EXTRACTS OF PFIZER DOCUMENTS RELEASED BY FDA

Compiled and Comments by Megan Redshaw - 13.12.2023

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The recent documents disclosed as part of a Freedom of Information Act (FOIA) lawsuit against the U.S. Food and Drug Administration (FDA) show the agency:

… Knew its safety monitoring system was "not sufficient" for assessing the risk of heart conditions associated with Pfizer's COVID-19 vaccine when it licensed the company's "Comirnaty" vaccine…. Documents also reveal numerous manufacturing problems in Pfizer batches released to the public and show the FDA knew about a phenomenon known as vaccine-associated enhanced disease (VAED) in those vaccinated who experience breakthrough COVID-19….

The final documents released from Pfizer's biologic product file reveal the agency knew its safety monitoring program was not sufficient to assess the serious risks of myocarditis and pericarditis associated with Pfizer's COVID-19 vaccine.

The memo states:

"The CBER Sentinel Program is NOT sufficient to assess the serious risks of myocarditis and pericarditis, and subclinical myocarditis associated with COMIRNATY (BNT162b2) in lieu of PMR safety studies under FDAAA [Food and Drug Administration Amendments Act].

"At the time of BLA [Biologics License Application] approval, the data sources in the CBER Sentinel Program are not sufficient to identify the outcomes due to lack of sufficient power to assess the magnitude of risk in patients 12-30 years of age. In addition, CBER Sentinel Program is not sufficient to follow up cases for recovery status and long-term sequelae, or for identification and characterization of subclinical myocarditis cases."

According to an Aug. 23, 2021, BLA Clinical Review Memorandum, there were more cardiac disorders in trial participants who received Pfizer's COVID-19 vaccine compared to the placebo group and more instances of tachycardia in the younger vaccinated age group.

Despite nearly double the number of reported cardiac events in vaccine recipients versus placebo recipients, the FDA concluded the deaths were "unlikely to be related to vaccination."

Vaccines Released Despite Manufacturing Issues

According to the Pfizer Andover Response to Form FDA 483 included in the released documents, numerous manufacturing issues and inadequacies in quality oversight were also identified. Several batches of COVID-19 vaccines were flagged for deviating from product quality standards, yet the affected batches were released to the public in various lots, the numbers of which were redacted.

In November 2021, whistleblower Brook Jackson, who worked as a regional director at testing sites by Pfizer contractor Ventavia, told the British Medical Journal that Pfizer's trial was riddled with issues. Ms. Jackson said the company "falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial."

Ms. Jackson, a trained clinical trial auditor with more than 15 years of experience in clinical research coordination and management, emailed a complaint to the FDA and was fired later that day. She subsequently filed a lawsuit against Ventavia and Pfizer, alleging Pfizer had defrauded the government while developing its COVID-19 vaccine.

FDA Acknowledges Vaccine-Associated Enhanced Disease

In its Pharmacovigilance Plan Review Memorandum, the FDA referenced a condition called "vaccine-associated enhanced disease." According to the journal Vaccine, VAED is the modified presentation of a clinical infection affecting

individuals exposed to the wild-type pathogen after having received a vaccine for the same pathogen.

Even though the FDA said in a news release it was committed to "ensuring full transparency, dialogue and efficiency" regarding COVID-19 vaccines and reiterated its commitment to full transparency when it licensed Pfizer's Comirnaty vaccine, they wanted 75 years to produce an estimated 451,000 documents at a rate of 500 pages per month. It previously estimated it had 329,000 pages of responsive records and wanted 55 years to release them to the public.

Attorney Aaron Siri, who filed the lawsuit on behalf of the group, said the federal government was shielding Pfizer from liability, gave it billions of dollars, and forced Americans to get vaccinated while preventing the safety and efficacy data supporting the licensure of Pfizer's COVID-19 vaccine from being released until the year 2076.

Yet it only took 108 days from when Pfizer started producing records to the agency for the FDA to license its vaccine.

Matthias Chang's Comments below:

ONLY ARSEHOLES WOULD STILL HAVE TRUST IN COVID 19 VACCINES FROM USA ETC, AFTER THE ENTIRE DISCLOSURE OF DOCUMENTS BY FDA AS ORDERED BY THE COURT .

BUT FOR THECOURT ORDER, NONE WOULD BE WISER!!

NOW ITS TIME FOR KARMIC RETRIBUTION FOR THOSE WHO FOLLOWED BLINDLY AND GOT THE SHOT OF THE COVID 19 VACCINES THE GLOBAL MEDICAL ESTABLISHMENT.

THE CRIMINALS ALMOST GOT AWAY WITH THEIR CRIMES, BECAUSE SO MANY KEPT THEIR MOUTH SHIT AND ONLY A FEW GOT THE GUTS TO EXPOSE THE CRIMINALITY OF THE PLAN-DEMIC…….

End of comments.