



**Comments from the American Cancer Society and the American Cancer Society Cancer Action Network on the U.S. Preventive Services Task Force (USPSTF) Draft Recommendation Statement: Tobacco Smoking Cessation in Adults and Pregnant Women: Behavioral and Pharmacotherapy Interventions**

*June 1, 2015*

The American Cancer Society (ACS) and the American Cancer Society Cancer Action Network (ACS CAN) are pleased to provide comments on *the Draft Recommendation Statement: Behavioral Counseling and Pharmacotherapy Interventions for Tobacco Cessation in Adults, Including Pregnant Women*. 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 U.S. Preventive Services Task Force (the Task Force) is updating its recommendations for tobacco cessation interventions for adults and pregnant women and is soliciting feedback from stakeholders.

Approximately one in four Americans use cigarettes or other tobacco products,<sup>1</sup> and more than 480,000 deaths in the U.S. each year are attributable to cigarette smoking.<sup>2</sup> Tobacco use is the leading cause of preventable death in the U.S., causing at least 30 percent of all cancer deaths and 80-90 percent of lung cancer deaths.<sup>3</sup> While more than half of all adult smokers attempt to quit each year,<sup>4</sup> only about 6 percent are successful<sup>5</sup>. A key barrier to successful quitting is lack of access to effective interventions that are available to tobacco users at no cost. Reducing death and disease caused by tobacco use is a priority for ACS and ACS CAN.

Our comments respond to the specific questions posed by the Task Force.

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<sup>1</sup> Centers for Disease Control and Prevention. Current Cigarette Smoking Among Adults—United States, 2005–2013. *MMWR* 2014;63(47):1108–12.

<sup>2</sup> 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>.

<sup>3</sup> American Cancer Society. *Cancer Facts & Figures 2015*. Atlanta: American Cancer Society, 2015.

<sup>4</sup> Centers for Disease Control and Prevention. Quitting Smoking Among Adults—United States, 2001–2010. *MMWR* 2011;60(44):1513–19

<sup>5</sup> National Cancer Institute. Quitting Smoking. *Cancer Trends Progress Report – 2011/2012 Update*. August 2012. Available at

[http://progressreport.cancer.gov/doc\\_detail.asp?pid=1&did=2011&chid=101&coid=1004&mid](http://progressreport.cancer.gov/doc_detail.asp?pid=1&did=2011&chid=101&coid=1004&mid).

## How could the USPSTF make this draft recommendation clearer?

**We strongly recommend that the USPSTF 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 the “or” between “pharmacotherapy” and “behavioral interventions” and replaces it with “and,” and also strikes the phrase “(alone or in combination).” We strongly recommend changing the language in this way to make it clear to clinicians that the combination of pharmacotherapy and behavioral interventions is the most effective way to help a tobacco user quit. This change in language should be incorporated throughout the recommendation statement.

We 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:

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.

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”. The Assessment section of the draft recommendation states: “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.” [emphasis added] In addition, the structured abstract of the evidence synthesis says: “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.” [emphasis added] 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*,<sup>6</sup> 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:

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<sup>6</sup> 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.

1. U.S. Departments of Health and Human Services, Labor and Treasury ACA Implementation [FAQ XIX](#);<sup>7</sup>
2. Office of Personnel Management’s [requirements for tobacco cessation benefits](#) in the Federal Employees Health Benefits program;<sup>8</sup> and
3. Joint Commission [tobacco cessation measure set](#) for inpatient settings.<sup>9</sup>

The American Society of Clinical Oncology also recommends that all tobacco users have access to evidence-based tobacco cessation therapies and counseling.<sup>10</sup>

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, it is important to clearly state in the recommendation summary that pharmacotherapy and behavioral interventions are more effective combined. 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.

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 aware, preventive services with 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 services are a part of this requirement with its ‘A’ grade. We are concerned that using “or” and “(alone or in combination)” in the summary statement 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 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 have large consequences in helping to ensure that clinicians have all available options for treatment for their patients.

**We recommend that the Recommendation statement 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).**

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<sup>7</sup> U.S. Departments of Labor, Health and Human Services, and Treasury. FAQs about Affordable Care Act Implementation (Part XIX). May 2, 2014. Available at <http://www.dol.gov/ebsa/faqs/faq-aca19.html>. Accessed May 26, 2014.

<sup>8</sup> U.S. Office of Personnel Management. FEHB Program Carrier Letter: All Fee-for-Service Carriers. Letter No. 2010-12(c). May 2010. Available at <http://www.opm.gov/healthcare-insurance/healthcare/carriers/2010/2010-12c.pdf>. Accessed May 26, 2015,

<sup>9</sup> The Joint Commission. Tobacco Treatment. October 2014. Available at [http://www.jointcommission.org/tobacco\\_treatment/default.aspx](http://www.jointcommission.org/tobacco_treatment/default.aspx). Accessed May 26, 2015.

<sup>10</sup> Hanna N, Mulshine J, Wollins DS, et al. Tobacco cessation and control a decade later: American society of clinical oncology policy statement update. *J Clin Oncol*.2013;31(25):3147-57.

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 communicating with clinicians and patients about the coverage and enforcing this very important coverage provision.

As such, we 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. We 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.

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

**We strongly urge the Task Force to acknowledge that evidence-based cessation interventions (including telephone and in-person cessation counseling) can occur in locations beyond primary care.**

While we recognize that the primary purpose of the Task Force is to make recommendations for evidence-based interventions that are appropriate for a primary care setting, the Task Force should also acknowledge that many of the recommended interventions can also effectively be provided in locations beyond primary care. Primary care physicians and practitioners often see a large number of patients and provide treatment for a wide variety of conditions each day, and they may not have the time, expertise, or resources to provide patients with a lengthy counseling session<sup>11</sup> and may prefer to refer eligible patients elsewhere for treatment. Research has shown that patients are more likely to receive referral to behavior change counseling when there are established linkages between primary care practices and resources for behavior change in the community,<sup>12</sup> including ongoing cessation support.

We appreciate that the “Implementation Considerations of Behavioral and Pharmacotherapy Interventions” section of the draft Recommendation statement states that “effective interventions can be delivered by various types of primary care providers, including physicians, nurses, psychologists, social workers and cessation counselors” and that effective telephone counseling interventions can be “provided by professional counselors or health care providers who are trained to offer advice over the telephone”. However, we recommend that the Task Force also clearly acknowledge that the recommended behavioral interventions, including in-person individual and group counseling, telephone counseling, and tailored self-help materials, can be equally effective when provided outside of a primary

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<sup>11</sup> Stange KC, Woolf SH, and Gjeltema K. One Minute for Prevention: The Power of Leveraging to Fulfill the Promise of Health Behavior Counseling. *Am J Prev Med* 2002; 22(4):320-323.

<sup>12</sup> Etz RS, Cohen DJ, Woolf SH, et al. Bridging Primary Care Practices and Communities to Promote Healthy Behaviors. *Am J Prev Med* 2008; 35:S390-S397.

care setting. The Task Force should also clarify that treatment may be provided by another physician, health care provider, quitline counselor or other trained professional who is not a primary care provider. Other types of health care providers who are not primary care providers, including oncologists, should ask their patients about tobacco use and provide evidence-based cessation interventions to those who use tobacco products. It is particularly important for adults with tobacco-related chronic diseases, such as cancer, to be guided and supported in quitting tobacco use.

**As noted in response to the previous question, we strongly recommend that the USPSTF 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 rationale for this change is further detailed in response to the first question.

**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.**

**We do believe that the USPSTF came to the right conclusion with the ‘A’ grade for tobacco smoking cessation in adults and pregnant women, but we recommend changing 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.”**

We 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. This change in language should be incorporated throughout the recommendation statement.

Our rationale for this change is further detailed in response to the first question.

**We also do not believe that the USPSTF came to the right conclusion with respect to the effectiveness of mobile phone-based cessation interventions.**

The Effectiveness of Interventions section in the draft recommendation statement states that the Task Force reviewed the evidence on mobile phone and Internet-based interventions and found that while findings were suggestive of a benefit, studies were too few and too heterogeneous to draw any definitive conclusions. This conclusion failed to differentiate between mobile phone-based interventions that are primarily text messaging-based (and for which there is strong supporting evidence), versus other types of mobile phone based interventions, such as smartphone apps for quitting. Three of the five mobile phone-based cessation interventions examined in a meta-analysis by the Community Preventive Services Task Force<sup>13</sup> were primarily text-messaging programs that provided smokers with daily reminders and tips to support and motivate smokers in their quit attempt; in one of

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<sup>13</sup> Community Preventive Services Task Force. Reducing Tobacco Use and Secondhand Smoke Exposure: Mobile Phone-Based Cessation Interventions. December 2011. Available at <http://www.thecommunityguide.org/tobacco/mobilephone.html>. Accessed May 26, 2015.

the studies, the text-messaging program was two to six times more effective than traditional cessation methods.<sup>14</sup> Based on their review, the Community Preventive Services Task Force stated:<sup>15</sup>

The Community Preventive Services Task Force recommends mobile phone-based interventions for tobacco cessation based on sufficient evidence of effectiveness in increasing tobacco use abstinence among people interested in quitting. Evidence was considered sufficient based on findings from six studies in which mobile phone-based interventions were implemented alone or in combination with Internet-based interventions.

Consistent with this conclusion, a more recent randomized controlled trial examining the efficacy of a mobile phone text messaging program for cessation (Text2Quit) significantly increased the likelihood of abstinence among smokers at a 6-month follow-up.<sup>16</sup> Text-messaging programs are also offered to many smokers who call telephone counseling quitlines because of the strong evidence supporting their effectiveness. Moreover, the World Health Organization is also now promoting the use of mobile phone interventions for tobacco cessation.<sup>17</sup> As a result of a complete review of the literature, the World Health Organization has concluded that “MCessation”, or the use of mobile phone technology for tobacco cessation, is at least two times more effective than traditional cessation methods.

Given the worldwide reach of mobile phones, text messaging-based programs such as the NCI’s Smokefree TXT program offer the potential to provide cessation interventions that are low-cost and have massive reach. We recommend that the Task Force reconsider its conclusion regarding the effectiveness of mobile phones for tobacco cessation. The Task Force should clearly state that text messaging mobile phone interventions are effective for tobacco cessation and recommended them as an evidence-based behavioral intervention for tobacco cessation.

**We were disappointed that the Task Force did not explicitly consider the need for additional research on cessation interventions in special populations, including individuals with mental health or behavioral disorders, and light or non-daily smokers.**

While we appreciate that the Task Force acknowledged the higher prevalence of smoking in young adults, less educated and lower income individuals, individuals who are lesbian, gay, bisexual, or transgender, and individuals with mental health conditions, the effectiveness of cessation interventions in these populations was, with few exceptions, not specifically examined. We agree with the Task Force that evidence on the benefits and harms of behavioral interventions in individuals with mental health conditions is limited. More research is needed to make tailored recommendations for individuals with mental health conditions and behavioral disorders, including substance abuse.

We are pleased that the Task Force separately considered the evidence on the benefits and harms of cessation interventions in pregnant women. We agree with the Task Force that with respect to pregnant women, behavioral interventions are effective; there is inadequate evidence to recommend NRT and some evidence of harm; and no evidence on the effectiveness of bupropion or varenicline.

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<sup>14</sup> Free C, Knight R, Robertson S, et al. Smoking Cessation Support Delivered Via Mobile Phone Text Messaging (txt2stop): A Single-Blind Randomised Trial. *The Lancet* 2011;378 (9785): 49-55.

<sup>15</sup> Community Preventive Services Task Force, 2011.

<sup>16</sup> Abroms LC, Boal AL, Simmens SJ, Mendel JA, Windsor RA. A randomized trial of Text2Quit: a text messaging program for smoking cessation. *Am J Prev Med.* 2014, 47:242-250.

<sup>17</sup> World Health Organization. Tobacco Control and Mobile Health: A New Initiative. Available at [http://www.who.int/tobacco/mhealth/mhealth\\_new\\_initiative.pdf](http://www.who.int/tobacco/mhealth/mhealth_new_initiative.pdf). Accessed May 26, 2015.

While we do not suggest that the Task Force recommend the routine use of NRT during pregnancy, clinicians should consider that the use of NRT is safer than smoking during pregnancy.<sup>18</sup>

We were disappointed that the Task Force did not consider the need for more research on smoking cessation interventions for light or non-daily smokers, defined by the U.S. Public Health Service guideline as individuals who smoke less than 10 cigarettes per day or non-daily, as well as smokeless tobacco users. The most recent U.S. Public Health Service guideline currently recommends behavioral counseling only for these subpopulations. The Task Force should also acknowledge that more research is needed on the effectiveness of interventions in this and other sub-populations, acknowledging that race/ethnicity and dual or poly use may be compounding factors.

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

**We urge the Task Force to clearly state its final recommendation in a format that is most useful to clinicians, patients, insurers, and other audiences.**

We suggest that the Task Force clearly state that the recommendation is for clinicians to provide both evidence-based behavioral interventions and FDA-approved pharmacotherapy for cessation in adults who use tobacco. The Task force should also note that the 'A' recommendation applies to all FDA-approved cessation medications, including the seven that are currently approved, and recommended behavioral interventions in the summary statement. The USPSTF should clearly state that the 'A' recommendation refers to all FDA-approved medications and the three types of counseling that have been proven effective in helping tobacco users quit successfully.

In addition, we recommend that the Task Force emphasize the importance of the most recent Public Health Service Guideline<sup>19</sup> 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 to most effectively 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 the Guideline.

Without these details in the Summary statement, some insurance plans are interpreting maximum flexibility in coverage requirements 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 USPSTF could help to correct this inconsistency by clearly stating in the Recommendation Summary exactly what the population and recommendation is with respect to each A- or B-rated preventive service. The Task Force should also seek information from insurers as to what would be the most useful format for them in understanding what the requirements are for coverage of preventive services.

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<sup>18</sup> Fiore, 2008.

<sup>19</sup> Fiore, 2008.

**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.**

**We urge the Task Force to also review the evidence and consider recommending computer-based cessation interventions.**

Computer-based programs have been shown to be effective in increasing cessation, with several reviews demonstrating they can help smokers quit at a higher rate compared to quitting on one's own.<sup>20, 21, 22</sup> One review found that programs based on theory (e.g., theory of planned behavior) were associated with greater efficacy, as was delivery of more behavior change techniques, and the addition of other ways of maintaining contact with participants such as through email or preferably text messaging. Although some programs may fail to provide evidence-based cessation assistance recommended by clinical practice guideline for treating tobacco use and dependence, or do not take full advantage of the interactive and tailoring capabilities of the internet,<sup>23</sup> the USPSTF should consider those web-based programs that have demonstrated effectiveness and consider including them in a recommendation for smokers who wish to use this mode of intervention.

**Consider the importance of and challenges in tobacco cessation for cancer survivors.**

Approximately 30 percent of all cancer deaths and up to 90 percent of lung cancer deaths are caused by tobacco use. An estimated 60-65 percent of cancer diagnoses occur in individuals who are current or former smokers.<sup>24</sup> Many cancer survivors continue to use tobacco products after their diagnosis. In fact, a recent study found that 9 percent of cancer survivors still smoke nine years after their diagnosis.<sup>25</sup> For individuals with some cancers, quitting smoking may reduce the risk of death by up to 30-40 percent.<sup>26</sup> In addition to primary care practitioners, oncologists should also ask patients about their tobacco use status and provide evidence-based cessation interventions. Cancer survivors who use tobacco products may be particularly motivated to make a quit attempt, especially if they have a cancer type that is often caused by tobacco use. Additional research is needed on the effectiveness of interventions for survivors of cancers that are not obviously tied to tobacco use (i.e., cancers other than head, neck, lung cancers).

**Do you have other comments on this draft Recommendation Statement?**

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<sup>20</sup> Myung SK, McDonnell DD, Kazinets G, et al. Effects of Web- and computer-based smoking cessation programs: meta-analysis of randomized controlled trials. *Arch Intern Med*, 2009;169(10):929-937.

<sup>21</sup> Walters ST, Wright JA, Shegog R. A review of computer and Internet-based interventions for smoking behavior. *Addict Behav*, 2006;31(2):264-277.

<sup>22</sup> Munoz RF, Bunge EL, Chen K, et al. Massive Open Online Interventions, A Novel Model for Delivering Behavioral-Health Services Worldwide. *Clinical Psychological Sciences*; published online before print May 13, 2015, doi: 10.1177/2167702615583840.

<sup>23</sup> Bock B, Graham A, Sciamanna C, et al. Smoking cessation treatment on the Internet: content, quality, and usability. *Nicotine Tob Res*, 2004;6(2):207-219.

<sup>24</sup> Warren GW, Kasza KA, Reid ME, et al. Smoking at diagnosis and survival in cancer patients. *Int J Cancer*, 2013; 132: 401-410.

<sup>25</sup> Westmaas JL, Alcaraz KI, Berg CJ, and Stein K. Prevalence and correlates of smoking and cessation-related behavior among survivors of ten cancers: findings from a nation-wide survey nine years after diagnosis. *Cancer Epidemiology Biomarkers and Prevention*, 2014; 23(9), 1783-92.

<sup>26</sup> US Department of Health and Human Services, 2014.



**We were surprised to see a recommendation, albeit an insufficient evidence recommendation, for electronic nicotine delivery systems, otherwise known as e-cigarettes.**

As noted in our comments on the Draft Research Plan, e-cigarettes were not included in either the condition or the interventions of the draft research plan. The Final Research Plan, on the other hand, specifically **excluded** “Medications and devices that are not approved by the U.S. Food and Drug Administration as first-line tobacco cessation agents (e.g., clonidine, nortriptyline, selective serotonin reuptake inhibitors, anxiolytics, benzodiazepines, beta-blockers, opioid antagonists/naltrexone, **electronic cigarettes** [emphasis added])” from the interventions included in the research approach.

As the Task Force is aware, an e-cigarette manufacturer is required to submit an application with the FDA’s Center for Drug Evaluation and Research to ensure a product is safe and effective prior to making any therapeutic claims including smoking cessation. No e-cigarette has been FDA-approved as safe and effective for smoking cessation. Additionally, the FDA’s Center for Tobacco Products is currently undergoing rulemaking to assert its authority over e-cigarettes *as a tobacco product*. Once FDA has asserted its authority, e-cigarettes will be required to have a nicotine warning and be prohibited from making any modified risk or health claims without prior approval from the FDA. As there is no such thing as a safe and effective tobacco product, a public health standard is applied to tobacco products creating a different market environment for tobacco products than what exists for cessation products.

The FDA provides evidence-based information to clinicians and patients on the safety and effectiveness of tobacco cessation drugs and devices, and for the last six years, on the harms of tobacco use. The inclusion of e-cigarettes as an unapproved intervention in the Task Force’s recommendation may inadvertently add to the confusion on these products by clinicians and patients given FDA’s current actions. Both the discussion section of the Draft Recommendation Statement and the Evidence Synthesis cite the lack of regulation and massive growth in variety of these products as reasons why any uniform recommendation on the use of these products is unable to be determined. We agree that the market environment, determined in part by how a product is regulated, is an important consideration in determining the effectiveness of an intervention. FDA’s approval of a drug or device for tobacco cessation provides the evidence and clinical mechanism the Task Force needs in order to make a clear recommendation to clinicians. The lack of approval, lack of any regulation, or regulation under a different standard hinders the ability of the Task Force to make a clear recommendation to clinicians, which could account for the exclusion of all unapproved drugs and devices as an intervention.

We agree with the Task Force that the confusion and misperceptions on the use of e-cigarettes by clinicians and patients is of great concern, especially with the noted lack of scientific research. We would encourage the Task Force to acknowledge e-cigarettes as unapproved cessation drugs and devices in the Final Recommendation Statement, and work with us to educate clinicians and patients on what is known about e-cigarettes and what FDA-approved, evidence-based cessation medications exist.

**We would like to reiterate our strong recommendation that the USPSTF revise the recommendation summary for all adults to state that FDA-approved pharmacotherapy and behavioral interventions for cessation should be provided.**

We strongly recommend changing the language in this way to make it clear to clinicians and insurers that the combination of pharmacotherapy and behavioral interventions is the most effective way to help a tobacco user quit. This change in language should be incorporated throughout the recommendation statement.

**We also would like to reinforce the importance of the Task Force recommendations in ensuring access to evidence-based cessation interventions.**

As was noted previously, revising the language in the summary statement and clarifying that the A-rated pharmacotherapy and behavioral cessation interventions are consistent with the most recent U.S. Public Health Service guideline on treating tobacco use and dependence will help to ensure that the final recommendation statement can be used to clarify and/or expand coverage for evidence-based cessation interventions.

### **Conclusion**

Thank you for the opportunity to provide input on this important topic. 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](mailto:Melissa.maitin-shepard@cancer.org), or Lee Westmaas, PhD, Director, Tobacco Control Research, at ACS at 404-329-7730 or [lee.westmaas@cancer.org](mailto:lee.westmaas@cancer.org).