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Latest FDA–Pfizer Document Dump: Why Did So Many Participants With 'Minor' Adverse Events Withdraw From Trial?

July's release of U.S. Food and Drug Administration documents pertaining to the Emergency Use Authorization granted to the Pfizer–BioNTech COVID-19 vaccine included reports of a significant number of participants who withdrew from the trials — and the reasons for these withdrawals.

By Michael Nevradakis, Ph.D.

July's release of U.S. Food and Drug Administration (FDA) documents pertaining to the Emergency Use Authorization (EUA) granted to the Pfizer-BioNTech COVID-19 vaccine included reports of a significant number of participants who withdrew from the trials — and the reasons for these withdrawals.

In some instances, participants withdrew or were withdrawn from the trial due to serious adverse events, which again were usually determined to be "not related" to the vaccination.

In other instances, participants ended their participation in the trial over seemingly minor adverse events, such as injection site pain, without any further explanation provided in the documentation about other factors that may have been at play in the decision to withdraw.

A greater proportion of these minor adverse events were determined to be "related" to the vaccination, as compared to the instances of serious adverse events, which usually were deemed "not related" to the vaccine.

This month's document cache also reveals a large number of trial participants who contracted COVID-19 during the trial period and a notable revelation regarding the COVID-19 vaccine and pregnant women.

The documents were released on July 1 as part of a court-ordered disclosure schedule stemming from an expedited Freedom of Information Act (FOIA) request filed in August 2021.

Public Health and Medical Professionals for Transparency, a group of doctors and public health professionals, submitted the initial FOIA request.

The next 80,000-page cache of FDA documents pertaining to the FDA's authorization of the vaccine is set to be released on August 1.

Withdrawals from vaccine trials raise more questions than they answer

A total of 34 withdrawals are detailed in a massive 3,611-page "confidential" document with no title — only the file name "fa_interim_narrative_sensitive."

All participants listed in the document received the 30 μg dose of the BNT162b2 candidate vaccine, which was the one ultimately issued an EUA by the FDA.

Of these 34 withdrawals, four can be identified as being the result of seemingly serious adverse events that were also classified as "related" to the vaccination.

They include:

• **A 56-year-old white female in the U.S.** (unique subject ID: C4591001 1112 11121118), who was vaccinated with her first dose on Aug. 11, 2020, and discontinued from the study the following day due to generalized pruritus and tachycardia.

She had no ongoing health conditions listed, nor any medical history involving heart conditions. According to the study investigator, "there was a reasonable possibility that the pruritus and tachycardia were related to the study intervention."

• **A 61-year-old Hispanic/Latino female from the U.S.** (unique subject ID: C4591001 1152 11521476) received her first dose of the vaccine on Sept. 25, 2020, but subsequently experienced unilateral deafness on Oct. 14, 2020, and was withdrawn from the trial the following day. Her condition lasted until Oct. 23, 2020.

The participant had "no pertinent medical history" and her only listed ongoing conditions were allergies to aspirin, penicillin and black olives. According to the study investigator, "there was a reasonable possibility that the unilateral deafness was related to the study intervention."

• **A 71-year-old white male from the U.S.** (unique subject ID: C4591001 1120 11201408), who was vaccinated on Oct. 28, 2020, but withdrawn from the trial the following day "because of worsening of the depression that was ongoing at the time of the last available report."

The participant already had an ongoing history of depression, in addition to nephrogenic diabetes insipidus, hyperlipidemia, anemia and the insertion of a cardiac pacemaker. According to the study investigator, "there was a reasonable possibility that the worsening of the depression was related to the study intervention."

• **A 36-year-old white female from the U.S.** (unique subject ID: C4591001 1134 11341174), who was vaccinated on Aug. 26, 2020, and in the days immediately following experienced adverse events such as chest tightness, worsening headache, hypokalemia, pain at the injection site and left arm pain, leading to her discontinuation from the trial on August 30.

All of these adverse events, except for the hypokalemia, were determined by the study investigator to likely be related to the vaccination, although it is unclear how the distinction was drawn between the hypokalemia and all of the other adverse events.

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.

Notably, all four of these instances came from participants based in the U.S., even though the 3,611-page document also contains participant data from trials in Argentina, Brazil and South Africa — with Argentina being home to the largest Pfizer vaccine trials in 2020.

Subjects withdrew after new — but 'unrelated' to the vaccine — conditions appeared

In several instances, the participation of subjects in the vaccine trial ceased following the onset of new medical conditions that did not correspond with anything in their medical history.

Nevertheless, study investigators determined these adverse events were "not related" to the vaccine.

Examples include:

• **A 36-year-old white male from Argentina with no medical history** (unique subject ID: C4591001 1231 12312982, which corresponds with that of Augusto Roux, the subject of a previous report by The Defender) experienced "severe anxiety," mild injection site pain and "suspected COVID-19" (which ultimately was never positively diagnosed) in the days following his second vaccination. He received his two doses on Aug. 21 and Sept. 9, 2020.

According to the narrative comments accompanying his record, Roux requested withdrawal from the study on Sept. 23, 2020. In the words of the study investigator:

> "In the opinion of the investigator, there was no reasonable possibility that the anxiety and suspected COVID-19 were related to the study intervention; anxiety was considered related to constitutive features and COVID-19 was suspected as a reactogenic systemic event. Pfizer concurred with the investigator's causality assessment for suspected COVID-19."

In other words, despite no pertinent medical history — including of any mental illness — and, as previously reported by The Defender, no input or diagnosis from a mental health expert, Roux's "severe anxiety" was chalked up to "constitutive features," an assessment with which Pfizer "concurred."

• **A 49-year-old Asian male from the U.S.** (unique subject ID: C4591001 1095 10951173) with no ongoing medical conditions save for seasonal allergies (and a BMI of 31.4) was discontinued from the study on Sept. 5, 2020, due to coronary artery disease and acute myocardial infarction. He received one dose of the vaccine, on Aug. 29, 2020.

Despite his withdrawal and no history of cardiac issues, the adverse events he sustained were determined to be "not related" to the vaccine, but instead "related to undiagnosed obstructive coronary artery disease." Pfizer "concurred" with this assessment.

• **A 64-year-old white female from the U.S.** (unique subject ID: C4591001 1109 11091503) was withdrawn from the study on Sept. 30, 2020, due to upper abdominal pain. She had received one dose of the vaccine, on Sept. 11, 2020, while her listed ongoing medical conditions were asthma and postmenopause.

According to the study investigator, the patient's abdominal pain was "not related" to the vaccine, but instead, "to gallbladder disease" – with no further explanation provided.

• **A 38-year-old Hispanic/American Indian or Alaskan native in the U.S.** (unique subject ID: C4591001 1127 11271022) experienced a host of adverse events in the weeks following his July 30, 2020, vaccination. These adverse events included schizophrenia, insomnia, joint pain, headache, flu-like symptoms and sinus infection.

According to the document, the subject was withdrawn due to "physician's decision." Though his only listed ongoing conditions were cholelithiasis, myopia and astigmatism, the narrative comments indicated that the onset of schizophrenia that was diagnosed was not related to the vaccination but instead "considered to be related to an ongoing psychiatric disease," with no further explanation provided. His sinus infection and insomnia were also deemed to be "not related" to the vaccination.

• A 34-year-old white female in Argentina (unique subject ID: C4591001 1231 12315441) with no pertinent medical history save for ongoing type 2 diabetes, was diagnosed with depression on Sept. 10, 2020, following her first dose of the vaccine on Aug. 30, 2020. She was withdrawn from the study on Oct. 22, 2020.

The cause of this depression was indicated as being "unknown," although it was deemed to be "not related" to the vaccine.

• A 75-year-old white female in the U.S. (unique subject ID: C4591001 1224 12241012) sustained a transient ischemic attack (also known as a "mini stroke") on Aug. 19, 2020, just days after her Aug. 13, 2020, vaccination. This attack led to a fall, ankle fracture and "diffuse weakness in [the] extremities."

The participant in question had ongoing medical conditions which included anxiety, Parkinson's disease, hypothyroidism, insomnia and postmenopause. She was withdrawn from the study on Aug. 25, 2020.

According to the study investigator, the cause of her ischemic attack was an unspecified "other," but nevertheless, it was deemed to be "not related" to the vaccine.

• A 71-year-old white female from the U.S. (unique subject ID: C4591001 1005 10051214) sustained an upper respiratory infection and facial swelling on Sept. 6, 2020, following her Sept. 3, 2020, vaccination. She was discontinued from the study on Sept. 13, 2020.

Her listed medical conditions included ongoing post-menopause, increased blood cholesterol, gastroesophageal reflux disease, hypertension, peripheral swelling, depression, chronic obstructive pulmonary disease and type 2 diabetes, as well as a BMI of 37.1.

The study investigator's assessment seemingly ignored her upper respiratory infection, stating only that "there was no reasonable possibility that the facial pain and facial swelling were related to the study intervention, but rather they were related to an allergic reaction to an unknown agent."

• A 21-year-old Hispanic/Latina female from the U.S. (unique subject ID: C4591001 1254 12541142) sustained a host of adverse events in the days immediately following her Sept. 12, 2020, vaccination. These included stomach pain, hair loss, elevated body temperature, intermittent chills, left eye irritation, intermittent headache, nausea, left eye redness, fever and weight loss.

The participant was discontinued from the study on Oct. 7, 2020, following a positive pregnancy test on Oct. 2, 2020.

The narrative comments pertaining to this participant mention nothing at all about any of the adverse events she sustained, save for her pregnancy:

> "In the opinion of the investigator, there was no reasonable possibility that the pregnancy was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment."

In the patient's adverse event chart, only the elevated body temperature, intermittent chills, intermittent headache and fever were deemed to be "related" to the vaccine.

Withdrawals from the trial following exacerbation of pre-existing conditions 'unrelated' to the vaccine

In several other instances, patients were discontinued from the trial following the worsening of pre-existing conditions — the exacerbation of which was, however, deemed to be "not related" to the vaccine.

Examples include:

• **A 56-year-old Black female from the U.S.** (unique subject ID: C4591001 1071 10711023) who was vaccinated on Aug. 12, 2020, withdrew from the study on Aug. 23, 2020, following "worsening coronary artery disease."

Her listed medical conditions included coronary artery disease, congestive cardiac failure, type 2 diabetes, blindness, peripheral oedema, gastroesophageal reflux disease, hypertension, hypercholesterolemia and allergic rhinitis.

The study investigator does not appear to entertain the possibility that the worsening of her cardiac condition could have been related to the vaccine. The investigator wrote in the narrative comments that it was "not related" to the vaccine, but instead was "due to hypertensive cardiovascular disease or arteriosclerotic heart disease," an assessment with which Pfizer "concurred."

• **A 46-year-old white female from Argentina** (unique subject ID: C4591001 1231 12312577) who was vaccinated on Aug. 20, 2020, was discontinued from the study on Aug. 28, 2020, following the onset of brain metastasis.

Her ongoing medical conditions, according to the document, simply indicated depression and hypothyroidism, and a BMI of 32.2. However, the study investigator made the assessment that the brain metastasis was "not related" to the vaccine, but instead "related to secondary disease from lung adenocarcinoma diagnosed in Jul 2019," an assessment with which Pfizer again "concurred."

• **A 50-year-old white female from the U.S.** (unique subject ID: C4591001 1095 10951141) who was vaccinated on Aug. 26, 2020, was withdrawn from the study on Sept. 16, 2020, following the onset of a diabetic foot ulcer two days earlier.

Her listed ongoing medical conditions included type 2 diabetes and diabetic neuropathy, as well as hypercholesterolemia, hyperhidrosis, hypertension, deep vein thrombosis, pruritus, post-traumatic stress disorder, hypersensitivity and procedural pain.

According to the study investigator, "there was no reasonable possibility that the diabetic foot ulcer was related to the study intervention."

• **A 67-year-old white male from the U.S.** (unique subject ID: C4591001 1087 10871121) was withdrawn from the trial on Sept. 9, 2020, following a series of adverse events which included acute blood loss anemia, worsening of alcoholic cirrhosis, GI [gastrointestinal] bleed, hematochezia, hypernatremia, worsening of esophageal ulcers, worsening of esophageal varices and thrombocytopenia.

All of these adverse events were diagnosed on Sept. 7, 2020, following his vaccination on Aug. 19, 2020.

The patient's listed ongoing medical conditions included insomnia, gastroesophageal reflux disease, alcoholic cirrhosis, esophageal ulcer and esophageal varices.

His adverse events were deemed, in their entirety, to be "not related" to the vaccine. For instance, the hypernatremia was listed as a "spontaneous event," the acute blood loss anemia was "due to varices," while the GI bleed and hematochezia were "due to ulcers."

The study investigator's narrative comments solely addressed the gastrointestinal hemorrhage, stating "there was no reasonable possibility" it was related to the vaccine, an assessment with which Pfizer "concurred."

• A 48-year-old white female from the U.S. (unique subject ID: C4591001 1079 10791004) was diagnosed with gastric adenocarcinoma on Aug. 20, 2020, and was withdrawn from the study on Aug. 27, 2020 as a result. She was vaccinated on July 29, 2020.

Her listed ongoing medical conditions included anxiety, irritable bowel syndrome, insomnia, seasonal allergy, gastroesophageal reflux disease, hypothyroidism, fibromyalgia, cholelithiasis, hydronephrosis and an ovarian cyst.

The cause of her gastric adenocarcinoma was listed simply as "other," with no further explanation provided, although the study investigator did determine that it was "not related" to the vaccine, to which Pfizer "concurred."

Withdrawals from vaccine trial for seemingly trivial adverse events raise questions

A series of withdrawals from the vaccine trial because of minor and trivial adverse events — including pain and swelling at the injection site and cold- and flu-like symptoms — raise questions.

In all instances, study investigators attributed the the minor adverse events, at least partially, to the vaccination.

These withdrawals beg the question as to whether these seemingly minor adverse events were the true cause of the patients' withdrawal, or whether there were other unspecified and potentially more serious factors at play.

These withdrawals included:

• A 37-year-old white female from Argentina (unique subject ID: C4591001 1231 12315429) who had been vaccinated on Aug. 30, 2020, was withdrawn from the study on Oct. 5, 2020, "because of … injection site pain."

• A 41-year-old white female from the U.S. (unique subject ID: C4591001 1012 10121163) was discontinued from the study on Sept. 24, 2020, due to "injection site dermatitis," following her vaccination on Sept. 9, 2020.

• A 42-year-old white female from Brazil (unique subject ID: C4591001 1226 12261072) was discontinued from the study on Sept. 1, 2020, due to myalgia. She was vaccinated on Aug. 18, 2020.

• A 43-year-old white female from the U.S. (unique subject ID: C4591001 1016 10161087), who was discontinued from the study on Aug. 31, 2020, "because of injection site swelling," following her vaccination on Aug. 10, 2020.

• A 44-year-old white female (unique subject ID: C4591001 1134 11341153), who was discontinued from the study on Aug. 25, 2020, one day after her vaccination, "because of … abdominal discomfort, diarrhea (2 episodes), right eye pain, fatigue, headache (2 episodes) and muscular weakness."

• A 45-year-old white female from South Africa (unique subject ID: C4591001 1246 12461025) was withdrawn from the study on Oct. 19, 2020, following a second onset of urticaria (rashes). She was vaccinated on Sept. 28, 2020, and suffered an initial onset of urticaria the following day, lasting until Oct. 2, 2020.

• **A 61-year-old white male from the U.S.** (unique subject ID: C4591001 1142 11421111) was discontinued from the study on Sept. 4, 2020, as a result of abdominal pain and night sweats, which he had begun experiencing between Aug. 26 and 29, 2020. He was vaccinated on Aug. 17, 2020.

• **A 65-year-old white female from the U.S.** (unique subject ID: C4591001 1112 11121255), who was discontinued from the study on Oct. 7, 2020, as a result of "chills, headache and pyrexia." She was vaccinated the prior day.

• **A 68-year-old Hispanic/Latina female from the U.S.** (unique subject ID: C4591001 1152 11521359) who was vaccinated on Sept. 4, 2020, was withdrawn from the study on Sept. 11, 2020, because of muscle spasms, which she began experiencing on the same day as her vaccination. She also reported adverse events including injection site tenderness, injection site induration and sour taste.

Notably, her muscle spasms were deemed by the study investigator to be "not related" to the vaccination, while her other adverse events were determined to be related.

Finally, a separate document providing a broader picture of trial withdrawals is "16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age," contains a 232-page list that was part of this month's document dump and which appears to list all patients who withdrew from the trial, as well as the date and reason of their discontinuation.

On average, approximately 10-11 patients per page are listed in this document as having withdrawn from the trial.

Documents reveal high number of COVID cases among trial participants

Pages 1,059 through 3,611 of the "fa_interim_narrative_sensitive" document list a long series of trial participants who were diagnosed with COVID-19 during the trial period, with the records for each patient averaging 8-9 pages in total length.

The list includes participants in the placebo group.

In one example, a 51-year-old white female from the U.S. (unique subject ID C4591001 1016 10161004) received her two doses of the vaccine on July 29 and Aug. 19, 2020. On Oct. 17, 2020, she reported a "loss of taste or smell" and "new or increased sore throat." She tested positive for COVID-19 following a nasal swab test.

This high number of COVID-19 cases among trial participants is further confirmed by a separate 430-page document listing trial participants who tested positive for COVID-19 following either the first or second dose of the vaccine.

Overall, an average of 3 to 9 patients per page is listed in this particular document, and although a majority of the listed COVID-19 cases are in the placebo group — interesting in itself when considering that the vaccinated also contract COVID-19 in significant numbers — there are approximately 215 trial participants listed in the latter document who received the candidate vaccine and who later tested positive for COVID-19.

Questions therefore arise as to whether, for instance, the study was conducted in such a way where placebo recipients were more likely to be tested for COVID-19 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.

March 2021 document admits vaccine impact on pregnant women 'unknown'

One final noteworthy item from this month's Pfizer document dump is titled "Determining RSV Burden and Outcomes in Pregnant Women and Older Adults Requiring Hospitalization."

Here, "RSV" refers to "Respiratory Syncytial Virus," a common respiratory virus typically causing cold-like symptoms.

The document outlines a study examining the "population-based incidence of RSV-related hospitalizations in pregnant women and adults ≥50 years of age" and compares "the population-based incidence of hospitalization, epidemiology, clinical presentation and outcomes observed in SARS-CoV-2-positive pregnant women and adults ≥50 years of age versus those with influenza, RSV, or other respiratory viral pathogens."

Page 9 of the document states:

> "Maternal vaccination, in addition to providing benefit to the mother, could provide benefit to the infant through decreasing maternal disease and through the passive transfer of maternal antibody to the infant."

However, in the same paragraph, the document states:

> "Data about the timing (wGA) and quantity of antibodies transferred across the placenta are limited for COVID-19.
>
> "The Advisory Committee on Immunization Practices noted that 'potential risks of mRNA vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people.' They advised that 'If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated.'
>
> "In addition, 'When making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.'"

The document, which admits mRNA vaccines were not studied on "pregnant people" and that risks to them and to the fetus "are unknown," is dated March 23, 2021 — even though the Pfizer vaccine was being administered to the public in the U.S. under an EUA since December 2020.

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the views of Children's Health Defense.

SUGGEST A CORRECTION

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Michael Nevradakis, Ph.D., is an independent journalist and researcher based in Athens, Greece.