FDA Announces Plan to Lower Nicotine in Cigarettes

Agency says new limits could help avoid millions of tobacco-related deaths.

March 15, 2018 By Food and Drug Administration (FDA)

Statement from FDA Commissioner Scott Gottlieb, M.D., on pivotal public health step to dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or non-addictive levels

When I returned to the U.S. Food and Drug Administration last year, it was immediately clear that tackling tobacco use – and cigarette smoking in particular – would be one of the most important actions I could take to advance public health. With that in mind, we're taking a pivotal step today that could ultimately bring us closer to our vision of a world where combustible cigarettes would no longer create or sustain addiction – making it harder for future generations to become addicted in the first place and allowing more currently addicted smokers to quit or switch to potentially less harmful products. As part of our comprehensive plan on tobacco and nicotine regulation announced last summer, we're issuing an advance notice of proposed rulemaking (ANPRM) to explore a product standard to lower nicotine in cigarettes to minimally or non-addictive levels. This new regulatory step advances a comprehensive policy framework that we believe could help avoid millions of tobacco-related deaths across the country.

Despite years of aggressive efforts to tackle the leading cause of preventable disease and death in the United States, tobacco use – largely cigarette smoking – still kills more than 480,000 Americans every single year. Tobacco use also costs nearly $300 billion a year in direct health care and lost productivity. In fact, cigarettes are the only legal consumer product that, when used as intended, will kill half of all long-term users. Given their combination of toxicity, addictiveness, prevalence and effect on non-users, it's clear that to maximize the possible public health benefits of our regulation, we must focus our efforts on the death and disease caused by addiction to combustible cigarettes.

The ANPRM being issued today provides a wide-ranging review of the current scientific understanding about the role nicotine plays in creating or sustaining addiction to cigarettes and seeks comments on key areas, as well as additional research and data for public review, as we continue our consideration of developing a nicotine product standard. We're interested in public input on critical questions such as: what potential maximum nicotine level would be appropriate for the protection of public health? Should a product standard be implemented all at once or

gradually? What unintended consequences – such as the potential for illicit trade or for addicted smokers to compensate for lower nicotine by smoking more – might occur as a result? As we explore this novel approach to reducing the death and disease from combustible cigarettes, it's critical that our policies reflect the latest science and is informed by the input we receive from our meetings with stakeholders, comments to the open public docket and future opportunities for comment.

We believe the public health benefits and the potential to save millions of lives, both in the near and long term, support this effort. Notably, new estimates included in the ANPRM that are being published in the New England Journal of Medicine evaluate one possible policy scenario for a nicotine product standard. If this scenario were implemented, this analysis suggests that approximately 5 million additional adult smokers could quit smoking within one year of implementation. And with this scenario, an even greater impact could be felt over time: by the year 2100, the analysis estimates that more than 33 million people – mostly youth and young adults – would have avoided becoming regular smokers. And smoking rates could drop from the current 15 percent to as low as 1.4 percent. All told, this framework could result in more than 8 million fewer tobacco-caused deaths through the end of the century – an undeniable public health benefit.

No statistical model can truly capture the full impact of this effort – including the joy from years of quality life gained with a loved one, or how much pain and suffering would be avoided for millions of families across the country. But what we're learning about the significant public health promise of this approach leaves me encouraged and optimistic. Our estimates underscore the tremendous opportunity to save so many lives if we come together and forge a new path forward to combat the overwhelming disease and death caused by cigarettes. And this unprecedented public health opportunity, contrasted against the cost of doing nothing, weighs heavily on me.

We're at a crossroads when it comes to addressing nicotine addiction and smoking in this country – with important new tools to address this devastating public health burden. And although a potential nicotine product standard for cigarettes is the cornerstone of our approach, we also continue to push forward on additional pieces of the FDA's multi-year plan designed to work in concert to better protect kids and significantly reduce tobacco-related disease and death. We said from the outset that ours was a comprehensive approach that requires us to pursue all of its parts in tandem.

For example, our 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. This will be achieved through our ongoing regulatory work to develop several foundational rules, guidances, product standards and other regulations. At the same time, we plan

to take vigorous enforcement steps to make sure that tobacco products aren't being marketed to kids, including e-cigarettes. No youth should use a tobacco product.

In addition, as we advance our framework to protect public health in the evolving tobacco marketplace, the FDA also plans shortly to issue two additional ANPRMs: one to seek comment on the role that flavors – including menthol – play in initiation, use and cessation of tobacco products. A second ANPRM will solicit additional comments and data related to the regulation of premium cigars. At the same time we're also jump-starting new work to re-evaluate and modernize our approach to the development and regulation of safe and effective medicinal nicotine replacement products such as nicotine gums, patches and lozenges that help smokers quit. This is a pivotal part of our overall public health approach.

Finally, we also plan to take new steps to make sure that our policies and processes for the regulation of tobacco products are efficient and predictable, and consistent with the mandate Congress gave us under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). We're committed to making sure that we have transparent regulatory policies and best practices in place to maximize our public health impact. To these ends, we plan to issue a series of foundational rules and guidance documents that will delineate key requirements of the regulatory process, such as the demonstration of substantial equivalence and the submission of applications for new tobacco products. We also plan to release soon a framework for how we'll address the so-called provisional substantial equivalence applications. These are for products that entered the market during a grace period set up in the law and for which companies submitted reports to demonstrate that the new product has the same characteristics as a predicate product, or has different characteristics, but such differences do not cause the new product to raise different questions of public health. These "provisional" products can remain on the market unless the FDA finds them not substantially equivalent. Our new framework aims to provide more clarity by delineating between individual provisional applications which the FDA intends to continue to review to reach a final determination on whether they can remain on the market and those provisional applications that the agency does not intend to review further and which can continue being sold.

All of these efforts complement our ongoing work to educate kids about the dangers of all nicotine-containing products, limit youth access and encourage adults to quit smoking cigarettes.

We believe this unprecedented approach to nicotine and tobacco regulation not only makes sense, but also offers us the best opportunity for achieving significant, meaningful public health gain. As we move forward with these efforts, we have an opportunity to more formally solicit feedback, and we'll continue to foster a public dialogue to re-shape our country's relationship with nicotine and seek public input on policies that will guide us toward a healthier future.

Today's ANPRM is a significant step in our efforts to confront nicotine addiction in combustible cigarettes. This milestone places us squarely on the road toward achieving one of the biggest public health victories in modern history and saving millions of lives in the process.

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.

This press announcement was originally published on February 15 on the Food and Drug Administration website.

© 2026 Smart + Strong All Rights Reserved.

http://beta.docker.cancerhealth.com/blog/fda-announces-plan-lower-nicotine-cigarettes