Congress of the United States
Washington, DC 20510

September 22, 2022

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We write concerned about the reports that the U.S. Food and Drug Administration (FDA) is refusing to provide records and analyses from the Vaccine Adverse Event Reporting System (VAERS), which your agency is obligated to disclose under 5 U.S.C. § 552(a)(3).[1]

As you know, VAERS is the early warning database that monitors the safety of vaccines after they are authorized for use by the FDA. Since the COVID-19 vaccine received an Emergency Use Authorization (EUA), VAERS has received over 1.4 million reports of adverse events following the administration of the vaccine. If an adverse reaction to a vaccine is identified through VAERS, scientists at the FDA should perform further tests to determine if the vaccine presents an actual risk to public health.

The database has helped researchers establish that those who receive the COVID-19 vaccine may be at a higher risk for developing the following conditions:

- Anaphylaxis, which is a severe and potentially life-threatening allergic reaction, from the first Pfizer/BioNTech vaccinations[2]
- Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen Biotech COVID-19 vaccination[3]
- Myocarditis (inflammation of heart muscle) or pericarditis (inflammation of the outer lining of the heart) after COVID-19 vaccination[4]
- Guillain-Barré syndrome (GBS) after Johnson & Johnson's Janssen Biotech COVID-19 vaccination[5]
- VAERS has received over 30,700 reports of death among recipients of the COVID-19 vaccine, although no causal link between the vaccine and death has been determined[6]

Additionally, the system has been able to identify populations that may experience a more severe adverse event after receiving the vaccine based on their medical history.

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[1] https://www.theepochtimes.com/exclusive-fda-refuses-to-provide-key-covid-19-vaccine-safety-analyses_4722586.html
[2] https://pubmed.ncbi.nlm.nih.gov/33475702/
[3] https://www.acpjournals.org/doi/10.7326/M21-4502
[4] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
[5] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html
[6] https://www.openvaers.com/covid-data/mortality

Ever since the first COVID-19 vaccine received an EUA, the FDA has been noncompliant in releasing relevant data regarding the safety of the vaccine. In 2021, a group of medical researchers sued the FDA, stating the agency denied a Freedom of Information Act (FOIA) request to expedite the release of Pfizer-BioNTech's COVID-19 vaccine review documents.[7] In response to the lawsuit, the FDA proposed releasing around 500 pages of the review documents each month, which would fulfill the organization's FOIA request in around 55 to 75 years. In January 2022, a federal judge ordered the FDA to release at least 55,000 pages of material every month. However, the FDA is still refusing to release their analyses of VAERS data following a FOIA request for the records.

The information contained within a VAERS report could be lifesaving. It is unacceptable that the FDA would withhold such important material from the public eye. Americans depend on the information provided in VAERS to be able to make conscious decisions about their health and well-being. It is critical that the FDA be transparent and release important sets of data to the public. We look forward to receiving your response within 30 days.

Sincerely,

W. Gregory Steube
Member of Congress

Michael Cloud
Member of Congress

Tom Tiffany
Member of Congress

[7] https://news.bloomberglaw.com/health-law-and-business/why-a-judge-ordered-fda-to-release-covid-19-vaccine-data-pronto