FDA Asks Federal Judge for 55 Years to Fully Release Data Supporting Licensure of Pfizer's COVID Vaccine

The U.S. Food and Drug Administration (FDA) asked a federal judge on Nov. 15 to give it fifty-five years to fully release all of the data and information it relied upon in licensing Pfizer and BioNTech's COVID vaccine.

The FDA's request was made in a filing as part of a Freedom of Information Act (FOIA) lawsuit by a medical transparency group made up of doctors and scientists, including Harvey Risch, a professor of epidemiology at the Yale School of Public Health.

The FDA said there were more than 329,000 pages responsive to Plaintiff's FOIA request and proposed releasing 500 pages per month. At that rate, the FDA would not fully release the records until the year 2076.

The Public Health and Medical Professionals for Transparency

(PHMPT) filed a lawsuit after the FDA denied their request to expedite the release of the records. Because PHMPT and the FDA were unable to reach an agreement on the disclosure of records, a judge will decide how the records will be disclosed.

"The FDA's promise of transparency is, to put it mildly, a pile of illusions," Aaron Siri, whose firm is representing PHMPT in the lawsuit, wrote in a blog post on Nov. 17.

"With that promise in mind, in August and immediately following approval of the vaccine, more than 30 academics, professors and scientists from this country's most prestigious universities requested the data and information submitted to the FDA by Pfizer to license its COVID-19 vaccine," Siri wrote.

"The FDA's response? It produced nothing. So, in September, my firm filed a lawsuit against the FDA on behalf of this group to demand this information. To date, almost three months after it licensed Pfizer's vaccine, the FDA still has not released a single page," Siri said.

"It took the FDA precisely 108 days from when Pfizer started producing the records for licensure to when the FDA licensed the Pfizer vaccine," Siri explained. "Taking the FDA at its word, it conducted an intense, robust, thorough and complete review and analysis of those documents in order to assure that the Pfizer vaccine was safe and effective for licensure. While it can conduct that intense review of Pfizer's documents in 108 days, it now asks for over 20,000 days to make these documents available to the public."

Siri said the federal government is shielding Pfizer from liability while giving it billions of dollars and forcing Americans to take its product — yet won't allow the safety and efficacy data supporting the licensure of its product to be

released until the year 2076.

The FDA licensed Pfizer's COVID vaccine under the Comirnaty label on Aug. 23, while leaving the Pfizer/BioNTech vaccine under emergency use authorization, less than four months after Pfizer began submitting documents for full approval of the drug.

A company involved in the clinical trials for Pfizer's COVID vaccine said earlier this month it was investigating alleged problems after a whistleblower told the British Medical Journal Pfizer's trial was riddled with issues, including the falsification of data.

Brook Jackson, a trained clinical trial auditor who previously held a director of operations position and came to Ventavia Research Group with more than 15 years experience in clinical research coordination and management, alerted the FDA and was fired within hours.

Since Jackson reported problems with Ventavia to the FDA, Pfizer has hired Ventavia as a research subcontractor on four other vaccine clinical trials, including a COVID vaccine trial in children and young adults, pregnant women and a booster dose, as well an RSV vaccine trial.