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> ***Pfizer hired about 600 additional full-time employees to process adverse event reports during the three months following authorization of its COVID-19 vaccine, with plans to hire 1,800 more by June 2021, newly released documents reveal.***

by **Michael Nevradakis, Ph.D.**, The Defender
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Pfizer hired about 600 additional full-time employees to process adverse event reports during the three months following the Emergency Use Authorization (EUA) of its COVID-19 vaccine, newly released documents reveal.

According to the documents, Pfizer said, "More are joining each month with an expected total of more than 1,800 additional resources by the end of June 2021."

The information was contained in a 10,000-page document cache released April 1 by the U.S. Food and Drug Administration (FDA) and made public as part of a court-ordered disclosure schedule stemming from an expedited Freedom of Information Act (FOIA) request.

The latest revelations appeared in a document, "Cumulative analysis of post-authorization adverse event reports" of the Pfizer-BioNTech vaccine, highlighting such adverse events

identified through Feb. 28, 2021.

The document was previously released in November 2021, but was partially redacted. The redactions included the number of employees Pfizer hired and/or was planning to hire.

According to the unredacted document released April 1:

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

"To date, Pfizer has onboarded approximately 600 additional full-time employees (FTEs).

"More are joining each month with an expected total of more than 1,800 additional resources by the end of June 2021."

The unredacted version also revealed the number of Pfizer-BioNTech vaccine doses shipped worldwide between December 2020 and February 2021:

"It is estimated that approximately 126,212,580 doses of BNT162b2 [the Pfizer EUA vaccine] were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021."

The number of shipped doses previously was redacted.

Remarking upon this newly revealed information, Brain Hooker, chief scientific officer of Children's Health Defense, told The Defender:

"The rollout of the Pfizer vaccine has led to an unprecedented number of adverse events reported — 158,000 adverse events in the first two-plus months of the rollout means that the rate of reported AE [adverse events] was approximately 1:1000, with many of the AEs graded as serious. This is based on a

denominator of 125,000,000 vaccines distributed.

"It is no wonder that an army of 1,800 individuals was needed to process all of the information."

Hooker noted the total number (1,205,755) of COVID vaccine adverse events reported to the Vaccine Adverse Event Reporting System between Dec. 14, 2020 and March 25, 2022, now eclipses the total number (930,952) of adverse events reported in the 32-year history of the database.

Dr. Madhava Setty, a board-certified anesthesiologist and senior science editor for The Defender, previously reported on the same Pfizer document, before the unredacted version was released.

"In that piece, I alluded to Pfizer's admission that they needed more staff to process all of the adverse events being reported to them," Setty said.

"It seems this document has now been updated. 600 FTEs [full-time employees]! … I wonder how many extra people the CDC [U.S. Centers for Disease Control and Protection] has hired? Given how they are operating, I would say zero."

Pfizer downplayed adverse reactions in request for full FDA license

The April 1 document release also included "request for priority review" — the documentation Pfizer in May 2021 submitted to the FDA for full licensure of its Comirnaty COVID vaccine.

In this document, Pfizer described its vaccine as fulfilling an "unmet medical need," claiming:

"Mass immunization with a safe and effective vaccine against COVID-19 can dramatically alter the trajectory of the pandemic.

“According to policy briefing by the Institute for Health Metrics and Evaluation published on 31 March 2021, COVID-19 remains a leading cause of death in the US with up to 100,000 additional deaths projected in the US between March and July 2021, many of which can likely be prevented with COVID-19 vaccination.”

Pfizer expressed “concerns” about lifting COVID-related measures, such as lockdowns, on the basis that the lifting of such restrictions would “counteract the impacts of this vaccination effort.”

The document states:

“Vaccination against COVID-19 began with EUA/conditional approvals in December 2020, in a phased rollout defined by national/regional guidance.

“However, there continue to be concerning trends that may counteract the impacts of this vaccination effort, including:

- “[L]imitations in access to obtaining a vaccine due to infrastructure challenges (ie, clinic and appointment capacity and systems)
- “[I]ncreasing viral transmission fueled by relaxed compliance with mitigations as the pandemic surpasses the 1-year mark (ie, masks, physical distancing, limiting travel)
- “[I]ncreasing circulation of emerging variants of concern (which are currently driving continued spread of viral infection in Europe despite extensive mitigation mandates).”

Pfizer justified its request for full licensure of its COVID vaccine on the following basis:

“A vaccine program must be implemented expediently and rapidly expanded to have a significant impact on the pandemic course.

“Licensure of BNT162b2 is likely to enhance vaccine uptake by facilitating supply of vaccine from Pfizer/BioNTech directly to pharmacies and healthcare providers/facilities.

“The greatest impact of BNT162b2 licensure may be direct supply to healthcare providers who serve vulnerable populations such as elderly patients and those who live in rural and underserved communities (ie, individuals who might be unable to navigate the challenges of securing vaccine access using the systems in place for EUA).

“Expansion of vaccine via licensure would ultimately improve the prospect of achieving population herd immunity to bring the pandemic under control.”

The same document glossed over the adverse effects for which the company previously admitted it hired a significant number of new employees to process, claiming:

“Based on Phase 1 data from the FIH Study BNT162-01, BNT162b1 and BNT162b2 [various vaccines tested during the trial period] were safe and well-tolerated in healthy adults 18 to 55 years of age, with no unanticipated safety findings.

“Phase 2/3 safety data were generally concordant with safety data in Phase 1 of the study, both overall and with regard to younger and older participants.”

This is despite hard figures regarding adverse reactions provided later in the document:

“Through 28 February 2021 (data lock point aligned with Pharmacovigilance Plan), there were a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Cases were received from 63 countries.

“Consistent with what was seen in Phase 2/3 of Study C4591001, most reported AEs were in System Organ Classes (SOCs) with

reactogenicity events: general disorders and administration site conditions (51,335), nervous system disorders (25,957), musculoskeletal and connective tissue disorders (17,283), and gastrointestinal disorders (14,096).

“Post-authorization data have also informed the addition of adverse drug reactions (ADRs) related to the experience of reactogenicity to the product labeling.”

Release of Pfizer vaccine documents still in progress

Many of the documents released as part of the April 1 tranche appear to include more mundane information and data related to the Pfizer COVID vaccine trials.

These documents include:

- Peer-reviewed scientific articles funded by Pfizer-BioNTech, titled “Phase 1/2 Study of COVID-19 RNA Vaccine” (August 2020) and “Safety and Immunogenicity of Two RANA-Based Covid-19 Vaccine Candidates,” published in the New England Journal of Medicine in October 2020.These studies supported “further evaluation of this mRNA vaccine candidate” despite the apparent appearance of serious adverse effects in one of the 12 participants receiving 30 µg and 100 µg doses of the BNT162b1 candidate vaccine during the trial phase. This, however, does not appear to have been the final vaccine formulation that ultimately received an EUA.
- A questionnaire that vaccine trial participants were required to complete, along with a study book displaying the information to be collected from those participating.
- Documents outlining the randomization scheme used for identifying vaccine trial participants and those who received doses of the vaccine or a placebo.
- Documents listing anonymized demographic characteristics of vaccine trial participants.

- An anonymized listing of important protocol deviations.
- Consent forms that vaccine trial participants were asked to complete, as well as other related documents submitted by Pfizer for Institutional Review Board (IRB) approval, and information regarding institutions participating in the IRB process.
- Clinical study approval forms.
- Audit certificates for vaccine trial locations.

The next set of documents – an expected 80,000 pages – is scheduled to be released on or before May 1.

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