United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510–6250

January 12, 2024

The Honorable Robert Califf
Commissioner
Food and Drug Administration

Dr. Mandy Cohen
Director
Centers for Disease Control and Prevention

Dear Commissioner Califf and Director Cohen:

For more than two years the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have failed to provide my office with requested records on COVID-19 vaccine lots associated with reports of adverse events. Recent data analyses based on information from the Vaccine Adverse Event Reporting System (VAERS) and records obtained through Freedom of Information Act (FOIA) requests show that certain Pfizer and Moderna COVID-19 vaccine lots have a higher rate of adverse events compared to other COVID-19 vaccine lots.[1] These data analyses are alarming and call into question the validity of the Department of Health and Human Services' (HHS) assertion to my office that "FDA's analysis of counts of serious adverse events reported by COVID-19 vaccine lot number showed no unusual concentration of reports with a single lot or small group of lots."[2]

Since December 29, 2021, FDA and CDC have failed to provide multiple items I have requested including the number of doses in each COVID-19 vaccine lot and lists of COVID-19 vaccine lots associated with high numbers of adverse events reported on VAERS. Despite years of waiting and reiterating my requests multiple times, to date, FDA and CDC have never provided that information to my office.[3] Thankfully, independent researchers have finally obtained and compiled the information your agencies apparently never wanted Congress or the public to see.

Through multiple FOIA requests, the Informed Consent Action Network (ICAN), obtained data showing the number of doses in specific Pfizer and Moderna COVID-19 vaccine lots.[4] Researchers at a private organization called OpenVAERS used this information to determine the rate of certain adverse

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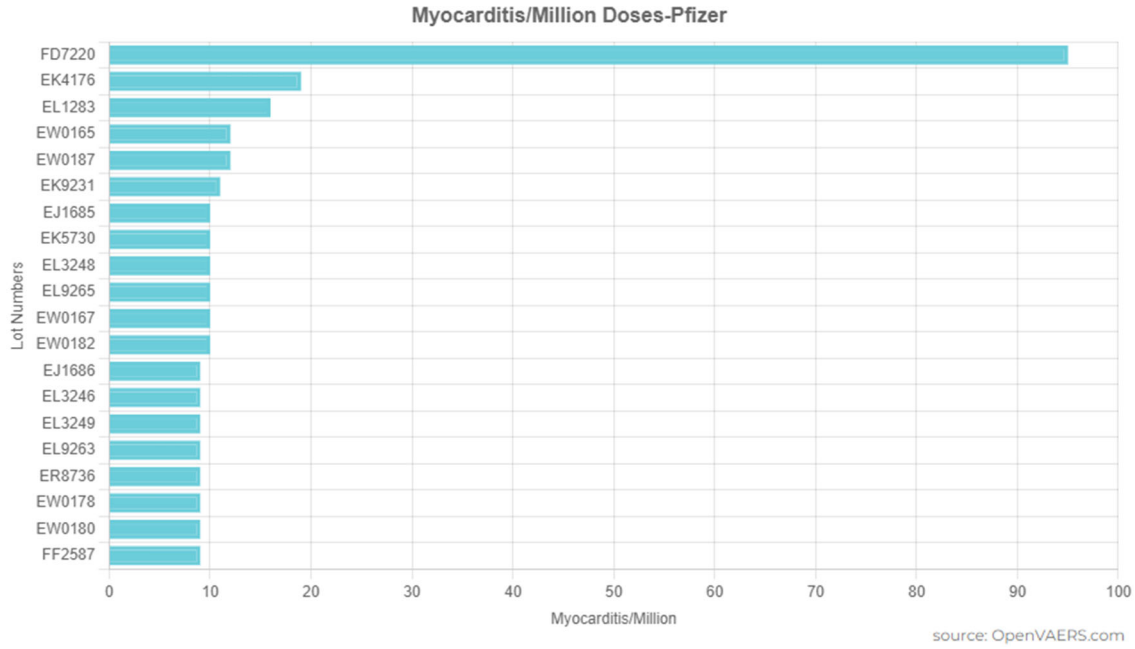
[1] COVID-19 Vaccine Lots, OpenVAERS, https://www.openvaers.com/covid-data/vaccine-lots; Press release, We Added Vaccine Lot Information, OpenVAERS, Dec. 28, 2023, https://www.openvaers.com/faq/we-added-vaccine-lot-information; Press release, Breaking: ICAN Obtains Data Used to Identify "Hot Lots" of Moderna and Pfizer COVID vaccines, Informed Consent Action Network, Jan. 8, 2024, https://icandecide.org/press-release/breaking-ican-obtains-data-used-to-identify-hot-lots-of-moderna-and-pfizer-covid-vaccines/.

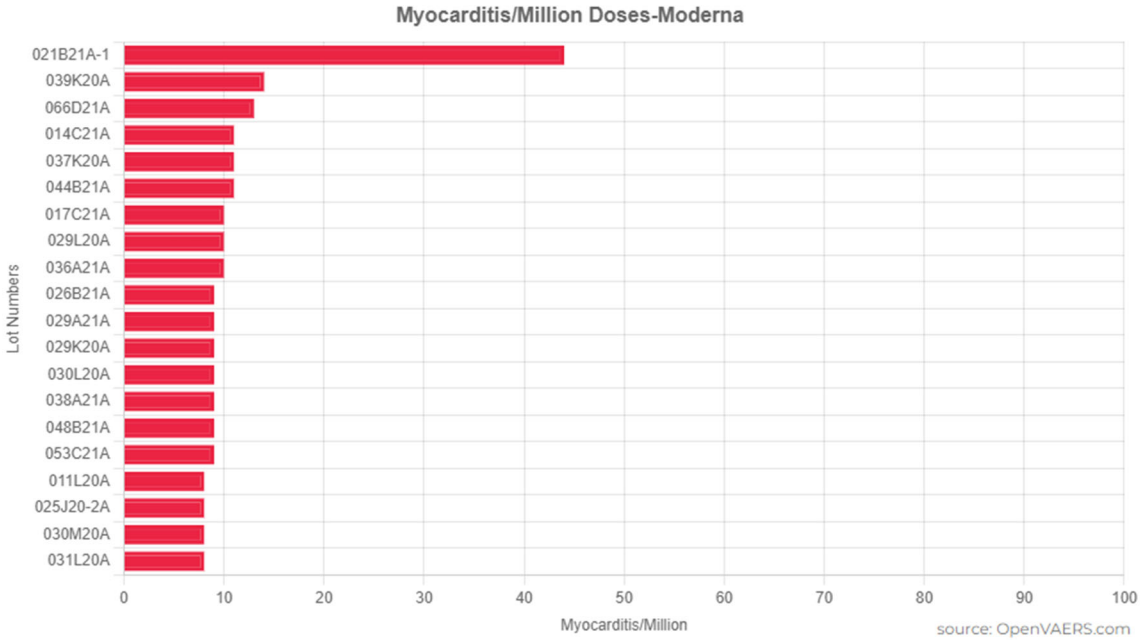
[2] Letter from Melanie Ann Egorin, Assistant Secretary for Legislation, Dep't of Health and Human Services, to Sen. Ron Johnson, Dec. 2, 2022 at 4 (Enclosure B).

[3] Letter from Sen. Ron Johnson, to Janet Woodcock, Acting Commissioner, Food and Drug Admin., and Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Dec. 29, 2021, https://wwwronjohnson.senate.gov/services/files/F564153D-89FD-40C9-A1B1-8663C22D2F0A (Enclosure A); Letter from Sen. Ron Johnson, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Mar. 1, 2022, https://www.ronjohnson.senate.gov/services/files/018E3CF9-DCE9-4F0D-836B-DC4DD9866FF2; Letter from Sen. Ron Johnson, to Xavier Becerra, Secretary, Department of Health and Human Services, et al., Oct. 25, 2023, https://www.ronjohnson.senate.gov/services/files/8989A37B-49B7-4E87-827F-9BE74D00D06A.

[4] Press release, Exclusive: Pfizer Lot and Dose Data Release, Informed Consent Action Network, Dec. 13, 2023, https://icandecide.org/article/pfizer-lot-dose-documents/; Press release, Exclusive: Moderna Lot and Dose Data Release, Informed Consent Action Network, Dec. 13, 2023, https://icandecide.org/article/exclusive-moderna-lot-and-dose-data-release/.

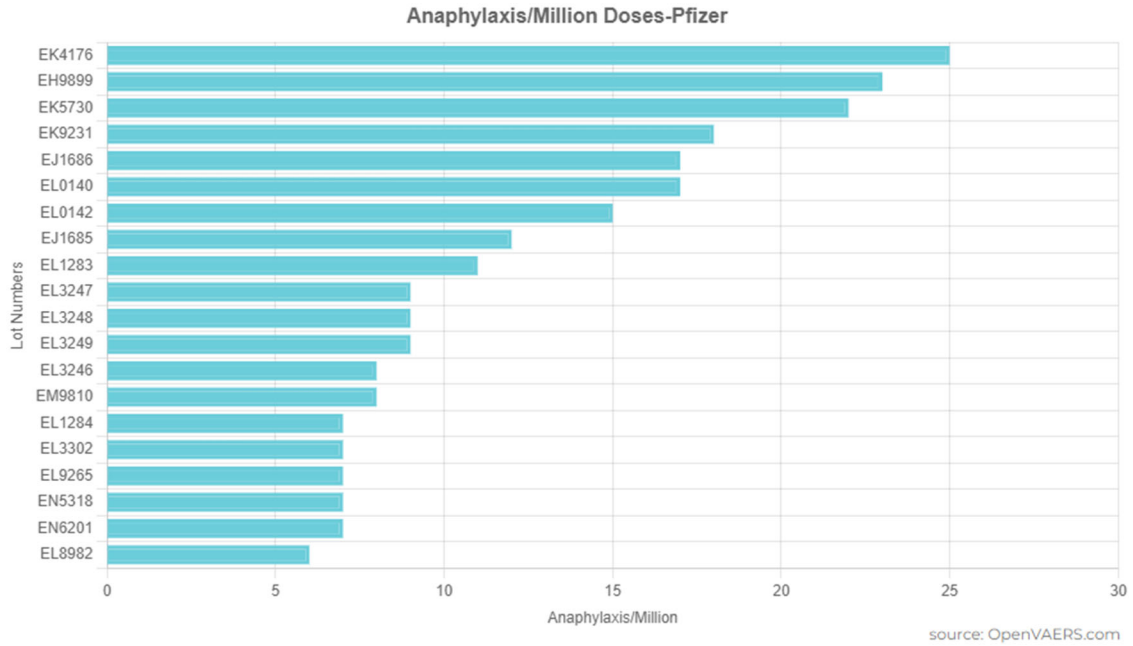
events by lot number based on publicly available VAERS data.[5] Below are a few charts of the data OpenVAERS compiled and made public showing higher rates of certain adverse events in specific vaccine lots per million doses of the Pfizer and Moderna COVID-19 vaccines:[6]

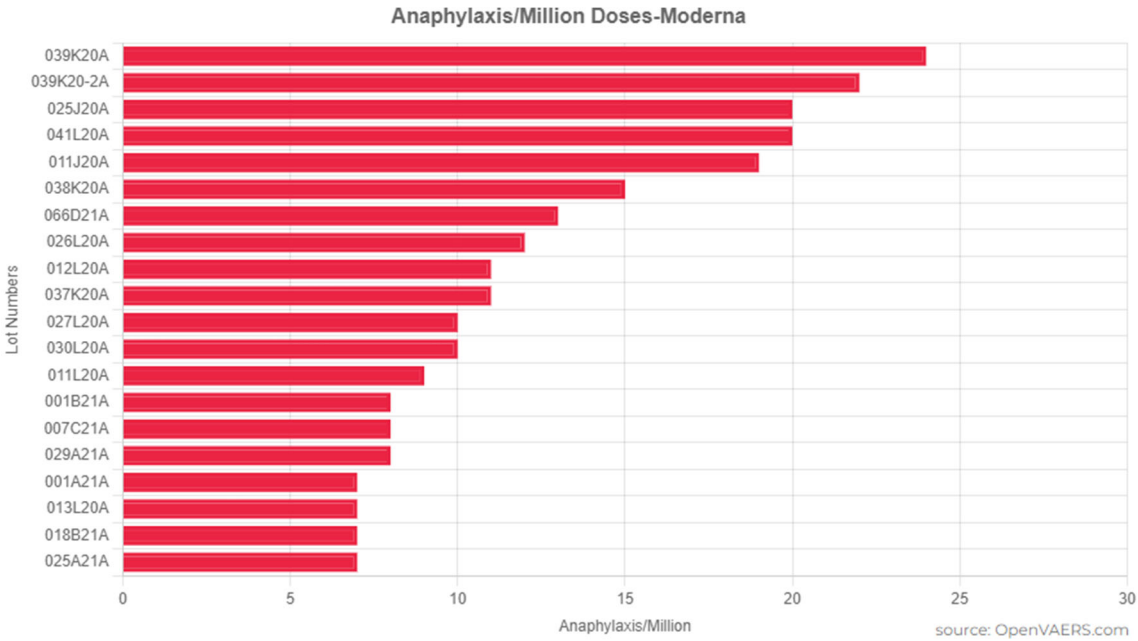


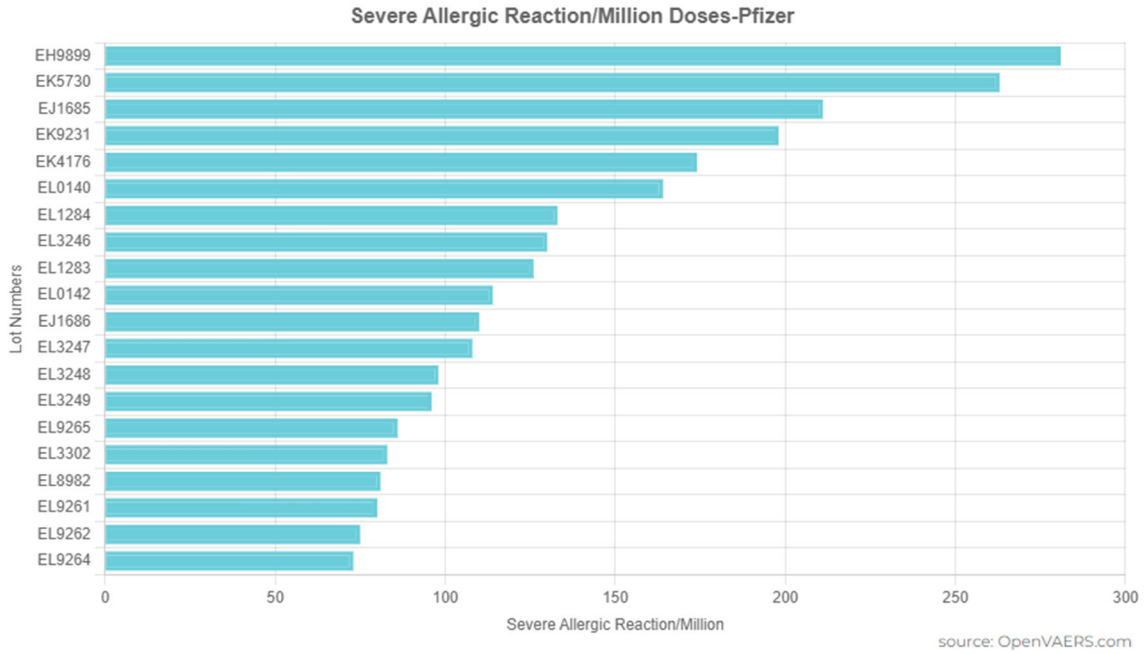


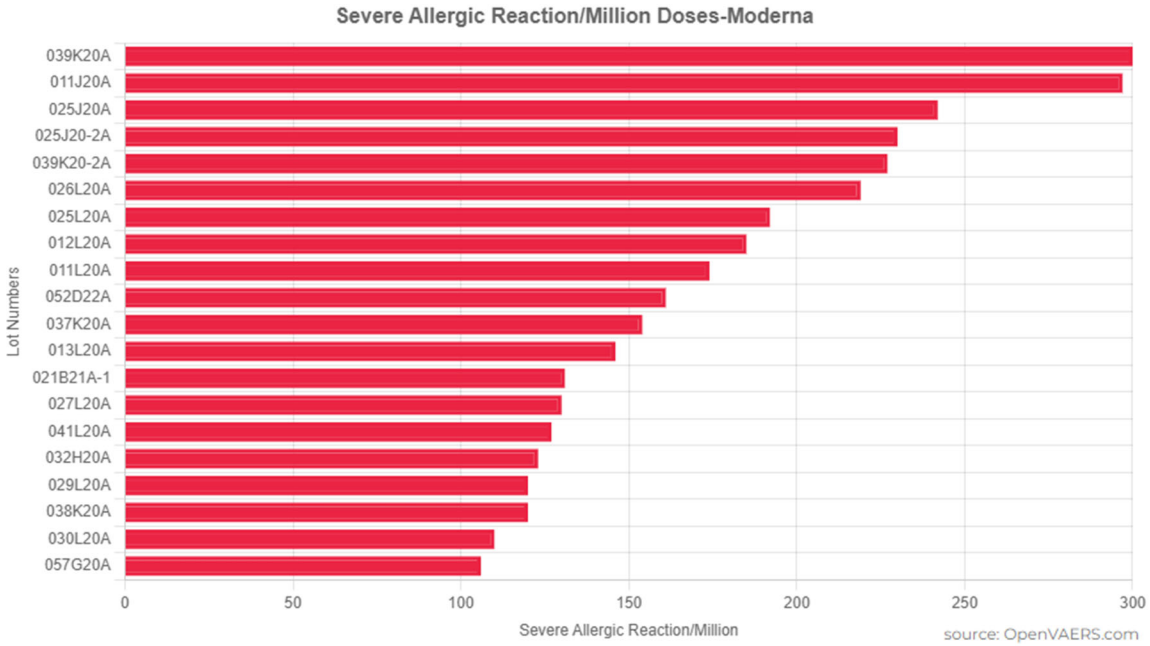
[5] Press release, We Added Vaccine Lot Information, OpenVAERS, Dec. 28, 2023, https://www.openvaers.com/faq/we-added-vaccine-lot-information; Press release, COVID-19 Vaccine Lots, OpenVAERS, Dec. 28, 2023, https://www.openvaers.com/covid-data/vaccine-lots.

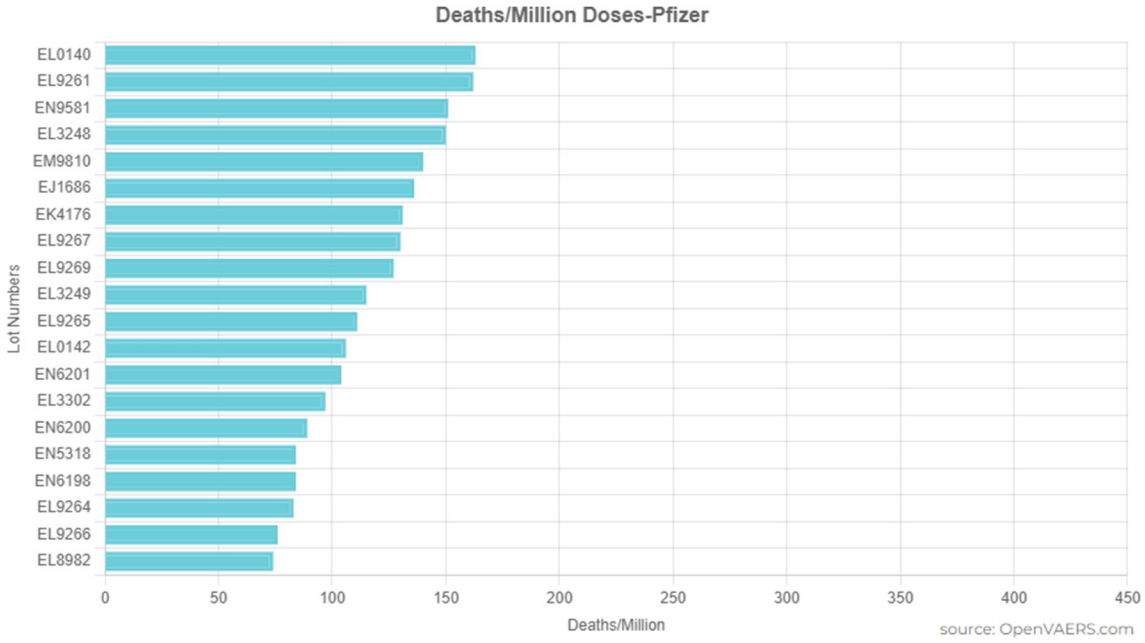
[6] Press release, COVID-19 Vaccine Lots, OpenVAERS, Dec. 28, 2023, https://www.openvaers.com/covid-data/vaccine-lots.

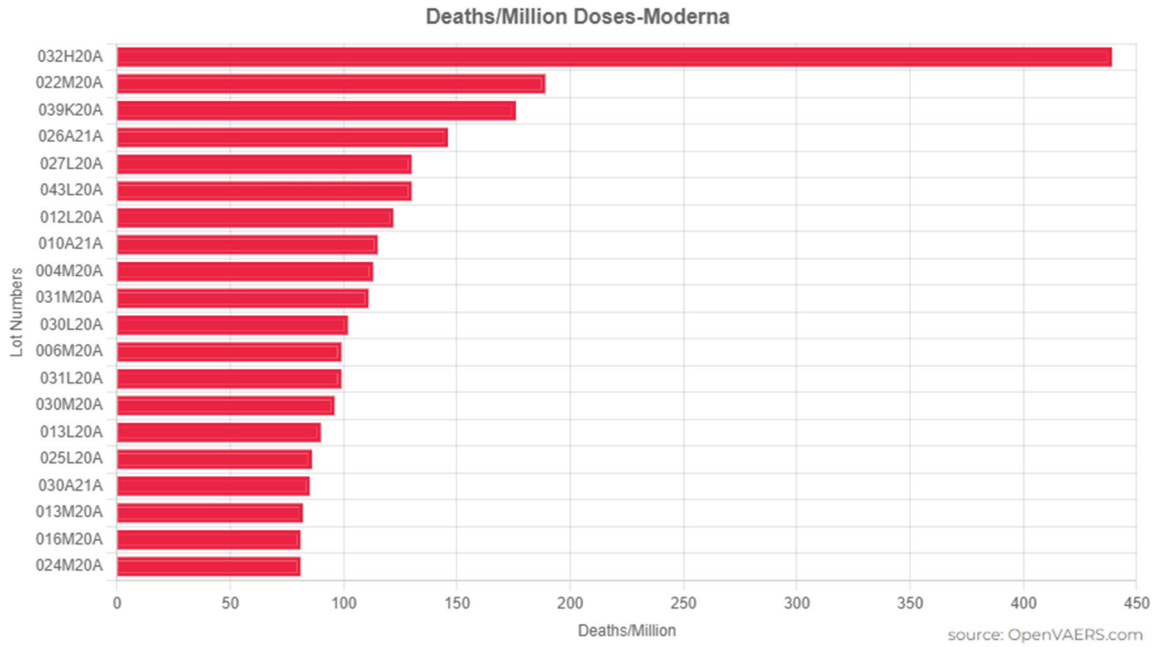

Anaphylaxis/Million Doses-Pfizer
EK4176
EH9899
EK5730
EK9231
EJ1686
EL0140
EL0142
EJ1685
EL1283
EL3247
EL3248
EL3249
EL3246
EM9810
EL1284
EL3302
EL9265
EN5318
EN6201
EL8982
Lot Numbers
0
5
10
15
20
25
30
Anaphylaxis/Million
source: OpenVAERS.com


Anaphylaxis/Million Doses-Moderna
039K20A
039K20-2A
025J20A
041L20A
011J20A
038K20A
066D21A
026L20A
012L20A
037K20A
027L20A
030L20A
011L20A
001B21A
007C21A
029A21A
001A21A
013L20A
018B21A
025A21A
Lot Numbers
0
5
10
15
20
25
30
Anaphylaxis/Million
source: OpenVAERS.com


Severe Allergic Reaction/Million Doses-Pfizer
EH9899
EK5730
EJ1685
EK9231
EK4176
EL0140
EL1284
EL3246
EL1283
EL0142
EJ1686
EL3247
EL3248
EL3249
EL9265
EL3302
EL8982
EL9261
EL9262
EL9264
Lot Numbers
0
50
100
150
200
250
300
Severe Allergic Reaction/Million
source: OpenVAERS.com


Severe Allergic Reaction/Million Doses-Moderna
039K20A
011J20A
025J20A
025J20-2A
039K20-2A
026L20A
025L20A
012L20A
011L20A
052D22A
037K20A
013L20A
021B21A-1
027L20A
041L20A
032H20A
029L20A
038K20A
030L20A
057G20A
Lot Numbers
0
50
100
150
200
250
300
Severe Allergic Reaction/Million
source: OpenVAERS.com





The charts above paint a very concerning picture indicating that certain COVID-19 vaccine lots are, in fact, associated with higher rates of adverse events. As a former manufacturer, this data provides strong evidence that the vaccine manufacturing process was not in control. If these data analyses are accurate, then your agencies have kept this vital information hidden from Congress and the American people for *years*, despite my requests for this data beginning in December 2021. Data produced to ICAN in December 2023 via FOIA should have been provided to my office years earlier pursuant to my December 2021 and subsequent requests.

How many families could have benefited from knowing whether their loved one received a COVID-19 vaccine from a lot associated with a higher rate of a specific adverse event? How many lives

could have been saved if the public had full awareness of the harms caused by the COVID-19 vaccines? Your agencies still refuse to produce all of the Proportional Reporting Ratio data analyses and empirical Bayesian data mining detailed in the January 29, 2021 Standard Operating Procedures that could shed light on other safety signals associated with the COVID-19 vaccines.[7] Rather than being honest and transparent with the American people regarding COVID-19 vaccine adverse events, your agencies have sowed distrust, downplayed vaccine safety concerns, and dismissed vaccine injuries as conspiracy theories.

As I presented to you both in my December 21, 2023 letter, the 25.5 deaths per million doses of the COVID-19 vaccine represents a 55 fold increase over the number of deaths per million doses of the flu vaccine.[8] From the charts above, it appears two Pfizer vaccine lots show approximately 160 deaths per million doses, and one Moderna vaccine lot shows approximately 440 deaths per million doses. That represents a 347 fold increase for the two Pfizer lots and a 956 fold increase for the Moderna lot in deaths per million doses versus a rate of 0.46 deaths per million doses of the flu vaccine assuming 70% of the distributed flu vaccines were administered.[9] These obvious and alarming safety signals cannot be ignored and the pressure will only continue to build for you and your colleagues to finally come clean with the American people about what you know regarding the harms caused by the COVID-19 vaccines.

As I continue to investigate the FDA's and CDC's role in the development of the COVID-19 vaccines I, once again, call on your agencies to provide a complete response to my December 29, 2021 letter and to also provide the following information by no later than January 26, 2024:

1. Please provide the information and analysis FDA used to support the following claim: "FDA's analysis of counts of serious adverse events reported by COVID-19 vaccine lot number showed no unusual concentration of reports with a single lot or small group of lots."[10]

2. Does your agency agree with OpenVAERS's data analyses on COVID-19 vaccine lots associated with higher rates of adverse events? If your agency has not made such a determination, what steps will your agency take to verify OpenVAERS's data analyses?

3. If your agency determines that a certain COVID-19 vaccine lot is associated with a higher rate of an adverse event, what steps will your agency take to notify the public?

In addition, I expect complete responses to my December 21, 2023 letter (with a deadline of January 18, 2024) which include the FDA and CDC providing all Proportional Reporting Ratio data analyses and empirical Bayesian data mining relating to the COVID-19 vaccines.[11]

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[7] Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.
[8] Letter from Sen. Ron Johnson, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Dec. 21, 2023, https://www.ronjohnson.senate.gov/services/files/0D09CBFB-7A6E-426F-813D-F89DFC4E2EFD.
[9] *Id*. As indicated in the December 21, 2023 letter: "Flu deaths based on VAERS data between June 2009 through May 2019. Flu doses calculated at a certain percent of distribution over ten flu seasons prior to COVID-19 (June 2009 to May 2019)."
[10] Letter from Melanie Ann Egorin, Assistant Secretary for Legislation, Dep't of Health and Human Services, to Sen. Ron Johnson, Dec. 2, 2022 at 4 (Enclosure B).
[11] Letter from Sen. Ron Johnson, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Dec. 21, 2023, https://www.ronjohnson.senate.gov/services/files/0D09CBFB-7A6E-426F-813D-F89DFC4E2EFD.

Thank you for your attention to this matter.

Sincerely,

Ron Johnson
Ranking Member
Permanent Subcommittee on Investigations

Enclosure

cc: The Honorable Richard Blumenthal
Chairman
Permanent Subcommittee on Investigations

The Honorable Christi Grimm
Inspector General
Department of Health and Human Services

Enclosure A

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.

Enclosure B

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

December 2, 2022

The Honorable Ron Johnson
United States Senate
Washington, DC 20510

Dear Senator Johnson:

Thank you for your December 29, 2021, and March 23, 2022, letters regarding coronavirus disease 2019 (COVID-19) vaccine adverse events data. I am pleased to respond on behalf of my colleagues.

The Department of Health and Human Services (HHS) shares your interest in COVID-19 vaccine safety, and staff from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are committed to the integrity and credibility of vaccine safety, monitoring, and research efforts. FDA and CDC use a multi-pronged approach to monitor vaccines following approval or authorization, which includes spontaneous reporting (or passive surveillance) and active surveillance using large population-based healthcare datasets, as well as public health surveillance, and vaccine safety research.[1,2] This includes review of claims data from the Centers for Medicare & Medicaid Services (CMS) and medical records from the Department of Veterans Affairs. CDC also provides technical assistance to FDA as requested with outbreak investigation or medical product safety issues. This vaccine safety infrastructure ensures that COVID-19 vaccines are undergoing intensive safety monitoring.

The Vaccine Adverse Event Reporting System (VAERS),[3] managed by CDC and FDA, serves as the nation's early warning system for vaccine safety and timely detection of the need for further safety studies and relevant guidance for healthcare providers and the public.[4] CDC and FDA continue to make improvements to VAERS to increase the speed, accuracy, and ease of reporting. Increased electronic reporting is essential to enabling rapid assimilation of reported adverse events, increasing the efficiency of the system, and rapidly identifying potential signals of adverse events after vaccination. Previously, VAERS reports were filed using paper forms and then submitted to CDC. Following modernization efforts to the system, most reports are now submitted electronically, increasing from 30 percent in 2011 to 98.5 percent in 2021.

VAERS relies on individuals reporting adverse events after vaccination. Anyone can submit reports to VAERS, including patients, family members, healthcare providers, and vaccine

[1] www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html
[2] www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html
[3] https://vaers.hhs.gov/
[4] www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html

manufacturers, regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. Data from VAERS are especially useful for the timely detection of unusual or unexpected patterns of adverse event reporting that might indicate a possible safety concern (or "safety signal") about a vaccine. Some reports of serious illnesses or deaths among people who have been recently vaccinated are not directly due to the vaccine itself. Limitations of VAERS include the lack of a control group (e.g., an unvaccinated control group) and that reports to VAERS may contain inaccurate or incomplete data. For example, VAERS reports can lack laboratory results that help establish (or rule out) a diagnosis. Thus, VAERS is not designed to assess causality. Rather, it is primarily a system for the collection of data, safety signal detection, and hypothesis generation.

If VAERS monitoring identifies a potential safety signal, additional scientifically rigorous active surveillance studies or investigations can be conducted by CDC in the Vaccine Safety Datalink (VSD),[5] FDA through its Biologics Effectiveness and Safety (BEST) Initiative,[6] and through CMS claims data.[7] CDC's VSD uses robust analytics and several large healthcare databases that together represent approximately 12 million persons in the United States, while FDA's BEST Initiative uses similar data and represents approximately 150 million persons in the United States. Both systems are routinely used to study potential vaccine safety concerns, including rare events. CDC uses multiple complementary systems to rapidly detect and assess possible safety signals, including: VAERS, v-safe[8] (which was created and brought online at the beginning of COVID-19 vaccine administration specifically to gather information directly from vaccine recipients about adverse events experienced after COVID-19 vaccination), VSD, and the Clinical Immunization Safety Assessment Project.[9] This coordinated vaccine safety infrastructure ensures that COVID-19 vaccines are undergoing intensive safety monitoring.

Healthcare providers who administer COVID-19 vaccines are required under the provider agreements for the CDC COVID-19 Vaccination Program and by FDA to report the following to VAERS:

- Serious adverse events regardless of whether the reporter thinks the vaccine caused the adverse event. Serious adverse events are defined as:
    - Death;
    - A life-threatening adverse event;
    - Inpatient hospitalization or prolongation of existing hospitalization;
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - A congenital anomaly/birth defect; or
    - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of myocarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine.
- Cases of pericarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine.

[5] www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html
[6] www.bestinitiative.org/
[7] www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/StandardAnalyticalFiles
[8] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html
[9] www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

- Cases of Multisystem Inflammatory Syndrome.
- Cases of COVID-19 that result in hospitalization or death.

Serious adverse events that happen shortly after vaccination are generally captured by VAERS, especially for instances involving medical care, due to reporting requirements. Non-serious (mild) side effects (e.g., pain or swelling at the injection site, headache, chills, or fever) are also commonly reported and resolve quickly; around 90 percent of reports to VAERS after COVID-19 vaccination have been non-serious. Nonetheless, compared to reporting in other systems, these mild side effects that do not come to medical attention are likely underreported in VAERS.

Healthcare providers who administer COVID-19 vaccines are also required to report vaccine administration errors to VAERS, whether they are associated with an adverse event. All providers enrolled in the CDC COVID-19 Vaccination Program, along with the requirements above, are encouraged to report to VAERS any additional clinically significant adverse events following vaccination, even if they are unsure whether the vaccine caused the event. However, because these and other adverse event reports are required to be submitted regardless of whether the person filing the report thinks the vaccine caused the event, many reports do not represent adverse events due to the vaccine. Moreover, for all vaccines approved by FDA, vaccine manufacturers are required to report to FDA all adverse events that are spontaneously reported to the manufacturer, in accordance with FDA regulations.[10]

CDC and FDA physicians continuously screen and analyze VAERS data for possible safety concerns related to COVID-19 vaccines. These analyses include review of individual reports, aggregate analysis of VAERS data, and generation of case series when indicated for possible safety concerns. As part of the review and analysis process, medical records are requested for any serious report. During these reviews, FDA and CDC have found that many reports do not represent adverse events caused by the vaccine. This may be because, among other reasons, the diagnosis is not correct, medical records reveal the symptoms began prior to vaccination, or the patient has underlying medical conditions that explain the adverse event.

As part of the review process, FDA and CDC compare the reporting rate for a particular adverse event in VAERS to the background rate in the general population. While this calculation has limitations, this method was used successfully to identify several safety signals for rare adverse reactions related to specific COVID-19 vaccines, including Guillain-Barré Syndrome, thrombosis with thrombocytopenia syndrome (TTS), and immune thrombocytopenia following use of the Janssen COVID-19 Vaccine, and myocarditis, pericarditis and anaphylaxis following use of the Pfizer-BioNTech and Moderna COVID-19 vaccines. This information is included in the fact sheets for healthcare providers administering vaccine and vaccine recipients and caregivers.[11] We continue to monitor these and other adverse events using our safety surveillance systems.

Reports of death after COVID-19 vaccination are rare. More than 619 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through September

[10] See 21 CFR 600.80.
[11] More information on adverse events reported after COVID-19 vaccination is available at: www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

28, 2022. During this period, preliminary reports of death comprised 0.0027 percent of reports to VAERS among people who received a COVID-19 vaccine. Because of the way that the data are collected, these deaths are not necessarily causally associated with the administration of the vaccine.

It should be noted that early in the COVID-19 vaccine rollout, the vaccines were primarily administered to many nursing home residents and older adults with multiple pre-existing medical problems that put them at higher risk for more serious COVID-19 outcomes and death, as well as non-COVID-19-related serious adverse events and deaths due to underlying medical problems. These underlying medical problems included conditions such as diabetes, chronic lung diseases, hypertension, heart conditions, obesity, and liver disease, which put individuals at a higher risk of dying regardless of vaccination status. FDA and CDC have reviewed available clinical information, including death certificates, autopsy reports, and medical records, and have not established a causal link between COVID-19 vaccines and death, except for death due to TTS associated with the Janssen COVID-19 vaccine.

As of October 2022, continued monitoring has identified nine deaths causally associated with the Janssen COVID-19 vaccine. On May 5, 2022, FDA revised the Emergency Use Authorization (EUA) for the Janssen COVID-19 vaccine to limit the authorized use of the vaccine to people ages 18 years and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to people ages 18 years and older who elect to receive the Janssen COVID-19 vaccine because they would otherwise not receive a COVID-19 vaccine.

FDA's analysis of counts of serious adverse events reported by COVID-19 vaccine lot number showed no unusual concentration of reports with a single lot or small group of lots. The number of reports submitted for a given lot could vary based on important factors such as the lot size and the length of time a lot has been in use. It is also important to point out that the sizes of vaccine lots vary, and some are in distribution much longer than others. As such, a larger lot, or one that is in distribution longer, may be associated with more reported adverse events simply because more people have received vaccines from that lot.

As noted in the Letters of Authorization[12] for COVID-19 vaccines authorized under EUA, the sponsors submit Certificates of Analysis (CoA) for each lot at least 48 hours prior to vaccine distribution. The CoA includes the established specifications and specific results for each quality control test performed on the final drug product lot.

FDA has worked to ensure the quality, safety, and effectiveness of the authorized COVID-19 vaccines by using all available tools, including site visits, previous compliance history, and inspection reports from other regulatory authorities, to assess compliance with current good manufacturing practice requirements. Part of FDA's evaluation of a request for EUA for a COVID-19 vaccine includes evaluation of the chemistry, manufacturing, and controls and facility information for the vaccine. FDA expects manufacturers to submit sufficient data to ensure the quality and consistency of the vaccine product. FDA issued guidance[13] for industry to

[12] See, e.g., www.fda.gov/media/150386/download
[13] www.fda.gov/regulatory-information/search-fda-guidance-documents/manufacturing-supply-chain-and-drug-and-biological-product-inspections-during-covid-19-public-health

provide information regarding common questions related to inspections for facilities manufacturing pharmaceutical products and sites involved in the conduct of clinical, analytical, and nonclinical studies, which will remain in effect only for the duration of the pandemic. COVID-19 vaccines authorized or licensed in the United States must meet all applicable statutory and regulatory requirements. For more information, see FDA's guidance documents, which are available on FDA's website.[14] Publicly available records of certain domestic inspections are available on FDA's website in the Office of Regulatory Affairs Freedom of Information Act Electronic Reading room.[15] Please contact the manufacturers of the COVID-19 vaccines for additional information related to their manufacturing sites.

Regarding the reports from BKK ProVita board member Andreas Schofbeck, HHS does not comment on the effectiveness of surveillance systems in use in other countries or regions. Regarding comments from OneAmerica's Chief Operating Officer, Scott Davison, we recommend reviewing his statements from a virtual meeting with the Indiana Chamber of Commerce and Indiana Hospital association.[16] During the meeting, he said his industry was seeing increased deaths and disability claims related to COVID-19, post-COVID conditions, and other repercussions of the pandemic, such as missed healthcare appointments, but does not mention vaccinations as a cause. He also said the industry is starting to add insurance premium loads on employers based in counties that have low COVID-19 vaccination rates.

In summary, FDA-approved and FDA-authorized COVID-19 vaccines have met FDA's regulatory and scientific standards for safety and effectiveness. Hundreds of millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history. Based on available information for the COVID-19 vaccines that are in use in the United States, the known and potential benefits of these vaccines outweigh their known and potential risks. As part of our efforts to be transparent about our COVID-19 vaccine safety monitoring activities, FDA continues to post summaries of the key safety monitoring findings.

As we obtain more data about the safety and effectiveness of COVID-19 vaccines, we will continue to evaluate the rapidly changing science and keep the public informed.

Thank you again for your interest in this matter. Should you have additional questions, please do not hesitate to reach out to the Office of the Assistant Secretary for Legislation at 202-690-7627.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

[14] www.fda.gov/vaccines-blood-biologics/biologics-guidances/vaccine-and-related-biological-product-guidances
[15] www.fda.gov/about-fda/office-regulatory-affairs/ora-foia-electronic-reading-room
[16] www.youtube.com/watch?v=5AOHrZHG5L0