Admiral Rachel L. Levine, MD Assistant Secretary for Health U.S. Public Health Service U.S. Department of Health and Human Services

Janet de Jesus, MS, RD Nutrition Advisor Division of Prevention Science Office of Disease Prevention and Health Promotion U.S. Department of Health and Human Services

Dear Assistant Secretary Levine and Ms. de Jesus,

The undersigned organizations are invested in ensuring that the 2025-2030 Dietary Guidelines for Americans are scientifically sound, transparently developed, and widely accepted and adopted by the general public. We strongly support the work of the U.S. Departments of Health and Human Services and Agriculture (collectively, the "Departments") in promulgating them.

For the 2025-2030 Dietary Guidelines for Americans to have the greatest impact on the health and nutrition of families across the country, it is crucial that the Departments facilitate public trust in the process. To that end, it is crucial to improve transparency and protect against conflicts of interest, including financial and other ties to industry, such as board service and affiliations. We therefore write to urge you to publicly disclose financial conflicts of interest of the newly appointed 2025 Dietary Guidelines Advisory Committee members. We request such disclosures to be made easily accessible to the public as soon as possible. We also request a meeting with you to discuss how the Departments defined and addressed financial conflicts of interest while selecting Committee members and how the Departments and Committee will manage conflicts for the duration of the 2025-2030 Dietary Guidelines for Americans development process.

The *Dietary Guidelines* are the foundation for nutrition programs and education campaigns at the federal, state, and local levels; their ultimate goal is to help individuals eat more healthfully and reduce the risk of chronic diet-related disease. To guide the process of developing the *Dietary Guidelines* every five years, the Departments establish an independent, expert, external Advisory Committee. One of the most important roles of the Advisory Committee is to review all relevant information in a scientifically rigorous process that puts the public's health first. These recommendations are then provided to the Departments which utilize them in issuing the final Guidelines.

Following the publication of the 2015-2020 Dietary Guidelines, Congress requested a National Academy of Sciences, Engineering, and Medicine (NASEM) report to evaluate the Dietary Guidelines development process. Among other things, NASEM concluded in 2017 that the

¹ United States Department of Agriculture. *Purpose of the Dietary Guidelines*. n.d. https://www.dietaryguidelines.gov/about-dietary-guidelines/purpose-dietary-guidelines. Accessed January 19, 2023.

Advisory Committee selection process needed improvements.² NASEM recommended that "a policy be shared with the public describing (1) a general plan for identifying and resolving biases and conflicts on the whole panel, and (2) plans for managing individuals' specific conflicts, as needed." The report also noted that even the "perception of biases and conflicts of interest can...undermine the public's trust in the process" of developing the *Dietary Guidelines*.³ Indeed, several reports by non-governmental organizations questioned the trustworthiness of the 2020 Dietary Guidelines Advisory Committee based on members' industry ties.^{4,5}

NASEM made four specific recommendations in its report, including that the Departments "make a list of provisional appointees open for public comment – including short biographies and any known conflicts - for a reasonable period of time prior to appointment." However, the Departments did not implement this recommendation during the 2020-2025 Dietary Guidelines development process, citing privacy concerns for provisional appointees.⁶ Regardless of the merits of publicizing a provisional list of appointees for public comment, the Departments did not identify an alternative method for disclosing Committee members' conflicts of interest following appointment. Instead, during the 2020-2025 Dietary Guidelines development process, the Departments, for the first time, requested specific information from Advisory Committee nominees pertaining to education, employment, peer-reviewed publications, presentations, blogs, funding sources, and other affiliations. The same was requested of 2025 Advisory Committee nominees, but this information has not been released to the public.^{7,8} In addition, the Departments reported requesting 2020 and 2025 Advisory Committee candidates under final consideration for membership to submit a Confidential Financial Disclosure Report (OGE 450)⁹ prior to selection. However, this form is exempt from public disclosure and so does not advance transparency. 10 Thus, the Departments did not fully implement NASEM's recommendations,

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² National Academies of Sciences, Engineering, and Medicine (NASEM). *Optimizing the Process for Establishing the Dietary Guidelines for Americans: The Selection Process.* 2017. https://nap.nationalacademies.org/catalog/24637/optimizing-the-process-for-establishing-the-dietary-guidelines-for-

https://nap.nationalacademies.org/catalog/24637/optimizing-the-process-for-establishing-the-dietary-guidelines-for americans. Accessed January 19, 2023.

³ National Academies of Sciences, Engineering, and Medicine (NASEM). *Optimizing the Process for Establishing the Dietary Guidelines for Americans: The Selection Process.* 2017. https://nap.nationalacademies.org/catalog/24637/optimizing-the-process-for-establishing-the-dietary-guidelines-for-americans. Accessed January 19, 2023.

⁴ Jackson DZ. Food Companies at the Table in Trump Administration's Dietary Guidelines Committee. The Equation – Union of Concerned Scientists. April 1, 2019. https://blog.ucsusa.org/derrick-jackson/trump-administrations-dietary-guidelines-committee/. Accessed January 19, 2023.

⁵ Corporate Accountability International. *Partnership for an Unhealthy Planet: How big business interferes with global health policy and science*. 2020. https://www.corporateaccountability.org/wp-content/uploads/2020/09/Partnership-for-an-unhealthy-planet.pdf. Accessed January 19, 2023.

⁶ Stoody E. Responding to the National Academies of Sciences, Engineering, and Medicine Study on the Process to Update the Dietary Guidelines for Americans. U.S. Department of Agriculture. 2019. https://www.dietaryguidelines.gov/sites/default/files/2019-05/Day%201%20Response%20to%20NASEM%20Study.pdf. Accessed January 19, 2023.

⁷ Stoody, 2019.

⁸ United States Department of Agriculture. *Learn About the Process*. n.d. https://www.dietaryguidelines.gov/learn-about-process#step-2-appoint-the-advisory-committee. Accessed January 19, 2023.

 $^{^9}$ U.S. Office of Government Ethics. $OGE\ Form\ 450,\ 5\ CFR\ Part\ 2634,\ Subpart\ I.\ 2021.$ https://www.oge.gov/web/oge.nsf/OGE%20Forms/072B8F6679028547852585B6005A2051/\$FILE/OGE%20Form%20450%20Nov%202021.pdf?open

¹⁰ 5a U.S.C. § 107(a)(2).

which were intended to not only assure appropriate management of conflicts of interest, but also reassure the public that this had occurred. At present, the public remains in the dark.

As the 2025-2030 Dietary Guidelines begin to take shape, we must ensure the Advisory Committee proceeds in a way that provides confidence in its recommendations. Mandatory public disclosure of conflicts of interest for appointed Advisory Committee members is an important first step in this effort. Recent events support this recommendation. During the COVID-19 pandemic, the problem of public distrust in federal recommendations has only grown. Transparency in the vaccine approval process, however, helped minimize the problem. A recent national study found that declines in COVID-19 vaccine hesitancy from October 2020 to March 2021 were associated with an increase in public trust in vaccine development and the government approval process. While all relevant financial interests among Committee members should be disclosed, those related to the food and pharmaceutical industries should be subject to particular scrutiny as they are most relevant to the subject matter of the Dietary Guidelines. Already press coverage has uncovered one 2025 Dietary Guidelines Advisory Committee member with a conflict of interest that seems relevant to their role. 12

However, in some instances, disclosure is insufficient to minimize bias. In a recent publication in the BMJ, Parker and Bero contend that an escalating, risk-based management approach is necessary to assess and respond to potential bias created by guideline committee members with conflicts of interest, accounting for the fact that different conflicts of interest pose different levels of risk of bias. 13 For more minor conflicts of interest, public disclosure will suffice. For more extensive conflicts, more comprehensive and strategic approaches will be necessary. For example, if a dietary guideline committee nominee is a current recipient of research grant money from a large national food corporation, Parker and Bero would classify the individual as being at high risk of biased decision-making and suggest managing that conflict of interest by rejecting the nominee's committee membership until 3 to 5 years have passed since the research grant ended. Canada adopted a similar provision for its Nutrition Science Advisory Committee, which provides scientific and technical advice for the development of Canada's Dietary Guidelines. 14 If the partner of a dietary guideline committee nominee is an employee at a small food company, Parker and Bero would consider that applicant at medium risk of biased decision-making and suggest that, while the applicant can still serve, they should not be allowed to chair a committee and should have only restricted participation in a committee until 3 to 5 years have passed since the conflict of interest has been resolved. Parker and Bero's framework should inform additional process improvements in future Dietary Guidelines cycles.

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¹¹ Daly M, Jones A, Robinson E. Public Trust and Willingness to Vaccinate Against COVID-19 in the US From October 14, 2020, to March 29, 2021. *JAMA*. 2021;325(23):2397–2399. doi:10.1001/jama.2021.8246

¹² Enjeti, S. [@esaagar]. (2023, January 23). 1/ The appointment of this Dr by the Biden admin to our dietary advisory council is the perfect illustration of how pharma and big government are rigging nutrition guidelines for \$ [Tweet]. Twitter. https://twitter.com/esaagar/status/1617589475277668382

¹³ Parker L, Bero L. Managing risk from conflicts of interest in guideline development committees. *BMJ*. 2022;379:e072252 doi:10.1136/bmj-2022-072252

¹⁴ Government of Canada. *External Conflict of Interest (COI) Advisor Selection Methodology*. February 24, 2021. https://www.canada.ca/en/health-canada/services/nutrition-science-research/nutrition-science-advisory-committee/external-conflict-interest-advisor-selection-methodology.html.

To better understand how the Departments are defining and addressing conflicts of interest, a few representatives of the undersigned groups would like to meet with you and your team in the next several weeks to learn more about the following:

- 1. The nomination review and Committee selection process, including how the Departments defined and addressed financial conflicts of interest.
- 2. The planned process for the public disclosure and management of potential and actual financial conflicts of interest for the 2025 Dietary Guidelines Advisory Committee going forward in the 2025-2030 Dietary Guidelines for Americans development process.

We thank you for your consideration of this request. Please direct your response to Catherine Cochran at the Center for Science in the Public Interest on behalf of the undersigned at 925-989-3322 or by email at cochran@cspinet.org.

Sincerely,

B.Komplete

Balanced

Center for Biological Diversity

Center for Science in the Public Interest

Coalition for Healthy School Food

Corporate Accountability

Healthy Food America

Johns Hopkins Center for a Livable Future

Laurie M. Tisch Center for Food, Education & Policy, Teachers College, Columbia University

National Association of Pediatric Nurse Practitioners

Physicians Committee for Responsible Medicine

Redstone Global Center for Prevention and Wellness at George Washington University

Society of Behavioral Medicine

Union of Concerned Scientists

Wholesome Wave

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