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June 1, 2015

Albert L. Siu, M.D., M.S.P.H
Chair, United States Preventive Services Task Force
540 Gaither Road
Rockville, MD 20850

Dear Dr. Siu:

The American Lung Association is pleased to submit the following comments regarding the U.S. Preventive Services Task Force (USPSTF) draft recommendation statement on tobacco smoking cessation in adults and pregnant women: behavioral and pharmacotherapy interventions. As the Task Force knows, these recommendations hold great importance with clinicians and also have far-reaching effects on patient access to treatments. The following are the Lung Association's responses to some of the questions USPSTF asked in its comment form:

How could the USPSTF make this draft Recommendation Statement clearer?

Recommendation #1. The American Lung Association urges USPSTF to change the recommendation summary for all adults to read: "The USPSTF recommends that clinicians ask all adults about tobacco use and provide U.S. Food and Drug Administration (FDA)-approved pharmacotherapy ***and*** *behavioral interventions for cessation in adults who use tobacco."*

The proposed language strikes "or" and replaces it with "and," and also strikes the phrase "(alone or in combination)." The Lung Association strongly recommends changing the language to make it clear to clinicians that the combination of these two types of treatment is the most effective way to help a tobacco user quit.

The American Lung Association is gravely concerned that the recommendation summary as proposed [using "or" and including "(alone or in combination)"] could be interpreted as stating that one type of treatment is just as effective as combining the two. This interpretation could have four serious implications detailed below:

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1. It would conflict with statements in other sections of the draft recommendation statement;
2. It would conflict with other important guidelines and recommendations on cessation treatment;
3. It could lead to confusion among clinicians and others; and
4. It could limit patient access to tobacco cessation treatments through health insurance.

The Lung Association wishes to highlight that other sections of the recommendation statement clearly acknowledge the superiority of the combination of pharmacotherapy and behavioral interventions, and use “and” instead of “or.” These include:

- The USPSTF Assessment section [emphasis added]: “The USPSTF concludes with high certainty that the net benefit of behavioral interventions **and** FDA-approved pharmacotherapy for tobacco cessation, alone or in combination, in nonpregnant adults who smoke is substantial.”[1]
- The structured abstract of the evidence synthesis [emphasis added]: “This review of reviews suggests that behavioral interventions **and** pharmacotherapy, alone or in combination, are effective in helping to reduce rates of smoking among the general adult population.”[2]

Revising the recommendation summary language to replace “or” with “and” and strike “(alone or in combination)” will accurately reflect the conclusions reached in the supporting scientific review and other supporting documentation.

Additionally, by using “or” instead of “and,” and including “(alone or in combination)” the Task Force is (perhaps unintentionally) contradicting several widely-accepted government guidelines, statements or actions, including the *Public Health Service Guideline on Treating Tobacco Use and Dependence, which states: “*Counseling and medication are effective when used by themselves for treating tobacco dependence. The combination of counseling and medication, however, is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.”[3] Additional guidelines that require or recommend use or coverage of tobacco cessation pharmacotherapy **and** behavioral interventions include:

1. *U.S. Departments of Health and Human Services, Labor and Treasury ACA Implementation* FAQ XIX*;* [4]
2. *Office of Personnel Management’s* requirements for tobacco cessation benefits *in the Federal Employees Health Benefits program;*[5] *and*
3. *Joint Commission* tobacco cessation measure set *for inpatient settings.*[6]

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[1] http://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement147/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1. Accessed May 22, 2015

[2] *Evidence Synthesis* Number 127 Behavioral Counseling and Pharmacotherapy Interventions for Tobacco Cessation in Adults, Including Pregnant Women: A Systematic Review for the U.S. Preventive Services Task Force p. iv

[3] Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update.* Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008. P. vii

[4] U.S. Departments of Health and Human Services, Labor and Treasury. Frequently Asked Questions About the Affordable Care Act. Part XIX. Q5.

[5] U.S. Office of Personnel Management. FEHB Program Carrier Letter. Letter No. 2010-12(c). May 17, 2010.

[6] Joint Commission. Tobacco Treatment. October 23, 2014.

It is clear that many rely on USPSTF's recommendation summaries without deeper examination of the full recommendation document, including the very important clinical consideration section. As such, the Lung Association wishes to underscore to the Task Force the importance of stating clearly that pharmacotherapy **and** behavioral interventions are more effective combined in the recommendation summary. As written, the draft recommendation summary may be confusing to many – including clinicians – resulting in less than best practice treatment. Therefore it is crucial to emphasize the best practice of offering both medications and counseling to patients.

Finally, the American Lung Association is also extremely concerned that the current recommendation summary language using "or" and "(alone or in combination)" will have serious consequences to patients' access to tobacco cessation treatments. As the Task Force is well aware, the preventive services it gives an 'A' or 'B' recommendation are required to be covered by all non-grandfathered private health insurance plans under the Affordable Care Act. Tobacco cessation has been included under this requirement with its 'A' grade, which rightfully continues under this draft recommendation. The American Lung Association is concerned that this summary recommendation using "or" and "(alone or in combination)" will be interpreted as only requiring health plans to cover pharmacotherapy **or** behavioral interventions, not both. Even if the Task Force makes it clear in the supporting information that the combination is recommended, our experience shows that health plans and regulators narrowly and literally interpret the recommendation summary language. The Task Force can have a huge impact on helping clinicians support their patients who want to quit using tobacco by making the summary recommendation consistent with the rest of the statement and replacing "or" with "and" and deleting "(alone or in combination)" as indicated above. These specific word changes will help ensure that clinicians have all available options when treating their patients.

Recommendation #2. The American Lung Association urges USPSTF to include language in its 'Clinical Considerations' section specifying that the combination of behavioral interventions and pharmacotherapy is preferred, but each type of treatment is effective alone and the use of counseling should not be a prerequisite to pharmacotherapy nor should pharmacotherapy be a perquisite for counseling.

This statement would be appropriate in the 'Combinations of Behavioral and Pharmacotherapy Interventions' section under 'Clinical Considerations' for nonpregnant adults. Accompanying the revisions specified in recommendation #1 above, adding this clear statement in this section will make the same point as the "(alone or in combination)" phrase deleted above; but in a more appropriate section of the statement where it will not jeopardize access to treatment or cause confusion for clinicians or others.

Recommendation #3. The American Lung Association asks USPSTF to specify that the 'A' recommendation for tobacco cessation interventions includes all treatments, consistent with the most recent Public Health Service-sponsored Clinical Practice Guideline on Treating Tobacco Use and Dependence (Guideline).

The Affordable Care Act insurance coverage requirements linked to USPSTF recommendations have been in place since 2010 for non-grandfathered private insurance plans. Five years of experience has shown that many insurance plans are not providing coverage for comprehensive cessation treatment. An insurance plan may cover some type of treatment for tobacco cessation, however it rarely provides access to all seven FDA approved medications and three forms of counseling that constitute a comprehensive tobacco cessation benefit as outlined in the Guideline. Absent a clear statement that the USPSTF recommendation includes all recommended cessation treatments, insurance plans interpret the recommendations in widely varying ways, including creating barriers or otherwise limiting or restricting access to treatment. The result is the recommendations are not being implemented and the preventive service is not available to patients. This absence of clarity also makes it more difficult for providers to direct their patients to recommended services, creates barriers to cessation for patients and increases confusion for the entire healthcare system. Lastly, it also creates confusion for some federal and state regulators, which creates major difficulties in enforcing this very important provision or communicating with providers and patients about the coverage.

The American Lung Association defines a comprehensive tobacco cessation benefit as including all treatments recommended by the most recent Public Health Service-sponsored Clinical Practice Guideline on Treating Tobacco Use and Dependence. As the Task Force knows, this Guideline is the recognized authority on evidence regarding tobacco cessation treatment. The current version recommends ten treatments: seven FDA-approved medications and three types of counseling. Tobacco users will have the best chance of quitting successfully when they have access to all of these treatments through their health insurance plan.

The Lung Association recommends the Task Force clearly and explicitly indicate that the ‘A’ recommendation is given to treatment consistent with the most recent Public Health Service-sponsored Clinical Practice Guideline on Treating Tobacco Use and Dependence, and includes all treatments recommended in this Guideline. This type of statement would be appropriate in the introduction of the “Implementation Considerations of Behavioral and Pharmacotherapy Interventions.’ section. This section already makes reference to the Guideline. The American Lung Association recommends that it be further clarified by adding “Treatment should be consistent with the most current version of the U.S. Public Health Service Guideline.” Creating this clear link will also point clinicians towards the appropriate source for more details about how to treat their patients.

Recommendation #4. The American Lung Association urges USPSTF to change the recommendation regarding ENDS from an “I” to a “D” and the recommendation summary to say “the USPSTF recommends that clinicians direct patients who use tobacco to other cessation interventions with established effectiveness and safety that are recommended by the most recent Public Health Service-sponsored Clinical Practice Guideline on Treating Tobacco Use and Dependence.”

In its final research plan, the USPSTF states that it would exclude from its research report “medications and devices that are not approved by the U.S. Food and Drug Administration as first-line tobacco cessation agents…. [Including] electronic cigarettes.” The Lung Association strongly supports USPSTF’s recommendation that clinicians direct their patients to interventions that are safe and effective but was

troubled to see that USPSTF concluded there was insufficient evidence instead of assigning a "D" grade – which would directly instruct clinicians to discourage the use of these products.

The Lung Association urges the USPSTF to reconsider using the two ENDS studies referenced in its recommendations. First, neither study was conducted in the United States using the products currently in the marketplace here. Second, one of the studies (Caponnetto et al)[7] did not use the current standard of care (use of FDA approved medications) as its comparison group. Instead, it used a different type of e-cigarette in its control group. It is therefore not possible to make any comparison to existing treatments – and the study should be disregarded.

It is clear that the public health harms of ENDS outweigh any current potential benefits. There are almost 500 brands of ENDS on the market today with 7700 flavors[8] and ENDS now include e-cigarettes, e-cigars, e-pens and others. Recognizing there is no federal oversight of these products, it is simply not possible to know the ingredients or potential individual or public health impacts.

Finally, the American Lung Association also urges USPSTF to take into consideration the following points:

- As USPSTF noted in its final research plan, the FDA has not approved any ENDS product as safe and effective in helping smokers quit.
- *Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010)* established that ENDS are tobacco products unless a therapeutic claim is made and goes through the FDA's Center for Drug Evaluation and Research process.
- Switching from one tobacco product to another product – such as an ENDS – is not cessation, as tobacco product use and the addiction to nicotine continues.
- The evidence also shows that cigarette smokers who use e-cigarettes also continue to use cigarettes. Among current e-cigarette (ENDS) users, 76.8 percent are dual users who continue to smoke regular cigarettes.[9] According to the Centers for Disease Control and Prevention, using e-cigarettes in addition to regular cigarettes will not safeguard one's health, as smoking even a few cigarettes a day can be dangerous.[10] The analysis conducted and resulting recommendation on ENDS must take into account the dangers and realities of dual use.

In summary, the Lung Association asks USPSTF to reconsider its "I" recommendation and instead assign a "D" recommendation – recognizing that harms of ENDS use outweigh the public health benefits, and as such, deserve a "D" rating.

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[7] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3691171/

[8] Zhu SH, Sun JY, Bonnevie E, et al. Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. Tob Control 2014;23 Suppl 3:iii3-9.

[9] King BA, Patel R, Nguyen K, Dube S. Trends in awareness and use of electronic cigarettes among U.S. adults, 2010-2013. Nicotine Tob Res 2015; 17(2):219-27.

[10] U.S. Department of Health and Human Services. *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: 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, 2010.

What information, if any, did you expect to find in this draft Recommendation Statement that was not included?

The absence of a clear statement on ENDS and pregnant women is a significant omission. USPSTF must make it clear that ENDS are not safe for use by pregnant women. The 2014 Surgeon General's report finds, "The evidence is sufficient to infer that nicotine exposure during fetal development, a critical window for brain development, has lasting adverse consequences for brain development."[11]

Additionally, a study conducted by the University of Maryland Baltimore found that 40 percent of pregnant women surveyed think electronic cigarettes are less harmful than tobacco cigarettes and only 57 percent of the women thought e-cigarettes contained nicotine.[12]

Based on the evidence presented in this draft Recommendation Statement, do you believe that the USPSTF came to the right conclusions? Please provide additional evidence or viewpoints that you think should have been considered.

The American Lung Association strongly supports the 'A' recommendation for FDA-approved pharmacotherapy **and** behavioral interventions for all adult tobacco users, with the recommendation summary language changed to read as follows: "The USPSTF recommends that clinicians ask all adults about tobacco use and provide U.S. Food and Drug Administration (FDA)-approved pharmacotherapy and behavioral interventions for cessation in adults who use tobacco." Further discussion of these proposed changes are submitted under question one.

The American Lung Association also strongly supports the 'A' recommendation for behavioral interventions for pregnant women who use tobacco as currently written in the draft recommendation summary.

However, the American Lung Association urges the Task Force to change its recommendation on ENDS from an "I" to a "D" and the recommendation summary to say "the USPSTF recommends that clinicians direct patients who use tobacco to other cessation interventions with established effectiveness and safety that are recommended by the most recent Public Health Service-sponsored Clinical Practice Guideline on Treating Tobacco Use and Dependence." The Lung Association asserts that the current practice, use and science demonstrate that the harms of ENDS use outweigh the benefits – thereby qualifying for a "D" recommendation. Further discussion of these proposed changes are submitted under question one.

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[11] 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.

[12] Health Day News. "ACOG: Pregnant Women May Believe E-Cigarettes OK" May 1, 2015. Available at: http://www.pri-med.com/PMO/MedicalNewsDetail.aspx?id=17659

What resources or tools could the USPSTF provide that would make this Recommendation Statement more useful to you in its final form?

The American Lung Association recommends that the Task Force emphasize the importance of the 2008 Public Health Service Guideline (or any Guideline published subsequently) in any supplemental tools or resources created for clinicians. The Guideline is an extremely important tool for physicians and other providers, and it provides the details a clinician needs in order to help a tobacco user quit. All public materials should clearly indicate that the 'A' recommendation is given to treatment consistent with the most recent Public Health Service-sponsored Clinical Practice Guideline on Treating Tobacco Use and Dependence, and includes **all** treatments recommended in this Guideline.

Additionally, as previously mentioned, the Task Force's recommendation will have an enormous impact on whether clinicians provide and patients have insurance coverage of comprehensive tobacco cessation services. The Lung Association urges the Task Force – working independently, with the Agency for Healthcare Research and Quality or another appropriate Health and Human Services Agency – to consider developing supporting materials for insurers, clinicians, and patients in order to ensure that the its' full recommendation is used as intended by the Affordable Care Act for insurance coverage decisions.

The USPSTF is committed to understanding the needs and perspectives of the public it serves. Please share any experiences that you think could further inform the USPSTF on this draft Recommendation Statement.

As the Task Force is aware, the Affordable Care Act (ACA) requires all preventive services USPSTF gives an 'A' or 'B' recommendation be covered in all non-grandfathered private health insurance plans. The American Lung Association would like to call the Task Force's attention to the problems translating the previous recommendation summary and '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. Many of these other services are easily translated into insurance coverage requirements. For example, if the Task Force gives an 'A' to a cancer screening for a particular population, it is obvious that insurance companies 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.

This lack of clarity has allowed health insurance plans to pick and choose which tobacco cessation treatments they cover, resulting in benefits that are far from comprehensive and not based on evidence or best practices. The following are several studies showing evidence of this:

- Georgetown University Health Policy Institute. "Implementation of tobacco cessation coverage under the Affordable Care Act: Understanding how private health insurance policies cover tobacco cessation treatments." November 26, 2012. Available at: http://www.tobaccofreekids.org/pressoffice/2012/georgetown/coveragereport.pdf
  - Report authors examined 39 plans that were required to follow the ACA preventive services requirement. The report concluded that none of the 39 contracts analyzed did all of the following: (1) stated clearly that tobacco cessation treatment was a covered benefit (without general exclusions); (2) provided coverage for individual, group and phone counseling, and FDA approved tobacco cessation medications; (3) provided tobacco cessation treatments by in-network providers with no cost-sharing; and (4) provided access to treatment without prerequisites such as medical necessity or health risk assessment.
- Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report. "Health Plan Implementation of U.S. Preventive Services Task Force A and B Recommendations --- Colorado, 2010." October 7, 2011. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6039a3.htm
  - Report authors examined coverage of several preventive services in Colorado health plans. Authors found significant variability in coverage for tobacco cessation services. Only one out of eight plan issuers covered all seven tobacco cessation medications. While "the vast majority of A and B recommendations addressed in the survey were interpreted consistently across all health plans," the report highlights tobacco cessation as an area with significant variability in benefit provision and design.
- Kolade, F. M., Public Health Nursing. "Tennessee Health Plan Tobacco Cessation Coverage. November 13, 2013. Available at: http://onlinelibrary.wiley.com/doi/10.1111/phn.12089/full
  - Study found that of nine private health plans in Tennessee, only one provided a comprehensive tobacco cessation benefit.
- American Lung Association. "Helping Smokers Quit: Tobacco Cessation Coverage." July 2014. Available at: www.lung.org/helpingsmokersquit
  - This report covers many aspects of tobacco cessation coverage. Particularly relevant is the state-by-state data on tobacco cessation coverage in state employee health plans (see appendix D), which shows wide variation in coverage among these health plans, many of which fall under the ACA preventive services requirement.

As the Task Force is aware, in May 2014, the U.S. Departments 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 http://www.dol.gov/ebsa/faqs/faq-aca19.html, 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 tobacco cessation experience of patients, clinicians and public health groups in the five years since preventive services were required to be covered by the ACA and tied to USPSTF recommendations shows major problems. A clearer recommendation statement from USPSTF would resolve most of these problems. Our recommended changes to the draft recommendation statement and summary detailed in these comments are crucial to giving clinicians the clarity they need to practice evidence based medicine and provides tobacco users the appropriate access to evidence-based best practice cessation benefits.

Thank you for the opportunity to submit these comments. The American Lung Association looks forward to continuing to work with dedicated health professionals like members of the Task Force to help tobacco users quit.

Sincerely,

Harold P. Wimmer
National President and CEO