U.S. Food and Drug Administration

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FTS-HHS FDA
Transcript for FDA's Media Briefing on Electronic Cigarettes
Moderator: Judy Leon
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Coordinator: Welcome and thank you for standing by. We'd like to inform all parties your lines will be in a listen only mode until today's question and answer session. At that time to ask a question please press star 1. Also today's conference is being recorded. If you have any objections you may disconnect at this time.

And now I'll turn today's call over to Judy Leon from the FDA Office of Public Affairs. Thank you, you may begin.

Judy Leon: Thank you very much. Welcome ladies and gentlemen. This is Judy Leon from FDA's Office of Public Affairs. This is an FDA teleconference for credentialed media to hear FDA's Principal Deputy Commissioner and other public health experts make an announcement about electronic cigarettes. This briefing is for credentialed media only.

Our speakers today are Dr. Joshua Sharfstein, Principal Deputy Commissioner of the Food and Drug Administration; Dr. Jonathan Winickoff, Chair of the American Academy of Pediatrics Tobacco Consortium; Dr. Jonathan Samet, Director of the Institute for Global Health at the University of Southern California; Dr. Matthew McKenna, Director of the Office of Smoking and Health at the Centers for Disease Control; Nick Westenberger from FDA's Center for Drug Evaluation of Research and Michael Levy, Division Director Office of Compliance Center for Drug Evaluation and Research of the Food and Drug Administration.

Now I will turn the call over to Dr. Sharfstein.

Joshua Sharfstein: Thank you very much Judy and thanks to everybody on the call. I am Josh Sharfstein, the Principal Deputy Commissioner of the Food and Drug Administration. Recently there has been increased public attention on products called electronic cigarettes or e-cigarettes. These are essentially battery operated devices that generally contain cartridges filled with nicotine flavor and other chemicals that turn nicotine and other chemicals into a vapor to be inhaled by the user.

They are readily available in places where youth can access them including online and in malls, but little is known about these products, including how much nicotine is there, it's getting in the body with other chemicals may be there and getting in the body and the impact of these products on the body.

Public health experts and organizations including the World Health Organization, the Centers for Disease Control and The American Cancer Society have expressed concerns about the safety of these products and the risk that electronic cigarettes may increase nicotine addiction among young people and ultimately lead kids to try conventional cigarettes.

The FDA has conducted a preliminary analysis of the ingredients in some samples of e-cigarettes and their components and we will be releasing and discussing the results of the analysis today. They have been posted at www.fda.gov. FDA is concerned about the safety of these products and how they are marketed. We believe it is important to convey these concerns about these products to the public and that's the reason we're holding the call today.

We are also examining, detaining and refusing shipments of certain e-cigarettes at the border and the agency is printing other activities to address

these concerns. I'd like turn to some experts and internal FDA and external FDA to discuss some of the issues related to electronic cigarettes and I'll be introducing them one followed by the other.

The first is Nick Westenberger. Mr. Westenberger is the Deputy Director at the Center for Drug Evaluation and Research at FDA in the Division of Pharmaceutical Analysis. He has served with FDA for 39 years. Mr. Westenberger?

Nick Westenberger: Thank you. Good afternoon. My name is Nick Westenberger, I'm the Deputy Director at CDER's Division of Pharmaceutical Analysis, where preliminary testing has been conducted on electronic cigarettes. Testing was performed by a team of analytical chemists under my supervision and I wrote the final report. FDA's Center for Drug Evaluation and Research was interested in the ingredients contained in electronic cigarettes. CDER's Office of Compliance purchased some samples of electronic cigarettes for analysis.

Along with the e-cigarettes were cartridges containing propylene glycol, nicotine and flavor mixtures that are inserted in the e-cigarette, vaporized and inhaled by the user. Some of the cartridges were labeled as containing no nicotine. Others were labeled as low, medium or high indicating different levels of nicotine present. These samples were subsequently provided to CDER's Division of Pharmaceutical Analysis for testing.

The products were evaluated by several different analytical techniques in this laboratory including, liquid chromatography with UV detection, liquid chromatography with mass detection, gas chromatography with mass detection, (head) space gas chromatography and finally nuclear magnetic resonance spectroscopy. The cartridges were analyzed in their entirety as a

complete unit and also in a pseudo smoking mode using the e-cigarette mechanism and trapping the dispelled vapors before testing.

Testing was performed in only one FDA laboratory on a limited number of samples and therefore additional testing needs to be conducted to confirm our findings and to survey the entire marketplace. Results from these various tests raised two areas of concern: safety and product quality.

With respect to safety the majority of the samples tested positive for the presence of tobacco specific impurities suspected of being harmful to humans such as anabasine, myosmine, and beta-nicotyrine. These impurities have well defined specifications in the FDA approved smoking cessation products but not in these.

Half the samples also tested positive for the presence of certain tobacco specific nitrosoamines that are known human carcinogens such as N-(nitrosonornicotine), and 4-(methylnitrosoamino)-1-(3-pyridyl)-1-butanone. In addition to these carcinogenic impurities one cartridge was found to have approximately 1% diethylene glycol present a toxic compound to humans. As far as the manufacturing quality some of the cartridges listed as containing no nicotine were actually found to have nicotine present.

Variability in the amount of nicotine delivered is also an issue. Three different cartridges with the same label contained significantly different amounts of nicotine per puff ranging anywhere from 27 to 43 micrograms. All of these results indicate a lack of general overall quality control. In summary these results suggest e-cigarettes could have safety and quality concerns. Thank you.

Joshua Sharfstein: Okay thank you Mr. Westenberger. I should have noted that you are in St. Louis is that correct?

Nick Westenberger: That is correct.

Joshua Sharfstein: In the lab there.

Nick Westenberger: CDER laboratory in St. Louis.

Joshua Sharfstein: Okay, we're now going to go across the country to Dr. Jonathan Samet in Los Angeles. Dr. Samet is the Director for the Institute for Global Health at the University of Southern California. He's a leading authority on the health effects of smoking and air pollution and he serves as Consulting Editor and Senior Scientific Editor for the Surgeon General Reports on smoking and health including the 1985, 1986, 1990, 2004 and 2006 reports. Dr. Samet, turn it over to you to comment on the finding and other aspects of electronic cigarettes.

Jonathan Samet: Okay thank you and good afternoon to everyone. I'm going to make a few very specific points. I think first point, we know very little about these devices and what they deliver to people. Consequently any claims as to possible benefits to health or utility in cessation just cannot be supported. Second and I think this speaks to the results that were just reviewed by Mr. Westenberger. The products are variable and at least the presence of tobacco specific nitrosoamines known carcinogens was established. I think finding - the finding of diethylene glycol, a known toxin, one that in fact has been found to be the cause of some tragic episodes of poisoning is of concern.

Again it speaks to the needs of the public to understand that in using a product that is poorly characterized, inhaling a vapor, a heated vapor into their body's

that has had very little characterization is assuming potentially some unknown risks.

An additional point is that these devices are a sharp contrast to the types of nicotine replacement therapy that are available, that are FDA approved that have gone through a rigorous testing. Their quality is controlled and we also know as to the degree of benefit of using these products for cessation, a substantial record of clinical trials and now actual population experience.

And I think the contrast with a device with absolutely no information of this sort available should be striking to all and I think told to the public very clearly. And I think the last point which will be addressed is that there's now placing another form of nicotine and other nicotine delivery system into the hands of the public.

And I know that Dr. Winickoff will be commenting on these points. So just I think the bottom line here is simple, these are devices of delivering nicotine through unknown magnitude into the body with no proven benefit for cessation and some indication that there may be risks. Thank you.

Joshua Sharfstein: Thank you very much Dr. Samet. We're now going to go over to Boston where Dr. Jonathan Winickoff is on the line. Dr. Winickoff is a practicing Pediatrician and Assistant Professor of Pediatrics at Harvard Medical School and the Chair of the American Academy of Pediatrics Tobacco Consortium. Dr. Winickoff?

Jonathan Winickoff: Thanks Dr. Sharfstein. There's two main points that I'll be covering in my remarks. Number one is the appeal of these products to young people and the second one is the concern that the e-cigarettes may serve as a gateway to smoking. The e-cigarette is unregulated both as to how it is constituted and

how and to whom it's marketed. It looks like a cigarette and it's used like a cigarette, it's marketed as a cigarette enough has the potential to normalize and queue smoking behavior. Advertising may promote modeling the use of e-cigarettes and regular cigarettes by use.

Now electronic cigarettes are available on the market in a variety of flavors such as bubblegum, chocolate and mint. Past experience suggests that these products may be particularly appealing to young people. The appeal of flavored cigarettes, a flavored regular cigarette has long been associated with young and novice smokers. Tobacco industry research has demonstrated that fruit and candy flavors increase the social acceptance of cigarettes, increase the excitement factor for example, sharing flavors and increase the curiosity to try the product.

Flavored regular cigarettes promote youth initiation and help young occasional smokers to become daily smokers. Similarly e-cigarettes might encourage children, teens and young adults to take their first step toward smoking cigarettes. Young people may be attracted to these products due to their novelty, safety claims and the av- availability of the products in a variety of fruit, candy, cola and chocolate flavors. In addition these products are easily accessed online, in stores and at mall kiosks where young people often hang out.

One cigarette company is claimed to be putting vitamins in the cartridges. This is either a direct or an implied health claim that may confuse some potential users into thinking that the product promotes health when it actually might lead to nicotine dependence. The advertising warning that "this product is for adults only" appears tailor made to appeal to kids. Once a youth has decided to try an e-cigarette there's nothing that protects him from getting

addicted to nicotine by puffing this product. Nicotine itself is not safe for children.

Nicotine addiction is one of the hardest addictions to break. An expanding pool of unregulated nicotine products that appeal to youth might increase the overall number of individuals who become nicotine dependent for life and later use regular cigarettes.

Once you've smoked the e-cigarette and are nicotine dependent the leap to a regular cigarette may not seem as great. Between 1/3 and 1/2 of all youth who try a regular cigarette will become daily smokers because of the highly addictive nature of nicotine. It is therefore vital to decrease exposure to products that would lead to experimentation with nicotine. It is not a safe drug to try.

My last point is that nicotine can be toxic in higher amounts for adults but it takes much less to have toxic effects in children. It is unclear what safety mechanisms are in place for these devices. For example, a young child modeling a parent might be able to inhale the entire nicotine load of an e-cigarette cartridge simply by puffing until it was empty. In my remarks I've discussed the appeal of the cigarette to young people and concern that the e-cigarette might serve as a gateway to smoking.

Joshua Sharfstein: Okay thank you very much Dr. Winickoff. The- the last person to make initial comments will be Dr. Matthew McKenna. Dr. McKenna is the Director of the Office on Smoking and Health at the Centers for Disease Control and Prevention. He is a commissioned officer in the United States Public Health Service. He supervises more than 100 scientists and other personnel who are responsible for leading federal activities in tobac- tobacco control at the nations leading public health agency, the CDC. Dr. McKenna?

Matthew McKenna: Thanks Dr. Sharfstein for including CDC on the- this very important call today. We at CDC are firmly committed to protecting our nation from tobacco use which is the number one preventable killer in this country. Behavior is responsible for over 400,000 premature deaths each year and every per- for every person who dies from smoking, 20 more suffer from at least one serious tobacco related illness. As a nation we can't lose our momentum in the fight to end the tobacco use epidemic. We have to maintain our drive to protect all our loved ones of the number one preventable cause of death.

And not only are tobacco products highly addictive but their use is fueled by an industry that's heavily in new product development. These products are promoted through innovative media that makes smoking appear to be attractive, sexy and maturing to use. These images have no other purpose than to hook new generations of smokers. Just today approximately 3,600 young people will try smoking for the first time and 1,100 will become addicted to tobacco. Without help to quit half of these will die prematurely from this addiction.

Over the last decades our nation has made tremendous progress in protecting our neighbors, family and friends from exposure to second hand smoke, reducing youth initiation and helping tobacco users quit successfully. E-cigarettes closely resemble a real cigarette. Users then exhale a vapor that mimics smoke. Therefore beyond potential harms to the user the use of these products could counter the impact from smoke free laws as well as other policies that have decreased the social acceptability of smoking behaviors.

E-cigarettes stand to reintroduce the appearance of smoking in other wise smoke free environments like malls, restaurants and even day cares. This could potentially impact use tobacco una- initiation in use of real cigarettes.

Now currently we don't have evidence to support claims as you heard that e-cigarettes are safe for effective quit aid for tobacco users. It's not clear what the misuse levels are that could lead to nicotine poisoning. But we do have a mountain of evidence demonstrating that the modeling of this behavior by peers, parents and other adults and even actors in the movies makes it more likely that exposed kids will pick up the habit.

As the nations prevention agency we need to protect our youth and the many generations to come from the seduction and influence of any form of tobacco use simulated or real. The CDC's committed to working with FDA, our communities and our close partners to ensure that the current and future generations of kids do not become victims of the tobacco use epidemic. I want to thank you again for providing us with the opportunity to share our perspectives on this call and I'll now turn our discussion over to Judy Leon at the FDA.

Judy Leon: Thank you very much. Operator at this time we would like to invite credentialed media to enter the queue to ask questions. I'd like to remind reporters that everyone in the interest of time will get one question and one follow up. So at this time we will take questions from reporters.

Coordinator: Thank you. At this time for questions please press star 1, unmute your line and record your name to be introduced. Again press star 1. To withdraw the request you may press star 2. Thank you. One moment for your first question.

Judy Leon: And one more reminder to reporters please state your name and your media affiliation.

Coordinator: Thank you, our first question comes from (Andrea Bruce). Your line is open and state your media outlet.

(Andrea Bruce): Hi everybody. I was wondering could you tell me how many of these devices you tested, how many cartridges. And I understand that you are seizing some shipments on the border. Are you moving towards seizing or asking products to be taken off shelves that are already existing at stores or kiosks around the country and finally are you expecting to make any moves for pre-market approval process for these things? Thanks.

Joshua Sharfstein: Hi this is Josh Sharfstein. I'm going to ask Mr. Westenberger in St. Louis to answer the first question about the number of samples that were tested and then I'll turn over to Michael Levy from the Center for Drugs at FDA to talk about the enforcement questions you made. Mr. Westenberger?

Nick Westenberger: Yes we had two different product manufacturers and there were 19 different cartridges that we tested from those two products.

Joshua Sharfstein: Great and Mr. Levy?

Michael Levy: Well, I think you were asking what our enforcement options are for domestic action?

Joshua Sharfstein: I think the first question, actually (Andrea) could you repeat the second...

(Andrea Bruce): Yeah, I mean you had mentioned that you were seizing some at borders. What I'm curious about is there any move to request recall off shelves that already exist in kiosks and malls around the country or any kind of (interjection) online where they're sold? Is there anything you're doing domestically?

Michael Levy: Well let me just tell you what we've been doing. We have actively been reviewing imported shipments of e-cigarettes. We've been examining and detaining them before entry into the United States.

We found so far that the products we've reviewed meet the definition of both the drug and the device under the Federal Food Drug and Cosmetic Act and therefore we've refused them to - we've refused to admit these products into the United States because they're not the subject of an approved drug or device application. To date we have refused 50 shipments of e-cigarettes and we are actively reviewing a number more.

Some of the shipments that we refused contain multiple products. In terms of domestic action we are actively considering all of our enforcement options for future action both against the imported e-cigarettes and at this point we think that all e-cigarettes are imported and against the domestic distributors of the imported cigarettes.

Judy Leon: And (Andrea) did you have a follow up question?

(Andrea Bruce): I'm sure I did but I can't remember.

Judy Leon: Okay thank you. Operator we'll take our next caller please.

Coordinator: Thank you, next (Jared Favole) your line is open and state your media outlet please.

(Jared Favole): Hi this is (Jared Favole) with Dow Jones Newswires. I appreciate you all taking my call. First is just a - a simple question. The gentlemen who spoke a second, I think Dr. Westenberger would, would you mind spelling your first and last name just for all of us.

Judy Leon: I will do that for the benefit of everybody on the phone.

(Jerrod Travoli): Okay.

Judy Leon: It is Benjamin Westenberger, W-E-S-T-E-N-B-E-R-G-E-R. And then (Jared) I'm sure that was not your whole question.

(Jared Favole): No that wasn't, that was to make sure I didn't get anybody's name incorrect. But so I'm confused. What action if any are you all taking today. So you did this analysis, what happens next? You continue reviewing, I'm confused as to what do we tell consumers?

Joshua Sharfstein: Sure let me, this is Josh Sharfstein. Today the FDA is expressing concern about these products based on the result of the laboratory analysis that we had and the input that we've gotten from experts that you've heard around the country. We, as you heard from Mr. Levy, have been taking some enforcement action and we are considering other enforcement actions but we want people to know why. We want people to understand the concerns the FDA has both about what's in the product and how they're being marketed.

(Jared Favole): What other if you can expand a little bit, what other enforcement actions are you considering?

Joshua Sharfstein: I'll ask, you know, Michael Levy. I'm not sure we talked about all our different enforcement actions beforehand but Michael do you want to...

Michael Levy: I wouldn't comment specifically on e-cigarettes but I would say that if the enforcement options that are usually available to FDA include seizure, injunction, recalls and possible criminal sanctions.

(Jared Favole): Okay, got you. Thank you very much.

Judy Leon: Thank you. Operator we'll take the next caller please.

Coordinator: Thank you, one moment please. Thank you, next we have (Debbie Elliott) your line is open and state your media outlet please.

(Debbie Elliott): Hi, it's (Debbie Elliott) with NPR. And I'm a little confused too. Does this now mean that it is illegal for these products to be sold in the U.S.?

Michael Levy: Well I - that is a bit of a complicated question. The products that we have reviewed so far we have found to be illegal. Now I will say that there is pending litigation on the issue of FDA's jurisdiction over e-cigarettes so I - and, you know, we're not going to comment on the pending litigation at this time.

Joshua Sharfstein: And let me, this is Josh Sharfstein, let me say that we felt that it's important while there is litigation and while we are considering our options there is not a reason to be confused about FDA's position on these as a public health issue. And that relates to our concerns over what's in the products and how they're being sold and what we've heard from experts including experts at the Centers for Disease Control.

Judy Leon: (Debbie) did you have a follow up?

(Debbie Elliott): Yes. Some of the companies that have imported these cigarettes or e-cigarettes that are selling them claim that they should be regulated under the - regulated the same way that tobacco is. So I guess my question is now that FDA does

have jurisdiction over tobacco how does that effect how you would enforce your position on these products?

Joshua Sharfstein: I'm going to ask Michael Levy to answer that.

Michael Levy: I'd go back to what I said before which is that the products that we've reviewed so far we found them all to be drugs and devices and we do not believe that the new Act will change our conclusion on any of those products. And that said, you know, we are also evaluating the new Act in terms of how does that res- how does that affect our ability to exercise jurisdiction over these products.

Judy Leon: And just for a point of clarification that is Michael Levy addressing the legal questions. His name is listed on your media advisory. Operator we'll take the next question now.

Coordinator: Thank you, next question a (Kim Dixon) your line is open and state your media outlet please.

(Kim Dixon): Hi it's (Kim Dixon) at Reuters. Can you tell me who are these two leading manufacturers that you mentioned in the release?

Joshua Sharfstein: I think it's Mr. Westenberger can talk about the brands that - that were tested.

Judy Leon: Is your question pertaining to the testing that was done?

(Kim Dixon): Well yeah, you could talk about both, the testing that was done, what the brands were and then what other national brands you know of that sell in the U.S.

Judy Leon: For some reason we're having trouble hearing you. Can you get closer to the phone and restate your question please?

(Kim Dixon): Yeah, hang on please.

Judy Leon: We can barely hear you.

(Kim Dixon): Yeah so the question is what were brands tested and what are the other national brands that are selling these products in the U.S.?

Joshua Sharfstein: So Mr. Westenberger from St. Louis could you mention which of the names of the brands that were tested?

Nick Westenberger: The two brands that we tested and I don't really have the manufacturers name in front of me but the product name was Smoking Everywhere and Njoy, that's spelled with a capital N, small j, small o, small y. The two products were Smoking Everywhere and Njoy.

(Kim Dixon): Okay.

Nick Westenberger: They're multiple cartridges with those two products with different flavor incentive, cherry, apple, menthol and also different levels of nicotine present. Though some of them had no nicotine which would imply that it was a smoking cessation type product, others had low, middle or high levels of nicotine present.

Joshua Sharfstein: Okay thank you Mr. Westenberger. I don't think we have a list of all the products that are on the market.

Judy Leon: Let me also add that we have now posted on the FDA Web site our lab results and more information where reporters can - can get that. Did you have a follow up (Kim)?

(Kim Dixon): Well just do you know if any of the large tobacco manufacturers sell these products in the U.S. or in Europe?

Michael Levy: Not that we're aware of.

Joshua Sharfstein: Michael Levy, not that we're aware of.

(Kim Dixon): Okay.

Judy Leon: Operator we'll take the next question please.

Coordinator: Okay thank you. (Liz Szabo) your line is open and state your media outlet please.

(Liz Szabo): Hi I'm with USA Today. I was wondering when did you begin this enforcement action seizing shipments of cigarettes at the border?

Michael Levy: We began examining and detaining shipments at the border when we first became aware of this type of product being imported which I believe was in July or August 2007, I'm sorry, 2008.

Joshua Sharfstein: That was Michael Levy.

(Liz Szabo): Okay thanks.

Judy Leon: (Liz) did you have a follow up?

(Liz Zabo): Yeah, I was just wondering do you have any idea how many of these products are used each year? Is it in the hundreds of thousands, millions?

Joshua Sharfstein: We don't know.

(Liz Szabo): Okay.

Judy Leon: Okay thank you. Operator we'll take the next call please.

Coordinator: Thank you. (Matt Perrone) your line is open and state your media outlet.

(Matt Perrone): Yes the Associated Press. Thanks guys. So it sounds like from what you're saying these products never should have been allowed on the market to begin with. Was there some oversight that they were, you know, they were entering commerce to begin with? It sounds like they're just plain illegal.

Michael Levy: This is Mike Levy again. Well I mean there are a number of ways for these products to get into the United States without them being properly declared for FDA review. Again the ones that we have reviewed we've found to be illegally marketed and we have reviewed - refused those products.

(Matt Perrone): Okay and what would these companies have to do for them to be legally marketed if they had submitted, you know, PMAs, pre-market applications? Would - would they be legal then?

Joshua Sharfstein: It would depend for what purpose, this is Josh Sharfstein, but if they were interested in having them marketed as a smoking cessation device they could submit an application that demonstrates that it's safe and effective for that use.

(Matt Perrone): I see. To your knowledge have any - have any done that?

Joshua Sharfstein: Not to my knowledge.

Judy Leon: Thank you (Matt). Operator we'll take the next call.

Coordinator: Thank you. (Harlan Spector) your line is open and state your media outlet please.

(Harlan Spector): Hi (Harlan Spector) from the Cleveland Plain Dealer. Can you tell me just in layman's terms in terms of the impurities you mentioned, the carcinogens, can you explain that? I'm not sure what the chemical - the chemicals you mentioned not exactly sure what they mean?

Joshua Sharfstein: Sure I may as that Dr. Samet in Los Angeles to maybe provide some context on that.

Jonathan Samet: So I'll - I'll mention first that the one group of compounds were the tobacco specific nitrosoamines which are quite closely linked in smokers to lung cancer and they were found in detectible - they were detected. And then a number of chemical impurities related to nicotine were detected and then in one sample there the diethylene glycol the presence of diethylene glycol was detected and this is a toxic of material somewhat akin to what is the ethylene glycols in antifreeze.

So I think the - perhaps the major point is that as was pointed out there's variation in the amount of material in these cartridges, the manufacturing processes themselves apparently we don't know much about. And the bottom line is that people are inhaling amounts of nicotine that don't seem to be

necessarily tightly controlled based on the testing and there are chemical impurities that are known to have health risks in what is inhaled.

Judy Leon: Okay thank you very much. Operator we'll take the next question.

Coordinator: Thank you. (Val Willingham) your line is open and state your media outlet please.

(Val Willingham): Yeah, (Val Willingham) from CNN I'm sorry this question may have been asked before but I'm going to ask it again. If a parent finds that their child is using this, any suggestions?

Joshua Sharfstein: I think that's a good question for Dr. Winickoff of the American Academy of Pediatrics in Boston.

Jonathan Winickoff: Thanks for the question. I think it's very important that parents be extremely clear with their children that these are not safe products. And that they recommend and perhaps put a rule in place that the child is not to use this product.

(Val Willingham): Thank you.

Joshua Sharfstein: Let me just see if Dr. McKenna from CDC would like to comment on the public health recommendations on these products.

Matthew McKenna: Yeah, you know, the other sort of message I would append to Dr. Winickoff's statement is that the - any parent that finds out their child is using this should also investigate whether or not they may be using tobacco products more generally. And there is evidence that adolescents and kids who are using these and becoming addicted to them can benefit from professional counseling

services from clinical providers as well as other sort of counseling assistance. And too, if the parent finds this out seek out that sort of professional service.

Those sorts of resources can be found on hotline numbers like the 1-800-QUITNOW number that's available and people can contact anywhere in the United States.

Judy Leon: Okay and (Val) did you have a follow up?

Joshua Sharfstein: And let me also just say, this is Dr. Sharfstein, that parents of children who aren't necessarily using these at home may want to talk to their kids about the potential danger. Because of the way these are marketed it may give kids a sense that it's easy to try and there are different flavors to try and parents whose children are not addicted to nicotine may want to make it be aware that this could potentially affect their when it (unintelligible) it turn into a nicotine problem for the child.

(Val Willingham): No I have no other follow up. Thank you.

Judy Leon: Our next ques- thank you. Operator we will take the next question.

Coordinator: Thank you. (Alicia Ault) your line is open and state your media outlet please.

(Alicia Ault): Yes, (Alicia Ault) with Internal Medicine News. I'm wondering if anybody could give me a sense of how these products are actually being marketed. Are they being marketed specifically to adults for smoking cessation or as a smoke free alternative to cigarettes?

Joshua Sharfstein: I'm going to ask Michael Levy to talk about the ones we've looked at at FDA.

Michael Levy: The ones we've looked at have been marketed in pretty much anyway you can imagine both as a smoking cessation product and as an alternative when you cannot smoke, in other words for a smoke free environment.

Joshua Sharfstein: And Dr. Winickoff is there anything you want to mention about?

Jonathan Winickoff: Yeah I would say they're also being marketed as an entry level product. In other words for people who or for children and young adults who are nicotine naïve this could and is being marketed as an entry level product to try nicotine. It's pretty clear with the use of fruit and candy flavored product even going so far as chocolate chip cookie flavored product what these are being marketed for.

Judy Leon: Okay thank you. Operator, we have time for one more question.

Coordinator: Okay thank you. (Dan DeNoon) your line is open and state your media outlet please.

(Dan DeNoon): Thanks this is (Dan DeNoon) with WebMD. I'm just not clear whether anything has changed at FDA. So you've already been intercepting these and banning them - banning entry of these products. Now you have two products that are clearly appear to be illegal. Will - is anything going to change? Will there be any action at all that's different from what we had yesterday since you've made these announcements? Thank you.

Joshua Sharfstein: This is Dr. Sharfstein. I think the first thing is we hope because of having media calls like this that people can understand why we're so concerned about these products. And we hope that does change things and second we do want people to know that we are concerned and we are going to be considering all

(talkful) and enforcement options for these products because of our public health concerns about them.

(Dan DeNoon): So will there be any action against these two specific brands that have been tested now?

Michael Levy: Can't comment on that today.

Judy Leon: Okay. Thank you very much. Ladies and gentlemen, this concludes today's media teleconference. I'd like to thank all of you for joining us and a special thank you to all of our speakers today. A replay will be available in one hour and will be available to you for the next seven days. If you have follow up questions please don't hesitate to call FDA's Office of Public Affairs at 301-796-4540 and please be advised I will repeat that we have posted the lab reports and others materials pertaining to today's teleconference on our Web site www.fda.gov. Thank you very much and have a great evening.

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