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Catalyzing Innovation for Healthy Aging

August 27, 2020

Stephanie Thomas ACIP Committee Management Specialist Centers for Disease Control and Prevention National Center for Immunization and Respiratory Diseases 1600 Clifton Road NE, MS–H24–8 Atlanta, GA 30329–4027

Re: Docket No. CDC–2020–0083 for Request for Comments for "August Advisory Committee on Immunization (ACIP) Practices Meeting"

Dear Ms. Thomas,

Thank you for the opportunity to submit a public comment to the Advisory Committee on Immunization (ACIP) August 2020 meeting. Our organization, the <u>Alliance for Aging Research</u> (the "Alliance"), is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. The Alliance believes that advances in research help people live longer, happier, more productive lives, and reduce health care costs over the long term.

For the past four years, the Alliance has led the <u>Our Best Shot campaign</u>, which encourages older adults to play an influential role in their families and communities to debunk myths and make sure their vaccinations are up to date. The Centers for Disease Control and Prevention (CDC) includes the campaign's educational film on its website. We would like to express our appreciation to the CDC for featuring this <u>important resource</u>.

We appreciate ACIP's important work in developing recommendations and guidance on the use of vaccines. We urge you to consider the below recommendations to better respond to the needs of the older adult population – especially in the face of the double threat of the COVID-19 pandemic and upcoming influenza season.

• The Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Council on Immunization Practices, 2020-21 Influenza Season avoids recommending enhanced influenza products over the standard-dose flu shots for adults aged 65 years and older, despite providing evidence of superior efficacy. The recommendations should encourage older adults to seek out enhanced vaccines to better protect their health, particularly amid the COVID-19 pandemic and the disease's disproportionate impact on the aging population. While we acknowledge that any influenza vaccination is better than no influenza vaccination, the recommendation should make a stronger statement in favor of enhanced vaccines for older adults. We urge ACIP and the CDC to state a preference for high-dose and adjuvanted

influenza vaccines over the standard-dose vaccine for older adults in the 2020-2021 Influenza Season recommendations.

- The ACIP is structured to have 15 voting members and eight ex officio members for making vaccine recommendations, who are nominated by the Secretary of Health and Human Services. Unfortunately, the Secretary does not explicitly nominate experts with expertise in geriatrics medicine. This has led to a lack of representation of medical professionals on ACIP focused on treating older adults. The aging population is more vulnerable to severe illness, hospitalization, and death from influenza, COVID-19, pneumonia; and complications for a number of other preventable infectious diseases. It is concerning that ACIP advises on vaccine products for older adults without appropriate representation of geriatric experts. We urge ACIP to add more experts in geriatrics and older adult vaccination research.
- We believe the committee's interpretation of "conflict of interest" for ACIP nominees is more
 restrictive than intended by the Federal Advisory Committee Act. Importantly, this overly strict
 interpretation may contribute to dissuading and preventing experts in older adult vaccinations
 from meaningfully contributing to ACIP. We recommend that the CDC review its interpretation
 of "conflict of interest" and develop publicly available guidance on "conflict of interest" akin
 to the Food and Drug Administration's (FDA) guidance on Financial Interest Information and
 Waivers. For example, for each financial interest held by a special government employee, the
 FDA looks for a close or "direct" causal link between any pending decisions or actions and any
 real or "predictable" (as opposed to a speculative), possibility that the matter will affect the
 financial interest.
- The objective of ACIP, as stated in its charter, is to "provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccinepreventable diseases in the civilian population of the United States." The objective is focused on disease control, yet the charter allows for consideration of "economic analyses" as part of ACIP's consideration to revise or withdraw vaccine recommendations. Additionally, in 2018 ACIP adopted the "Evidence to Recommendations Framework" that includes the question, "Is the intervention a reasonable and efficient allocation of resources?"; and in October 2019, ACIP adopted updated guidance for consideration of health economics studies. We do not believe economic analyses should be included as part of ACIP's consideration of vaccine recommendations, nor should it be tasked with deciding whether a vaccine under its consideration is cost-effective. U.S. federal civil rights laws - including the American Disabilities Act, the Rehabilitation Act, and the Patient Protection and Affordable Care Act – prohibit the use of quality-adjusted life-year (QALY) and similar cost-effectiveness assessments for coverage and reimbursement decision-making in both the Medicare and Medicaid programs. Further, the National Council on Disability has recommended a prohibition on the use of QALYs and for Congress to avoid creating provisions that would "cover only the most cost-effective drugs or treatments, or to require the agency to impose restrictions on less cost-effective treatments."1 The QALY is a discriminatory metric that assigns a financial value to the patients for whom a given treatment is intended. If the respective group is sicker, older, and/or disabled, the QALY

¹ National Council on Disability. *Quality-Adjusted Life Years and the Devaluation of Life* with Disability. 6 Nov 2019. <u>https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf</u>

calculates treatments for them as less valuable. When applied to healthcare decision-making, the results can mean that some patients—people with disabilities, veterans, and older adults are deemed "too expensive" to receive care. Effectiveness should be measured by improvements to a patient's condition and quality of life, rather than personal characteristics or health status. We urge ACIP to immediately eliminate economic considerations and analyses from its charter.

Thank you again for the opportunity to provide written comments for ACIP's August 2020 meeting. If you have any questions regarding our comments, please contact the Alliance for Aging Research's Vice President of Health Education and Advocacy, Lindsay Clarke at <u>lclarke@agingresearch.org</u>.

Sincerely,

Lindsay Carke

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Michael Ward, MS Director, Public Policy Alliance for Aging Research