

'The FDA, e-cigarettes, and the demise of combusted tobacco'

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The popularity of E-cigarettes could lead to the "demise" of cigarette smoking and save thousands of lives, but not until they are proven safe and are regulated by the U.S. Food and Drug Administration (FDA). That's the message from two Georgetown University Medical Center researchers in a perspective piece published Oct. 16 in the *New England Journal of Medicine*.

In "The FDA, E-Cigarettes, and the Demise of Combusted Tobacco," Nathan K. Cobb, MD, and David B. Abrams, PhD, call on the FDA "to accelerate their regulations to eliminate uncertainty regarding safety, drive the substitution and use of clean [nicotine](#), and hasten the demise of lethal combusted tobacco."

The authors point out that some published studies of e-cigarette devices suggest that they can be as safe and effective as [nicotine replacement therapy](#) (NRT) products such as gum, patches and inhalers that are regulated by the FDA.

However, the authors explain that the "safety of individual devices cannot be assumed" because of "various chemicals and aerosolization techniques resulting in variable nicotine and contaminant delivery."

In addition to the FDA regulation of e-cigarettes, Cobb and Abrams suggest the agency use its authority to "cripple the addictive potential of lethal combusted products by mandating reduction of nicotine levels to below those of e-cigarettes and NRT products and eliminating

flavorings." They also advocate for minimizing taxes on NRT while increasing taxes on cigarettes.

Finally, Cobb and Abrams call on the FDA's Center for Drug Evaluation and Research to streamline the approval process and remove regulatory burdens for companies willing to invest in research and development of clean-nicotine products like e-cigarettes.

"If e-cigarettes... are thoughtfully regulated, they could play the same role as NRT, but at a truly national population scale. Their use could shift smokers permanently away from lethal cigarettes to cleaner, safer nicotine products, saving innumerable lives," they conclude.

More information: *New England Journal of Medicine*. [DOI: 10.1056/NEJMp1408448](https://doi.org/10.1056/NEJMp1408448)

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