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Pfizer's Analysis of Vaccine Data Reveal Safety Concerns, Newly Released "Confidential Documents" Show

A document released by the U.S. Food and Drug Administration shows Pfizer's own analysis of adverse events following its COVID vaccine revealed safety concerns yet the FDA refuses to acknowledge them.

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Importat article bt Dr. Madhava Setty. M.D.

In August, Public Health and Medical Professionals for Transparency (PHMPT) submitted a Freedom of Information Act (FOIA) request to the U.S. Food and Drug Administration (FDA) for all of the data within Pfizer's COVID-19 vaccine biological product file — a body of information comprising some 329,000 pages.

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The FDA, arguing its poorly staffed Center for Biologics Evaluation and Research did not have the capacity to quickly redact legally exempt material, such as Pfizer proprietary information and personal private information of trial participants, the agency asked to be allowed to release only 500 pages of this data per month, thus necessitating 55 years for full disclosure.

The agency later requested up to 75 years to complete the task. As of Nov. 17, only a fraction of the data in question had been released.

Here I will discuss one of these released documents, the "Cumulative Analysis of Post-authorization Adverse Event Reports." This document constitutes one part of Pfizer's responsibility for pharmacovigilance with respect to their Biological License Agreement with the FDA.

Pharmacovigilance refers to the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.

Before we examine the quantity, seriousness and nature of the adverse events included in this document it is worthwhile to pause and consider just how significant this report should have been to the public.

Pfizer's vaccine had yet to complete full safety and efficacy testing, yet its product was being rapidly deployed on a healthy population that dwarfed the size of the vaccine's clinical trial.

The FDA and Pfizer were well aware that very real risks, if they existed, could not have been identified from the trials alone. There weren't enough participants, and the participants had not been observed for very long.

Everything may seem okay if you experiment on 20,000 people, but what happens when you experiment on a million people?

The "Cumulative Analysis of Post-authorization Adverse Event Reports" should have been the "everything looks good so far" reassurance the FDA was seeking. Why was it necessary to impel the FDA to make this information public through a court order?

In the discussion section of the document (section 4), Pfizer assures the FDA it "… performs frequent and rigorous signal detection on BNT162b2 cases."

What does "rigorous" signal detection mean? Did Pfizer survey a large number of vaccine recipients for adverse events and investigate them? No, it didn't.

This report is merely a compilation of unsolicited, in other words, passive, reports of adverse events directly brought to Pfizer's attention by recipients, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies and cases of serious adverse events reported from clinical studies regardless of causality assessment.

In the report, Pfizer admitted the "magnitude of underreporting is unknown."

It is well accepted that passive reporting will inescapably lead to underreporting. Nevertheless, according to Pfizer's report:

> "Due to the large numbers of spontaneous adverse event reports received for the product, the MAH (Marketing Authorisation Holder) has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity."

The authors continued:

> "Pfizer also taken a [sic] multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, [sic] and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues."

In other words, the number of adverse events reported overwhelmed Pfizer's expectations, yet the vaccine maker concluded, "The findings of these signal detection analyses are consistent with the known safety profile of the vaccine."

This paradoxical statement will prove to be an important clue as we dissect the data below.

What does the document reveal?

Through Feb. 28, a total of 42,086 recipients (cases) reported 158,893 events, or adverse reactions to the Pfizer vaccine. Approximately 50% of these events were deemed serious.

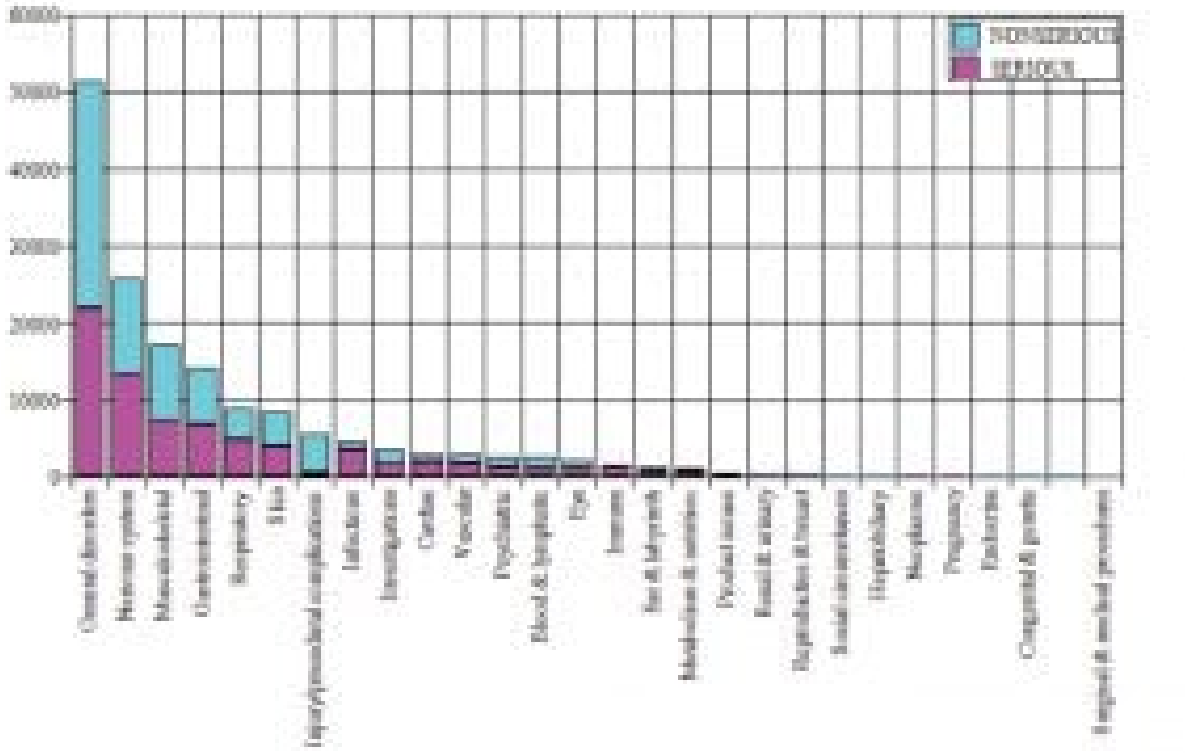

Figure 1: Total Numbers of BNT162b2 AEs by system organ classes and event seriousness

An overview of the characteristics of the recipients is given here:

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17	175[a]
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3898
	≥ 75	5214
	Unknown	6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 48 cases reported age was <18-year-old and in 34 cases <12-year-old.

Of note, 1,223 recipients of the vaccine had a fatal outcome. More than 11,000 had not recovered. The outcome of 9,400 was unknown. Nearly three-quarters were female.

These numbers are concerning, but do they represent a significant safety concern? The answer to that question depends entirely upon the number of people who had been vaccinated up to that point.

Pfizer provided this number to the FDA in the general overview section of the document, section 3.1.1. — but in the document released under the FOIA request, that number was redacted:

> "It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021."

In the above, "(b)(4)" indicates that this number has been redacted.

The cumulative number of doses distributed worldwide as of Feb. 28 is not proprietary information, nor does it constitute personal, private data of individuals.

Yet without this key number there is no way to calculate the incidence of serious events, i.e., a safety signal.

The FDA chose, without explanation or any legal justification, to withhold this crucial piece of data.

Despite the FDA's obvious intention to obfuscate, Pfizer provided a means of estimating this number when it unequivocally concluded: "… these signal detection analyses are consistent with the known safety profile of the vaccine."

What was the known safety profile of the vaccine?

As of Feb. 28, the only known safety profile of the vaccine was determined by the initial results from the phase 3 trials from the autumn of 2020.

Of 21,621 Pfizer vaccine recipients, 126 [Polack FP, Thomas SJ, Kitchin N, et al., NEJM, Table S3] suffered a serious adverse event in the trials. This is roughly one severe adverse event in 171.6 recipients.

Thus, if these data are consistent with its known safety profile, and roughly 79,000 serious adverse events had occurred up to that time, we can estimate that approximately 13,550,000 (79,000 x 171.6) doses had been distributed.

Admittedly there is uncertainty in this calculation. Perhaps a different interpretation of the safety profile was implied.

However, Pfizer reported the number of doses that had been distributed, not administered.

Fewer doses would have been administered than delivered. Moreover, serious adverse events in the trials were distributed across participants who were fully vaccinated (having received two doses).

Here we are using the number of doses as the denominator. This estimation will result in the lower limit of the true incidence of adverse events.

In other words, by using these assumptions we are giving Pfizer's vaccine the maximum benefit of the doubt.

Using this estimate of total doses given, the incidence of a fatal outcome is 1223/13.55 million or 1 in 11,079.

Permanent sequelae (conditions that result as a consequence of vaccination) = 520/13.55 million, or 1 in 26,057. Furthermore, 11,361 out of 13.55 million, or 1 in 1,193, had not yet recovered from an adverse event.

Pfizer inexplicably chose to group recipients who "recovered" with those who were "recovering." How many in this large group (19,582) were still suffering from harm at the time of the report? On what basis did Pfizer determine a recipient still had a chance of full recovery?

With no clarification from the vaccine manufacturer, we are forced to lump them in with another large group of 9,400 whose ultimate outcome was "unknown" — leaving us with a high limit of 1 in 466 recipients having had an undetermined outcome.

Although none of these adverse events and fatalities were shown to be directly or indirectly caused by vaccination, Pfizer offered more data of concern around adverse events of "special Interest" (AESI).

According to Pfizer, 1,403 cardiovascular AESIs, 932 hematologic, 3,600 musculoskeletal, 501 neurologic and 3,674 "other" serious AESIs all occurred with a median time of onset of 24 hours or less from vaccination.

The 275 strokes and 449 cases of facial paralysis reported occurred with a median time of onset of two days from vaccination.

Though it is impossible to establish an unassailable causative link between vaccination and injury at this time, the temporal relationship between them is correlative and highly suggestive of causation.

Nevertheless, the authors of the Pfizer report concluded at the end of each AESI category that "This cumulative case review does not raise new safety issues."

The report also included 24 serious cases in children younger than 12. Of those, 13 cases had not yet been resolved at the time of reporting. The mean age of these recipients was 3.7 years.

We must assume that very few children of that age were inoculated at that time given that Pfizer had authorization for use on adults only. With no number of inoculated children reported, we cannot know what the risk of injury is in children under 12.

Conclusions

Pfizer's repeated assurances that no new safety issues exist are disingenuous at best.

The FDA was overtly obstructive by withholding crucial information required to make an accurate assessment of harm. However, by using reasonable estimations based on Pfizer's own claims and published trial data, it is likely a safety signal does exist — and that safety signal was ignored by the very organization that is supposed to be listening for it, the FDA.

Pfizer's estimated incidence of potential vaccine fatality, 1 in 11,079, is approximately twice

that reported in VAERS. Given that the potential vaccine fatalities in this document have been passively reported, we can assume the actual incidence is higher.

More comprehensive analyses have demonstrated a VAERS underreporting factor of vaccine fatality approaching 41 or greater.

Underreported or not, the real and growing tragedy is that until an injury associated with vaccination is proven to be caused by it, it remains, for all intents and purposes, a non-existent signal to the very institutions responsible for public health and safety.

On what grounds can we as physicians and healthcare providers assure our patients this vaccine is safe if adverse events are not investigated or even acknowledged?

Is a nod from the FDA really good enough?

Or should we demand transparency, discussion or at the very least, unredacted data? What does the public expect of us?

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