‘Criminal’: Confidential EU Documents Reveal Thousands of Deaths From Pfizer-BioNTech Shots

By Michael Nevradakis, Ph.D. – 23.6.2023

“Confidential” documents released by BioNTech to the European Medicines Agency reveal tens of thousands of serious adverse events and thousands of deaths among people who received the Pfizer-BioNTech mRNA COVID-19 vaccine during a time period when the vaccine makers insisted they saw no “safety signals.”

Documents released by BioNTech to the European Medicines Agency (EMA) reveal tens of thousands of serious adverse events and thousands of deaths among people who received the Pfizer-BioNTech mRNA COVID-19 vaccine.

The documents (See Attachment marked “A”), dated Aug. 18, 2022, and marked “confidential,” show that cumulatively, during the clinical trials and post-marketing period up to June 18, 2022, a total of 4,964,106 adverse events were recorded. The documents included an appendix with further details about the specifics about the identified adverse events.

Among children under age 17, 189 deaths and thousands of serious adverse events were reported.

The documents present data collected between Dec. 19, 2021, and June 18, 2022 (the “PSUR #3 period”), in addition to cumulative data on adverse events and deaths that occurred among those who received the vaccine during clinical trials and during the post-marketing period, beginning December 2020 up until June 18, 2022.

During this time, Pfizer-BioNTech said it identified almost no safety signals and claimed the vaccine demonstrated over 91% “efficacy.”

Remarking on the documents, Brian Hooker, Ph.D., P.E., senior director of science and research for Children’s Health Defense, told The Defender:

“These adverse event reports are ‘off the charts,’ with myocarditis reports at over 10,000 and pericarditis reports at over 9,000.

“Historically, we know that this would be an under-ascertainment of the actual numbers. It is criminal for the EMA to keep this vaccine on the market.”

According to an analysis by commentator and author Daniel Horowitz, the percentage of adverse events classified as serious was “well above the standard for safety signals usually pegged at 15%,” and women reported adverse events at three times the rate of men.

Sixty per cent of cases were reported with either “outcome unknown” or “not recovered,” suggesting many of the injuries “were not transient,” Horowitz said.

The highest number of cases occurred in the 31-50 age group, of which 92% did not have any comorbidities, making it very likely it was the vaccine causing “such widespread, sudden injury.”

There were 3,280 fatalities among vaccine recipients in the combined cumulative period including the clinical trials and post-marketing, up to July 18, 2022.

According to Horowitz, the documents “show that Pfizer knew about a sickening level of injury early on,” yet continued to distribute its COVID-19 vaccine.

The documents are not part of the ongoing court-ordered release of the so-called “Pfizer documents” in the U.S., but according to Horowitz, are pharmacovigilance documents requested by the EMA, the EU’s drug regulator.

The documents were made available to an Austrian science and politics blog, TKP, following “a FOIA [Freedom of Information Act] request from an anonymous reader.” They were subsequently published on March 4. However, once published, no European English-language media outlet appears to have reported on them.

As a result, they remained under the radar until recently, when several independent English-language bloggers discovered and published the documents.

Thousands of pediatric serious adverse events and deaths

The main Pfizer-BioNTech document revealed 9,605 adverse events (3,735 serious) during the PSUR #3 and 25 cases during the clinical trials among children ages 11 and younger. These included 20 fatalities, in children as young as 5 years old.

Causes of these fatalities included dyspnea, cardiac arrest, cardio-respiratory arrest, pyrexia and myocarditis, though “all events were assessed as unrelated” to the vaccine.

In one example listed in the document, an 11-year-old boy died of acute respiratory failure two days after the first dose of the vaccine. In another case, a 6-year-old girl died seven days following her initial dose of complications that included renal impairment, epilepsy, apnea, seizure and “sudden death.”

The document lists another case, that of a 6-year-old boy whose listed causes of death are myocarditis, cardio-respiratory arrest and COVID-19. He died seven days after the first dose of the vaccine, and although autopsy results were “pending,” “the reporter concluded that the death ‘had nothing to do’ with

the administration of BNT162b2 [the Pfizer-BioNTech vaccine] and was due to natural causes."

For children ages 12-17, the document listed 21,945 adverse events (19,558 serious) in the post-marketing period and 15 cases during clinical trials. A total of 169 deaths were recorded, with listed causes including dyspnea, pyrexia, cardiac arrest, myocarditis, cardiac failure, seizure and shock. Nevertheless, the document states "No new significant safety information was identified based on the review of the cases reported in the overall paediatric population."

'No safety signals' despites deaths, injuries of pregnant women and newborns

Pregnant and lactating women also were significantly affected. There were 3,642 post-authorization adverse events and 697 clinical trial adverse events in this population, including spontaneous abortion, fetal death, postpartum hemorrhage, premature separation of the placenta, premature labor or delivery, live birth with congenital anomalies and stillbirths.

Nevertheless, the documentation again states, "There were no safety signals regarding use in pregnant/lactating women that emerged from the review of these cases or the medical literature," despite two key admissions elsewhere in the documentation.

In one instance, the document stated, **"The safety profile of the vaccine in pregnant and/or breastfeeding women was not studied in the pivotal clinical trial and the maternal clinical trial was terminated early due to participant recruitment difficulties."**

And in another instance, Pfizer-BioNTech identified the following as "missing information":

"Use in pregnancy and while breastfeeding; Use in immunocompromised patients; Use in frail patients with co-morbidities … Use in patients with autoimmune or inflammatory disorders; Interaction with other vaccines; Long term safety data."

Pfizer-BioNTech stated a "commitment" to track "pregnancy outcome[s] in clinical trials."

Myocarditis and pericarditis deaths among children, young adults

A notable discrepancy appears in terms of reported cases of myocarditis in the clinical trials as compared to the post-marketing period — one myocarditis case (0.15% of all cases) is listed for the clinical trial period, while 5,422 cases (1.1% of all cases) and 5,458 serious events were reported in the PSUR #3 period.

Of these, 87 cases were fatal and 1,608 were listed as "not resolved." Among children and young adults, 48 cases were reported for those between the ages of 5 and 11 (two deaths), 366 among 12-15-year-olds (three deaths), 345 among 16-17-year-olds and 968 among 18-24-year-olds (four deaths).

In one instance, an 11-year-old girl developed myocarditis two days after her first dose and subsequently died, with the listed causes of death including myocarditis, respiratory failure, acute cardiac failure and cardio-respiratory arrest.

Separately, a 13-year-old boy developed myocarditis five days after his second dose, and subsequently died of myocarditis, cardiac arrest, multiple organ dysfunction syndrome, ventricular tachycardia and renal failure.

A 13-year-old girl with no medical history developed myocarditis six days after her first dose and also later died.

In the case of a 19-year-old male who developed myocarditis three days after his third dose and who eventually died, an autopsy "revealed extensive necrosis of the left ventricular myocardium (myocardial necrosis); myocarditis/fulminant myocarditis."

And a 26-year-old male who also took the flu vaccine developed myocarditis four days after his third dose of the Pfizer-BioNTech COVID-19 vaccine, and subsequently died. The listed causes of death included myocarditis, arrhythmia, inflammation and left ventricular dysfunction. Autopsy results "showed myocarditis."

Similarly, while no cases of pericarditis were recorded during the clinical trial, 4,156 were recorded during the PSUR #3 period, including 4,164 serious adverse events and 19 fatalities. This included 30 cases among 5-11-year-olds, 118 cases among 12-15-year-olds, 106 cases among 16-17-year-olds, 479 cases among 18-24-year-olds (and one death), and 417 cases among 25-29-year-olds, again including one death.

In one example, a 22-year-old male developed pericarditis 31 days after his second dose and eventually died of pericarditis and other causes, including multiple organ dysfunction syndrome, pericardial mass, pericardial effusion, malignant pericardial mesothelioma and right ventricular failure.

Numerous other cardiovascular adverse events were recorded, totaling 32,712 cases during the PSUR #3 period (496 fatal) and 27 during the clinical trials (two fatal — with none of the events listed as "related" to vaccination).

Causes of death included in this category include arrhythmia, cardiac failure and acute cardiac failure, cardiogenic shock, coronary artery disease, postural orthostatic tachycardia syndrome (POTS) and tachycardia.

Nevertheless, “No new significant safety information was identified.”

Many ‘very severe and very rare’ adverse events identified

The 393-page confidential Pfizer document shows that Pfizer observed more than 10,000 categories of diagnosis, many “very severe and very rare,” Horowitz wrote.

These include 73,542 cases of 264 categories of vascular disorders from the shots, many of which “are rare conditions,” hundreds of categories of nervous system disorders, totaling 696,508 cases and 61,518 adverse events from well over 100 categories of eye disorders, “which is unusual for a vaccine injury,” according to Horowitz.

In addition, “there were over 47,000 ear disorders, including almost 16,000 cases of tinnitus,” “roughly 225,000 cases of skin and tissue disorders,” “roughly 190,000 cases of respiratory disorders” and “over 178,000 cases of reproductive or breast disorders, including disorders you wouldn’t expect, such as 506 cases of erectile dysfunction.”

“Over 100,000 blood and lymphatic disorders, for both of which there’s a wealth of literature linking them to the spike protein” were indicated, as well as “almost 127,000 cardiac disorders, running the gamut of about 270 categories of heart damage, including many rare disorders, in addition to myocarditis.”

There were also “3,711 cases of tumors — benign and malignant,” and “there were over 77,000 psychiatric disorders observed.”

“What is so jarring is that there are hundreds of very rare neurological disorders that reflect something so systemically wrong with the shots, a reality that was clearly of no concern to the manufacturers and regulators alike,” Horowitz wrote, referencing 68 listed cases of a rare diagnosis, chronic inflammatory demyelinating polyneuropathy.

In another example, the “Pharma Files” Substack identified 3,092 neoplasms, noting that ”malignant neoplasms means cancer.”

Pfizer-BioNTech usually identified ‘no safety signal’ despite thousands of deaths

Numerous deaths and serious adverse events were recorded for a wide range of other conditions:

- Stroke: 3,091 cases and 3,532 serious adverse events during PSUR #3, including 314 fatalities, and 19 cases during the clinical trial (one death).

The document stated, “Cerebral venous sinus thrombosis … and Cerebrovascular Accident/Stroke were evaluated as signals during the reporting period and were not determined to be risks causally associated with the vaccine

… No additional safety signals … have emerged based on the review of these cases."

- Respiratory: 2,199 cases and 1,873 serious adverse events during PSUR #3, including 363 fatalities, and 33 cases during the clinical trial (four deaths). Serious adverse events included cardio-respiratory arrest, pneumonia, respiratory failure, acute respiratory failure, hypoxia and acute respiratory distress syndrome. Yet, "No safety signals have emerged based on the review of these cases."
- Bell's palsy: 733 cases were reported during PSUR #3, in addition to 1,428 cases of facial paralysis. Six cases were fatal, with all victims over age 60. One additional case of Bell's palsy, in a 75-year-old female from the U.S., was recorded in the clinical trial but was deemed "not related" to her vaccination. Again, "No new significant safety information was identified."
- Neurological: 5,111 cases and 4,973 serious adverse events during PSUR #3, including 67 fatalities, and 15 cases during the clinical trial. Once more, "No safety signals have emerged based on the review of these cases."
- Immune-mediated/autoimmune adverse events: 11,726 cases and 8,445 serious adverse events during PSUR #3, including 133 fatalities, and 19 cases during the clinical trial. Serious adverse events included thrombocytopenia, interstitial lung disease, cerebral hemorrhage, encephalitis, multiple organ dysfunction syndrome, renal failure, pneumonia and pulmonary embolism. Yet, "No new safety signals have emerged."
- Multisystem inflammatory syndrome: 207 cases and 210 serious adverse events during PSUR #3, including 56 deaths, with 35 involving the elderly. In addition, 38 cases were reported in children. Nevertheless, "No new safety signals have emerged based on a review of these cases [or] literature."

Pfizer-BioNTech stated a "commitment" for "closely monitoring multisystem inflammatory syndrome in children and in adults … and reporting of new cases."

- Thromboembolic adverse events: 6,102 cases and 6,724 serious adverse events during PSUR #3, including 265 fatalities, and 17 cases during the clinical trial (one death). Serious adverse events included pulmonary embolism, thrombosis and deep vein thrombosis. Again, "No safety signals have emerged based on the review of these cases."

Elsewhere in the document, the case of a 14-year-old male who died of peripheral swelling after getting the COVID-19 vaccine was mentioned, with no additional details.

In another example, a 67-year-old male "with a history of diabetes and idiopathic thrombocytopenic purpura" suffered chest and gastrointestinal discomfort less than 30 minutes after receiving his third dose of the vaccine. A diagnosis of anaphylaxis was made, while an electrocardiogram showed "signs

of a myocardial infarction." He later sustained cardiac arrest and died 12 days following his vaccination.

Moreover, 204 fatalities (and 24,077 cases) of vaccination failure, 81 deaths from "vaccination stress," 24 deaths (and 1,402 cases) of suspected vaccination failure, two deaths from glomerulonephritis and nephrotic syndrome, two deaths (1,326 cases) from "medication error" and 166 deaths from "other" adverse events — mostly pyrexia — were recorded.

Pfizer-BioNTech and EMA: 'nothing to see here'

Pfizer and BioNTech claimed that the overall efficacy of their COVID-19 vaccine for the PSUR #3 period was 91.3% — and 100% for some populations.

Moreover, only one safety signal was definitively identified: hearing loss, with Pfizer-BioNTech committing to perform a "safety evaluation of tinnitus and hearing loss."

Two other conditions, myocarditis and pericarditis, were determined to be an "important identified risk," while irritability was determined to be an "identified risk (not important)."

"A statement regarding the reporting rates of myocarditis and pericarditis after primary series and booster doses" was added to their vaccine's European product label.

Labeling was changed for Guillain-Barré syndrome, but in Japan. The document stated:

"Although not considered by definition a regulatory action taken for safety reasons because it does not significantly impact the benefit risk balance of use of the product in authorised populations, due to the receipt of spontaneous reports of Guillain-Barre syndrome (GBS) after vaccination with mRNA COVID-19 vaccines including BNT162b2 … Japan has required class changes to include GBS in the important precautions section of the Japan package insert."

Despite the large number of deaths and serious adverse events, Pfizer and BioNTech wrote, "Based on the available safety and efficacy/effectiveness data from the reporting interval for BNT162b2, the overall benefit-risk profile of BNT162b2 remains favorable" and that "no further changes … or additional risk minimization activities are warranted."

The EMA appears to have agreed with this conclusion. In its "assessment report," its Pharmacovigilance Risk Assessment Committee (PRAC) wrote that "The benefit-risk balance for the use of Comirnaty in its authorized indication remains unchanged."

"The PRAC considers that the risk-benefit balance of medicinal products containing tozinameran (Comirnaty) remains unchanged and therefore

recommends the maintenance of the marketing authorisation(s)," the PRAC added.

However, Horowitz argues that the documents "show that Pfizer knew about a sickening level of injury early on," yet continued to distribute its COVID-19 vaccine.

Earlier this month, BioNTech was sued in Germany by a woman alleging injuries from the Pfizer-BioNTech COVID-19 vaccine. The lawsuit demands at least 150,000 euro ($161,500) in damages for bodily harm and unspecified compensation for material damages.