

United States Senate

WASHINGTON, DC 20510

July 13, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Rockville, MD 20892

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

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

Dear Drs. Collins, Walensky, and Woodcock:

I write to request information regarding your agencies' efforts to monitor and effectively utilize reports of adverse reactions to COVID-19 vaccines. On October 22, 2020, prior to the granting of Emergency Use Authorizations (EUA) for the COVID-19 vaccines, your agencies held and participated in a day-long videoconference.¹ A portion of that meeting detailed the multiple surveillance systems that would monitor the safety and efficacy of any vaccines obtaining an EUA or full Food and Drug Administration (FDA) approval (licensure). I have recently reviewed a 27-page slide deck (attached) from that videoconference and watched relevant presentations from the meeting.²

In general, the vaccine surveillance plan described on October 22 appeared comprehensive, and would have instilled a great deal of confidence in the agencies' commitment to vaccine safety and efficacy to anyone listening to the presentations at that time. Unfortunately, your agencies' lack of response to congressional oversight letters, combined with my discussions with agency officials and individuals who believe they have experienced vaccine injuries, leads me to believe the preauthorization safety surveillance hype does not appear to match the agencies' actual performance.

¹ Center for Biologics Evaluation and Research, Food and Drug Administration, 161st Vaccines and Related Biological Products Advisory Committee Meeting: Open Session, Oct. 22, 2020 (via Web Conference), available at <https://www.youtube.com/watch?v=1XTiL9rUpkg&t=9211s>, transcript available at <https://www.fda.gov/media/143982/download>.

² Steven Anderson, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), available at <https://www.fda.gov/media/143557/download>.

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Although the main subjects of my oversight letters do not deal directly with vaccine safety and efficacy, the almost total lack of transparency in response to legitimate and important information requests from Congress does not instill confidence. When I did specifically raise the alarming safety signals emanating from VAERS (Vaccine Adverse Event Reporting System, established July 1, 1990) with Director Collins in a meeting with other Senate Republicans on April 27, 2021, his dismissive reaction to my concerns was more than troubling.³ By that date, the number of deaths following COVID-19 vaccination reported to VAERS had already reached 3,411, with 1,349 or 39.5 percent of those deaths occurring on Day 0, 1, or 2 following vaccination.⁴ I expected the director of NIH to share my concerns, but he, together with our other federal health agencies, has continued to downplay the significance of what VAERS is signaling.

During the October 22 videoconference, Dr. Tom Shimabukuro stated that VAERS averages 50,000 adverse event reports annually (approximately 1,000 per week).⁵ The Centers for Disease Control and Prevention (CDC) and FDA subsequently informed my staff that as of June 28, 2021, VAERS had received 410,000 submissions detailing adverse events following a COVID-19 vaccination.⁶ Of those submissions, approximately 41,000 reports meet the regulatory definition of “serious adverse event” and are supposedly followed-up upon.⁷ As of July 2, 2021, VAERS reported 5,247 domestic deaths with 1,814 or 34.6 percent of those deaths occurring on Day 0, 1, or 2 following receipt of a COVID-19 vaccine.⁸

With the inclusion of foreign adverse events, VAERS is reporting 9,048 deaths, 26,818 hospitalizations, 56,915 emergency room visits, and 438,441 total reports.⁹ Those adverse

³ Centers for Disease Control and Prevention, Vaccine Adverse Event Reporting System (VAERS), accessed July 13, 2021, available at <https://wonder.cdc.gov/wonder/help/vaers.html>.

⁴ See VAERS Database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 – 4/23/2021, CDC WONDER On-line Database. Accessed the week of 04/25/2021. Query Criteria – Event Category: Death. State/Territory: The United States/Territories/Unknown. Vaccine Product: COVID19 VACCINE (COVID19). Group By: Onset Interval, Age. Show Total: TRUE. Show Zero Values: FALSE.

⁵ Tom Shimabukuro, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), transcript available at <https://www.fda.gov/media/143982/download>, (See page 94).

⁶ Briefing on Vaccine Adverse Events Reporting System (VAERS) from Department of Health and Human Service, Centers for Disease Control and Prevention, Food and Drug Administration, to Senator Ron Johnson staff, June 28, 2021.

⁷ Briefing on Vaccine Adverse Events Reporting System (VAERS) from Department of Health and Human Service, Centers for Disease Control and Prevention, Food and Drug Administration, to Senator Ron Johnson staff, June 28, 2021 (severe adverse events include death, hospitalization, permanent disability, or birth defects).

⁸ See VAERS Database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 07/02/2021, CDC WONDER On-line Database. Accessed at <http://wonder.cdc.gov/vaers.html> on Jul 13, 2021 10:58:53 AM. Query Criteria – Event Category: Death. State/Territory: The United States/Territories/Unknown. Vaccine Product: COVID19 VACCINE (COVID19). Group By: Onset Interval, Age. Show Total: TRUE. Show Zero Values: FALSE.

⁹ See VAERS Database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 07/02/2021, CDC WONDER On-line Database. Accessed at <http://wonder.cdc.gov/vaers.html> on Jul 13, 2021 10:37:41 AM. Query Criteria – Event Category: Death,

events have been recorded over a time span of 29 weeks for an average of 15,000 per week – 15 times the weekly average prior to the COVID-19 vaccines.¹⁰

On June 28, 2021, I held a press event where five women and one 13 year-old child described the neurological symptoms they experienced following vaccination.¹¹ One of the women had participated in the AstraZeneca clinical trials and the 13 year-old participated in the 12-15 year-old Pfizer clinical trial.¹² As a requirement for trial participation, they were both healthy prior to vaccination. Their neurological injuries have been significant. At the time of the event, membership of their Facebook support groups totaled more than 2,000 individuals who suffered from similar post vaccination neurological injuries. Within a few days of the press event, their group size had grown close to 5,000 members.

Although one member of their group has been recently evaluated at the National Institutes of Health (NIH), this type of follow-up appears to be rare. These individuals feel abandoned by the drug companies, federal health agencies, and the medical community. It is also rare that anyone in the medical community will even acknowledge the possibility that their symptoms might be related to the vaccine. This state of denial prevents doctors from acknowledging a possible root cause for their illnesses thereby reducing the probability of finding effective treatments.

In October 2020, prior to any vaccine receiving an EUA, your agencies were expressing and conveying a great deal of confidence in your early warning vaccine safety systems like VAERS. Both CDC and FDA included VAERS as one of the primary passive surveillance tools for monitoring COVID-19 vaccine safety.¹³ CDC highlighted that VAERS covered the entire U.S. population and its ability to “rapidly detect safety signals” and “detect rare adverse events.”¹⁴ Now, nine months and 438,441 reported adverse events later, health care professionals are publicly downplaying the effectiveness and validity of these same systems. For

Hospitalized, Emergency Room Visits. State/Territory: All Locations. Vaccine Product: COVID19 VACCINE (COVID19). Show Total: TRUE. Show Zero Values: FALSE; *See also* VAERS Database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 07/02/2021, CDC WONDER On-line Database. Accessed at <http://wonder.cdc.gov/vaers.html> on Jul 13, 2021 10:40:32 AM. Query Criteria –State/Territory: All Locations. Vaccine Product: COVID19 VACCINE (COVID19). Group by: Symptoms. Show Total: TRUE. Show Zero Values: FALSE.

¹⁰ Ben Gaurno, et al., ‘The weapon that will end the war’: First coronavirus vaccine shots given outside trials in U.S., Washington Post, Dec. 14, 2020, available at <https://www.washingtonpost.com/nation/2020/12/14/first-covid-vaccines-new-york/> (29 weeks: Time from the week the first US patient received a COVID-19 vaccination under EUA through 7/2/2021).

¹¹ Press Conference, Senator Ron Johnson, People Who Want to Be Seen, Heard and Believed by the Medical Community, June 28, 2021, available at <https://rumble.com/vj5xbf-senator-ron-johnson-milwaukee-news-conference.html>.

¹² *Id.*

¹³ *See* Tom Shimabukuro, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), transcript available at <https://www.fda.gov/media/143982/download>, (*See* page 94); and Steven Anderson, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), slides available at <https://www.fda.gov/media/143557/download>.

¹⁴ Tom Shimabukuro, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), transcript available at <https://www.fda.gov/media/143982/download>, (*See* page 94).

example, on May 3, 2021, Dr. Paul Offit, who is member of an FDA advisory committee, stated “So [VAERS is] a noisy system that frankly is more frightening than helpful.”¹⁵ Which is it?

It is precisely these kind of contradictory statements and attitudes that have eroded the public’s confidence in your agencies’ pronouncements and recommendations. Full disclosure, honesty and transparency will be the only way to regain your credibility and restore the public’s confidence in your agencies. For that purpose, I am asking for your agencies to provide full and transparent responses to the following requests based on the October 22, 2020, presentation on COVID-19 vaccine safety monitoring by no later than 5:00 p.m. on July 27, 2021:

Questions for Acting Commissioner Woodcock

1. FDA stated it planned to use the Sentinel System to monitor adverse events following COVID-19 vaccination.¹⁶ Has FDA used the Sentinel System? If yes, please answer the following subquestions; if no, please explain why not.
 - a. What information has FDA gathered in the Sentinel System and how has it been used?
 - b. Has FDA made this information public? If not, why not?
 - c. Please provide all information concerning adverse events gathered from the Sentinel System.

2. FDA stated it planned to use the Biologics Effectiveness and Safety System (BEST System) to monitor adverse events following COVID-19 vaccination.¹⁷ Has FDA used the BEST System? If yes, please answer the following subquestions; if no, please explain why not.
 - a. What information has FDA gathered in the BEST System and how has it been used?
 - b. Has FDA made this information public? If not, why not?
 - c. Please provide all information concerning adverse events gathered from the BEST System.

3. FDA listed an additional 18 data sources of electronic health records and claims records it planned to use to monitor adverse events following COVID-19 vaccination.¹⁸ Has FDA used these 18 data sources? If yes, please answer the following subquestions for each data source used; if no, for each data source not used please explain why not.
 - a. What information has FDA gathered and how has it been used?

¹⁵ Gabrielle Settles, Federal VAERS database is a critical tool for researchers but a breeding ground for misinformation, May 3, 2021, available at <https://www.politifact.com/article/2021/may/03/vaers-governments-vaccine-safety-database-critical/>; Roster of the Vaccines and Related Biological Products Advisory Committee, FDA, accessed July 13, 2021, <https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/roster-vaccines-and-related-biological-products-advisory-committee>.

¹⁶ Steven Anderson, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), transcript available at <https://www.fda.gov/media/143982/download> (See page 116 and 117).

¹⁷ *Id.* (See pages 117 and 118).

¹⁸ Steven Anderson, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), slides available at <https://www.fda.gov/media/143557/download> (See slides 11 and 12).

- b. Has FDA made this information public? If not, why not?
 - c. Please provide all information concerning adverse events gathered.
4. FDA stated “Division of Epidemiology physicians will be reviewing the serious adverse event reports that come into the vaccines.”¹⁹ Have these physicians conducted reviews of serious adverse events following COVID-19 vaccination? If yes, please answer the following subquestions; if no, please explain why not.
 - a. What have the physicians’ reviews found and how have their findings been used?
 - b. Has FDA made this information public? If not, why not?
 - c. Please provide all information concerning adverse events gathered from these reviews.
5. FDA stated it planned to do near real-time surveillance or rapid cycle analysis on adverse events following COVID-19 vaccination.²⁰ Has FDA done this analysis? If yes, please answer the following subquestions; if no, please explain why not.
 - a. What are the results of FDA’s near real-time surveillance or rapid cycle analysis and how has FDA used these results?
 - b. Has FDA made this information public? If not, why not?
 - c. Please provide all information concerning adverse events gathered by this surveillance or analysis.
6. FDA mentioned a list of possible adverse events that FDA would be monitoring following COVID-19 vaccination.²¹ Please provide a complete list of all adverse events that FDA is monitoring relating to COVID-19 vaccines.
7. Has FDA used databases and other sources to monitor adverse events relating to children and adolescents who have received a COVID-19 vaccine? If so, please identify which databases and other sources FDA has used, including what information it identified, in what source, and whether that information was made public. Please provide all information FDA has gathered from these sources.

Questions for Director Walensky

1. CDC stated it planned to use v-safe to monitor for adverse events following COVID-19 vaccination. Has CDC used v-safe?²² If yes, please answer the following subquestions; if no, please explain why not.
 - a. What information has CDC gathered in v-safe and how has it been used?
 - b. Has CDC made this information public? If not, why not?
 - c. Please provide all information concerning adverse events gathered from v-safe.

¹⁹ Steven Anderson, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), transcript available at <https://www.fda.gov/media/143982/download> (See page 123).

²⁰ *Id.* (See page 121).

²¹ *Id.*

²² Tom Shimabukuro, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), transcript available at <https://www.fda.gov/media/143982/download>, (See page 97).

2. CDC stated v-safe would include active telephone follow-ups on clinically important adverse event reports – such as an individual missing work.²³ Has CDC conducted active telephone follow-ups? If yes, please answer the following subquestions; if no, please explain why not.
 - a. How many active telephone follow-ups has CDC conducted?
 - b. What information has CDC gathered from these active telephone follow-ups?
 - c. Please provide all information concerning adverse events gathered from these active telephone follow-ups.

3. CDC stated it planned to “do facilitated VAERS reporting for healthcare workers and long-term care facility residents in CDC’s National Health Care Safety Network.”²⁴ Has CDC facilitated this VAERS reporting? If yes, please answer the following subquestions; if no, please explain why not.
 - a. What information has CDC gathered in the facilitated VAERS reporting and how has it been used?
 - b. Has CDC made this information public? If not, why not?
 - c. Please provide all information concerning adverse events gathered from the facilitated VAERS reporting.

4. CDC stated it planned to use the Vaccine Safety Datalink to monitor for adverse events following COVID-19 vaccination.²⁵ Has CDC used the Vaccine Safety Datalink? If yes, please answer the following subquestions; if no, please explain why not.
 - a. What information has CDC gathered in the Vaccine Safety Datalink and how has it been used?
 - b. Has CDC made this information public? If not, why not?
 - c. Please provide all information concerning adverse events gathered from the Vaccine Safety Datalink.

5. CDC stated it planned use the Clinical Immunization Safety Assessment Project to monitor adverse events following COVID-19 vaccination.²⁶ Has CDC used the Clinical Immunization Safety Assessment Project? If yes, please answer the following subquestions; if no, please explain why not.
 - a. What information has CDC gathered in the Clinical Immunization Safety Assessment Project and how has it been used?
 - b. Has CDC made this information public? If not, why not?
 - c. Please provide all information concerning adverse events gathered from the Clinical Immunization Safety Assessment Project.

²³ *Id.*

²⁴ *Id.* (See page 98).

²⁵ *Id.* (See page 96).

²⁶ *Id.* (See page 97).

Questions for Director Collins

1. Please explain how NIH monitors for adverse events relating to COVID-19 vaccines.
2. Please explain how NIH plans to monitor for special interest adverse events following COVID-19 vaccination during the two-year post vaccination period, including a list of all special interest adverse events it monitors and all data sources NIH uses to monitor those events.
3. I have sent three oversight letters, talked with you over the phone in December, 2020 and in person in April, 2021 regarding what NIH did to explore early treatment using generic repurposed drugs.²⁷ During the December phone call, you indicated NIH has spent hundreds of millions of dollars and researched hundreds of potential existing drugs for treating COVID-19. Unfortunately, even though I have repeatedly asked for you to provide detail and documentation of these efforts, NIH has stonewalled my oversight request and to date I've received no relevant information. Please consider this letter as yet another legitimate request for this important information that should be made public.

I also believe that FDA, CDC, and NIH should as soon as possible convene a public hearing of the Data and Safety Monitoring Board to review overall safety with a focus on serious adverse events including instances of hospitalizations and deaths, which have been reported through VAERS. The hearing should discuss the rate at which Americans are experiencing severe adverse events, such as hospitalization or death, the proximity between occurrence of a severe adverse event and vaccination, and what risk mitigation measures are being put in place to make the vaccination program safer for our country.

Thank you for your attention to this important matter.

Sincerely,



Ron Johnson
U.S. Senator

Enclosure

²⁷ See Letter to Francis Collins, Director, National Institutes of Health, from Ron Johnson, Chairman, Senate Comm. on Homeland Security and Governmental Affairs, and Rand Paul, U.S. Senator, Dec. 10, 2020; Letter to Francis Collins, Director, National Institutes of Health, from Ron Johnson, Chairman, Senate Comm. on Homeland Security and Governmental Affairs, Jan. 22, 2021; and Letter to Francis Collins, Director, National Institutes of Health, from Ron Johnson, U.S. Senator, Mar. 1, 2021.