USPSTF Coordinator
c/o USPSTF
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

On behalf of the Obesity Care Advocacy Network (OCAN), we are pleased to provide public comment regarding the United States Preventive Services Task Force (USPSTF) Draft Research Plan on Weight Loss to Prevent Obesity-Related Morbidity and Mortality: Interventions.

Founded in 2015, OCAN is a diverse group of organizations focused on changing how we perceive and approach obesity in the United States. OCAN works to increase access to evidence-based obesity treatments by uniting key stakeholders and the broader obesity community around significant education, policy and legislative efforts. We aim to fundamentally change how the U.S. healthcare system treats obesity, and to shift the cultural mindset on obesity so that policymakers and the public address obesity as a serious chronic disease.

We are pleased that the USPSTF has begun the process of updating its 2018 recommendations and is proposing to evaluate intensive behavioral therapy (IBT) services and pharmacotherapy as part of the obesity care continuum. However, we believe the Task Force should consider all evidence-based treatment avenues, such as IBT, pharmacotherapy, and surgery in developing an appropriate research plan for evaluating the scope of interventions the Task Force plans to recommend.

Proposed Analytic Framework

The proposed title is troubling in that it begins with one of the intermediate health outcomes. We strongly urge USPSTF to amend its language to “Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults”.

The term “weight loss and weight loss maintenance,” which is used frequently throughout this draft research plan, describes an intermediate outcome, not interventions. We urge that this term be replaced with the term “interventions for chronic weight management”.

The list of intermediate outcomes seems to mix chronic conditions with measurable outcomes or changes in biophysical measurements. We believe that the list of intermediate outcomes would be more accurate if it listed: change in weight; change in blood glucose; change in blood pressure, change in blood cholesterol levels; etc. Well-designed randomized clinical trials will be measuring biophysical measures at various intervals throughout the study, and, while these

biophysical measures may lead to a diagnosis of diabetes or hypertension or dyslipidemia, the impact of the intervention should be on biophysical measures not prevalence of these chronic conditions. For example, if someone is diagnosed with prediabetes or type 2 diabetes, a reduced blood glucose level post intervention does not necessarily mean the condition has been eradicated. Instead, the intervention may have led to effective secondary prevention.

Proposed Key Questions 1 and 2

Do primary care–relevant behavioral or pharmacotherapy weight loss and weight loss maintenance interventions for adults with higher body mass index (BMI) affect health outcomes?

Do primary care–relevant behavioral or pharmacotherapy weight loss and weight loss maintenance interventions for adults with higher BMI affect weight outcomes or cardiometabolic outcomes?

USPSTF's target population of "adults with higher body mass index (BMI)" is a heterogenous group with respect to approved or recommended treatments. Anti-obesity medications (AOMs) are generally labeled for individuals with a BMI over 30 kg/m^2 or over 27 kg/m^2 with at least one associated comorbid medical condition. While AOMs are generally studied as an adjunct to behavioral interventions or lifestyle modifications, in real-world clinical practice, they are most often prescribed after behavioral/lifestyle interventions fail.

Therefore, we believe that asking the questions as an either/or does not accurately reflect how weight management interventions are used in primary care settings. USPSTF should consider breaking this question down into 2 queries:

- Do primary care-relevant behavioral interventions for chronic weight management for adults with higher body mass index (BMI) affect health outcomes?

- Does adding pharmacotherapy to behavioral interventions in adults with a BMI over 30 kg/m^2 or over 27 kg/m^2 with at least one associated comorbid medical condition, affect health outcomes?

In its review of evidence on behavioral interventions, USPSTF should consider whether data on behavioral interventions reflect divergent treatments (e.g., different modalities, frequency or duration of services, follow-up timeline, patient populations, content of services, etc.) and clarify (quantitatively and qualitatively) the contours of any behavioral interventions the task force recommends.

USPSTF's review of pharmacotherapy interventions should consider whether studied populations are adults that have tried and failed on behavioral/lifestyle interventions. If so, a simple comparison in effectiveness between pharmacotherapy and behavioral interventions would lead to distorted conclusions.

USPSTF should also amend its terminology from "weight loss and weight loss maintenance" to "chronic weight management" to align with the current FDA-approved label language for

AOMs. As innovations like anti-obesity medications evolve, we recommend that USPSTF recommendations include language that matches FDA-approval label updates.

It is also important to note that the draft research plan key questions 1 and 2 specifically reference care delivery in the primary care setting. In reality, most evidenced-based obesity care takes place with specialty providers like endocrinologists, dietitians, obesity medicine specialists, etc. The majority of primary care providers are not trained or adequately equipped to deliver effective chronic weight management interventions.

Proposed Key Question 3

What are the harms associated with weight loss interventions for adults?

Obesity is a chronic disease that, if unaddressed, can lead to serious comorbidities and complications. Proposed key question 3 should, at a minimum, differentiate between short- and long-term (i.e., impacting long-term health outcomes) harms associated with interventions. Withdrawal of medication due to side effects and exercise-induced injury are generally experienced in the short-term and unlikely to be harmful to patient outcomes unless they are significant (e.g., fractures, soft-tissue injuries requiring surgery, hospitalization due to AEs) or discourage continued efforts to address obesity.

USPSTF appropriately includes unhealthy weight management efforts as a potential harm from interventions. It should also include other harms from ineffective weight loss/management interventions such as continuing/worsening obesity and its complications that may result from clinician failure to offer additional approaches/modalities.

Another major and real risk for many patients with obesity is the lack of access and inadequate health insurance coverage for chronic weight management interventions. Most patients also face high out-of-pocket costs for obesity care, which often results in no care and worsening in disease severity and health outcomes.

Proposed Contextual Questions

Weight Bias and Stigma

OCAN applauds USPSTF for including a number of key issues in its contextual questions surrounding both bias and stigma as well as health inequities surrounding access to obesity care.

Weight bias and stigma continue to play a role in everyday life and remains a socially acceptable form of prejudice in American society and is rarely challenged. It can be overt or subtle and occur in any setting, including employment, healthcare, education, mass media and relationships with family and friends. It also takes many forms – verbal, written, media, online and more. Weight bias is dehumanizing and damaging. It can cause adverse physical and psychological health outcomes and promotes a social norm that marginalizes people.

Research suggests that beliefs about the causality and stability of obesity are important factors contributing to negative attitudes. For example, studies show that individuals affected by

obesity are more likely to be stigmatized if their overweight condition is perceived to be caused by controllable factors compared to uncontrollable factors (e.g., overeating versus a thyroid condition), and if obesity is perceived to be a condition of personal choice, versus a serious health condition. This stigma affects quality of care with provider interactions, resulting in less time spent in appointments, less discussion with patients, more assignment of negative symptoms, reluctance to perform certain screenings, and fewer interventions.

Inequities in Relation to Weight Management Interventions

We are also pleased that the Task Force is evaluating health inequities related to obesity care. We know that obesity disproportionately impacts communities of color that already face systemic inequities in care. Addressing the disease of obesity must be part of our response on health equity issues. Racial and ethnic minorities experience disproportionately poorer health outcomes for infectious and chronic diseases. Race and ethnicity affect both obesity prevalence and obesity treatment outcomes.

American Indians, Black Americans, Hispanic Americans, and Asian Americans are all more likely than White Americans to have diabetes. Additionally, Black women have the highest rates of obesity among any demographic group—approximately 4 out of 5 have overweight or obesity. In pediatric and adult female populations, Black and Hispanic Americans experience higher rates of obesity than White Americans. Both Latino adults and children have higher obesity rates than other groups. When sex is considered, Black women experience the highest obesity rates, followed by Latina women. Disparities exist not only in obesity prevalence, but also in obesity treatment outcomes. Weight management therapies have been shown to be less effective for racial and ethnic minorities. These disparities are not limited to infectious diseases; racial minorities experience higher rates of chronic diseases, death, and disability compared with white Americans.

Effectiveness and Comparative Effectiveness and Safety of Bariatric Procedures

There is a well-established body of evidence that demonstrates the effectiveness of bariatric surgery. Bariatric surgery can address several complications of obesity like diabetes, improve quality of life, and increase life expectancy. While we recognize that primary care providers are not surgeons, they are at the forefront of identifying the intervention as an option and it is important for them to refer a patient if needed.

Settings

Evidence-based intensive behavioral therapy programs are widely available in the community. We note that the prior evidence reviews on interventions to treat obesity relied on evidence from interventions that were provided in the community in person, through online virtual means, or through telephonic coaching. We urge USPSTF to use language in the inclusion criteria to capture community-based settings of care.

We urge USPSTF to use the language that it has used in the past for the inclusion criteria:

- “Studies conducted in or recruited from primary care or a health care system or that could feasibly be implemented in or referred from primary care;

- In order for an intervention to be feasible for primary care referral, it would need to be conducted as part of a health care setting or be widely available in the community at a national level (e.g., commercial weight loss programs, technology interventions)"

This month marks the 10-year anniversary of the American Medical Association (AMA) adopting formal policy recognizing obesity as a complex and chronic disease and expressing their "support for patient access to the full continuum of care of evidence-based obesity treatment modalities such as behavioral, pharmaceutical, psychosocial, nutritional, and surgical interventions." AMA's recognition of obesity as a disease in 2013 was the catalyst behind numerous other organizations coming out in support for ensuring patient access to obesity care, such as the National Council of Insurance Legislators, National Lieutenant Governors Association, National Hispanic Caucus of State Legislators, and the National Black Caucus of State Legislators.

Clearly, many national, federal, and state organizations now recognize obesity as a complex and chronic disease and worthy of coverage for comprehensive evidence-based treatment avenues. OCAN encourages USPSTF to embrace this approach by recommending that adults affected by overweight or obesity be referred to all appropriate evidence-based treatment avenues.

Sincerely,

Christine Gallagher, MPAff
OCAN Co-Chair
Redstone Global Center for Prevention and Wellness, George Washington University
cqgallagher@gwu.edu

Anthony G. Comuzzie, Ph.D., FTOS
OCAN Co-Chair
Chief Executive Officer, The Obesity Society
tcomuzzie@obesity.org

Rob Goldsmith
OCAN Co-Chair
Director, Advocacy and Policy, The Endocrine Society
rgoldsmith@endocrine.org