AACR Backs FDA Effort to Decrease Nicotine Content in Certain Tobacco Products

The FDA's proposed rule would limit the amount of nicotine in certain combusted tobacco products to non-addictive or minimally addictive levels.

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PHILADELPHIA – The American Association for Cancer Research (AACR) today [November 6] released a policy statement in support of a rule proposed by the U.S. Food and Drug Administration (FDA) that would limit the amount of nicotine in certain combusted tobacco products to non-addictive or minimally addictive levels. The policy statement, written by the AACR Tobacco Products and Cancer Subcommittee, was published in the AACR journal Clinical Cancer Research.

Chronic use of tobacco products is driven by nicotine, a highly addictive chemical present in tobacco. Sustained, long-term tobacco use is the leading preventable cause of 18 cancer types and premature death in the United States. While all nicotine products are dangerous to individuals who use them, combusted tobacco products, including cigarettes, present the greatest risk of harm.

AACR has long supported the FDA's proposed rule. In 2018, AACR submitted a public comment to the FDA's Advanced Notice of Proposed Rulemaking supporting a tobacco product standard that would limit the maximum nicotine level in cigarettes to minimally or non-addictive levels. In 2022, the FDA announced its intent to issue a proposed rule on this topic. The rule was formally proposed in January 2025. If finalized, the rule would reduce nicotine levels in cigarettes and other selected products by approximately 95%.

Rigorous clinical trials have demonstrated that combusted tobacco products with very low nicotine content encourage smoking cessation. Indeed, an FDA analysis determined that, if the rule were finalized, 12.9 million additional people who smoke would quit smoking within the first year, 19.5 million would quit within five years, and 1.8 million deaths would be avoided by 2060.

"This rule is supported by a vast body of research," said AACR Tobacco Products and Cancer Subcommittee Member Dorothy Hatsukami, PhD, a professor of psychiatry and behavioral sciences at the University of Minnesota and the corresponding author of the AACR policy statement.

“Numerous clinical trials have shown that reducing the amount of nicotine in cigarettes to very low levels decreases smoking and dependence on the cigarette and increases quit attempts and quit rates. There is also a lot of research that shows that this rule can help people who smoke from all walks of life and that the occurrence of negative consequences is likely to be minimal.”

The AACR policy statement also proposes additional supporting policies that would magnify the impacts of the FDA rule, including increased access to nicotine replacement therapies to help facilitate quitting, continued support for federal tobacco control programs, track and trace programs to prevent the growth of illegal cigarette markets, and sustained and broad communication efforts to inform the public of policy changes.

“The main message of our paper is that the United States has the potential for a watershed moment, where we can truly affect public health on a massive scale to reduce the burden of cancer in this country,” said AACR Tobacco Products and Cancer Subcommittee Member Benjamin Toll, PhD, co-author of the AACR policy statement and director of the Tobacco Treatment Program at the Medical University of South Carolina. “Implementing this nicotine product standard is probably the single biggest action that we could do to improve public health for decades to come.”

An interview with Hatsukami and Toll about the AACR policy statement, the FDA’s proposed rule, and strategies to reduce tobacco use is available on Cancer Research Catalyst, the official blog of AACR.

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