

December Release of FDA's Moderna and Pfizer Data Sheds Further Light on the Purported "Safety and Efficacy" of COVID-19 Vaccines



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As required by court order, in December, FDA released another batch of documents related to Moderna's COVID-19 vaccine for ages 18+ and Pfizer's COVID-19 vaccine for ages 12-15. The productions contain over 200,000 pages of data, including information on a Department of Defense study related to myocarditis that appears to have been mysteriously terminated.

As ICAN supporters will recall, the attorneys who represent ICAN have won several lawsuits related to obtaining the documents FDA relied upon to license COVID-19 vaccines. While the document production for Pfizer ages 16+ is complete, the rest of the documents are still being released.

The December 2023 release of documents related to Moderna's Spikevax consisted of 1,069 pages, including:

- **Serious Adverse Events 4.5x higher:** An October 8, 2021 Moderna report titled "CBER Requested Tables" provided detailed vaccine adverse event data that had been requested by FDA, including a Safety Overview table showing that **solicited serious Grade 3 or Grade 4 systemic adverse reactions were 4.5 times greater** in the vaccine arm (17.4%) versus the placebo arm (3.8%).
- **No safety data collected:** In a response to FDA's request for additional safety data, on September 17, 2021, Moderna made clear that it had no intention of providing the additional requested data, which consisted of long-term data from original study participants as well as short-term data from the more than ten thousand original placebo

participants who were unblinded and then vaccinated. Moderna claimed that analyzing the additional data would “not serve any additional analytical purpose” and additionally admitted “[t]here was no systematic collection or analysis of [adverse reactions]” in the additional data.

- **Natural immunity ignored:** Additional efficacy data was also requested by FDA and supplied in a follow-up response by Moderna on September 28, 2021. [Table 4-1](#) showed that participants in the placebo arm who had a history of SARS-CoV-2 infection at the start of the study **had significantly lower case rates than those who had no history of infection**. Instead of acknowledging the effectiveness of natural immunity, Moderna insisted that “Due to the small sample size of participants with positive SARS-CoV-2 status at baseline, and the number of COVID-19 cases are too small in these participants, the results can not [sic] be interpreted in a meaningful way.”
- **Why the interest in shingles?** Two documents, dated [November 10, 2021](#) and [January 7, 2022](#), show FDA was very interested in the incidence of **herpes zoster (shingles) after vaccination**. Note that a previously produced Moderna document provided details on fatal case reports involving herpes zoster.

The December release of [documents related to Pfizer’s 12-15](#) vaccine consisted of 214,549 pages, including:

- **Military myocarditis study disappears:** An April 29, 2022 [Pharmacovigilance Plan](#) states that study C4591011 was designed “To assess whether **individuals in the US DoD Military Health System (MHS) experience increased risk of safety events of interest, including myocarditis and pericarditis**, following receipt of the Pfizer-BioNTech COVID-19 Vaccine.” However, a footnote below Pfizer’s “Action Plan for Important Identified Risk ‘Myocarditis and Pericarditis’” states: “Milestones deleted as this is a voluntary sponsor study (as per FDA ... characterize[ing] [the study] as ‘voluntary’ and therefore no longer commitment).” Further investigation led to this October 2023 European Medicines Agency [report](#) where a footnote showed that **Pfizer requested to terminate the study** “based on delays in data access and overlap between C4591011 and on-going parallel studies with respect to key safety endpoints, analyses, and broad target populations.” Because it was not required by FDA, Pfizer decided to terminate it and so one can only speculate what the early results from that particular study of healthy young adults may have shown.
- **Appendicitis caused by vaccine:** A December 10, 2021 document submitted to FDA wherein Pfizer reports there was a case of appendicitis within 4 days of vaccination that the Pfizer investigator, surprisingly, **determined was “related” to the vaccine**.
- **Eighteen teenage death reports:** A [response](#) by Pfizer to FDA regarding **post-authorization adverse event reports** for ages 12 to 15, included detailed data on

5 fatal U.S. cases and 13 fatal foreign cases. Cases included a 13-year-old boy who died in his sleep three days after vaccination, another 13-year-old boy who died 3 days after vaccination and whose autopsy “showed enlarged heart and fluid surrounding the heart caused by the Covid vaccination” and a 15-year-old girl whose cause of death was listed as “Anoxia cerebral and Cardiac arrest while outcome of the other events was unknown.”

We encourage those interested to download the productions and review the data. ICAN will continue to keep you updated as more documents are released.

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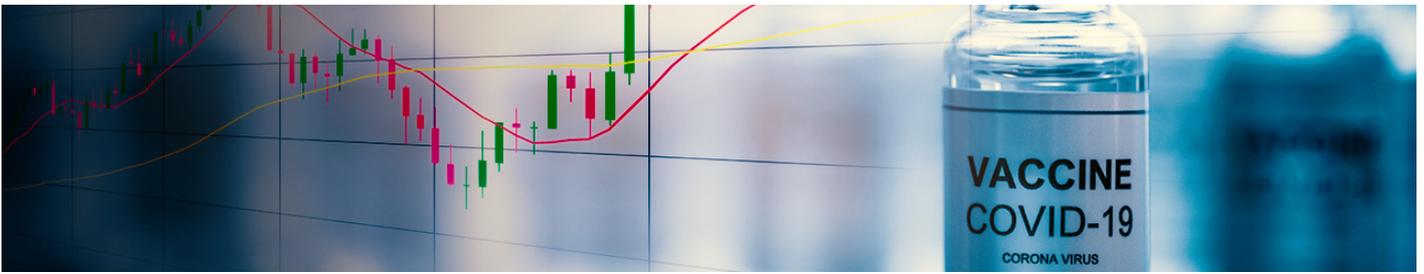
In the meantime, catch up on some of ICAN’s other updates related to COVID-19 vaccines:

- FINAL BATCH OF PFIZER DOCUMENTS FOR AGES 16+ (ACCORDING TO FDA) FINALLY RELEASED TO THE PUBLIC
- PFIZER MONTHLY SAFETY REPORTS FINALLY INCLUDED IN OCTOBER’S DOCUMENT RELEASE
- PFIZER CLINICAL TRIAL DATA ERRORS REVEALED IN SEPTEMBER BATCH OF DOCUMENTS
- LATEST BATCH OF PFIZER DOCUMENTS REVEALS EVEN MORE HIGHLY SUSPICIOUS DEATHS AND HOSPITALIZATIONS IN THE CLINICAL TRIAL
- LATEST PFIZER DOCUMENTS REVEAL HIGHLY SUSPICIOUS DEATHS AND HOSPITALIZATIONS IN THE CLINICAL TRIAL DATA
- BREAKING: ICAN’S ATTORNEYS SCORE ANOTHER MAJOR WIN AGAINST FDA WITH PFIZER AND MODERNA COVID-19 VACCINE DOCUMENTS
- ICAN’S ATTORNEYS UNCOVER EARLY PFIZER VACCINE STUDY REVEALING ALARMING SYSTEMIC REACTIONS IN RATS
- PFIZER ADDS 600 FULL-TIME EMPLOYEES TO HANDLE VOLUME OF REPORTED ADVERSE EVENTS

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CONTACT US

Informed Consent Action Network
1401 Lavaca Street Unit #7022
Austin, Texas 78701

info@icandecide.org

whistleblower@icandecide.org

512-522-8739

MEDIA INQUIRIES

For media requests only

press@icandecide.org

512-522-8739

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