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June 14, 2023

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

# RE: Response to USPSTF Draft Research Plan for Weight Loss Interventions to Prevent Morbidity and Mortality

Dear Members of the United States Preventative Services Task Force,

The Alliance for Aging Research ("Alliance") appreciates the opportunity to review and comment on the USPSTF Draft Research Plan for Weight Loss Interventions to Prevent Morbidity and Mortality. The Alliance is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health. Central to the Alliance's work is our commitment to ensuring that patients have access to the care they need to support healthy aging.

It is of the utmost importance that modern weight loss interventions are accurately assessed both for how successful they are at reducing weight, weight-related risk factors, and their long-term effectiveness. The USPSTF must prioritize a comprehensive review of possible interventions to ensure that recommendations align with the most up-to-date scientific evidence and prioritize patient outcomes.

The scientific landscape regarding weight loss interventions has evolved since the Task Force's 2018 recommendations. Recent studies have demonstrated the safety and effectiveness of anti-obesity medications (AOMs) as a supplemental approach to behavioral interventions for weight management. Obesity is the leading cause of death in the United States. For that reason, it is imperative that preventative treatments be made available to patients broadly. At present, AOMs

<sup>&</sup>lt;sup>1</sup> NHLBI (National Heart, Lung, and Blood Institute). "Overweight and Obesity: What You Need to Know." 24 Mar 2022. <a href="https://www.nhlbi.nih.gov/health/overweight-and-obesity#:~:text=Obesity#:~:text=

are covered for by Federal Employee Health Plans,<sup>2</sup> Tricare,<sup>3</sup> less than half of commercial insurance plans,<sup>4</sup> and 15 state Medicaid programs.<sup>5</sup> AOMs are not currently covered by Medicare.<sup>6</sup> These disparate coverage policies have a disproportionately adverse impact on older adults – a population where over one in five individuals (as measured among Medicare fee-for-service beneficiaries) combats obesity.<sup>7</sup>

Preventative care for obesity in older adults has significant benefits, improving their overall health and well-being, extending life expectancy, and helping them to avoid stigmatization in society and their doctor's offices. To promote long-term health and sustainable outcomes, it is essential to adopt a holistic approach to weight management. The focus should incorporate near-term weight reduction interventions and include long-term weight management strategies. This comprehensive perspective will promote the broader individual and societal value of weight loss interventions, such as reducing the risk of chronic diseases, improving quality of life, and enhancing overall well-being.

The Task Force should prioritize patient-reported outcomes and measures of functional improvement to provide a comprehensive understanding of the benefits of weight loss interventions beyond mere numerical metrics. This patient-centered approach will ensure that the recommendations reflect the real-life impact of interventions on individuals' well-being and productivity.

# **Proposed Changes to Key Questions**

**Key Question 1:** 

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?

<sup>&</sup>lt;sup>2</sup> Office of Personnel Management. "2023 FEHB Program Carrier Letter." 18 Jan 2023. <a href="https://www.opm.gov/healthcare-insurance/healthcare/carriers/2023/2023-01.pdf">https://www.opm.gov/healthcare-insurance/healthcare/carriers/2023/2023-01.pdf</a>

<sup>&</sup>lt;sup>3</sup> Express Scripts. "TRICARE Formulary Search Tool." <a href="https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/">https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/</a>

<sup>&</sup>lt;sup>4</sup> Popke, Michael. "Obesity is a Disease: That's Why 22% of Employers are Now Covering Weight Loss Drugs." BenefitsPro. 12 Jan 2023. <a href="https://www.benefitspro.com/2023/01/12/obesity-is-a-disease-thats-why-22-of-employers-are-now-covering-weight-loss-">https://www.benefitspro.com/2023/01/12/obesity-is-a-disease-thats-why-22-of-employers-are-now-covering-weight-loss-</a>

 $<sup>\</sup>frac{drugs/\#:\text{``:text=The\%20survey\%20} indicates\%20 that\%2022, organizations\%20 offer\%20 weight\%20 management\%20 programs.}{}$ 

<sup>&</sup>lt;sup>5</sup> Stephenson, Joan. "Report Finds Large Variation in States' Coverage for Obesity Treatments." JAMA Health Forum. 01 March 2022. <a href="https://jamanetwork.com/journals/jama-health-forum/fullarticle/2789704">https://jamanetwork.com/journals/jama-health-forum/fullarticle/2789704</a>

<sup>&</sup>lt;sup>6</sup> Centers for Medicare & Medicaid Services. "National Coverage Determination (NCD) for Bariatric Surgery for the Treatment of Morbid Obesity." Accessed 14 June 2023. <a href="https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=38&ncdver=3&DocID=40.5&kq=true&bc=gAAAABAAAQAAAAAA&="https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=38&ncdver=3&DocID=40.5&kq=true&bc=gAAAABAAAQAAAAAA&=</a>

<sup>&</sup>lt;sup>7</sup> Centers for Medicare & Medicaid Services. "Data Snapshot: Addressing Obesity Disparities in Medicare Beneficiaries." January 2022. <a href="https://www.cms.gov/files/document/omh-datasnapshot-obesity.pdf">https://www.cms.gov/files/document/omh-datasnapshot-obesity.pdf</a>

To enhance the clarity, accuracy, and scope of the question, we recommend that the question be split into two separate parts:

- 1. Do primary care-relevant behavioral weight loss and weight loss maintenance interventions for adults with higher body mass index (BMI) affect health outcomes and are those effects ongoing?
- 2. Does adding pharmacotherapy to behavioral interventions in adults with BMI of 30 or higher, or BMI over 27 and one or more weight-related comorbid conditions affect health outcomes?

The question as asked does not capture the full picture of weight management interventions in primary care settings. The term "adults with higher body mass index" outlines a diverse population in terms of bodily makeup and approved or recommended treatments. Weight management medications are typically indicated for individuals with a BMI of over 30, or over 27 with at least one associated comorbid medical condition. These medications are often studied and prescribed in addition to behavioral interventions or lifestyle modifications and are commonly prescribed after such interventions have failed.

When reviewing pharmacotherapy interventions, the USPSTF should assess whether the studied populations consist of adults who have previously attempted and failed on behavioral or lifestyle interventions. Research suggests that roughly 80 percent of people who lose a significant portion of body fat will not maintain that loss for more than one year. Therefore, time horizons are a critically important component when considering the efficacy of weight management tactics.

Breaking this question down into two parts allows the Task Force to focus separately on behavioral outcomes (over the short and long-term) and on the relative benefits of pharmacotherapy in addition to behavioral interventions for those populations for which pharmacotherapy is indicated.

Additionally, the USPSTF should consider aligning its terminology with FDA-approved label language for pharmacotherapy interventions. Instead of "weight loss and weight loss maintenance," using the term "weight management" would ensure consistency and clarity.

#### Key Question 3:

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

While the USPSTF appropriately considers unhealthy weight management efforts as a potential harm, it should also include other harms that can arise from ineffective weight loss or management interventions. This includes the continuation or worsening of obesity and its associated

<sup>&</sup>lt;sup>8</sup> Engber, Daniel. ""Unexpected Clues Emerge About Why Diets Fail." Scientific American. 13 January 2020. <a href="https://www.scientificamerican.com/article/unexpected-clues-emerge-about-why-diets-fail/#:~:text=Research%20suggests%20that%20roughly%2080,they%20lose%20within%20two%20years.">https://www.scientificamerican.com/article/unexpected-clues-emerge-about-why-diets-fail/#:~:text=Research%20suggests%20that%20roughly%2080,they%20lose%20within%20two%20years.</a>

complications, and psychological distress including the development of significant eating disorders such as anorexia nervosa or bulimia.

Furthermore, when exploring the harms associated with pharmacotherapy, the question should be refined to assess the specific harms of adding pharmacotherapy as an adjunct to lifestyle-directed interventions. This evaluation should focus on individuals for whom pharmacotherapy is indicated and who have failed to adequately respond to lifestyle-directed interventions alone.

## **Responses to Proposed Contextual Questions and Research Framework**

### Proposed Contextual Question 1:

What is the association between intentional weight loss and health outcomes, including harms?

It is important that the USPSTF acknowledge the significant step taken by the American Medical Association in 2013, in which they recognized obesity as a chronic disease. This shift in perspective reflects evolving views within the medical and scientific communities, which now recognize that the social and cultural implications of excess weight have historically overshadowed its medical implications. We now have a better understanding of the complex factors that contribute to obesity, including genetic, metabolic, environmental, and behavioral influences. This growing evidence challenges the common public perception that obesity is solely a result of personal choices or limited motivation, highlighting the need for evidence-based interventions rather than judgment based on personal responsibility. Responses to or evidence examined for this question should therefore be weighed against the negative outcomes and implications of chronic obesity over time. Further, discussion of health outcomes should include the impact of untreated obesity on elevated risk for negative outcomes related to other primary diagnoses.

#### Proposed Contextual Question 3:

What are the important issues related to weight stigma and bias in the clinical setting?

As the USPSTF considers bias in the clinical setting, it is important to consider the perspective of the patient. Weight stigma can have detrimental effects on healthcare experiences and outcomes. Diagnostic overshadowing and other biases may lead to delayed or missed diagnoses, while access to healthcare can be hindered as individuals fear judgment and mistreatment. Quality of care may be compromised, mental health can be impacted, and disparities in treatment can arise. Trust and communication may break down, and body dissatisfaction and eating disorders can be exacerbated. The USPSTF could also consider which approaches to care may be least susceptible to bias in the clinical setting. Addressing weight stigma and bias requires training for healthcare providers, adoption of a weight-inclusive approach, and advocacy for systemic changes to create a supportive and equitable healthcare environment.

**Proposed Contextual Question 5:** 

What inequities exist in relation to weight management interventions?

When evaluating this question, it is crucial to consider the role of insurance coverage. As noted above, the availability and coverage of AOM's varies significantly across payers, creating inequities in access to care. As a result, individuals from lower socioeconomic backgrounds or those with limited insurance coverage may face barriers in accessing these interventions, perpetuating disparities in healthcare. Recognizing the impact of insurance coverage as a limiting factor for equity for weight management interventions is essential in addressing and advocating for fair and accessible healthcare options for all individuals.

## Proposed Approach to Assessing Health Equity and Variation in Evidence Across Populations

We commend the USPSTF for this approach to incorporating health equity in your review. Ensuring that patient perspectives are incorporated across age, race, ethnicity, cultural identity, socioeconomic and insurance status, and comorbid conditions will provide a robust, data-driven basis for the final recommendation. This goes beyond the standards and typical expectations of the scientific community. The only change we recommend to this robust framework is that the Task Force should not rely solely on randomized controlled clinical trials (RCTs). To ensure a more comprehensive understanding of weight management interventions, it would be beneficial for the USPSTF to include prospective studies, meta-analyses, real-world evidence, and pilot studies. By incorporating these additional study designs, the USPSTF can better capture the diverse experiences and needs of underrepresented populations, ultimately promoting more equitable and effective recommendations.

#### Conclusion

The USPSTF plays an incredibly significant role in ensuring that patients have access to care, and obesity is quickly becoming one of the most deadly, common conditions that patients in the United States face. Revised recommendations would not only enhance patient care but also empower healthcare providers with the necessary guidance to navigate the complexities of weight management interventions. We look forward to the updated recommendations that will improve the health and well-being of individuals struggling with obesity. With any questions, please reach out to Adina Lasser, the Alliance's Public Policy Manager, at <a href="mailto:alasser@agingresearch.org">alasser@agingresearch.org</a>.

Sincerely,

Adina Lasser

Public Policy Manager

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