

Transcript of FDA Media Briefing on Pivotal Public Health Step to Explore Dramatically Reducing Smoking Rates by Lowering Nicotine in Combustible Cigarettes to Minimally or Non-Addictive Levels

Moderator: Michael Felberbaum

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Coordinator: Good morning and thank you standing by and welcome to today's briefing. Today's conference is being recorded. If you have any objections, please disconnect at this time.

Your lines are in a listen-only mode until the question and answer session of today's conference. At this time, you may press Star followed by the number 1 to ask a question.

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

Michael Felberbaum: Thank you. Good morning and thank you for participating in today's call. My name is Michael Felberbaum and I'm with the FDA's Office of Media Affairs. This is a media briefing regarding FDA's pivotal public health step to explore dramatically reducing smoking rates by lowering nicotine in combustible cigarettes to minimally or non-addictive levels. By now, the Commissioner's statement on this announcement has been issued.

Today, I'm joined by FDA Commissioner Dr. Scott Gottlieb, Mitch Zeller, director for the FDA's Center for Tobacco Products, and Anna Abram, the FDA's deputy commissioner for policy planning, legislation, and analysis who will discuss some of the details of today's announcement.

After the remarks, we will then over to the question and answer portion of the call. Participants on the call 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 your 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.

Dr. Scott Gottlieb: Thank you, Michael, and good morning to everyone, and thank you for taking the time to join us today to discuss this significant announcement. Addressing the addiction crises that have been claiming young lives in this country and hurting American families has been one of our most pressing mandates here at the FDA. In particular, examining the presence of nicotine and combustible cigarettes has to be part of a much broader strategy.

When I first returned to FDA last year, I immediately began working closely with the leadership of the FDA's tobacco center and in particular, Mitch Zeller, on how we could use our tobacco authority to dramatically change the trajectory of death and disease from tobacco

– and how we could sharply bend the curve on the use of deadly combustible cigarettes, in particular.

At the same time, we agreed that we wanted to put in place foundational rules that would place our entire tobacco program on a stronger and more enduring footing. And while at the same time, seeing how we can set up a science-based regulatory structure that could properly evaluate the risks and potential opportunities offered by new tobacco products like electronic nicotine delivery systems.

Despite years of aggressive efforts, tobacco use, largely cigarette smoking, remains the leading cause of preventable disease and death in the United States, and in fact, tobacco use kills more than 480,000 Americans every single year, and cost nearly \$300 billion a year in direct healthcare costs and lost productivity.

In order to address this devastating public health burden and achieve all of our long-term goals, we announced a new comprehensive plan last summer that uses our authorities and our regulatory tools to better protect kids and significantly reduce tobacco-related disease and death. That plan has been set in motion to pursue our vision of a world where combustible cigarettes would no longer create or sustain addiction. This would make it harder for future generations of vulnerable teens to become addicted in the first place, and it would allow more currently addicted smokers to quit or completely switch to potentially less harmful products.

And today, we're taking a pivotal step that could ultimately bring us closer to this vision and advance the policy framework that we believe could avoid millions of tobacco-related deaths across the country. Earlier this morning, we issued an advance notice of proposed rulemaking, or an ANPRM, to explore a product standard to lower nicotine in cigarettes to minimally or non-addictive levels. While Mitch will provide an in-depth discussion on some of the topics we're exploring in the ANPRM, I'd like to talk for a moment about the undeniable public health benefit of such an approach and why we should seriously consider a product standard of this magnitude.

Notably, the new estimates included in the new ANPRM evaluate one possible policy scenario for a nicotine product standard and the potential millions of lives saved, both in the near and long term. We anticipate in this analysis we published in the *New England Journal of Medicine* very soon. If this scenario were implemented, this analysis suggests that about 5 million additional adult smokers could quit smoking within one year of implementation of such a plan. And with this scenario, an even greater impact will be felt over time. By the year 2100, the analysis estimates that more 33 million people, mostly use in young adults, would have avoided becoming regular smokers altogether, and smoking rates could drop from the current 15 percent to as low as 1.4 percent.

All told, this framework could result in more 8 million fewer tobacco caused deaths through the end of the century. Our estimates underscore the tremendous opportunities to save so many lives if we come together and forge a new path forward to combat the overwhelming

disease and death caused by cigarettes. Today's ANPRM is a significant step forward in our efforts to confront nicotine addiction in combustible cigarettes. But it's just the first key step and we have many actions to follow.

We will continue to take enforcement actions against companies who inappropriately target children as well as pursue other new steps to keep kids from using nicotine products. No child should use a tobacco product including an e-cigarette, and we plan to vigorously enforce the current law that gives us regulatory tools related to all newly deemed tobacco products, including e-cigarettes. We will use these tools to protect kids.

We'll also advance other key pieces of our comprehensive approach to tobacco very soon. As we said from the onset, our comprehensive approach requires us to pursue all of its parts in tandem. We've been plain spoken in what we intend to do, we say what we want to do, and we intend to do what we say.

Today's milestone places us squarely on the road toward achieving one the biggest public health victories in modern history by saving millions of lives. There are few things as Commissioner that can save so many lives which is why I'm so committed to our comprehensive plan on nicotine and tobacco. I want to thank the people who worked hard to advance this historic effort, especially Mitch Zeller and his team at the Center for Tobacco Products, and FDA's Deputy Commissioner Anna Abram.

And now I have the pleasure of turning this over to Mitch who will give you a more in-depth look at some of the topics addressed in today's nicotine standard ANPRM.

Mitch Zeller: Thank you, Scott.

As Dr. Gottlieb mentioned, the release of today's ANPRM is a major step on the path to dramatically changing the future of smoking in the United States. Given their combination of toxicity, addictiveness, prevalence, and effect on non-users, cigarettes are the category of tobacco product that causing the greatest public health burden.

In fact, cigarettes are the only legal consumer product, that when used as intended, will kill half of all long-term users prematurely. Almost 90 percent of adult smokers started smoking by the age of 18 and, we've known for decades that cigarettes are highly engineered and designed to get and keep users addicted. More than half of adult cigarette smokers make a serious quit attempt each year, but most do not succeed due the highly addictive nature of cigarettes. Those statistics underscore why we believe the establishment of a maximum nicotine level in cigarettes could help two key populations: currently addicted adult smokers who could switch to a potentially less harmful tobacco product, or better yet, quit altogether. And limiting the level of nicotine in cigarettes could help keep future generations of kids who experiment with cigarettes from making the deadly progression from experimentation to addiction and regular cigarette smoking.

This ANPRM provides a wide-ranging review of the current scientific understanding about the role nicotine plays in creating or sustaining addiction to cigarettes, and seeks comments on key areas, as well as addiction research and data for consideration.

Let me give you a few examples of the issues we're seeking comments, research, and data on related to a potential product standard. This is not an exhaustive list, but the topics were interested in include, what maximum nicotine level would be appropriate for the protection of public health? How a maximum nicotine level should be measured? Whether such a product standard should be implemented all at once or with a gradual stepped approach? And what unintended consequences might occur as a result of such a standard, such as the potential for illicit trade, or for addicted smokers to compensate when using lower nicotine cigarettes by increasing the amount they smoke?

On the issue of illicit trade, we have also released a draft concept paper today, that discusses the potential illicit trade implications of product standards more generally, and this draft concept paper's available on our website. Beginning tomorrow, separate dockets for the ANPRM and the draft concept paper will be open for public comment through mid-June. As we explore this novel approach to reducing the disease and death from cigarettes, it's critical that our policies reflect the latest science and are informed by the input we receive from our meetings with stakeholders, from comments from all the open public documents, and from responses to future opportunities for comment.

We often refer to rule making at FDA as a participatory process and we encourage comment on this ANPRM to help inform the agency's thinking and regulatory options. Should FDA move forward with a nicotine product standard, further steps would include a proposed rule, which would give the public another opportunity to comment on a more detailed proposal from the FDA, including a potential timeline for implementation.

And now, I'm happy to turn things over to Anna, who will provide more details on our comprehensive plan we announced last July.

Anna Abram: Thank you Mitch.

As part of the FDA's overall commitment to protect and promote public health, our policies and regulations, including those related to tobacco and nicotine, must keep pace with the challenges we face in protecting consumers and the opportunities we have to improve their lives. Through this plan and our regulatory frameworks, we have an important opportunity to meaningfully reduce the public health burden of tobacco use and provide pathways for beneficial innovations to reach consumers.

For example, our plan demonstrates a greater awareness that nicotine, while highly addictive, is delivered through products on a continuum of risk, and to successfully address cigarette addiction, we must ensure that it is possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources. To that end, the agency's regulation of

both novel nicotine delivery products -- such as e-cigarettes and traditional tobacco products -- will encourage the innovation of less harmful products while still ensuring that all tobacco products are put through an appropriate series of regulatory gates to maximum any public health benefits and minimize their harm.

This will be achieved through our ongoing regulatory work to develop several foundational rules, guidance, product standards, and other regulations. In addition, as we advance our framework to protect public health in the evolving tobacco marketplace, the FDA also plans shortly to issue two additional ANPRMs.

One will seek comment on the role that flavors, including menthol, play in initiation, use and cessation of tobacco products. A second ANPRM will solicit additional comments and information related to the regulation of premium cigars. We also committed to making that our policies and processes for the regulation of tobacco products is efficient and predictable. And consistent with the mandate Congress gave us under the Family Smoking Prevention and Tobacco Control Act.

At the same time, we're working across the FDA to also jump-start new work to re-evaluate and modernize our approach the development and regulation of states and effective medicinal nicotine replacement products, such as nicotine gum, patches, and lozenges that help smokers quit. All of these efforts complement our ongoing work to educate kids about the danger of all nicotine-containing products, limit youth access, and encourage adults to quit smoking cigarettes.

We believe this unprecedented approach to nicotine and tobacco regulation not only makes sense, but also offers us the best opportunity to achieving meaningful public health gain. As we move forward with these efforts, we will have an opportunity to more formally solicit feedback on a variety of important topics, and we'll continue to foster a public dialogue to reshape our country's relationship with nicotine and seek public input on policies that will guide us toward a healthier future.

With that, we are happy to take your questions.

Michael Felberbaum: Thank you, Anna.

At this time, we will begin the question and answer 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 to as many questions as possible.

Operator, we'll take the first question, please?

Coordinator: Thank you. Once again, that is Star 1 if you'd like to ask a question.

Leigh Ann Winick from CBS News, you may go ahead.

Leigh Ann Winick: Thank you. Wondering why this hasn't been done before? I think it's been stated previously that the FDA does not have jurisdiction to regulate the nicotine levels. Is that the case and why is this being done now?

Mitch Zeller: The FDA absolutely has the authority to regulate nicotine levels in tobacco products. The only limitation on the authority in the statute is that where we use the product standards authority, we couldn't take nicotine levels down to zero. That's why we're doing this ANPRM to share the science that we have to explore whether there's an evidence base to move forward with the rulemaking to establish a product standard for minimally or non-additive level of nicotine cigarettes.

Dr. Scott Gottlieb: And I think just for a higher-level policy formulation, as we talked about when we announced this comprehensive plan. We see it as an historic opportunity here and the unique opportunity to try to use that product standard to potentially, more rapidly, migrate smokers off of combustible cigarettes, combustible products, that we know cause a lot of death and disease related to tobacco use, and potentially on to products that are a modified risk that can be put into either appropriate series of regulatory gates that can provide adults with access to nicotine without all the harms associated with combustion.

I think we're at a very unique time right now where we can combine the opportunities offered, potentially by some of the product innovation that we're seeing in the marketplace, with the regulatory tools that Congress gave us under the Tobacco Control Act to regulate cigarettes and pursue such a product standard.

Leigh Ann Winick: Now as a follow up, does that mean that you would be encouraging e-cigarettes as a bridge to quitting?

Dr. Scott Gottlieb: Those products, those and other products that potentially could offer a bridge to quitting, need to be properly evaluated. I mean, those are questions that need to be properly evaluated through an appropriate regulatory process. We have a process in place, there needs to be a science-based assessment, and some of those potentially modified risk products or products that want to make claims that they could be modified risk products to deliver nicotine, as you know, are currently going through that process.

So, I think the jury's still out on, you know, the value of those products as alternatives to combustible tobacco. But, I think that there are opportunities to pursue such product innovations generally.

Mitch Zeller: But consistent with our thinking about what everybody calls, "the continuum of risk", and recognizing that combustible cigarettes are far and away the deadliest way to deliver nicotine, even though it turns out to be the most efficient way to deliver nicotine. We are only putting out an ANPRM to talk about nicotine levels in cigarettes, and part of the

thinking is, in the spirit of the continuum of risk is, not to touch the nicotine content of any non-combustible products.

And to the Commissioner's point of figuring out a way to transition people who are currently getting their nicotine from the deadliest and most harmful form; for those who are still going to be seeking nicotine, we understand that we absolutely have a responsibility to make it available in alternative and less harmful ways.

Dr. Scott Gottlieb: And that includes medicinal products, and so, we started a process here at FDA to look at how can re-evaluate the regulatory structure around nicotine sold in medicinal forms, for example, patches, sucking candies, as another opportunity for smokers to transition off of combustible forms of tobacco onto other delivery vehicles that propose far less risk.

Michael Felberbaum: Great. Thank you.

Operator, we'll take the next question, please?

Coordinator: Thank you. Dennis Thompson from HealthDay. You may go ahead?

Dennis Thompson: Sorry, my question was just answered. Thank you though.

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

Coordinator: Thank you. Matt Perrone from Associated Press. You may go ahead?

Matt Perrone: Hi guys. So, to that point then. These estimates, which are very interesting, particularly this figure you might be able to get the smoking rate down to 1 percent. Does that assume the availability of alternative nicotine sources, things like e-cigarettes? Or, is this model you're envisioning only speaking to, you know, if we left everything the way it is now and just cut nicotine in these combustible cigarettes? I'm just trying to understand the model you're using for these estimates.

Mitch Zeller: It assumes that alternative and less harmful sources of nicotine are available.

Matt Perrone: Okay. Do you, since there is much that's still uncertain about the public health benefits and risks of these products -- the National Academy raised a number of concerns last month -- how confident can you be talking about something in 2100 today?

Mitch Zeller: Well, as you read through the paper that's going to be published and how we described, I think with appropriate conditions and qualifications, the modeling that's been done. This is part of a vision and the public health potential for this. But the model is created after extensive consultation with a group of experts who assisted in providing the inputs that then drove that model.

And what the numbers suggest is that, the generational effect of a minimally or non-addictive cigarette are so profound, the magnitude of the impact, tens of millions of people who would otherwise have gone to become regular smokers who won't. More than 8 million people who would have died prematurely between now and the end of the century who will live longer, healthier lives because they won't become addicted to cigarettes. This is because of the potential generational effect of such a product standard, were we to do it. And by the generational effect, what we mean and what the modeling reflects is, kids will always engage in risky behavior. But future generations of kids who will experiment with cigarettes, we can't stop them from experimenting, would only be able to engage and experiment with a cigarette that wouldn't be capable of creating and sustaining addiction. And were that to happen, that's where you get this demonstrable public health impact at a population level.

And we understand that, literarily, the online version of the paper is now available on the New England Journal Website for all to see.

But, so, that's what we're trying to get at with the modeling numbers, Matt.

Matt Perrone: One quick question, can you talk a little bit about, if nicotine is naturally in tobacco, I believe. What is the process like to, to get the levels down to what you're talking about? Does it, do growers have to do something different? Is it strictly up to the manufacturers?

Mitch Zeller: So, that's one of the important questions that we're seeking comment on. How to go about implementing such a product standard, were we to go forward with a proposed and final rule. And in this advanced notice of proposed rulemaking, we share all of the information that we have on hand now about what we know about how it could be done. And understand, it already has been done.

From the last 20 plus years, time and again in the previously unregulated marketplace, tobacco companies have put very low nicotine cigarettes on the market. But basically, you can reduce nicotine levels through tobacco blending and cross-breeding, you can reduce nicotine levels through chemical extraction, and you can reduce nicotine levels through genetic engineering. It's all been done over time and those are the ways that we are aware of, where nicotine levels can be taken down.

Matt Perrone: Okay. Thank you.

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

Coordinator: Thank you. Rob Stein from NPR, you may go ahead.

Rob Stein: Yes. Thanks for taking my questions.

So, I was just, was wondering if you could give us an idea of what the possible new maximum nicotine levels might be, what they might look like? What, for example, I see in

the announcement that you're particularly interested in comments about nicotine levels in the range of 0.3 to 0.5. Why, are those, is that the scenario you're looking at most closely? And then, are those the numbers that produced that scenario that they laid out of, cutting the smoking rate to 1.4 percent?

Mitch Zeller: Again, so, Rob, not to pre-judge any possible proposed rule that we would do or any possibly level. Again, that's the purpose of an advanced notice of proposed rulemaking. But we share all the science that we are aware of and we characterize the studies that have been done to date in trying to find out what that right level is, as promising in the advanced notice of proposed rulemaking.

And the dosing studies that have been done on specially manufactured test cigarettes that had cigarettes at varying nicotine levels, so that researchers could study one of the most important, unintended consequences from such a policy. Which is, what if we pick the level that wasn't low enough, so that it actually enabled smokers to compensate by either smoking more cigarettes, inhaling more deeply, holding -- the same kind of behavior that we have come to understand too late over time, occurred with the marketing of light cigarettes in the unregulated marketplace, and there is promising research but we're sharing all the evidence in the ANPRM about the studies that have been done. And as you said, we're particularly interested in comments on nicotine level in cigarettes in the range of 0.3, 0.4, 0.5 milligrams, and that's only based upon our reading of the existing published literature that is out there.

Obviously, this would be one of the key issues that we would have to address in any subsequent rule making.

Rob Stein: And in which of those numbers was used, though, produce an absolute scenario that you talked about? That, you know, cutting the rate that would result in cutting the rate to 1.4 percent, you know?

Mitch Zeller: So, purely for research purposes to drive the model ...

Rob Stein: Yes.

Mitch Zeller: Not with any eye towards regularity policy ...

Rob Stein: Yes.

Mitch Zeller: The level of 0.4 was used.

Rob Stein: That was it. Okay. Thanks.

Mitch Zeller: But folks should not read anything in that. That's why we're asking critical questions about what the right level is in the ANPRM.

Rob Stein: Great. Thank you very much.

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

Coordinator: Thank you. Tom Howell from the Washington Times. You may go ahead?

Tom Howell: Hey, that's for doing the call.

Just want to know if you kind of give me a big picture, status report, of where the government stands in its fight against tobacco use? Specifically, just, how much progress has been made since 2009, when FDA got new authorities and how much of an acceleration do you think this rulemaking might give you in that fight?

Mitch Zeller: The federal government, for decades, has had a comprehensive approach to tobacco control, that, prior to Congress passing the law that added product regulation to the mix, had the tried and true approach to public education, clean indoor air, excise taxes, and the funding of efforts at the state and local level. And over the decades that that approach has been tried, smoking areas, adult, and youth smoking rates, have consistently declined, and they have continued to decline since the passage of the Family Smoking Prevention and Tobacco Control Act in 2009.

The additive effect of product regulation is already coming into play. With the resources that we have, especially when it comes in the area of public education, our public educational efforts have independently resulted in preventing 350,000 kids who would otherwise have gone to become smokers, from going down that pathway. The modeling results here show the powerful generational impact of a product standard, where we to continue with the rulemaking here, to drive nicotine levels down in cigarettes to a minimally or non-addictive level.

But it's really a comprehensive approach where product regulation, if you will, now has a seat at the table. So, we are putting this ANPRM out at a time when fortunately, overall smoking rates have continued to go down, despite all that progress. As the Commissioner said in his remarks, tobacco use primarily because of cigarettes, and primarily because of how highly addictive cigarettes are -- with all that progress, tobacco use remains the leading cause of preventable disease and death, both in the country, and in the world.

And so, we're taking a long and hard look at these powerful regulatory tools to see what difference we can make.

Michael Felberbaum: Great. Thank you. Operator, can we take the next question, please?

Coordinator: Thank you. Angelica Lavito from CNBC. You may go ahead?

Angelica Lavito: Hey there. Thanks for taking the question today.

I wonder if you could add any details on when we could expect the next ANPRMs on the flavors and the premium cigars?

Dr. Scott Gottlieb: We said in a statement today that they're going to be issued very soon. I think imminently is the fair word. They've cleared the Office of Management and Budget and OIRA. So, if you look in the system that tracks regulations and ANPRMs as they're moving through the system, you'll see that all three have cleared. We chose to announce today the ANRPM related to nicotine, but I think you can expect the other components of this very soon.

Angelica Lavito: Okay. And then, could you add any additional details on that now, especially the flavors? I know that's been sort of a hot topic, especially with the menthol.

Dr. Scott Gottlieb: We want you to call into our next media call.

Angelica Lavito: Right.

Dr. Scott Gottlieb: Thanks.

Michael Felberbaum: Thank you, Operator. We have time for one last question?

Coordinator: Thank you. Angel Abcede from Convenience Store Petroleum Magazine. You may go ahead?

Angel Abcede: Yes. Thank you. Can you clarify the timeframe for which this review process is for the nicotine levels in cigarettes as my initial question?

Mitch Zeller: I'm not sure, sir, what you mean by review process.

Angel Abcede: I mean, the ANPRM.

Dr. Scott Gottlieb: The rulemaking process?

Angel Abcede: Yes. The rulemaking process. Can you, what is this, what expectation of a timeframe is followed by this?

Mitch Zeller: We don't do, legally, we're not to pre-judge what, how long this will take, or what will happen. But this is an early step in what could be a potential rulemaking process using the product standard authority. We'll take a long and hard look at all the comments that come in over the next 90 days. And based upon our review of all the information, all the comments that come in, all the feedback that we have, we will then make a decision about taking the next step in the rulemaking process. It would be very hard to speculate as to how much time that would take.

Anna Abram: And as the first step, there's a 90-day commentary being provided for this ANPRM.

Angel Abcede: Okay. And my follow up is during this process, what happens to products already in the marketplace and new product introductions? What, below all of that, the stuff that you're going with nicotine levels in cigarettes, what happens to all the product innovation and the stuff that's going out into the marketplace right now?

Mitch Zeller: Nothing. Nothing. This has absolutely no impact on currently marketed products and this has no impact on the pre-market review of new products.

Angel Abcede: Okay. Thank you.

Michael Felberbaum: Thank you.

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 website for the Commissioner's statement. If you have any follow-up questions, please don't hesitate to contact the Office of Media Affairs.

Thank you very much.

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

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