The public health impact of the FDA's request for additional safety data on cytisine for tobacco cessation

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Center at Massachusetts General Hospital and an Associate Professor of Medicine at Harvard Medical School, is the lead author of a study in *JAMA Health Forum*, titled "Public Health Impact of FDA's Request for Additional Safety Data on Cytisine for Tobacco Cessation".

Nancy Rigotti, MD, director of the Tobacco Research and Treatment Center, is senior author of the study.

Tobacco smoking is the leading preventable cause of death in the US. No new tobacco cessation medication has been licensed in the US since 2006.

Cytisine, a plant-based medication, has been used to treat tobacco dependence for decades in other countries. It is available as a generic or prescription medication in at least 18 countries, was licensed as an over-the-counter natural health product in Canada in 2017 and became available by prescription in the UK in January 2024.

In the US, however, it is neither approved for use nor commercially available. The US FDA has requested additional data supporting the safety of cytisine, delaying its review and potential approval by at least one year.

In the study, researchers developed a model that accounted for current rates of smoking cessation and relapse, life expectancy gains from smoking cessation at different ages, and how cytisine could increase smoking cessation rates among some people.

They found that making cytisine available immediately could lead approximately 71,000 more people to quit smoking over one year and maintain long-term abstinence. This would create more than 500,000 additional life-years. Each additional year of delay in the availability of cytisine might reduce the population-level gains by 10,000 life-years.

Therefore, say the authors, a timely review of cytisine for approval in the US is warranted.

More information: Krishna P. Reddy et al, Public Health Impact of FDA's Request for Additional Safety Data on Cytisine for Tobacco Cessation, *JAMA Health Forum* (2024). DOI: 10.1001/jamahealthforum.2024.2647