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## **Alliance for Aging Research's Public Comment to U.S. Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee Meeting – October 22, 2020**

Hello, I'm Sue Peschin, President and CEO of the Alliance for Aging Research. The Alliance receives industry funding for non-branded, older adult vaccine and COVID-19 education, but we have no conflict of interests for this meeting.

It's hard to comprehend the horror of mass COVID-19 deaths among those 65 and older in the U.S.—totaling more than 160 thousand people. That's 80 percent of all COVID-19-related deaths, in a group that accounts for only 16 percent of the U.S. population. Please keep that in mind as you do your work.

Research shows our immune systems grow weaker as we age. This phenomenon, known as immunosenescence, makes the immune systems of older adults less responsive to standard vaccines. Thankfully, there are FDA-approved, enhanced flu vaccines specifically designed for older adults that help overcome the effects of immunosenescence.

Unfortunately, in their most current recommendations, the CDC's Advisory Committee on Immunization Practices, or ACIP, once again avoided recommending enhanced flu products over standard-dose for those ages 65 plus. This was a missed opportunity to encourage older adults to better protect themselves during the worst pandemic in 100 years. Yes, any flu shot is better than no flu shot, but older adults need all the protection they can get.

It's critically important to understand geriatric immune response as you review COVID-19 vaccines. The Alliance implores the FDA and VRBPAC to be transparent about all steps being taken to ensure COVID-19 vaccines are safe and effective for older adults, particularly those 80 and older. Sponsors should be required to explicitly demonstrate how their vaccines were tested, and how they performed, among stratified older age groups in late-stage trials. And because COVID-19 vaccines may be granted EUA status, we strongly advocate the FDA require public reporting of post-market studies.

It makes sense public health experts are recommending that those in nursing homes be among the first groups to receive a COVID-19 vaccine. However, we ask the FDA, VRBPAC, and ACIP to consider which COVID-19 vaccines will provide the most protection to our oldest citizens, and balance it with efforts to prioritize vaccine distribution and administration.

Additionally, COVID-19 vaccines will be considered for EUA during flu season. The FDA's thinking on COVID-19 vaccines and coadministration with flu, or other CDC-recommended adult vaccines, is very important. We urge you to make this information a priority in provider and patient education efforts.

Lastly, the Alliance continues to call on our federal health agency leaders to be straight with policymakers and the public about what lies ahead in the COVID-19 fight, without sugarcoating or political spin. Continue to champion science because science is what will save us. Thank you for the opportunity to speak.