

FDA STATEMENT**FDA Statement on Following the Authorized Dosing Schedules for COVID-19 Vaccines****For Immediate Release:**

January 04, 2021

Statement From:

Commissioner of Food and Drugs - Food and Drug Administration

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Two different mRNA vaccines have now shown remarkable effectiveness of about 95% in preventing COVID-19 disease in adults. As the first round of vaccine recipients become eligible to receive their second dose, we want to remind the public about the importance of receiving COVID-19 vaccines according to how they've been authorized by the FDA in order to safely receive the level of protection observed in the large randomized trials supporting their effectiveness.

We have been following the discussions and news reports about reducing the number of doses, extending the length of time between doses, changing the dose (half-dose), or mixing and matching vaccines in order to immunize more people against COVID-19. These are all reasonable questions to consider and evaluate in clinical trials. However, at this time, suggesting changes to the FDA-authorized dosing or schedules of these vaccines is premature and not rooted solidly in the available evidence. Without appropriate data supporting such changes in vaccine administration, we run a significant risk of placing public health at risk, undermining the historic vaccination efforts to protect the population from COVID-19.

The available data continue to support the use of two specified doses of each authorized vaccine at specified intervals. For the Pfizer-BioNTech COVID-19 vaccine, the interval is 21 days between the first and second dose. And for the Moderna COVID-19 vaccine, the interval is 28 days between the first and second dose.

What we have seen is that the data in the firms' submissions regarding the first dose is commonly being misinterpreted. In the phase 3 trials, 98% of participants in the Pfizer-BioNTech trial and 92% of participants in the Moderna trial received two doses of the vaccine at either a three- or four-week interval, respectively. Those participants who did not receive two vaccine doses at either a three- or four-week interval were generally only followed for a short

period of time, such that we cannot conclude anything definitive about the depth or duration of protection after a single dose of vaccine from the single dose percentages reported by the companies.

Using a single dose regimen and/or administering less than the dose studied in the clinical trials without understanding the nature of the depth and duration of protection that it provides is concerning, as there is some indication that the depth of the immune response is associated with the duration of protection provided. If people do not truly know how protective a vaccine is, there is the potential for harm because they may assume that they are fully protected when they are not, and accordingly, alter their behavior to take unnecessary risks.

We know that some of these discussions about changing the dosing schedule or dose are based on a belief that changing the dose or dosing schedule can help get more vaccine to the public faster. However, making such changes that are not supported by adequate scientific evidence may ultimately be counterproductive to public health.

We have committed time and time again to make decisions based on data and science. Until vaccine manufacturers have data and science supporting a change, we continue to strongly recommend that health care providers follow the FDA-authorized dosing schedule for each COVID-19 vaccine.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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