DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

June 9, 2023

Risa Evans
Children's Health Defense
852 Franklin Ave., Suite 511
Franklin Lakes, New Jersey 07417
Via email: risa.evans@childrenshealthdefense.org

Dear Ms. Evans:

This is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of August 23, 2022, assigned #22-02105-FOIA by the agency, and has now been assigned case # 23-cv-00431 by the court. This response relates to the 4th item of your request for:

> Copies of or links to all papers, articles, presentations, or other scientific data that provided the basis for the CDC spokeswoman's Epoch Times statement that Empirical Bayesian data mining is a "more robust data mining technique" than PRR.

There are no records for this item of your request. CDC conducted Proportional Reporting Ratio (PRR) analysis from March 25, 2022, through July 31, 2022. It was used, at that time, to corroborate the results of empirical Bayesian data mining which the CDC and FDA chose to rely on for analyzing disproportionate reporting because it is a more robust data mining technique. Empirical Bayesian data mining is conducted by FDA using VAERS data. The results of the PRR analysis within the time period mentioned above were generally consistent with empirical Bayesian data mining, revealing no additional unexpected safety signals.

To clarify, a proportional reporting ratio (PRR) is a calculation. While PRRs can provide a rough means of examining disproportionate reporting, they are at best a crude measure prone to many false signals. Therefore, to detect disproportionate reporting, CDC and FDA chose to rely on Empirical Bayesian data mining. Given that it is a "gold standard" mining technique, CDC will continue relying upon empirical Bayesian data mining at this time.

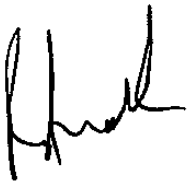
It is important to note that the Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures (SOP) for COVID-19 is a CDC planning document developed with interested internal and external partners, including federal partners. CDC publicly shared the VAERS SOP to make its efforts transparent to healthcare providers, the public, and other stakeholders. The VAERS SOP was designed to be a dynamic resource that is used, revised, and

implemented based on the current science of the COVID-19 pandemic. The following disclaimer appears on page three of the VAERS SOP:

This document is a draft planning document for internal use by the Centers for Disease Control and Prevention, with collaborating contractors. Numerous aspects (including but not limited to specific adverse events to be monitored, timeframes for report processing, data elements to be reported, and data analysis) are dynamic and subject to change without notice.

If you have any questions regarding this response, please contact U.S. Department of Justice attorney Jared Littman at jared.littman@usdoj.gov.

Sincerely,



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