US experts convene to decide whether to OK Pfizer vaccine

December 10 2020, by Lauran Neergaard and Matthew Perrone

A pharmacist labels syringes in a clean room where doses of COVID-19 vaccines will be handled, Wednesday, Dec. 9, 2020 at Mount Sinai Queens hospital in New York. The hospital expects to receive thousands of doses once a vaccine is approved. (AP Photo/Mark Lennihan)

A U.S. government advisory panel convened on Thursday to decide

whether to endorse large-scale use of Pfizer's COVID-19 vaccine to help conquer the outbreak that has killed close to 300,000 Americans.

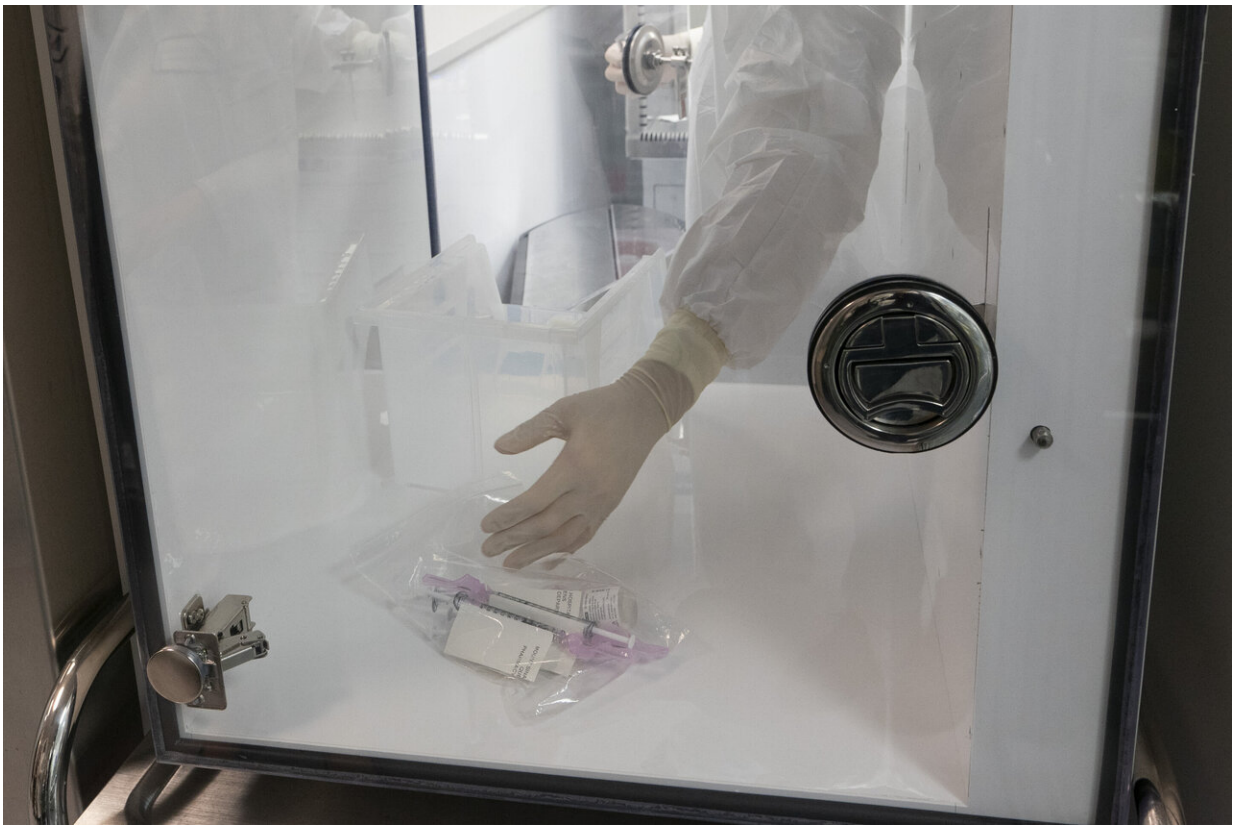
The meeting of outside advisers to the Food and Drug Administration represented the next-to-last hurdle before the expected start of the biggest vaccination campaign in U.S. history. Depending on how fast the FDA signs off on the panel's recommendation, shots could begin within days.

The FDA panel functions like a science court. During the scheduled daylong session, it was expected to debate and pick apart the data—in public—on whether the vaccine is safe and effective enough to be cleared for emergency use. With unprecedented interest in the normally obscure panel, the allergic reactions shouldn't get the vaccine. Government authorities there are investigating two reports of reactions that occurred on Tuesday when Britain became the first country in the West to begin mass vaccinations against the scourge.

Pfizer representatives told the panel they are aware of the British reports but have seen no signs of allergic reactions in their trial of the vaccine.

A positive recommendation and speedy U.S. approval appear nearly certain after FDA scientists issued an overwhelmingly positive initial review of the vaccine earlier this week.

FDA said results from Pfizer's large, ongoing study showed that the shot, which was developed with Germany's BioNTech, was more than 90% effective across people of different ages, races and underlying health conditions, including diabetes and obesity. No major safety problems were uncovered. Common side effects included fever, fatigue and pain at the injection site.



A pharmacist passes syringes from a clean room into the main pharmacy, Wednesday, Dec. 9, 2020 at Mount Sinai Queens hospital in New York. The hospital expects to receive thousands of doses once a COVID-19 vaccine is approved. (AP Photo/Mark Lennihan)

"The data presented in the briefing report were consistent with what we heard before and are really exciting," said Dr. William Moss, head of Johns Hopkins University's International Vaccine Access Center. "Nothing that I see would delay an emergency use authorization."

The meeting also represented an opportunity for regulators to try to boost public confidence in the breakneck development process that has produced the Pfizer vaccine and a string of other upcoming shots with remarkable speed—less than a year after the virus was identified.

The FDA has also faced weeks of criticism from President Donald Trump for not rushing out a vaccine before Election Day.

"There have been a lot of questions about why it takes us so long or are we being rigorous enough?" FDA Commissioner Stephen Hahn said in an interview. "I'm hoping that people will see with our transparency that we have taken a very rigorous stance on this."

Hahn said the agency had already teed up the process to authorize the vaccine by filling out all the legal paperwork in advance, regardless of the ultimate decision.

On Thursday's agenda:

In this Sept. 23, 2020 file photo, Dr. Stephen Hahn, commissioner of the U.S. Food and Drug Administration, testifies during a Senate Senate Health, Education, Labor, and Pensions Committee Hearing on the federal government response to COVID-19 on Capitol Hill in Washington. Hahn said Thursday's meeting on Dec. 10 of the vaccine advisory panel is "an important day for all of America." He hopes it will lead to the beginning of the end of the coronavirus pandemic. (Graeme Jennings/Pool via AP, File)

RARE ADVERSE REACTIONS

The FDA uncovered no major safety problems in its review of Pfizer's 44,000-person study, including no allergic reactions of the type reported in Britain. But such studies can't detect rare problems that might only affect a tiny slice of the general population.

FDA reviewers noted four cases of Bell's palsy that occurred among people getting the vaccine. They concluded the cases were probably unrelated to the vaccine because they occurred at rates that would be expected without any medical intervention. But the agency did say cases of the nerve disorder should be tracked, given that other vaccines can cause the problem.

EFFICACY QUESTIONS

The FDA found the vaccine highly effective across various demographic groups. But it is unclear how well the vaccine works in people with HIV and other immune-system disorders.

The study excluded pregnant women, but experts were expected to tease apart the data for any hints in case women get vaccinated before realizing they're pregnant.

In this Nov. 9, 2020, file photo, pedestrians walk past Pfizer world headquarters in New York. (AP Photo/Bebeto Matthews, File)

A study of children as young as 12 is underway.

IMPACT OF EMERGENCY AUTHORIZATION

Answering some of these questions will require keeping Pfizer's study going for many more months. And the FDA has made clear it wants vaccine developers to continue tracking people who got their shot and those who received a placebo for as long as possible, to compare their outcomes.

But Pfizer and BioNTech said Thursday they have an "ethical responsibility" to switch the 22,000 placebo recipients to real shots after FDA gives the vaccine its OK.

In a compromise, the companies proposed moving those patients to the vaccine group gradually, giving participants priority according to age, health conditions and other factors. Under that plan, 70-year-old participants would cross over before healthy 30-year-olds.