

**Comments of Anne DiGiulio – As Prepared for Delivery**  
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**For: FDA and NIH Joint Public Meeting on Advancing Smoking Cessation Priorities**  
**October 21, 2024**

Hello, my name is Anne DiGiulio. I'm the Senior Director of Nationwide Tobacco Cessation and Health Policy at the American Lung Association.

The Lung Association believes that everyone who uses and is addicted to tobacco products can quit, not just switch to another tobacco product. Our mission is to save lives by improving lung health and preventing lung disease. And one of our four strategic imperatives is to create a tobacco-free future. Helping people quit their addiction to tobacco is both integral to our mission and is of the utmost national importance. Almost a half a million people die each year from a tobacco related disease and over 16 million people in the United States live with a tobacco-caused illness.<sup>1</sup> And while new data shows a decline in tobacco use among youth, 10.1% of high school students or 1.58 million students use tobacco products. These numbers show an urgent need for more FDA-approved tobacco cessation treatments for adults and efficacious, FDA-approved cessation treatments for kids.

Data show that approximately two-thirds adults who smoke want to quit.<sup>2</sup> This holds true across demographics. Unfortunately, these data also show that people who smoke did not frequently use medication in their quit attempt and were not ultimately successful at quitting tobacco.

While the desire to quit is consistent among adults in the United States, despite differences in socioeconomic status, education and race, the burden of tobacco use is not even. For example, lower income people in the United States, use tobacco at a significantly higher rate than their wealthier counterparts.<sup>3</sup> FDA and NIH need to understand the disparities that exist related to tobacco use and ensure any action taken reduces these disparities and does not exacerbate them.

The Lung Association urges FDA to take the following steps:

1. FDA can consider new indications for cessation products and consider labeling changes for existing cessation products. These can include combination use, Longer-term use of cessation products and pre-quit use of cessation products as part of a “reduce to quit” regimen.
2. FDA should take affirmative steps to explore alternatives to long-term clinical trials for promising new cessation products or for new indications for existing cessation products where sufficient evidence is available to meet both safety and efficacy.
3. FDA needs to establish criteria for use of accelerated pathways for approval for promising cessation drugs. This is especially important given the fast-changing landscape of commercial nicotine products, including e-cigarettes and pouches. Additionally, Congress has directed FDA to consider treating cessation products as fast track research and approval products at an applicant's request.<sup>4</sup> FDA should establish these criteria so potential applicants have a clear understanding of the process.
4. FDA should consider modifying its organizational structure by moving cessation products from CDER's Division of Anesthesia, Analgesia and Addiction to another office, such as one

that has experience with evaluating treatments caused by tobacco use, such as the Office of Hematology and Oncology Products.

Additionally, NIH has an important role to play. The Lung Association encourages the NIH to prioritize research on effective cessation treatment for youth. Tobacco use is unsafe for kids, and unfortunately, many are currently addicted to tobacco. NIH has an important role to play in this space.

The danger of not doing anything is millions of people in the United States, including kids, continuing to use tobacco products, including cigarettes, and suffer from the death and disease they cause. Action from today's meeting by FDA and NIH could help realize the promise of the President's Cancer Moonshot and address the epidemic of tobacco use our country faces.

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<sup>1</sup> [Cigarette Smoking | Smoking and Tobacco Use | CDC](#)

<sup>2</sup> VanFrank B, Malarcher A, Cornelius ME, Schechter A, Jamal A, Tynan M. Adult Smoking Cessation — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:633–641.

DOI: <http://dx.doi.org/10.15585/mmwr.mm7329a1>

<sup>33</sup> Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. MMWR Morb Mortal Wkly Rep 2023;72:475–483. DOI: <http://dx.doi.org/10.15585/mmwr.mm7218a1>

<sup>4</sup> 21 U.S.C. 387r.