therapies, the nasal spray and the oral inhalation system require a prescription. That continues to be the case.

If I as a pharmacist with expertise in use of those products was to dispense the nicotine oral inhalation system without a prescription, I would be placing my license in jeopardy. Yet nicotine containing products are routinely available even to the youth to whom they are not supposed to be sold.

Nicotine is no less of a drug when it is delivered in an electronic delivery system. Indeed, I would contend that it has greater hazards. These systems like JUUL have not been studied. In fact, I hear comments about the adverse events of nicotine replacement therapies and Chantix. The reason we know

that is they've been comprehensively studied. Where are the studies for JUUL and related nicotine containing products?

Yes, the advertisements for JUUL and related products say they are to be used only by adults. In their strategy to try to get FDA permission to continue marketing them they say they will use their systems to regulate to make sure they are not available. These companies cannot be given the responsibility of self-regulation and monitoring.

There is an advertisement for JUUL starting with this product contains nicotine, the theme is the average smoker tries to quit 30 times. Make the switch from cigarettes to JUUL. How many years have to go by before another company comes along and aggressively promotes a product and then they'll say the average JUUL user tries to quit 30 times?

The chemical is the same. It is nicotine. Individuals become addicted to JUUL. Unlike the nicotine replacement therapies these products have been permitted to escape regulation. Why has the FDA not exercised its authority with respect to the marketing

of these products, that it has insisted on with respect to the approval and marketing of the nicotine replacement therapies? Why has the FDA not required these products to be available only on prescription in the same manner in which it currently restricts the availability of nicotine nasal solution and nicotine oral inhalation system? If the FDA does not exercise its authority and does not comply with its own regulation and policies, why should anyone else feel they need to comply with those policies.

The chaos and the insufficient action with respect to the present situation has been at the expense of thousands of teenagers who are now addicted to nicotine.

If JUUL and related products are permitted to remain on the market I contend that under current policies and regulations the FDA has no other option but to rule that JUUL and other nicotine delivery systems be available only on prescription.

The good news is there are some other strategies that might be considered. I urge the FDA to take the following actions:

First, establish a class of medications that are available in pharmacies without a prescription from a pharmacist. We currently have a distribution system that is well regulated through pharmacies. For decades the FDA has resisted or ignored recommendations to more effectively use the expertise of pharmacists for assuring the availability and the appropriate use of selected medications without a prescription. The current debacle with respect to nicotine delivery systems provides an opportunity to establish a classification of medications that are available without a prescription from a pharmacist.

Secondly, nicotine nasal spray, nicotine oral inhalation system and Chantix, Varenicline should be designated as products that may be provided by pharmacists without a prescription. The continued restricted availability of these products that have little risk is an unjustifiable barrier to greater access that will result in reduced use of tobacco products that cause hundreds of thousands of deaths each year.

Third JUUL and other nicotine delivery system

products should be available to adults in pharmacies without a prescription from a pharmacist. This would continue to permit their availability but through a regulated system that would at least add an additional element of control that does not exist now. These products have not been studied and there would be justification for the FDA to say they cannot be marketed. I will acknowledge that for some individuals JUUL may help them stop smoking. But the addiction to nicotine persists.

I feel these steps will provide consistency with nicotine replacement therapies and how they are regulated by the FDA.

My other recommendation is that these actions should become effective on January 1, 2020. Although sooner would be better perhaps Commissioner Gottlieb will join us at the end of this session and he could sign off on some of these actions now. I couldn't resist the symbolism of 2020 as representing the clarity of vision in moving on some of these actions to help prevent the addiction to nicotine and the unnecessary deaths that currently occur.

If the FDA fails to take progressive action, I contend that it will not be in compliance with its own regulations and policies and will be complicit in many more thousands of teenagers addicted to nicotine.

Thank you for your attention. I'd be happy to respond to any comments. And I would say I am retired now and I'd be happy to apply for a position at FDA and help --

[Laughter.]

-- out at these efforts and I commend your willingness to work without pay during the shutdown and I'm willing to do that too.

DR. PIPPINS: Thank you very much for the offer. And thank you for the presentation.

I want to open it to the panel to see if there are any clarifying questions.

DR. HUSSAR: I'm sorry, did you ask a question?

DR. PIPPINS: I don't believe there are any questions.

DR. HUSSAR: Okay.

DR. PIPPINS: Thank you again for the

presentation.

And with that we will turn to our next speaker, Mr. Don Seibert.

THE NEED FOR NON-DRUG THERAPIES IN REDUCING TEEN VAPING

MR. SEIBERT: Good morning. I'm Don Seibert. I'm an owner of a company called Smokenders in Birmingham, Alabama. I come here without a lot of alphabet after my name. But I have a little experience. I was a 20-year three-pack-a-day smoker and I quit in 1981, have never wanted a cigarette since. I quit using a program called Smokenders and have been so excited about it I bought the company.

So I come here today to talk about transferring that technology from smoking cessation to vaping cessation.

By means of introduction Smokenders is a behavioral approach to smoking cessation, was taught all over the country from 1969 until 2012 and since then we've had it online course. And we've taught over a million people how to quit. It is a seven-week course across four threads and involve the physical, psychological, cultural and social aspects of smoking.

We do it now by a one week, a video class each week with daily action steps that the student uses. And we guarantee that they'll quit smoking or they get their money back. I have no association with any organization. I get all of my pay from smokers who are trying to quit.

A little history lesson, this goes back, this is a CDC slide from -- the green line represents adult smoking from 1965 when C. Everett Koop the Surgeon General announced the epidemic of tobacco until 2014. And you can notice there's been a gradual decline in smoking cessation. Advent of NRT happened with patches in 1997 and with Chantix and other drugs in 2006. And they have not affected the rate of reduction significantly at all.

Before 1996 when NRT patch was introduced a smoker could only do cold turkey or they could do Smokenders. There was no other option. Now smokers have four options. But here's the therapies that are out there now, there is nicotine replacement therapies, drug therapies; they all have limited success rates of seven to 20 percent effective. And we use a behavioral

approach. Our participants continue to smoke while they learn how to quit, and we treat them along the physical aspect. We wean them effectively over four weeks from their nicotine addiction down to where they are smoking nothing but a filter at the end. It becomes very easy for them to quit at that point.

But more importantly for us are the psychological issues dealing with the dependency on smoking, conditioned responses, those sorts of things. And the social aspects, breaking the linkages between nicotine and food, nicotine and caffeine and alcohol. Culturally we address their stress, anxiety and depression characteristics.

Our program requires a commitment to the process of quitting. You can't just go to a course and say oh, we are going to give you this because we've learned that the smoker has to have skin in the game; they have to have something to motivate them, an incentive to make them want to quit. Without that commitment we've had even giving our program away we've had very little success. But we are still effective 60 percent of the time.

So we are about to introduce a product called Vapenders which is a derivative product from our Smokenders course. We began planning this about this time last year and it is based on our Smokenders course. We've taken out everything out of the Smokenders course that had to do with physical cigarettes and we put in things having to do with vaping and with teens in particular. And we are now in the final throes of developing a mobile app so that the teens can have it on their phone which is how they communicate.

And our first release we currently have focus groups going for parents and for youth and our first release is due out this quarter, should be by the end of March with general consumption available sometime spring/summer.

We are going to develop another product which is for adult vape users who have been smokers, that is a whole different world from what we are talking about today. It is acceptable to us, to a lot of people that vaping is a least harmful alternative to smoking. We are going to address that but that's not the topic of

Vapenders today.

So addressing the teen vaping market we are going to take a little different approach than what I've been hearing. We have to market it through the parents, parents and guardians of these teens. We, first of all it is illegal for us to sell anything to a teen. We can't enter into a contract especially for a product that they are not even allowed to buy. We ask them to continue to vape for four weeks while we teach them to get off of it, is we wean them. We can't recommend they do that, it would be against the law for us to do that. So we are going back to the parents and to do that we are -- it is a big challenge to educate the parents about what their teen is involved with. Many of them don't even know that the teen is vaping. And we're -- what did I do here, I backed it up the wrong way. Okay. We want the teen to have the support of the parent for education and motivation and to provide an awareness of the dangers. The teens deal in the here and -- the teens only look at the here and now, they can't think about the future. We want to obtain commitment to quitting as a family team of

parent and teen to provide a level of accountability and support and open communications. When I say open communications that many times doesn't happen at all between parents and teens so we have to help educate that to make it happen. It is an educational process as much as a marketing thing.

We will only provide our course where commitment between parent and teen exists. Along those lines there is a document that is out by the CDC, it is talk with your teen about e-cigarettes. It's a very, very good document. I would encourage you to go on the CDC site and get it down, go on my site, vapeneders.com, we'll get it downloaded free. It is a great vehicle for parents to use in talking with their teen. And it helps in the communication of the problem and what can be done about it.

When we sell the course, it will be sold for $250 upfront, which is nothing compared to the lifetime cost of nicotine addiction. If the teen quits within the first couple of weeks, they get $200 back and we walk away. If the teen completes the course, they get $100. That is a motivation. It is a reward for them

on the successful completion of the program. If they fail to complete the program, we take that $100 and donate it to the Drug-Free Clubs of America which is a school-based program that is coming all over the country to assist in helping teens to be drug free.

Our biggest obstacles in marketing this are gaining market awareness of the problem, the product, and helping parents deal with it. Educating them about the vaping epidemic. We've created a little booklet. And when you buy a car you get an instruction manual in the car teaches you all about how the radio works and vents and everything else. When you get a baby at the hospital all you get is a bag of diapers and some formula maybe but --. So we've put together an instruction manual for parents that are dealing with the vaping crises to show them how to deal with it and how to work with their teen. And that is a difficult thing to get the education going at two different levels because educating the teens is a whole different animal because they consider themselves invulnerable to any kind of health risks or financial risks or any other risk, there are no risks in their life. They

live in the here and now, in and for the moment. They have little interest in the future except whether they can have a date with Mary on Saturday night, whatever. So we've got to get the parents and teens talking to one another unemotionally. Usually when parents find out their teen is vaping, they try to stop them with disciplinary action. You are grounded. I'll cut off your budget. All that doesn't work. We're dealing with an addiction here. You can't overcome addiction with legality.

So we've got to get them talking to one another and we've got to achieve a commitment from all parties to crush the vaping.

We compared Vapenders to Smokenders, we know that nicotine is nicotine, it has got the same two-hour half-life all that but the psychological dependencies many are the same but vape users can't have a 20-year addiction like I had. They can only have a few years. But their other issues are bigger. The flavors in vapes versus cigarette taste. Dealing with handling the peer pressure. There is never going to be a drug that handles peer pressure. So we can't fight this

with drugs alone. We are certain that Vapenders can effectively deal with the situation. We just need to figure out how to get commitment from a parent teen group to have skin in the game.

I thank you very much and am open to questions.

DR. PIPPINS: Thank you very much for your presentation.

I'd like to open it to the panel for clarifying questions.

DR. WINCHELL: I may have missed this, but can you speak to what experience you have with Smokenders for adolescent and teenage smokers?

MR. SEIBERT: We've had the same level of success with adolescents and teens in smoking cessation as we have with adults. If we -- if they are committed to being in the program and they have a financial investment up front which for teen, it is usually the parents paying for it but where we have that commitment, we haven't experienced any difference.

DR. GREEN: Thank you for your presentation.

MR SEIBERT: Uh-huh.

DR. GREEN: So you mention that about 50 percent of the time you are effective with this program for helping smokers. Can you give us any insight on what have been some of the factors or risk factors associated with not being successful in your program and particularly for adolescents and teens that suggest that they will not stick with the program or will not be adherent?

MR. SEIBERT: Well, we don’t have experience with the vapers yet. All we have is focus group information from parents and a focus group of teens. But on the Smokenders side of things the people who are unsuccessful they lack the commitment or they fall off the wagon during the course of the course. So we have daily things to try to keep them adhering to the course. Where they adhere to the course we have pretty high success rates. So we don't know that we can do a whole -- 50 years of experience we don't know that we can improve on that very much.

DR. GREEN: But just to clarify any indicators on who would be adherent; are there any factors that suggest someone may not be adherent early on?

MR. SIEBERT: May not be what?

DR. GREEN: Adherent to the program early on?

MR. SIEBERT: Well, we see the flavoring of vapes being a big issue. It is a really big issue. When you are smoking anybody that has tried cigarettes knows that they taste like hell. Okay. When you change that from and yet you talk to smokers and they all say they enjoy their cigarette. Well, they've told themselves that they like it because it satisfies their cravings. But not because it really really tastes good. But if you ask a smoker, they will all say it tastes good. But in terms of vapers they say it tastes good and they mean it because they are getting things -- they are candy, it is candy flavors and there is nothing consequential about that.

DR. PIPPINS: Dr. Murphy, I believe you had a question?

DR. MURPHY: Thank you for your presentation. I am curious to understand based on your experience whether you find that one approach for all the teenagers is sufficient in that you know there is a big difference between a 12-13-year-old and a 17-18-year-

old. And also there is comorbidities, whether they have ADHD, depression, anxiety.

MR. SIEBERT: If we get into comorbidity, we have a problem if they are also on marijuana, alcohol or anything else. Right now we are at the beginning stages of this. We don't have the experience with the various age groups. A year from now we will probably be able to tell you that. But right now we don't have that experience.

DR. MURPHY: The other consideration is also use patterns and the amount of exposure dependence. And so you know it would be interesting to understand if this you know one approach to teenagers or kind of a little bit more tailored approach depending on these other factors, if that would be more helpful.

MR. SEIBERT: Right. Exactly. Thank you.

DR. PIPPINS: One last question. In your pilot testing of the Vapenders program have you identified what are the main motivators for youth who are interested in actually quitting?

MR. SIEBERT: That is an interesting thing, it is heavily dependent upon the communication level

between the teen and their parent. We've intentionally not been going after teens without the parent for obvious reasons but the better we see communication between the parent and the teen the more committed they are to success. We just feel a lot better about them. We don't have the experience yet, but it is very exciting to see when they talk to one another. Unfortunately. there are a lot of broken homes and that where it is hard to get the parent and the teen together and you know we are running into all kinds of issues there. But where we do get them together there is high -- I think we are going to have real high success.

DR. PIPPINS: Thank you very much the presentation.

MR. SIEBERT: Thank you.

DR. PIPPINS: With that we will turn next to Ms. Lauren Lempert.

FDA IS ASKING THE WRONG QUESTIONS TO HELP ELIMINATE YOUTH E-CIGARETTE USE

MS. LEMPERT: Good morning. While FDA has appropriately recognized the gravity of the youth e-

cigarette epidemic it is asking the wrong questions about how to solve the problem.

This morning I'd like to talk about the questions I think FDA should be asking to tackle this crisis. As we've been hearing the factors that motivate youth to use e-cigarettes are very different from those that drive adult use. Let's face it kids think e-cigarettes are cool. And they use them as recreational products, not as FDA approved medicines and not as interventions for cessation. In fact, as far as I know there is not one e-cigarette product that has been approved by the FDA as a cessation or a therapeutic aid.

Nevertheless, FDA's own statements characterizing e-cigarettes as less harmful nicotine delivery devices can be misunderstood by kids to suggest that e-cigarettes would help them quit smoking or e-cigarettes are generally safe for them to use. FDA has issued many statements, but one example is Dr. Gottlieb's March 15th statement which I excerpt here when he said, "to successfully address cigarette addiction we must make it possible for current adult

smokers who still seek nicotine to get it from alternative and less harmful sources." However, the reduced harm claims that are embedded in this statement and others like that have not been substantiated. In fact, if e-cigarette companies made these very same claims, they would be illegal under Section 9-11 as unsubstantiated modified risk claims.

And while these statements may be intended for adult audiences, the problem is that e-cigarette companies have been repeating them in their ads which kids see and hear and they can easily be misled. And also I think it is statements like these that are reflected in the specific questions that were posed by FDA before today's meeting which seem to be based on the assumption that kids use e-cigarettes in the same way adults do or that some policy that theoretically might help a middle aged three-pack-a-day smoker quit smoking would also be appropriate for kids.

Rather than focusing on NRT and other drug therapies for cessation that we've heard are not effective for youth FDA instead should be focusing on how to prevent youth from initiating with e-cigarettes

to begin with and to prevent youth from becoming addicted to nicotine.

So what questions should FDA be asking? One, do messages promoting e-cigarettes for adults actually attract kids? Well, as I mention many of these messages state or imply or suggest that e-cigarettes are harmless or safe which is a bad message for kids to get. Also the tobacco industry knew what created its youth smoking prevention programs in the 80s and 90s messages that say something is for adults only or an adult choice actually have the perverse effect of attracting youth and do more harm than good. But as we'll hear later today strategies that de-normalize the industry like the Truth Initiatives Campaign do much better job of preventing youth use.

Two, why are e-cigarettes so attractive to kids. Well, as we've been hearing most kids report that it is the flavors that first attract them to use e-cigarettes and also because of this variety of messages they are hearing they believe e-cigarettes are safe. Perhaps you saw the piece in the New York Times in November that featured a teen boy who said well, he

knew he should never start smoking convention cigarettes because they were unsafe, he thought it would be safe to try JUULs. And in fact this teen initiated with mint flavored JUULs. And because of their very high nicotine content quickly became addicted to mint flavored JUULS. Also we know that e-cigarette companies are aggressively targeting kids with ads in all kinds of media including social media. And a huge problem is that kids can get e-cigarettes so easily. All they need to do is get online click on a button that they are over 18 and they can buy anything.

Three, so knowing this what regulatory tools does FDA have to make e-cigarettes less attractive and less available to kids. Well, FDA has the authority right now under the Tobacco Control Act to regulate e-cigarettes in a variety of ways. And I'll talk about a few options.

As a starting point Section 9-10 of the Act mandates that no tobacco product including no e-cigarette can be marketed in the United States unless it first receives FDA pre-market review and authorization. And to obtain that authorization

companies must demonstrate that their product is appropriate for the protection of the public health. However, because FDA decided to delay e-cigarette reviews by extending the compliance date for making applications FDA has allowed thousands of e-cigarettes to remain on the market that have received no agency review and have not demonstrated public health benefits. FDA's recent announcement that it would reconsider this policy as to some e-cigarettes does not go far enough. FDA should fulfill its legal mandate and immediately pull from the market all e-cigarettes that have not been pre-authorized including mint, menthol and tobacco-flavored JUULs and other nicotine products that are popular with youth.

For products that remain on the market FDA should use its authority under Section 9-11 to clamp down on unauthorized cessation, health and other modified risk claims. And this includes not only explicit claims like you see here but also implicit claims such as testimonials from smokers that say that they used e-cigarettes to help them quit smoking.

To minimize e-cigarettes appeal as we've been

hearing FDA should use its authority under Section 9-07 to prohibit all flavors including mint and menthol. There is no scientific basis for excluding mint and menthol from any prohibition.

And FDA has broad authority under Section 906(d) to impose a variety of marketing and advertising regulations. I'll suggest a few. First they should prohibit all internet sales of e-cigarettes. FDA's recent announcement that it would require more robust age verification does not go far enough. The evidence shows that there is no age verification scheme that is effective to prevent youth from purchasing e-cigarettes online.

Also FDA must prohibit all e-cigarette ads that target kids including ads on social media. There is a variety of other tools that they could use under Section 906(d).

In summary FDA has broad authority right now to tackle the youth e-cigarette epidemic. First it should pull from the market all e-cigarettes that have not received pre-market authorization. And next they should enforce against all unauthorized cessation and

other modified risk claims. FDA should prohibit all flavors in e-cigarettes including mint and menthol. And FDA should impose a variety of marketing and advertising restrictions including for example prohibiting internet sales and prohibiting ads targeting kids.

Thank you.

DR. PIPPINS: Thank you very much for your presentation.

We'll open up for clarifying questions from the panel.

Dr. Murphy?

DR. MURPHY: Thank you for your presentation. Understanding the impact of ad statements and claims is challenging and so any data that you may have to understand the interpretation of claims especially the implicit claims of cessation or potential modified risk claims would be helpful.

MS. LEMPERT: Yes, some of my colleagues have actually done a lot of work on that and we will improve that in our written comments that we'll be submitting.

DR. MURPHY: Thank you.

MS. LEMPERT: Thank you.

DR. PIPPINS: Thank you.

Next we'll turn to presentation from Mr. Mark Anton.

REDUCING YOUTH ACCESS TO VAPOR PRODUCTS

MR. ANTON: Good morning. My name is Mark Anton. I'm the Executive Director of the Smoke-Free Alternative Trades Association. We represent small, large manufacturers, retailers, distributers in the vape industry.

So we are here today to discuss reducing youth access to vapor products. As SFATA agrees with the position of limiting the onramp of youth use and access to electronic cigarettes. However, we believe the true epidemic lies with the 480,000 Americans that are lost every year to smoking related disease. With this in mind, we believe the FDA should not limit the offramp for adult users of vapor products that may assist them in quitting cigarettes.

We are here today to discuss the factors driving e-cigarette use among youth and how they likely differ from those in the adult population. But what we

most know about nicotine addiction in teens we know from cigarette use because vapor products have had many forms and shapes over the course of the time the FDA has actually been asking questions about them. So we'd like to look at some of this.

But we'd like to go back and talk about how all cigarette use or nearly all cigarette use begins during youth and young adulthood. While the current use of any tobacco product among U.S. middle and high school students has decreased from 2011 to 2017 there has been an increase in e-cigarette use over this time. While youth e-cigarette use raises a number of concerns including risk of addiction to nicotine early on in life, we must remember the devastating effects cigarettes have on teens when looking at this issue and the full range of possible health effects. It is not quite understood yet regarding the youth use of e-cigarettes.

Now on April 24, 2018, the FDA announced its Youth Tobacco Prevention Plan. This plan focuses on three key issues: prevention of youth access to tobacco products, curbing the marketing of tobacco

products aimed at youth, and educating teens about the dangers of using any tobacco products.

Now, SFATA, or the Smoke-Free Alternative Trades Association, has been in existence since 2012 and in 2014 we recognized that there was an issue because this issue revolved around the existing laws in the states, the local communities and at the federal level. There was no laws restricting access to teens at this particular time. So SFATA initiated amongst its members the Age Debate Program which was designed to mimic the current smoking laws. So if your state had 19, our members would voluntarily card these children at 19. So we wouldn't just sell to anyone. So we were taking a responsible position early on in the industry when there was no structures.

Now I'm showing this slide because we want to talk about the numbers a little bit here. As we see daily and frequent e-cigarette use by sixth to twelfth-graders trough 2017 has remained pretty stable, right. But we see an uptick in year 2018 at you know one plus use and 20 plus use. Now flavors have been on the market for a real long time and have been very stable.

In fact, the FDA has received over three million submissions on different flavors for registration of those products. So the question really has to be asked what is the reason for this uptick because electronic cigarettes have been around for a long time. We've just had multiple forms and functions of delivery.

Now in this particular slide we're looking at the compilation of the NYTS data and it indicates that out of the 3.3 million current users of cigarettes, cigars and e-cigarettes there is a 40 percent overlap. And the chart here also shows a large majority of exclusive vapors used e-cigarettes infrequently. That is one to five days in the past where only 12 percent reported using 20 to 30 days.

Vapers who smoke cigarettes or cigars were much more likely to be frequent e-cigarette users. So we have to look at the youth and how they are actually using these products when we are dealing with structures of how to help them. How to keep it from them. So this is just a portion of it.

And this next chart shows that while e-cigarette experimentation increased among American high

school students from 2000 to 2015 the year JUUL was introduced vaping stabilized in 2015 and smoking rates continued to drop. In 2017 1.15 million American high school students were current past 30-day e-cigarette users. Now according to the Center for Disease and Control survey when we compare these numbers to 2016 smoking and dual use declined marginally by about 2 percentage points while vaping increased. Now we look at this spike here in 2015 and some things that should also be of note the questions changed in the format from 2014 to 2015 because vaping became its own separate category as a question. But also there was a little product that was a fad, it was called an e-Hookah that didn't even contain nicotine. It was on the convenience store markets for about six to eight months. And the kids grabbed them up. But there was no nicotine. But it was just a fad which we see a lot of times. But we want to watch this and make sure that this doesn’t become a fad.

Now this slide here and what we talk about here is where teens are getting access to this. We've broken down from Brad Rodu's Tobacco Truth that we find

that almost 73 percent of the youth are accessing these products not directly from direct sales in convenience stores or vape shops or online. But we are finding the majority of it is from family and friends. Now it could be from those 18-year-olds that we talked about earlier today because when you look at the amount of 18-year-olds that are in high school in some states they are legal to purchase. In other states they are not. I mean we know there are some states that have tobacco 21 now. So we still have to look at these numbers a little bit more deeply. Where are they getting these products and how can we educate and help these people from actually helping their kids have an addiction.

Now in the next slide here is something that we currently have, right. This basically shows a list of penalties and fines. And this is something that we feel that the FDA could look at immediately to make this a more serious consequence because you know first time a store sells a product and gets caught it is a warning letter. And then after two times in a year it is $285. That is certainly not a significant deterrent

for a retailer that doesn't really care. So and it takes six times within a 48-month period to actually -- in a 36- month period to lose your license to sell tobacco product.

Now we also have the issues of fake IDs and what the kids are doing here. I'm just showing this because we're actually addressing this now. We are instituting a program to help with the fake ID market. Authentication is needed because 3.85 percent of IDs scanned in the United States for age restricted products is 3.85 percent.

Now this goes into the prevalence of past 30-day drug use of American high school students also brought up from Bradford Dew, it comes from the CDC study. I know we have the conversation of an epidemic, but we also have to look at youth access to products, of adult products. I mean alcohol is still by far used more in high school than anywhere else and that pretty much throughout the country is 21 to have access and you can even be penalized for possession of it.

So and then marijuana that is a schedule one compound, so as a schedule 1 compound they are using

that product at even greater rates than electronic cigarettes. So we have to look at how we are going to address this a little bit pragmatically.

DR. PIPPINS: Thank you very much for your presentation. I'm sorry we are at time.

I want to give opportunity to the panelist to see if there are any questions they may have.

I have one question. What sort of educational programs or initiatives might your organization be involved in developing or executing?

MR. ANTON: Well, that is one thing I didn't get to the next slide. It is -- because of these issues, we've had meetings with the FDA and we addressed the youth issue. We've developed with some psychologists and addiction specialists and a number of others and it is called The Youth Education Prevention Program. And The Youth Education Prevention Program is designed in a three-stage approach. It is to educate the teens to the dangers of nicotine use and addiction and peer pressure. And at the same time, it is to educate parents because parents really don't understand what these products do. They don't understand what

they look like. They don't understand how they function. If I was to go around, I could do what's called stealth vaping. None of you would even now that I would vape in this building. But I'm not doing it because I didn't bring it here. But the whole point is is we understand this market, so we understand how the kids can do this. And then the third thing is the retail aspect. We're bringing into the retail aspect a full training program for age verification, carding and we're working with an organization that is actually approved by the Department of Defense for all of their identification processes so they actually check who gets on Air Force One. We are that serious about restricting access to the youth. But we don’t want that to be at the expense of the offramp for the adults because we really believe that the 480,000 people are a very serious epidemic. So that is what we are looking at in Youth Education Program because that really -- we believe if we all work this together, we can make a difference. But right now it is so fragmented you have to go through rulemaking, states are putting in flavor bands, states are putting in tobacco 21. All of these

things are fragmented, they are not focused on helping the teens realize what this product really is.

DR. PIPPINS: Thank you very much.

If there are no further questions, we'll move on to the next presentation which is Mr. Jack O'Toole.

EFFECTIVE DETECTION OF VAPING AS A METHOD OF REDUCING YOUTH USE

MR. O'TOOLE: Hi, good morning. I'm Jack O'Toole from FreshAir Sensor. As H. L. Mencken purportedly said, for every complex issue there is a simple clear answer that is wrong. But I'd like to talk about something we think might be helpful.

Adults can vape whenever they want. Teens have less unsupervised time than adults. And decreasing their opportunities for unsupervised time where they can vape reduces the amount of time they spend taking in nicotine and optimally will reduce their addiction to nicotine.

You can see here today that most of a teens typical schedule is supervised or has the risk of supervision. It is a little hard to read the things at the bottom, but you see their time is pretty

structured. This is from Department of Health and Human Services Office of Adolescent Health. So they have pretty structured days and for them school bathrooms and locker rooms are a common place to vape. I think everybody has heard about schools locking bathrooms, even Broncs Science locks most of their bathrooms now and doesn't let kids use them which is shocking to me.

So what we do is we develop and commercialize novel sensors. You can see that our first device that we have on the market this has sensors that detect cigarette and marijuana smoke. It -- they are the only sensors that can monitor for and specifically detect cigarette smoke and marijuana smoke. It is similar to a biological receptor in that they only mate with a specific target molecule which gives them high sensitivity and high selectivity. You can see where you know we have a thousand of devices installed in two-thirds of the states.

And the way our system works is people buy our devices, these, and then they install them with our app to our cloud-based monitoring platform. And then when

somebody smokes, we let them know that somebody is smoking in Apartment 307 or room 2415. And then we give them scientific proof that someone was smoking. We give them a time-stamped chart showing measurement of the substance. We've been 100-percent successful with credit card companies against charge-backs for cleaning fees and hopefully today we'll have our first case that actually goes to court. But previously every case that has gone to court over this the defense attorneys has withdrawn the day of or the day prior to the trial because they look at all the charts of smoking events that look like that thing down in the corner and they don't want to go into court with that because they'll look ridiculous. We are hoping for like a dumb or lazy attorney today so fingers crossed.

So we have recently developed a sensor for vaping. It detects the -- we can't use our sensors to detect nicotine to detect vaping because most nicotine that enters the body is metabolized, just not enough comes out. But we've invented a sensor for the compounds that carry the nicotine in vaping devices. So this allows us -- it is at the laboratory level

right now. It will take a while for us to commercialize it. But we get contacted by schools about this constantly. But we are in the process of commercializing these sensors that would allow schools, bathrooms, locker rooms, that kind of thing to specifically detect vaping. They could also go on a device like this with our other two sensors so they could also catch smoking in the bathroom. Some schools identify that as a problem, others don't. It seems inconsistent.

So our contention is that reducing teens opportunity to vape reduces the harm of them vaping. It reduces and it will overall reduce the number of teens vaping.

Thank you.

DR. PIPPINS: Thank you for your presentation.

Any clarifying questions from the panel?

In the absence of any questions we'll move on to the next presentation which is Mrs. Jennifer Folkenroth.

STEPS FDA CAN TAKE TO ELIMINATE YOUTH E-CIGARETTE USE.

MS. FOLKENROTH: Good afternoon. My name is

Jennifer Folkenroth and I am Certified Tobacco Treatment Specialist, National Senior Director for Tobacco Programs at American Lung Association and a mother of two boys.

The Lung Association works on behalf of 33 million Americans living with lung disease including lung cancer and COPD which are primarily caused by tobacco use and exposure to second hand smoke. The Lung Association has served as a leader in cessation for over 40 years.

As you all well know tobacco use remains the leading preventable cause of death and disease in the United States killing 480,000 Americans each year. Another 16 million Americans living with tobacco-caused death and disease. Unfortunately, while youth use of cigarettes is declining there is still a massive spike in the use of e-cigarettes. Last month the CDC released data showing a 78 percent increase in e-cigarette use among high schoolers and a 50 percent increase in use among middle schoolers in just the last year. That equals over three and a half million children using e-cigarettes in early 2018. This trend

cannot continue.

In response to that study the American Lung Association's national president and CEO, Harold Wimmer issued a statement where he said teen e-cigarette use is a public health emergency and it requires a comprehensive nationwide response to protect this generation of children and teens.

With that I would like to talk today about what FDA can do and should be doing to support that comprehensive nationwide response.

In order to take immediate action we need to focus our efforts on preventing our youth from initiating and use of e-cigarette products. On November 10, 2018, the Campaign for Tobacco-Free Kids, Truth Initiative, America Academy of Pediatrics, American Cancer Society, Cancer Action Network, American Heart Association, and American Lung Association submitted a letter urging the FDA to take immediate action to protect the nation's young people and public health.

This is a dramatic rise in teen use of electronic cigarettes including JUUL. Consistent with

core principles essential to reducing tobacco use these organizations are unified in the conclusion that to be effective FDA's actions including its regulations need to address the following four specific areas.

FDA must enforce pre-market review.

FDA must actively enforce the legal requirement preventing products that were not commercially marketed as of August 8, 2016 or that were modified after that date from being sold without pre-market review.

FDA must also rescind the four-year suspension of pre-market review for newly deemed products on the market as of that date.

FDA needs to require the immediate removal of all flavored tobacco products that have not been thoroughly vetted in advance by FDA to assess their public health impact.

FDA needs to institute restrictions on e-cigarette marketing including on social media and make sure they are at least as stringent as those applied to cigarettes.

FDA needs to restrict internet sales of these

products and continue to aggressively enforce the law against sales to minors.

As you have acknowledged the use of e-cigarettes by youth is a public health crisis. We urge FDA to take these actions as critical first steps. We look forward to working with you to ensure that a new generation does not become addicted to tobacco.

We are here today to discuss eliminating youth electronic cigarette and other tobacco product use as it pertains to the role for drug therapies. Although cessation medications are a vital component to an individual's quit journey youth cessation medication is a long-term strategy, not an answer to the immediate epidemic.

I'd like to review those cessation strategies implemented among youth that have proven immediate and continually effective results. Behavioral counseling programs that are available today to support our youth. The American Lung Association encourages the FDA to coordinate with other agencies such as the National Cancer Institute, State Quit Lines and the Lung Association on youth cessation to take immediate action

in providing evidence-based and proven effective programs to support our nation's youth in ending their addiction before it becomes lifelong.

To provide you with further insight into the impact these programs have in the communities that you serve I'd like to share with you some evaluation results from implementation of American Lung Association's premier youth cessation program Not On Tobacco. American Lung Association's N-O-T approach to youth cessation includes as what was mentioned earlier today a biological, psychological and sociocultural team approach to quitting. And I think the team component is very important for that peer to peer support. The curriculum is youth-centered and intended to be voluntary which also is very important that our youth are voluntarily participating in these programs, not as a punitive measure. It is for teens ages 14 to 19 that are actively wanting to quit. Activities are gender sensitive which is also important as we found that teens identifying as female possess different motivators for quitting than those teens identifying as male. Classes include multiple learning strategies

including group discussions but also individual journaling for personal inflection. It is tailored for smokers and based on theories of behavioral change. Not On Tobacco is designed to provide a total help approach to helping adolescents with a step-by-step plan to quit smoking or at least to reduce the number they are smoking should they be unable to quit.

I think it is really important that we highlight the total help approach. It focuses on increasing healthy life style behaviors in the areas of physical activity and nutrition. Also activities enhance their sense of self-control and further improve life skills to stress management, decision making, coping, and intra-personal skills.

A behavior change program including biological, psychological and sociocultural approaches works. Evaluation of the American Lung Association's Not On Tobacco program over the past 22 years shows a 90 percent of all teen participants were successful in quitting or reducing their smoking.

N-O-T participants identifying as female were four times more likely to be smoke free six months

after completion of the program compared to those receiving a brief intervention. Although brief interventions may be effective among youth with low nicotine dependence, programs that give an all-three angle of addiction approach model to their counseling such as N-O-T is truly able to serve youth in all ranges of nicotine dependence.

In addition to leading healthier tobacco-free life styles, participants also reported improved grades, higher motivation, fewer absences. For those teens using e-cigarette products wanting to quit, proven effective cessation programming provides them with immediate support and the results are far more than just quitting. They provide development of life skills to maintain healthier life styles for years to come.

In summary, there are three main points the American Lung Association would like to convey. FDA must take meaningful action to prevent initiation that goes well beyond sale restrictions. Youth cessation medication is a long-term strategy, however not an answer to the immediate epidemic. And counseling can

work. FDA should coordinate with other public health agencies on youth cessation programming taking those lessons learned from those proven programs.

In the meantime, the Lung Association will continue to work to prevent kids from becoming addicted to nicotine whether it be with e-cigarettes, cigarettes, cigars or other tobacco products that are supported through the Not On Tobacco Program. We will continue to advocate for policies that discourage kids from starting smoking including additional actions from FDA and raising the minimum age of sale to 21.

On behalf of the American Lung Association and the 33 million Americans living with lung disease including lung cancer and COPD we thank you for your time today hearing our voices. Thank you.

DR. PIPPINS: Thank you very much for your presentation.

Any clarifying questions from the panel?

Dr. Murphy.

DR. MURPHY: Thank you for your presentation. You talk about your goal being tobacco-free teenagers but it seems like a lot of the language is based on

smoking and smoke behavior. So what is your experience with other tobacco products and also with this electronic cigarette product use teenagers may not associate these products as being tobacco products. So do you think there is some challenge in using tobacco cessation programs for vaping because they might not -- they may be like I don't use tobacco products.

MS. FOLKENROTH: Thank you so much, Dr. Murphy. That is an excellent question. So American Lung Association really kind of focuses a lot of the verbiage and the naming on smoking because we are a lung health organization. However, as a tobacco treatment specialist I can say that our programs have benefited individuals in using all varieties of tobacco products including smokeless tobacco and e-cigarette use. The number of participants in our Not On Tobacco programs in the communities and schools currently that are specifically trying to quit use of e-cigarette products with no other dual use is increasing tremendously. And in some cases is the majority of the classroom. So we are seeing much success. I think the total approach of the triangle of addiction with the

biological, psychological, and sociocultural it really certainly does apply to all of these different tobacco products.

I do believe in responding to your second question that kids do not see e-cigarettes as tobacco products. However, I think we need to clearly define its policies that we are implementing to change the social norming as well as just general understanding. But these are in fact derived from tobacco products and therefore are tobacco products.

DR. MURPHY: Thank you.

DR. PIPPINS: Are there any further questions?

I am not seeing -- we'll break -- oh, I spoke too quickly, Dr. Green?

DR. GREEN: A very brief question. Thank you for your presentation. You mentioned noting differences in gender as it relates to motivation, can you speak about that a little more.

MS. FOLKENROTH: Absolutely. So we have noticed over the last 22 years implementing this program that a gender-specific curriculum can be really helpful in terms of how the teen identifies themselves

either female or male. For those individuals female, a lot of our -- I would say a lot more focusing on the aging. There are certain motivators that are different among our young females than our young males particularly for our males the athletic ability, military readiness, there is a lot of kind of takes on the behavioral component and sociocultural component that we are noticing different activities for those identifying as female versus those identifying as male tend to be more effective.

DR. PIPPINS: Any other questions. If not, we'll start our break for lunch just a little bit early. We will break and we will resume at 12:55. Thank you very much.

BREAK

DR. PIPPINS: Good afternoon. The speaker next listed on the agenda has cancelled, Mr. Larry Flick which means we'll turn to Mr. Michael Diaz. I don't believe he is here either, but I just wanted to call just to make sure. Michael Diaz.

Since he is not present, we will move on to the next scheduled speaker which is Dr. Amanda Graham.

COMMENT ON ELIMINATING YOUTH ELECTRONIC CIGARETTE USE: THE ROLE FOR DRUG THERAPIES.

DR. GRAHAM: Great. Thank you very much. Good afternoon everyone. My name is Amanda Graham. I lead the Innovation Center at Truth Initiative which is the largest non-profit public health foundation in the U.S. exclusively dedicated to ending the tobacco epidemic. I'm also a professor of oncology at Georgetown University Medical Center.

Our mission at Truth Initiatives centers around four key competencies. The first is large scale education campaigns. Many of you know us for our award-winning Truth Campaign which has historically focused on combusted tobacco. Most recently we've launched a campaign in October around vaping.

We are also active in treatment and policy research, community activism and engagement. And the work that I lead in building and deploying digital programs for tobacco cessation.

Just briefly since 2008 we have run a free digital smoking cessation program called the BecomeAnEX. The program was developed in collaboration

with our partners at the Nicotine Dependence Center and has helped over 800,000 tobacco users on their journey to quit tobacco. We launched an enterprise version called the X program in 2017 designed specifically for employers and health plans to offer to their employees and dependents. And we run This is Quitting which is a freely available mobile app through IOS and Android that was designed by and for young people.

So the central premise of my comments today is that as the FDA pursues drug therapies to help youth quit vaping it should not lose sight of the critical role that behavioral and social factors play in e-cigarette and other tobacco product use. And importantly the power of digital cessation approaches to address this epidemic today.

Young people are digital natives. This is a picture that probably reminds us of many of the kids that we all have. They've grown up with computers, with mobile devices and with social media and they use them in literally all aspects of their lives.

The most recent data from the Pew Research Center support what we see in the world around us which

is the ubiquity of smart phones. Even in households where parents are earning under $30,000 a year we see that 93 percent of teens have access to a smart phone. Among young adults ages 18 to 29 100 percent are cell phone owners and 94 percent are smart phone owners.

These are data from a national survey among 13 to 17-year-olds which show a slight preference for texting in terms of connecting with friends over in person communications. And we also see that social media play an influence role in the lives of young people. When most of us think of social media we are probably thinking of Facebook and Twitter. Young people are on YouTube, they are Instagram, they are on Snapchat, they are using different platforms that have yet to make it into the peer reviewed scientific literature for the most part.

Nearly half of teens say they are online almost constantly, these are checking updates to social network profiles, status updates, often using their smartphone to simply avoid boredom. The thing to know is that this is not simply frivolous socializing. What we see is that 87 percent of young people go online for

health information, 64 percent use mobile apps related to health, 61 percent say that they've read or watched someone else's health story online. We see this every day at Truth Initiative when it comes to quitting cigarettes and quitting e-cigarettes. Young people are quitting all the time and they are quite verbal about it on social media, posting thousands of tweets and images and videos and blog posts about their quitting related experience, both the struggles and also the successes.

I wanted to give you just a couple of examples in terms of some of these comments. What we see on Reddit prediction for the future, give it ten years and people will be using cigarettes to quit~~e~~ JUULing. I quit JUULing a little over a month ago and I am still feeling withdrawal. And here is someone who was able to quit using cigarettes using JUUL but then says it felt like an achievement until I realized I was way more addicted to vape than I was to the cigarettes. On Twitter I can't believe how hard it is to quit the JUUL. I'm not quitting but just thinking about it is giving me anxiety. I quit JUUL and I just wanted to

let everyone know because it was hard. Here's a dual user, someone needs to get me to quit smoking because between my JUUL and my regular cigs I can feel the end of my life when I extend my arm out. And of course, Twitter wouldn't be Twitter without some profanity. It is hard to quit the JUUL when every person on campus has one and JUUL is in your face.

Commented [TD2]: Should the text -based post comments have " "?

These are just text-based posts. This is a young woman who literally took an axe to her JUUL as a measure of last resort to quit. She videoed it and put it on Instagram. And you can see the range of hashtags that she uses. This is how social medial users search for and find each other's content online.

The notion that quit smoking platforms are strictly for adults has really been turned on its head. And on BecomeAnEX we see that 30 percent of our users are under the age of 30. This is a woman who is 29, she is asking a question about smoking and vaping saying she mainly vapes. And the important thing to notice is the breadth of comments. Twenty-nine people respond to her posts. These are likely to be both current smokers looking to quit, current vapers looking

to quit and also people who have successfully quit sharing and modeling their experiences.

What we see is that they get good advice. This is often a question that comes up when it comes to online networks and social media. Me Plus Three who is between the ages of 18 and 24 says, is it considered a relapse to use a vape or an e-cig and she gets a reply from Dale who notes the importance of addressing the behavioral connection. Tomas responds they are safer but not safe. And final Free and Easy wraps up with advice that we would have offered which is e-cigs are not an approved quit therapy. It's better to use an NRT.

So there is demand, there is significant demand for help in quitting. There are questions, people looking online for answers. Unfortunately, as has been talked about all day today the science is much farther behind. There are very few published studies about quitting e-cigarettes. This is a case report that we were able to find, a young man who successfully used NRT to quit e-cigarettes. To date we are not aware of any evidence-based program that is digital and

so what that means is that young people are likely to find a wiki page on how to quit e-cigarettes or Allan Carr's easy way to quit on ten tips how to quit vaping. There is simply a gap here.

When we turn to the youth cessation literature much of this has been covered today, there is evidence that behavioral and psychosocial approaches can be effective. We also know that there are challenges with engagement and adherence. There is promising work in the young adult literature especially signaling text messaging approaches.

And so with the rapid and dramatic increase in e-cigarette use among youth we simply can't wait for the science to catch up. At Truth Initiative we've taken action. In December we launched a first of its kind e-cigarette cessation program. We developed the program in collaboration with our partners at the Nicotine Dependence Center and with input from people trying to quit e-cigarettes or who had successfully quit.

This is a text messaging program. We went with text messaging given the solid evidence base in

both adults and young adults. We also know that this is a modality that teens prefer, they can do it anonymously, they can do it privately without their parents needing to know. We've created a flexible program that can be used on demand and we know that it reaches across demographic groups. People can enroll directly by texting quit to a dedicated phone number or enrolling in the text services through BecomeAnEX and This is Quitting. We ask their age and then route them to one of four different libraries either a program for teens, for young adults, for adults 25 and older and importantly for parents.

We've tailored the program by age to make sure that we are providing evidence-based recommendations about nicotine replacement therapy. We also have adjusted the language to be referring to JUUL and JUULing in our teen library. We know how that -- that is how they talk about it.

We've basically taken the best available evidence that we have from the cessation treatment literature and adapted it for e-cigarette use to be able to take action.

The program was featured this morning on the Today Show, we had a really nice piece with Cynthia McFadden who came to our office earlier this week. It aired at 8:14 this morning East Coast time. These are numbers that are current as of about 15 minutes ago, we've had 2,000 people enroll, about 1200 parents, about 430 adults and about 200 young people.

We'll be conducting ongoing evaluation efforts, sharing what we know, what we're learning and are happy to share that with the FDA.

And thank you for the opportunity to be here and to share our comments.

DR. PIPPINS: Thank you very much for your presentation.

And actually I'll kick off with a question. I'm interested in what metrics you might be using moving forward to evaluate the effectiveness and outcomes of your program?

DR. GRAHAM: That's a great question. The first thing that we are going to be monitoring are obviously patterns of uptake and engagement to determine the response similar to what we've seen this

morning. Gathering outcome data from young people can be challenging but we baked in evaluation questions into the text message library themselves to be able to gather abstinence metrics at intervals like seven days and 30 days.

DR. PIPPINS: Any additional clarifying questions from the panel?

If not, thank you very much for your presentation.

DR. GRAHAM: Thank you.

DR. PIPPINS: That concludes our planned presentations. We'll next move on to the open public hearing.

OPEN PUBLIC HEARING

DR. PIPPINS: Our first speaker and I know that some speakers may not be in attendance. But the first speaker to call would be Dr. Amarpreet Sawhney. I don't believe they have checked in, but I wanted to do one call just in case they arrived late.

The second speaker I have listed is Dr. Carrie Wade.

So we'll turn to our third speaker then

registered Ms. Laura Searcy.

Apologies we'll hold a moment as we trouble shoot some of our technical issues.

MS. SEARCY: Good afternoon. My name is Laura Searcy. And I am a past president of the National Association of Pediatric Nurse Practitioners. In addition to my clinical role I have been working for the last ten years in community-based substance abuse prevention. And have been speaking about youth trends in nicotine use and doing educating to parents, teachers, professional associations, community providers, prevention specialists and have been around my state talking about the rising use.

The message that I've been asked to bring is that we have an epidemic that cannot be argued. And that the pod-based high nicotine level devices were an absolute game changer. If we know that JUUL has 75 percent of the market and we have evidence that 16 times greater use by 15 to 17-year-olds than by 25 to 34-year-olds, we know youth are using these products. While we know there is science and research to be done, the trajectory research about tobacco use shows that

youth with their developing brains who are much more vulnerable to addiction can become nicotine dependent with as few as 100 lifetime cigarettes.

A JUUL pod has the equivalent nicotine of a pack of cigarettes, that is 20 cigarettes. So five JUUL pods is enough nicotine to addict some of our youth.

We are here today because to date our policies have failed our kids, their parents and their communities. And there is real anger and frustration especially in the last year I've been in so many schools because they are frantic to try to figure out what they can do about this epidemic that is affecting their kids. We know we don't have adequate treatments and that medications alone won't work.

JUUL is a social and cultural phenomenon, it has taken youth by swarm. It hits all of the biologically determined adolescent drives for rebellion, risk taking, seeking new and novel experiences. Stopping this epidemic is going to require much broader base and will be different than other epidemics of substance use.

And I just want to focus on my little bit of time on marketing. Why do we need mass marketing, prime time, radio drive time that started in my community the second week of school to reach 15.5 percent of the public that are current cigarette users and that may benefit from switching to an e-cigarette use? It seems like overkill and our youth are the victims.

So at the National Association of Nurse Practitioners we advocate a comprehensive approach that includes at a minimum raising the legal age to purchase tobacco and nicotine products to 21 and requiring strict enforcement of age limit with significant penalties for violations and restricting or prohibiting the use of flavorings.

And I will tell you, two days ago I went on the Suorin site and they still had the box, it only said are you of legal age in your state, and you could click on it. So there still is, despite what the FDA is trying to do, no age verification that is happening for online.

So thank you very much for your time.

DR. PIPPINS: Thank you very much for your presentation.

Any questions from the panel?

Thank you.

We'll turn to our next speaker. Mr. Patrick Hedger) who I don't believe is here.

We'll turn next to Mrs. Kelly Kinard.

MS. KINARD: Hi, I'm just a mom of a recovering JUUL addict. It took 39 days of residential treatment to get my 15-year-old off the JUUL. Battled his addiction for 15 months. We sought assistance from therapists, school counselors, pediatricians, emergency rooms, a cardiologist, a neurologist, a psychiatrist and an attention deficit specialist.

I talked until I was blue in the face. I tried to get through to them that the extreme behavioral changes we were seeing in our son all appeared after he started JUULing. Not one medical professional would consider or acknowledge that my son's symptoms that mimic serious psychiatric issue or other substance abuse problems could be signs of nicotine abuse. We tried putting him on Wellbutrin,

but it had no effect whatsoever. A cookie-cutter approach to nicotine cessation will not work for an adolescent who doesn’t have the maturity, cognitive awareness, or will to quit. He had no interest in quitting and his addiction was completely out of his control.

We didn't have time to wait for research to catch up. So I turned to the internet for information and read that adolescent nicotine abuse should be treated as substance abuse. I was fortunate to find an adolescent residential treatment center in California that would treat JUUL addiction the same as any other drug addiction.

Three weeks into treatment we finally heard the voice of a boy we hadn't seen or heard in more than a year. And after 39 days he thanked me for sending him for treatment.

Now he is clean and thriving. He is relieved to be free of the JUUL. He has rediscovered his leadership skills and is speaking out at local schools trying to help others avoid the same mistakes he made. He is embarrassed about the messages he is receiving

from across the country from kids having to do homework assignments on his story. But I am happy to be able to say that our previous feelings of being the failure as parents have turned once again into being proud parents of a normal teenager.

Next week he'll return to school where every classroom and every bathroom is filled with kids puffing on their JUULs. While we were in the middle of this nightmare, we thought our son's symptoms were unusually severe, but since I came forward to share our experience, I'm hearing from distressed parents from across the country every day. Their good kids are showing the same similar severe symptoms. There are more families in crises than people realize but they don't know where to turn for help.

Thank you.

[Applause.]

DR. PIPPINS: Thank you for your comments. I have one question for you. Have you received any input about what might be useful in terms of maintenance of cessation moving forward?

MS. KINARD: During his 39 days in treatment a

big part of the program was not just getting him off the JUUL but maintaining and giving him techniques for mindfulness, the tools to deal with the anxiety. And all of his friends are still doing it and he has learned to be around them and not partake. Part of that is the threat of going back to treatment.

DR. PIPPINS: If there are no further questions. Thank you for your comments.

Next I like to call up Ms. Dorian Fuhrman.

MS. FUHRMAN: Hi, Thank you. My name is Dorian Fuhrman and I am one of the co-founders, the three co-founders of Parents Against Vaping E-cigarettes or PAVE. We would like to thank the FDA not only for having us to this very important meeting but also for all the work you have done to try to protect our children from what the Commissioner himself and the Surgeon General have both called growing epidemic of e-cigarette use among teens.

Thanks to the FDA and other anti-tobacco organizations and years of public service messages the cigarette smoking rate among high-schoolers had gone down from 28 percent in 1998 to around five percent

last year. This was a major achievement. Most kids today would never have dreamt of picking up a cigarette.

Then along came JUUL with its hip social media marketing campaign targeted towards young people. It's sleek high-tech design, sweet flavors and its well-chosen name took parents and kids by surprise. Parents many of whom are not present on their kids' social media had no way of knowing what had just launched.

Little by little we began to discover that our kids were doing something that we didn't understand. JUUL is stealth by design. It is made to blend into the high-tech devices that all young people have lying around their rooms. And it closely resembles a flash drive that they all use in school. It is practically imperceptible in the sense that one can barely smell its sweet odor and the vapor which is not vapor at all but really an aerosol containing a myriad of chemical and metals can be blown into one's sweatshirts or even swallowed and can barely be seen.

Two very addictive products nicotine and technology had just been combined and the kids were

flocking to it in droves. Drawn in by flavors such as fruit medley, crème brulee and mint kids were buying them online with no age verification, on eBay and at the corner store. And they didn't understand that JUUL contained high levels of nicotine, highly absorbable nicotine and were extremely addictive and very expensive.

As we became aware of this new trend and I myself discovered that my son who will be speaking next was using it. My friends and I tried to inform ourselves about the health risks and dangers and the availability of e-cigarettes. Unfortunately, we could not find an organization that was dedicated to helping parents navigate this new world, so we decided to create one, Parents Against Vaping E-cigarettes.

We were not prepared for the overwhelming response we received. We quickly built a very esteemed board of advisors and associates from top research university prevention group and medical institutions around the country and we started getting emails from parents all around the country whose kids were addicted to JUULing. They didn't know what to do. Never before

had such a product been created where people were able to absorb such high doses of nicotine in such a short time. There was no precedent.

We have begun advocating on state and national levels with our boys to call for a flavor ban and advocate for stricter laws of advertising and taxation. As we have seen prevention is key. As our sons will attest kids are drawn in by the flavors and ease of finding them. Some of them will now turn to cigarettes if they cannot get their daily dose of the nicotine through their e-cigarettes.

The money wasted on these products is astonishing and many kids are turning to buying pods in bulk and selling them to their friends.

What we need first and foremost --

DR. PIPPINS: I apologize, I'll have to call you to close.

MS. FUHRMAN: All right.

DR. PIPPINS: But I do have a question for you. What is the size of your organization? Are there members or is it -- is there a size estimate of your organization?

MS. FUHRMAN: So, we are three co-founders and we have several people who are working with us. We have over 600 people registered on our website. We have people based in all different parts of the country from California to New York, to Texas to Oregon and we have been advocating on you know Capitol Hill and we had a private listening session last month with the FDA and we have organizations, not only parents but schools who we are dealing with and working with.

DR. PIPPINS: Thank you very much.

Are there any further questions from the panel? I think we have one from Dr. Murphy.

DR. MURPHY: I just wanted to see if maybe the organization was aware that Center for Tobacco Products has a Safety Reporting Portal and so if parents or anyone public can report adverse experiences related to tobacco product use and make FDA aware.

MS. FUHRMAN: Yes, we actually do know that. However, something like eBay I went on just two days ago and it is still possible to buy tobacco products on eBay and I don't know if that is possible to alert the FDA to. But you know you can buy JUUL on eBay and

there is no age verification.

As someone said before Suorin has no age verification and Eon Smokes has no age verification.

DR. MURPHY: Thank You.

MS. FUHRMAN: So can we report that?

DR. PIPPINS: I'm sorry, Dr. Murphy, go ahead.

DR. MURPHY: The safety reporting portal is focused on product problems and adverse -- so product problems specifically and health problems. But if there are things you want to report there is a way to AskCTP.gov.

MS. FUHRMAN: Okay.

DR. PIPPINS: I'd also mention that again we are welcoming comments to the docket on any of these matters, that would be useful to us.

MS. FUHRMAN: Great. Thank you.

DR. PIPPINS: With that we will turn to our next scheduled speaker who is Mr. Phillip Fuhrman.

MR. FUHRMAN: Hi, my name if Phillip Fuhrman and I'm here to talk about my experiences with JUUL and vaping. The first time I JUULed was at the end of eighth grade. My friend handed it to me, and I had no

idea what it was. I took it and I took my first hit and I coughed a little and I liked it. The thing that I liked most was the minty feel in my throat. The thing that enticed me most about this device was the mint and the cool device and the technology that came with it. It was the mint tasted like gum and who didn't like gum.

A few weeks after I bought my first JUUL for myself for the summer and I started using it more and more often as the summer went on. I would get my pods online before my mom saw and I could get them on eBay very easily.

When I got to my school in the ninth grade, I was surprised to see how many other kids had also started or had been JUULing and how easily I could connect with them about this. It started to cause tension in my family when my mom found my first JUUL. After she found it, I got a new one a few days later and the cycle continued.

This had not only caused tension in my family, but I also wasted a tremendous amount of money on new JUULs and pods.

By the time I realized how bad this device actually was it was already too late, and I was addicted. That happened around the end of ninth grade. Every time I tried to stop I couldn't because at every single party, social event or anything there would always be JUULs or other vapes floating around that I could use.

I would end up taking a hit, liking it so much and then getting another one the next day. And I'd keep it for a few weeks until once again I'd think that it was bad and throw it away. I see so many of my friends who had the same problem I did and don't even know it and have no idea how to stop it.

DR. PIPPINS: Thank you very much for your comments.

Any comments from the panel?

DR. MURPHY: I just want to thank you. I want to echo and say thank you for sharing your experience with us today. Doing that is very helpful.

DR. PIPPINS: I also want to add that we are particularly interested in hearing from people your age. So if there is anyone that you think would be

helpful for us to hear from there are ways of online sending comments to us. We would really take those seriously. So we would be grateful for that.

MR. FUHRMAN: Okay.

DR. PIPPINS: We'll turn to our next speaker who is Ms. Meredith Berkman.

Apologies, we are jumping to speaker, could you introduce yourself, I'm sorry.

MR. MINTZ: My name is Caleb Mintz. I'm 17 years old.

DR. PIPPINS: Mr. Mintz.

MR. MINTZ: And I am here today with my mom and our grassroot movement Parents Against Vaping and E-cigarettes. Now in the beginning I experimented with JUUL as did many of my peers. And I think JUUL has become so prevalent that I know all too well the smell of mint pods and mango pods, yet I don’t really consistently JUUL.

I think in a way JUUL slang has kind of become a universal code amongst teens in a way that if I go to a different town and I say to another kid do you play basketball you know it is making a connection with that

kid. I can say things now do you have a JUUL pod on you or do you JUUL and it is kind of like I instantly make a connection with that kid. I think it is that prevalent.

I really believe the extent of JUULing is far worse than many believe. Previously in regard to the cigarettes there was a negative stigma associated with kids who smoked cigarettes. And these kids would often be characterized as rebels or people with negative behavior and risk takers. And I think JUUL has become so widespread that there is no specific group you can pinpoint who JUULs. I think it is no longer a specific group who JUULs. It is almost as if one teen from every social group no matter how good their grades, no matter how well-behaved they are, has a JUUL and consistently JUULs.

Many people saw smoking cigarette as gross, largely due to the combustibility required to light a cigarette and with JUUL the device looks sleek and modern and as a 17-years-old I recognize that my generation isn't the priority. Preventing younger kids from JUULing to me is the priority. I can't help but

feel as my generation is going to be known as the generation of damage control.

DR. PIPPINS: Thank you for your comments. I do have a question if you don't mind. In your conversations with peers have there been any conversations about quitting and if so, what are reasons people would give for wanting to quit?

MR. MINTZ: I would say that in the beginning there wasn't much conversation about quitting as it was a new technology and I think a lot of people were excited about it and there was peer pressure. I feel now a lot of kids or some kids do understand that it is harmful and want to quit and try very hard to quit but it is just extremely addictive, and I know very few kids who can just go off their JUUL for more than three days.

DR. PIPPINS: Any other comments from the panel?

If not, again we'd encourage any additional comments from you or from friends. We really do welcome them, receiving them electronically. Thank you.

MR. MINTZ: Thanks.

DR. PIPPINS: Do we have Ms. Meredith Berkman?

MS. BERKMAN: I apologize for the change in order, but my son wanted to go before me and if you are a parent you will understand and in this situation I was going to let him do that.

First of all I'm Meredith Berkman and I'm a co-founder along with Dorian. Unfortunately, our third partner Dina Alessi and her son Luke who joined us for our private listening session in December could not be here.

But we are very, very grateful for all of the attention today on cessation because we know thanks to what the Commissioner has said and continues to say and now what the Surgeon General has said the use of the word epidemic not only is it correct, but it also allowed parents to understand and so many still do not.

And as Dorian said you know we're coming here and speaking to you as just moms. And I don’t think saying just moms is in any way derogatory. I'm saying that because we are here to speak to you from the heart. But we were moms concerned when we realized

what our three boys, two of whom are here today and I'm really proud of for having the guts to stand up and talk about their own experiences. But we were three moms who were so upset when we started to do our own research online last year and put the pieces together. We were smart enough to connect with some of the smartest people who have the experience and the knowledge that we don't. You know one of our advisory board members for Parents Against Vaping E-cigarettes spoke this morning, Dr. Bonnie Halpern-Felsher. Another person who has been very helpful in guiding us to help us understand is Lauren Lempert of UCSF who is here today. We've met with experts at the Harvard School of Public Health. We've been on Capitol Hill; our boys and we've met with Senator Ron Wyden. We spent time yesterday and with Congressmember Jamie Raskin. We are advocating as hard as we can and when people troll us online or are very critical on Twitter because of our message that this isn't good for kids. People often say you don't care about adults. But I want to make it clear everyone wants harm reduction. Who doesn't want harm reduction? But we are parents

advocating for kids. And the research has proven and as you heard today specifically today about JUUL from Dr. Bonnie Halpern-Felsher the research has shown that flavors are hooking our kids and keeping them from perceiving nicotine and danger. Now since we know that the flavors are hurting the kids by drawing them to a product like JUUL and its copycats we all know especially after the announcement of the Altria deal, $13 billion of a tobacco company investing in JUUL that JUUL is big tobacco 2.0. And this is just the beginning of a repetition of what the FDA and many of the stakeholders who are coming together across the country now including these accidental public health care advocates the just moms, we don't want to see it happen again.

And we beg you to please to take those flavors off the market. We know they hurt kids. We don't have any evidence that taking them off the market would harm any adult. We just don't want any kid to say my generation is damage control. What teenager should feel that way?

We thank you for what you are doing but we

hope you'll take that final step because we need it.

DR. PIPPINS: Thank you very much for your comments.

Any questions from the panel?

Thank you.

So received word that Mr. Luke Alessi is not present. We'll turn next to Mr. Dennis Henigan.

MR. HENIGAN: My name is Dennis Henigan. I'm Vice President for Legal and Regulatory Affairs at the Campaign for Tobacco-Free Kids. I want to thank the Commissioner and the FDA for convening this meeting.

The fact that this meeting is being held demonstrates the seriousness of the epidemic of youth nicotine addiction that our nation is facing.

This is not experimentation. This is addiction. And we are so pleased that the FDA has recognized the nature of this problem. It is a crisis that has been fueled by JUUL and similar products that were designed to be addictive and then were marketed to make them appealing to kids.

And certainly no one here can fail to be moved by the stories by teens who began JUULing unaware that

the product even has nicotine but whose lives have been transformed by their struggle against addiction. You have heard those compelling stories here today.

Now as the testimony here today shows there is precious little in the way of answers for teens that are already addicted to e-cigarettes particularly regarding the safety and efficacy of FDA approved cessation products for use with youth.

As we have argued in other forums, we do not believe the FDA should even be satisfied with the performance of these FDA approved products for adults. Only about a third of smokers who try to quit even use these medications. Though most smokers want to quit in any given there are only seven percent actually do so.

We believe there is much more FDA should be doing now to create a regulatory environment that will stimulate innovation in cessation products and the expanded and successful use of current products. And we recognize that the treatment of nicotine addiction among kids particularly e-cigarette addiction raises many unanswered questions and poses very special challenges. So we join others in calling upon FDA to

do everything within its power to advance the necessary research to answer these questions and meet these special challenges.

But while FDA seeks these answers it must do more to prevent additional kids from becoming addicted. It must take stronger action against the products that are the cause of the crises. We know that flavored tobacco products appeal to kids. E-cigarettes are no exception. And I'm afraid that the steps announced by FDA so far, threaten companies unless they reduce access to these flavored products among kids are destined to not be enough.

Given the intense appeal of JUUL and these similar products FDA must use its current authority to take these products off the market until they pass FDA public health review. There is simply no statutory authority for products like JUUL that were not on the market in 2007 and, therefore, are not grandfathered by the Tobacco Control Act to remain on the market without FDA review. So FDA must take that step right now. Anything FDA fails to do now to prevent future addiction of kids undercuts what FDA is seeking to do

to help the kids who are already addicted.

Thank you so much for allowing me to speak.

DR. PIPPINS: Thank you very much for your comments.

Any questions from panel?

We have on question for you, sir.

DR. MURPHY: Yes, so you mentioned that FDA should do more not only for preventing but also to stimulate development of new cessation therapies. And I was wondering if you had any suggestions for what exactly we should do?

MR. HENIGAN: Yes, as a matter of fact we have submitted a number of filings at FDA including a recent letter to the Commissioner of FDA joined by other public health groups and experts in the field calling upon FDA to chart an entirely new cessation agenda at the agency which would include the re-evaluation of new indications for existing products for example the use of combination products in addition to longer term use of existing products. These are alternatives that have been presented to the agency in the past bolstered by sufficient science and the agency has done very little

to actually encourage the development of the application of these new indications.

We also believe that FDA has done very little to create a general regulatory environment that will stimulate new products to be developed to go through the clinical trials necessary to show safety and effectiveness and bring products on the market that will actually work and that will be actually appealing to the vast majority of smokers. So there is much more that CDER needs to do in order to bring new safe and effective products on the market as it attacks this current crisis of youth e-cigarette use.

DR. PIPPINS: Thank you.

Our next speaker is Dr. Bonnie Halpern-Felsher.

DR. HALPERN-FELSHER: Good afternoon. And thank you again for pulling this together on this day and as I've been listening to the comments today which have been fantastic it brought up a few things to me that I think weren't said that I want to make sure are stated for the record.

The first thing is and actually I think this

was alluded to, but I think it is really important to differentiate our terms between vaping and JUULing. Youth don't -- when we talk about addiction campaigns or cessation campaigns or anything youth and you heard from the young people don't consider JUULs to be vapes and they don’t consider them to be tobacco products, but they are tobacco products. We continue to have this misperception on the part of youth because we aren't clear on our names. Just like Kleenex is Kleenex, Band-Aids, Q-tips, JUULs are JUULs they are not -- they are vapes, they are tobacco products but youth don't see those. So we really have to be very clear on our terms. That is the first thing.

Second thing is in terms of data I want to really make it very clear that there is really no evidence that the reduction in cigarettes is due to the increase in e-cigarettes. They happen separately. There is a temporal gap in them. So it is not that the advent of e-cigarettes was the solution to cigarettes. And that is important to know.

The other thing is I asked the FDA to please consider youth to be on a spectrum of ages that goes

all the way up to the mid-20s. When we talk about adolescents and young adults it is a developmental, a biological reason why that goes to 25 when we are talking about nicotine addiction. The brain continues to develop and you are just as addicted in your early 20s, potential for addiction in your early 20s than you are in your mid-teens. So that is important to know.

And then the other point I want to make is in terms of the nicotine replacement therapy, NRTs, that there is a different abuse liability in NRTs compared to e-cigarettes. So even if -- first of all there is not as much nicotine in there but even if there would the delivery is such that you are not getting a buzz, you are getting addicted to it. The abuse liability is very different compared to electronic cigarettes. And along that note something like JUULs that has such an incredibly high level of nicotine and salt-based nicotine we need more research on that, very important to understand it. And I would also argue that we need a reduction in the amount of nicotine that is allowed in these products like we have in the U.K. and in Israel.

And then finally it is very important to consider that no industry, e-cigarette, cigarette, tobacco industry should be doing their own prevention research, prevention programs or should be doing their own regulation of their products. We need to do it upon ourselves in the public health community. Published a paper on this in the Journal of Adolescent Health, the JUUL curriculum for example has a number of problems that it is not going to be effective and we cannot let the tobacco, e-cigarette, whatever industry you want to all it be doing their own prevention work.

Thank you.

DR. PIPPINS: Thank you for your comments.

Any questions from the panel?

I believe we have one from Dr. Murphy.

DR. MURPHY: So you had mentioned reduction in nicotine levels allowed and you mentioned U.K. but do you have information to demonstrate that the U.K. or the European limits are sufficient?

MS. HALPERN-FELSHER: I do not other than their use rates are lower. But I don't. But I have colleagues I can ask and be able to submit it to the

docket.

DR. MURPHY: Thank you.

DR. PIPPINS: Any further questions from the panel?

If not, I'll provide some closing remarks.

CONCLUDING REMARKS

DR. PIPPINS: On behalf of the FDA panel I'd like to thank all the presenters and everyone in the audience whether you attended in person or via webcast for participating in today's hearing.

We greatly appreciate your attention and your interest in this topic and all the presentations.

In addition, I would be remiss if I didn’t take a moment to recognize the FDA staff involved in organizing today including Dr. Allison Hoffman, Ms. Theresa Wells, Brian Lee, other colleagues at the DRT, the Great Room staff along with all of the panel participants and everyone at the Centers who collaborated on this important hearing.

Thank you.

As a reminder we strongly encourage you to submit comments to the docket which will be open until

February 1, 2019. If you would like details on how to do so we've placed some copies of the Federal Register Notice announcing this hearing at the registration table and it can provide guidance.

Also, please note that a transcript from this hearing should be posted to the hearing web within 30 days.

We will provide copies of the presentations today upon request. Contact information is available at the registration table.

And on that I'm closing this public hearing.

Thank you.

[Applause.]

CERTIFICATE OF NOTARY PUBLIC

I, MICHAEL FARKAS, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

MICHAEL FARKAS
Notary Public in and for the
STATE OF MARYLAND

CERTIFICATE OF TRANSCRIBER

I, CHERYL LaSELLE, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

January 29, 2019 _____

DATE CHERYL LaSELLE