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Why Is the FDA Hiding the Pfizer Vaccine Data?

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STORY AT-A-GLANCE

- Weeks after the FDA gave full approval to the Pfizer-BioNTech vaccine under the name Comirnaty, the only documentation publicly available was found in press releases and journal articles
- A nonprofit group filed a Freedom of Information Act request for the data used to license Comirnaty and subsequently had to file a lawsuit to release the documents the FDA has a statutory obligation to publish within 30 days of approving a drug
- Peter Doshi and Matthew Herder note the review team was likely understaffed and was rushed to finalize the review in three weeks, a process that normally takes 10 months. The review did not address concerns that the trial was unblinded or the high number of side effects from the vaccine
- The package inserts for medical professionals in the Moderna and J&J vaccines are intentionally left blank, sending people to a website where they can download the information

Despite the FDA's claim that it is committed to transparency, especially for COVID-19 emergency use authorizations (EUAs),[1] the agency first requested 55 years to release the data supporting the approval of Comirnaty after a Freedom of Information Act (FOIA) request was filed,[2] and then asked for an extra 20 years to fully comply.[3]

Pfizer has been in the news for over a year as a leading contender in the development

of the genetic therapy injection for COVID-19. Their unwillingness to release data to support the FDA's approval of their product should come as no surprise since the company has a long history of criminal activity.

During the Civil War, Pfizer flourished and expanded under the war's demand for pain killers and antiseptics.[4] Unfortunately, in the century and a half since, Pfizer has been a habitual offender in shady dealings, having been sued in multiple venues over unethical drug testing, illegal marketing practices,[5] bribery in multiple countries,[6] environmental violations — including illegal dumping of PCBs and other toxic waste[7] — labor and worker safety violations and more.[8,9]

Now, in Pfizer's latest debacle with the COVID-19 jabs, the FDA is complicit in the shroud of secrecy around the drug company's genetic therapy clinical trials. The extraordinary length of time requested for the data release is tantamount to hiding.

Nonprofit Group of Medical Professionals Files Lawsuit

December 11, 2020, the FDA[10] issued an emergency use authorization (EUA) for the first COVID-19 genetic therapy injection produced by Pfizer-BioNTech. Days later BMJ editor Peter Doshi, Ph.D., and pharmacology professor Matthew Herder penned an insightful examination of the FDA data analysis that led to the approval.[11]

Doshi is an associate professor of pharmaceutical health services research at the University of Maryland School of Pharmacy and Matthew Herder is the director of the Health Law Institute at the Schulich School of Law and associate professor of pharmacology at Dalhousie University in Canada.[12]

The article raised significant doubts about the speed of the approval process. By August 23, 2021, the FDA[13] had granted full approval to the Pfizer-BioNTech vaccine under the name Comirnaty. Weeks later, the only publicly available data was limited to press releases and journal articles, which investigative journalist Maryanne Demasi, Ph.D., notes, is "subject to conflicts of interest and bias."[14]

This lack of information triggered a group of over 80 medical researchers, public health officers, scientists and journalists to form an alliance with the sole mission of obtaining and disseminating "the data relied upon by the FDA to license COVID-19 vaccines."[15]

The nonprofit group is called the Public Health and Medical Professionals for Transparency (PMHPT). They moved quickly to file a lawsuit September 16, 2021[16] in the United States District Court Northern District of Texas in which they allege the FDA denied the organization's request:

> *"… for expedited processing on the basis that PHMPT did "not demonstrate a compelling need that involves an imminent threat to the life or physical safety of an individual" or "that there exists an urgency to inform the public concerning actual or alleged Federal Government activity." PHMPT brings this action to challenge the FDA's determination and seeks an order compelling the FDA to produce responsive records on an expedited basis."*

Dr. Aaron Kheriaty, director of the medical ethics program at the University of California Irvine,[17] is one of the founding members of PHMPT. He commented on the concerns that led to this lawsuit, saying:[18]

> *"A group of us were concerned about the trial design, the shortened duration of the clinical trial, and the patchwork system that was in place for the post-marketing surveillance of adverse events. The placebo group was basically eliminated because the vaccine was offered to everyone who had the placebo, so they failed to maintain a control group."*

FDA Wants 75 Years to Release Pfizer's Data

The Pfizer COVID jab has come under scrutiny since its EUA approval, including claims the company falsified data and underreported adverse events. After receiving the FOIA, lawyers for the FDA proposed to release the Pfizer documentation over

many decades, ultimately asking a federal judge to give them 75 years to completely process the request.[19]

They argued the agency didn't have the staff to process the 451,000 pages included in the documentation. Aaron Siri is the attorney representing PHMPT. He expressed disbelief that an organization with $6.5 billion in funding could not produce the documentation expediently. He noted:[20]

> *"It is dystopian for the government to give Pfizer billions, mandate Americans to take its product, prohibit Americans from suing for harm, but yet refuse to let Americans see the data underlying its licensure.*
>
> *The FDA has not disputed that it should produce these documents. Rather, it proposes doing so at a rate so slow that the documents will not be fully produced until almost all of the scientists, attorneys, and most of the Americans that received Pfizer's product, will have died of old age."*

Demasi writes[21] that the FDA claims they have only 10 employees currently processing FOIA requests, and the sheer volume of work could not be completed quickly. However, Siri explains that there have been many other instances when the FDA has expedited processing these requests by transferring staff or hiring more.

In fact, it is their statutory obligation to publish this documentation within 30 days of drug approval.[22] In their brief to the court,[23] the DOJ, acting as attorneys for the FDA, conceded that the FDA has produced quick turnarounds for FOIA requests in the past with hundreds of thousands of pages each.

Granted, some key Pfizer documents have been released by the FDA, but as Kheriaty explains, until all the data are released, analyzing it piecemeal may lead to inaccurate conclusions.[24] However, he did clarify that while the number of deaths reported in the Pfizer documentation is in the early stages, it did strike him as being 'high'. Kheriaty notes:[25]

> *"Basically, we just have raw numbers. If you look at that document, they*

> *redacted information about how many Pfizer doses had been shipped out. So, if we don't know how many total doses were given, we cannot establish what percentage of people who got the vaccine may have had those adverse events."*

Many people have openly criticized the FDA's request to delay the release of data,[26] including U.S. Sen. Ted Cruz, R-Texas, former Pfizer scientist Jacob Glanville, Dr. Teck Khong of the Alliance for Democracy and Freedom and U.S. urologist Dr. David Samadi.

Another problem is that, as Kyle Becker points out on Twitter, under FDA rules,[27] when a product is fully authorized, "it would be illegal for Moderna and J&J shots to be offered under EUA."[28]

So, now that this has been made public, how long will it take the FDA to "update" their rules to reflect the current situation — that the EUAs for the other jabs should be dropped, since Pfizer's shot has been "approved"?

Experts Ask: Was FDA Pfizer Shot Review Understaffed?

Doshi and Herder called the EUA of the Pfizer-BioNTech vaccine "arguably the most important decision the Food and Drug Administration has made this year."[29] However, referencing the Unapproved Product Review Memorandum from the FDA,[30] the pair note the agency assigned one clinical and one statistical reviewer while assigning three for chemistry, manufacturing and controls (CMC) and two for pharmacovigilance.[31]

Unlike in other countries, the U.S. is the only place where regulatory agencies review patient-level data from clinical trials. This commonly takes the FDA 10 months to perform. Yet they finalized the review of the Phase III trial data with 44,000 participants in the three weeks from November 28, 2020, to December 11, 2020.

Doshi and Herder questioned why additional reviewers were not used to complete the

task, why the researchers unblinded the trial and how the FDA accounted for the fever and pain-reducing medications participants in the intervention arm of the study took three to four times more often than those in the placebo arm.

In a rebuttal, Dr. Peter Marks, director of the Center for Biologics Evaluation and Research at the FDA, sent a letter to the editor responding to the article, saying it was "inaccurate and mischaracterized the work of FDA career scientific staff involved in the review."[32] He explained that agency staff worked around the clock for months, long before the request was submitted.

He stated the writers failed to understand the individuals listed on the memorandum were leads for the disciplines and not the entire team. In turn, Doshi and Herder responded, noting that Marks did not address their concern that the review of the Phase III trial results work was completed in just three weeks, which is "lightning speed compared to FDA's normal monthslong process."[33]

Marks also did not provide examples of how the patient-level data were critically analyzed and, importantly, did not address the impact of unblinding participants during the trial, given the number of side effects from the vaccine.

Doshi and Herder made an important point when they wrote:[34] "If the goal was speed at all costs, we should just get rid of regulators." The FDA analysis of the Pfizer data appears to have been so superficial as to have been nearly no evaluation at all.

Pfizer Clinical Trial Auditor Reveals Data Integrity Issues

Doshi's and Herder's concerns are supported by reports from Brook Jackson, a former regional director of Ventavia Research Group, a research organization charged with testing Pfizer's COVID jab at several sites in Texas.[35] Paul Thacker, investigative journalist for The British Medical Journal, wrote that Jackson repeatedly "informed her superiors of poor laboratory management, patient safety concerns and data integrity issues."[36]

When her concerns were ignored, she called the FDA and filed a complaint via email. As Thacker wrote, Jackson, a trained clinical auditor with more than 15 years' experience in clinical research and coordination, was fired later the same day after just two weeks on the job. According to her separation letter, management decided she was "not a good fit" for the company.

Jackson provided The BMJ with "dozens of internal company documents, photos, audio recordings and emails" proving her concerns were valid.[37] Consultant cardiologist Dr. Aseem Mulhotra expressed his disbelief and concern that the story has not made international news. He noted:[38]

> *"That Pfizer trial, that pivotal trial… because of that data, millions and millions of people have taken the vaccine. The problem is, as we have been doing for a long time … clinical decisions are being made on incomplete, biased and, in many cases, potentially corrupted data … The reason why it hasn't been tackled is there have not been any effective sanctions that have been put on the pharmaceutical industry."*

Package Inserts Blank, Reportedly to Keep Information Updated

As is demonstrated in this short video, the Moderna COVID-19 genetic therapy injection does not contain the standard package insert. Instead, the page is blank, referencing the reader to find the information they're looking for on a website.[39] The same is happening with the Johnson & Johnson vaccine insert.[40]

Fact-checkers claim the package insert is not complete and intentionally left blank because the authorized insert is available online. However, as you can see from the package insert the pharmacist shows in the video, the inserts are not small notifications to the pharmacists and doctors that the information is online, but instead appear to be a complete package insert folded and sealed — but blank.

Additionally, when you go to the Johnson & Johnson vaccine package insert website, you find the site is not functional in Chrome. When tested in Firefox, Safari and Microsoft Edge, the links are functional. Yet, Chrome had 64.06% of the market in 2021.[41] The Apple-based browser Safari garnered 19.22% and only 4.19% of users have Microsoft Edge; just 3.91% used Firefox — which means a huge portion of people won't see the insert information if they're using Chrome.

Once accessed, the package inserts for Moderna,[42] Johnson & Johnson[43] and Pfizer[44] are all available to download. This means the information cannot be recorded and referenced.[45]

By maintaining the insert online and only available as a download, the companies place another barrier between the user and the data. They can also alter the information with impunity without the public's ability to easily compare previously published information as you might on Archive.is[46] or Archive.org.[47]

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