



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 undersigned public health and medical organizations are 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 our organizations' responses to some of the questions USPSTF asked in its comment form:

How could the USPSTF make this draft Recommendation Statement clearer?

*Recommendation #1. Our organizations urge 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."*

Our proposed language strikes "or" and replaces it with "and," and also strikes the phrase "(alone or in combination)." Our organizations strongly recommend changing the language in this way 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.

Our organizations are very 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 by itself is just as effective as combining the two. This interpretation could have four serious implications detailed below:

1. It conflicts with the state of the science as detailed 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.

Our organizations wish to highlight that other sections of the recommendation statement and evidence synthesis 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.”
- 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.”

Editing the recommendation summary language to replace “or” with “and” and strike “(alone or in combination)” will more accurately reflect the evidence summarized in the rest of the recommendation statement.

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.” Additional guidelines/statements/actions 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](#);
2. Office of Personnel Management’s [requirements for tobacco cessation benefits](#) in the Federal Employees Health Benefits program; and
3. Joint Commission [tobacco cessation measure set](#) for inpatient settings.

It is clear that many in the healthcare space rely on USPSTF’s recommendation summaries without deeper examination of the full recommendation document, including the very important clinical consideration section. As such, our organizations wish 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 undersigned groups are also extremely concerned that the current recommendation summary language using “or” and “(alone or in combination)” will have serious consequences for patients’ access to tobacco cessation treatments. As the Task Force is well aware, 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 always been part of this requirement with its ‘A’ grade, and rightfully continues under this draft recommendation. Our organizations are concerned that this summary recommendation using “or” and “(alone or in combination)” will be interpreted as only requiring 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 take a literal interpretation of the recommendation summary language specifically. The Task Force can have a huge impact on helping clinicians support their patients who use tobacco by making its draft summary recommendation consistent with the rest of the statement by replacing “or” with “and” and deleting “(alone or in combination)” as indicated above. These seemingly small changes will help ensure that clinicians have all available options when choosing a course of treatment for their patients.

Recommendation #2. Our organizations ask 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 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 while insurance plans may cover some type of treatment for tobacco cessation, it is rarely a comprehensive tobacco cessation benefit as outlined in the Guideline. Without a specific statement that the USPSTF recommendation includes all recommended cessation treatments, insurance plans are interpreting maximum flexibility in this requirement and therefore restricting access to these treatments. Furthermore, some federal and state regulators are unsure which treatments are included in the requirement, which creates major difficulties in enforcing this very important provision or communicating with providers and patients about the coverage.

The undersigned groups support access to comprehensive cessation services. As noted in the current draft recommendation statement, the 2009 USPSTF recommendation and the most recent Guideline, the seven FDA-approved medications and three types of counseling that have been proven effective give tobacco users the best chance of quitting successfully and should be accessible.

Our organizations recommend the Task Force 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. This type of statement would provide additional clarity and be appropriate in the introduction of the “Implementation Considerations of Behavioral and Pharmacotherapy Interventions.” section. This section already makes reference to the Guideline. Our organizations recommend that it be further clarified by adding “Treatment should be consistent with the 2008 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.

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 undersigned organizations strongly support the 'A' given to FDA-approved pharmacotherapy and behavioral interventions for all adult tobacco users, with 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.

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

Our organizations recommend 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 goes into the details a clinician needs in order to help a tobacco user quit. Any 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. We urge you to consider developing supporting materials for insurers, clinicians, and patients in order to ensure that the Task Force's full recommendation is used as intended by the Affordable Care Act for insurance coverage decisions.

We thank the Task Force for its consideration of our comments and recommendations.

Sincerely,

American Academy of Otolaryngology— Head and Neck Surgery
American Association for Cancer Research
American Association for Respiratory Care
American Cancer Society
American Cancer Society Cancer Action Network
American College of Radiology
American Heart Association
American Lung Association
American Psychological Association
American Public Health Association
American Society of Clinical Oncology
Association of Women's Health, Obstetric and Neonatal Nurses
Campaign for Tobacco-Free Kids
Cancer Prevention and Treatment Fund
ClearWay Minnesota

College on Problems of Drug Dependence
Friends of the National Institute on Drug Abuse
National African American Tobacco Prevention Network
National Association of County and City Health Officials
North American Quitline Consortium
Oncology Nursing Society
Partnership for Prevention
Prevent Cancer Foundation
Smoking Cessation Leadership Center
Society for Cardiovascular Angiography and Interventions
Society for Research on Nicotine and Tobacco
The Ohio State University Comprehensive Cancer Center
The Society of Thoracic Surgeons
University of Wisconsin Center for Tobacco Research and Intervention