



June 29, 2020

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Chairperson  
U.S. Preventive Services Task Force  
5600 Fishers Lane  
Mail Stop 06E53A  
Rockville, MD 20857

**Re: Draft Recommendation Statement - Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions**

Dear Dr. Krist:

The American Lung Association appreciates the opportunity to provide comments on the Draft Recommendation Statement – *Tobacco Smoking Cessation in Adults, Including Pregnant Persons: 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 480,000 Americans annually.<sup>1</sup> An additional 16 million Americans live with a disease cause by tobacco.<sup>2</sup>

In January 2020, Surgeon General Jerome Adams released *Smoking Cessation: A Report of the Surgeon General*.<sup>3</sup> One of the major conclusions of this report was that “quitting smoking is beneficial at any age,” repeating a conclusion reached 30 years previously in the 1990 Surgeon General’s report. Data show that across demographics, including age, insurance status and education level, most smokers want to quit.<sup>4</sup> This recommendation, if put into practice by providers across the country, could have a substantial impact on helping smokers quit and improving health.

Unfortunately, the Surgeon General’s Report on Smoking Cessation also found that four out of nine adult cigarette smokers who saw a healthcare professional in the past year did not receive advice to quit smoking. The Lung Association recognizes the important role of the U.S. Preventive Services Task Force (USPSTF) in getting evidence-based guidelines into the hands of clinicians to help smokers quit, however, providers need to actually advise their patients to quit to further spur quitting of tobacco use.

Non-Pregnant Adults

The American Lung Association agrees with the “A” grade given to the recommendation that:

*“Clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration (FDA)--approved pharmacotherapy for cessation to adults who use tobacco.”*

Tobacco use is the leading cause of preventable death and disease in the United States. The Surgeon General found that clinicians are not consistently advising smokers to quit. This recommendation is based upon the available evidence and will help smokers quit.

This recommendation, if followed consistently by clinicians, has great potential to save lives and money. A recent study found that if there was just a one percent reduction in the adult smoking rate, Medicaid expenditures would decrease by \$2.5 billion the following year.<sup>5</sup>

Additionally, as the Task Force is aware, the Affordable Care Act (ACA) requires all preventive services for which USPSTF gives an 'A' or 'B' recommendation to be covered in ACA-compliant private health insurance plans and Medicaid expansion plans. The American Lung Association would like to call the Task Force's attention to the problems translating recommendation summaries and the 'A' grade for tobacco cessation in all adults into insurance coverage requirements.

Tobacco cessation is somewhat different from many of the other preventive services the Task Force evaluates. We recognize that USPSTF puts out clinical, not insurance guidelines; however, because of the ACA, the guidelines must be able to be translated into coverage. Many other prevention services are easily translatable. For example, if the Task Force gives an 'A' to a cancer screening for a particular population, it is obvious that insurance companies and Medicaid programs must cover that cancer screening for that population. Tobacco cessation is different, in that there are ten different treatments recommended in the Public Health Service Guideline *Treating Tobacco Use and Dependence* and in USPSTF's own draft recommendation statement. The previous USPSTF recommendation indirectly applies to multiple treatments with no clarity on which of these treatments are included in the ACA requirement for health insurance.

As the Task Force is aware, in May 2014, the U.S. Department of Health and Human Services, Labor and Treasury issued an ACA implementation FAQ addressing the preventive services requirement for tobacco cessation coverage. The FAQ, available at [https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca\\_implementation\\_faqs19](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19), provided some clarity about some of the problems in translating the USPSTF recommendation into insurance coverage requirements. The insurance benefit presented in the FAQ is a comprehensive benefit. The Departments also state that plans may use "reasonable medical management techniques" to determine the frequency, method, treatment or setting for a recommended preventive service. The Departments also present the detailed benefit as an example of compliance. The FAQ was an encouraging step towards obtaining access to a comprehensive tobacco cessation benefit for all tobacco users; however, clarification is needed that compliance requires the health plan or issuer to cover all FDA approved tobacco cessation medications and types of counseling without cost sharing.

In summary, the actual tobacco cessation experience of patients, clinicians and public health groups in the years since preventive services were required to be covered by the ACA and tied to USPSTF recommendations continues to have problems. Emphasizing that all ten treatments are considered first line treatments as well as listing out all ten treatments would help ensure all adult smokers have access to the treatment they need to quit smoking.

The draft recommendation also lacks concrete methods for encouraging providers to counsel patients on the importance of quitting tobacco. The recommendation should include specific steps, including modifications to provider practice that better encourage cessation. Providers should incorporate health impacts of quitting tobacco, including a lower risk of severe case of COVID-19, as they counsel patients to quit.

### Pregnant Persons

The recommendation for pregnant persons is divided into two grades. There is an “A” grade that all pregnant persons receive advice to quit and behavioral interventions. The Lung Association supports this recommendation.

The recommendation also has an “I” grade for pharmacotherapy interventions for pregnant persons. We recognize that there is scant evidence on the benefits and harms of pharmacotherapy cessation interventions on both pregnant persons and fetuses; however, there is a body of evidence on the harms of smoking on both pregnant persons and fetuses. This body of evidence should not be discounted. The interpretation of the existing data appears very conservative given the long experience with tobacco products and their known health effects.

The Lung Association encourages USPSTF to bolster the language around shared decision making between a clinician and a pregnant person when quitting smoking. The decision to use pharmacotherapy should be based on an individual patient’s smoking history and medical history. Language should be included in the recommendation to support the unique challenges of quitting tobacco during pregnancy.

### E-Cigarettes

The USPSTF’s recommendation for use of e-cigarettes as a cessation device is an “I” grade. 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. The American Lung Association encourages USPSTF to remove this grade and solely classify e-cigarettes as tobacco products that have yet to be studied as cessation devices for approval by the Food and Drug Administration (FDA).

In the draft recommendation, tobacco products are defined to include e-cigarettes. The Lung Association believes this is the appropriate place for these products and is their current designation following the deeming process undertaken by the Center for Tobacco Products of the Food and Drug Administration.

There are many flaws in the Draft Evidence Review<sup>6</sup> regarding e-cigarettes. First, the document acknowledges the 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.

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. As part of the Draft Research Plan<sup>7</sup>, medications not approved by FDA as first line cessation treatments are excluded. 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. The review of e-cigarettes as a cessation device and draft recommendation are at odds with the research plan.

E-cigarettes in the United States are not required to follow the same strict regulatory requirements and quality control as FDA- approved medications. As a result, these products can have unintended consequences, including the EVALI outbreak in 2019 and 2020 that lead to

2,807 hospitalizations or deaths.<sup>8</sup> While there is a strong link between EVALI cases and the additive vitamin E acetate, some patients used products from commercial sources that USPSTF is evaluating in terms of cessation. This outbreak illustrates the need to exclude products that do not have FDA approval. There are very dangerous unintended consequences due to the lack of regulation and quality control standards.

Additionally, the research that was reviewed for the grade on e-cigarettes is flawed. First, only four studies were included. Their designs were varied and the findings are mixed. All four were conducted outside of the United States, with vastly different regulatory systems for tobacco products and health systems. There is no reason to believe that the results would be applicable in the United States, with its particular regulatory system. There was also no evidence presented to show how the results would be replicable in the United States healthcare system. Secondly, at least one of the trials allowed participants to use the e-cigarette of their choice. As previously stated, these products vary greatly and are not consistent in their delivery of nicotine and/or other chemicals. Any study that does not look at specific products, should be considered methodologically flawed and not included in the review, given the variation among products

#### Other Considerations

Smoking is the leading cause of preventable death and disease. It is important that providers encourage their patients to quit, but even those that quit are at increased health risk, including risk of lung cancer. Former smokers are still at a higher risk of lung cancer. The American Lung Association encourages additional research to determine additional populations eligible for lung cancer screenings as USPSTF continues to re-evaluate their recommendation on lung cancer screening.<sup>9</sup>

The Lung Association also encourages USPSTF to include better information on the grading hierarchy that is being utilized. Adding this key information will help providers use the recommendation in their practice and better understand the evidence behind the recommendations.

The American Lung Association appreciates the work of the USPSTF in continuing to evaluate and publish recommendations on cessation treatment. For more than a decade there has been no new FDA-approved cessation medication for those who are addicted to nicotine. No cessation medication is approved for anything beyond addiction to cigarettes. More research and investment from the federal government is needed. Most smokers want to quit. They need to be given every opportunity to use the tools that are proven to be safe and effective. Thank you for the opportunity to submit comments on this important issue.

Sincerely,



Harold Wimmer  
National President and CEO

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<sup>1</sup> 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

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and Health Promotion, Office on Smoking and Health, 2014.

<sup>2</sup> 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.

<sup>3</sup> U.S. Department of Health and Human Services. Smoking Cessation. 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, 2020.

<sup>4</sup> Babb S, Malarcher A, Schauer G, Asman K, Jamal A. Quitting Smoking Among Adults — United States, 2000–2015. MMWR Morb Mortal Wkly Rep 2017;65:1457–1464. DOI: <http://dx.doi.org/10.15585/mmwr.mm6552a1>

<sup>5</sup> Glantz SA. Estimation of 1-Year Changes in Medicaid Expenditures Associated With Reducing Cigarette Smoking Prevalence by 1%. JAMA Netw Open. 2019;2(4):e192307. doi:10.1001/jamanetworkopen.2019.2307

<sup>6</sup> United States Preventive Services Task Force. Draft Evidence Review: Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions. June 2, 2020, Accessed at: <https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-evidence-review/tobacco-smoking-cessation-in-adults-including-pregnant-women-interventions>

<sup>7</sup> United States Preventive Services Task Force. Draft Research Plan: Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions. March 15, 2020. Accessed at: <https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-research-plan/tobacco-smoking-cessation-in-adults-including-pregnant-women-interventions>

<sup>8</sup> Centers for Disease Control and Prevention. Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products. February 25, 2020. Accessed at: [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html)

<sup>9</sup> United States Preventive Services Task Force. Final Recommendation Statement: Lung Cancer Screening. Dec 31, 2013. Accessed at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening>