American Lung Association.

March 26, 2025

Michael Silverstein, M.D., M.P.H.
Chairperson
U.S. Preventive Services Task Force
5600 Fishers Lance Mail Stop 06E53A
Rockville, MD 20857

Re: Draft Research Plan – Tobacco Cessation in Adult: Interventions

Dear Dr. Silverstein and Members of the Task Force:

The American Lung Association appreciates the opportunity to provide comments on *Draft Research Plan – Tobacco Cessation in Adults: Interventions*.

The American Lung Association is the oldest, voluntary public health organization in the United States and is committed to eliminating tobacco use and tobacco-related disease. Tobacco use is the leading cause of preventable death and disease in the United States, responsible for the deaths of 490,000 Americans annually.[1] An additional 16 million Americans live with a disease cause by tobacco.[2]

The Lung Association supports the work of the United States Preventive Services Task Force as it reviews the evidence for tobacco cessation for adults, including individuals who are pregnant. The new recommendation could help adults in the United States end their addiction to tobacco. While nearly 70% of adults who smoke want to quit, less than 10% are successful.[3] More troubling that that, data show that just over 50% of those individuals who smoke received advice to quit from a healthcare professional and only 38.3% used medication or counseling in a quit attempt.[4] The United States Preventive Services Task Force recommendations encourage providers to advise their patients to quit tobacco using evidence-based treatment. In order for the recommendations to be successful, it is important that the research plan adequately defines both tobacco use and cessation.

The *Draft Research Plan's* proposed analytical framework defines tobacco use as: "use of cigarettes, cigars, dissolvables, hookah tobacco, nicotine gels, pipe tobacco, roll-your-own tobacco, smokeless tobacco products including dip, snuff, snus, and chewing tobacco, and e-cigarettes, vapes, and other electronic nicotine delivery systems (ENDS)." This list does not include popular emerging products, including oral nicotine pouches. The Lung Association believes the definition of tobacco use should be expanded to include oral nicotine pouches. This would cast a wider net, with the potential of helping more people end their addiction.

The *Draft Research Plan's* proposed contextual questions excludes the question, "What factors are associated with disparities in access to and utilization of tobacco cessation interventions?" The Lung Association recognizes that access to and utilization of tobacco cessation is not the subject of this recommendation, however the burden of tobacco use is not felt evenly across populations. If there are differences in treatment outcomes discovered during the research process, those should be noted in the final recommendation.

The Lung Association commends the *Draft Research Plan's* proposed research approach for excluding any study with the aim of harm reduction. Harm reduction is not cessation and the

Lung Association appreciates the Task Force recognizes the difference. The Lung Association hopes that this important distinction guides the Task Force's work on tobacco cessation. There is a lot of misinformation about so called, harm reduction products, it is vital that the Task Force provide clear evidence on safe and efficacious cessation treatment.

In the proposed Analytical Framework, the Lung Association suggests that oral nicotine pouches be included in tobacco use. While their use is still relatively small (less than 1% of adults report daily use), their popularity is increasing.[5] From 2019 to 2022, sales of these products increased by 641%.[6] If there are randomized clinical trials for cessation of oral nicotine pouches, they should be included in the research plan, as part of the proposed Research Approach.

The proposed Research Approach excludes studies where 50% or more of the participants have co-morbidities, including individuals with chronic obstructive pulmonary disease (COPD) and cancer. This is misguided. COPD and many types of cancer are frequently caused by smoking and tobacco use.[7] Quitting can improve these patients' health outcomes. For example, studies show that cancer patients who quit smoking have improved prognosis, including reducing mortality.[8] The National Institutes of Health's Cancer Center Cessation Initiative (3CI) specifically looked at tobacco cessation for patients in active cancer treatment.[9] People with comorbidities use tobacco and want to quit. It would be prudent to include them in the population studied, as they are part of the population that uses tobacco and in some cases people with co-morbidities may be over-represented in the overall population that uses tobacco.

The proposed Research Approach lists out the interventions it will test as cessation treatments. The interventions include using e-cigarettes as an intervention, which the Lung Association strongly cautions against. Evaluating e-cigarettes, a tobacco product, as a cessation treatment is completely inappropriate and not consistent with their classification by the Food and Drug Administration (FDA). *E-cigarettes are tobacco products and none have been found safe and effective to help tobacco users quit by the FDA.* The Lung Association strongly believes that only drugs and devices given approval from the FDA as a cessation drug should be included in the Research Plan.

Currently, the FDA has not found any e-cigarette product safe and effective in helping smokers quit nor has there been an application for classification of an e-cigarette product as effective for cessation. An e-cigarette manufacturer can apply to the FDA's Center for Drug Evaluation and Research to be designated as safe and effective as a cessation medication but to our knowledge, no manufacturer has done so. As such, these products should be excluded from your review until there is an FDA approval regarding safety and efficacy of them as a cessation device.

There are vast number and diversity in e-cigarette products. There is no consistency in products, and they cannot and should not be treated as a single product, but rather the thousands of unique products that they are. Many come in exotic flavors that appeal to kids. Additionally, e-cigarettes in the United States are not required to follow the same strict regulatory requirements and quality control as FDA- approved medications.

E-cigarettes are defined as tobacco products by both your own proposed Research Plan and the FDA. Entertaining e-cigarettes as an intervention for tobacco cessation is just as absurd as identifying pipe tobacco or cigars as an intervention. Using one tobacco product to quit another

tobacco product is switching, not quitting. There is also significant evidence that a number of adult e-cigarette users also use cigarettes or other tobacco products at the same time, which research is starting to show is worse for people than using either product alone[10]. This should be removed from the Research Plan when finalized.

The United States Preventive Services Task Force is an important voice in the research community. There hasn't been a new FDA-approved tobacco cessation medication in 18 years.[11] There are promising treatments, including cytisine and GLP-1 inhibitors, undergoing research into their effectiveness. The Task Force should call for more research into these emerging treatments. Healthcare providers need more tools to help patients quit tobacco for good.

Thank you for the opportunity to comment on the *Draft Research Plan – Tobacco Cessation in Adults: Interventions*. The American Lung Association looks forward to the recommendations of the Task Force.

Sincerely,

Harold P. Wimmer
President and CEO

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[1] U.S. Department of Health and Human Services. Eliminating Tobacco-Related Disease and Death: Addressing Disparities—A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2024.

[2] U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

[3] VanFrank B, Malarcher A, Cornelius ME, Schecter 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

[4] Ibid.

[5] Dai HD, Leventhal AM. Prevalence of nicotine pouch use among US adults. JAMA. 332(9):755–757. Accessed at: https://jamanetwork.com/journals/jama/fullarticle/2820917

[6] Ibid.

[7] U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

[8] Centers for Disease Control and Prevention. Cancer Care Settings and Smoking Cessation. May 15, 2024. Accessed at: https://www.cdc.gov/tobacco/hcp/patient-care-

settings/cancer.html#:~:text=For%20patients%20with%20cancer%2C%20studies,mortality%20and%20improve%20their%20prognosis.

[9] https://cancercontrol.cancer.gov/brp/tcrb/cancer-center-cessation-initiative

[10] Hamoud J, Hanewinkel R, Andreas S, et al. A Systematic Review Investigating the Impact of Dual Use of E-Cigarettes and Conventional Cigarettes on Smoking Cessation. ERJ Open Res 2024; in press (https://doi.org/10.1183/23120541.00902-2024).

[11] Drug Approval Package: Chantix (Varenicline) NDA #021928