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Pfizer Overwhelmed With Vaccine Side-effect Reports

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Pharmaceutical giant Pfizer needed "an army of 1,800" new full-time employees in 2021 to handle the deluge of adverse-event reports that followed public rollout of its Covid-19 vaccine. This, according to an analysis by Brian Hooker, chief scientific officer of Children's Health Defense, after the U.S. Food and Drug Administration (FDA) disclosed information April 1 per an expedited Freedom of Information Act (FOIA) request.

FDA's newly released documents include a report titled "Cumulative analysis of post-authorization adverse event reports … received through 28-Feb-2021." It reads in part:

> Pfizer has also taken a multiple actions 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 fulltime 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 admission means that between the FDA's Emergency Use Authorization on December 11, 2020, and the end of February 2021, Pfizer had to hire some 600 full-time employees just to manage adverse-event complaints. At the time it anticipated adding 1,200 more, in an obvious acknowledgment that the company expected problems to grow over time.

Hooker calls the tallied number of side effects unprecedented. "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 news flies in the face of safety claims Pfizer made when it requested full FDA licensure of its Covid vaccine, Comirnaty. Its May 2021 "Request for Priority Review" maintained that the product was "safe and well-tolerated in healthy adults" as well as "younger and older participants" of clinical trials, "with no unanticipated safety findings."

The newly released documents mark the latest wave of data that a U.S. District Court in January ordered the FDA to release. Claiming limited resources and personnel, the agency had requested 75 years to publish the information it used to authorize the Pfizer Covid vaccine, in response to a FOIA demand from Public Health and Medical Professionals for Transparency. PHMPT founders say they formed their nonprofit "solely to obtain and disseminate that data relied upon by the FDA to license COVID-19 vaccines."

They submitted their FOIA request last August, but had to sue FDA in September for failure to comply. Federal judge Mark Pittman ordered the agency to release the nearly 400,000 pages of documents on a staggered schedule over the next few months. Documents already relinquished list nearly 1,300 different types of adverse events, including cardiac and neurological damage and pregnancy complications. The next set of documents, at least 80,000 pages, is due by May 1. Children's Health Defense says that the remainder of the April 1 cache appears "to include more mundane information and data related to the Pfizer COVID vaccine trials."