

Transcript of FDA Media Availability on Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes

Moderator: Michael Felberbaum

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Coordinator: Thank you for standing by and welcome to the FDA media briefing. Today's conference is being recorded. If you have any objections to please disconnect at this time. Your lines have been placed in a listen only mode until the question-and-answer session of today's conference. At that time you may press Star followed by the 1 to ask a question.

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

Michael Felberbaum: Good morning and thank you for participating in today's call. My name is Michael Felberbaum and I am with the FDA's Office of Media Affairs. This is a media briefing regarding the proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes.

By now, the commissioner's statement on this announcement has been issued.

Today I am joined by FDA Commissioner Dr. Scott Gottlieb and Mitch Zeller, Director of the FDA Center for Tobacco Products, who we will discuss some of the details of today's announcement.

After the remarks we will move to a question-and-answer portion of the call. Reporters will be in 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 everyone for joining us today and thank you Michael for the introduction. I will just start off with a little bit of historical context of how we got to where we are today and (how) we find ourselves in a difficult circumstance today.

As many of you know, last summer we announced a comprehensive plan with respect to our approach to tobacco products generally. And the key element of that was to try to put nicotine at the center of our regulatory efforts and seek to regulate nicotine in combustible cigarettes to render them minimally and non-addictive; at the same time that we saw an opportunity to try to migrate adult smokers off of combustible products onto forms of nicotine delivery that didn't have all the harmful effects associated with it and that came with combustion.

So at the very time that we were seeking to regulate nicotine content in combustible cigarettes to hopefully more rapidly migrate adult smokers off of those products which no longer would be able to sustain addiction, we saw an opportunity to both open up more opportunities to facilitate innovation when it came to nicotine replacement therapies and we have advanced new policies and guidance to try to do that.

And we also saw an opportunity from the electronic nicotine delivery systems (ENDS) principally e-cigarettes as a way to offer adults vehicle to get access to satisfying levels of nicotine through an inhaled route if they preferred to do that without all the harmful effects of combustion.

We never presumed that e-cigarettes were risk-free. There are risks associated with them. We recognize that. We have to fully characterize those as risks through an appropriate regulatory process.

But we do believe that they offer a less harmful alternative if we can currently switch an adult smoker -- someone who is currently an adult who is addicted to cigarettes -- fully switch them onto an e-cigarette we would provide for public health benefit.

But when I announced this policy last summer, when I spoke at my own confirmation hearing coming into this job, when I gave my remarks to the staff of the FDA, the professional staff of the FDA on my third day on the job, and countless times in between, I said over and over again that any accommodation that we make to try to facilitate a way for e-cigarettes to come into compliance and file success applications with the agency, any accommodation can't come at the expense of addicting a generation of young people on e-cigarettes and that we wouldn't countenance a world in which we saw the dramatic gains that we have made in recent years in reducing youth cigarette use rates, reversed by creating a whole pool of risk for the future of potential smokers for the future among kids who are becoming addicted to nicotine through e-cigarettes.

And we now data that demonstrates including the National Academies of Medicine study, RAND and others that when kids do initiate on e-cigarettes, some proportion of them are going to become cigarette users. That kids who initiate on e-cigarettes and become addicted to nicotine through e-cigarettes are more likely to use cigarettes.

We now have data showing that this is exactly what is happening. That an alarming number of kids are becoming addicted to nicotine through e-cigarettes. The CDC will publish its Morbidity and Mortality Weekly Report later today. We put out a lot of that data already in the press release that we have announced.

I have already spoken about a lot of that data in recent weeks that shows nothing short of an epidemic growth in the use of e-cigarettes by teens. A full 78 percent rise year-over-year from 2017 to 2018 in the number of high school kids using e-cigarettes.

Almost a 50 percent increase in the number of middle school students using e-cigarettes year-over-year increase. And we are getting at very alarming absolute numbers of kids now who are vaping, who are using e-cigarettes, and very alarming numbers of kids who are using it regularly who are consistent users defined as 20 days or more of use.

We simply can't countenance this. We said we wouldn't. We will not. We are going to step into the market with actions we are taking today to reverse these trends. Not just slow these trends. Not just stop these trends but we need to reverse them. We need to bring these numbers down.

And if the actions that we are taking today aren't successful and we are going to monitor our progress very closely. We are doing our own surveys now to assess what's happening in the marketplace.

If this doesn't start to reverse, we will be back here on a phone call soon talking about additional steps that the agency is going to take.

To walk you through just sort of a top line fashion some of those steps -- and Mitch is going to get into more detail -- I really see this as two problems: One of access -- these products are too accessible to kids; and one of appeal -- these products are too appealing to kids. And the primary vehicle by which these products have appealed to kids are the flavors - are the fruity flavors and we need to address that.

And so we are taking steps today to put in place significantly enhanced age-verification requirements that would limit sales of the fruity products to locations that can require stringent age-verification. To make sure people who are going into those establishments are over the age of 18 or 18 or older.

You know we think that by-and-large the adult vaping shops -- of which there are approximately 10,000 if you go online and look at some of the data online -- could comply, will comply, and many even do comply.

But you know for convenience stores, our goal is to make sure that these fruity flavors are not accessible to kids in those retail sites period. No exceptions.

And we are going to be monitoring to make sure that they comply. If a convenience store wants to contemplate how they can continue to sell a fruity flavor product to a kid, they can consider some options. There might be ways for them to create separate structures that are maybe a separate room, but you know a curtain is not going to cut it. They are going to need to have a separate structure where they can have age verification for people going into that structure. It is not simply a matter of putting it behind the counter or sticking a curtain around it.

You know I am not going to foreclose the possibility that they might be able to contemplate ways that they can stay in this business if they want to invest in infrastructure to sell fruity flavors, but the goal here is to make sure that fruity flavors are not going to be accessible to kids and bought by kids at those retail sites -- and that is what this policy is designed to do.

Now some of you are going to ask why we allowed menthol to be continued to be sold in the retail locations without these enhanced age-verification requirements. And quite simply we live in a world today where there are combustible tobacco products that are tobacco flavored and that are menthol flavored, and as a matter of public health I didn't want to create a marketplace where an adult walks into a convenience store and has the option of buying a mentholated cigarette but doesn't have the option of buying a mentholated e-cigarette.

At the very least I want to make sure there is parity. And in an ideal environment I would like to have a world where the non-combustible products are more attractive and have features that make them more attractive to adult smokers than the combustible products so that we can shift the entire direction

of this market away from the combustible products to the non-combustible products.

But right now we live in a world where the menthol is available in the combustible products and we didn't want to foreclose the menthol in the non-combustible products at that time.

We recognize the mint and the menthol is being used by children. We will be watching that very closely. And if these trends don't reverse we are going to be examining what steps we might take with respect to the mint and the mentholated e-cigarette products as well as.

But in recognizing this careful public health balancing that we are engaging in and the compromises that we've had to make here in order to make sure there is parity in the market and we are not biasing purchases in a direction – back in the direction of the combustible products, we are also setting out to advance the notice of proposed rulemaking that would seek to ban menthol in the combustible products. I think the menthol in the combustible products has long been a pernicious problem. I have spoken about it many times in the last 19 months that I have been on this job.

It is the on-ramp for kids for the use of combustible tobacco products. Fully 54 percent of kids who use combustible products who smoke cigarettes use mentholated cigarettes. And for African-American use it is 7 out of 10.

And I will tell you I have worked in environments where I served underserved populations. I have seen the impact of smoking-related disease. The morbidity and mortality and death that come from smoking related illness, and we simply have to create a world where kids are no longer being initiated on tobacco and we are no longer creating a pool of future smokers.

There are other elements of the plan. I will just sort of briefly touch on them and let Mitch get into more detail. We are also going to require this enhanced age verification for online sites. We will be putting out guidance that will

outline what sites have to do – online sites have to do in order to meet requirements and be able to sell online.

But there are ways to create very stringent sets of conditions on how these products can be sold online in a way that makes it far more difficult for them to get into the hands of children.

We are going to be monitoring the market very closely. And for e-cigarette manufacturers who market their products in ways that are meant to appeal to kids, where it is obvious that they are marketed to kids or in fashions that are appealing to kids with cartoon characters or the like, we will immediately end our enforcement discretion policy with respect to these products and require them to come into the market - to come in with a PMTA (Premarket Tobacco) application.

So if they are looking to engage in that sort of marketing. They better think twice about doing it.

And we are also going to be seeking to ban flavors in the cigarillos and cigars. You know I think that this is another vehicle by which kids are becoming initiated on tobacco.

When Congress set out to ban characterizing flavors in cigarettes. We saw a market be created for flavored cigarillos that look a lot like cigarettes and have fruity flavors in them.

The number one category of tobacco use among African-American youth is actually the cigars. And so these flavored cigars are another pernicious on ramp for kids and initiating kids on tobacco. And we are going to banning them outright.

For the products that haven't been grandfathered in we will be seeking to take them off the market right away. And for the cigar products that have been grandfathered under the law, we will address them rulemaking. But flavored

cigars and cigarillos, you know, we will be advancing the process to remove those products from the market.

We feel this is a robust set of actions we are taking today. We fully recognize that we have made some very difficult balancing and difficult considerations in trying to balance competing priorities. In terms of trying to make certain products available for adults and continue to transition adults off of combustible products onto modified risk products, we have had to strike certain public health compromises. That is part of our jobs. We make these hard decisions every day. But make no mistake, if we don't start to reverse these trends and start to watch youth use of e-cigarettes start to come down sharply in the coming months, we'll be back here.

And so my message, my final message is to the manufacturers. I hope that they will start right away putting in place these requirements, recognizing that they are coming.

Because I think it is in all of our interests -- all of our public health interest -- to start making sure that we are taking steps to shift this trajectory of disease and potential death for the future.

With that, Mitch, I will turn it over to you. Thanks a lot.

Mitch Zeller: Thanks so much Commissioner. From a public health perspective given the startling and disturbing data that was released today. It was clear that FDA had to act and had to do more than we had been doing.

Specifically the target would appear to be the central problems as you heard the Commissioner outline them: youth appeal and youth access to flavored tobacco products across the board.

We have many more details about this policy framework that is available in the press statement that was issued this morning but let me provide some highlights.

Some of the changes that we are talking about involve revisiting what was the agency's compliance policy that had been issued in 2017, which extended the dates by which the manufacturers of the so-called deemed tobacco products that were on the market as of Aug. 8, 2016, were expected to submit what are called pre-market applications to FDA for review.

And under the 2017 policy of what is called enforcement discretion, the pre-market application compliance date for these newly regulated, non-combustible tobacco products including most ENDS products, electronic nicotine delivery systems or e-cigarettes was extended to August of 2022.

Well in light of everything that you have heard the Commissioner say and the alarming results of the National Youth Tobacco Survey data that has been released today, we are revisiting this compliance policy as it applies to deemed ENDS products that are flavored, including all flavors other than tobacco, mint and menthol. So this would include ENDS products such as e-liquids, cartridge-based systems, cig-a-likes in fruit and candy flavors like cherry or vanilla, tropical, melon, you name it.

To advance this goal we are revisiting the compliance policy on pre-market tobacco product application authorization for such flavored products that are sold in physical locations where people under the age of 18 have access.

We are not revisiting the compliance policy with respect to ENDS products sold exclusively in age-restricted locations. For instance, any standalone tobacco retailer -- it could be a vape shop, it could be others -- that adequately prevent persons under the age of 18 from entering the store at any time.

Or, as you heard the Commissioner say, a section of any establishment that adequately prevents entry of persons under the age of 18 and the flavored ENDS products are neither visible nor accessible to kids.

In addition, we will seek to curtail the sale of applicable flavored ENDS products that are sold online without heightened age-verification processes. We are working to identify these measures for age verification and other restrictions to prevent youth access via online sales, and these best practices will be made available soon so that the sites can quickly adopt them.

At this time ENDS products with tobacco, mint or menthol flavors as well as any non-flavored ENDS products sold in any location will not be included in any policy revisions.

As you heard the Commissioner allude, this distinction among flavor seeks to maintain access for adult users of these products, including adults who live in a rural or remote locations who may not have access to an age-restricted location.

What this reflects is a careful balancing of some really important public health considerations.

Among all ENDS users, the data suggests that mint and menthol flavored ENDS are more popular with adults than with kids. But as you heard the commissioner say, we will evaluate this approach to mint and menthol flavored ENDS over time as evidence of its impact develops and we will revisit this policy at the drop of a dime.

Now, we recognize that combustible cigarettes are still sold in that menthol flavor, including in lots of convenience stores. And we don't want to create a situation where the combustible products have features like menthol that make them more attractive than the non-combustible products, or a situation where those who currently use menthol flavored cigarettes might find it less attractive to switch completely to an e-cigarette.

Now additionally, we are going to pursue the removal from the market of those ENDS products that are marketed to children or appealing to youth. What does it mean? Well this could include using popular children's cartoon

or animated characters, names of products favored by kids like brands of candy or soda. We are going to pursue the removal of those products.

We are also proposing new steps to address the availability of flavors in combustible tobacco, as you heard the Commissioner describe.

We believe that menthol flavored products represent one of the most common routes by which kids initiate on combustible cigarettes, and therefore we are seeking to propose on menthol and combustible tobacco products, including cigarettes and cigars via the rulemaking process -- and the Commissioner walked you through the data in support of that.

We are taking a comprehensive approach here, and that means we have to address flavored cigars. Flavors are added to cigars and other tobacco products for a bunch of reasons, such as reducing the harshness or the bitterness during inhalation, and to soothe the irritation during use.

The research shows that compared to adults who are 25 or older who smoke cigars, a higher proportion of youth who smoke cigars use the flavored cigars.

This data also indicate that eliminating flavors from cigars would likely help prevent cigar initiation by kids, and accordingly we are revisiting the compliance policy for applicable flavored cigars and intend to propose a product standard through that rulemaking process that would ban flavors in all cigars.

So with implementation of the forceful and far-reaching actions that are being outlined today, and with the commitment of tobacco manufacturers, take additional actions to reduce youth access to their products, we can reverse the disturbing trends that we are seeing today and that were announced with the most recent data.

Let me close by reiterating something that is in the Commissioner's statement. Where he made clear that he can think of no more impactful action the FDA

could possibly take on his watch to help American families than the actions that are being announced today.

And with that we would be happy to take your questions. Thanks.

Michael Felberbaum: Thank you Mitch. At this time we will begin the question-and-answer portion of this 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 to as many questions as possible. Operator we will take the first question please.

Coordinator: Thank you. Once again to ask a question you may press star 1. To withdraw your question you may press star 2.

Jennifer Maloney you may ask your question. Please state your affiliation.

Jennifer Maloney: Hi it's Jennifer from the Wall Street Journal. Altria, Reynolds and Juul have all said that they would support a federal minimum tobacco age of 21, and Dr. Gottlieb I wonder if you would support a minimum age of 21 nationwide?

Scott Gottlieb: I would. You know obviously I don't write legislative policy but if you know Congress comes to us and asks for technical assistance about 21, it is something that we would certainly support. We think there is data to support it, and something I would certainly advocate for.

Jennifer Maloney: Thanks.

Michael Felberbaum: Operator we will take our next question please.

Coordinator: Thank you. And our next question comes from Anna Edney you may go ahead. Please state your affiliation.

Anna Edney: Bloomberg News. I wondered if you could lay out sort of the timeline a little better for some of these? Obviously they will come at different times but if you could talk about the sales restrictions on flavored e-cigarettes, the menthol and the flavored cigars and how you see those coming about and how long you think they will take?

Scott Gottlieb: We think the issues with respect to what we are trying to do, you know, the framework to restrict access to the fruity flavored, the fruit flavored e-liquids and e-cigarettes products in the retail establishments is going to be a matter if, you know, a short number of months.

I would say weeks to months probably more likely. You know a couple of several months in terms of getting that fully implemented. We have to give the market time to transition as well. It is not just a question of getting the policy fully implemented but giving the market some reasonable period of time to transition.

The issue of the rulemaking -- I mean you know you are obviously a student of the rulemaking process. We have the ANPRMs that were out, we've gone through the comments, we're going to advance the notice the proposed rulemakings. We have some of that work underway already, and so, you know, I think we are looking at some point in 2019 being in a position to advance NPRMs out of the agency. It is harder to give you a sort of more definitive timeline than that. Sometimes things get sped up, sometimes things can get delayed because of the complexity, and then there is obviously a clearance process within the government. But I am hopeful that we could advance the notices and proposed rulemakings at some point in 2019 and it is hard to be more definitive than that.

Mitch I don't know if you have anything you want to add.

Mitch Zeller: No nothing to add thanks.

Anna Edney: Can I just be clear on the e-cigarettes? When you said a matter of months or many even weeks -- that is for the policy to be written and for them to transition out of convenience stores?

Scott Gottlieb: Well I mean you can presume the announcement today we put out a pretty broad statement today, 3,000-4,000-word statement today, I mean I think it is fair to presume that there is a policy development behind that statement and there has been a lot of work that has been done to frame out how we would effectuate the goals that we have outlined today.

I am talking about a matter of months to, you know, implement that policy in sort of a final form, put it out for public notice, and then provide a period of time for the market to transition, you know, to fully implement it. And so that is really the process we are talking about.

This isn't something that should take an extended period of time. But in the interim as I said and as you have seen in recent days. I would hope that the large manufacturers whose products are being used by kids -- and we know which ones they are -- would start to take steps to effectuate this right away.

There is nothing preventing a manufacturer from voluntarily withdrawing the fruit-flavored products from retail locations and putting in place significantly enhanced age verification online. Some sites already have that. Some companies have already taken steps to do that and we acknowledge that.

I would welcome all manufacturers to do that. This is an inevitability. We are going to implement this policy, and I think if we don't start to see these youth rates decline, we are going to be back here. And we are going to be in the market, you know, early in the spring of 2019 with another National Youth Tobacco Survey.

We can't have another year where we have a 78 percent increase year-over-year in youth use -- youth e-cigarette use rates. We can't have that. We can't have a country where 50 percent of high school teens are using e-cigarettes.

That won't happen on our watch. It won't happen on the watch of this Administration. We won't countenance that.

So the sooner that we can start to reverse these trends, you know the sooner we can put in place stable policy and these companies can put in place stable business models that allow these to be sustainable opportunities for adults.

This is right now an existential threat to this business and they need to address it as a matter of their business prerogatives. We need to address it as a matter of our public health prerogatives.

Anna Edney: Thank you.

Michael Felberbaum: Thank you. Operator we will take the next question please.

Coordinator: Thank you. Robert King you may go ahead. Please state your affiliation.

Robert King: Hi this is Robert King with the Washington Examiner. Thanks for taking my question. You said that, you know, you will be back next year and might do something if rates haven't gone down.

Can you elaborate what could be a potential next step if rates aren't going in the right direction? Are you hinting at a potential overall ban of all e-cigarettes?

Scott Gottlieb: No I mean look I didn't give a timeline in terms of when we would "be back". And I am hopeful we won't be back. I mean I didn't expect to be here today. We put out a very comprehensive plan last summer to try to outline what our policy was going to be with respect to tobacco products broadly.

And but for what we have seen happen on the youth side we probably wouldn't be back here today taking the steps that we are. But we are unfortunately in a place that we never hoped we'd be.

What would we consider next? You know I think I was pretty clear that we have made a very careful compromise in allowing the mint and the menthol e-cigarette to continue to be available in the retail locations -- recognizing that those products are still used by youth and still attractive to youth.

And I think if we don't start to see these rates start to come down. The first consideration that I would make would be whether or not we should apply the same restrictions that we are now imposing for seeking to impose to the fruity products also to the mint and the mentholated e-cigarette products as well.

I don't want to go there because I think that that will disadvantage adult smokers in a way that could be contrary to some of our public health goals, but once again the issues around the epidemic of youth use and use among kids is a paramount concern and one of our most significant concerns right now.

And so we will have to consider some other steps. That is again why I said you know I am hopeful that the manufacturers are going to step in and start to take, you know, strong steps Day 1 to try to address these trends.

The other thing I would say is that we did the biggest ever enforcement operation in the history of the agency three months ago targeting sales of e-cigarettes in convenience stores to kids.

Based on the resources we put against that effort we expected to find maybe 300 violations. I asked my folks before we undertook that operation how many violations we will find based on the resources we are putting behind it, because at sort of a rate of recidivism you expect. We found 1,300 violations. We were shocked by that. It was horrifying to us.

So there is rampant sales of these e-cigarette products to kids in these retail sites I suspect, just as a parent, there might be a retail location that understands that it is inappropriate to sell a combustible product to kids, (but)

it might not have the same disinclination when it comes to an e-cigarette. That needs to change.

And so we are shifting our oversight resources as well to target retail sites to make sure they are not selling e-cigarette products to kids. So we are going to be monitoring this very closely and we are going to be testing those retail locations to make sure these sales aren't going into the hands of kids, so that is another barometer by which we are going to be judging the success of our efforts.

Michael Felberbaum: Thank you. Operator we will take the next question please.

Coordinator: Thank you. Chris Kirkham you may ask your question. Please state your affiliation.

Chris Kirkham: Yeah, hi, Chris Kirkham with Reuters. I just had a question kind of on the broader issue of flavors. I mean a lot of I think public health and other advocates have sort of questioned if flavors are sort of the primary issue for kids and for teen usage, why not sort of widen the restrictions? Why sort of still allow this even in the age restricted ones given concerns about straw purchases or, you know, other means by which, you know, these flavors might still sort of get in the hands of kids?

So just kind of wanted to get a little bit sense of what your wider thinking is on flavors, you know if there is importance of some of these flavors for adult users.

Scott Gottlieb: Well I think you answered your own question, quite frankly. There is importance of these flavors for adult users. The flavors are both an opportunity and a risk.

They are an opportunity to transition adults off of combustible products and we have data that demonstrates that adult smokers who transition off of

combustible products onto non-combustible products some proportion of them do prefer the flavors and the flavors help them make that transition.

But they are also an on-ramp to the kids and they are what are making these products appealing to kids.

We are trying to strike a very careful public health balance here, and you know we want to not foreclose these opportunities for adults. That is why we have differentiated between the cartridge-based systems which are the ones that are primarily being used by kids and the open tank system which primarily are used by adults who go into baking stores and buy the more sophisticated devices.

But, you know, make no mistake. This is not a static policy. This is not one and done. We will be back if we need to be. If we don't see these policies effectuate the kind of change in the market with respect to the youth addition and the youth usage of these products that has us all deeply concerned.

And so, you know, we don't want to have to intervene with additional steps that would encumber adults and could forestall opportunities for adults and make it too hard for certain adults to make the transition.

But again we are going to look at whether or not we have to put in place additional speed bumps along the pathway for the adults in order to prevent the kids from getting to the same products.

We think we struck the right balance with what we have done today. We have worked and thought about this very hard -- looking at our data, looking at our authorities -- but you know we will be monitoring the market very closely.

I am hopeful that between the voluntary steps that the manufacturers are now taking and the mandatory steps that we are going to be putting in place that we are going to start to reverse these trends and be in a much better place next

year to continue on a policy that allows us to strike a very careful balance while making sure that kids aren't accessing these products.

We will never eliminate any youth experimentation. You know we are not – we are not wide eyed about this. Kids are going to experiment with the e-cigarette products, but the levels of youth use and the growth of in the youth use that we see simply are intolerable.

Mitch Zeller: This is Mitch. Let me just add one additional point to part of your question Chris about these bulk purchases. One of the things that we have learned from conversations with the companies that we have had meetings with is the ability to put limits on quantity of purchase.

And we are concerned about these bulk purchases. Think about it. There could be 18-year-olds who are still in high school but who are able to make these bulk purchases and then become quite entrepreneurial in high school bathrooms reselling these products.

And so look for additional information to come out of the agency over time with the types of age restrictions and access restrictions that we would be looking for to minimize the possibility of that happening. And that is separate and apart from what the minimum age of sale should be.

Michael Felberbaum: Thank you. Operator we will take the next question please.

Coordinator: Thank you. Rob Stein you may ask your question. Please state your affiliation.

Rob Stein: Thanks for taking my question. It is Rob Stein from National Public Radio. I just was hoping that Commissioner Gottlieb you could talk a little bit more about the proposed ban on menthol cigarettes? Why are you going after menthol cigarettes and how does that relate to the youth smoking and use of e-cigarettes?

Scott Gottlieb: Well I think the two are interrelated for certain, but menthol is also a consideration even in isolation of the issue around e-cigarettes. I think that from a standpoint of how this factors into our consideration around e-cigarettes, I said that we need to really consider flavors broadly.

And we have made a careful balance here to allow the menthol- and the mint-flavored e-cigarettes to be sold in retail locations because the mentholated products, the mentholated combustible products are also available in those locations.

And I really at this point am not willing to countenance a world where an adult walks into a convenience stores and sees tobacco-flavored and menthol-flavored combustible cigarettes but only sees tobacco flavored e-cigarettes.

That is not the market that I want. I want a market that is biased in favor of the non-combustible products and hopefully gives incentives for adults to transition away from the combustible products onto the non-combustible products which we know pose less risk -- not risk free but less risk.

So that is how it factors in. You know we have made that accommodation on the assumption that we are also going to be seeking to ban menthol in those combustible products. And continue down a path where the market creates – it is biased in favor of the non-combustible products if you will, so that we are providing incentives for adults to hopefully switch. That is again why we sought to regulate nicotine in the combustible products or render the combustible products minimally and non-addictive.

That is another element of how we are trying to create a market where the non-combustible products have features that make them more attractive to adults who want to get access to nicotine than the combustible products.

But menthol in and of itself is pernicious. Menthol is an on-ramp to smoking for kids. I quoted statistics fully, 54 percent of kids who use cigarettes, use mentholated cigarettes. We know that the menthol itself has features that mask

some of the undesirable aspects of smoking, so it makes it easier for someone who is uninitiated to smoking to begin smoking.

The burning, the coughing that comes with that first cigarette or starting on tobacco is masked by the menthol, and so the menthol becomes a very pernicious tool by which it becomes easier for children to start smoking.

And we see a very disproportionate impact of menthol on the African-American community and underserved communities. And I spent a lot of my clinical years at the hospitals working in those communities, and I have to tell you that a very large percentage of the work that I did and the practice I did was treating people and helping people who had smoking related diseases. And it is an awful way to die and it is an awful way to suffer. And we simply must put an end to this.

Rob Stein: Thanks very much. Appreciate it.

Michael Felberbaum: Thank you operator. We will take the next question please.

Coordinator: Thank you. Angelica LaVito you may ask your question. Please state your affiliation.

Angelica Lavito: This is Angelica from CNBC. I just wanted to get some clarity around how long you anticipate the process of rulemaking on menthol cigarettes to be? Since that process technically already started in 2013, do you think that will accelerate any rulemaking and what can we expect?

Scott Gottlieb: Well we are not inheriting sort of a continuous process that has been underway since 2013. There has been, you know, as you referenced past the attempts to initiate a process.

But we have initiated process anew based on new data under new terms, under new authorities, under new policy framework with, you know, new political

leadership and the strong support of the Secretary of the Department of Health and Human Services.

And so have ANPRM amount, we have gotten back comments, and we are going forward with the notice of proposed rulemaking. I don't want to prejudge the outcome of that process or put a timeline on it, other than to say that you know this isn't something that we don't understand.

All of the past work that we have done, all the information we have is going to inform our rule making process including and especially the comments we got on the ANPRM.

And so we are hopeful that we should be able to move with, you know, some added efficiency because of our deep understanding of the role of menthol in cigarettes and the past work that we have done on this and all the expertise that we have in-house and the comments that we have been the beneficiaries of.

Angelica Lavito: And then my follow up question is there has been talk about that one-year mandatory kind of waiting period. But is that, if this rule were to be implemented, would you exercise your authority to deem it, you know, within the best interest of public health to expedite implementation?

Scott Gottlieb: I think that that's – you are speaking about an issue of the product standard? I am not – I don't want to speak to that because I am not sure that the way it was framed in the question is precise.

But, you know, we can certainly if we feel from a public health standpoint that there is a greater urgency to take action, you know we could certainly have discussions about different legislative authorities that the agency might need, and you have seen FDA provide technical assistance and have discussions with Congress in the past in other areas including opioids, where we have gotten many additional and robust authorities to try to address what isn't, you know, an ensuing public health crisis.

And so we haven't been shy about raising our hand in areas where we think there is a public health prerogative to need stronger tools to effectuate an outcome.

Angelica Lavito: Thank you.

Michael Felberbaum: Thank you. Operator we will take the next question please.

Coordinator: Thank you. Rachel Rouben you may ask your question. Please state your affiliation.

Rachel Rouben: Hi Rachel Rouben with Politico. I was curious if you could sort of clarify something for me on moving up the compliance deadline for flavored vapors that want to be sold online and in convenience stores.

The deadline for approving e-cigarettes is August 22nd. But as I understand the announcement deadline for menthol, mint, tobacco flavors would that remain August 22nd? Sorry August 2022, but would this approval review for flavors begin immediately?

Scott Gottlieb: You know what we are doing is – I will let Mitch chime in here. But what we are doing is effectively putting in place significantly enhanced age-verification requirements for the fruity-flavor products that would have certain practical effects that I think are interpretable to all of you.

If a manufacturer wanted to not have to comply with those enhanced age requirements and be able to market their fruity-flavored product free from those requirements in a convenient store, they would have to have a successful PMTA application -- for them they would have to come in and file a PMTA and have it approved by the FDA to be able to, you know, position it in the market without having to put it in age-restricted commercial setting.

Mitch I hope I got that right. Correct me if I am wrong.

Mitch Zeller: Let me add a couple of points. We are talking about whether we are going to preserve our use of enforcement discretion to allow these products to remain on the market -- and the distinction is between menthol and tobacco flavored and all others.

For the all others if they can't get the right restrictions on location for age in place, they can't be sold. And the only way that they could be sold is as the Commissioner said to come in on a pre-market basis with a new application, at which point there is no deadline because the products are off the market.

And it is up to the companies to decide when they want to come in and file an application. The deadline really only applies to the products that remain on the market, and as you correctly stated in the question at least for the mint and the menthol there is no change to the current compliance policy, which is August of 2022.

But a point in time is going to come in the next weeks or months, where we will be in the marketplace looking to see what is going on with the other flavored products. We will give the industry time to get the restrictions in place, if it is really urgent that they sell unicorn puke e-liquids. And if they want to sell a product like that it better be in an age restricted location. If it is not and if we see it that product is going to have to come off the market.

Michael Felberbaum: Thank you we have time for one last question please.

Coordinator: Thank you and that comes from Andrew Siddons you may go ahead. Please state your affiliation.

Andrew Siddons: Thanks it is Andrew Siddons from CQ. You said that you want to see this trend reversed, but it seems like if you are basing that off of next year's youth tobacco survey we wouldn't really know the results of all of this for another year.

Is that soon enough for you? Is there any way to do maybe more regular or faster surveillance than the annual CDC surveys?

Scott Gottlieb: I mean I said it a couple of times and I appreciate the question Andrew so I can clarify the point. We are monitoring the market differently and more closely now.

So we will have, you know, a snapshot, and we will have repeated snapshots of what is happening in the marketplace now. We are not going to just rely on the National Youth Tobacco Survey given what we now know and what is underway.

You know this isn't going to turn on a dime. You know it is going to take a period of time for these trends to start to reverse. But we are going to be looking at that very closely and we think we have a good feel for what we need to see in the marketplace to have confidence that we are starting to reverse these trends.

And we will be in the market with our own surveys and we are going to be in the market with a lot of additional enforcement and surveillance activity.

Andrew Siddons: Thank you.

Michael Felberbaum: Ladies and gentlemen this concludes today's media briefing. A replay will be available in about an hour and will be available for 30 days. Please remember to check the FDA Web site for the Commissioner's statement.

If you have any follow up questions, please don't hesitate to contact the FDA's Office and Media Affairs. Thank you.

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