Operator: Welcome, and thank you for standing by. I would like to inform all participants that your lines have been placed on a listen-only mode until the question-and-answer session of today’s call.

Today’s call is also being recorded. If anyone has any objections, you may disconnect at this time. I would now like to turn the call over to Michael Felberbaum. Thank you, you may begin.

Michael Felberbaum: Good morning, and thank you for participating in today’s call. My name is Michael Felberbaum. I’m with the Office of Media Affairs, here at FDA. This is a media briefing regarding the FDA’s new adult smoking cessation education campaign: “Every Try Counts.”

By now, the press release on this announcement has been issued. Today, I’m joined by FDA Commissioner Dr. Scott Gottlieb, and Mitch Zeller, director of the FDA’s Center for Tobacco Products, 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 a listen-only mode until we open up 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.

Dr. Scott Gottlieb: Thank you, Michael, and good morning, and thank you all for taking your time to join us today.
Today we’re delighted to announce the FDA’s newest public education campaign: “Every Try Counts,” which builds on our comprehensive plan on tobacco and nicotine to reduce disease and deaths from combustible cigarettes.

Before I turn it over to Mitch to take us through the details of this latest campaign, I’d like to take a moment to share why I believe our public education efforts, like the one we’re announcing today, are such a foundational part of our efforts to reduce the enormous public health burden of tobacco use, and cigarette smoking, in particular.

Cigarette smoking remains, as many of you know, the leading cause of preventable disease and death in the United States, and is responsible for an estimated 480,000 deaths each year. Cigarettes are also the only legal consumer product that, when used as is intended, will kill half of all long-term users.

While we’ve seen declining rates of use, 15 percent -- about 36 million -- adults in the U.S. still smoke, and of those adult smokers, approximately 2 out of 3 say they’d like to quit.

Cigarettes are designed to create and sustain addiction, which is why only a small fraction of adult smokers who attempt to quit are successful. These are unacceptably high statistics and why we must do all we can through both public health and policy efforts to change course.

“Every Try Counts” is an adult smoking cessation education campaign that aims to encourage cigarette smoker to quit, through messages of support that underscore the health benefits of quitting.

The campaign hopes to be an encouraging voice to help more adult smokers try to quit. The campaign is focusing these positive messages at smokers, aged 25 to 54, who’ve tried to quit smoking in the last year but were unsuccessful.

Building upon the individual-level successes we hope to see from “Every Try Counts,” the FDA is working hard to advance our comprehensive plan for tobacco and nicotine regulation that we announced last July.
Our approach places nicotine and the issue of addiction at the center of the agency’s tobacco regulatory efforts. A centerpiece of our comprehensive regulatory plan is acknowledging that nicotine, while highly addictive, is delivered through products on a continuum of risk, and it’s the delivery mechanism, not the nicotine itself, that’s truly the issue at hand.

On one end of the spectrum, when nicotine is delivered through a medicinal product, such as therapeutic gums, lozenges and patches, it can be found so safe and effective, the FDA doesn’t even require a prescription for them.

However, it’s the other end -- the combustible cigarette -- where nicotine’s delivery vehicle leads to incredible amounts of disease and death. As I said in July, we’re at a unique moment in history, with profound new tools to address the devastating public health burden of cigarette smoking.

Our aim is to render combustible cigarettes minimally or non-addictive, while encouraging the development of potentially less-harmful tobacco products for adults who still want or need access to nicotine.

At the same time, we’re also taking new steps to improve access to and use of FDA-approved medicinal nicotine products to help smokers quit. While we work to put these policies in place, the “Every Try Counts” campaign is here today to offer encouraging words to addicted smokers at one of the most critical places, the point of sale. We look forward to the campaign launching next month.

And with that, it’s my pleasure to turn things over to Mitch, who will provide additional details on the campaign, including the research behind its targeted strategy.

Mitch Zeller: Thank you, Scott.

We are thrilled to be announcing the “Every Try Counts” campaign today. It’s truly a unique effort to help adult cigarette smokers to successfully quit through a motivation-based approach.
“Every Try Counts” speaks to celebrate each quit attempt as a positive step toward success. And that’s because research shows those who have tried quitting before are more likely to try again. And those who have tried to quit multiple times have a high likelihood of quitting for good.

Based upon the insights from this research, we have come up with encouraging and empowering messages such as, “You didn’t fail at quitting, you just haven’t finished the process,” and “If at first you don’t succeed, try, try, try, try again.”

In our research, smokers had an incredibly positive response to these types of messages. In addition to the positive messaging, location plays an important and unique role in the campaign.

The tobacco companies have long used advertisements at gas stations and convenience stores to promote their product. Studies show that in-store displays and other tobacco advertisements can trigger unplanned cigarette purchases, making quitting even more difficult than it already is.

According to the Federal Trade Commission, tobacco companies spent more than $8 billion on advertising and promotional expenditures in 2015, and industry data suggests that 86 percent of total cigarette sales occur at convenience stores.

The campaign ads that we’re announcing today will be placed in various locations at the point-of-sale, including at the gas pump and other places around the retail environment, such as the front door, the cash register and the shelves.

We believe placing ads in those same locations where so many cigarette purchases occur will help to disrupt the urge to buy a pack of cigarettes and encourage another quit attempt instead.

In addition to the ads in tobacco retail settings, the campaign will also feature print, digital, radio and out-of-home ads, such as billboards. The two-year campaign will launch in 35 markets next month. These markets were selected based on smoking preference, smoking population and the availability of media properties in the point-of-sale environment.
FDA has also partnered with the National Cancer Institute to create a brand new website, EveryTryCounts.gov, to provide focused resources and tools to help with quitting.

This new website includes a free text message program that sends tips and offers words of encouragement, a mobile app to track smoking triggers, trained coaches accessible online or by phone, and information about the risks of smoking and the variety of FDA-approved smoking cessation products.

We’re very proud of this campaign, and the important role that we play in FDA’s ongoing efforts to reduce the enormous public health burden of tobacco use.

With that, we’d be happy to take your questions.

Michael Felberbaum: And 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 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.

Operator: Thank you. We will now begin the question-and-answer session. Please press Star-1 if you would like to ask a question, and please speak clearly and promptly. Thank you. One moment for the first question.

One moment for the first question. Matt Perrone, your line is open, with Associated Press.

Matt Perrone: Will this campaign make any mention of some of these alternate products that are out there now -- for example, snus, or electronic cigarettes?

The FDA’s been talking a lot about this continuum of risk, and I think it seems to be suggesting that some of these other products might have a role in helping people, but I’m just wondering, you know, specifically, are you going to be guiding people to those or mentioning those in any way?
Mitch Zeller: Well, thanks for the question, Matt. This is a laser beam focus on encouraging cigarette smokers to make another quit attempt. And yes, we’ve had a lot to say over the past months about issues related to harm reduction and the continuum of risk, but this is a cigarette cessation public education campaign.

And the kinds of tools and resources that will be available at the EveryTryCounts.gov website are things like access to FDA-approved medicinal products that are safe and effective, many of which are available without a prescription.

There’s a time and a place for the harm reduction discussion and the continuum of risk debate, but this is trying to reach smokers at a place where they’re very vulnerable to an impulsive cigarette purchase, to try to send an encouraging message about not buying that pack of cigarettes and making another attempt to quit.

Matt Perrone: Okay.

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

Operator: Thank you. Next is Angel Abcede with Convenience Store Petroleum Magazine. Your line is open.

Angel Abcede: Yes, hello. So, my question is how do you decide which convenience stores the ads will go in? What’s that process? Are you going to pay for ad space, or - and if so, how can retailers get involved?

Mitch Zeller: So, as we said, we’re going to be in 35 markets that were picked based upon smoking prevalence, smoking population and access to places to place the media. And yes, these are all paid ads.

And we have worked through a media buying agency that we understand has already selected the outlets where these variety of messages are going to be placed in 35 different markets.
Kathy, I don’t know if you have anything that you want to add. Kathy Crosby from our Office of Health Communication and Education.

Kathy Crosby: No, that’s accurate.

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

Operator: Next, we have Beth Wang with Inside Health Policy. Your line is open.

Beth Wang: Hi. Thanks for taking my question. I was wondering, the press announcement says that the user fees from the tobacco industry are going to be used to create all of this, for this campaign.

I was wondering if you could go into a little more detail about that, as I know they are typically used for hiring of resources at the agency, so I was wondering if you could tell me a little bit more about how it’s going to be used for the campaign. And what part is it?

Mitch Zeller: Sure, by law, all of the agency’s program expenses are paid by industry user fees, which are really a market-share assessment placed on companies, based upon their market share within the categories of tobacco products named by statute as having to basically pay for the budget of the Center for Tobacco Products at FDA.

As with all other programmatic investments, we are 100 percent user-fee funded, so these are not taxpayer-appropriated dollars that will be used to purchase this media at retail. These are industry user fees.

Beth Wang: Okay. Thank you.

Operator: As a reminder, if you would like to ask a question, please press Star-1, and ensure your name and affiliation is recorded. One moment. There’s no further questions at this time.

Michael Felberbaum: Thank you, Amanda.
Ladies and gentlemen, this concludes the 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 press release, and if you have any follow-up questions, please don’t hesitate to contact FDA’s Office of Media Affairs. Thank you.

Operator: That concludes today’s conference. Thank you for participating. You may disconnect at this time.

END