Pfizer and COVID-19 Vaccines: Very Good Reasons For Concern

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Last year (2021), an organization called Public Health and Medical Professionals for Transparency filed a Freedom of Information (FOIA) lawsuit against the FDA for documents concerning approval of the Pfizer/BioNTech COVID-19 vaccine. In response, the FDA requested that the court agree to a deadline of 2076 to deliver the documents. According to the FDA's response, the agency has in its possession 329,000 pages of documents and proposed that 500 pages per month be provided in response to the request. The proposed time frame seems particularly egregious since the FDA took only 108 days to review Pfizer's documents in order to approve the vaccine under Emergency Use Authorization.[1]

There are good reasons to want to see this information sooner rather than later. A whistleblower told a writer for the *British Medical Journal* that there were serious issues with Pfizer's vaccine trials. Brook Jackson worked for Ventavia Research group, which operated several of the trial sites. According to Jackson, these issues included falsification of data, unblinding patients, employing unqualified people to administer vaccines, and inadequate follow up on serious adverse events related to the phase III trial. Jackson said that she repeatedly notified Ventavia management about these problems and when the company failed to take action, she wrote to the FDA. After Ventavia fired her, Jackson provided the *BMJ* with dozens of internal documents, recordings of conversations, and emails to document her claims.[2]

Jackson is a trained clinical trial auditor with 15 years of experience. When it became clear that Ventavia did not plan to investigate her concerns, she started taking pictures of documents, one of which showed vaccine packaging materials with the trial participants' identification numbers in plain sight. According to Jackson, the unblinding may not have been limited to the site at which she worked. She told the *BMJ* that drug assignment confirmations were placed in participants' charts and that these charts were accessible to blinded staff. It was two months after the trial recruitment began and after almost 1000 participants were enrolled, that staff were finally instructed to remove assignments from participants' charts.

A recording of a meeting in September 2020 between Jackson and two of the trial directors revealed that the company could not determine the types and number of errors they found after reviewing trial paperwork. One of the directors said, "In my mind, it's something new every day. We know that it's significant." For example, Ventavia was not following up with queries concerning vaccine side effects. Staff members were disciplined for changing or falsifying data. And the staff was clearly concerned that the FDA might show up for an inspection. The problems dated back to before Jackson was hired.

According to former Ventavia employee Jill Fisher, there is little reason to be concerned about FDA visits. She reports that FDA auditors usually just look at paperwork. A 2007 Inspector General Report concerning the FDA's oversight of clinical trials reported that the FDA only inspects only 1% of clinical trial sites. Things have not improved - only 50 inspections were conducted during the entire fiscal year 2020.

What did the FDA do in response to Jackson's concerns? Apparently, nothing. She received an email thanking her for voicing her concerns. She also received a phone call from an FDA inspector to discuss her report but was told that no more information could be provided at that time. An FDA advisory committee meeting was held on December 10 2020 to discuss Pfizer's application for emergency use authorization, and there was no mention of the problems reported by Jackson during this meeting. The next day, Pfizer's COVID-19 vaccine was approved under the EUA.

Jackson's complaints have been confirmed by other former Ventavia employees. They also said that after Jackson was fired, nothing was done to remedy the quality control issues that she reported. Additionally, and even more concerning, they reported that full swabs were not taken from 477 trial participants who were suspected of having symptomatic COVID-19. This is significant since symptomatic COVID-19 was the trial's main endpoint. The exclusion of this data may have made the vaccine look considerably more effective than it actually was.

Not surprisingly, Pfizer has hired Ventavia as a research contractor for four other trials – COVID-19 vaccines for children and young adults, pregnant women, a booster dose, and an RSV vaccine trial. Since none of the issues in the first trial were addressed, Pfizer can count on Ventavia to provide fraudulent data to submit to the FDA for future approvals. And it's clear that Pfizer can also count on the FDA to approve its submissions regardless of the quality of the data, or lack thereof.

In view of this information, it's easy to understand why the FDA does not want to provide data concerning its review of the Pfizer vaccine.

Thankfully, Pfizer does not enjoy the same power and influence over the courts that it does over the FDA. In January 2022, a judge ordered the FDA to produce 55,000 pages of documents per month which would result in the release of all documents in a little over eight months. The first group of documents is due by March 1, 2022.[3]

Lawyers representing Pfizer quickly responded, asking the judge to allow Pfizer's employees to help FDA staff to review the documents to ensure that proper redactions are made.[4] FDA officials told the court that they welcomed Pfizer's assistance, and wanted to make sure that they could coordinate "…with Pfizer to obtain the company's views as to which portions of the records are subject to Exemption 4, the Trade Secrets Act…"[5] In other words, the FDA seems more concerned with protecting Pfizer's interests than it is in full transparency and accountability to the American public, many of whom

have been forced to take Pfizer's vaccine against their will. After a January 28 hearing, the judge ruled that he would defer ruling on Pfizer's motion until and unless conflicts arise during the review.[6]

In my opinion, there is only one reason why the FDA and Pfizer are trying to slow down the release of documents to the public concerning the Pfizer BioNTech vaccine: because both know that there was fraud involved in obtaining approval under the EUA. The PREP ACT states the following:

"In general, the liability immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in a Declaration. The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct."[7]

Note: a longer version of this article with additional information is posted on the *Informed on COVID* site. Access to this site, which features only those videos and documents that are fully vetted using Wellness Forum's rules of evidence, can be purchased by calling 614 841 7700.

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[1] Ivan Pentchoukov. FDA Asks Court for 55 Yeats to Fully Release Pfizer COVID-19 Vaccine Data. *Epoch Times* Nov 17 2021

[2] Paul D Thacker. "Revelations of poor practices at a contract research company helping to carry out Pfizer's pivotal covid-19 vaccine trial raise question about data integrity and regulatory oversight." *BMJ* 2021;375:n2635

[3] Mimi Ngyen Ly. Judge Gives FDA Just Over 8 Months to Produce Pfizer's Safety Data. *Epoch Times* Jan 6 2022

[4] https://www.documentcloud.org/documents/21190083-pfizer-moves-to-intervene

[5] https://www.documentcloud.org/documents/21190165-fda-responds-to-pfizers-motion

[6] https://phmpt.org/wp-content/uploads/2022/02/Order-February-7-2022.pdf

[7] https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx#q3