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FDA-Pfizer Docs: High Number of Trial Participants Dropped Out

During the clinical trials of the Pfizer-BioNTech genetic agent against Covid (aka "vaccine"), an unusually high number of participants withdrew or were withdrawn due to adverse events ranging from mild to severe, according to newly released official documents.

As reported by Children's Health Defense (CHD), many serious adverse events were labeled as "not related" to the vaccinations, and many of the minor ones were established to be "possibly" related to the shots.

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According to a 3,611-page "confidential" FDA document with no title, all participants received either one or two doses of a 30 mcg shot of the BNT162b2 candidate vaccine. This was the one ultimately issued an emergency use authorization (EUA) by the FDA — which means that it is the formulation that has been being administered to American adults since December 2020.

Serious events linked to the shots

Of the withdrawals, 34 do not contain a unique patient number, as they should. Of those, four can be identified as being the result of serious adverse events that were categorized as "related" to the shots.

In one case, a 61-year-old woman developed unilateral deafness within 19 days following her first shot and was withdrawn from the trial the next day. The patient's only listed ongoing conditions were allergies to aspirin, penicillin, and black olives.

In another case, a 71-year-old man experienced a worsening of the depression that he already suffered and was withdrawn from the trials the day after getting his only dose.

Then there was a 36-year-old woman who experienced adverse events such as chest tightness, worsening headache, hypokalemia (low potassium level), pain at the injection site, and left arm pain within days following the administration of her first dose, and was withdrawn from the study on the fourth day after the vaccination.

According to CHD, "Of note, the participant's only ongoing health conditions, as indicated in the documentation, were headaches and back pain, in addition to a body mass index (BMI) of 31.4," meaning she was obese.

In all these cases, the trial investigator reported that there was a "reasonable possibility" that the vaccine caused or worsened adverse conditions.

New conditions "unrelated" to the shots

Then, the documents revealed that some of the participants developed new conditions that were classified as "unrelated" to the vaccines and were withdrawn from the trials.

The examples include a 36-year-old man with no medical history who received his second dose on September 9, got a "suspected" Covid infection the same day, and was diagnosed with severe anxiety on October 14.

"Despite no pertinent medical history [and] no input or diagnosis from a mental health expert, [the participant's] 'severe anxiety' was chalked up to 'constitutive features,' an assessment with which Pfizer 'concurred,'" observed CHD.

Another participant, a 49-year-old man, was diagnosed with coronary artery disease and acute myocardial infarction seven days after he received his first dose. The investigator blamed an undiagnosed condition, saying that there was "no reasonable possibility" the heart issues were a result of inoculation.

In the weeks following vaccination with his only dose, a generally healthy 38-year-old man experienced a host of adverse events, including schizophrenia, insomnia, joint pain, headache, flu-like symptoms, and sinus infection. None of the events was classified as being related to the shot.

An array of adverse events was suffered by a 21-year-old woman, who developed stomach pain, hair loss, pyrexia (elevated body temperature), intermittent chills, left eye irritation, intermittent headache, nausea, left eye redness, fever, and weight loss in the days following her first and only shot. The woman was dropped from the trials on October 7 following a positive pregnancy test on October 2, 2020. Only some of the mildest events were officially linked to the vaccines.

Worsening of preexisting conditions "unrelated" to the shots

In several instances, participants were discontinued following the exacerbation of preexisting conditions. This, however, was considered to be "not related" to the vaccine.

A 56-year-old woman with a history of heart issues withdrew from the trials on August 23, following "worsening coronary artery disease." She received her first and only dose on August 12.

A 46-year-old woman who received her only dose on August 20 was diagnosed with brain metastasis (a cancer that has metastasized to the brain from another location in the body) on August 28 and discontinued from the trial.

Another example includes a worsening of diabetes. Nineteen days after receiving her only dose, a 50-year-old woman with a history of diabetes and related disorders developed a diabetic foot ulcer.

Among other conditions whose worsening was ruled out as being connected to the shot were acute blood loss anemia, alcoholic cirrhosis, gastrointestinal bleed, hematochezia (the passage of fresh blood through the anus), hypernatremia (high concentration of sodium in the blood), esophageal ulcers (a type of peptic ulcer), esophageal varices (enlarged or swollen veins on the lining of the esophagus), and thrombocytopenia (low blood platelet count), per the CHD report.

Withdrawals due to minor events

A surprising number of study participants quit or were withdrawn by the investigators due to relatively mild events, such as injection site pain, injection site dermatitis, injection site swelling, abdominal discomfort, diarrhea, eye pain, fatigue, headache, muscular weakness, night sweats, and abdominal pain. Most of the events were linked to the shots at least "partially."

The CHD report notes that in a separate document "providing a broader picture of trial withdrawals," "on average, approximately 10–11 patients per page are listed in this document as having withdrawn

from the trial."

Covid as a side effect

The 3,611-page document posted by CHD shows a long series of trial participants who were diagnosed with Covid during the trial period, and this high number of Covid cases suggesting the abysmal vaccine efficacy is further confirmed by a separate 430-page document.

As observed by CHD, suspiciously, "placebo recipients were more likely to be tested for Covid at the first sign of relevant symptoms, as compared to participants in the vaccine group, for whom similar symptoms may have been attributed to other causes." That means the trials could have been manipulated to make the vaccine appear more effective than it actually was.

July's release of FDA documents was part of a court-ordered disclosure schedule of the documents that the agency used to authorize the Pfizer-BioNTech vaccine on December 11, 2020.

The agency previously argued that it might take decades, possibly until 2096, to complete the Freedom of Information Act (FOIA) request filed by an international organization of medical professionals, scientists, and journalists called Public Health and Medical Professionals for Transparency (PHMPT).