US expands COVID boosters to all adults, final hurdle ahead
19 November 2021, by Lauran Neergaard and Matthew Perrone

A healthcare worker fills a syringe with the Pfizer COVID-19 vaccine at Jackson Memorial Hospital on Oct. 5, 2021, in Miami. U.S. regulators have opened up COVID-19 booster shots to all and more adults, Friday, Nov. 19, letting them choose another dose of either the Pfizer or Moderna vaccine. Credit: AP Photo/Lynne Sladky, File

U.S. regulators on Friday moved to open up COVID-19 booster shots to all adults, expanding the government's effort to get ahead of rising coronavirus cases that experts fear could snowball into a winter surge as millions of Americans travel for the holidays.

The Food and Drug Administration's decision stands to simplify what has been a confusing list of who's eligible by allowing anyone 18 or older to choose either a Pfizer or Moderna booster six months after their last dose—regardless of which vaccine they had first. The move came after about a dozen states had started offering boosters to all adults.

"We heard loud and clear that people needed something simpler—and this, I think, is simple," FDA vaccine chief Dr. Peter Marks told The Associated Press.

There's one more step before the approach becomes official: The Centers for Disease Control and Prevention must agree to expand Pfizer and Moderna boosters to even healthy young adults. Its scientific advisers were set to debate it later Friday.

If the CDC agrees, tens of millions more Americans could have three doses of protection before the new year. Anyone who got the one-dose Johnson & Johnson vaccine can already get a booster.

All three COVID-19 vaccines used in the U.S. offer strong protection against severe illness including hospitalization and death without boosters, but protection against infection can wane with time. Previously, the government had cleared boosters of Pfizer's vaccine, as well as the similar Moderna vaccine, only for vulnerable groups including older Americans and people with chronic health problems.

But Pfizer last week asked the FDA to expand that decision to everyone, citing new data from a study of 10,000 people. Ultimately, the FDA decided there was enough evidence, from studies and real-world use of boosters, to back the expansion for both Pfizer and Moderna.
A syringe is prepared with the Pfizer COVID-19 vaccine at a clinic at the Reading Area Community College in Reading, Pa., on Sept. 14, 2021. U.S. regulators have opened up COVID-19 booster shots to all and more adults, Friday, Nov. 19, letting them choose another dose of either the Pfizer or Moderna vaccine. Credit: AP Photo/Matt Rourke, File

The move comes as new COVID-19 cases have climbed steadily over the last two weeks, especially in states where colder weather is driving people indoors. Some states didn't wait for federal officials to act and opened boosters to all adults.

Marks said he understood why some governors got out ahead of the FDA.

"We're going into a cold season, cases going up, high travel season, people indoors sharing good holiday times together," he said. "They probably saw the specter of what could happen here, and were trying—well intentioned—to do something."

Boosters for everyone was the Biden administration's original goal. But in September, a panel of FDA advisers voted overwhelmingly against that idea based on the vaccines' continued effectiveness in most age groups. Instead, they endorsed an extra Pfizer dose only for the most vulnerable.

Last month, backed by its advisory panel, the FDA cleared Moderna boosters—using a dose half as big as the first two shots—for the same vulnerable groups.

But there has been some frustration inside the White House and among allies of the president that the long and public regulatory process contributed to misinformation and confusion around the boosters.

Administration officials, including Dr. Anthony Fauci, continued making the case for using boosters more widely, noting that even milder infections in younger people can cause "long COVID" and other complications.

A patient waits to be called for a COVID-19 vaccination booster shot outside a pharmacy in a grocery store, on Nov. 3, 2021, in downtown Denver. U.S. regulators have opened up COVID-19 booster shots to all and more adults, Friday, Nov. 19, letting them choose another dose of either the Pfizer or Moderna vaccine. Credit: AP Photo/David Zalubowski, File

"I don't know of any other vaccine where we only worry about keeping people out of the hospital," Fauci said Wednesday.

But the administration had pledged that the decision would fall to scientists. This time around, the FDA didn't consult its advisers, saying scientific issues surrounding Pfizer's and Moderna's boosters "do not raise questions that would benefit from additional discussion."

Regulators concluded the overall benefits of added protection outweighed risks of rare side effects from Moderna's or Pfizer's vaccine, such as a type of heart inflammation seen mostly in young men.

Pfizer and its German partner BioNTech argued that broader boosters could help tamp down infections at a critical period.

The companies studied 10,000 adults of all ages and found that a booster restored protection against symptomatic infections to about 95% even while the extra-contagious delta variant was...
surging. It's too soon to know if that high level of protection will last longer after a third shot than after the second. BioNTech CEO Ugur Sahin said the companies will carefully track that.

Britain recently released real-world data showing the same jump in protection once it began offering boosters to middle-aged and older adults, and Israel has credited widespread boosters for helping to beat back another wave of the virus.

More than 195 million Americans are fully vaccinated, defined as having received two doses of the Pfizer or Moderna vaccines or the single-dose Johnson & Johnson vaccine. More than 30 million already have received a booster.

People who don't meet the criteria have been able to get an extra shot because many vaccine sites don't check qualifications.

The FDA previously ruled that people getting a booster can receive a different brand from the vaccine they received initially.

Some experts worry that all the attention to boosters may harm efforts to reach the 60 million Americans who are eligible for vaccinations but haven't gotten the shots. There's also growing concern that rich countries are offering widespread boosters when poor countries haven't been able to vaccinate more than a small fraction of their populations.

"In terms of the No. 1 priority for reducing transmission in this country and throughout the world, this remains getting people their first vaccine series," said Dr. David Dowdy of Johns Hopkins Bloomberg School of Public Health.

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Licensed practical nurse Yokasta Castro, of Warwick, R.I., draws a Moderna COVID-19 vaccine into a syringe at a mass vaccination clinic, Wednesday, May 19, 2021, at Gillette Stadium, in Foxborough, Mass. U.S. regulators have opened up COVID-19 booster shots to all and more adults, Friday, Nov. 19, letting them choose another dose of either the Pfizer or Moderna vaccine. Credit: AP Photo/Steven Senne

Before the expansion, people who received the Pfizer or Moderna vaccinations were eligible for a third dose if they're elderly or at high risk of COVID-19 because of health problems, their jobs or their living conditions. Because a single J&J shot hasn't proven as effective as its two-dose competitors, any J&J recipient can get a booster at least two months later.