



September 15, 2025

Martin A. Makary, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

Bret Koplow, Ph.D  
Acting Director  
Center for Tobacco Products  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

Dear Commissioner Makary and Acting Director Koplow,

We write to express our continued support for the Food and Drug Administration's (FDA) proposed rule to establish maximum nicotine levels in cigarettes and other combusted tobacco products. This bipartisan rule would create a groundbreaking standard to cap nicotine levels at rates 95% lower than most products currently on the market— helping millions of Americans to quit smoking and saving future generations from a lifetime of addiction.<sup>1</sup> We urge you to move swiftly to finalize the rule and remain steadfast in your commitments to protect public health.

Despite years of progress, smoking remains the leading cause of preventable death in the United States, claiming the lives of approximately 480,000 Americans every year.<sup>2</sup> Additionally, it costs the country more than \$600 billion in health care costs and lost productivity annually.<sup>3</sup> With that said, nearly 70 percent of adults who smoke reported wanting to quit smoking<sup>4</sup>, but nicotine is a highly addictive chemical that makes cessation incredibly challenging. Therefore, it is no surprise that less than 1 in 10 adults who smoke cigarettes succeed in quitting each year.<sup>5</sup> This rule is a pivotal chance to address one of the root causes of the problem. As you know, the

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<sup>1</sup> Crosby, Kathy. "Proposal to Lower Nicotine Levels Represents Historic Steps Forward for Public Health." Truth Initiative. January 16<sup>th</sup>, 2025. <https://truthinitiative.org/press/press-release/proposal-lower-nicotine-levels-represents-historic-step-forward-public-health>

<sup>2</sup> "Tobacco." Center for Disease Control and Prevention. Accessed September 9, 2025. <https://www.cdc.gov/tobacco/about>

<sup>3</sup> "Tobacco Economic Trends." Center for Disease Control and Prevention. Accessed September 9, 2025. <https://www.cdc.gov/tobacco/php/data-statistics/economic-trends>

<sup>4</sup> "Smoking Cessation." Center for Disease Control and Prevention. Accessed September 9, 2025. <https://www.cdc.gov/tobacco/php/data-statistics/smoking-cessation>

<sup>5</sup> Ibid.

Family Smoking Prevention and Tobacco Control Act allows FDA to require tobacco companies to reduce the nicotine content of cigarettes to nonzero levels<sup>6</sup>, and given the negative health impact of nicotine addiction, it is critical that the agency uses every tool at their disposal to make them as minimally and non-addictive as possible.

It is no secret that the tobacco industry has a long history of manipulating loopholes—to prevent unintended consequences, FDA should consider applying the new nicotine standard to all combustible and heated tobacco products. Doing so would help prevent tobacco manufacturers from circumventing the standard by developing or promoting non-cigarette substitutes. Not including some combustible tobacco products and heated tobacco products from the nicotine standard would reduce the benefits of the rule.

As you know, scientific evidence shows that early exposure to nicotine can be extremely harmful. Capping nicotine levels could benefit millions of Americans by significantly reducing smoking rates and preventing younger generations from becoming addicted to begin with.<sup>7</sup> By FDA's own estimates, this rule could prevent more than 48 million youth and young adults from initiating smoking by 2100 and prompt 12.9 million people who smoke to quit within one year of the rule being finalized.<sup>8</sup>

We know that nicotine is the primary addictive agent in cigarettes and other tobacco products. We know that significantly reducing nicotine levels in cigarettes reduces smoking and increases quitting. And we know that it is technologically feasible to reduce nicotine levels in tobacco products. That is why it is so critical for FDA to act quickly.

We urge you to finalize the rule as soon as possible to give Americans a fighting chance against the destructive grip of nicotine addiction.

Sincerely,



Richard Blumenthal  
United States Senator



Jeffrey A. Merkley  
United States Senator

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<sup>6</sup> Bach, Laura. "Reducing Nicotine in Cigarettes will Reduce Addiction and Save Lives." Campaign for Tobacco Free Kids. April 22, 2024. <https://assets.tobaccofreekids.org/factsheets/0395.pdf>

<sup>7</sup> <https://www.axios.com/2025/01/07/biden-administration-nicotine-rule-tobacco>

<sup>8</sup> "FDA Proposes Significant Step Toward Reducing Nicotine to Minimally or Nonaddictive Level in Cigarettes and Certain Other Combusted Tobacco Products." U.S. Food and Drug Administration. January 15, 2025. <https://www.fda.gov/news-events/press-announcements/fda-proposes-significant-step-toward-reducing-nicotine-minimally-or-nonaddictive-level-cigarettes>



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Richard J. Durbin  
United States Senator



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Kirsten Gillibrand  
United States Senator



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Jack Reed  
United States Senator



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Andy Kim  
United States Senator