Comments from the American Cancer Society and the American Cancer Society Cancer Action Network on the U.S. Preventive Services Task Force Draft Research Plan for Tobacco and Nicotine Use Prevention in Children and Adolescents: Primary Care Interventions

July 19, 2017

The American Cancer Society (ACS) and the American Cancer Society Cancer Action Network (ACS CAN) are pleased to provide comments on the U.S. Preventive Services Task Force (USPSTF) *Draft Research Plan for Tobacco and Nicotine Use Prevention in Children and Adolescents: Primary Care Interventions*. ACS is a nationwide community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives lost to cancer, and diminishing suffering from cancer through research, education, advocacy, and service. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of ACS that supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS and ACS CAN are pleased that the USPSTF is beginning the process to update its recommendations for preventing tobacco use in children and adolescents and is soliciting feedback from stakeholders.

Tobacco use is the leading cause of preventable death in the U.S., with more than 480,000 deaths each year caused by cigarette smoking.[1] This includes 32 percent of all cancer deaths and 80 percent of lung cancer deaths.[2] Nearly 90 percent of adult cigarette smokers first tried smoking by age 18 and in 2016, more than 1.4 million middle and high school students smoked cigarettes.[3,4] In addition, 3.9 million middle and high school students used any tobacco product, including electronic cigarettes.[5] Preventing youth from using any tobacco product and reducing death and disease caused by tobacco use are priorities for ACS and ACS CAN.

Our comments respond to the specific questions posed by the Task Force, but first we want to address an overarching issue. The research plan uses the phrase "tobacco or nicotine use." This can be confusing given that nicotine use could include nicotine replacement therapies (NRT) approved by the U.S. Food and Drug Administration (FDA). It does not appear the Task Force is intending to review whether to counsel against nicotine use through FDA-approved NRT by youth and so we recommend removing the phrase "nicotine use." An option for the Task Force is to use the definitions that exist under federal law

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[1] US Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General.* Washington, DC: US Department of Health and Human Services, CDC; 2014. Available at http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.

[2] American Cancer Society. *Cancer Facts & Figures 2017*. Atlanta: American Cancer Society, 2017.

[3] U.S. Department of Health and Human Services. *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General.* Atlanta: 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, 2012.

[4] Centers for Disease Control and Prevention. Tobacco Use Among Middle and High School Students—United States, 2011–2016. *Morbidity and Mortality Weekly Report,* 2017;66(23):597-603.

[5] Centers for Disease Control and Prevention. Tobacco Use Among Middle and High School Students—United States, 2011–2016. Morbidity and Mortality Weekly Report, 2017;66(23):597-603.

for tobacco products and those products approved by the FDA as a drug, device, or combination product.

Do you have any comments about the Analytic Framework?

The diagram is difficult to understand. For example, it is not clear what the numbered circles refer to, or what the arrows refer to (typically arrows refer to a sequence, or a cause-and-effect relationship). A table format may be the better approach, or readers may be better served if this path diagram is simply eliminated.

We also recommend clarifying that the primary care interventions that are the subject of this plan *exclude pharmacotherapies*. As it is, it is not until the reader sees the proposed research approach that they realize that it does not include medications for cessation. At the same time, and as noted below, we recommend that the USPSTF review the existing research on the safety and effectiveness of the use of FDA-approved smoking cessation medications by adolescents. In addition, we recommend that USPSTF include a review of the adverse effects of pharmacotherapy for adolescents in its review of adverse effects (Key Question 3).

Key Question 1:

Do primary care interventions to prevent tobacco or nicotine use or improve tobacco or nicotine cessation rates in children and adolescents improve their health outcomes (i.e., respiratory, dental, and oral health) and reduce the likelihood of their tobacco or nicotine use in adulthood?

Do you have any comments about Key Question 1?

We have concerns; see comments below.

We recommend that this question be split into three questions, as follows:

a. *Do primary care interventions prevent tobacco use in children and adolescents?*
b. *Do primary care interventions to prevent tobacco use or improve cessation in children and adolescents improve health outcomes (i.e., respiratory, dental, and oral health)?*
c. *Do primary care interventions to prevent tobacco use or improve cessation in children and adolescents reduce the likelihood of tobacco use in adulthood?*

It is important to establish the extent to which primary care interventions are effective in preventing tobacco use or improving cessation before it will be possible to determine if they are effective in improving tobacco-related health outcomes in youth or in preventing future tobacco use as the youth become adults. In addition, before conducting its review of the above-listed questions, the USPSTF should determine if there are sufficient high-quality studies on these issues.

Key Question 2:
Do primary care interventions prevent tobacco or nicotine use or improve tobacco or nicotine cessation rates in children and adolescents who use tobacco or nicotine?

Do you have any comments about Key Question 2?
Generally, we agree with it; see comments below.

We recommend that this question be tweaked to say:
Do primary care interventions ~~prevent tobacco use or~~ improve tobacco cessation rates in children and adolescents who use tobacco ~~or nicotine~~?

We understand this question focuses on the effectiveness of primary care interventions among youth who have already tried a tobacco product. The goals should be to prevent additional or more established tobacco use and to promote cessation. We recommend that this question be tweaked to reflect these goals.

In addition, we recommend that question 2 be placed between new questions 1a and 1b, noted above. All of the questions should be renumbered accordingly. Therefore, we recommend that the first four questions read as follows:

a. *Do primary care interventions prevent tobacco use in children and adolescents?*
b. *Do primary care interventions improve tobacco cessation rates in children and adolescents who use tobacco?*
c. *Do primary care interventions to prevent tobacco use or improve cessation in children and adolescents improve health outcomes (i.e., respiratory, dental, and oral health)?*
d. *Do primary care interventions to prevent tobacco use or improve cessation in children and adolescents reduce the likelihood of tobacco use in adulthood?*

The analytic framework should also be revised to reflect the revised key questions listed above.

Key Question 3:

What adverse effects are associated with primary care interventions to prevent tobacco or nicotine use or improve tobacco or nicotine cessation rates in children and adolescents?

Do you have any comments about Key Question 3?
We have concerns; see comments below.

The "adverse effects" should be identified in the question itself. The adverse effects to be studied, as described in the proposed research approach, are predominantly an increase in tobacco use, depression, and demoralization due to a failed attempt.

We believe demoralization due to a failed attempt, however, should *not* be included, because this could be the outcome of a failed attempt regardless of whether the attempt was motivated by an intervention. Thus, demoralization about not having quit is not necessarily an effect of an intervention, but rather an effect of failure to quit. There is also the question of how demoralization would be operationalized as, to our knowledge, there is no valid and reliable measure of this construct.

Similarly, depression after an intervention to reduce tobacco use is more likely to be due to temporary tobacco withdrawal (with prolonged abstinence associated with depression levels significantly lower than continuing smokers). The way in which this question currently is worded suggests that the intervention itself might cause depression, rather than depression being primarily a result of temporary withdrawal from tobacco use. The USPSTF should be aware of this distinction, and its impact on the reporting of results based on this outcome.

With regard to the "adverse effect" of a primary care intervention inadvertently increasing tobacco use, any evidence for this occurring for this would be uncovered in the review of research for Key Question 2, which examines whether interventions reduce nicotine and tobacco use. There is, thus, no need for it to be identified separately as a special adverse outcome.

Contextual Question 1:
What is the relationship between use of electronic nicotine delivery systems (ENDS) and use of conventional tobacco products?

Do you have any comments about Contextual Question 1?
We have concerns; see comments below.

We recommend the Task Force broaden this question to address poly use of all tobacco products. There has been a steep increase in the use of electronic cigarettes by youth from 2011-2016, and while use declined slightly from 2015-2016, any use of a tobacco product by youth is concerning.[6] In fact, 1.8 million middle and high school students reported using two or more tobacco products in 2016.[7] In 2013, almost half (46 percent) of high school students had ever tried two or more tobacco products.[8] It is important that the Task Force consider the relationships among use of any tobacco products.

Contextual Question 2:
Does adjunctive use of nicotine replacement therapy or pharmacotherapy (i.e., bupropion and varenicline tartrate) reduce tobacco use in children and adolescents?

Do you have any comments about Contextual Question 2?
We have concerns; see comments below.

We recommend that the USPSTF consider making this question a Key Question that is part of the Research Approach, rather than a contextual question that is not systematically reviewed. While NRT and other pharmacotherapy for smoking cessation support have not been approved by the FDA for use

[6] Centers for Disease Control and Prevention. Tobacco Use Among Middle and High School Students—United States, 2011–2016. *Morbidity and Mortality Weekly Report,* 2017;66(23):597-603.
[7] Centers for Disease Control and Prevention. Tobacco Use Among Middle and High School Students—United States, 2011–2016. *Morbidity and Mortality Weekly Report,* 2017;66(23):597-603.
[8] Centers for Disease Control and Prevention. Tobacco Use Among Middle and High School Students—United States, 2013. *Morbidity and Mortality Weekly Report*, 2014;63(45):1021–6.

by youth under 18, these medications are recommended for adults (except for pregnant women)[9,10] and some research has been conducted on the safety and effectiveness of NRT and bupropion in adolescents.[11] We recommend that the USPSTF review the existing research on the safety and effectiveness of the use of FDA-approved smoking cessation medications by adolescents. In addition, we recommend that USPSTF include a review of the adverse effects of pharmacotherapy for adolescents in its review of adverse effects (Key Question 3).

Do you have any comments about the Research Approach?
Generally, we agree with it; see comments below.

Overall, we believe that the proposed research approach is solid. We are pleased that the list of interventions include interventions that are primary-care relevant and are not limited to those interventions that were actually conducted in a primary care setting. We recommend that the list of settings included explicitly state that research conducted in community-, phone-, computer-, and other technology-based settings be included, as interventions in these settings are primary-care relevant or can be referred from primary care.

As noted in response to Contextual Question 2, we also recommend that use of NRT or other pharmacotherapy for smoking cessation be included as interventions in the research plan.

Conclusion
Thank you for the opportunity to provide input on this important topic. We look forward to the results of the evidence review and the Task Force's recommendations on this important service. Furthermore, we strongly encourage the Task Force to write its recommendation as clearly and comprehensively as possible. Health care providers and patients will rely on these recommendations to make clinical recommendations and, importantly, health care payers will look to these recommendations to make coverage decisions based on the requirements under current law.

If we can provide additional information, please contact Melissa Maitin-Shepard, MPP, Senior Analyst, Policy Analysis & Legislative Support, at ACS CAN at 202-585-3205 or melissa.maitin-shepard@cancer.org, or Lee Westmaas, PhD, Strategic Director, Tobacco Control Research, at ACS at 404-329-7730 or lee.westmaas@cancer.org.

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[9] USPSTF. Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* 2015;163:622-634. doi:10.7326/M15-2023.
[10] 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.
[11] Karpinski JP, Timpe EM, and Lubsch L. Smoking Cessation Treatment for Adolescents. *J Pediatr Pharmacol Ther.* 2010 Oct-Dec; 15(4): 249–263.