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More Deaths, Injuries Revealed in Latest Pfizer Vaccine Trial Document Dump

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This month's release of Pfizer COVID-19 vaccine documents by the U.S. Food and Drug Administration reveals three more reports of deaths among vaccine trial participants and more instances of Pfizer listing injuries as "not related" to the vaccine.

This month's release of Pfizer-BioNTech COVID-19 vaccine documents by the U.S. Food and Drug Administration (FDA) reveals three more reports of deaths among vaccine trial participants and further instances of Pfizer downplaying serious adverse events sustained by participants and listing the injuries as "not related" to the vaccine.

Of the approximately 80,000 pages released this month, the most revelatory is a 3,611-page "confidential" document with no title — only the file name "fa_interim_narrative_sensitive."

The document contains information about vaccine trial participants who died, who sustained adverse events during the trial or who contracted COVID-19 during the trial.

All participants listed in the document received the 30 µg dose of the BNT162b2 candidate vaccine, which the FDA in August 2021 granted Emergency Use Authorization.

The FDA on July 1 released the documents 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, initially submitted the FOIA request.

Document details deaths of three trial participants

The "interim narrative" document contains reports of three clinical trial participants who

died — and in all cases, the investigator ruled out the possibility the deaths were related to Pfizer's vaccines.

One instance pertains to a 56-year-old white female in the U.S. (unique Subject ID C4591001 1007 10071101), who suffered cardiac arrest on Oct. 18, 2021, and died three days later. She was vaccinated on July 30, 2020, and Aug. 20, 2020.

The "narrative comments" accompanying the report on the woman's death stated her death could not have been related to the vaccine, due to the amount of time that had elapsed following her second dose:

"In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention or clinical trial procedures, as the death occurred 2 months after receiving Dose 2."

The woman's medical history did not indicate any cardiovascular problems, although ongoing obesity, gastroesophageal reflux disease and sleep apnea syndrome were listed.

The second report of a death was that of a 60-year-old white male in the U.S. (unique Subject ID C4591001 1162 11621327), who received one dose of the vaccine (on Sept. 10, 2020) and died sometime in the following three days of atherosclerotic disease.

According to the document:

> "The study site received a police report indicating that the police visited the subject's home to perform a welfare check on 13 Sep 2020 (Day 4) and found him dead."

The participant's medical history indicated ongoing autoimmune thyroiditis, obesity and depression, and a prior craniocerebral injury and prior hip arthroplasty.

According to the report:

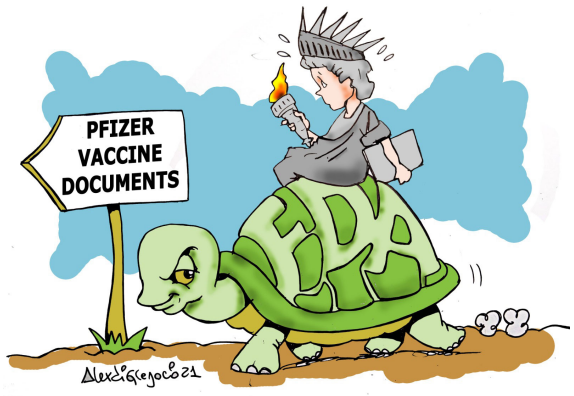
> "It was reported that the subject's body was cold and had visible lividity. According to the medical examiner, the probable cause of death was progression of atherosclerotic disease. Relevant tests were unknown. Autopsy results were not available at the time of this report.
>
> "In the opinion of the investigator, there was no reasonable possibility that the arteriosclerosis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to *suspected* [emphasis added] underlying disease. Pfizer concurred with the investigator's causality assessment."

In other words, the participant's death was attributed to a "suspected" cause, while the possibility that it was vaccine-related in any way, was dismissed.

The third death listed in the "fa_interim_narrative_sensitive" documents was listed under the section in the document listing reports from trial participants who withdrew, not those who died.

The report pertained to a 72-year-old Hispanic/Latino male in the U.S. (unique Subject ID: C4591001 1152 11521497) who received one dose of the vaccine, on Oct. 7, 2020.

The subject sustained vasovagal syncope (a fainting incident) on Oct. 26, 2020, and was admitted to the hospital, causing him to miss his scheduled follow-up vaccination appointment on Oct. 28, 2020.



According to the document:

> "The subject was transferred to the intensive care unit. Family medical history relevant to the syncope was unknown.
>
> "On an unspecified date, the syncope resolved and the subject was discharged from the hospital."

He was withdrawn from the study on Nov. 6, 2020. However, according to the subject's sister, he died of "unknown" causes on Nov. 11, 2020.

As stated by the document (dated Nov. 22, 2020):

> "The cause of death was reported as unknown. It was not reported if an autopsy was performed. A death certificate might be available at a later date."

Nevertheless, this lack of information did not prevent the study investigator or Pfizer from dismissing the possibility that the participant's death was vaccine-related. The document states:

> "In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, concomitant medications, or clinical trial procedures.
>
> "Pfizer concurred with the investigator's causality assessment. Per Pfizer, the syncope was most likely coincidental and associated with underlying clinical conditions."

The document contained no reports of deaths among trial participants who received the placebo.

Investigators attribute 4 serious adverse events to vaccine, Pfizer disagrees

According to the latest document release, investigators attributed the vaccine to serious adverse events in four cases, however, Pfizer disagreed with the investigators' conclusions in three out of the four cases.

The incidents are:

• **A 53-year-old white female in the U.S.** (unique Subject ID: C4591001 1018 10181159), who developed "lower back pain and bilateral lower extremity pain with radicular paresthesia" on Oct. 20, 2020, which was ongoing as of the date of the document (Nov. 22, 2020).

She was vaccinated on Aug. 14 and Sept. 4, 2020.

The woman's medical history did not indicate lower back or lower extremity pain, just ongoing migraines and a prior history including a right shoulder dislocation, fibrocystic breast disease and Vitamin D deficiency.

The study investigator and Pfizer disagreed on whether the serious adverse event she experienced was related to the vaccination. As stated in the document:

"In the opinion of the investigator, there was a reasonable possibility that the lower back pain and bilateral lower extremity pain with radicular paresthesia were related to the study intervention, but not related to concomitant medications or clinical trial procedures.

"Pfizer did not concur with the investigator's causality assessment and considered that there is not enough evidence to establish a causal relationship with the study vaccine apart from a chronological association at this time of the report.

"Based on the information currently available, it was more likely that the lower back pain and bilateral lower extremity pain with radicular paresthesia was associated with the subject's underlying known neurological condition."

• **A 71-year-old white female in the U.S.** (unique Subject ID: C4591001 1142 11421247) sustained ventricular arrhythmias on Oct. 14, 2020 — the same day she received the second dose of the vaccine — and which continued until Oct. 21, 2020.

The woman received her first dose on Sept. 21, 2020. Her medical history indicated she was wearing a cardiac pacemaker and was experiencing ongoing atrioventricular block (complete), atrial fibrillation and supraventricular tachycardia.

Again, the study investigator and Pfizer could not agree as to whether this adverse event was related to the vaccination. The document states:

"In the opinion of the investigator, there was a reasonable possibility that the ventricular arrhythmia was related to the study intervention based on the temporal relationship since the arrhythmias began within 24 hours of Dose 2, but not related to concomitant medications or clinical trial procedures.

"Pfizer did not concur with the investigator's causality assessment. Additionally, Pfizer commented that there was not enough evidence to establish a causal relationship with the study intervention apart from a chronological association at this time of the report.

"In absence of evidence for an inflammatory response to study intervention, it was more likely that the ventricular arrhythmia was associated with the subject's underlying known cardiac conditions."

Pfizer dismissed the possibility that the vaccine may have exacerbated the subject's existing cardiac conditions.

• **A 48-year-old white female in the U.S.** (unique Subject ID: C4591001 1178 11781107), who received one dose of the vaccine on Sept. 4, 2020, and withdrew from the study on Sept. 25, 2020.

In the interim, the participant sustained right axilla lymphadenopathy, with "at least four enlarged lymph nodes" — a condition that was still ongoing as of the document date of Nov. 22, 2020.

Her medical history indicated ongoing positional vertigo, osteoarthritis, eczema, sinus headaches, seasonal allergies and a Pitocin allergy, as well as prior menorrhagia, uterine fibroids and a past hysterectomy. In addition, her body mass index (BMI) was listed as being 36.9.

Pfizer also in this case did not agree with the study investigator's assessment:

"In the opinion of the investigator, there was a reasonable possibility that the lymphadenopathy was related to the study intervention. Pfizer did not concur with the investigator's causality assessment."

• **A 30-year-old Asian female in the U.S.** sustained a shoulder injury related to vaccine administration (SIRVA).

The documents did not list any severe adverse events occurring in anyone outside the U.S., even though the documents contain reports from trials in Argentina, Brazil and South Africa.

'Unrelated' adverse event reports habitually dismiss possibility injuries were vaccine-related

The documents reveal a large discrepancy between the number of adverse events deemed to be related to the vaccination (four) compared to those reported to be "not related" (113 non-placebo participants).

The reports associated with each incident reveal an ongoing tendency to dismiss any possibility injuries were vaccine-related — even in instances where no alternative cause was identified or where patients had no relevant prior medical history.

In still other instances, the cause of the adverse event was attributed to itself, while in several other cases, pre-existing conditions worsened following vaccination.

A significant number of accidents and falls — and subsequent injuries — also were reported.

Instances where severe adverse events were brushed over as being "not related" to the vaccination, despite no relevant medical history, include:

• **A 75-year-old white male in the U.S.** (unique Subject ID: C4591001 1013 10131176), who was vaccinated on Aug. 13 and Oct. 7, 2020, sustained 13 adverse events between Aug. 29 and Sept. 16, 2020, many of which were ongoing as of the document date of Nov. 22, 2020.

These adverse events included congestive heart failure, acute hypoxic respiratory failure, acute renal failure, aspiration pneumonia, anemia, hypokalemia, hyponatremia, leukopenia, sepsis, small bowel obstruction and mild concentric left ventricular hypertrophy.

The participant had ongoing gastroesophageal reflux disease, hiatus hernia, hypercholesterolemia, hypertension and constipation, in addition to prior small intestinal and knee surgery.

The report attributed the patient's adverse events to his prior surgical history. The document stated:

"In the opinion of the investigator, there was no reasonable possibility that the abdominal adhesions, small intestinal obstruction, pneumonia aspiration, and acute respiratory failure were related to the study intervention, concomitant medications, or clinical trial procedures, but were rather likely related to subject's previous surgery.

"Pfizer concurred with the investigator's causality assessment."

• **A 73-year-old white female in the U.S.** (unique Subject ID: C4591001 1079 10791246) sustained a "cerebrovascular accident" (stroke), as well as expressive aphasia, on Oct. 22, 2020. She was vaccinated on Sept. 4 and Sept. 25, 2020.

Her medical history listed osteoarthritis, seasonal allergies and being postmenopausal. Nevertheless, her stroke and aphasia were deemed to be "not related" to the vaccine, although no cause was listed. Instead, the document stated, "pending medical records" with regard to the cause of her adverse events.

• **A 66-year-old white female in the U.S.** (unique subject ID: C4591001 1021 10211190) suffered a stroke on Nov. 2, 2020, with ongoing symptoms as of the document date on Nov. 22, 2020. She was vaccinated on Sept. 10 and Oct. 1, 2020.

Her medical history indicated ongoing gastroesophageal reflux disease, seasonal allergies and postmenopause, as well as a BMI of 28.5.

Her stroke was dismissed as being "not related" to the vaccine, although no alternative cause was listed.

• **A 68-year-old white male in the U.S.** (unique Subject ID: C4591001 1092 10921015) sustained arrhythmia atrial fibrillation and elevated troponin on Aug. 26, 2020. He received his first dose on Aug. 19, 2020, and his second dose on Oct. 6, 2020, as it required "clearance from his cardiologist."

His medical history did not specifically indicate heart conditions. Instead, it indicated ongoing basal cell carcinoma on his nose, as well as hypersensitivity, seasonal allergies, myopia, dyslipidemia, hypertension, actinic keratosis and gastroesophageal reflux disease.

Although the study investigator wrote, in reference to the cause of his injuries, that "medical records [are] being reviewed not able to answer at this time," the report dismissed possibility that his adverse events were related to the vaccine.

• **A 45-year-old Black male in the U.S.** (unique Subject ID: C4591001 1156 11561006) with ongoing Type 1 diabetes sustained deep vein thrombosis and a pulmonary embolism

on Aug. 31, 2020. He received one dose of the vaccine, on Aug. 20, 2020, and was discontinued from the study on Sept. 8, 2020, "because he no longer met the eligibility criteria."

Both adverse events were deemed as being "not related" to his vaccination, and were instead indicated as being "related to medical history of Type 1 diabetes mellitus."

• **A 67-year-old white male in the U.S.** (unique Subject ID: C4591001 1178 11781015) sustained several adverse events on Oct. 10-11, 2020, including ascending aorta ectasia, diastolic dysfunction of the left ventricle and transient global amnesia. These conditions were ongoing as of the document date of Dec. 4, 2020. He was vaccinated on Aug. 25 and Sept. 15, 2020.

The patient's medical record indicated ongoing depression, attention deficit hyperactivity disorder, hypertension, insomnia and neck pain.

While the cause of his adverse events was deemed as being "not related" to the vaccination, the study did state a cause, listing it as "possibly" having been hypertension.

• **A 58-year-old Hispanic/Latino female from Argentina** (unique Subject ID: C4591001 1231 12313674) sustained adverse events including panlobular emphysema, pneumonitis, and left submaxillary sialadenitis beginning on Sept. 29, 2020. The first two conditions were indicated as continuing as of the document date of Dec. 4, 2020.

She was vaccinated on Aug. 24 and Sept. 13, 2020. Her medical record indicated ongoing Sjogren's syndrome and insomnia.

The cause of these adverse events was deemed as being "not related" to the vaccines, although for the first two adverse events, the stated cause was listed as "unknown," while for the third, the cause was listed as Sjogren's syndrome.

• **A 56-year-old Hispanic/Latino female from Argentina** (unique Subject ID: C4591001 1231 12314001) was diagnosed with acute coronary syndrome on Nov. 8, 2020, which was still ongoing as of the document date of Dec. 4, 2020. She was vaccinated on Aug. 25 and Sept. 15, 2020.

Her medical history consisted of ongoing hypothyroidism, allergic rhinitis and asthma — but no coronary troubles.

Nevertheless, according to the study investigator, her condition was determined to be "not related" to the vaccination, although the cause was listed as "unknown."

'Cause unknown' but no chance the vaccine was to blame

In other examples, adverse events were assigned no specific cause or only a "probable" cause, but investigators dismissed the possibility the vaccines may have caused the injuries.

For example:

• **A 34-year-old Hispanic/Latino male from Brazil** (unique subject ID: C4591001 1226 12261745) developed a Leydig cell tumor in his left testicle on Sept. 23, 2020. He received the first dose of the vaccine on Sept. 16, 2020, and second dose on Oct. 7, 2020.

His medical history listed only ongoing allergic rhinitis.

While the study investigator claimed that the adverse event was "not related" to the vaccination, the cause was listed as "unknown."

• **A 19-year-old Hispanic/Latino female from Brazil** (unique Subject ID: C4591001 1231 12311281) with no indicated medical history was diagnosed with acute appendicitis and QT interval prolongation — a heart condition — on Sept. 18, 2020. She was vaccinated on Aug. 15 and Sept. 4, 2020.

These conditions were deemed to be "not related" to the vaccination, although the causes were indicated as "unknown."

• **A 41-year-old Hispanic/Latino female from Argentina** (unique Subject ID: C4591001 1231 12311315) was diagnosed with anemia and malignant melanoma on Sept. 25, 2020, with symptoms continuing as of the document date of Dec. 4, 2020.

She was vaccinated on Aug. 15 and Sept. 3, 2020.

The adverse events were indicated as being "not related" to the vaccination, but instead due to a "probable relationship with [a] vaginal tumor under study."

• **A 44-year-old Hispanic/Latino male from Argentina** (unique Subject ID: C4591001 1231 12312854) was diagnosed with supraventricular arrhythmia on Sept. 17, 2020. He received the two vaccine doses on Aug. 21 and Sept. 11, 2020.

His medical history listed only ongoing sleep apnea syndrome and a BMI of 50.4.

According to the study investigator, the arrhythmia was "not related" to the vaccines, but instead "probably" corresponded "to an accessory intraventricular line."

• **A 56-year-old mixed-race male from Brazil** (unique subject ID: C4591001 1241 12411825) was diagnosed with acute pyelonephritis on Nov. 2, 2020, and hypochromic anemia two days later. Both conditions were still listed as ongoing as of the document date of Dec. 4, 2020.

The participant was vaccinated on Sept. 17 and Oct. 8, 2020. His medical history listed ongoing hypertension.

According to the study investigator, these adverse events were "not related" to the vaccination. Instead, his acute pyelonephritis was due to a "possible" bacterial urinary tract infection, while the hypochromic anemia cause was "to be clarified."

Worsening of pre-existing conditions 'not related' to vaccine

In other instances, participants experienced a worsening of pre-existing conditions. However, in all instances, no relation to the COVID-19 vaccine was determined.

For instance:

• **A 72-year-old white male in the U.S.** (unique Subject ID: C4591001 1092 10921187) sustained congestive heart failure on Oct. 1, 2020. He received his first dose of the vaccine on Sept. 15, 2020, and his second dose on Oct. 6, 2020.

The participant's medical history included ongoing coronary artery disease, atrial fibrillation, type 2 diabetes, asthma, obesity, dyslipidemia, hypertension, insomnia and seasonal allergies. Moreover, he had previously had a defibrillator installed.

The cause of his adverse event was simply indicated as "progression of cardiovascular disease" unrelated to the vaccine. The possibility that the vaccine may potentially have precipitated the worsening of his heart condition was not considered.

• **A 73-year-old white female in the U.S.** (unique Subject ID: C4591001 1111 11111095) was reported as having sustained an "undiagnosed mental disorder" on Sept. 25, 2020, which was still ongoing as of the document date of Dec. 4, 2020. She was vaccinated on Aug.11 and Sept. 1, 2020.

The participant's medical history did not indicate any prior mental disorders or conditions. Nevertheless, the cause of the adverse event was indicated by the study indicator as being "not related" to the vaccination and instead simply due to "mental instability."

• **A 58-year-old white male from the U.S.** (unique Subject ID: C4591001 1109 11091387), who sustained worsening osteoarthritis of the right knee on Oct. 14, 2020, and later also experienced deep vein thrombosis on Oct. 20, 2020, which was still ongoing as of the document date of Dec. 4, 2020.

The participant's medical history indicated ongoing osteoarthritis, ongoing hypercholesterolemia, hypothyroidism, sleep apnea syndrome, rosacea and an enlarged prostate. A prior knee surgery was also listed.

Both adverse events were deemed to be "not related" to the vaccination and instead attributed to the patient's prior knee surgery and "previous medical history."

• **A 70-year-old white female from the U.S.** (unique subject ID: C4591001 1127 11271023) experienced a worsening of her asthma on Oct.1, 2020. She later also developed malignant invasive ductal carcinoma in her left breast, on Nov. 5, 2020. Both cases were still ongoing as of the document date of Dec. 4, 2020.

She received her two doses of the vaccine on July 30 and Aug. 18, 2020. Her medical history, aside from ongoing asthma, also indicated a recurrent urinary tract infection and ongoing bronchitis, seasonal allergies, myopia, migraines, hypothyroidism, hypertension, insomnia, hyperlipidemia, osteoarthritis, bilateral deafness and postmenopause.

According to the document, both adverse events were "not related" to the vaccination, and instead were attributed to an "allergy" and to a "malignancy," respectively.

Reports of multiple adverse events ignored

Other examples include cases where patients sustained multiple adverse events, many of which were entirely ignored by the study investigators' assessments.

These include:

• **A 61-year-old white male from the U.S.** (unique Subject ID: C4591001 1114 1114108), who sustained 10 vaccine injuries beginning on Sept. 12, 2020, after he received the first dose of the vaccine on Aug. 24, 2020, and his second dose on Sept. 30, 2020.

The adverse events he experienced included acute kidney injury, atrial fibrillation, chest pain, left ventricular hypertrophy, mitral valve regurgitation, bilateral hand pain, pulmonary hypertension, skin avulsion on his left finger, a Staphylococcal infection and tricuspid regurgitation. Several of these conditions were still ongoing as of the document date of Dec. 4, 2020.

The patient's medical history indicated ongoing peripheral neuropathy, type 2 diabetes, anxiety, depression, asthma, Staphylococcal infection, hypertension, hyperlipidemia and a prior leg amputation.

According to the study investigator, "the staphylococcal infection" was "not related" to the vaccine, but instead was connected to the patient's hypertension, musculoskeletal causes and an "infection." No mention was made in this assessment as to the probable causes of the other adverse events.

Some adverse events 'caused' by … the adverse event

In still other cases, the "cause" of participants' adverse events was indicated as being the same as the adverse event itself.

Examples include:

• **A 68-year-old white male from the U.S.** (unique Subject ID: C4591001 1095 10951204), who was diagnosed with bladder cancer on Nov. 2, 2020. He was vaccinated on Sept. 2 and Sept. 21, 2020.

According to the document, the participant's ongoing medical history included hypertension, benign prostatic hyperplasia, hypercholesterolemia, angina pectoris, coronary arterial stent insertion, coronary artery disease, erectile dysfunction and osteoarthritis.

However, the cause of his bladder cancer was attributed as "cancer" and deemed to be "not related" to the vaccination and "most likely coincidental and associated with the underlying clinical conditions."

• **A 48-year-old white male from the U.S.** (unique Subject ID: C4591001 1124 11241106) sustained an acute myocardial infarction on Sept. 27, 2020. He previously received two doses of the vaccine, on Aug. 26 and Sept. 16, 2020.

His medical history indicated ongoing high cholesterol, gastroesophageal reflux disease and back pain.

According to the study investigator, the adverse event sustained by the participant was "not related" to the vaccination, but instead "related to cardiovascular risk," with no further elaboration provided.

• **A 73-year-old white female in the U.S.** (unique Subject ID: C4591001 1223 12231159) was found to have a pancreatic mass on Nov. 5, 2020. She was vaccinated on Sept. 10 and Oct. 1, 2020.

Her medical records indicated ongoing osteoarthritis, menopause, gastroesophageal reflux disease, hypertension, dyslipidemia, hypothyroidism, Eustachian tube dysfunction, prophylaxis, irritable bowel syndrome, osteoporosis and benign monoclonal

hypergammaglobulinemia.

The cause of her adverse event, which was indicated to be “not related” to the vaccination, was listed as “new development of pancreatic mass” without any elaboration as to the factors that may have caused it to appear.

Other explanations for participants’ vaccine injuries include:

• **A 78-year-old white male from the U.S.** (unique Subject ID: C4591001 1097 10971011), who suffered from pneumonia between Sept. 20 and Oct. 5, 2020. He had previously received two doses of the vaccine, on Aug. 20 and Sept. 9, 2020.

According to the document, the cause of his pneumonia was “not related” to the vaccines. Instead, the listed cause was “pt [patient] contracted pneumonia from somewhere.”

• **An 84-year-old white male from the U.S.** (unique Subject ID: C4591001 1097 10971084) contracted pneumonia on Oct. 7, 2020, symptoms of which were still ongoing as of the document date of Dec. 4, 2020. He had previously been vaccinated on Sept. 1 and Sept. 23, 2020.

Similar to the patient above, the cause of the participant’s pneumonia was indicated as being “not related” to the vaccination. The narrative comment instead stated that “Pt [patient] contracted pneumonia from unknown source.”

Very few severe adverse events — and no deaths — were reported in other countries, although Argentina, for instance, was home to the largest of the Pfizer vaccine trials in 2020.

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

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