

Transcript of FDA Media Briefing on Proposed New Required Health Warnings with Color Images for Cigarette Packages and Advertisements to Promote Greater Public Understanding of Negative Health Consequences of Smoking

Moderator: Michael Felberbaum

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11 a.m. ET

Coordinator: Hello and thank you for standing by. I'd like to let all participants know that today's call is being recorded. If you have any objections you may disconnect at this time.

You've been placed on listen-only mode until the question and answer session of today's call. If you would like to ask a question please press star 1. Please make sure that your phone is unmuted as well so I can announce you for your question. Thank you and you may begin with your host, Mr. Michael Felberbaum.

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 Office of Media Affairs here at FDA.

This is a media briefing regarding the FDA's proposed new required health - cigarette health warnings. By now the press release on this announcement has been issued.

Today I'm joined by Acting FDA Commissioner Dr. Ned Sharpless and Mitch Zeller, director of the FDA's Center for Tobacco Products, who will discuss some of the details of today's announcement who will discuss some of the details of today's announcement.

After the remarks we will then move to the question and answer portion of the call. Reporters on the call will be in listen-only mode until we open up the call for questions.

As a reminder this call is being recorded. When asking a question please state your name and affiliation. Also please ensure questions pertain to today's announcement and 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. Sharpless.

Norman Sharpless: Thank you Michael. Good morning and thank you for taking the time to join us today to discuss this important announcement. Today the FDA issued a proposed rule to require new cigarette health warnings on cigarette packages and in advertisements to promote greater public health understanding of the negative health consequences of smoking.

The proposed warnings feature photo-realistic color images depicting some of the lesser-known but serious health risks of cigarette smoking. These new warnings stand to represent the most significant change to cigarette labels in more than 35 years.

As a cancer doctor and researcher, I am well aware of the staggering toll inflicted on the public health by tobacco products which cause cancer, heart disease, stroke, emphysema and many other medical problems.

While most people assume in this day and age that the harms of cigarette smoking are pretty well understood by the public this is not true. In fact, a substantial fraction of youth and adult smokers as well as non-smokers are surprisingly unaware of many of the risks of smoking.

While these proposed new cigarette health warnings - with these new proposed health cigarette warnings we have an enormous public health opportunity to increase the public's understanding of the full scope of the serious negative health consequences of cigarette smoking, and there's a lot at stake to ensure the public understands these risks.

About 34 million adults and nearly 1.4 million youth age 12 to 17 years in the United States smoke. Additionally, tobacco use remains the leading cause of preventable death and disease in the United States and is responsible for about 480,000 deaths every single year.

Health warnings first appeared on cigarette packages in 1966 and were most recently updated in 1984 to include the surgeon general's warnings that appear on packages and in advertisements today.

However, research shows that these warnings have become virtually invisible to both smokers and non-smokers. The unchanged content of these health warnings as well as their small size, location and lack of an image all impair their ability to convey relevant

information about the negative health consequences of cigarette smoking in an effective way to the public.

Additionally, research shows substantial gaps remain in the public's knowledge of the harms of smoking, and smokers have misinformation regarding cigarettes and the products' negative health impacts.

For example, consider bladder cancer, an important and highly morbid human malignancy. While many people are aware that smoking causes lung cancer, research has shown that the public is generally not aware of the very strong link between bladder cancer and smoking.

In fact, current smokers have nearly four times the risk of bladder cancer compared to people who have never smoked. It has been estimated that smoking is responsible for approximately 5000 deaths from bladder cancer alone in the US each year.

Some of the other risks highlighted in the proposed warnings include diabetes and conditions that cause blindness. This proposal when finalized would fulfill a requirement in the Family Smoking Prevention and Tobacco Control Act and complement additional important work the FDA is undertaking to advance the health of American families.

We remain committed to educating the public and especially America's youth about the dangers associated with using cigarettes and other tobacco products. And now I'll turn the call over to Mitch who will provide some more specific details of the proposed rule.

Mitch Zeller: Thank you Dr. Sharpless. Cigarette packages and advertisements can serve as an important channel for communicating health information to both smokers and non-smokers.

In fact, daily smokers potentially see warnings on cigarette packages more than 5,100 times per year, and all members of the public including adolescents are exposed to cigarette advertisements in print and digital media as well as in and around stores where cigarettes are sold.

However, as you heard from Dr. Sharpless, the Surgeon General warning that appear on packages and in ads today have become virtually invisible to both smokers and non-smokers.

And while the public is generally aware of the conditions mentioned in these older warnings such as lung cancer, to address gaps in public understanding of other health risks, the FDA undertook a science-based approach to develop and evaluate the 13 new proposed cigarette health warnings we're announcing today.

Participants in FDA's final consumer research study reported that the information provided by the proposed cigarette health warnings was both new to them, and that they learned something from the proposed warnings when compared to the current surgeon general warnings on cigarette packs and in ads.

So 15 months following issuance of the final rule these new cigarette health warnings would appear prominently on cigarette packages and in ads. In particular, the warnings would occupy the top 50% of the area on the front and rear panels of cigarette packages and at least 20% of the area at the top of cigarette advertisements.

In conclusion, the FDA took the necessary time to get these new proposed warnings right by developing distinct and clear messages about the lesser-known negative health consequences of smoking.

We are especially encouraged that the comprehensive science-based research and development process we implemented on these new proposed warnings demonstrated improved understanding of these risks among both youth and adults and smokers and non-smokers.

Well thank you for your time and with that we'd be happy to take your questions.

Michael Felberbaum: Thank you Mitch. At this time, we'll 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 ensure questions pertain to today's announcement and 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. Operator we'll take the first question please.

Coordinator: Yes the line is open for Angelica Lavito. Ma'am you can go ahead and ask your question.

Angelica Lavito: Hello. This is Angelica Lavito through CNBC. I'm just wondering why do you think this rule will stand up in court? It's likely to be challenged. Why does this one have a better chance than the previous one?

Norman Sharpless: Yes, Angelica thanks for the question. We have thought carefully about the prior district court ruling and used science to drive this present decision.

I'll let Mitch comment on the specifics of the legality of this particular proposal.

Mitch Zeller: Sure. The mandate in the statute is clear and that is we have an obligation to put out a rule that depicts the negative health consequences of smoking. We learned a lot from what happened the last time around and we took the time through the research to get this right.

And these 13 images and text warnings including some new text warnings - because recall the last time that these warnings were updated was 35 years ago and there's a much longer list of diseases and conditions associated with cigarette smoking than was the case back in 1984.

We think we've gotten it right. The rulemaking process is important. We want to hear from all interested parties. If we are sued after we issue a final rule, we strongly believe that this will hold up under any legal challenges under the First Amendment, under our statute or under the administrative procedure.

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

Coordinator: Yes, next question comes from Matt Perrone from the Associated Press.

Matthew Perrone: Hi gentlemen. Thanks for taking questions. What if any impact do you think this will have on the national smoking rate? Is that part of what you're proposing the benefit is here?

Mitch Zeller: We started by looking at what the statute says, and the statute says that we have a mandate, an obligation, to improve the public's understanding of the negative health consequences of cigarette smoking.

That is the governmental interest here and when we did the research, and even going back to the diseases that got added to the list since our first rulemaking between 2010 and 2011, the list is even longer.

And what we learned from the research is that, while the public generally understands that cigarette smoking is dangerous, there are significant gaps in their understanding of all of the diseases and conditions associated with cigarette smoking.

You heard the Acting Commissioner talk about bladder cancer. It's a longer list of diseases and conditions that the public is really unaware of, and so the governmental interest here is to improve the public's understanding of the negative health consequences of smoking.

And what was so reassuring from the research that we've done, which informed why we came up with these 13, is that across the board adults, kids, smokers, non-smokers - this was new information to all of them and that's the goal here to improve the public's understanding of the negative health consequences of smoking.

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

Coordinator: Yes sir. And again if you would wish to ask a question over the phone, please press star 1. Thank you. Next question comes from Arthur Allen from Politico.

Arthur Allen: Yes hi. Thanks for taking this call. What - my question is, you know, I'm curious as to whether just some iteration of all the different cause, you know, possible health threats will have as big an impact as making sure that the images are very graphic I guess.

I mean, I don't know. I mean, is there a - how do you decide, you know, what level of sort of graphicness or, you know, disgust that these ads would sort of impair, you know, cause in someone looking at them?

The other real quick question I had is can you say which diseases or conditions you've added since you did the earlier elaboration of the list? Thanks.

Normal Sharpless: So as stated the government interest here is in educating the public about these lesser-known causes, and the ads are intended to be compelling but educational in a way that will, you know, increase the public understanding of these issues. I'll let Mitch provide the specific list of new things added.

Mitch Zeller: So just a couple of comments on the images themselves. The research is clear that when you look at the current warning in capital letters, in small print, on the side of cigarette packs, as you've heard us both say, they're virtually invisible.

The point of combining color graphics with either some of the statutory warnings or new text warnings that the law absolutely gives us the right to propose and finalize is to call the public's attention to as you heard the Acting Commissioner say the less-known conditions.

And these 13 images combined with the text warnings are the ones that emerged from all of the qualitative and quantitative research that we did as having the best chance of closing that knowledge gap.

And we look forward to all the comments that will come in from all interested parties on this between now and October 15. We will review all of the comments with an eye towards which of these images and warnings should make their way into a final rule.

As to the list of diseases the 2014 50th anniversary surgeon general's report added diabetes, erectile dysfunction and conditions that can cause blindness, macular degeneration and cataracts to the list.

There is a much longer list of diseases that got added between 1984 and the 50th anniversary report in 2014 by the surgeon general, but three of the conditions and diseases that we are highlighting today and that are embedded in these images were added to the list in 2014.

Arthur Allen: You - you're sort of shying away from talking about sort of what effect the, I mean, you were - you're talking about informing the public. How do you factor in, you know, how you

inform the public, I mean, whether you inform them by shocking them or just by giving them additional information? Sort of - and is that an issue that has to be legally considered with care?

Mitch Zeller: We have come up with a proposed set of images and text warnings to achieve the fundamental governmental interest here, which is to improve the public's understanding of the negative health consequences of cigarette smoking.

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

Coordinator: Yes, next question comes from Arden Farhi from CBS News.

Arden Farhi: Hi there. Thanks for doing the call. I had a question about involvement from HHS and the White House. Were they - was Secretary Azar or anyone from the White House involved in making - creating this proposal?

Norman Sharpless: The White House and the Department have been fully briefed on this topic and are very supportive of our efforts to promote a greater understanding of the negative health consequences of smoking.

Mitch Zeller: And the only thing that I would add is just the process issue, which is anything like this has to be cleared all the way through the Department and the White House, and as the Acting Commissioner said that happened and it came with the support along the way.

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

Coordinator: Yes, the last question comes from Nikole Killion from CBS Newspath.

Nikole Killion: Hi. Thanks for doing the call. I just wanted to know, you know, more specifically - obviously I realize this has been tied up in court for some time but, you know, why did this take so long?

I mean, you're saying this is like the first time in 35 years that, you know, these labels have been updated. And also if you don't face any court challenges and this rule is approved, when would these new labels hit the store shelves?

Mitch Zeller: So we are currently under a court order to issue a final rule by March of next year, and by law the rule would go into effect 15 months after any final rule - not going to make any predictions about the likelihood of litigation.

One of the reasons why we are where we are today in terms of proposing this in the summer of 2019 is we took a run at this as the law mandated with a first final rule that came out in 2011.

The tobacco industry sued and they got that final rule overturned. We began the work on the research to inform this proposed rule roughly in the middle part of 2013 after there was an appellate decision that the government decided not to take to the Supreme Court.

And as you heard me say we took the time to get this right so that we had when this is final the strongest set of combination of color graphics and text warnings to advance this fundamental governmental interest, which is to improve the public's understanding of the negative health consequences of smoking.

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 Web site for the press release.

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

Coordinator: That concludes today's conference. Thank you for joining and have a great day. You may disconnect at this time.

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