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Pfizer Classified Almost All Severe Adverse Events During COVID Vaccine Trials 'Not Related to Shots'

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The case reports included in Pfizer clinical trial documents, released June 1 by the U.S. Food and Drug Administration, reveal a trend of classifying almost all adverse events — and in particular severe adverse events — as being "not related" to the vaccine.

The latest release by the U.S. Food and Drug Administration (FDA) of Pfizer-BioNTech COVID-19 vaccine documents reveals numerous instances of participants who sustained severe adverse events during Phase 3 trials. Some of these participants withdrew from the trials, some were dropped and some died.

The 80,000-page document cache includes an extensive set of Case Report Forms (CRFs) from Pfizer Phase 3 trials conducted at various locations in the U.S., in addition to other documentation pertaining to participants in Pfizer-BioNTech vaccine trials in the U.S. and worldwide.

The FDA on June 1 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 (PHMPT), a group of doctors and public health professionals, submitted the FOIA request.

CRFs show deaths, severe reactions to the vaccines during Phase 3 trials

The CRFs included in this month's documents contain often vague explanations of the specific symptoms experienced by the trial participants.

They also reveal a trend of classifying almost all adverse events — and in particular severe adverse events (SAEs) — as being "not related" to the vaccine.

For example:

- A female in her early 50s (randomization number 86545) who participated in the trial at the Sterling Research Group in Cincinnati, Ohio, died of an apparent myocardial infarction on Nov. 4, 2020. She had received two doses of the vaccine, on Sept. 10 and Sept. 29, 2020.

The patient had a medical history of chronic obstructive pulmonary disease, hypertension, hypothyroidism, osteoarthritis of the knees and attention deficit disorder. Her death was listed as "not related" to the vaccine, and was instead attributed to "hypertensive cardiovascular disease."

- A female in her late 50s (randomization number 220496), who participated in the trial at Cincinnati Children's Hospital Medical Center, died of cardiac arrest on Oct. 21, 2020. Her death, however, was indicated as "not related" to her vaccinations (which occurred on July 30, 2020, and Aug. 20, 2020) as it "occurred 2 months after last receipt of study agent," according to her CRF.

The participant's medical history included obesity, placement of a gastric sleeve, gastroesophageal reflux, sleep apnea, supraventricular tachycardia, hypothyroidism, depression and asthma.

- A male in his mid-60s (randomization number 221076) who participated in the trial operated by the Texas-based Ventavia Research Group died of an apparent myocardial infarction on Nov. 28, 2020. He had received the two doses of the vaccine on July 31, 2020, and Aug. 19, 2020.

The participant had a medical history that included a previous myocardial infarction, high blood pressure, high cholesterol, anxiety, bilateral hip pain, type 2 diabetes, fluid retention, angina (intermittent), restless leg syndrome, Vitamin D deficiency, tobacco dependency and the placement of a coronary arterial stent in 2017.

According to the CRF, he sustained the myocardial infarction on Oct. 27, 2020, and was diagnosed with pneumonia the following day. While both diagnoses were classified as "serious" in his CRF, they were both listed as "not related" to the vaccination, with his myocardial infection attributed to a "failed cardiac stent" and the pneumonia simply attributed to "infection."

- A female in her teens (randomization number 104650) was diagnosed with right lower extremity deep vein thrombosis on Nov. 15, 2020, which was still ongoing as of Mar. 29, 2021, the date of the CRF. She was hospitalized and her condition was classified as "serious," but it was indicated as "not related" to the vaccine, instead attributed to a "fracture" occurring prior to her vaccination on Sept. 11, 2020.

The patient had a medical history including asthma, attention deficit hyperactivity disorder, Charcot-Marie-Tooth disease and obesity.

- A male in his mid-70s (randomization number 227629) participating in the trial at Clinical Neuroscience Solutions Inc. (operating in Florida and Tennessee) sustained a series of adverse events following his vaccinations on Aug. 13 and

Oct. 7, 2020.

He was diagnosed with COVID-19 on Aug. 30, 2020, which coincided with several other diagnoses classified as "serious," including abdominal adhesions (Aug. 29, 2020), altered mental status (Aug. 29, 2020, lasting through Sept. 16, 2020), and acute hypoxic respiratory failure (Aug. 30, 2020). These diagnoses required his hospitalization.

He was also listed as having suffered from congestive heart failure on Aug. 30, 2020, but this diagnosis was listed as "not serious" and as "not related" to the vaccine, but to "prior surgery," with no further details given. Similarly, his other serious adverse events were listed as being related to "prior" or "previous" surgery, or to "concomitant non-drug treatment."

Other "non-serious" adverse events listed in this patient's CRF include hypokalemia, anemia, acute renal failure, sepsis, hyponatremia, leukopenia, small bowel obstruction, aspiration pneumonia, mild concentric left ventricular hypertrophy (symptoms of which were still ongoing as of the CRF date of Mar. 29, 2021) and urinary tract infection.

The patient had a medical history encompassing ongoing hypertension, hypercholesterolemia, gastroesophageal reflux disease, constipation, hiatal hernia and previous diagnoses of small bowel resection, small bowel perforation, inguinal hernia, osteoarthritis in both knees and knee replacement (both knees).

- A male in his mid-70s (randomization number 266982) participating in the trial at Boston Medical Center suffered a series of adverse events following vaccination, including pneumonia and peripheral edema. He had received two doses of the vaccine, on Oct. 2, 2020, and Oct. 27, 2020.

The patient was hospitalized for pneumonia on Jan. 20, 2021, in an event classified as "serious" but also as "not related" to the vaccine. However, the cause of his pneumonia was listed in the CRF simply as "un-related to vaccine," while his peripheral edema diagnosis was attributed to "existing neuropathy."

During his hospitalization with pneumonia, his blood pressure was measured as high as 179/72, with a heart rate reaching 105 beats per minute and an oxygen saturation level that fell to 92.0. In total, he had three emergency room visits during the observation period.

The patient had a medical history that included type 2 diabetes, alcoholic cirrhosis, hypothyroidism, asthma, sleep apnea, hypertension, diabetic neuropathy, congestive heart failure, generalized anxiety disorder, depression, insomnia, excessive urination, chronic obstructive pulmonary disease and HIV-positive status.

A protocol deviation also occurred involving this patient, as his diary was not activated following administration of the first dose of the vaccine.

- A male in his early 40s (randomization number 68489) who participated in the trial at Cincinnati Children's Hospital Medical Center sustained chronic myelogenous leukemia on Sept. 24, 2020, with the condition ongoing as of the date of the CRF on Mar. 29, 2021.

This was classified as a "serious" and "life-threatening" adverse event, albeit one that did

not require hospitalization, but it was listed as "not related" to the vaccination but instead to a "genetic change in stem cells."

The patient had been vaccinated on Aug. 26, 2020, and Sept. 17, 2020, and had a medical history of asthma and seasonal allergies. Other "non-serious" adverse events he sustained included leukocytosis and thrombocytosis.

- A female in her mid-40s (randomization number 49018) who participated in the trial at Clinical Neuroscience Solutions Inc. was diagnosed with kidney stones on Jan. 4, 2021.

This was classified as a "serious" adverse event that required hospitalization, but was listed as "not related" to the vaccine, instead being related, again, to "kidney stone" (sic). She had received the two doses of the vaccine on Aug. 17, 2020, and Sept. 8, 2020.

The patient was diagnosed with COVID-19 on Jan. 27, 2021. Her prior medical history included migraine headaches, hypercholesterolemia and a Tarlov cyst.

- A female approximately 30 years old (randomization number 53307) participating in the trial at Boston Medical Center, with nothing to report in her medical history, sustained a shoulder injury related to vaccine administration (SIRVA) on Sept. 9, 2020, with symptoms continuing until Feb. 8, 2021.

This injury was listed as being related to the second dose of the vaccine, which she received on Sept. 9, 2020 (she had previously received her first dose on Aug. 17, 2020).

- A female in her late 50s (randomization number 260125) participating in the trial at Clinical Neuroscience Solutions Inc., suffered from acute exacerbation of asthma. The symptoms appeared in mid-December 2020, following her vaccination on Sept. 16, 2020, and Oct. 5, 2020.

Her symptoms were classified as serious but not life-threatening, and she was hospitalized. However, her asthma symptoms were listed as "not related" to the vaccine, instead being related to "asthma" with no further explanation provided. On Jan. 12, 2021, her blood pressure was recorded as 183/130, with a heart rate of 98 beats per minute.

Other less serious adverse events sustained by the patient included injection site pain, body pain, chills and a low-grade fever.

Her medical history included cholecystitis (and a cholecystectomy), herniated disc, total abdominal hysterectomy, bilateral oophorectomy, bilateral salpingectomy, endometriosis, hypertension, hypercholesterolemia, rheumatoid arthritis in remission, asthma, seasonal allergies, irritable bowel syndrome and obesity.

- A male in his late 20s (randomization number 48413) who participated in the trial at Clinical Neuroscience Solutions Inc., sustained a bilateral pulmonary embolism on Dec. 14, 2020, with symptoms still ongoing as of the CRF date of Mar. 29, 2021.

This was listed as a "serious" adverse event that required hospitalization, but was attributed to the patient's habit of vaping and his "sedentary lifestyle." He had received the two doses

of the vaccine on Aug. 13, 2020, and Sept. 2, 2020.

Other post-vaccination symptoms listed for the patient included fever, fatigue, headache, chills, vomiting, diarrhea, new/worsened muscle pain, new/worsened joint pain and swelling.

The patient had a medical history that included elevated triglycerides, genital herpes and seasonal allergies, in addition to a vaping habit.

The many serious adverse events – and several deaths – recorded during the Phase 3 trials are also apparent in a separate, massive document, exceeding 2,500 pages, cataloging such adverse events.

This document lists a wide range of adverse events suffered by trial participants classified as toxicity level 4 — the highest and most serious such level.

However, not one of the level 4 (most severe) adverse events listed in this particular document is classified as being related to the vaccination.

Level 4 adverse events listed in the document include but are not limited to the following, many of which occurred in multiple patients:

- Acute cholecystitis
- Acute respiratory failure
- Adrenal carcinoma
- Anaphylactic shock
- Aortic valve incompetence
- Appendicitis
- Arrhythmia, supraventricular
- Arteriosclerosis
- Brain abscess
- Cardiac arrest
- Chronic myeloid leukemia
- Complicated appendicitis/acute appendicitis with necrosis
- Congenital heart disease/heart anomaly
- Coronary artery occlusion
- COVID-19 illness
- Deep vein thrombosis
- Diverticulitis
- Hemiplegic migraine
- Hemorrhagic stroke
- Interstitial lung disease
- Myocardial infarction
- Orthostatic hypotension/possible postural hypotension
- Osteoarthritis
- Pericolic abscess
- Peritoneal abscess
- Renal colic
- Ruptured diverticulum
- Small bowel obstruction/small intestinal obstruction
- Spontaneous coronary artery dissection
- Subarachnoid hemorrhage

- Suicidal ideation (and suicidal ideation with attempt)
- Syncope
- Type 2 diabetes
- Worsening of abdominal pain
- An “unevaluable event/“unknown of unknown origin”

Similarly, only a small number of toxicity level 3 adverse events were indicated as having been “related” to vaccination. Such adverse events included but are not limited to the following, some of which occurred in multiple trial participants:

- Arthralgia
- Blood glucose increase/glucose spike
- Deafness/hearing loss
- Dyspepsia
- Hypotension
- Lymph node pain
- Lymphadenopathy/lymph node swelling
- Musculoskeletal chest pain (non-cardiac)
- Neutropenia
- Pain in fingers/bilateral hands
- Pruritus
- Pyrexia/febrile syndrome
- Severe headache
- Shoulder injury related to vaccine administration
- Sleep disorder/sleep disturbance
- Tachycardia
- Urticaria
- Ventricular arrhythmia
- Vertigo

Page 2,525 of the document in question also lists six trial participant deaths, with causes of death including arteriosclerosis, cardiac arrest, hemorrhagic stroke and myocardial infarction.

The small number of adverse events listed as being connected to the vaccine follows a trend noted in the previous tranche of Pfizer-BioNTech documents, released in May.

An additional document released in this month’s tranche catalogs patients who discontinued their participation in the Phase 3 trial, or whose participation was discontinued by physicians or other medical professionals.

While many patients were discontinued because they could not be located, because of a physician’s orders, because they moved to another region or for other personal reasons, numerous patients ended their participation due to adverse events, including but not limited to the following symptoms:

- Acute myocardial infarction
- Amnesia
- Anorexia
- Atrial fibrillation
- Cerebral infarction

- Congestive cardiac failure
- Coronary artery disease
- Deafness (unilateral)
- Depression
- Diabetic foot
- Diverticular perforation
- Exposure during pregnancy
- Eye pain
- Gait instability
- Gastric adenocarcinoma
- Gastrointestinal hemorrhage
- Hypertension
- Irregular heart rate
- Loss of taste and smell
- Myalgia
- Paraparesis
- Parkinsonism
- Presyncope
- Pulmonary embolism
- Pyrexia
- Swelling face
- Tachycardia
- Transient ischaemic attack
- Urticaria
- Vaccine allergy
- Vertigo

In other instances, subjects withdrew because of fears connected to safety concerns related to the vaccine, or discomfort in receiving the second dose.

Clinical review document glosses over adverse events during trials

Also included in June's FDA document dump was a 334-page "clinical review" document, which appears to have been approved by the FDA on Apr. 30, 2021, and which presents "pivotal data" from Phase 1/2/3 Study C4591001, conducted in the U.S., along with "supporting" Phase 1/2 data from Study BNT162-01, performed in Germany.

This document refers to both Pfizer-BioNTech vaccine, which received an EUA from the FDA, and the Pfizer Comirnaty vaccine, which received full FDA approval but is reportedly almost impossible to find at vaccination locations in the U.S.

As previously reported by The Defender, a federal judge found the Pfizer-BioNTech and Pfizer Comirnaty vaccines are legally distinct.

The clinical review document states:

> "BNT162b2 has received temporary authorizations for emergency supply in 28 countries and conditional marketing authorizations in 39 countries globally.
>
> "The name of the product supplied under emergency/temporary use authorization for all applicable regions is Pfizer-BioNTech COVID-19 Vaccine.

> "The name of the product supplied under conditional marketing authorization for all applicable regions is COMIRNATY [COVID-19 mRNA Vaccine (nucleoside modified)]."

The document states that trial participants were administered one of two candidate vaccines, labeled BNT162b1 and BNT162b2 (the latter of which ultimately received an EUA from the FDA), or a placebo. A variety of dosage levels were also tested, ranging from 10 µg to 100 µg for BNT162b1, and 10 µg to 30 µg for BNT162b2.

In Phase 1 of Study BNT162-01, the clinical review reports that "40% to 45% of participants who received BNT162b1 and BNT162b2 across age groups and across dose levels reported one or more AEs [adverse events] from Dose 1 through 28 days (i.e., 1 month) after Dose 2."

In what will turn out to be a general pattern throughout the clinical review, we are told that "most AEs were considered by the investigator as not related to study intervention and mild to moderate in severity, and all AEs were reported as resolved."

Some specific adverse events highlighted in this part of the clinical review include:

> "Among BNT162b1 recipients, 1 younger participant in the 10 µg group discontinued the study due to a moderate AE of malaise (considered as not related to study intervention) after Dose 1 and 1 younger participant in the 60 µg group discontinued due to a dose-limiting toxicity of pyrexia after Dose 1.
>
> "One older participant in the 20 µg group had an SAE of severe syncope (considered as not related to study intervention) after Dose 1 and study treatment was withdrawn.
>
> "Among BNT162b2 recipients, 1 younger participant in the 10 µg group discontinued the study due to a moderate AE of nasopharyngitis (considered as not related to study intervention) after Dose 1.
>
> "One older participant in the 20 µg group had an SAE of ankle fracture (considered as not related to study intervention) after receiving both doses, was listed as recovering, and remains in follow-up."

The clinical review also states "no deaths occurred in the Phase 1 part of Study BNT162-01."

The review adds that "from Dose 1 of BNT162b2 30 µg to the unblinding date, 6 (50.0%) participants in the younger age group and 3 (25.0%) participants in the older age group reported at least 1 AE."

Specifically, in this portion of the study, "two (16.7%) participants in the BNT162b2 30 µg younger age group and 1 (8.3%) participant in the BNT162b2 30 µg older age group reported at least 1 severe AE," and "in the BNT162b2 30 µg younger age group, 3 (25.0%) participants reported at least 1 related AE and 1 (8.3%) participant reported 1 severe SAE."

These specific adverse events, according to the review, were reported in "the system organ class (SOC) of nervous system disorders (3 [25.0%] participants in the younger age group and 1 [8.3%] participant in the older age group), followed by musculoskeletal and connective tissue disorders (1 [8.3%] participant in each age group). All AEs by preferred term (PT) were reported by no more than 1 participant."

The review adds, “from Dose 1 to the unblinding date, 1 participant in the BNT162b2 30 µg younger age group reported a severe SAE (neuritis) that was assessed by the investigator as not related to study intervention,” and “there were no Phase 1 participants randomized to BNT162b2 30 µg or corresponding placebo who died through the data cutoff date of 13 March 2021.”

Review of results from Study C4591001

While “incidences in the BNT162b2 and placebo were similar within the age groups for younger (9.1% vs 11.1%) and older (4.3% vs 8.9%) participants, among those who received BNT162b2 instead of the placebo, “two severe events of myalgia and gastric adenocarcinoma (which was also an SAE) were reported for 2 participants in the … younger age group, both assessed by the investigator as not related to study intervention.”

It is further mentioned that “the only discontinuation due to an AE during this time was the participant in the BNT162b2 younger age group who reported an SAE of gastric adenocarcinoma (discontinued from the study on Day 23 after Dose 1 of BNT162b2).”

Ultimately, from dose 1 to 1 month after dose 2 for participants during the blinded safety follow-up of study C4591001, “the numbers of overall participants who reported at least 1 AE and at least 1 related AE were higher in the BNT162b2 group (30.2% and 23.9%, respectively) as compared with the placebo group (13.9% and 6.0%, respectively).”

Specifically, “severe AEs were reported by 1.2% and 0.7% in in the BNT162b2 and placebo groups respectively, and life-threatening AEs were similar (0.1% in both groups),” and “SAEs and “AEs leading to withdrawal were reported by ≤0.6% and ≤0.2%, respectively, in

both groups,” while “discontinuations due to related AEs were reported in 13 participants in the BNT162b2 group and 11 participants in the placebo group (0.1% in both groups).”

Overall, as reported for this part of the study, “in the younger age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 4233 (32.6%) and 1871 (14.4%) in the BNT162b2 and placebo groups, respectively. In the older age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 2384 (26.7%) and 1177 (13.2%) in the BNT162b2 and placebo groups, respectively.”

The review specifies that “the most frequently reported AEs in the BNT162b2 group … were injection site pain (2915 [13.3%]), pyrexia (1517 [6.9%]), fatigue (1463 [6.7%]), chills (1365 [6.2%]), headache (1339 [6.1%]), and myalgia (1239 [5.7%]),” however, some more serious adverse events that were reported during this stage of the trial included facial paralysis, cardiac disorders, hepatic cirrhosis, cholecystitis/cholecystitis acute, biliary colic, bile duct stone, biliary dyskinesia, lymphadenopathy, appendicitis, optic neuritis and hypersensitivity/anaphylaxis.

Overall, according to the review, “from Dose 1 to 1 month after Dose 2, severe AEs reported during the blinded follow-up period were low in frequency, reported in 1.2% of BNT162b2 recipients and 0.7% of placebo recipients.”

During the “open-label follow-up period,” referring to the period when the initial trial has been completed but participants are invited to continue taking the study drug for an additional period, the review states “three participants originally randomized to BNT162b2

died during open-label follow-up."

While one of these deaths was reportedly due to a road accident, the other two were attributed to lung metastases and myocardial infarction. However, none of these deaths "were assessed by the investigator as related to study intervention."

Furthermore, according to the report, during this period "there were 12,006 participants who had at least 6 months of follow-up. Among these, 3,454 participants (28.8%) reported at least 1 AE and 2245 participants (18.7%) reported at least 1 related AE. Severe AEs and SAEs were reported by 2.1% and 1.6%, respectively."

The review provides data for participants from dose 3 (first dose of BNT162b2) to the data cutoff date. The severe adverse event incidence rate (IR) was 6.0 per 100 PY (patient-years), with specific conditions reported including pulmonary embolisms, thrombosis, urticaria, a cerebrovascular accident and COVID-19 pneumonia.

Here, the review adds that the IR for original placebo participants who had at least 1 life-threatening AE from Dose 3 to the data cutoff date was 0.5 per 100 PY. Only one such life-threatening event, an instance of anaphylactoid reaction, was considered to be related to the vaccination. Other life-threatening, serious adverse events included cardio-respiratory arrest, gastrointestinal necrosis, deep vein thrombosis and pulmonary embolism.

The report also notes, "There were 15 deaths in the BNT162b2 group and 14 deaths in the placebo group from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period."

However, the report does not appear to go into detail about the causes of death for either group, other than to state, "None of these deaths were assessed by the investigator as related to study intervention."

In the "Blinded Follow-Up Period from Dose 1 Through 1 Month After Dose 2," in the BNT162b2 group, "SAE [serious adverse events] was similar in the BNT162b2 group (0.6%) and in the placebo group (0.5%)," with three SAEs in the non-placebo group deemed to be related to the vaccine. These included ventricular arrhythmia, lymphadenopathy and SIRVA.

During the "open-label follow-up period" for "original BNT162b2 participants," the report states "one younger participant with no past medical history had a life-threatening SAE of myocardial infarction 71 days after Dose 2 that was assessed by the investigator as related to study intervention."

However, despite its life-threatening nature, this condition "lasted 1 day and resolved the same day."

Overall, "from Dose 1 to 6 months after Dose 2, during the blinded and open-label follow-up periods, 190 (1.6%) participants in the BNT162b2 group reported at least 1 SAE," and "the number of participants who reported at least 1 SAE was 73 (1.1%) and 117 (2.2%) in the younger and older age groups, respectively."

These SAEs were categorized as neoplasms, infections and infestations, gastrointestinal disorders, hepatobiliary disorders, respiratory/thoracic/mediastinal disorders and injury/poisoning/procedural complications.

An original placebo participant who received BNT162b2 for Dose 3 experienced a severe adverse event that "was assessed by the investigator as related to study intervention; specifically, "an anaphylactoid reaction 2 days post Dose 3" leading to the participant's withdrawal from the study, despite a reported resolution.

A separate subsection in the report specifically addressed cases of Bell's palsy and facial paralysis among trial participants. Specifically, "during the blinded placebo-controlled follow-up period, 6 participants developed one-sided facial paralysis (Bell's palsy): 4 were randomized to BNT162b2 (all male) and 2 were randomized to placebo (1 male; 1 female)," according to the review.

Regarding the four vaccinated trial participants, their ages ranged from 40 to 70, with symptoms appearing three to 48 days after their last dose. Their symptoms were recorded as "mild to moderate in severity," with duration ranging "from 3 to 68 days," and with two of these cases "considered by the investigator to be related to study intervention."

Moreover, "during the open-label follow-up period, 3 participants who received BNT162b2 as Dose 3 or Dose 4 (after originally being randomized to placebo) experienced facial paralysis," according to the review. These patients were all female, with an age range between 19 and 34. Events were recorded as beginning two to eight days after administration of the third dose, and "were mild to severe." One case had a duration of 12 days, while the other two cases were ongoing as of the cutoff date of the trial.

Notably, according to the review, "all these events of facial paralysis were considered by the investigator as related to study intervention."

The review adds, "during the open-label follow-up period for participants originally randomized to BNT162b2, a male participant 51 years of age developed Bell's Palsy 154 days after receiving Dose 2." No indication is given as to whether this was deemed to be related to the vaccination or not.

From dose 1 to the unblinding date, heart-related adverse events included "6 acute myocardial infarctions, 4 myocardial infarctions group, and 1 acute coronary syndrome" in the BNT162b2 group.

According to the review, "most of these events had onset distant (ie, >30 days following) to receipt of vaccine or placebo. None of these events were assessed by the investigator as related to study intervention."

Moreover, "there was 1 participant in the older BNT162b2 age group with pericarditis. The event had an onset of 28 days after Dose 2, was ongoing at the data cutoff date, and was assessed by the investigator as not related to the study intervention."

Additionally, "there were 8 cases of pulmonary embolism in the BNT162b2 group," in addition to four hemorrhagic strokes and "2 ischemic strokes, 4 cerebral vascular accidents, 2 transient ischemic attacks" in this group, plus "1 case of thrombocytopenia and 1 case of platelet count decreased."

Furthermore, "there were 9 thrombotic events in the BNT162b2 group," including seven instances of deep vein thrombosis, one case of coagulopathy and one case of ophthalmic vein thrombosis.

Regarding autoimmune issues in the BNT162b2 group, the review states "there were 10 autoimmune disease cases identified," with one case each of "autoimmune thyroiditis, ulcerative colitis, Crohn's disease, reactive arthritis, fibromyalgia, systemic lupus erythematosus, alopecia areata, psoriasis," and two cases of psoriatic arthropathy.

Pregnancies were largely glossed over in the review, which states:

> "At the time of the data cutoff date (13 March 2021), a total of 50 participants who had received BNT162b2 had reported pregnancies, including 42 participants originally randomized to the BNT162b2 group and 8 participants originally randomized to the placebo group who then received BNT162b2."
>
> "In total, 12 participants (n=6 each in the randomized BNT162b2 and placebo groups) withdrew from the blinded placebo-controlled vaccination period of the study due to pregnancy, and 4 participants originally randomized to placebo who then received BNT162b2 withdrew from the open-label vaccination period due to pregnancy.
>
> "These participants continue to be followed for pregnancy outcomes. No births have been reported from individuals who have become pregnant in Study C4591001 as of the time of this submission.
>
> "All pregnancies have a risk of birth defect, loss, or other adverse outcomes. Available data on BNT162b2 administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy."

Pfizer concludes vaccines are 'safe and well-tolerated'

Overall, despite the incidence of severe adverse events — some of which were admitted to be related to the vaccine — and deaths, as well as an admitted lack of data regarding outcomes for pregnant women who participated in the trial, the "safety conclusions" of the review indicate the following:

> "Based on Phase 1 data from the FIH Study BNT162-01, BNT162b1 and BNT162b2 were safe and well-tolerated in healthy adults 18 to 55 years of age, with no unanticipated safety findings … and the AE profile and clinical laboratory results did not suggest any safety concerns.
>
> "Based on Phase 1 data from Study C4591001 and Study BNT162-01, BNT162b1 and BNT162b2 were safe and well-tolerated in younger healthy adults 18 to 85 years of age, with no unanticipated safety findings … and the AE profile did not suggest any safety concerns, including up to approximately 6 months after Dose 2 for BNT162b2 30 µg groups.
>
> "Based on Phase 2/3 data from approximately 44,000 participants ≥16 years of age with up to at least 6 months of follow-up after Dose 2 in Study C4591001, BNT162b2 at 30 µg was safe and well-tolerated across age groups … and the AE profile did not suggest any serious safety concerns. The incidence of SAEs and deaths were low in the context of the number of participants enrolled and comparable in BNT162b2 and placebo. The incidence of discontinuations due to AEs was also generally low and similar between BNT162b2 and placebo groups.
>
> "Cumulative safety follow-up to at least 6 months after Dose 2 for approximately

> 12,000 Phase 2/3 participants originally randomized to BNT162b2, comprising the combined blinded and open-label periods, showed no new safety signals or suggested [any] new safety concerns arising from this period of follow-up.
>
> "Similarly, open-label follow-up of participants originally randomized to placebo from the time of unblinding to receive BNT162b2 until the data cutoff date showed no new safety signals or concerns.
>
> "The AE profile among approximately 44,000 participants ≥16 years of age enrolled to date as of the most recent safety cutoff date (13 March 2021), was mostly reflective of reactogenicity events with low incidences of severe and/or related events. The incidence of SAEs was low and similar in the vaccine and placebo groups. Few participants withdrew from the study due to AEs. Few deaths occurred overall in both the vaccine and placebo groups with no imbalance.
>
> "For participants randomized to placebo and then unblinded to receive BNT162b2 vaccination, open-label data from the time of unblinding to the data cutoff date (13 March 2021) showed no new safety findings or signals.
>
> "Taken together, efficacy and immunogenicity data suggest the BNT162b2 (30 µg) 2-dose regimen induces a strong immune response and provides durable protection from COVID-19 across a spectrum of individuals representative of the population at large for individuals ≥16 years of age: those with or without prior exposure to SARS-CoV-2 and those in higher-risk categories based on age, race, ethnicity, and/or comorbidity."

As a result, and based on the above data, the review makes a case for the approval of BNT162b2:

> "A vaccine program must be implemented expediently and rapidly expanded to have a significant impact on the pandemic course. Licensure of BNT162b2 is likely to enhance vaccine uptake by facilitating supply of vaccine from Pfizer/BioNTech directly to pharmacies and healthcare providers/facilities.
>
> "The greatest impact of BNT162b2 licensure may be direct supply to healthcare providers who serve vulnerable populations such as elderly patients and those who live in rural and underserved communities (i.e., individuals who might be unable to navigate the challenges of securing vaccine access using the systems in place for EUA).
>
> "Expansion of vaccine via licensure would ultimately improve the prospect of achieving population herd immunity to bring the pandemic under control.
>
> "Overall, the potential risks and benefits, as assessed by the safety profile and the efficacy and immunogenicity of BNT162b2 (30 µg), are balanced in favor of the potential benefits to prevent COVID-19 in immunized individuals.
>
> "Likewise, the BNT162b2 30 µg benefit and risk profile support further development in pediatric, maternal, and other at-risk populations."

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