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The Pharmacovigilance Betrayal of the COVID-19 Era

Karl Jablonowski, PhD [1]; Risa Evans, JD [1]; Brian Hooker, PhD [1]

[1] Children's Health Defense

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ABSTRACT

Pharmacovigilance is a necessary safeguard to protect the population from adverse effects of approved pharmaceuticals. The FDA and CDC fell short in their obligation to surveil pharmaceutical harms. Children's Health Defense has revealed through legal action and freedom of information act requests that neither agency conducted the necessary and stipulated acts to monitor for safety of COVID-19 mRNA products, betraying their core obligations and the American people.

Introduction

Two separate incidences of immunization contamination resulted in the deaths of 22 children in Missouri[1] and New Jersey[2] in 1901. These disasters are the basis for the Biologics Control Act of 1902[3] and later the Pure Food and Drugs Act of 1906[4], which gave rise to the Federal Food, Drug, and Cosmetic Act of 1938[5] and the modern-day Food and Drug Administration (FDA) – charged with keeping our food and our drugs safe.

The FDA granted emergency use authorization to Pfizer-BioNTech's COVID-19 vaccine on December 11th, 2020[6] and Moderna's seven days later[7]. The mRNA based vaccines would eventually be approved by the FDA and recommended by the Centers for Disease Control and Prevention (CDC) for everyone six months old and older[8], including during pregnancy[9].

The Need for Pharmacovigilance

A vaccine clinical trial phase 1 and 2 involve up to a few hundred very healthy people, to make sure the vaccine is safe enough for phase 3 involving a few thousand very healthy people - all of it orchestrated by the pharmaceutical company that stands to profit. By the time it is approved by the FDA, if a bad reaction is uncommon we're not going to see it in a few-thousand person study - but, like how not every single cigarette causes cancer, the dangers are still real. We simply do not know what adverse events will look like in a diverse large population until vaccines are administered to a diverse large population. In essence, the clinical trial never ends, it's just that our children become the subjects of the uncontrolled experiment. We had better be watching awfully closely - that is pharmacovigilance.

For the COVID-19 shots, pharmacovigilance through the Vaccine Adverse Events Reporting System (VAERS) is described in the CDC's 2021 VAERS Standard Operating Procedure (SOP) for COVID-19 Vaccines[10]. The VAERS SOP stated that the CDC and the FDA would each use a different data-mining method to look for "safety signals" in VAERS, and would collaborate to investigate any detected signals to determine whether there is a causal relationship between the shots and the adverse event with the signal.

The Need for Transparent Pharmacovigilance

Pharmacovigilance behind-closed-doors should give everyone pause. It is simply too important to not do transparently. Accordingly, Children's Health Defense (CHD), a non-profit dedicated to ending childhood health epidemics, filed a number of Freedom of Information Act (FOIA) requests with U.S. public health agencies for records of their monitoring of the safety of COVID-19 shots. These included requests to the FDA and CDC seeking records of the Agencies' monitoring using the methods described in the VAERS SOP. After neither Agency produced the requested records, CHD sued both agencies, in litigation that is still ongoing[11,12].

Pharmacovigilance Betrayal

When CHD peeked behind closed doors, we did not find vigilance at work. According to the VAERS SOP, the FDA was supposed to conduct regular Empirical Bayesian data mining in VAERS to look for statistical alerts indicating a potential safety signal. In the course of litigation, the FDA produced records[13,14] containing 18 months of data mining data, revealing consistent alerts for serious adverse events (including death) for Janssen vaccine, but almost no safety signals for the Moderna and Pfizer-BioNTech mRNA products - failing to produce a single alert for widely recognized adverse events such as myocarditis, pericarditis or anaphylaxis. Rather, for all of the promises of continued monitoring and "the most intensive safety analysis in U.S. history,"[15] the FDA's VAERS safety monitoring program was broken, finding merely 3 clinically relevant signals for the mRNA platform: a rash, exposure via breast milk, and drug ineffective[16].

Meanwhile, under the VAERS SOP, the CDC was supposed to run a parallel and distinct monitoring program using Proportional Reporting Ratios (PRR). However, in the course of litigation, the CDC admitted that it did not perform this basic promise[17], and instead chose to rely on FDA's empirical Bayesian data mining[18].

The CDC conducted PRR for four months in 2022[19], but according to the CDC, this was merely "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." Notably, in stark contrast to the three clinical safety signals the FDA's data mining showed for the mRNA products, the CDC's mere four months of PRR analysis returned 743 clinical safety signals, including death, stroke, heavy menstrual bleeding, and myocarditis. The extent to which the Agencies have investigated these signals is still unknown.

Conclusion

The failure of the FDA and CDC to monitor COVID-19 vaccine safety in the promised manner is a monumental betrayal, as is the Agencies' lack of full transparency regarding this monitoring. There are 1.6 million VAERS reports for the COVID-19 vaccines. The Agencies promised to study VAERS in a manner that would help determine which of these reported adverse events were caused by the shots, yet—based on the limited information the Agencies have provided to date—it appears that the Agencies have failed to keep that crucial promise.

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