FDA documents show over 150K serious adverse events in first 3 months of Pfizer jab approval

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The FDA has made public the first batch of documents it used to authorize Pfizer's COVID shots, including a report detailing over 150,000 serious adverse events and more than 1,200 deaths connected to the jabs.

Pfizer's COVID-19 injectionFlowersandtraveling/Shutterstock

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Tens of thousands of serious adverse events and more than 1,200 deaths were reported in the first three months after Pfizer's COVID-19 jab was approved under emergency use authorization (EUA), newly released documents indicate.

The data had been reviewed by the U.S. Food and Drug Administration (FDA) before it granted full approval to the Pfizer-BioNTech COVID-19 (BNT162b2) shots over the summer but had not been released to the public until last month.

The FDA released the documents on November 19, months after the governmental agency was hit with a Freedom of Information Act (FOIA) request filed by attorney Aaron Siri on behalf of a group of some 30 scientists, academics, and researchers who demanded transparency about the information that had been used to assess the safety profile of the injections.

In response, the FDA moved to challenge the group's request in court, raising eyebrows when it asked a federal judge to grant it 55 years to fully release the documents it reviewed before ultimately granting full approval for the Pfizer shots for people age 16 and up in August.

Now the FDA has made public some 91 pages of the documents it reviewed before authorizing the Pfizer shots, a fraction of the roughly 329,000 pages still in its possession.

"Two months and one day after it was sued, and close to three months since it licensed Pfizer's Covid-19 vaccine, the FDA released the first round of documents it reviewed before licensing this product," Aaron Siri wrote in a November 19 substack post.

While the released documents consist of only a tiny percentage of the massive amount of data still withheld, the information revealed in the documents has given cause for serious concerns about the true safety of the increasingly mandated drugs.

Tens of thousands of serious adverse events in only three months

Among the documents released is a 38-page document entitled "CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS," detailing a bevy of serious adverse events connected with the double-shot mRNA jabs in only the first three months after the FDA granted an EUA for the drugs in December.

According to the report, between December 1, 2020 and February 28, 2021, some 42,086 case reports were recorded in Pfizer's safety database, of which 25,379 were medically confirmed and 16,707 non-medically confirmed. The reports contained a total of 158,893 serious adverse events after vaccination in dozens of countries around the world.

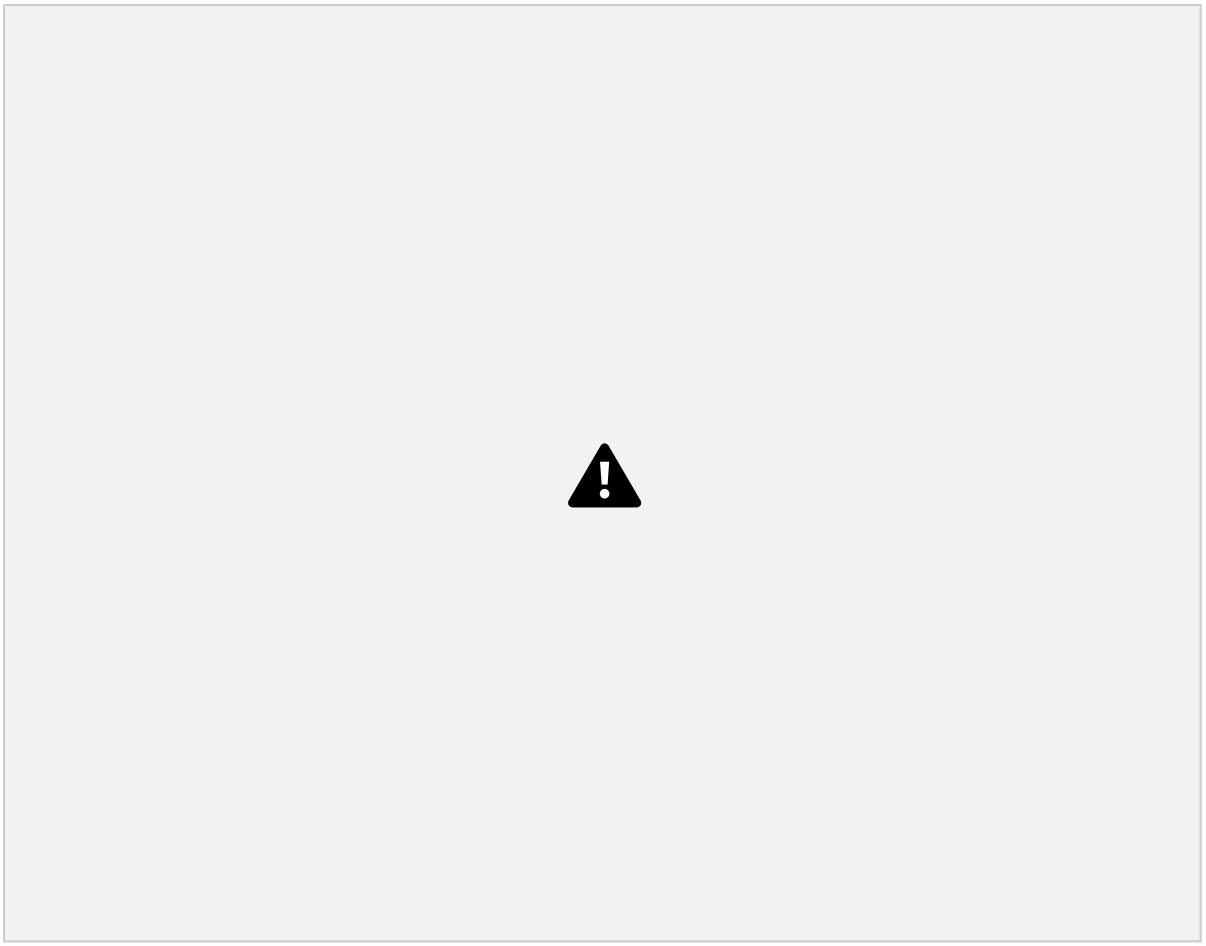
"Most cases (34,762) were received from United States (13,739), United Kingdom (13,404), Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries," the document states.

Citing “large numbers of spontaneous adverse event reports received for the product,” the document includes only serious reported adverse events.

It’s unclear how many reports considered “non-serious” were made during that period.

According to the data, the vast majority of the events occurred in women (29,914) compared with men (9,182). The largest proportion of adverse events based on age occurred in people age 31-50 (13,886), an age range generally at low risk of serious effects from the virus the drug is designed to treat.

Among reported adverse events were some 25,957 cases of nervous system disorders, 17,283 musculoskeletal and connective tissue disorders, 14,096 gastrointestinal disorders, 8,848 respiratory, thoracic and mediastinal disorders, 8,476 skin and subcutaneous tissue disorders, and 4,610 infections and infestations.



Full or ongoing recovery was reported in 19,582 cases, with 520 having recovered with sequelae (a chronic condition), while at the time of the report some 11,361 cases had not recovered. The status of another 9,400 was unknown.

Troublingly, 1,223 cases were reported to have ended fatally.

While direct causality is unclear, the data raise concerns about the safety of the shots

It's unclear how many of the reported deaths and injuries were directly attributable to Pfizer's COVID-19 injections.

The document states that its database contains descriptions of adverse events "reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment."

Additionally, the document notes that "[a]n accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication."

For example, "[t]here were four individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia that likely contributed to their deaths."

While it's unclear to what extent the injections themselves caused the severe adverse events found in the report, the sheer number and severity of the events and fatalities reported in connection with the shots should have been cause for deep concern. At least a temporary halt to the injections pending further investigation has been a normal response when that level of possible negative harmful reactions are experienced with new vaccines. But for some reason that did not happen in this case.

Moveover, the reported fatalities and serious adverse events align with a growing body of data submitted to the Vaccine Adverse Events Reporting System (VAERS) — the U.S. government's passive reporting system to log reactions to vaccines — which indicate a serious spike in vaccine adverse events since the rollout of the COVID-19 injections from Pfizer and the other major drug manufacturers, including Moderna and Johnson & Johnson.

As of November 19, some 664,744 reports of adverse events after COVID-19 vaccination have been made to VAERS in the United States alone, including 8,898 deaths and 41,501 hospitalizations. If the scope is expanded to include non-domestic VAERS reports, there have been 913,266 total reported adverse events, including 19,249 deaths and 97,561 hospitalizations.

While causation is not explicitly confirmed through the VAERS reporting system, neither can it be presumed that all side effects are reported. One study in 2010 found that "fewer than 1% of vaccine injuries" are reported to VAERS, suggesting the actual numbers of deaths and injuries may be significantly higher.

Despite the potential for harm, Pfizer is completely protected from liability

News of the serious adverse events and even deaths connected with the jabs in the first three months after being granted an EUA comes as the U.S. government has granted complete immunity from liability to Pfizer and the other COVID-19 jab manufacturers whose drugs have been increasingly mandated by governments and employers.

Under the March 2020 Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (PREP) pursuant to section 319F–3 of the Public Health Service Act, COVID-19 vaccine manufacturers are shielded from all liability, including "from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure [COVID-19 vaccine]."

"The federal government has given complete immunity to Pfizer, Moderna, and J&J for any injury caused by their Covid-19 vaccines," wrote Siri in another Substack post on October 27. "That's right: you cannot sue them if you are injured by their Covid-19 vaccine."

"So while their product may not give you immunity, they are guaranteed immunity," the attorney remarked.

Siri went on to explain that the pharmaceutical companies manufacturing COVID jabs are even protected from lawsuits for alleged "willful misconduct," noting that under Title 42 [42 U.S.C. § 247d-6d(c)(5)] individuals "can only sue [the companies] for willful misconduct if the federal government first sues them for such conduct."

"And what are the odds the federal government will do so after wildly promoting the vaccine?" Siri continued, suggesting the likelihood of federal litigation is "[a]bout as likely as the FDA ever admitting they promoted a vaccine that caused widespread harm."

Pfizer's complete immunity from lawsuits related to its COVID-19 injections comes in spite of the fact that the company has a storied history of civil and criminal liability for other drugs.

In 2009, in the largest health care fraud settlement in the history of the U.S. Department of Justice at the time, Pfizer was forced to pay out $2.3 billion "to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products."

For Siri, the lesson to be learned as the FDA slowly releases the data it reviewed before approving Pfizer's COVID-19 jabs "is that civil and individual rights should never be contingent upon a medical procedure."

“It is the last and final backstop to the dangerous authoritarianism that results when we permit the government to decide what must be injected or placed into or onto our bodies,” Siri said, adding, “Whatever your views are on the Covid-19 vaccine itself, every American should reject letting the government decide what medical procedures they must engage in to have a job.”