

NIH and FDA Leaders Call for Innovation in Development of Smoking Cessation Treatments

Engagement across stakeholders is critical to accelerate smoking cessation and reduce smoking-related disease and death.

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In [a new commentary](#) in the Annals of Internal Medicine, leaders at the National Institutes of Health (NIH) and U.S. Food and Drug Administration (FDA) highlight recommendations and opportunities to promote innovation in research and development of smoking cessation therapies, for which there is an urgent need.

The authors provide an update on regulatory pathways for smoking cessation treatment, as well as an overview of innovative therapeutic targets, research gaps, and opportunities. They emphasize that active engagement across clinicians, academia, industry, public health, patient advocacy groups, and other stakeholders is critical.

Cigarette smoking kills nearly 500,000 Americans each year, and over 28 million adults currently smoke in the United States. Though most adults who smoke report that they want to quit, only 31% of those interested in quitting receive counseling and/or medications, and less than 8% effectively quit each year.

The commentary authors highlight recommendations to address these gaps, including from [FDA's 2023 nicotine replacement therapies guidance](#). To spark greater innovation in the development of smoking cessation products, the authors highlight the importance of considering meaningful study endpoints in addition to abstinence in smoking cessation trials. For instance, clinically meaningful reductions in smoking, especially if such reductions increase the probability of eventual cessation.

The authors also emphasize the urgent need for greater research on e-cigarettes, including on long-term health outcomes and rigorous toxicology studies. In addition, they discuss ongoing initiatives at NIH and FDA that aim to facilitate innovative research on smoking cessation, including among groups that have been historically underrepresented in research trials.

The commentary is publishing in advance of an [FDA and NIH Joint Public Meeting on advancing smoking cessation priorities](#), which is being held on Monday, Oct. 21, from 9 a.m. to 4:30 p.m.

EDT. [Registration for the meeting is available here.](#)

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