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FDA Dumps More Pfizer Documents: Why Were So Many Adverse Events Reported as 'Unrelated' to Vaccine?

The latest release by the U.S. Food and Drug Administration of Pfizer-BioNTech COVID-19 vaccine documents raises questions about how frequently adverse events experienced by clinical trial participants were reported as "unrelated" to the vaccine.

By Michael Nevradakis, Ph.D.

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The 80,000-page document cache released May 2 by the U.S. Food and Drug Administration (FDA) includes an extensive set of Case Report Forms (CRFs) from Pfizer trials conducted at various locations in the U.S.

The documents also include the "third interim report" from BioNTech's trials conducted in Germany (accompanied by a synopsis of this report and a database of adverse events from this particular set of trials).

The FDA released the documents, which pertain to the Emergency Use Authorization (EUA) of the vaccine, 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 FOIA request.

Adverse events during Pfizer vaccine trials in the U.S. usually reported as 'unrelated' to vaccination

Pfizer conducted a series of vaccine trials at various locations in the U.S., including the New York University Langone Health Center, Rochester Clinical Research and Rochester General Hospital (Rochester, New York) and the J. Lewis Research, Inc. Foothill Family Clinic (Salt Lake City, Utah).

The Pfizer documents released this month by the FDA included a series of CRFs for patients who suffered some type of adverse event during their participation in the COVID-19 vaccine trials.

As the documents reveal, despite the occurrence of a wide range of symptoms, including serious cardiovascular events, almost none were identified as being "related" to the vaccine.

Such serious yet "unrelated" adverse events included:

- Acute asthma exacerbation
- Aortic aneurysm (listed as a pre-existing condition)
- Appendicitis (requiring hospitalization)
- Atrial defibrillation

- Cardiac arrest and acute respiratory failure, requiring hospitalization, sustained by a patient who then was "lost" (could not be located for continued participation in the trial)
- Chest pain (requiring hospitalization, later listed as cardiac ischemia)
- Coronary artery occlusion (listed as both serious and life-threatening)
- Injuries sustained from a fall
- Intermittent non-cardiac chest pain (requiring hospitalization)
- Left breast cancer (listed as a pre-existing occult malignancy)
- Neuritis (peripheral nerve Injury), listed as "unrelated" to the vaccine but related to the blood draw during vaccination
- Pulmonary embolism and bilateral deep venous thrombosis
- Respiratory failure (requiring hospitalization)
- Right ureteropelvic junction obstruction (requiring hospitalization, listed as congenital)
- Small bowel obstruction, listed as "unplanned," and a panic attack

Of the CRFs found in the documents released this month, only one adverse event is clearly specified as being related to the vaccination: a participant who suffered from psoriatic arthritis, with no prior history of the condition.

In addition, several CRFs indicated exposure during pregnancy (see here and here), or during a partner's pregnancy (see here and here). However, the documents provided do not appear to have provided any follow-ups regarding any outcomes or potential adverse events for the participants, their partners or their newborn babies once born.

In some instances, while the CRFs claimed the adverse events suffered by patients were not related to the vaccine, their cause was unspecified, simply indicated as "other," while in another case, a participant's "unplanned" small bowel obstruction and panic attacks were listed as being unrelated to the vaccination despite no relevant medical history pertaining to the SAEs (severe adverse events) in question.

Did Pfizer hide critical information from regulators?

It is difficult to draw concrete conclusions about any specific case from the data provided by CRFs and vaccine trial summaries.

However, what raises eyebrows is the very large number of adverse events — often serious and often requiring the hospitalization of the patients involved — that were determined to be "unrelated" to the administration of the COVID vaccine.

Previously released Pfizer documents also included discrepancies in the recording of adverse events.

According to investigative journalist Sonia Elijah, these discrepancies include:

- Trial participants were entered into the "healthy population" but were, in actuality, far from healthy.
- SAE numbers were left blank.

- Barcodes were missing from samples collected from trial participants.
- The second vaccine dose was administered outside the three-week protocol window.
- New health problems were dismissed as "unrelated" to the vaccination.
- A remarkable number of patients with an observation period of exactly the same duration — 30 minutes, with very little variety in observation times and raising questions as to whether patients were adequately observed or were put at risk.
- Oddities pertaining to the start and end dates of SAEs – for instance, a "healthy" diabetic suffered a "serious" heart attack on October 27, 2020, but the "end" date for this SAE is listed as the very next day, even though the patient was diagnosed with pneumonia that same day.
- Impossible dating: in the aforementioned example of the patient who sustained a heart attack and pneumonia, the individual in question later died, but the date of death is indicated as the day before the patient was recorded as having gone to a "COVID ill" visit.
- Unblinded teams, who were aware of which patients received the actual vaccine or a placebo, were responsible for reviewing adverse event reports, potentially leading to pressure to downplay COVID-related events in the vaccinated, or to indicate that adverse events were related to the vaccine.
- Other adverse events were indicated as "not serious" despite extensive hospital stays, of up to at least 26 days in the case of one patient who suffered a fall which was classified as "not serious," yet facial lacerations sustained as a result of the fall were attributed to hypotension (low blood pressure).

Many of these practices seem to appear in the trial-related documents released this month.

Medical and scientific experts who spoke to The Defender expressed similar concerns about what this month's tranche of documents reveals, and addressed cases of "disappearing" adverse events.

Brian Hooker, chief scientific officer for Children's Health Defense, remarked:

> "I'm most concerned about 'disappearing' patients. One cannot conduct a valid trial and simply omit the results that they don't like!
>
> "With the stories about Maddie de Garay and Augusto Roux surfacing, I have to wonder how many other participants were dropped in order to hide vaccine adverse events/effects.
>
> "If you look at the data in VAERS [Vaccine Adverse Event Reporting System], COVID-19 vaccines are the most dangerous ever introduced into the population."

Dr. Madhava Setty, a board-certified anesthesiologist and senior science editor for The Defender, said:

> "The 'unrelated' label the investigators use to divert attention from AEs [adverse events] is a powerful point that stands on its own. We haven't pushed back on this enough.
>
> "Equivalently, we can say that the meager and short-lived benefit of these shots is also 'unrelated' using their 'standards.' On what grounds can they say that their product is preventing infection (which it isn't anymore), or death (marginally)?
>
> "They cannot have it both ways. They cannot claim a benefit through short-term outcomes while denying that side effects of any kind are related to their product.
>
> "That's the whole point of doing a trial. You cannot prove causation, only statistically significant correlation."

Setty provided further context for his remarks in an April 2022 article for The Defender and in a March 2022 presentation, in which he discussed the number of these adverse events and how Pfizer swept them away (timestamp 24:00).

In Setty's view:

> "There's a high likelihood of malfeasance going on. [Pfizer whistleblower] Brook Jackson says the PIs [principal investigators] were unblinded. If true, it would make it very easy for the investigators to bump up the AEs in the placebo group while ignoring some of the AEs in the vaccine group.
>
> "Pfizer claims that 0.5% of placebo recipients suffered a serious adverse event compared to 0.6% in the vaccine group. This is how these events were obscured."

The extant body of evidence indicates Pfizer "is hiding critical information from regulators," Setty said:

> "The clincher is in the memorandum to the VRBPAC [Vaccines and Related Biological Products Advisory Committee] (Table 2, efficacy populations), where they show us that five times more people in the vaccine group were pulled out of the trial than the placebo within seven days of their second shot for 'important protocol deviations.'
>
> "In a trial that big the chances that could have happened coincidentally is infinitesimally small (less than 1 in 100,000).
>
> "Moreover, months later, the same thing happened in the pediatric trial (Table 12). This time, six times more children were pulled from the trial after their second dose.
>
> "There are, of course, procedural differences when administering a placebo versus the mRNA vaccine, but why didn't it happen after the first dose as well?
>
> "Mathematically, that is about as close as you can get to eliminating any 'shadow of doubt.' With a formal allegation by a trial coordinator that states the same thing [referring to whistleblower Brook Jackson], we can be assured Pfizer is hiding critical information from regulators."

BioNTech trials in Germany claim few adverse events 'related' to vaccine

The BioNTech trial in Germany tested various dosages of two COVID-19 vaccine formulas, labeled BNT162b1 and BNT162b2 — the latter granted EUA by the FDA.

The latest cache of Pfizer documents suggests a pattern, similar to the one in the U.S. trials, of not reporting adverse events as related to the vaccine.

According to the third interim report, dated March 20, 2021, among trial participants who were administered the BNT162b2 candidate vaccine granted EUA in the U.S.:

- 87% of younger participants reported solicited local reactions, and 88% reported solicited systemic reactions, with 10% reporting solicited systemic reactions of Grade 3 or higher.
- 87% of younger participants experienced "mild" solicited local reactions, and 35% experienced "moderate" solicited local reactions.
- 88% of younger participants experienced "mild" solicited systemic reactions, and 38% experienced "moderate" solicited systemic reactions. As stated in the report:

> "The most frequently reported solicited systemic reactions of any severity were fatigue (n=40, 67%), followed by headache (n=32, 53%), malaise (n=24, 40%), and myalgia (n=23, 38%). The remaining symptom terms were less frequent.

> "For nausea, headache, fatigue, myalgia, chills, arthralgia and malaise each symptom was assessed as severe in <10% of participants."

- 43% of younger participants reported a total of 51 unsolicited TEAEs (treatment-emergent adverse events, referring to conditions not present prior to treatment or that worsened in intensity after treatment) within 28 days of the first or second dose, nine of which were deemed to be "related" to the vaccination. One participant in this category sustained a TEAE assessed as Grade 3 or higher, but "which was assessed as not related by the investigator."
- TEAEs among younger participants included hypoaesthesia, lymphadenopathy, heart palpitations, external ear inflammation, blepharitis, toothache, non-cardiac chest pain, cestode infection, oral herpes, tonsillitis, neck pain, insomnia, anosmia and dysmenorrhea.
- No unsolicited treatment-emergent serious adverse events (TESAEs) or deaths were reported among younger participants, but one discontinued participation due to moderate nasopharyngitis.
- One younger participant "discontinued due to a moderate AE (nasopharyngitis)."
- 86% of older participants reported solicited local reactions, with 6% reporting solicited local reactions of Grade 3 or higher, 78% reporting "mild" solicited local reactions and 36% reporting "moderate" solicited local reactions.
- 72% of older participants reported solicited systemic reactions, with 11% of these participants sustaining solicited systemic reactions of Grade 3 or higher, 69% sustaining "mild" solicited reactions and 36% sustaining "moderate" solicited reactions.
- 33% of older participants reported a total of 20 unsolicited TEAEs, four of which were determined to be "related" to the vaccination. Among older participants, 8% reported a TESAE of Grade 3 or higher, with "one event assessed as related by the investigator."
- One older participant was reported to have sustained a "not related TESAE" (an ankle fracture).
- TESAEs among older participants included back pain, chest pain, facial injury, increased lipase, increased amylase, muscle spasms, musculoskeletal pain, tendon pain, orthostatic intolerance, renal colic, seborrhoeic dermatitis and "painful respiration."

Among trial participants who received the BNT162b1 candidate vaccine (not granted EUA):

- 86% of "younger participants" reported solicited (expected) localized reactions (remaining in one part of the body), with 18% reporting Grade 3 or higher solicited local reactions, 86% of younger participants reporting "mild" solicited local reactions and 54% reporting "moderate" solicited local reactions.
- 92% of younger participants reported solicited systemic reactions (spreading to other parts of the body), with 44% reporting Grade 3 or higher solicited systemic reactions, 90% reporting "mild" solicited systemic reactions and 74% experiencing "moderate" solicited systemic reactions.

> The report states:

> "The most frequently reported solicited systemic reactions of any severity were fatigue (n=68, 81%), headache (n=66, 79%), myalgia (n=51, 61%), malaise (n=50, 60%), and chills (n=47, 56%). The remaining symptom terms were less frequent.
>
> "For nausea, vomiting, diarrhea, myalgia, arthralgia and fever each symptom was assessed as severe in ≤10% of participants."

- 45% of younger participants reported a total of 83 unsolicited (unexpected) TEAEs within 28 days of receiving the first or second dose.

  A total of 51 of these unsolicited TEAEs were reported as "related" to the vaccination, while 2% of participants sustained Grade 3 or higher TEAEs (four in total), "of which three events were assessed as related by the investigator."

  No unsolicited TESAEs or deaths were reported in this category.

- According to the report, among younger participants, TEAEs included:

  > "'General disorders and administration site conditions' reported by 9 participants (11%)," including influenza-like illness and injection site hematoma.
  >
  > "'Nervous system disorders' reported by 10 participants (12%)," including presyncope, hyperaesthesia, paraesthesia, and headache.
  >
  > "'Respiratory, thoracic and mediastinal disorders' reported by 9 participants (11%)," including cough and oropharyngeal pain.

  Other symptoms included back pain, musculoskeletal chest pain, cervicobrachial syndrome, taste disorder, sleep disorder, depression, hallucination, dysmenorrhoea, pruritus and pityriasis rosea, while one participant required the excision (removal) of a papilloma.

- One younger participant discontinued participation in the trial, "due to a moderate AE (malaise)," while another participant discontinued participation "due to dose-limiting toxicity."
- 83% of "older participants" reported solicited local reactions, but none were reported as Grade 3 or higher, while 83% of solicited local reactions were "mild" and 42% were "moderate."
- 92% of older participants reported solicited systemic reactions, with 28% of participants experiencing Grade 3 or higher solicited systemic reactions, 89% experiencing "mild" solicited systemic reactions, and 61% experiencing "moderate" solicited systemic reactions.

  According to the report:

  > "The most frequently reported solicited systemic reactions of any severity were headache (n=29, 81%), fatigue (n=27, 75%), myalgia (n=18, 50%), and malaise (n=18, 50%). The remaining symptom terms were less frequent."

- 36% of participants reported a total of 24 unsolicited TEAEs within 28 days of the first or second dose, nine of which were assessed as "related" to the vaccination.

  Of the participants in this category, 11% reported TEAEs of Grade 3 or higher (four events in total), with one of these events assessed as "related" to the vaccination.

- TEAEs reported by older participants included oropharyngeal pain, nasopharyngitis, bladder dysfunction, sleep disorder, musculoskeletal pain and musculoskeletal chest pain, pollakiuria, migraine, syncope and alopecia.
- One older participant receiving the BNT162b1 candidate sustained a TESAE (syncope), and there were no deaths in this category.

Of note, none of the participants for either vaccine candidate were pregnant, which raises questions about recommending and administering the vaccine to pregnant women despite the absence of any clinical trial data.

As the documents show, a wide range of adverse effects were reported, including cardiovascular and nervous system conditions, most of which were determined to be unrelated to the vaccination itself.

SUGGEST A CORRECTION

Michael Nevradakis, Ph.D.

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