May 30, 2018

Susan J. Curry, Ph.D.
Chairperson
U.S. Preventive Services Task Force
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

Dear Dr. Curry:

The American Lung Association is pleased to have the opportunity to provide feedback to the U.S. Preventive Services Task Force (USPSTF) on the "Draft Research Plan for Lung Cancer: Screening."

The American Lung Association is the oldest voluntary health organization in the United States. For more than 110 years, the Lung Association has been working to save lives by improving lung health and preventing lung disease through education, advocacy and research. The Lung Association works on behalf of the 33 million Americans living with lung diseases, including lung cancer.

During 2018, an estimated 234,030 new cases of lung cancer are expected to be diagnosed.[1] Lung cancer remains the leading cause of cancer death, with 148,945 deaths due to lung cancer in 2016.[2] The Lung Association strongly supports lung cancer screening for high risk populations, as we know that early detection improves the chances of survival. Lung cancer five-year survival is only five percent for those diagnosed at a late (distant) stage after the tumor has spread, but increases to 56 percent for those diagnosed at an early (local) stage before the tumor has spread.[3]

The American Lung Association's LUNG FORCE initiative and the Ad Council teamed up to create Saved By The Scan. This campaign aims to raise awareness of the benefits of early detection through lung cancer screening and drive individuals to take a lung cancer screening eligibility quiz at SavedByTheScan.org so that the approximately 8 million people in this country who are at high risk will talk to their doctor about getting screened for lung cancer. Saved By The Scan drives anyone who thinks they may be at high risk to take a lung cancer screening eligibility quiz at SavedByTheScan.org. Since the launch of Saved By The Scan in August of 2017, more than 120,000 individuals have taken the lung cancer screening eligibility quiz. Of those, approximately 90,000 individuals were found to be

at high risk and encouraged to have a discussion with their doctor about whether or not they should be screened.

The Lung Association supports the USPSTF's systematic review of the literature on lung cancer screening as the USPSTF prepares to update its recommendation statement on this topic and overall supports the proposed draft research plan and approves of its mostly comprehensive scope. To help guide the development of the research plan, the Lung Association has consulted with our scientific advisors and provides the following comments and recommendations that we believe could benefit the research plan.

The Lung Association is concerned that the analytic framework is overly focused on the harms of the screening process, both overall and at each step. While it is important to consider the risks and harms of screening, it is misleading to do so disproportionately to, and at the cost of, the benefits. The experience of large institutions who have implemented screening, such as the Lahey Clinic, shows the positive impact of a fully implemented program. At Lahey, screening has been found to cause a stage shift in lung cancer detected. In 2011, prior to program implementation, 44 percent of lung cancer were found at an early stage. Their now well-established screening program (which started in Jan 2012) now has screened 5,000 people and found 167 lung cancers; over 80 percent were found at an early stage, with 70 percent found at Stage I. Almost 80 percent of lung cancers found are adenocarcinoma. This work demonstrates the positive impact of lung cancer screening.[4]

The Lung Association also recommends that certain variables be added to the research plan. First of all, the type of healthcare site (e.g. academic center, cancer center, large tertiary care center versus community based radiology groups) should be included as a variable. This could be particularly helpful when comparing the effectiveness and accuracy of screening, harms associated with screening and workup or surveillance of nodules, and effectiveness of and harms associated with surgical resection of early non-small cell lung cancer. Additionally, the Lung Association recommends including length of time a patient should be screened as a variable. The research plan should also explore whether this length should vary by parameters such as age, sex, race/ethnicity, presence of comorbid conditions, or risk of lung cancer.

The Lung Association recommends that Proposed Key Question 1-a would be more accurate if revised to ask if screening will change the *reported* incidence of lung cancer, as screening itself would only be expected to change the actual incidence through the increased exposure to radiation associated with the low-dose CT scan, and this actual change should be marginal. Another recommended revision is in Proposed Key Question 2, where asking whether the use of *alternative* risk predictions models improve the balance. This would clarify that the NLST criteria were themselves a form of risk prediction model.

Finally, the Lung Association believes the draft research plan would benefit from examining whether the availability of screening for lung cancer impacts smoking cessation interest and behavior among both high-risk and other smokers. It would be particularly interesting to learn the

impact of screening availability on quitting among those in the high-risk population. There has been some evidence of a positive effect, which merits further confirmation.[5]

The American Lung Association has included a list of studies that would be beneficial for USPSTF to review as it implements the research plan (Appendix A). The Lung Association is pleased to have the opportunity to engage in these critical questions about the nation's leading cause of cancer death. Thank you for considering our comments.

Sincerely,

Harold P. Wimmer
National President and CEO

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[1] Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2018. CA: A Cancer Journal for Clinicians. 2018; 68:7-30.
[2] Centers For Disease Control And Prevention. National Center For Health Statistics. CDC WONDER On-Line Database, Compiled from Compressed Mortality File 1999-2016 Series 20 No. 2V, 2017.
[3] SEER Cancer Statistics Review, 1975-2015
[4] Private communication from Dr. Andrea McKee. May 24, 2018.
[5] Borondy Kitts AK, McKee AB, Regis SM, Wald C, Flacke S, McKee BJ. Smoking cessation results in a clinical lung cancer screening program. *J Thorac Dis*. 2016;8(Suppl 6):S481-487.

Appendix A

Alshora S, McKee BJ, Regis SM, Borondy Kitts AK, Bolus CC, McKee AB, French RJ, Flacke S, Wald C. Adherence to Radiology Recommendations in a Clinical CT Lung Cancer Screening Program. *J Am Coll Radiol*. 2018;15(2):282:286. doi: 10.1016/j.jacr.2017.10.014.

Borondy Kitts AK, McKee AB, Regis SM, Wald C, Flacke S, McKee BJ. Smoking cessation results in a clinical lung cancer screening program. *J Thorac Dis*. 2016;8(Suppl 6):S481-487.

McKee BJ, Regis S, Borondy-Kitts AK, Hashim JA, French Jr RJ, Wald C, McKee AB. NCCN Guidelines as a model of extended criteria for lung cancer screening. *J Natl Compr Canc Netw*. 2018;16:444-449. doi: 10.6004/jnccn.2018.7021.

McKee BJ, Regis SM, McKee AB, Flacke S, Wald C. Performance of ACR Lung-RADS in a clinical CT lung screening program. *J Am Coll Radiol*. 2014;13(2), Supplement: (R25-R29). https://doi.org/10.1016/j.jacr.2015.12.009.

Taylor KL, Hagerman CJ, Luta G, et al. Preliminary evaluation of a telephone-based smoking cessation intervention in the lung cancer screening setting: A randomized clinical trial. *Lung Cancer*. 2017;108:242-24.

Walker BL, Williamson C, Regis SM, McKee AB, D'Agostino RS, Hesketh PJ, Lamb CR, Flacke S, Wald C, McKee BJ. Surgical Outcomes in a Large, Clinical, Low-Dose Computed Tomographic Lung Cancer Screening Program. *Ann Thorac Surg*. 2015;100(4):1218–1223.