FDA Produces the First 91+ pages of Documents from Pfizer's COVID-19 Vaccine File

Only 54 years, 11 months to go...

Aaron Siri
Nov 20 ♡216 82

Two months and one day after it was sued, and close to 3 months since it licensed Pfizer's Covid-19 vaccine, the FDA released the first round of documents it reviewed before licensing this product. The production consisted of 91 pdf pages, one xpt file, and one txt file. You can download them here.

While it is for the scientists to properly analyze, let me share one observation. One of the documents produced is a *Cumulative Analysis of Post-Authorization Adverse Event Reports of [the Vaccine] Received Through 28-Feb-2021*, which is a mere 2 ½ months after the vaccine received emergency use authorization (EUA). This document reflects adverse events following vaccination that have completed Pfizer's "workflow cycle," both in and outside the U.S., up to February 28, 2021.

Pfizer explains, on page 6, that "Due to the large numbers of spontaneous adverse event reports received for the product, [Pfizer] has prioritised the processing of serious cases..." and that Pfizer "has also taken a [sic] multiple actions to help alleviate the large increase of adverse event reports" including "increasing the number of data entry and case processing colleagues" and "has onboarded approximately [REDACTED] additional fulltime employees (FTEs)." Query why it is proprietary to share how many people Pfizer had to hire to track all of the adverse events being reported shortly after launching its product.

As for the volume of reports, in the 2 ½ months following EUA, Pfizer received a total of 42,086 reports containing 158,893 "events." Most of these reports were from the U.S. and disproportionately involved women (29,914 vs. 9,182 provided by men) and those between 31 and 50 years old (13,886 vs 21,325 for all other age groups combined, with another 6,876 whose ages were unknown). Also, 25,957 of the events were classified as "Nervous system disorders."

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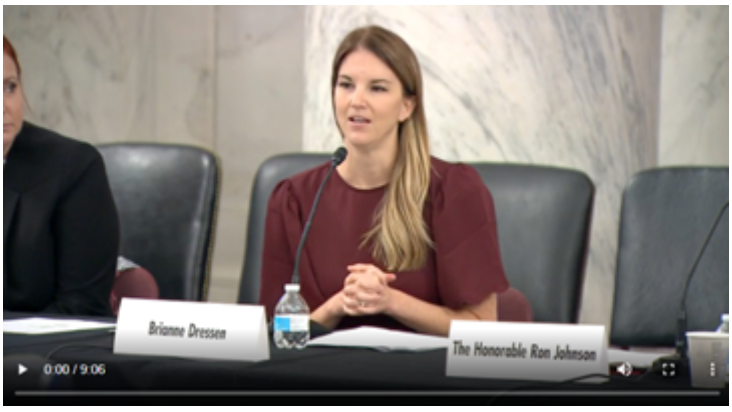
Females between the ages of 30 and 51. Nervous system disorders. That sounds familiar. As a matter of fact, that sounds similar to the concerns raised by some of the women testifying or described in the videos below.

But no cause for alarm since Pfizer explains to the FDA: "The findings of these signal detection analyses are consistent with the known safety profile of the vaccine." So if they *knew* these issues were going to arise, then why didn't they appear to have enough staff to process this expected volume of reports? The grand conclusion by Pfizer to the FDA: "The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine."

Nothing to see here. Just ask all those women.

Brianne Dressen Part 1 and 2 - Describing Group Inured by Various COVID-19 Vaccines



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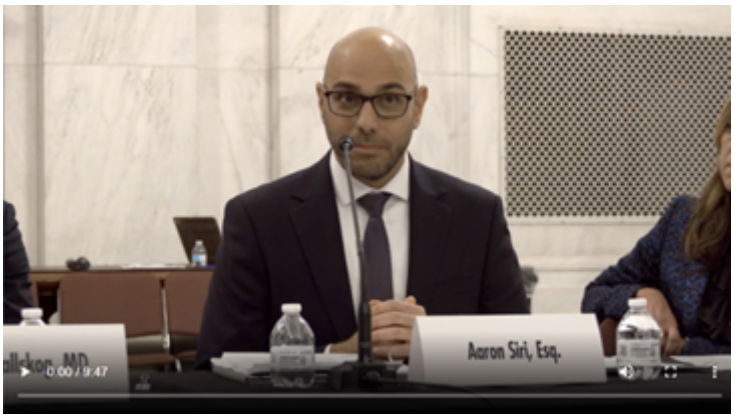

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