

FDA Investigates Allergic Reactions to Pfizer COVID Vaccine After More Healthcare Workers Hospitalized

By [Children's Health Defense](#)

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The FDA is investigating allergic reactions in “multiple states.” The agency acknowledged the reactions may have been caused by PEG, a compound in the Pfizer vaccine that CHD previously told the FDA could put millions of people at risk.

The U.S. Food and Drug Administration (FDA) [told reporters](#) late Friday the agency is investigating “about five” allergic reactions to the Pfizer [COVID-19 vaccine](#) in “multiple states.”

The announcement followed Friday’s news that an Illinois hospital [temporarily shut down](#) its [COVID](#) vaccination program after four healthcare workers there experienced allergic reactions — one of which was severe — to the vaccine.

Also on Friday, [CNN reported](#) that a third healthcare worker in Alaska was hospitalized for six hours for an anaphylactic reaction to the [Pfizer](#) vaccine. The report came on the heels of [last week’s](#) news that two Alaskan healthcare workers had severe allergic reactions — including one woman who was hospitalized for at least two nights after going into anaphylactic shock.

Anaphylaxis is a severe, potentially life-threatening allergic reaction that can occur within seconds or minutes of exposure to something a person is allergic to. If not treated immediately, it can be fatal, the Mayo Clinic [explains](#).

According to Reuters and [other news reports](#), the director of the FDA’s Center for Biologics Evaluation and Research, Dr. Peter Marks, said [polyethylene glycol](#) (PEG), a compound in the Pfizer and [Moderna](#) vaccines, may have triggered the allergic reactions in the U.S.

The Pfizer and [newly approved](#) Moderna vaccines contain PEG. Both vaccines were approved by the FDA for [emergency use](#), but are not yet licensed.

Lyn Redwood, president of [Children’s Health Defense](#) (CHD), said there shouldn’t be any mystery at this stage about whether or not PEG caused the reactions.

“It’s a simple blood test,” Redwood said. “If they’ve tested the people who had these allergic reactions for anti-PEG antibodies, then they know. If they haven’t, why haven’t they?”

FDA's Marks on Friday also acknowledged that allergic reactions to PEG could be "somewhat more common than previously understood."

But, Robert F. Kennedy, Jr., CHD chairman and chief legal counsel, said:

"As we [told the FDA](#) in September, studies show that one in seven Americans may unknowingly be at risk of experiencing an allergic reaction to PEG."

"At the very least, everyone should be screened for anti-PEG antibodies before getting the Pfizer and Moderna vaccines," Kennedy said. "It is unconscionable that instead, the FDA and CDC are encouraging people to go ahead and risk a life-threatening anaphylactic reaction and just assume that someone will be on hand to save them."

In September, before either vaccine had been approved, CHD [asked the FDA](#) to inform Moderna trial participants that the vaccine contained PEG, and to inform them of the "well-documented evidence of adverse PEG-related immune reactions, including life-threatening anaphylactic immune reactions."

[In a letter](#) to Marks and FDA Commissioner Stephan Hahn, Kennedy also said Moderna should ask trial participants if they'd ever had an allergic reaction to any other drug containing PEG, and the company should prescreen trial participants for PEG allergies, as many people who have anti-PEG antibodies don't know they have them.

The FDA responded by suggesting that CHD take its concerns directly to Moderna. On Saturday, after the reports of allergic reactions in Alaska and Illinois, Hahn [told the Hill](#):

"One of the things that the FDA does very well and uniquely is really getting to the bottom of events like allergic reactions so we can completely understand the circumstances and better inform the public and also our regulatory decisions."

Following last week's reports of allergic reactions, including anaphylaxis, the FDA [said](#) it is "working closely" with the Centers for Disease Control (which has officially [acknowledged](#) six allergic reactions) and "colleagues" in the UK, where the [first allergic reactions](#) to the Pfizer vaccine were reported.

An initial investigation into the allergic reactions experienced by the UK healthcare workers suggested PEG may have been the culprit, [according to Reuters](#).

UK health officials [have since advised](#) that anyone who has a history of any severe allergic reactions should not get the vaccine. The country is [reportedly rolling out](#) "resuscitation centers" equipped to respond quickly to anyone who experiences anaphylactic shock after receiving the vaccine.

In the U.S., however, the CDC says anyone who has a history of severe allergic reactions not related to vaccines or injectable medications — such as allergies to food, pet, venom, environmental or latex — may still get vaccinated but should be monitored for 30 minutes instead of the usual 15 minutes after the vaccine is administered. [New CDC guidelines](#) issued after the allergic reactions in the U.S. state:

“If you have ever had a severe allergic reaction to any ingredient in a COVID-19 vaccine, CDC recommends that you should not get that specific vaccine. If you have had a severe allergic reaction to other vaccines or injectable therapies, you should ask your doctor if you should get a COVID-19 vaccine. Your doctor will help you decide if it is safe for you to get vaccinated.”

These guidelines are inadequate, Redwood said.

“Many people who have never previously experienced any type of allergic reaction may be at risk of a severe reaction to the Pfizer and Moderna vaccines,” Redwood said. “That’s because millions of people may have developed anti-PEG antibodies as a result of having unknowingly been exposed to PEG in the past.”

According to [research published in 2018](#), there are more than 1,000 products on the market — including pharmaceuticals, processed foods, cosmetics and disinfectants — that contain PEG. PEG is also the [main ingredient](#) in antifreeze.

“Anyone who’s had a colonoscopy, depending on what was used for preparation for the procedure, may have anti-PEG antibodies,” Redwood said, because many of those products contain PEG.

“It’s a simple blood test,” Redwood said. “Everyone considering getting the Pfizer or Moderna COVID vaccine should ask their doctor for a blood test to rule out anti-PEG antibodies before getting the vaccine.”

Some of the healthcare workers who suffered severe allergic reactions to the Pfizer vaccine, including the woman hospitalized in Alaska, had no prior history of allergic reactions to anything, including other vaccines or pharmaceuticals.

Studies estimate that approximately [72% of the U.S. population](#) has acquired anti-PEG antibodies. The referenced study used blood samples taken from 1990-1999 and earlier, showing a steady increase over time in the percentage of those with antibodies to PEG, making it conservative to estimate, after two decades, that the incidence is closer to 80% today.

According to a [2018 physicians survey](#), only 22% of respondents were aware of anti-PEG antibodies, and only 35% were aware of having been prescribed medications containing PEG.

The authors of a [2012 study](#) on PEG antibodies concluded, “patients should be pre-screened and monitored for anti-PEG prior to and throughout a course of treatment with a PEGylated compound.”

According to [news reports](#), documents published by Pfizer and Moderna showed that people with a history of severe allergic reactions were excluded from the clinical trials, which explains why the adverse reaction to PEG didn’t show up in the trials.

Last week Kennedy [called on](#) the co-chair of the new COVID Advisory Board to consider the long-overdue review and reform of the government’s [Vaccine Adverse Event Reporting System](#). Kennedy said his request is urgent in light of the push to vaccinate millions of

people using vaccines approved for emergency use following abbreviated pre-approval clinical trials.

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