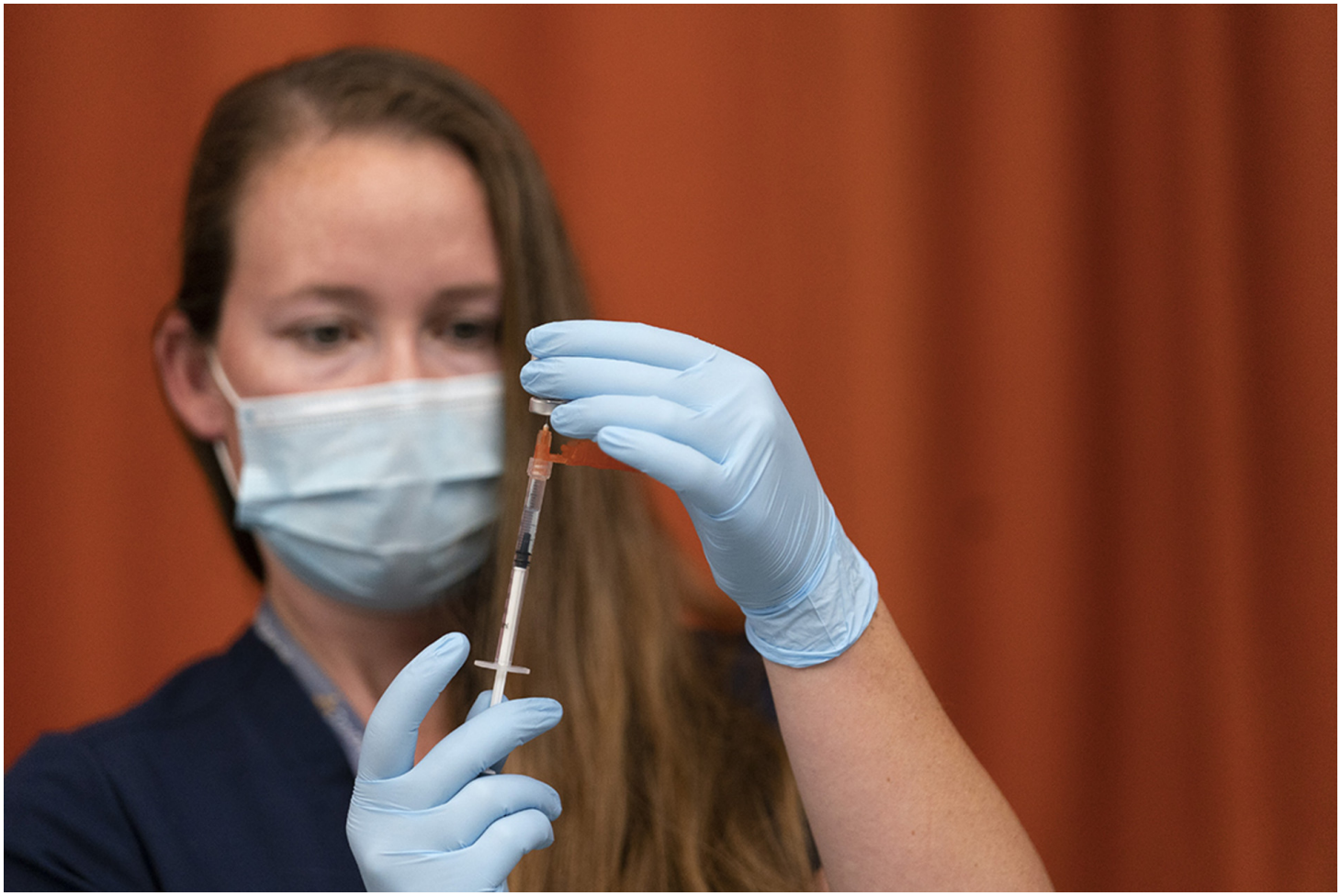
CORONAVIRUS

FDA authorizes third dose of Pfizer, Moderna shots for immunocompromised

Acting Commissioner Janet Woodcock emphasized that people whose immune systems are not compromised — the vast majority of Americans — do not need additional vaccine doses.



Katrina Taormina draws the Pfizer COVID-19 vaccine into a syringe at Lehman High School, Tuesday, July 27, 2021, in New York. | Mark Lennihan/AP Photo

By **LAUREN GARDNER**
08/13/2021 06:46 AM EDT
Updated: 08/13/2021 04:04 PM EDT

The FDA updated its emergency-use authorizations for the Pfizer and Moderna Covid-19 vaccines on Thursday, sanctioning third doses for a small percentage of Americans with compromised immune systems.

The broadened EUAs specifically permit solid-organ transplant patients or people with other conditions "that are considered to have an equivalent level of immunocompromise" to access additional doses, the agency said in a press release.

"After a thorough review of the available data, the FDA determined that this small, vulnerable group may benefit from a third dose of the Pfizer-BioNTech or Moderna Vaccines," acting Commissioner Janet Woodcock said in a statement.

Woodcock emphasized that people whose immune systems are not compromised — the vast majority of Americans — do not need additional vaccine doses.

The agency's action is intended to help people who may not have gotten adequate protection from the initial two-dose Pfizer or Moderna regimen due to their conditions. It comes as the virus' Delta variant spurs a surge of Covid cases nationwide.

The Centers for Disease Control and Prevention's vaccine advisory panel will meet Friday to discuss the FDA policy. The committee will vote on whether to recommend third shots for people with weakened immune systems. Its expected endorsement of FDA's decision is important but not legally required before third doses can be administered.

The CDC panel's discussion could provide more clarity to health care providers about which patients qualify for a third shot, given the broad definition set forth by the FDA. The agency has said that only a small number of Americans

will be affected by the new policy, although the only specific set of patients it mentioned was recipients of solid-organ transplants.

The FDA's decision does not apply to recipients of Johnson & Johnson's single-dose vaccine, though federal officials believe that very few immunocompromised people got that shot given the timing of its rollout compared to when many of those patients were allowed to get inoculated during the late-winter vaccination campaign. Data from the company's two-dose trial have yet to be released.

"The strong recommendation would be to stay with the shot that you" initially received when getting an additional dose, Anthony Fauci, President Joe Biden's chief medical adviser, said Thursday.

Countries like France, Germany, Hungary and Israel have already announced plans to dole out additional vaccine doses to vulnerable populations.

What's next: FDA is expected to fully license Pfizer's vaccine for individuals ages 16 and older in the coming weeks. There are currently no plans to authorize booster doses for the broader U.S. population, public health officials said Thursday, despite preparations being made to ensure a robust supply of extra shots.

“Apart from the immunocompromised, we do not believe that others — elderly or not elderly — who are not immunocompromised need a vaccine right at this moment," Fauci said. "But this is a dynamic process — the data will be evaluated.”

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