

**“Assessing America’s Vaccine Safety Systems, Part 1”
February 15, 2024**

**Responses to Questions for the Record
Select Subcommittee on the Coronavirus Pandemic
Committee on Oversight and Accountability
U.S. House of Representatives**

Questions from Rep. Debbie Lesko

- 1. How many of the VAERS reports about the COVID vaccine have been fully investigated?**

- 2. How many of the VAERS reports about the COVID vaccine have been confirmed?**

Response: The Vaccine Adverse Event Reporting System (VAERS) is co-managed by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) and serves as the nation’s early warning system to detect possible safety signals for U.S. vaccines. VAERS is not designed to determine if a vaccine caused a reported adverse event or if it was a coincidental event unrelated to vaccination.

CDC and FDA staff continuously assess VAERS data for vaccine adverse event reports. This includes review of individual reports, aggregate analysis of VAERS data, and review of case series data when indicated for possible safety concerns. As VAERS reports are received, CDC and FDA staff monitor for potential vaccine safety concerns or unusual patterns of rare and serious adverse events. If a serious adverse event is reported, VAERS staff from CDC and FDA can request additional information such as medical records, death certificates, or autopsy reports from the healthcare provider of record. If multiple reports indicate similar potential safety concerns, CDC and FDA staff can investigate further by incorporating VAERS data and data from CDC’s and FDA’s other monitoring systems. This analysis helps us determine if the occurrence, or risk of occurrence, is higher than expected when compared to the general population or for previous vaccines.

As of February 2, 2024, CDC has received 1,005,792 domestic VAERS reports for COVID-19, 116,468 of which were for alleged serious adverse events. VAERS staff follow up on every serious adverse event reported into the system. In many instances, CDC was able to obtain follow-up records to complete additional review of the reported event to confirm the event occurred and assess its potential as an adverse event. Review of these cases have informed:

- Messaging for healthcare providers and the public regarding potential safety signals following COVID-19 vaccination;
- Public presentations at meetings for CDC’s Advisory Committee on Immunization Practices (ACIP), the FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC), and the Health Resources and Services Administration’s (HRSA) Advisory Commission on Childhood Vaccines (ACCV); and

- Several peer-reviewed COVID-19 vaccine safety studies published in reputable scientific outlets¹ and in CDC’s Morbidity and Mortality Weekly Report (MMWR).

We continue to evaluate new data as it becomes available while monitoring the safety and effectiveness of the COVID-19 vaccines as the virus continues to evolve. As these data make clear, the benefits of COVID-19 vaccination continue to outweigh any potential risks, and vaccination remains the best available protection against the most severe outcomes of COVID-19, including hospitalization and death.² For this reason, CDC continues to recommend that everyone six months and older receive an updated COVID-19 vaccine.

¹ CDC. COVID-19 Vaccine Safety Articles and Studies by Topic.

www.cdc.gov/vaccinesafety/research/publications/index.html#anchor_1639772389647

² www.cdc.gov/mmwr/volumes/71/wr/mm7114e1.htm; www.cdc.gov/mmwr/volumes/70/wr/mm7035e5.htm

Questions from Rep. Michael Cloud

1. Do you own individual stocks in any of the following companies?
 - a. Pfizer
 - b. Moderna
 - c. BioNTech
 - d. Novavax

Response: No. CDC employees are required to comply with applicable Government-wide conflict of interest laws, rules, and policies, including the Standards of Ethical Conduct for Employees of the Executive Branch.

2. Several of the COVID-19 vaccines have received full FDA approval and are no longer being used under emergency authorization. Is it standard practice for the countermeasures that have received such approval to continue receiving liability protection under the PREP Act and for injury claims regarding these countermeasures to be compensated via the Countermeasures Injury Compensation Program?

Response: CDC defers to HRSA on questions related to the Countermeasures Injury Compensation Program.

3. Have any CDC employees who had any role in formulating or promoting the CDC's guidance regarding the COVID-19 vaccines at any point left the CDC to work at any of the following companies within the last four years?
 - a. Pfizer
 - b. Moderna
 - c. BioNTech
 - d. Novavax

Response: While CDC does not track the employment of former employees, under applicable laws and regulations, a federal employee seeking non-federal employment must immediately recuse themselves from participation in any official matter that involves the prospective employer as an identified party, including grants, contracts, applications, audits, investigations, and lawsuits. The recusal must extend to any matter of general applicability that affects the discrete industry, economic sector, or other defined class of organizations in which the prospective employer operates, such as a legislative initiative, regulatory proposal, or policy determination that affects the prospective employer as a member of such class. *See* 5 CFR Part 2635, Subpart F.

Former employees are subject to a number of restrictions including the following:

- Former employees are subject to a lifetime ban on communicating to or appearing before the Government on behalf of their new employer or anyone else regarding specific party matters in which they participated personally and substantially during their entire government service. *See* 18 U.S.C. 207(a)(1).

- For two years after leaving federal employment, former employees cannot make representational communications to or appearances before the Government regarding specific party matters that were pending under their official responsibility during their last year of government service. *See* 18 U.S.C. 207(a)(2).