

**FDA Media Availability On Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death**

**July 28, 2017**

**10:30 a.m. ET**

Coordinator: Welcome and thank you for standing by. We'd like to inform all participants your lines will be in a listen-only mode until the question-and-answer session. For questions you may press Star, "1" on your touchtone phone.

Today's conference is being recorded. If you have any objections you may disconnect at this time. And now I'll turn today's meeting over to Jennifer Rodriguez. Thank you, you may begin.

Jennifer Rodriguez: Thank you. Good morning and thank you for participating in today's Media Availability. My name is Jennifer Rodriguez and I'm with the FDA's Office of Media Affairs.

This is the media availability to provide an opportunity for reporters to ask questions about the FDA's new comprehensive plan for tobacco and nicotine regulation. By now the press release on this announcement has been issued and the Commissioner's remarks on this announcement are posted to the FDA website.

Today I'm joined by FDA Commissioner Dr. Scott Gottlieb and Mitch Zeller, director of the FDA's Center for Tobacco Products. They're here to help answer questions regarding today's announcement.

Reporters on the phone will be in a listen only mode until we open the call for questions. As a reminder this call is being recorded. When asking questions please remember to state your name and affiliation. Also please

limit your calls to one questions and one follow-up so that we can get to as many questions as possible.

With that operator we'll take the first question please.

Coordinator: Thank you. And again for questions or comments press Star, "1". Please record your name. Again press Star, "1". If you'd like to withdraw the request you may press Star, "2". Thank you, please stand-by for your first question.

Thank you, we do have our first question from Lydia Wheeler. Your line is open and please state your affiliation.

Lydia Wheeler: Yes, hi. Thanks so much for holding this call. I'm with The Hill. So does this rule change mean that the costly pre-market approval processes previously required for products that hit store shelves after February 15 of 2007 will now only be required for products that hit the marketplace after August 8, 2016? Is this correct?

Mitch Zeller: No the policies that were announced – this is Mitch Zeller, Director of CTP – the policies that Dr. Gottlieb announced today do not alter the Feb. 15, 2007 date which is known as the predicate or grandfather date. So the way it will work is manufacturers of e-cigarettes and cigars will now have much more time to get their applications in.

The way that that Feb. 15, 2007 date is relevant is if they choose to file what's called a Substantial Equivalence application. They will have to demonstrate that their new product is substantially equivalent to a product that was on the market as of that magical date, Feb. 15, 2007. This is an issue that has been before Congress for a number of years because legally only Congress can change a date in the statute, not FDA.

Lydia Wheeler: Okay so how does this change? It just gives them more time to file those applications for a pre-market approval?

Mitch Zeller: That's right. Using enforcement discretion that the agency has for the newly deemed products as part of this overall, comprehensive package focused on nicotine, designed to reduce the disease and death from tobacco use primarily cigarettes. Part of the plan is to give companies more time for the newly deemed products currently on the market to get out of their substantial equivalence of pre-market tobacco applications in; extended either to 2021 for combustible products or 2022 for non-combustible products.

Jennifer Rodriguez: Thank you operator, we'll take the next question please.

Coordinator: Thank you. Next question is Jennifer Maloney, your line is open. Please state your affiliation.

Jennifer Maloney: Hi it's Jennifer Maloney from the Wall Street Journal. I just want to make sure I understood your comments correctly. It sounds like you're considering A, a possible exemption for premium cigars; B, the potential consequences of a black market for cigarettes opening up and; C, considering delaying the implementation of new rules for e-cigarettes and other vaping products.

Do I have all that right?

Dr. Scott Gottlieb: The issue of the black – this is Scott Gottlieb, FDA Commissioner. The issue of the black market is going to be one of the issues of many that we consider in the rulemaking process. There is some available data speaking

to that issue now. We'll collect more; solicit information with respect to that.

The issue of the premium cigars – we're going to undertake a new rule-making starting with an advance notice of a proposed rule-making to solicit information related to premium cigars and the available science that could speak to the issue of patterns of use and help address questions of youth-use of premium cigars and how they're being used in the market.

And re-develop the administrative record with respect to the cigars. Your third question – Mitch do you want to?

Mitch Zeller: What was the third question Jennifer?

Jennifer Maloney: Oh, I just wanted to circle back on the – in the e-cigarette. Would it be fair to say that you're considering delaying the implementation of new rules on the e-cigarettes and other vaping devices?

Mitch Zeller: So what the Commissioner announced is that there are two parts of the deeming rule related to how much time companies would have to file their marketing applications that are being extended. No other provision of the final deeming rule; either already in effect or scheduled to go into effect is affected or is being delayed.

It's just more time to file applications; which gives us time to work on regulations and guidances to bring greater transparency and clarity to the companies so that they can file the highest quality and most complete applications while we're working through all of these nicotine issues.

Dr. Scott Gottlieb: So these other – you can speak to some of the other regulations but there's provisions already in place where we are providing regulatory oversight

on the newly deemed products. We are inspecting facilities. We are requiring certain warning labels.

We are requiring notice and registration requirements. We are implementing restrictions on sales to minors and inspecting for – related to the potential to sell to minors. All of those provisions, all of those regulations will continue to apply. We've been exercising them. We'll continue to exercise them.

This relates only to the product applications.

Jennifer Maloney: Got it.

Jennifer Rodriguez: Thank you operator, we'll take the next question.

Coordinator: Thank you. Next question is Andrew Siddons. Your line is open and please state your affiliation.

Andrew Siddons: Thanks, this is Andrew Siddons from Congressional Quarterly. So it's possible during the course of this rule-making that the regulatory standards for e-cigarettes and other ENDS products could change from last year's regulations, right?

Mitch Zeller: The deeming rule didn't establish regulatory standards for the products. We called the deeming rule a foundational step because it took those products from a world of absolutely no regulation, where the marketplace was the Wild, Wild West to being within our jurisdiction and being regulated. And set the stage for us to figure out, over time, as you heard the Commissioner outline this morning how they should be regulated now that we have the regulatory authority.

And what was laid out this morning is a comprehensive approach that's built on the principles of relative risk and harm reduction to account for the leading cause and the greatest contributor to tobacco related disease and death is combustible cigarettes. What about a world where those are no longer capable of creating and sustaining addiction? But adult smokers are still going to need to get their nicotine and that's what we have to account for using all of the regulatory tools at our disposal as we take this approach to regulations through the lens of addiction and nicotine.

Andrew Siddons: And can I ask if – do you hope that some of these companies, you know, obviously a lot of these products there's like a wink and a nod that they're supposed to be used to help you quit smoking. But they obviously can't market them in that way.

Do you hope more companies will actually, you know, put these through as smoking cessation devices?

Mitch Zeller: There are multiple pathways available to the manufacturers of electronic nicotine delivery systems. It's their choice. If they want to be on the market as a cessation aid, then as you heard the Commissioner say this morning, the door is open for them to come in and talk to our sister center, the Center for Drug Evaluation and Research to discuss what evidence would be needed to get one of those indications.

On the other hand they can be regulated under the tobacco authority so you can't make a cessation claim. But there are other possible claims that could be made. And a number of companies have filed applications to make either exposure reductions or risk reductions. Both doors are open and we encourage companies to come in and talk to us.

Dr. Scott Gottlieb: And just a follow-up on what Mitch said. As I said – outlined in my speech this morning, part of this plan also is going to encompass potential policy-making on the drug side of our house. So we've had discussions already inside the agency what additional steps we can do to better define the new drug regulatory process related to products that could help reduce incidence of smoking, help consumers quit smoking.

And to get that claim on labeling; which would be a therapeutic claim, that would require a new drug application. So we're going to be looking more extensively about how we can put in place guidance that could enable more innovation on that side of our house as well.

Jennifer Rodriguez: Thank you operator, we'll take the next question.

Andrew Siddons: Thank you.

Coordinator: Thank you. As a reminder for others – again for questions or comments press Star, "1". Our next question is from (Salen Boils). Your line is open and please state your affiliation.

Salynn Boyles: Hi. I'm with MedPage Today. I want to make sure I understand. So the product application for all e-cigarettes is now pushed to 2022? Is that correct?

Dr. Scott Gottlieb: That is correct. For under an exercise of what we call enforcement discretion and this will all result in a guidance document that we will issue shortly. We are going to permit manufacturers of electronic nicotine delivery systems including e-cigarettes to have until August of 2022 to get them marketing applications in.

It's very important to state that this change in policy only applies to products that were on the market as of Aug. 8 last year. Anything that a company was thinking of doing after Aug. 8 that involves products not on the market – and companies are free to come in with those kinds of applications whenever they want – we're putting some flexibility into the system for the products that were on the market as of August of last year by giving this extra time.

Salynn Boyles: Okay, thank you.

Coordinator: Thank you. Next question is from Rob Stein. Your line is open and please state your affiliation.

Rob Stein: This is Rob Stein is from National Public Radio. So I just want to clarify just exactly what is being postponed and what's not being postponed. And so if I'm understanding this correctly all the restrictions on sales of e-cigarettes like sales to minors, sales from – in vending machines. All that stuff, that's not being affected by any of this.

The only thing that's being affected with regards to e-cigarettes is you're giving them – companies more time to submit the products for review, the ones that were already on the market.

Dr. Scott Gottlieb: So this is Scott. Nothing is being extended today except one thing which are when the product applications for the newly deemed products are due. And the newly deemed products are primarily the cigars and the e-cigarettes.

The reason we're extending those deadlines is because we want to take the time to put in place foundational regulations that will allow us to properly

regulate those products against a clear set of standards and properly enforce those standards.

And so that - the delays will allow us the time to put in place those regulations. We want to make sure these products, particularly the e-cigarettes go through an appropriate set of regulatory dates and make sure that they're safe, make sure they're meeting standards, make sure they're not being used by kids, make sure we have rules in place to address issues like kid-appealing flavors.

That's why we're taking that time to do that. At the same time we're going to be advancing a regulation to reduce nicotine levels in combustible cigarettes to non-addictive levels.

We believe that in a world where we are rendering combustible cigarettes no longer addictive we can take a more balanced approach to some of the newer innovation that might have the potential to help current cigarette smokers – current combustible cigarette smokers transition off of combustible cigarettes and on to products that might be less harmful.

And our regulatory process will help determine whether in fact those products are less harmful.

Rob Stein:

Thank you for that. If I could just follow up, I actually understand why you might – would want to be delaying on e-cigarettes but why cigars? Are they considered in any way a smoking cessation product? And just in terms of reducing nicotine in combustible cigarettes, any idea how quickly the nicotine might be reduced?

Dr. Scott Gottlieb: Well I'll speak to the cigar issue. I'll turn the nicotine question to Mitch which is frankly a question that's going to be evaluated in the rulemaking process.

But we're delaying the application dates on the cigars by less time so we're delaying it by less time so that we can again initiate a rulemaking process to re-solicit information around patterns of use related specifically to premium cigars. And whether or not premium cigars pose the same public health risk based on their patterns of use.

And so once again we need the time in order to engage in that rulemaking process.

Mitch Zeller: What I would answer that before getting to the nicotine question is this will also give us time to put out regulations that will make it clearer to cigar manufacturers what needs to be in any of the applications that they would have to file with us. This will address issues that we've experienced with the first generation of applications that we've received when the Center opened its doors in 2009 and 2010.

And that was applications that were incomplete. And to the degree that we can get more regulations and guidances out in the interim to make crystal clear to cigar manufacturers what needs to be in those applications. It will make the applications stronger and more complete. And it will be a win/win for everyone.

On your nicotine question there is increasing evidence in the literature that nicotine levels can be reduced in combustible cigarettes. And help people quick and avoid some of the unintended consequences such as what the experts call compensatory smoking behavior where someone using a

lower nicotine cigarette winds up smoking more cigarettes to get the nicotine, take in more puffs, holds the puffs more deeply.

There's promising studies in the peer reviewed literature that suggests that those issues can be addressed if nicotine levels are taken far enough down. We're going to put out all the information that we have. Ask all the questions about the potential benefits and the downside because you heard the Commissioner talk about this morning and the principle negative impact would be the increased availability of a black market for higher nicotine cigarettes.

We're going to ask all those questions in a comprehensive way in this advanced notice of proposed rule-making.

Dr. Scott Gottlieb: I just want to reiterate the point that Mitch made about the delays. The delays are primarily to allow us the time to put in place the implementing regs and the foundational regulations that I outlined in my speech so that we have a proper regulatory framework to – in which to enforce standards against.

As I said I'm in this for the long run. I want to put in place a sustainable architecture that can help us achieve long-term public health goals. And that's what we're looking to do here.

Jennifer Rodriguez: Thank you. We'll take the next question please.

Coordinator: Thank you. Next question is from William Wan. Your line is open and please state your affiliation.

William Wan: Hi this is William Wan from The Washington Post. My question is is there any kind of even rough timeline for the lowering of nicotine levels on

combustible cigarettes? Then just a follow up would be just you talked a little bit about the huge bridge – this huge divide on harm reduction. Could you explain a little further on how – I mean it's been such an existing – long existing divide.

How do you bridge that divide? Like concrete steps, what are there?

Dr. Scott Gottlieb: This is Scott. I'll just start out that I've spent a considerable amount of time developing this policy. And we're ready to get started right away advancing these regulations. And I have a degree of confidence that we'll be able to move forward with this right away.

And so I'll let Mitch speak to the timeline for that. But in terms of actually starting to implement these policies we're going to move quickly here.

Mitch Zeller: As the Commissioner said, we're going to get started with an advance notice of proposed rulemaking. One of the issues that will be addressed is how much time is needed if there were ever to be a product standard in place that mandates minimally or non-addictive levels of cigarettes.

To your harm reduction question what you heard the Commissioner say this morning is that for years there has been a robust debate in the United States about the benefits or the risk and the downsides of e-cigarettes. And what Dr. Gottlieb said is there are pitched camps here.

There are zealous advocates in favor of e-cigarettes and equally zealous opponents of these cigarettes. And it's our assessment that that debate primarily focused on are e-cigarettes or are e-cigarettes bad. Is not really advancing and establishing common ground. The point of the Commissioner's remarks this morning is to say to anybody who cares about this, here's an opportunity to reframe the debate.

Yes we need to ask some tough questions about the benefits and the potential risks of any new technology. But those questions should be asked through a reframing of what's it going to take to address the leading cause of disease and death related to tobacco use; which is cigarettes. Everybody agrees with that.

And is especially important because cigarettes are incredibly addictive and the addictions starts as a result of youthful experimentation when it's children and adolescents. And we have it within our power to address that and then everything else falls into place from that.

If cigarettes are no longer addictive probably addictive adult smokers may need to get their nicotine from other forms that in a regulated marketplace could be made as least harmful as possible.

William Wan: To follow up on that – apologies. But would you – just (want those) – you talked about the pitched camps and obviously, you know, those do exist. And so to those who would be on the side, you know, who have been really kind of against the e-cigarettes and worried about the potential harms of it – would some of those in that camp see the kind of announcement today as siding with, you know, for being a proponent for e-cigarettes as a way of combating nicotine addiction in combustibles?

Mitch Zeller: I think all sides will hopefully look at what we're doing as advancing and promoting public health. Acknowledging that there is a continuum of risk; that there are more or less harmful ways for the nicotine to be delivered; and in a properly regulated marketplace there's an appropriate place for the least harmful forms of nicotine delivery; whether it's medicinal nicotine products or electronic cigarettes.

William Wan: Really appreciate it.

Jennifer Rodriguez: Thank you. We have time for one last question.

Coordinator: Thank you. Our final question comes from Brent Griffiths. Your line is open and please state your affiliation.

Brent Griffiths: Yes this is Brent Griffiths with Politico. A quick clarification for Commissioner Gottlieb. How did your involvement with today's action and future rule-making effect your agreement with the Office of Government Ethics, given your past involvement with Kure?

Dr. Scott Gottlieb: I'm perfectly permitted to work on these issues. I've been cleared by Office of Government Ethics to work on issues related to tobacco. We can get you a more formal statement related to that.

Jennifer Rodriguez: I'll follow up with you. This is Jennifer. Thanks so much ladies and gentlemen this concludes today's media availability. A replay will be available in about an hour. And is available for 30 days.

Please remember to stop the FDA Website for the press release and the Commissioner's remarks. If you have follow-up questions, please don't hesitate to contact Michael Felberbaum or myself, Jennifer Rodriguez. Thank you.

Coordinator: Thank you for your participation. Again that does conclude today's conference. You may disconnect at this time.

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