February 25, 2021

[Sent via email]
Peter Marks, M.D., Ph.D.
Director, Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Marks:

As the COVID-19 vaccination campaign has rolled out nationally, ASHP's members have been focused on ensuring that every single vaccine dose finds its way to patients. In service of that goal, we believe that additional doses of COVID-19 vaccine could be saved from wastage if clinicians are able to combine partial doses remaining in vials after full doses have been administered. Understanding that patient safety is paramount, we want to explore every potential opportunity for low-risk means of increasing vaccine supply.

To prevent any avoidable vaccine wastage, we respectfully request that the Food and Drug Administration (FDA) consider the viability of combining partial doses from vials to create a full dose for administration, as well as the circumstances under which such combination would be viable. Given that neither the Moderna nor the Pfizer-BioNTech vaccines contain preservative, we share FDA's concerns about limiting any microbial growth or contamination.

Specifically, we are asking that the FDA consider the viability of allowing vaccinators to combine partial doses only when:

1) Doses are derived from combining remaining partial doses in vials from which all full doses have been used;
2) Combined doses are administered within 6 hours of opening any vial from which partial doses are derived; and
3) Doses are only combined from vials with the same lot number.

We are hopeful that a carefully tailored approach to vial combination could limit safety risks while increasing supply.

ASHP is extremely appreciative of FDA's efforts to get safe and effective vaccines to patients. We look forward to continuing to work with the agency to ensure that every available dose is safely administered to patients. Please let us know if we can provide any additional information that would assist the agency in its consideration of our request.

Sincerely,

Tom Kraus, J.D.
Vice President, Government Relations

cc: USP Vaccine Resource Work Group