FDA Supports Novel Nicotine Replacement Therapies to Help Smokers Quit Cigarettes

Our ultimate goal is to help more smokers completely quit cigarettes.

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Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps the agency is taking to support the development of novel nicotine replacement drug therapies to help smokers quit cigarettes

As a public health agency, there is no greater impact we can have to improve the health of our nation than to significantly reduce the rate of tobacco-related disease and death. Through the U.S. Food and Drug Administration's comprehensive framework for regulating nicotine and tobacco, we're developing policies that support the possibility of a world where combustible cigarettes could no longer create or sustain addiction. A key part of this framework are steps to pave the way for products that help currently addicted smokers move away from the deadliest form of nicotine delivery.

Part of this work requires that we recognize that nicotine, while highly addictive, is delivered through products posing a continuum of risk – with combustible cigarettes at one end, to nicotine replacement therapy (NRT) products at the other. We're working on multiple fronts to recognize the role that more novel forms of nicotine delivery could play in achieving our public health goals, as part of an appropriately regulated marketplace. This not only includes encouraging innovation of potentially less harmful tobacco products for those adults who still seek to use nicotine (such as e-cigarettes), but also taking a closer look at our overall approach to the development and regulation of NRT products that are regulated as drugs, and designed to safely reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking.

The development of novel NRT products, regulated as new drugs, is a critical part of our overall strategy on nicotine.

We know that about 70 percent of adult smokers in the U.S. want to quit. In fact, nearly half try to quit each year. But few succeed. Use of FDA-approved NRT products is generally considered to double the likelihood of a successful quit attempt (with variations between products). Our ultimate goal is to help more smokers completely quit cigarettes.

But most of the existing NRTs – such as gums, patches and lozenges – have been approved for more than 20 years. With novel forms of nicotine delivery being developed, it's possible that new kinds of NRTs – with different characteristics or routes of delivery – can offer additional opportunities for smokers to quit combustible tobacco.

We want to explore what new steps we can take using our regulatory policies to enable opportunities for innovation, while making sure these products are demonstrated to be safe and effective for their intended use.

To achieve these goals, the Nicotine Steering Committee that we established last September has been evaluating new, evidence-based opportunities to advance therapeutic nicotine products for combustible tobacco product cessation. We have been examining the types of safety and efficacy studies that we suggest be conducted and the way that these products are used and labeled. This work to re-evaluate and modernize our framework aims to provide clarity for companies seeking to avail themselves of the pathway to market safe and effective smoking cessation products.

Today, and as a result of this work, we're releasing the first of two draft guidances aimed at supporting the development of novel, inhaled nicotine replacement therapies that could be submitted to the FDA for approval as new drugs, similar to current over-the-counter pharmaceutical NRT products. The guidance, "Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products," focuses on data recommended to evaluate potential toxicities associated with orally inhaled nicotine-containing drug products. This includes products such as electronic nicotine delivery systems like e-cigarettes that are intended for smoking cessation and other long-term uses that would make them subject to regulation as drugs.

This is draft guidance. We're interested in public comment. We want to strike the right balance between enabling a viable, efficient path for these products to be regulated as drugs – where we have substantial tools to evaluate their safety and efficacy for their intended use as smoking cessation products. At the same time, we want to make sure we're asking sufficient questions about the long-term health effects of these inhaled products, especially their effect on the lungs, to ensure that they are safe for their intended use. This information will help FDA advance this new guidance.

This draft guidance, when finalized, is aimed at providing sponsors with recommendations on the nonclinical information appropriate to support development and approval of orally inhaled nicotine-containing drug products. It recognizes that a great deal of toxicity information is available for nicotine. But such information may not be available for other compounds contained in e-liquids and delivered by these products. These include the flavorings and heat-generated chemicals. These products can be used for six months or more over the course of a lifetime. So, it's important to understand the risks to humans from these exposures, including developmental and reproductive toxicity and carcinogenicity.

We anticipate releasing the second draft guidance this fall. This second guidance will help lay out a framework for new potential clinically relevant outcomes for smoking cessation products, such

as reducing the chance of a smoker going back to using cigarettes long term and showing a positive impact on certain measures of cardiovascular health.

That future guidance also is expected to address potential alternative treatment regimens like pre-treatment before quit day, quitting by gradual reduction (reduce-to-quit), or using two NRT drug products together.

These guidances are one part of larger policy efforts to address the public health crisis of tobacco usage in this country. Given some of these products are relatively new technologies, or innovations that haven't yet been through the product development and evaluation process, we'll be seeking input on these draft guidances and welcome feedback on whether we've struck the right balance between innovation and safety; and set the right framework to encourage companies to use the new drug pathway to bring novel NRT products to market, with our public health mission leading the charge.

This work is aimed at creating a more flexible framework that enables the development of safe and effective product innovations that have the potential to be helpful in assisting smokers quit combustible cigarettes and improve their health.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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