Advancing Medicinal Nicotine Replacement Therapies as New Drugs – A new step in FDA's comprehensive approach to tobacco and nicotine

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By FDA Voice

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As the leading cause of preventable disease and death in the United States, tobacco causes more than 480,000 deaths every year. To address this devastation, earlier this year FDA announced a new regulatory plan to lower this burden of tobacco-related disease and death. The plan takes a comprehensive approach to nicotine and tobacco, including an initiative to lower nicotine in cigarettes to minimally addictive or non-addictive levels. Aimed at shifting the trajectory of tobacco-related disease and death, the agency's approach recognizes that nicotine is delivered through products posing a continuum of risk. This ranges from combusted cigarettes at one end, to nicotine replacement therapy (NRT) products – designed to safely reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking – at the other.

Today, FDA is taking an additional step in our new, comprehensive approach to the regulation of nicotine and tobacco. We are announcing the formation of a new Nicotine Steering Committee that will be charged with re-evaluating and modernizing FDA's approach to development and regulation of nicotine replacement therapy products that help smokers quit. These products are typically sold as over-the-counter drugs in the form of gums, patches and lozenges.

Scott Gottlieb, M.D., is Commissioner of the U.S. Food and Drug Administration

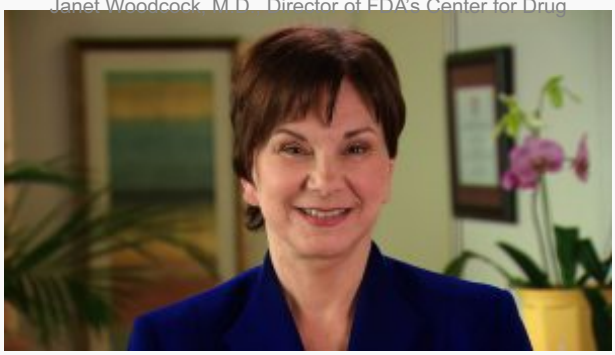
The primary focus of the new Committee will be on these therapeutic nicotine products for combustible tobacco product cessation. This reflects the need to critically examine the evolving science behind FDA's evaluation of the safety and efficacy of NRTs. Key topics will be the types of safety and efficacy studies we require and the way these products are used and labeled.

The aim is to make sure FDA has the right policies in place to enable the development of product innovations that have the potential to be more helpful in helping smokers quit combustible cigarettes and maintain abstinence. This could include changes to the labeling and indications for existing products or a new product that might deliver nicotine at different rates, or through different delivery mechanisms entirely. To enable innovation, FDA might contemplate additional approaches to developing these products, including new clinical trial endpoints.

This new Committee will include Senior Agency Leadership from the Center for Tobacco Products, the Center for Drug Evaluation and Research, and the Office of the Commissioner. While one significant focus will be on NRT, the mandate of this committee will be to address the FDA's overall approach to nicotine. It will create a forum for developing and implementing nicotine policy and regulation to address the public health crisis of tobacco usage in this country.

Among adult smokers in the U.S., around 70% report that they want to quit. Nearly half try to quit each year, and few succeed. Many treatment-seeking smokers often use medications such as NRTs. FDA has approved nasal

spray and inhaler NRTs for prescription-only use; and gum, transdermal patch and lozenge formulations for over-the-counter (OTC) sale. In addition, FDA has also approved pharmacological therapies to aid in smoking cessation.


Janet Woodcock, M.D., Director of FDA's Center for Drug Evaluation and Research

FDA has found these therapeutic products to be safe and effective in helping smokers quit. Using approved NRTs is generally considered to double the likelihood of a successful quit attempt, with variations between products. While most existing NRTs have been approved for over 20 years, novel forms of nicotine delivery are being developed based on new technologies and innovations. These may develop into FDA-approved therapies that help more smokers quit.


Mitchell Zeller, J.D., Director of FDA's Center for Tobacco Products

When it comes to the discussion around transitioning current smokers to safer alternatives for the delivery of nicotine, a lot of public debate, to date, has been placed on the potential for modified risk tobacco products like electronic nicotine delivery systems and e-cigarettes. FDA also sees compelling opportunities to explore additional opportunities for the development of new and improved products that can be sold as new drugs, typically as over-the-counter pharmaceuticals.

If there are new kinds of NRTs — with different characteristics or routes of delivery – that can offer additional opportunities for smokers to quit combustible tobacco, we want to explore what steps we can take using our own regulatory policies to enable these opportunities, while making sure these products are demonstrated to be safe and effective for their intended use.

We'll be joined on the Nicotine Steering Committee by Rachel Sherman, M.D., M.P.H., Principal Deputy Commissioner, who will chair the Committee; Grail Sipes, J.D., Director, Office of Regulatory Policy, CDER; Melissa A. Robb, B.S.N., M.S., Associate Commissioner for Clinical Policy, Office of Medical Products and Tobacco (OMPT); Allison Hoffman, Ph.D., Associate Director for Health Science, OMPT; and Priscilla Callahan-Lyon, M.D., Deputy Director, Division of Individual Health Science, CTP.

Public participation will be central to the Committee's discussions. As the Committee's first action, we've scheduled a public hearing on Jan. 26, 2018, to consider FDA's Approach to Evaluating Nicotine Replacement Therapies. We encourage those interested to join the discussion on this important topic, including stakeholders from the public health community, researchers, health care professionals, manufacturers, and industry and professional organizations. FDA believes it is critical to obtain input from the public on how evolving science could influence the agency's approach to evaluating the safety and effectiveness of NRT products.

FDA's approach to the regulation of nicotine is a key element of its efforts to address crises of addiction that are impacting families. The nicotine in cigarettes doesn't directly cause tobacco-related cancer, lung disease, or heart disease. But the powerfully addictive nature of the delivery of nicotine in combustible cigarettes makes tobacco use the leading cause of preventable death in the United States. So FDA is putting nicotine at the center of our regulatory strategy.

We're taking steps to render combustible cigarettes minimally- or non-addictive. This could prevent future generations of kids from becoming addicted to cigarettes, the deadliest form of nicotine delivery. At the same time, FDA is committed to the proper development of products that can allow adults who still need or want to enjoy satisfying levels of nicotine to get it through products that don't have all of the risks associated with the combustion of tobacco. Our goal is to enable greater use of safe and effective options to help those who are

addicted to nicotine get the help they need to quit combustible cigarettes altogether.

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