United States Senate
WASHINGTON, DC 20510

December 29, 2021

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Rochelle P. Walensky, M.D., MPH
Director
Centers for Disease Control and Prevention
395 E Street SW
Washington, DC 20024

Dear Drs. Woodcock and Walensky:

Due to the unprecedented number of adverse events and deaths associated with the COVID-19 vaccines on the Vaccine Adverse Event Reporting System (VAERS), independent researchers have downloaded VAERS data and begun analyzing the apparent variation in the distribution of adverse events between vaccine lots. If the production of vaccines were under control, with quality systems working properly, one would expect to see relatively even distribution of adverse events and deaths across all lots.

According to these researchers, the variation of adverse events among COVID-19 vaccine lots stands in stark contrast to a much lower degree of variation of adverse events associated with seasonal flu vaccine lots reported over a 30-year period. Furthermore, the total number of adverse events reported in COVID-19 vaccine lots appear to be much higher than the total number of adverse events reported in the context of seasonal flu vaccine lots.

Using VAERS data, these researchers found that for the past 30 years, seasonal flu vaccines have never had more than 137 adverse events reported for a single lot in VAERS. In stark contrast, in less than one year, 5,297 adverse events were associated with a single COVID-19 vaccine lot. In addition, 186 lots of COVID-19 vaccine had over 1,000 reports of adverse events, and an additional 70 lots between 500-999 reports. The researchers' analysis further shows that approximately 80% of U.S.-only adverse events reported to VAERS for COVID-19 vaccines are associated with approximately 1% of vaccine lots reported to VAERS, and approximately 80% of serious adverse events (those involving emergency room visits, hospitalization, or death) are associated with approximately 5% of specific vaccine lots reported to VAERS.

According to the researchers, as of December 3, 2021, the data comparing COVID-19 vaccine lots to seasonal flu vaccine lots spanning 30 years show the following:

	COVID-19 Vaccines	**Seasonal Flu Vaccines**
Total # of lots reported:	24,945	22,334
Highest # Adverse Events in one lot:		
(COVID-19: Moderna lot# 039K20A)	5,297	
(Flu: Novartis lot # 1514501)		137
# of lots with Adverse Events totaling between:		
3,000 to 5,297:	12	0
1,000 to 2,999:	174	0
500 to 999:	70	0
100 to 499:	109	10
50 to 99:	73	150
10 to 49:	695	3,779
5 to 9:	1,136	2,588
1 to 4:	22,676	15,807

Over the last year, public reporting has revealed instances where specific COVID-19 vaccine doses or lots were contaminated or linked to safety concerns. For example, in January 2021, California temporarily paused administering doses from a Moderna COVID-19 vaccine lot following reports of people having severe allergic reactions to the doses from that lot.[1] It is unclear how the California Department of Public Health made the decision to lift the pause and whether individuals from the other states that received doses from this lot experienced similar severe allergic reactions.[2]

Reports also revealed that in March 2021, Johnson & Johnson confirmed that "one vaccine batch was discarded over production issues."[3] In August 2021, Moderna reportedly recalled three lots of its vaccine in Japan after detecting a contaminant in vaccine vials.[4] These examples underscore concerns about potential problems with specific vaccine lots.

In addition, the total number of adverse events and deaths reported to VAERS for the COVID-19 vaccines should have prompted serious investigations and corrective action many

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[1] John Bonifield, *UPDATE: California pauses giving out shots from one lot of coronavirus vaccine*, CNN, Jan. 19, 2021, https://www.cnn.com/2021/01/18/health/ca-vaccine-lot-pause/index.html.

[2] According to reports, 37 states received shipments from this vaccine lot. *Id.*

[3] *Johnson & Johnson Confirms One Vaccine Batch Was Discarded Over Production Issues*, NBC News, Mar. 31, 2021, https://www nbcchicago.com/news/coronavirus/johnson-johnson-confirms-one-vaccine-batch-was-discarded-over-production-issues/2476078/.

[4] Miho Inada, *Moderna Says Covid-19 Vaccine Contaminant in Japan Was Stainless Steel*, Sees No Safety Issue, Wall Street Journal, Sept. 2, 2021, https://www.wsj.com/articles/moderna-says-covid-19-vaccine-contaminant-in-japan-was-stainless-steel-sees-no-safety-issue-11630596275.

months ago. As noted by federal health agencies, the reports on VAERS are "only a small fraction of actual adverse events."[5] Through December 17, 2021, there have been 983,758 total adverse events and 20,622 deaths reported worldwide associated with the COVID-19 vaccines. Of the 20,622 deaths, 6,232 (30%) have occurred on day 0,1, or 2 following vaccination. In contrast, over 30 years of reporting on seasonal flu vaccines, there have been a total of 200,264 adverse events and 2,078 deaths.

The significant differences between adverse event reports in the contexts of COVID-19 and seasonal flu vaccines, both in terms of absolute numbers and vaccine lot variation, should be raising major alarms with the vaccine manufacturers and federal health agencies. However, it remains unclear the extent to which vaccine manufacturers and federal health agencies have reviewed or conducted robust safety investigations based on the COVID-19-associated VAERS data.

Fortunately, VAERS data is publicly available, and these alarming safety signals have not remained totally hidden. Also fortunately, scientists and researchers have revealed, and continue to reveal, potential serious safety signals and are attempting to bring these revelations to the public and to the regulatory agencies. The experienced opinions of these independent researchers, some of whom are veterans of the pharmaceutical industry, is that the extent of variability in product safety between batches is completely outside of any normal boundaries of properly manufactured products of this highly-regulated sector.

The information detailed above raises a number of questions that need to be answered.

1. Is the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) aware of VAERS data showing certain COVID-19 vaccine lots with high numbers of adverse events?
    a. If so, please identify those lots.
    b. If so, what investigations or corrective action have the FDA and CDC undertaken?
    c. If no action has been taken, please explain why.
    d. If not aware, please describe what action(s) you are taking to ensure you identify such events in the future.
    e. In the past, has there ever been such a wide variability in the safety profile of any pharmaceutical product under the oversight of your agency?

2. Please provide a definitive listing of all COVID-19 vaccine lots by manufacturer.

3. Identify the COVID-19 vaccine lots that:
    a. Have been discarded;
    b. Are no longer administered; and
    c. Are under investigation.

[5] *Guide to Interpreting VAERS Data*, Centers for Disease Control and Prevention, Food and Drug Administration, accessed Dec. 22, 2021, https://vaers.hhs.gov/data/dataguide.html.

4. Describe what, if any, actions FDA and CDC took to investigate reports of severe allergic reactions or other adverse events linked to the Moderna vaccine lot that the California Department of Public Health reportedly examined in January 2021 (vaccine lot # 041L20A).[6]

5. How many doses are in each COVID-19 vaccine lot?

6. If vaccine lots contain different numbers of doses, what is the range of doses across all vaccine lots?

7. How many FDA audits have been conducted at each COVID-19 vaccine manufacturing site since the vaccines received Emergency Use Authorization?
    a. Please provide the results and findings of those audits.

8. Were all COVID-19 vaccine manufacturing sites found to be in full FDA and Current Good Manufacturing Practice compliance?
    a. If not, have there been any instances where any amounts of drug substance or drug product have not been locatable at the time of the inspection? If so, how often has this occurred?

9. What specific quality control checks are performed on each vaccine lot?

10. What is the statistical sampling criteria for each quality check?

11. What quality control information is provided to your agency by the COVID-19 vaccine manufacturers?
    a. On a routine basis?
    b. As part of your ongoing quality surveillance requirements?

12. What do the numbers and alpha characters represent in the lot numbering system?
    a. Can the manufacturing location be identified by the lot number? How?
    b. Can the manufacturing date be identified by the lot number? How?
    c. What other manufacturing information is captured in the lot number?

Please provide this information no later than January 12, 2022. Thank you for your attention to this important matter.

Sincerely,

Ron Johnson
United States Senator

[6] John Bonifield, *UPDATE: California pauses giving out shots from one lot of coronavirus vaccine*, CNN, Jan. 19, 2021, https://www.cnn.com/2021/01/18/health/ca-vaccine-lot-pause/index.html.