

Top FDA officials say two full doses of COVID-19 vaccines a must

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(HealthDay)—Two top officials at the U.S. Food and Drug

Administration said Monday that any American who gets the Moderna or Pfizer coronavirus vaccines must get two full doses, despite international debate on possible ways to stretch vaccine supply.

"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," FDA Commissioner Dr. Stephen Hahn and Dr. Peter Marks, who heads FDA's [vaccine](#) division, said in an agency statement.

"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," they added.

On Sunday, Operation Warp Speed's top adviser, Moncef Slaoui, told *CNN* that the FDA would consider giving half-doses of Moderna's vaccine to people aged 18 to 55—which could deliver the vaccine to twice as many people in that age group.

Slaoui said earlier data showed that the vaccine appeared to rouse similar antibody responses among volunteers under age 55 who received either the full 100-microgram dose or a half dose.

But Marks and Hahn said these preliminary findings covered only a few people who were not followed long enough to see if their immune responses held up over time.

"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," they said in their statement. "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."

Changing the dosage could also hamper the U.S. vaccine effort just as the public is starting to trust the program, Dr. Anthony Fauci told *The New York Times*.

"One of the dangers of making a change in midstream is that it could confuse the public," he explained.

He also suggested that changing the vaccine dosage was "the right answer to the wrong question. At the present time, we are not dealing with a shortage of doses—we are dealing with the need to increase our efficiency in getting people vaccinated," he said.

In the U.K., where England and Scotland have entered a third national lockdown as officials battle a more contagious variant of coronavirus, officials have said they will allow more than 21 days between doses of Pfizer's vaccines and would consider allowing people to get vaccinated with two different vaccines.

But Hahn and Marks rejected those policies for the United States.

"The available data continue to support the use of two specified doses of each authorized vaccine at specified intervals," they wrote. It's understandable that people may want to stretch the [vaccine supply](#), but it's not safe to do so, they added.

"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," they explained.

Dr. Paul Offit, an infectious disease specialist at the University of Pennsylvania, told *CNN* that he thought halving vaccine doses was a bad idea.

"There's no data on efficacy of a half dose. If you use a half dose, you're just making it up. You're just hoping that you're right," said Offit, a member of the FDA's Vaccines and Related Biological Products Advisory Committee. "Why would you dare to make up something when you don't know whether or not it works?"

New coronavirus variant now spotted in 4 U.S. States

On Monday, New York joined Florida, California and Colorado as states with a known case of the new and more contagious variant of the coronavirus.

Experts believe the new variant is probably already spreading elsewhere in the United States.

"The virus is becoming more fit, and we're like a deer in the headlights," Dr. Eric Topol, head of Scripps Research Translational Institute, told the *Associated Press*.

Topol said that the United States does less genetic sequencing of the virus to discover variants than other nations, and thus was probably slow to detect this new mutation.

No evidence has been found that this variant is more deadly or causes more severe illness, and scientists are saying that the vaccines will work against it. But a faster-spreading virus could swamp hospitals with seriously ill patients.

Researchers estimate the variant is 50% to 70% more contagious, Dr. Eric France, Colorado's chief medical officer, told the *AP*.

"Instead of only making two or three other people sick, you might actually spread it to four or five people," France said. "That means we'll have more cases in our communities. Those number of cases will rise quickly and, of course, with more cases come more hospitalizations."

The rapid spread of the new variant within Britain has triggered a third national lockdown there, with many countries banning or restricting flights from the United Kingdom.

A global scourge

By Tuesday, the U.S. coronavirus case count passed 20.8 million while the death toll passed 353,700, according to a *Times* tally. On Tuesday, the top five states for coronavirus infections were: California with over 2.4 million cases; Texas with more than 1.8 million cases; Florida with over 1.3 million cases; New York with over 1 million cases; and Illinois with more than 987,000 cases.

Curbing the spread of the coronavirus in the rest of the world remains challenging.

In India, the [coronavirus](#) case count was over 10.3 million on Tuesday, a Johns Hopkins University tally showed. Brazil had over 7.7 million cases and more than 196,500 deaths as of Tuesday, the Hopkins tally showed.

Worldwide, the number of reported infections passed 85.7 million on Tuesday, with more than 1.8 million deaths recorded, according to the Hopkins tally.

More information: The U.S. Centers for Disease Control and

Prevention has more on the new [coronavirus](#).

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