

**Congress of the United States**  
**Washington, DC 20515**

March 10, 2021

Janet Woodcock, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

We would like to thank the Food and Drug Administration (FDA) for its strong commitment to making decisions based on data and science, which is of utmost importance during the COVID-19 pandemic. We are also glad that, after vigorous review, FDA has approved the Johnson & Johnson vaccine and approximately four million doses were distributed throughout the United States last week. We write today regarding the FDA's policies related to the pooling of the COVID-19 vaccine to help vaccine doses get into the arms of the American people.

Northern Virginia is experiencing a high demand for the COVID-19 vaccine but lacks supply. Nearly half of all Virginians are eligible for the vaccine under Phase 1b. In Fairfax County the wait list for the vaccine exceeds 108,000 and in Loudoun County the wait list exceeded 45,000 people in February. The INOVA health system—a major vaccine source for Northern Virginians—has the infrastructure to administer thousands more doses but is unable to due to limited supply.

It has been reported that there are significant amounts of leftover vaccine in almost every Pfizer-BioNTech drug vial, even after using the additional sixth doses in the vials. With this leftover supply it could be possible for a hospital that typically administers 4,000 shots in a day to provide an additional 400 vaccine shots – a 10 percent increase in vaccine distribution capacity. Currently, however, clinicians are throwing away the extra doses in these vials due to FDA guidance that says, “any further remaining product that does not constitute a full dose should not be pooled from multiple vials to create one.”

The FDA's concerns about cross-contamination of vaccine doses due to a lack of preservatives in the Pfizer-BioNTech and Moderna vaccines is based on public health and patient safety. However, the FDA should continue to explore ways to increase vaccine supply without putting patients at risk, including safe ways to avoid vaccine waste by combining leftover doses from drug vials.

- How did you come to the conclusion that remaining product from Pfizer-BioNTech and Moderna vials should not be pooled from multiple vials to create one full dose?
- Has the FDA considered allowing clinicians to pool the COVID-19 vaccine when the following conditions are met:
  - Combined doses are used within 6 hours of opening any vial to avoid cross contamination;
  - Vaccine doses are only combined from vials with the same lot number to allow clinicians to track the vaccine doses;
  - Allowing vaccine doses to be pooled and administered only at certain settings of care that FDA identifies has the capability to adhere to standards like those described above to ensure patient safety.
- Has FDA reviewed any data that shows this practice can be done safely?

Sadly, we have reached a tragic milestone where over 500,000 Americans have died from COVID-19. We should be doing everything in our power to increase vaccine supply to help put an end to this pandemic and save lives.

Thank you for all that you have done to help stop the spread of COVID-19 and the steps you have taken to ensure vaccine safety and efficacy. We look forward to your response.

Sincerely,



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Jennifer Wexton  
Member of Congress



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Gerald E. Connolly  
Member of Congress



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Donald S. Beyer Jr.  
Member of Congress