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April 11, 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 comment and provide feedback to the U.S. Preventive Services Task Force (USPSTF) on the "Draft Research Plan for Tobacco Smoking Cessation in Adults, Including Pregnant Women: Interventions."

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 and COPD – which are primarily caused by tobacco use and exposure to secondhand smoke. Approximately 70 percent of smokers say they want to quit but this is an incredibly powerful addiction. The Lung Association has been helping people quit smoking for over 35 years through our Freedom from Smoking® program, which is ranked as one of the most effective programs in the country.

The total estimated cost attributable to cigarette smoking is over \$332 billion annually. This includes over \$175 billion in direct medical expenses in 2013, productivity losses from premature death of over \$150 billion among current and former smokers and over \$5.6 billion from secondhand smoke exposure among nonsmokers.

It is well established that tobacco use is the leading cause of preventable excess mortality in countries which rank very high on the Human Development Index. It is also well established that the deleterious effects of tobacco use are cumulatively dose related and that smoking cessation, at least of cigarettes, at virtually any age is associated with improved health outcomes. Accordingly, understanding the efficacy of various

smoking cessation modalities in achieving long term abstinence from tobacco use is of utmost importance to the health of the public. and the American Lung Association supports the regular comprehensive literature review by the USPSTF towards this end.

The Lung Association is concerned that the primary proposed outcome measures, tobacco related mortality and morbidity, for this proposed mode of study will likely lead to misleading inferences. This is because development of respiratory, cardiovascular and other diseases related to tobacco use takes many years. It seems unlikely that there will be many [if any] studies available which follow subjects exposed to a cessation intervention long enough to evaluate an actual reduction in tobacco related diseases. The vast majority of these studies will have followed subjects for six months to a year, a time far too short to assess amelioration of serious health risks. Thus, there is a strong possibility that the results on mortality and morbidity will conclude that no “significant” effects were found. This result is understandable by epidemiologists but likely to be misinterpreted by the public. Accordingly, the Lung Association suggests that this review be confined to the most important testable outcome: long term abstinence from tobacco use.

Additional questions include:

1. Why are pregnant women included but not their offspring?
2. Will people with behavioral health issues be excluded as “persons with other comorbid conditions?” This population has high rates of smoking related mortality and morbidity and knowledge about the effectiveness of smoking cessation modalities for it is an urgent need.
3. Why are ‘social” sites such as churches, worksites and other settings excluded? Many cessation programs are offered in these settings, particularly as part of efforts to reach certain racial and ethnic minority groups.

Finally, the American Lung Association urges USPSTF not to include any ENDS or electronic cigarettes as an intervention for its review. The Food and Drug Administration has not found any e-cigarette or ENDS product to be safe and effective for tobacco cessation or for any other purpose. In its proposal, USPSTF excludes FDA-approved interventions [e.g. clonidine and SSRIs] which are used off-label for smoking cessation. It would be highly inappropriate for USPSTF to include a tobacco product not approved for cessation in its review of quit smoking therapies.

The American Lung Association is pleased to have the opportunity to engage in these critical questions about the nation’s leading cause of preventable death and looks forward to contributing in any way we can about ways to help smokers quit.

Sincerely,



Harold P. Wimmer
National President and CEO

