

**Transcript of FDA Media Availability on FDA and FTC Actions Against Companies Misleading Kids
With E-Liquids That Resemble Children's Juice Boxes, Candies and Cookies**

Moderator: Michael Felberbaum

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Coordinator: Good morning and thank you for standing by. And welcome to today's media availability conference. Today's call is being recorded. If you have any objections, please disconnect at this time. Your lines have been placed on a listen-only mode until the question and answer of today's conference. At that time you may press star followed by the number 1 to ask a question.

I would now like to turn the conference over to Mr. Michael Felberbaum. Sir, you may begin.

Michael Felberbaum: Thank you. Good morning and thank you for your participation in today's media availability. My name is Michael Felberbaum and I'm with the FDA's Office of Media Affairs. This is a media availability to provide an opportunity for reporters to ask questions about warning letters issued today by the FDA and the FTC to companies who are selling e-liquids that are putting kids at risk because they resemble products children may consume.

By now, both agencies have issued a press release on this announcement. Today, I'm joined by FDA Commissioner Scott Gottlieb and FTC Acting Chairman Maureen Ohlhausen who will provide brief remarks and then take questions regarding today's announcement. We also have Mitch Zeller, director of the FDA's Center for Tobacco Products, who will also be available during the question or answer portion of the call.

Reporters will be on a listen-only mode until we open the call for questions. As a reminder, this call is being recorded. When asking a question, please remember to state your name and affiliation. Also, please limit yourself to one question and one follow-up so we can get to as many questions as possible.

With that, I will now turn the call over to Dr. Gottlieb.

Scott Gottlieb: Thank you, Michael. Good morning and thank you for taking the time to join us today to discuss this important announcement of this action. As part of our ongoing efforts to protect

youth from the dangers of nicotine and tobacco products, the FDA and the FTC today issued warning 13 letters to companies selling e-liquids with labeling and/or advertising that could cause them to resemble kid-friendly food products such as juice boxes, candy, or cookies.

Today's effort with our partners at the FTC is part of a series of escalating actions we intend to take under our new youth tobacco prevention plan that began last week with our actions targeting JUUL products and will continue with additional actions next week and actions going forward so we can make sure that we're protecting youth from the harms of these products.

As it relates to the warning letters that were issued today, I urge you to take a look at the side-by-side comparisons of these products yourself. The images are alarming and it's easy to see how a child could confuse these e-liquid products for something they believe they have consumed before. And if a child would consume these products with highly concentrated amounts of nicotine in them, the potential harms are serious and even potentially deadly.

Today's announcement should send a clear signal that companies selling these products have a responsibility to ensure they aren't putting children in harm's way or enticing youth use. And we'll continue to take action against those who sell tobacco products to youth and market products in this egregious fashion.

While we encourage the development of potentially less harmful forms of nicotine delivery for currently addicted adult smokers, we're not going to allow that work to come at the expense of addicting our children. No child should be using any tobacco product and no tobacco product should be marketed in a way that endangers kids.

We appreciate very much the FTC joining us in these efforts. I will now turn the call over to FTC Acting Chairwoman Maureen Ohlhausen.

Maureen Ohlhausen: Thank you, Dr. Gottlieb. The FTC is pleased to join you today in this important initiative to protect America's youth. Our agencies have a long tradition of working together on tobacco issues as well as many other areas where we share jurisdiction.

For example, in January 2018 the FTC and FDA issued joint warning letters to the marketers and distributors of 12 opioid cessation products for marketing products with unsupported claims about their ability to help in the treatment of opioid addiction and withdrawal.

The 13 warning letters we announced today demonstrate the continued partnership between the FTC and FDA to ensure American consumers, including and especially children, are protected from unsafe products and unscrupulous advertising and practices.

Now, we know that tobacco use -- including e-cigarettes -- is harmful for any child under the age of 18. Nicotine is a potent drug and the liquid nicotine marketed by the recipients of these warning letters is highly toxic. As Dr. Gottlieb just pointed out, young children who ingest the liquid nicotine risk acute nicotine poisoning and even death.

Now, the companies receiving these warning letters are marketing their e-liquids in packaging that mimics popular children's foods and beverages -- brands targeted to and easily recognized by the very youngest children including apple juice boxes, candies, and lollipops. The e-liquid packaging not only looks like these foods, some of them carry their scent. The apple juice box packaging and the e-liquid inside it actually smell like apple juice. And even worse, the odor is detectable without opening the package. And one marketer even included a lollipop as part of the package sold.

In other words, these companies are marketing their e-liquids in a matter that makes the product particularly appealing to young children. Given the significant number of serious child poisonings due to ingestion of liquid nicotine, marketing these products in such a matter could present an unwarranted risk to health and safety. This potential safety risk underscores the FTC's concerns with the marketing methods used by the companies receiving these warning letters.

Consumer safety has long been one of the highest priorities of the FTC. And our straight forward message today is clear -- it is not acceptable to use marketing methods that put our nation's young children at unwarranted risk of harm.

Before I close, I'd like to thank the FTC and the FDA staff for their hard work on these enforcement warning letters and I'd also like to thank Dr. Gottlieb. And I'm happy to take any questions.

Coordinator: Thank you.

Michael Felberbaum: Thank you. At this time we will begin the question and session portion of the briefing. As a reminder, this call is being recorded. When asking a question, please state your name and affiliation. Also please limit yourself to one question and one follow-up so we can get through as many questions as possible. Operator, we'll take the first question.

Coordinator: Thank you. Once again that is star 1 if you would like to ask a question. Malcolm Spicer you may ask your question. Please state your affiliation.

Malcolm Spicer: Thank you. This is Malcolm Spicer from the Pink Sheet. Dr. Gottlieb, you mentioned that FDA will not allow the work of perhaps novel smoking cessation products to come at the risk of addicting children to nicotine. I understand that, but my question is this kind of reckless behavior, this certainly noncompliant practices putting at risk the chance that novel products -- e-cigarettes for instance -- will be able to get smoking cessation indication?

Scott Gottlieb: Well look, I think longer term you know, I think that this kind of egregious behavior and the rate of youth use that we see of e-cigarettes could potentially put at risk what I think is a careful balance that we tried to strike with the announcement we made last summer where we set out to try to create a pathway to allow these novel nicotine delivery products like e-cigarettes to go through an appropriate series of regulatory gates so that they could be available for adult smokers who want to migrate to potentially less harmful forms of, you know, accessing satisfying levels of nicotine and not do it through the most harmful form, which is combustible cigarettes.

At the same time we did that, we sought to regulate the nicotine levels in combustible cigarettes to render them minimally addictive but I do believe that, you know, if we continue to see activity like we're seeing in the market where we're seeing things deliberately marketed to kids like the actions we're taking today where we just see youth use of e-cigarettes continue to grow at the level which they are and we see a whole generation of young people becoming addicted to nicotine through e-cigarettes, I think we could lose the potential support we need for the careful balance that we struck in that announcement.

And I want to maintain that support and I want to maintain the balance that we sought in the policy that we outlined. And I think the way we're going to do that is to set out a good objective regulatory pathway for these products to go through at the same time that we take rigorous enforcement actions against products that are being deliberately marketed to kids or products that are being, you know, designed in ways or used in ways or sold in ways that kids are getting access to them where they shouldn't.

And that's the essence of the announcement we made last week. It's the essence of the plan we set out with respect to youth prevention. And it's the essence of the actions you're going to continue to see us take in the marketplace.

This is just the opening salvo. These are just the initial steps in what's going to be a sustained campaign because there are bad actors out there and there's a lot of youth use and we're going to set out to try to address it.

I will just close by saying we have vigorous enforcement tools. All of the tools available to us and available to us with respect to the newly deemed products are in place. We can inspect. We can inspect the manufacturers. We can impose restrictions on age, on sales. So we have a robust set of tools and we plan to use them.

Malcolm Spicer: Thanks very much for that. If I may ask a follow up as far as any progress or update on the smoking cessation update as far as updating that indication for novel products? What is the latest progress there?

Mitch Zeller: This is Mitch Zeller, CTP Director. I think everyone knows the Commissioner created the Nicotine Steering Committee last September. He has been leading that and the Commissioner has signaled that updated guidance is coming on the drugs side of the house on issues related to toxicology and efficacy.

On the tobacco side of the house, just to add to what the Commissioner said, to go to the first part of your question, the law mandates us to consider the impact on initiation which is anyone who would be starting on any tobacco product. And these are tobacco products by law.

So, to echo the Commissioner's point, impact on initiation is a mandatory statutory consideration for us on the tobacco side of the house as we look at any of the new and novel products coming through for marketing authorization or for claims. And obviously we are very concerned about youth uptake of the e-cigarette category in general and the harm that these particular products pose because of how appealing they are to kids.

Malcolm Spicer: Thanks very much.

Michael Felberbaum: Operator, we'll take the next question please.

Coordinator: Thank you. Matt Perrone, please you may go ahead and ask your question. Please state your affiliation, sir.

Matt Perrone: Yes, Associated Press. Hi, guys. Can you tell us anything? Does FDA know anything about when these products were introduced? And you know, beyond the misleading packaging are any of these companies violating the FDA rules on introducing new products, new varieties that haven't been reviewed by the agency?

Mitch Zeller: Matt, this is Mitch. I'll take a shot at that. We are continuing to do surveillance and monitoring on the issues that you have raised. We are aware that allegations have been made that the very marketing of these products may have begun after the cutoff date of August 8th of 2016. We can't comment on that other than to say it remains a subject of ongoing monitoring and surveillance by us.

Matt Perrone: Okay. And just one follow-up to that point - I mean, has FDA at any time yet sanctioned a company for introducing a product after that August 8, 2016 date?

Mitch Zeller: I'll ask the Ann Simoneau, director of the Office of Compliance and Enforcement to comment on that.

Matt Perrone: Okay, thanks.

Mitch Zeller: Ann?

Ann Simoneau: Yes, we have issued a warning letter in the past for marketing an unapproved tobacco product. But there hasn't been any relating to youth-appealing marketing or sales unapproved.

Michael Felberbaum: Operator, we'll take the next question please.

Coordinator: Thank you. Once again as a reminder you may press star followed by the number 1 to ask a question. Katie Thomas, you may ask your question. Please state your affiliation.

Katie Thomas: Hi. Katie Thomas from the New York Times. I spoke quickly to one of the manufacturers, that was the Lifted Liquids that makes the Vape Head product. And he said that they took that off the market about six months ago and repackaged it and that it's not for sale anywhere. So I just wondered if you could comment on that, but also more broadly, you know, when were these products, when were the images pulled for this? And I know you commented that they're all still being sold.

Mitch Zeller: We have evidence that these products were all on the market within the last several months.

Katie Thomas: Within the last several - would that include like if somebody had took it off six months ago or?

Mitch Zeller: No. We have evidence of marketing more recent than that.

Katie Thomas: Okay.

Scott Gottlieb: And evidence of sales to children.

Katie Thomas: Of sales to children?

Scott Gottlieb: Yes.

Mitch Zeller: Yes. For six of the warning letters that were issued there were dual violations, not only have we called these products out for being misbranded because of their resemblance to foods, but these were also products that were illegally sold online to minors.

And if a company received the second violation, it specified in their warning letter.

Katie Thomas: Okay. Thank you.

Michael Felberbaum: All right, Operator. Next question, please.

Coordinator: Thank you. Tamara Mathias you may ask your question. Please state your affiliation.

Tamara Mathias: Hi. I'm calling from Reuters. Thanks for taking my question. I was just wondering if you could talk a little bit more about the incidents that you encountered in your research, a little bit more about the nicotine poisoning or death incidents that you encountered. And, you know, if you have any statistics that you could give me.

Mitch Zeller: Let's make sure we understand your question. You were asking about nicotine poisoning and nicotine deaths and any numbers that we have?

Tamara Mathias: Yes, any numbers that you have on that and as specifically deaths or poisoning incidents related to the products that you sent letters about.

Mitch Zeller: Okay. So, we have seen no reports of deaths associated with these products. We are aware of one reported death from youth exposure to e-liquids but let me make clear not these products. There has been an increase in the number of reports to the Poison Control Centers and those numbers continue to go up. And understand that it takes a very small amount of these e-liquids -- in some cases, less than half a teaspoon -- to be at the low end of what could be a fatal effect for a kid, and even less than that to make them very sick.

And we also assume that for the reports that go to the Poison Control Center, there may be many other cases that don't get reported. Frankly, we're trying to nip this in the bud.

Tamara Mathias: All right.

Maureen Ohlhausen: And this is Chairman Ohlhausen. I just wanted to jump in and mention that under FTC case law, we don't have to wait until there's been an actual injury of a child. We can take action if it's likely to cause substantial injury. And I think for this kind of packaging, the risks here are pretty obvious.

Tamara Mathias: All right. Thank you.

Michael Felberbaum: Great. Thank you very much. Operator, we'll take the next question please.

Coordinator: Thank you. Anna Edney you may ask your question. Please state your affiliation.

Anna Edney: Hi, I'm with Bloomberg News. Dr. Gottlieb, I wondered you talked about the potential for losing support for the careful balance. When FDA took that regulatory action in the summer, was it always the plan to have this later action to go after youth e-cigarette use or has your thinking sort of evolved on this topic and that's what we're seeing now?

Scott Gottlieb: Well we stated in that original plan, we stated very clearly if you go back and look at the remarks we gave when we announced the plan that we would vigorously enforce all of the, you know, all of the new requirements that are going into place with respect to the newly deemed products, which included the e-cigarettes and ENDS (electronic nicotine delivery systems).

And I remember specifically talking about the youth access issues and issues around restrictions around age, for example and sales to youth. So that was always part of the plan.

I think that as the, you know, scope of the youth use of these products has continued to grow over the past year I think you're going to continue to see us match it with commensurate actions on our part, and you know, even more vigorously step into this to make sure that we're adequately addressing it. This is going to be a big component of how we address this overall market and meet our regulatory obligations and our public health obligations here.

Anna Edney: Thank you.

Michael Felberbaum: Operator, we'll take the next question, please.

Coordinator: Thank you. Kimberly Leonard, you may ask your question. Please state your affiliation.

Kimberly Leonard: Hi. Thank you for holding this call. I'm with the Washington Examiner. And someone kind of asked my question about whether there are already cases of harm. But I guess my question

then would be for those who are less familiar with what a warning letter might mean, what are kind of the next steps if they refuse to comply? Thank you.

Mitch Zeller: Well, this is Mitch Zeller with CTP. We're hoping that the companies are going to comply. They're given 15 business days to report back to FDA on what their plan is to remedy the violations of the law that we are calling out in the warning letters.

So really the next step is up to the individual companies. Ultimately, we have additional enforcement tools under the Food, Drug, and Cosmetic Act that could include seizure of product, but that's down the road. We've taken the first step with the warning letters. We've called out the violations. The next step is up to the companies.

Kimberly Leonard: Thank you.

Michael Felberbaum: Thank you. And just wanted to check whether our FTC colleagues would like to respond regarding their requirements for FTC.

Maureen Ohlhausen: Yes, thank you. So, we can bring enforcement action subsequent to warning letters if it's appropriate. And we're certainly going to continue to vigilantly monitor e-cigarette marketing to ensure that companies aren't engaging in similar marketing that presents unwarranted risks to children.

So, while warning letters have -- like it allows us to partner with the FDA and send the message and get it out quickly -- we then determine whether other options, other paths like litigation should be pursued.

Michael Felberbaum: Thank you very much. Operator, we have time for one more question please.

Coordinator: Thank you. And our final question comes from Lynh Bui. You may go ahead. Please state your affiliation.

Lynh Bui: Hi. This is Lynh with the Washington Post. You all today have spoken about products that appeal to children. Can you also speak about the concern of products disguised or that, you know, look like benign things like USB port pens? I know there's been a lot of discussion of

JUUL. Just the combination of these sort of products that, you know, children might be able to take into schools and hide and that sort of thing.

Scott Gottlieb: Well, you know -- this is Scott Gottlieb -- with respect to these products that we took action against, look I'm the parent of young children. A lot of people on the phone probably are. I think any reasonable person could look at these products -- it's hard to look at these products and not conclude that these are deliberately being packaged and marketed in a way that they're not just potentially appealing to kids -- they can be deliberately, you know, confused by kids.

You look at the lollipop, for example. I don't see how my four or five-year-old doesn't just look at that and see a lollipop. It's a lollipop. So, these are being deliberately designed in ways that they can be just mistakenly confused by a child. Any child can be deceived into thinking that this is the normal product that they eat, the normal candy that they eat, the normal cookie that they eat.

With respect to JUUL, you know, we took a series of actions last week. We're going to be taking more actions going forward. The blitz continues. We're going to continue to look at retailers that could potentially be selling that product to use. We're going to try to continue to work with online retailers where children are accessing that product. We have a pretty broad request for information that we put to the company. Depending on how they comply with that and what we learn based on that information, there could be additional steps that we take.

Michael Felberbaum: Great. Thank you very much. Ladies and gentlemen this concludes...

Coordinator: Thank you. This concludes today's conference call. You may go ahead and disconnect at this time.

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