

FDA to Consider Whether and How to Lower Permissible Nicotine Levels in Cigarettes

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On March 15, 2018, the U.S. Food and Drug Administration (FDA) issued an advance notice of proposed rulemaking (ANPRM) entitled *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes*. FDA states that it is considering setting a maximum nicotine level for traditional (a.k.a. “combusted”) cigarettes in order to make them minimally addictive or nonaddictive. This notice begins what could be a complex, contentious, and multi-year process during which FDA will solicit public comments (the public comment period for the initial ANPRM will expire on June 14, 2018) and marry that feedback with its own expertise, evidence, and conclusions to decide whether and how to set such a limit.

FDA is pursuing this process due to the potentially significant public health benefit associated with lowering nicotine levels in cigarettes. According to FDA, “lowering nicotine to a minimally or non-addictive level could potentially save millions of lives, both in the near and long-terms.” The Centers for Disease Control and Prevention estimates that cigarette smoking in the United States results in 480,000 deaths every year, or about 1 in 5 U.S. deaths.

The ANPRM includes findings from an FDA-funded study, “Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States,” published in the March 2018 issue of the *New England Journal of Medicine*, which suggests that a nicotine-lowering product standard could result in 5 million additional adult smokers quitting smoking within the first year of implementation. The study also projects that by 2100, more than 33 million people could avoid becoming regular smokers, resulting in more than 8 million fewer tobacco-caused deaths.

FDA is seeking comments on several matters regarding lowering nicotine levels in cigarettes, including whether any standard to reduce nicotine levels should be limited to cigarettes or include other combustible tobacco products and how maximum nicotine levels should be measured. Also of interest to FDA are whether any standard to reduce nicotine levels should take immediate effect or be phased in—and possible unintended consequences of a new standard, such as causing addicted smokers to smoke

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more in order to obtain the level of nicotine they desire from lower-yield products.

FDA Looks at Cigarettes Along a Spectrum of Risk

Over the past year, FDA has been considering a regulatory framework for tobacco and nicotine-containing products (i.e., drugs and tobacco products) to achieve maximum public health benefit by incentivizing the use of the least harmful products along a continuum of risk. According to FDA Commissioner Dr. Scott Gottlieb:

[O]ur plan demonstrates a greater awareness that nicotine, while highly addictive, is delivered through products on a continuum of risk, and that in order to successfully address cigarette addiction, we must make it 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 maximize any public health benefits and minimize their harms.

In publishing the ANPRM, FDA says it plans to assess how this approach fits into its broader risk strategy. If a product standard were put in place, FDA and other stakeholders involved in tobacco control (e.g., industry, health providers, advocates, taxing authorities) could make decisions about whether and how to incentivize (positively or negatively) the use of lower-nicotine cigarettes compared to medicinal nicotine, noncombustible electronic cigarettes, or total abstinence. These incentives—not all of which are within FDA's authority—could involve regulatory approval pathways, marketing and advertising statements, and the price or taxation structures for different products.

The publication of the ANPRM takes place at a time when FDA is trying to balance competing concerns and potential opportunities with respect to products such as electronic cigarettes. On one hand, FDA is assessing the appeal of electronic cigarettes to youth and their potential for nicotine addiction and progression to using other tobacco products (including traditional cigarettes). On the other hand, FDA is looking at the potential of electronic cigarettes (or other electronic nicotine delivery systems) to serve as less harmful alternatives to traditional, combusted tobacco products such as cigarettes by adults.

Why Not Eliminate Nicotine from Cigarettes Entirely?

Aptly, one author has said, "People smoke for nicotine but they die from the tar." Congress provided FDA's authority to regulate tobacco products in 2009 in the Family Smoking Prevention and Tobacco Control Act (P.L. 111-31). The law allows FDA to regulate the levels of tar, nicotine, and other harmful components in tobacco products and to establish appropriate tobacco product standards. The law places limits on FDA's authority, including prohibiting FDA from "banning all cigarettes," although the law does permit FDA to take actions in specific circumstances if, for example, a specific product is considered to be misbranded (i.e., false or misleading labeling) or adulterated. The law also expressly prohibits FDA from requiring the reduction of nicotine levels in a tobacco product to zero. As a result, FDA proposes in the ANPRM to exercise its authority within the discretion it was given under the law to establish a nonzero nicotine standard—a standard that, while not zero, could be set at a level that FDA determines to be nonaddictive or at a low risk of resulting in nicotine addiction.

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