Unmasked:
How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals

U.S. Senate Permanent Subcommittee on Investigations
Chairman Ron Johnson
Majority Staff Interim Report

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I. Executive Summary

Documents produced by the Department of Health and Human Services ("HHS") to the Permanent Subcommittee on Investigations ("PSI" or "the Subcommittee") show that beginning in early 2021, Dr. Ana Szarfman, who at the time was a senior medical officer and safety data mining developer at the Food and Drug Administration ("FDA"), used an updated data analysis technique that identified dozens of statistically significant safety signals for adverse events associated with the COVID-19 vaccines.[1] She immediately shared her findings with other FDA officials, including officials responsible for COVID-19 vaccine safety surveillance, but they largely ignored her and eventually told her to stop her data analyses.

Specifically, on March 26, 2021, Dr. Szarfman, who worked in the FDA's Center for Drug Evaluation and Research ("CDER"), shared a data mining analysis of COVID-19 vaccine adverse events using a newer methodology that reduced masking.[2] Masking is a known data limitation with FDA's current data mining method that can inhibit the detection of safety signals for adverse events.[3] Dr. Szarfman's analysis—which was done in collaboration with Dr. William DuMouchel, the then-Chief Statistician at Oracle and inventor of the data mining algorithm that supported FDA's current data mining system—found "**49 examples of extreme masking**" with over twenty of those examples of adverse events now showing a statistically significant safety signal when adjusted for masking.[4] In other words, by using a methodology that accounted for the masking limitation, Dr. Szarfman and Dr. DuMouchel uncovered approximately 25 statistically significant safety signals for adverse events associated with the COVID-19 vaccines that were not previously detected by FDA's current methodology, including sudden cardiac death, Bell's palsy, and pulmonary infarction.[5]

Dr. Szarfman shared similar findings with other senior officials at the FDA in this instance and at least three other times in April 2021, May 2021, and July 2021 when her and Dr. DuMouchel's analyses yielded even more statistically significant safety signals with higher

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[1] HHS records also credit Dr. Szarfman as someone who "worked to develop the data mining system" that FDA was using at the time. See PSI-HHS-000008257238; David Wiseman, Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines, ResearchGate, Sept. 2025, https://www.researchgate.net/publication/395382959_Signal_loss_by_truancy_masking_and_filtering_and_underestimation_of_potential_risks_and_suspected_adverse_reactions_in_the_Disproportionality_Signal_Analyses_of_VAERS_data_associated_with_COVID-19_pro at 8-9. Dr. Szarfman retired from the FDA in 2025. The Subcommittee applied Bates stamps to the records cited in the report that were produced by HHS.

[2] PSI-HHS-000008257443-44 (with attachment).

[3] *Id.*; See e.g., David Martin et al., Data Mining for Prospective Early Detection of Safety Signals in the Vaccine Adverse Event Reporting System (VAERS): A Case Study of Febrile Seizures after a 2010–2011 Seasonal Influenza Virus Vaccine, Drug Safety (2013), https://link.springer.com/article/10.1007/s40264-013-0051-9; Rave Harpaz et al., Signaling COVID-19 Vaccine Adverse Events, Drug Safety (2022), https://link.springer.com/article/10.1007/s40264-022-01186-z.

[4] PSI-HHS-000002293255; PSI-HHS-000008263190-91 (emphasis added). Records show that FDA's threshold for determining a statistically significant safety signal was when the lower bound of the reporting estimate (EB05) exceeded 2.0. See PSI's March 25, 2026 document release on EB data mining: https://www.ronjohnson.senate.gov/services/files/F92FBB0A-CCFD-412A-A02D-243AA1844D6E at 166; FOIA production: https://www.fda.gov/media/184988/download?attachment at 23.

[5] PSI-HHS-000008257443-44 (with attachment).

values for adverse events, including acute myocardial infarction associated with the Moderna and Pfizer-BioNTech ("Pfizer") COVID-19 vaccines, non-site specific embolism and thrombosis associated with the Janssen ("Johnson & Johnson") and Pfizer vaccines, dementia associated with the Pfizer vaccine, and **"Death and sudden death" associated with the Moderna and Pfizer vaccines**.[6]

However, rather than warn the public or hold distribution of the vaccines for further investigation, records appear to indicate that Biden health officials ignored the statistically significant safety signals uncovered through the new methodology and were more concerned about Dr. Szarfman's efforts rather than her troubling findings. In April 2021, after Dr. Szarfman emailed a data mining analysis apparently underscoring the limitations of FDA's current system, one senior FDA official wrote to his colleagues, "[b]efore we potentially reach out to Ana, we should meet internally – **many considerations not suited to email…**"[7]

By May 2021, senior officials in the FDA's Center for Biologics Evaluation and Research ("CBER" – the unit responsible for COVID-19 vaccine safety surveillance), including Drs. David Menschik, Narayan Nair, and Craig Zinderman drafted an email to Dr. Szarfman, that Dr. Zinderman eventually transmitted to her, directing Dr. Szarfman to "hold off on creating and sending data mining reports and analyses."[8] Dr. Peter Marks, a staunch supporter of the COVID-19 vaccines who at the time led CBER, eventually warned Dr. Patrizia Cavazzoni, the then-Director of CDER, that Dr. Szarfman's data mining could "create erroneous conflicts that feed in to anti-vaccination rhetoric."[9]

Although senior officials at FDA instructed Dr. Szarfman to "hold off" on generating and distributing her and Dr. DuMouchel's analyses, she continued.[10] Dr. Szarfman tried to convince her colleagues that the data mining method she was sharing was more effective than the method FDA was using. She wrote to FDA officials in early May 2021 that her and Dr. DuMouchel's method "strongly reduces confounding" and that the safety signals in this method are much higher than the signals detected in FDA's method, particularly for acute myocardial infarction.[11]

As highlighted in Chairman Johnson's report on myocarditis and the COVID-19 vaccines, on May 24, 2021, draft notes from a meeting involving federal health officials contained the question, "Is [the Vaccine Adverse Event Reporting System ("VAERS")] signaling for myopericarditis?"[12] The answer stated: "For the age groups 16-17 years and 18-24 years,

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[6] PSI-HHS-000008258306 (with attachment); PSI-HHS-00008258202-03; PSI-HHS-000002208944-45; PSI-HHS-000004592364-65 (with attachment) (emphasis added).
[7] PSI-HHS-000008251979 (emphasis added, ellipsis in original).
[8] PSICOVID_00017246; PSI-HHS-000008251530; PSI-HHS-000008251912-13; PSI-HHS-000001195617-19; PSI_HHS-000008253450-51; PSI-HHS-000001175745-47; PSI-HHS-000001148712-14; PSICOVID_00017246-47.
[9] PSI-HHS-000002213753; PSICOVID_00017246-47. See also, Testimony of Dr. Peter Marks before the Select Subcomm. on the Coronavirus Pandemic Comm. on Oversight and Accountability, U.S. House of Representatives, Feb. 15, 2024, https://oversight.house.gov/wp-content/uploads/2024/02/FDA-SSCP-Vaccine-Safety-and-Surveillance-FDA-Written-Testimony-FINAL-Clean.pdf.
[10] PSICOVID_00017246-47.
[11] PSICOVID_00017245; PSI-HHS-000002208944-45. In a May 6, 2021 email to her FDA colleagues, Dr. Szarfman wrote, "Note that the ER05 signals of RPGS are higher than the EB05 signals of MGPS." *Id.*
[12] Chairman Ron Johnson, Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination, Permanent Subcomm. on Investigations, May 21, 2025,

yes."[13] Despite this unambiguous acknowledgement of the myopericarditis signal, Biden health officials continued to fail to immediately warn the public about the risks of cardiac events associated with the COVID-19 vaccines.[14]

In early June 2021, Dr. Szarfman emailed an FDA colleague about ongoing discussions between the FDA and the Centers for Disease Control and Prevention ("CDC") about COVID-19 vaccines and "myocardial events and the lack of signals in VAERS and other data resources."[15] She enclosed Dr. DuMouchel's data mining analysis from a month earlier showing higher statistically significant safety signals for acute myocardial infarction and noted that she and Dr. DuMouchel "also detected clear signals for other similar events."[16] Dr. Szarfman wrote, "I am not astonished that [FDA's data mining system] was unable to detect these signals."[17]

In July 2021, Dr. Szarfman warned FDA officials that her and Dr. DuMouchel's data mining method detected "an increased mortality signal with the COVID-19 vaccines," reminding her colleagues that she and Dr. DuMouchel use "a method that automatically unmask[s] signals that remain hidden by other data mining methodologies, including by MGPS [FDA's current data mining method abbreviated for Multi-item Gamma Poisson Shrinker]."[18] Again, in September 2021, Dr. Szarfman urged senior FDA officials to utilize her and Dr. DuMouchel's data mining method underscoring that this method is "much better at unmasking signals than MGPS. It automatically identifies and corrects for confounders. This is an important function to have, given the pandemic situation."[19]

Records indicate that FDA did not make any adjustments to its data mining methodology as recommended by Dr. Szarfman. However, Dr. Szarfman continued to advocate for the newer methodology, eventually co-authoring a June 2022 paper with Dr. DuMouchel and others published in the journal *Drug Safety*, which discussed their data mining technique and stated that masking "is roughly eight times more likely to occur with COVID-19 vaccines than with other vaccines."[20] In July 2022, Dr. Szarfman emailed this article to then-FDA Commissioner Dr. Robert Califf noting that her paper describes advances in data mining methodology "especially in the capacity to unmask hidden signals[.]"[21] Upon receipt of this and another article, Dr. Califf

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https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-to-Warn.pdf at 20.

[13] *Id.* It is unclear what data mining system was used to determine that VAERS was signaling for myopericarditis.

[14] *Id.* Chairman Johnson's May 21, 2025 report discussed how Biden health officials failed to issue a formal warning about myocarditis, despite increasing cases in VAERS, through the Health Alert Network which would have notified health care providers about the risk of myocarditis associated with the mRNA COVID-19 vaccines. The FDA did not announce changes to the labels "to include a warning about myocarditis and pericarditis" for the Moderna and Pfizer COVID-19 vaccines until June 25, 2021, months after first becoming aware of reports of increased cases of the adverse events. *Id.* at 3, 6, 27-28.

[15] PSI-HHS-000002208944.

[16] PSI-HHS-000002208944-45.

[17] PSI-HHS-000002208944.

[18] PSI-HHS-000004592364.

[19] PSI-HHS-000008254471.

[20] Rave Harpaz et al., Signaling COVID-19 Vaccine Adverse Events, Drug Safety (2022), https://link.springer.com/article/10.1007/s40264-022-01186-z.

[21] PSI-HHS-000004461747-48.

simply replied, "Thanks. These are good."[22] Documents reviewed to date do not indicate whether Dr. Califf took any action based on his review of Dr. Szarfman's article.

Other FDA officials were not so thrilled with Dr. Szarfman's publication. In August 2022, Dr. Richard Forshee, the then-Deputy Director of CBER's Office of Biostatistics and Pharmacovigilance, wrote to Dr. Marks, "we have just learned that Dr. Szarfman is a co-author on a recently published paper based on COVID-19 vaccines and VAERS. We believe there are a number of issues with the paper and its findings, and we are discussing how to best respond."[23] It remains unclear based on the records received to date whether FDA officials confronted Dr. Szarfman about her paper.

A. The FDA's "Gold Standard" of Data Mining (and its flaws)

i. Background

According to HHS, empirical Bayesian ("EB") data mining is a "statistical method for identifying disproportionality (excess of reported [adverse events] for [a] product relative to other products) in large database[s]."[24] HHS records credit Dr. DuMouchel as the individual who "invented the empirical Bayesian data mining algorithm known as Gamma-Poisson Shrinker (GPS) and its successor MGPS [Multi-item Gamma Poisson Shrinker], which have been applied to the detection of safety signals in databases of spontaneous adverse drug event reports."[25]

In January 2021, one month after the FDA issued emergency use authorizations ("EUA") for the Pfizer and Moderna COVID-19 vaccines, the FDA and CDC published a Standard Operating Procedure ("SOP") document describing how the agencies will perform VAERS surveillance analyses to identify safety concerns for the COVID-19 vaccines.[26] One of the analyses the FDA and CDC utilized was EB data mining, using the Multi-item Gamma Poisson Shrinker ("MGPS") algorithm invented by Dr. DuMouchel. FDA oversaw the data mining which was conducted through software developed by Dr. DuMouchel at Oracle called Empirica

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[22] *Id.*

[23] PSI-HHS-000004594929.

[24] Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://web.archive.org/web/20210319091240/https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at 16-17. See also PSI's March 25, 2026 document release on EB data mining: https://www.ronjohnson.senate.gov/services/files/F92FBB0A-CCFD-412A-A02D-243AA1844D6E at 160; FOIA production: https://www.fda.gov/media/184988/download?attachment at 22.

[25] PSI-HHS-000002293255. See also, William DuMouchel, Bayesian Data Mining in Large Frequency Tables, with an Application to the FDA Spontaneous Reporting System, The American Statistician (1999), available at https://www.jstor.org/stable/2686093?seq=1.

[26] The FDA issued the EUA for the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020. Moderna received the EUA for its vaccine on December 18, 2020. COVID-19 Timeline, Centers for Disease Control and Prevention, https://www.cdc.gov/museum/timeline/covid19.html; Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://web.archive.org/web/20210319091240/https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.

Signal ("Empirica").[27] Dr. Szarfman is also credited for developing and helping FDA adopt the data mining system.[28] Records show that FDA's threshold for determining a statistically significant safety signal was when the lower bound of the reporting estimate (EB05) exceeded 2.0.[29]

ii. Federal Health Officials' Reliance on EB Data Mining

Federal health officials publicly touted the strength of EB data mining as "a more robust technique" for analyzing VAERS reports.[30] Internal emails between HHS officials also showed a preference for EB data mining over other types of data analyses. In June 2022, Dr. Tom

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[27] Letter from Jeff Reezek, Centers for Disease Control and Prevention to Sen. Ron Johnson, Permanent Subcomm. on Investigations, Mar. 14, 2023 (on file with Subcomm.); PSI's March 25, 2026 document release on EB data mining: https://www.ronjohnson.senate.gov/services/files/F92FBB0A-CCFD-412A-A02D-243AA1844D6E at 161; FOIA production: https://www.fda.gov/media/184988/download?attachment at 23; David Wiseman, Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines, ResearchGate, Sept. 2025, https://www.researchgate.net/publication/395382959_Signal_loss_by_truancy_masking_and_filtering_and_underestimation_of_potential_risks_and_suspected_adverse_reactions_in_the_Disproportionality_Signal_Analyses_of_VAERS_data_associated_with_COVID-19_pro at 8-9.

[28] Robert O'Neill and Ana Szarfman, Some US Food and Drug Administration perspectives on data mining for pediatric safety Assessment, Current Therapeutic Research (2001), https://www.sciencedirect.com/science/article/abs/pii/S0011393X01800710; Ana Szarfman et al., Use of screening algorithms and computer systems to efficiently signal higher-than-expected combinations of drugs and events in the US FDA's spontaneous reports database, Drug Safety (2002), https://link.springer.com/article/10.2165/00002018-200225060-00001; David Wiseman, Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines, ResearchGate, Sept. 2025, https://www.researchgate.net/publication/395382959_Signal_loss_by_truancy_masking_and_filtering_and_underestimation_of_potential_risks_and_suspected_adverse_reactions_in_the_Disproportionality_Signal_Analyses_of_VAERS_data_associated_with_COVID-19_pro at 8-9; PSI-HHS-000008257238. One FDA official referred to Dr. Szarfman as someone who "worked to develop the data mining system[.]" *Id.* In 2002, Dr. Szarfman was reportedly awarded "the FDA and CDER Outstanding Scientific Achievement Awards for contributions to safety data mining." See Professional Activities, Ana Szarfman, ORCID, https://orcid.org/0000-0001-6680-1423.

[29] PSI's March 25, 2026 document release on EB data mining: https://www.ronjohnson.senate.gov/services/files/F92FBB0A-CCFD-412A-A02D-243AA1844D6E at 166; FOIA production: https://www.fda.gov/media/184988/download?attachment at 23. Although FDA officials used 2.0 as their threshold for a statistically significant signal, an FDA official's April 5, 2021 PowerPoint presentation before the Advisory Committee on Immunization Practices appeared to recognize that, "Technically, any [Empirical Bayes Geometric Mean] value above one indicates disproportional reporting." See PSI's March 25, 2026 document release on EB data mining: https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-Supporting-Documents-Failure-to-Warn-Part-08.pdf at 47. As medical researcher Dr. David Wiseman wrote in his September 2025 Preprint article, because health officials used the higher threshold of 2.0, as opposed to 1.0 which would "technically" indicate a signal, "[s]ignals were filtered out by an inappropriately high detection threshold." David Wiseman, Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines, ResearchGate, Sept. 2025, https://www.researchgate.net/publication/395382959_Signal_loss_by_truancy_masking_and_filtering_and_underestimation_of_potential_risks_and_suspected_adverse_reactions_in_the_Disproportionality_Signal_Analyses_of_VAERS_data_associated_with_COVID-19_pro at 3.

[30] Letter from Rochelle Walensky, Dir., Centers for Disease Control and Prevention to Sen. Ron Johnson, Sept. 2, 2022 (on file with Subcomm.).

Shimabukuro, one of the most senior CDC officials working on the COVID-19 vaccine safety team, lauded FDA's use of EB data mining, calling it the "'gold standard' for disproportionality analysis" and stating that it "supersedes" other data mining methods "from the perspective of generating informative data."[31]

iii. EB Data Mining Limitations

Even though EB data mining was considered the "gold standard" by some at HHS for assessing safety signals associated with the COVID-19 vaccines, its effectiveness was limited by the statistical phenomenon called "masking." According to Dr. Szarfman's 2022 article published in the journal *Drug Safety*, masking can occur when "signals for a vaccine of interest are hidden by the presence of other reported vaccines. This masking effect may in turn limit or delay our understanding of the risks associated with new and established vaccines."[32]

PSI Chairman Ron Johnson described masking in his March 23, 2026 letter to HHS, writing:[33]

> Essentially, if the baseline data used by federal health agencies for determining the statistical significance of a safety signal combines the signals of other COVID-19 vaccines, that baseline data will drown out or mask the signals of any single COVID-19 vaccine. To help explain the effects of masking in layman's terms, consider this hypothetical: If 100,000 deaths were reported for Moderna's vaccine, 100,000 deaths were reported for Pfizer's vaccine, and 10,000 deaths were reported for all other vaccines, Moderna's 100,000 deaths may not look significant compared to an inflated baseline of 110,000 deaths that is made up of 100,000 Pfizer deaths combined with the 10,000 deaths from all other vaccines.
>
> In this hypothetical, EB data mining would not detect a statistically significant safety signal because the true rate of deaths was masked for one product when compared to a baseline that is inflated by the inclusion of deaths from one or more products with similarly high death rates.
>
> Another simplified way to hypothetically explain the effects of masking would be to test the adverse events of hemlock by comparing them to the adverse events of arsenic. Both may be equally dangerous when each is compared separately against a non-toxic substance such as saline. But, if the effects of hemlock were compared against a baseline that combines the data for the effects of arsenic and saline, the adverse events of hemlock may not result in a significant signal because they have been drowned out or masked by the baseline data which includes the toxic effects of arsenic.

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[31] PSI-HHS-000005235281.

[32] Rave Harpaz et al., Signaling COVID-19 Vaccine Adverse Events, Drug Safety (2022), https://link.springer.com/article/10.1007/s40264-022-01186-z.

[33] Letter from Ron Johnson, Chairman, Permanent Subcomm. on Investigations to Robert F. Kennedy, Jr., Sec., Dep't of Health and Human Services, Mar. 23, 2026, https://www.ronjohnson.senate.gov/services/files/CA500350-195E-472C-9F26-BE93B290B9D9.

> According to a September 2025 preprint article, medical researcher David Wiseman identified several limitations with EB data mining, including masking, that resulted in an underestimation of COVID-19 vaccine adverse events.[34] Wiseman pointed out "FDA's analysis neglected to correct for masking, where signals for one vaccine are concealed by signals from other vaccines."[35]

As explained further in Chairman Johnson's March 23, 2026 letter, the Subcommittee is aware that when reports for certain adverse events are so prevalent, a safety signal may overcome FDA's data mining statistical limitations.[36] For example, statistically significant safety signals appeared for ischemic stroke in individuals 65 years and older following injection of the Pfizer-BioNTech bivalent booster in February and March 2023.[37] Likewise, as discussed above, a signal for myopericarditis was detected in May 2021 for age groups 16-17 and 18-24 years (it is unclear what data mining system detected this signal).[38] Yet, in both of these cases, even after detecting the safety signal, Biden health officials still failed to immediately issue a formal public warning about the potential risks.

iv. Dr. Szarfman's and Dr. DuMouchel's New and "Superior" EB Data Mining Methodology

For decades, FDA relied on Dr. Szarfman's and Dr. DuMouchel's research into data mining. In 2004, Dr. Szarfman, who at the time worked at FDA in the Office of Pharmacoepidemiology and Statistical Sciences, published a paper advocating for the FDA's use of the Bayesian data mining system that Dr. DuMouchel invented called MGPS.[39] Her paper noted that FDA was evaluating MGPS as a method to "enhance the FDA's ability to monitor the safety of drugs, biologics, and vaccines after they have been approved for use."[40] Records indicate that by January 2021, the MGPS algorithm served as the basis for FDA's EB data mining system.[41]

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[34] David Wiseman, Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines, ResearchGate, Sept. 2025, https://www.researchgate.net/publication/395382959_Signal_loss_by_truancy_masking_and_filtering_and_underestimation_of_potential_risks_and_suspected_adverse_reactions_in_the_Disproportionality_Signal_Analyses_of_VAERS_data_associated_with_COVID-19_pro.

[35] *Id.* at 3.

[36] Letter from Ron Johnson, Chairman, Permanent Subcomm. on Investigations to Robert F. Kennedy, Jr., Sec., Dep't of Health and Human Services, Mar. 23, 2026, https://www.ronjohnson.senate.gov/services/files/CA500350-195E-472C-9F26-BE93B290B9D9 at 15.

[37] *Id.* at 16.

[38] Chairman Ron Johnson, Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination, Permanent Subcomm. on Investigations, May 21, 2025, https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-to-Warn.pdf at 20.

[39] Ana Szarfman et al., Pharmacovigilance in the 21st century: new systematic tools for an old problem, Pharmacotherapy (2004), https://accpjournals.onlinelibrary.wiley.com/doi/epdf/10.1592/phco.24.13.1099.38090.

[40] *Id.* at 1.

[41] See, e.g., PSI-HHS-000008254390-92; FOIA production: https://www.fda.gov/media/184988/download?attachment at 2-5.

On March 1, 2021, just over one month after the publication of the SOP that named FDA as the agency in charge of using EB data mining to identify statistically significant safety signals associated with the COVID-19 vaccines, Dr. Szarfman briefed CBER Director Dr. Marks and other senior FDA officials about a new, "state of the art" EB data mining algorithm, also invented by Dr. DuMouchel, called Regression-Adjusted Gamma Poisson Shrinker ("RGPS").[42] In her presentation, Dr. Szarfman described RGPS's performance as "superior" compared to MGPS, noting that it "can better adjust for both, masking (false negatives) and confounding (false positives)."[43] She emphasized that the "MGPS data mining method currently in use at the Agency and at the CDC is not state of the art" and that "**RGPS is the state of the art**" because it "incorporates more information into the signal generation process. This leads to a lower rate of missed signals and less false alerts."[44] Despite Dr. Szarfman's advocacy for a new and apparently more reliable data mining method, FDA failed to take her expert advice and adopt the "state of the art" method.[45]

It is somewhat ironic that Drs. DuMouchel and Szarfman, who were crucial in the development of MGPS and its implementation at FDA, respectively, were, in early 2021, leading an effort to replace that data analysis method with another one. However, it is because of their expertise and familiarity with the data mining system that Drs. DuMouchel and Szarfman were uniquely qualified to critique the MGPS methodology, acknowledge its limitations, and offer a solution to better detect safety signals.[46]

Records indicate that certain senior FDA officials openly acknowledged their own limited understanding of data mining, as well as Drs. DuMouchel and Szarfman's expertise. In a March 2021 email among FDA CBER officials, Dr. Bethany Baer wrote, "I know Ana [Szarfman] worked to develop the data mining system," referring to FDA's current method.[47] Dr. Baer recognized Dr. Szarfman's "knowledge and experience" with data mining and later added "I know that she knows a lot more about data mining than I do!"[48] In an April 2021 email among FDA CBER officials discussing Drs. DuMouchel and Szarfman's data mining analysis, Dr. Craig Zinderman admitted "I don't pretend to understand it, but sounds like they are suggesting an analysis not stratified by year."[49]

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[42] Dr. Szarfman referred to Dr. DuMouchel's RGPS methodology as "new." PSI-HHS-000008257443-44; Dr. DuMouchel co-authored a white paper in 2012 about RGPS. William DuMouchel and Rave Harpaz, Regression-Adjusted GPS Algorithm (RGPS), Oracle, Nov. 2012, https://docs.oracle.com/health-sciences/empirica-signal-811/ESIUG/Regression-Adjusted_GPS_Algorithm.pdf; PSI-HHS-000004783470-71; PSI-HHS-000008257443; PSI-HHS-000008259555, 62; Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://web.archive.org/web/20210319091240/https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at 16-17.

[43] PSI-HHS-000008259555, 57.

[44] *Id.* at 61 (emphasis in original).

[45] *Id.*

[46] In a March 26, 2021 email to senior FDA officials, Dr. Szarfman left little doubt about her and Dr. DuMouchel's expertise in data mining, stating explicitly that she and Dr. DuMouchel "extensively studied the increased value of RGPS over MGPS for reducing false positives and negative signals." PSI-HHS-000008257443-44.

[47] PSI-HHS-000008257238.

[48] PSI-HHS-000008257237.

[49] PSI-HHS-000008251980.

Throughout 2021, it appears that each time Dr. Szarfman distributed an RGPS-driven data mining analysis to her colleagues, she also included the results of the MGPS-generated data mining analysis.[50] By doing this, FDA officials could clearly see the alarming statistically significant safety signals detected by the newer RGPS method compared to the silent and apparently outdated MGPS method.[51]

B. Locking Down Access to FDA's Data Mining Analyses

In September 2021, Dr. Marks informed Dr. Cavazzoni, the then-Director of CDER, that Dr. Szarfman, who is a CDER employee, "has been asked to cease and desist" conducting her data analyses."[52] He complained that Dr. Szarfman's work has "become a major distraction."[53] Dr. Peter Stein, the then-Director of CDER's Office of New Drugs, reported to Dr. Marks that his office has "made it clear" to Dr. Szarfman "that she should not be discussing or providing internal analyses externally, and needs to focus on her assigned work."[54]

FDA officials' decision to prevent Dr. Szarfman from conducting data mining on COVID-19 vaccines appeared to be part of a larger effort to restrict access and distribution of FDA's COVID-19 vaccine data mining analyses. About a month before Dr. Szarfman was directed to "cease and desist," Dr. David Menschik, a senior official in FDA CBER who had been distributing weekly data mining reports to individuals at FDA and CDC, informed a CDC official, in August 2021, that FDA's "plan is actually to limit its distribution, largely for data security reasons."[55] It is unclear what specific "data security reasons" Dr. Menschik referred to when he informed his CDC colleagues about the need to limit the distribution of the data mining reports.

Based on records reviewed by the Subcommittee, Dr. Menschik continued to distribute the weekly data mining reports to a limited number of FDA and CDC officials, but it appears that the final weekly data mining report for the COVID-19 vaccines was distributed by another FDA CBER official, Dr. Zinderman, on July 12, 2022.[56]

In a September 2022 email to his FDA colleagues, FDA CBER official Dr. Narayan Nair admitted that he was responsible for suggesting to CDC that FDA discontinue its distribution of

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[50] In a March 26, 2021 email, Dr. Szarfman wrote to her FDA colleagues, "the attached excel comparisons between RGPS and MGPS were generated by Bill DuMouchel using the VAERS public domain data incorporated into the Empirica Signal. RGPS is included with the public domain version of Empirica Signal." PSI-HHS-000008257443; See e.g., PSI-HHS-000008257443-44 (with attachment); PSI-HHS-000008258306 (with attachment); PSI-HHS-00008258202-03; PSI-HHS-000002208944-45; PSI-HHS-000004592364 (with attachment).

[51] *Id.*

[52] PSI-HHS-000002213753.

[53] *Id.*

[54] PSI-HHS-000002213752-53.

[55] PSI-HHS-000005524064. See e.g., PSI's March 25, 2026 document release on EB data mining: https://www.ronjohnson.senate.gov/services/files/D4D8B767-A092-455C-9CDE-DC8EC1419B31.

[56] PSI-HHS-000001217046 (with attachment); PSI's March 25, 2026 document release on EB data mining: https://www.ronjohnson.senate.gov/services/files/D4D8B767-A092-455C-9CDE-DC8EC1419B31 at 231-234; See also Dr. Menschik writing to his FDA colleagues on Aug. 5, 2022, "we are no longer routinely sending COVID data mining to CDC[.]" One FDA official responded, "I was also hoping we would stop doing that at some point!" PSI-HHS-000008266854.

the weekly data mining reports.[57] Instead, Dr. Nair informed his colleagues that FDA would continue its data mining, but would only "notify CDC if we found any datamining [*sic*] alerts that were clinical [*sic*] relevant and required further action."[58] He noted that this method would save time and "reduce email traffic."[59] Dr. Nair pointed out further, "[s]ince it had been some time that we had a datamining [*sic*] alert that required further evaluation, CDC agreed with this approach."[60]

Emails among CDC officials point to another reason behind FDA's decision to stop distributing its data mining reports. In November 2022, certain CDC officials recalled how they used to receive data mining reports from FDA official Dr. Menschik, but no longer do. One CDC official noted, "**I think that because of the FOIAs [Freedom of Information Act requests] we may have asked FDA to stop sending these weekly data mining outputs**."[61]

Indeed, in the months and weeks leading up to FDA's decision to discontinue its distribution of the weekly data mining reports, there were several public requests made to CDC and FDA for that information. On May 9, 2022, about two months before the FDA stopped sending CDC its weekly data mining reports, Children's Health Defense sent a FOIA request to CDC for the EB data mining analyses.[62] On June 23, 2022, 19 days before FDA sent its final weekly data mining report, Senator Johnson wrote to then-CDC Director Dr. Rochelle Walensky requesting the same information.[63] Then, on June 30, 2022, 12 days before FDA's last distribution, the Informed Consent Action Network submitted a FOIA request to FDA for the EB data mining records.[64]

In light of these public and Congressional requests, the timing of FDA's decision to end its distribution of its weekly data mining reports seems particularly suspect.[65] The notion that Biden health officials took steps to limit its distribution of COVID-19 vaccine safety data in order to avoid more internal review or public scrutiny is completely unacceptable.

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[57] PSI-HHS-000001160286.
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] PSI-HHS-000002480132.
[62] FOIA request, May 9, 2022, https://jackanapes.substack.com/api/v1/file/44421d00-9c02-4fc9-9471-65fcdb24152c.pdf.
[63] Letter from Senator Ron Johnson to Rochelle Walensky, Director, Centers for Disease Control and Prevention, June 23, 2022, https://www.ronjohnson.senate.gov/services/files/9914278B-A73B-4434-8349-91091138E18B.
[64] Letter from Aaron Siri, Attorney, Siri Glimstad, et al., to Food and Drug Administration, Oct. 31, 2022, https://icandecide.org/wp-content/uploads/2023/02/001-Complaint-Exhibits-January-25-2023-IR0802M.pdf at 7. According to the Informed Consent Action Network, FDA denied the entire FOIA request on Aug. 26, 2022. *Id.* at 8.
[65] The first FOIA production of EB data mining reports did not occur until January 22, 2025, under the Trump administration. David Wiseman, Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines, ResearchGate, Sept. 2025, https://www.researchgate.net/publication/395382959_Signal_loss_by_truancy_masking_and_filtering_and_underestimation_of_potential_risks_and_suspected_adverse_reactions_in_the_Disproportionality_Signal_Analyses_of_VAERS_data_associated_with_COVID-19_pro at 51, see footnote 41.

C. FDA Officials Acknowledge EB Data Mining Limitations and Continue to Fail to Make Necessary Adjustments

In September 2021, following Dr. Szarfman's multi-month effort to convince FDA officials to utilize a better EB data mining algorithm that can adjust for masking, records show FDA officials acknowledging the masking limitation in the current data mining system.[66] However, rather than adhering to Dr. Szarfman's recommendation to implement a "state of the art" method that will "lead[] to a lower rate of missed signals," FDA officials appeared to continue to use their same data mining method "rather than take an experimental approach."[67]

Records show Dr. Menschik working on a draft article in September 2021 about the safety of mRNA vaccines.[68] Dr. Menschik circulated proposed language for that manuscript that explained EB data mining limitations, including masking. Dr. Menschik wrote:

> EB data mining has multiple limitations including that an absence of a disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately [*sic*] scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) **can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event.**[69]

In another discussion in September 2021 involving the draft paper, Dr. Menschik also raised the masking effect, noting:

> [I]f the comparison group is enriched with so many mRNA COVID-vaccine reports, tha[n] **it becomes very difficult to exceed the EB05>2 alert threshold**

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[66] PSI's March 25, 2026 document release on EB data mining: https://www.ronjohnson.senate.gov/services/files/F92FBB0A-CCFD-412A-A02D-243AA1844D6E at 117.
[67] PSI-HHS-000008259561; PSI-HHS-000001136460; PSICOVID_00015642; PSICOVID_00014435.
[68] PSI's March 25, 2026 document release on EB data mining: https://www.ronjohnson.senate.gov/services/files/F92FBB0A-CCFD-412A-A02D-243AA1844D6E at 117.
[69] *Id.* (emphasis added). As explained in Chairman Johnson's March 23, 2026 letter to HHS, the Subcommittee uncovered several emails regarding the evolution of this excerpt in the manuscript. Similar language referencing EB data mining limitations appeared into two preprint versions of the manuscript, one dated Oct. 27, 2021, and one dated Oct. 28, 2021. The final version of the paper appeared in the *Lancet* in March 2022 without the reference to EB data mining limitations. See Letter from Ron Johnson, Chairman, Permanent Subcomm. on Investigations to Robert F. Kennedy, Jr., Sec., Dep't of Health and Human Services, Mar. 23, 2026, https://www.ronjohnson.senate.gov/services/files/CA500350-195E-472C-9F26-BE93B290B9D9; See Hannah Rosenblum, et al., Safety Monitoring of mRNA Vaccines Administered During the Initial 6 Months of the U.S. COVID-19 Vaccination Program: Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe, MedRxiv, Oct. 27, 2021, https://www.medrxiv.org/content/10.1101/2021.10.26.21265261v1.full.pdf at 13; Hannah Rosenblum, et al., Safety Monitoring of mRNA Vaccines Administered During the Initial 6 Months of the U.S. COVID-19 Vaccination Program: Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe, MedRxiv, Oct. 28, 2021, https://www.medrxiv.org/content/10.1101/2021.10.26.21265261v2.full.pdf at 13; Hannah Rosenblum et al., Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe, The Lancet, https://pmc.ncbi.nlm.nih.gov/articles/PMC8901181/.

> **for an adverse event that may be associated with mRNA vaccines – thus data mining has blind spots** and this is why it's so good to have so many complimentary vaccine safety surveillance systems (e.g., VSD [Vaccine Safety Datalink]) that can cover different blind spots of other systems…[70]

In November 2022, Dr. Menschik emailed Dr. Nair and referenced the masking limitation which could lead to misinterpretations of the data mining.[71] In October 2023, Dr. Nair wrote a comprehensive email to federal health officials including, Drs. John Su and Tom Shimabukuro, both from CDC, about the masking effect in data mining. Dr. Nair explained:

> As you know, data mining has all the limitations of passive surveillance as well as others. However, during the COVID vaccine era there is an additional limitation. Since most reports received involve COVID-19 vaccines, disproportionately [*sic*] scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be driven towards the null by COVID-19 vaccine reports contributing substantially to the comparator group.[72]

Dr. Nair added, "**We were aware of this limitation before and during the pandemic.** There are many data mining tools and **there was some discussion about utilizing a novel tool to adjust for this**. However, we thought it would be problematic to use a brand new, possibly unvalidated tool in the context of an EUA."[73] It appears likely that Dr. Nair's reference to a "novel tool to adjust for" masking was Drs. Szarfman's and DuMouchel's proposed newer data mining algorithm. Although Dr. Nair claimed the tool was "possibly unvalidated," he failed to mention its efficacy in detecting statistically significant safety signals which, one would think, would be invaluable especially if it is being used to monitor the effects of a novel vaccine that just received an EUA.

D. Top FDA CBER Officials Eventually Acknowledge the Effectiveness of the New Data Mining Model Compared to the Current Methodology

In September 2024, CBER officials Drs. Baer and Menschik discussed FDA's current data mining methodology, MGPS, and RGPS, the methodology that Dr. Szarfman had lobbied for years earlier.[74] Dr. Baer noted that when she compared results of the RGPS and MGPS models for the Gardasil vaccine, she found that the RGPS model yielded "significantly higher" numbers than the MGPS model for certain adverse events.[75] She also found that the RGPS numbers were higher than MGPS numbers for certain adverse events associated with the Pfizer

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[70] PSI's March 25, 2026 document release on EB data mining: https://www.ronjohnson.senate.gov/services/files/7DD643F9-BF66-4923-B791-7766870C8856 at 120 (ellipses in original, emphasis added).
[71] PSICOVID_00015642.
[72] PSI-HHS-000001136460.
[73] *Id.* Dr. DuMouchel co-authored a paper in 2012 about the RGPS data mining method. William DuMouchel and Rave Harpaz, Regression-Adjusted GPS Algorithm (RGPS), Oracle, Nov. 2012, https://docs.oracle.com/health-sciences/empirica-signal-811/ESIUG/Regression-Adjusted_GPS_Algorithm.pdf.
[74] PSI-HHS-000008253424.
[75] *Id.* It is unclear what adverse events Dr. Baer reviewed that were associated with the Gardasil vaccine.

COVID-19 bivalent vaccine.[76] Dr. Menschik appeared to concur with Dr. Baer's finding and wrote that "in general the [RGPS model] appears way more sensitive in that its scores are generally higher than corresponding [MGPS model] scores when sampling different [adverse events]."[77]

In the same email, Dr. Baer, who mentioned Dr. Szarfman's 2022 paper about the masking limitation in data mining, appeared to acknowledge that the lower numbers from the MGPS model were a result of masking.[78] She wrote, "I understand the theory behind masking and trying to adjust for it, but I feel that comprehending the details of the approach and, importantly, which approach is 'better,' is beyond my training and experience. I think someone with more data mining expertise would have to be involved in that decision."[79]

Drs. Menschik and Baer's September 2024 email exchange acknowledging the effectiveness of the RGPS model compared to the MGPS model and referencing the need for a data mining expert is beyond ironic. Since 2021, because of Drs. Szarfman and DuMouchel's efforts, top FDA officials, including Drs. Marks and Menschik, were well aware of the effectiveness of the RGPS model as a means to adjust for masking and better detect statistically significant safety signals. Dr. Baer herself acknowledged in March 2021 that Dr. Szarfman had "knowledge and experience" with data mining and even admitted at that time, "I know that [Dr. Szarfman] knows a lot more about data mining than I do!"[80] FDA officials had ample opportunity to involve Drs. Szarfman and DuMouchel—both experts in data mining—in their safety surveillance efforts, but instead, cast them and their analyses aside.

# # # #

The enclosed timeline will detail Dr. Szarfman's attempts to inform her colleagues at the FDA about increases in statistically significant safety signals associated with the COVID-19 vaccines. The timeline will also show how FDA officials reacted to Dr. Szarfman's findings, their growing concern about her access to the safety data, and their failure to adjust the FDA's data mining analysis to account for the significant flaws in their methodology that masked dozens of statistically significant adverse events for the COVID-19 vaccines.

[76] *Id.* It is also unclear what adverse events Dr. Baer reviewed that were associated with the Pfizer COVID-19 bivalent vaccine.
[77] *Id.*
[78] *Id.*
[79] *Id.*
[80] PSI-HHS-000008257237-38.

II. Timeline – Biden Health Officials Ignore Safety System that Can Better Detect Signals for COVID-19 Vaccine Adverse Events

- **Nov. 18, 2020:** Manette Niu, an official at the Food and Drug Administration's ("FDA") Center for Biologics Evaluation and Research ("CBER"), Office of Biostatistics and Pharmacovigilance ("OBPV"), emails Steven Anderson, the Director of that office at that time, to inform him that she has a meeting the next day with Ana Szarfman, a medical officer and safety data mining developer who works in FDA's Center for Drug Evaluation and Research ("CDER"), Office of Cardiology, Hematology, Endocrinology, and Nephrology ("OCHEN"), "to discuss [Szarfman's] proposal on instituting new methods to improve data mining."[81] It is unclear what specific "new methods" Szarfman wanted to discuss and whether this meeting occurred.

- **Dec. 11, 2020:** FDA issues an Emergency Use Authorization ("EUA") for the Pfizer COVID-19 mRNA vaccine for individuals ages 16 and older.[82]

- **Dec. 18, 2020:** FDA issues an EUA for the Moderna COVID-19 mRNA vaccine for individuals ages 18 and older.[83]

- **Dec. 23, 2020:** Szarfman organizes a virtual meeting to discuss proposals for a new safety data mining methodology designed by Oracle Chief Statistician William DuMouchel, the architect of FDA's existing data mining system.[84] Meeting invitees include Richard Forshee, Associate Director for Research at CBER OBPV/Acting Deputy Director for CBER OBPV; Narayan Nair, a CBER OBPV official; and Norman Stockbridge, an official at CDER OCHEN.[85] Szarfman notes in her introductory remarks for the meeting that among other problems with current data mining practices "safety signals may remain hidden."[86]

- **Jan. 8, 2021:** As FDA officials discussed the use of empirical Bayesian ("EB") data mining to detect safety signals for adverse events associated with COVID-19 vaccines, David Menschik and Bethany Baer, two officials at CBER OBPV, communicate about "a few classic data mining references" written by Szarfman and DuMouchel.[87] Baer notes

[81] PSI-HHS-000004585100. Until 2022, The Office of Biostatistics and Pharmacovigilance was named the Office of Biostatistics and Epidemiology. For purposes of this document, the office will be referred to by its current name. See National Science Foundation, NI Protocol, FDA CBER Reorg & More—March '22 Pharma News, Mar. 1, 2022, available at https://www.nsf.org/news/march-pharma-news.
[82] COVID-19 Timeline, Centers for Disease Control and Prevention, https://www.cdc.gov/museum/timeline/covid19.html.
[83] *Id.*
[84] PSICOVID_00014194.
[85] PSICOVID_00014194; PSI-HHS-000002185990-91. Szarfman's Dec. 23, 2020 email thanking Forshee for attending the presentation notes that she has attached an updated version of the slides. One such update appears to be a slide including DuMouchel's background as the inventor of MGPS. *See* PSI-HHS-000002293255.
[86] PSICOVID_00014198.
[87] PSI-HHS-000008254390.

that FDA's current EB data mining system uses the Multi-item Gamma Poisson Shrinker ("MGPS"), which is the algorithm DuMouchel invented.[88]

- **Jan. 29, 2021:** The Centers for Disease Control and Prevention ("CDC") releases its Standard Operating Procedures ("SOP") for the Vaccine Adverse Event Reporting System ("VAERS").[89] The SOP identifies the "analyses for COVID-19 vaccine safety signals" noting that FDA will be responsible for "using empirical Bayesian data mining to identify [adverse events] reported more frequently than expected following vaccination with COVID-19 vaccines."[90]

- **Feb. 14, 2021:** Szarfman raises concerns to CBER Director Peter Marks regarding COVID-19 vaccine safety monitoring issues with the FDA's current practices and asks "if you want Bill DuMouchel and I to discuss our proposal for more effective monitoring, including the need to use an updated algorithm by DuMouchel for data mining spontaneous reports at [FDA.]"[91] Marks arranges a time to meet with her in the following weeks.[92]

- **Feb. 27, 2021:** FDA approves an EUA for Johnson & Johnson's COVID-19 vaccine for all people ages 18 years and older.[93]

- **March 1, 2021:**
    - Szarfman meets with CBER Director Peter Marks, as well as Forshee, Anderson, and others at CBER, to discuss confounding issues with MGPS, particularly data masking, which is a known limitation with MGPS that can lead to missed or reduced signals in data mining.[94] Szarfman also showcases "the superior performance" of DuMouchel's Regression-Adjusted Gamma Poisson Shrinker ("RGPS"), an "updated algorithm" for data mining that DuMouchel first outlined in a 2012 white paper.[95] Szarfman states that "[t]he MGPS data mining method currently in use at [FDA]" is "not the state of the art."[96] In contrast, she emphasizes, "**RGPS is the state of the art**," noting that the new method can "**better adjust for both, masking** (false negatives) and confounding (false positives)."[97]

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[88] *Id.*; PSI-HHS-000002293255.
[89] Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://web.archive.org/web/20210319091240/https:/www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.
[90] *Id.* at 16-17.
[91] PSI-HHS-000002213369.
[92] *Id.*
[93] COVID-19 Timeline, Centers for Disease Control and Prevention, https://www.cdc.gov/museum/timeline/covid19.html.
[94] PSI-HHS-000004783471-72; PSI-HHS-000002134656.
[95] PSI-HHS-000004783471-72; PSI-HHS-000008259555; William DuMouchel and Rave Harpaz, Regression-Adjusted GPS Algorithm (RGPS), Oracle, Nov. 2012, https://docs.oracle.com/health-sciences/empirica-signal-811/ESIUG/Regression-Adjusted_GPS_Algorithm.pdf.
[96] PSI-HHS-000008259561.
[97] *Id.* (emphasis in original); PSI-HHS-000002134652 (emphasis added).

- Marks thanks Szarfman "for taking the time to go over everything so carefully with us."[98] He writes, "[w]e will work through the issues that you presented."[99] Afterwards, Marks schedules a meeting with Forshee and Anderson to discuss "how to proceed" apparently on the issues raised by Szarfman and DuMouchel's updated data mining algorithm.[100] It is unclear whether this meeting occurred.

- **March 10, 2021:** Szarfman confirms that she has access to VAERS data through Oracle's Empirica, a tool for detecting and analyzing vaccine safety signals.[101] It appears other CBER officials, including Anderson, were aware of and did not object to Szarfman's access, even though she works in CDER.[102]

- **March 11, 2021:** Craig Zinderman, a CBER official, affirms to Baer that he has no issue granting Szarfman access to VAERS data through Empirica.[103] Baer responds writing "we will leave Ana's account as is with a CBER login."[104]

- **March 12, 2021:**
  - A day later, Baer appears to take issue with Szarfman having access to a database controlled by CBER, an office that Szarfman is not a part of, saying, on calls with the contractor supporting Empirica and FDA's data mining, Commonwealth Informatics ("Commonwealth") Szarfman "has twice now expressed interest in COVID vaccine data mining and made some broad statements that I don't think [the Division of Pharmacovigilance] would agree with[.]"[105] Baer also questions who at CBER will be coordinating with Szarfman and interpreting her results.[106] However, Baer appears to recognize Szarfman's expertise in data mining and writes, "**I know Ana [Szarfman] worked to develop the data mining system and this might be a special circumstance due to her knowledge and experience.**"[107]
  - Zinderman, replies that "[r]efusing her access just for vaccines seems a little disingenuous" but that it "[s]eems reasonable to try to understand why [Szarfman] wants to use VAERS data instead of [CDER's] data, and to caution her that while its [*sic*] fine for her to do methodological work, **we aren't interested in additional data mining studies of COVID data** outside of CBER's usual processes."[108]

[98] PSI-HHS-000004783470-71.
[99] *Id.*
[100] PSI-HHS-000004584613.
[101] PSI-HHS-000008257240-41.
[102] PSI-HHS-000008257239.
[103] PSI-HHS-000008257238-39.
[104] PSI-HHS-000008257238.
[105] *Id.* At the time of Baer's email the Division of Pharmacovigilance was known as the Division of Epidemiology.
[106] *Id.*
[107] *Id.* (emphasis added).
[108] PSI-HHS-000008257237-38 (emphasis added).

- **March 14, 2021:** Responding to Zinderman, Baer acknowledges that "[Szarfman] knows a lot more about data mining than I do[.]"[109] However, Baer reiterates her earlier concerns about Szarfman's apparent comments she made during a regularly scheduled call between officials at CBER, CDER, and Commonwealth.[110] Baer characterizes Szarfman's comments as atypical and speculates that Szarfman may have been "just brainstorming and theorizing" which was "unusual compared to the typical topics covered on the call."[111]

- **March 16, 2021:** Niu writes to Baer that she and Zinderman have decided to schedule a meeting with Szarfman to discuss her "VAERS objectives/rationale."[112]

- **March 17-18, 2021:**
  - Menschik emails Brian Hendrix, a contractor at Commonwealth, and Baer to request a "'special project' run" of MGPS that will apparently adjust for masking with COVID-19 vaccines, though he does not use that specific term.[113] He notes that he observed a "**muting trend**" for adverse events, which he attributes to the volume of COVID-19 vaccine reports.[114] Menschik specifies that the viewers of this potential data analysis should be limited to himself, Baer, and the contractor.[115]
  - The "'special run'" was completed, but the results do not appear in the records reviewed to date.[116]

- **March 26, 2021:**
  - After speaking with Zinderman, Niu, and Baer earlier that day, Szarfman sends them, as well as Menschik and Stockbridge, an earlier email and spreadsheet from DuMouchel that includes his RGPS analysis showing "**49 examples of extreme masking**," with over twenty of those examples of adverse events now showing a statistically significant safety signal when adjusted for masking.[117] Some of the statistically significant safety signals for adverse events associated with the COVID-19 vaccines that were not previously detected through MGPS include sudden cardiac death, Bell's palsy, and pulmonary infarction.[118] Szarfman also attaches her March 1 presentation she gave to Marks and other FDA officials.[119]
  - Szarfman notes that the "comparisons between RGPS and MGPS were generated by Bill DuMouchel using the VAERS public domain data incorporated into Empirica Signal." Szarfman explains that she and DuMouchel "extensively studied the increased value of RGPS over MGPS for reducing false positives and

[109] PSI-HHS-000008257237.
[110] *Id.*
[111] *Id.*
[112] *Id.*
[113] PSICOVID_00017214.
[114] *Id.*
[115] *Id.*
[116] PSICOVID_00017210.
[117] PSI-HHS-000008263190-91 (emphasis added).
[118] PSI-HHS-000008257443-44 (with attachment).
[119] *Id.*

negative signals."[120]

- **March 30, 2021:** Menschik circulates a list of adverse events with safety signals identified by FDA's data mining methodology to FDA senior officials, as well as several officials at CDC, including John Su and Tom Shimabukuro.[121] Menschik also attaches a draft presentation detailing limitations with the FDA's current MGPS data mining system.[122] Some of the limitations highlighted in the draft presentation, such as "confounding" and "false alerts from statistical interaction," appear to be similar to the concerns Szarfman previously raised regarding the effectiveness of the FDA's MGPS algorithm.[123] It is unclear how the senior CDC and FDA officials responded to the draft presentation.

- **April 10, 2021:**
  - DuMouchel sends additional data to Szarfman and others that appears to analyze VAERS reports while adjusting for the fact that "99% of all reports" for the year 2021 are for the COVID-19 vaccines. [124] DuMouchel's analysis appears to adjust for the masking effect. [125] He notes, "[o]nly if you mix in more non-covid reports within each stratum can you get enough diversity to allow larger disproportionalities." [126]
  - Szarfman forwards the email to Niu and other FDA officials, flagging the "[i]mportant analysis by DuMouchel," and writes, "I think that we need to invite [DuMouchel] to talk with us about the effect of adjustment factors, given the data, so we can all learn from his knowledge."[127]

- **April 12-13, 2021:** Two days after Szarfman flags DuMouchel's "[i]mportant analysis," Niu replies to her in a separate chain asking, "Does this effect the data mining results we are receiving in 2021?"[128] Szarfman responds the next day, saying, "Exactly. As DuMouchel pinpointed, there is a need to extend the stratification brackets by the fact that 99% of the results for FY2021 are for COVID-19 vaccines this indeed affects the results."[129]

- **April 14, 2021:** Niu forwards the emails containing DuMouchel's writeup of his analysis and Szarfman's comments to Zinderman (removing Szarfman from the email chain), but it does not appear Niu shares DuMouchel's data mining results at this time.[130] Zinderman in turn sends DuMouchel's writeup and Szarfman's comments to Menschik and Baer with

[120] *Id.*
[121] PSI-HHS-000001187885 (with attachment); PSI-HHS-000001187886-88.
[122] *Id.*
[123] PSI-HHS-000001187888.
[124] PSI-HHS-000008251981-82; PSI-HHS-000008258306-07 (with attachment).
[125] *Id.*
[126] PSI-HHS-000008251982.
[127] PSI-HHS-000008251981-82.
[128] PSI-HHS-000008251981.
[129] PSI-HHS-000008251980-81.
[130] *Id.*

Niu copied.[131] Zinderman questions whether DuMouchel's apparent adjustment for masking "[m]ight be worth considering[.]"[132] He adds, "I don't pretend to understand it, but sounds like they are suggesting an analysis not stratified by year."[133]

- **April 15, 2021:**
  - The next day, Baer responds, stating, "I think we should welcome any expert input," acknowledging that she and Menschik "are concerned about the effect of so many COVID reports on the standard system [FDA] use[s]."[134] She asks if there is any way to have DuMouchel more involved in FDA's "data mining process and interpretation during this unprecedented reporting time?"[135]
  - Niu answers stating she will send them DuMouchel's data mining results and that "[t]he best person to ask would be Ana [Szarfman] as she has close ties with Bill DuMouchel."[136]
  - A few minutes later, Menschik removes Niu from the email chain and replies only to Zinderman and Baer, and appears to push back on immediately speaking with Szarfman, saying, "**Before we potentially reach out to Ana [Szarfman], we should meet internally – many considerations not suited to email…**"[137] It is unclear if Menschik, Zinderman, and Baer met.

- **April 17-19, 2021:**
  - Szarfman forwards Niu an analysis that DuMouchel compiled the day before using his new data mining method (RGPS), which revealed six statistically significant safety signals for adverse events, which were not previously detected by FDA's current system.[138] DuMouchel's analysis uncovered statistically significant safety signals, currently masked by MGPS, including Bell's palsy associated with the Pfizer vaccine and thrombosis associated with the Moderna vaccine.[139]
  - Two days later, Niu forwards Szarfman's email containing DuMouchel's analysis to Zinderman, Baer, and Menschik.[140]

- **April 22, 2021:**
  - After receiving Szarfman's distribution of DuMouchel's analysis, Baer informs Menschik, Zinderman, and Niu that during a call that day with Commonwealth officials, Szarfman "offered to show individuals the interesting VAERS analysis

[131] *Id.*
[132] PSI-HHS-000008251980.
[133] *Id.*
[134] *Id.*
[135] *Id.*
[136] PSI-HHS-000008251979-80.
[137] PSI-HHS-000008251979 (emphasis added) (ellipses in original).
[138] PSI-HHS-000008258202-03. Records show that FDA's threshold for determining a statistically significant safety signal was when the lower bound of the reporting estimate (EB05) exceeded 2.0. See PSI's March 25, 2026 document release on EB data mining https://www.ronjohnson.senate.gov/services/files/F92FBB0A-CCFD-412A-A02D-243AA1844D6E at 166.
[139] PSI-HHS-000008258203.
[140] PSI-HHS-000008258202.

she has been doing with Manette. A couple of the Commonwealth folks expressed interest in meeting with her to see it."[141]

- Niu responds, distancing herself from Szarfman, writing, "I have not been working with Ana directly, although she has sent me data mining runs that I've forwarded to this group. I will speak to her about this."[142]

- **April 25-26, 2021:**
  - Szarfman resends DuMouchel's analysis to Niu and includes several additional FDA officials.[143] In the email, Szarfman reiterates that she is sending all of DuMouchel's analysis to Niu.[144] Szarfman further writes regarding how DuMouchel's new method (RGPS) "is better at removing false positives and negatives than MGPS. Note the **safety signals for cardiac events with the Pfizer and Moderna vaccines, now in the news, that are better identified by RGPS than by MGPS.**"[145]
  - Niu separately asks Zinderman for advice on how to respond to Szarfman who had apparently described Niu as her collaborator on Szarfman's data mining work to FDA's data mining contractors.[146] In response, Zinderman sends Niu draft language to respond to Szarfman, and tells Niu that asking Szarfman to stop sending data mining results "would create a bigger problem for us I think."[147]
  - Niu, responds to Szarfman's earlier email and writes, **"**[w]hile we are aware that CDER is using the vaccine data to explore new calculations and various deviations of analysis parameters in disproportionality analysis, I haven't been, and are unable to, work as a collaborator with you on this project due to our higher priority work, and because this sort of statistical development work falls outside of my area of expertise."[148] Niu's email to Szarfman contains similar language to the draft response Zinderman sent Niu earlier that day.[149]
  - Szarfman responds to Niu that she understands but she will keep her up to date with her findings.[150]

- **April 29, 2021:**
  - Szarfman shares with Niu and other FDA officials an analysis of EB data mining issues unrelated to DuMouchel's new data mining method.[151] Niu forwards Szarfman's analysis to Zinderman, Baer, and Menschik.[152] In response, Menschik asks, "[d]id you request this or anything else (COVID vaccine data mining

[141] *Id.*
[142] *Id.*
[143] PSI-HHS-000008258271.
[144] *Id.*
[145] *Id.* (emphasis added).
[146] PSI HHS-000008260150.
[147] *Id.*
[148] PSI-HHS-000008258271.
[149] PSI HHS-000008260150.
[150] PSI-HHS-000008258271.
[151] PSI-HHS-000008258153-54; PSICOVID_00017031; PSICOVID_00017032-33; PSICOVID_00017034-81.
[152] PSI-HHS-000008258153.

related) from Ana and/or are you working with Ana on any data mining projects? (if so, please specify)[.]"[153]

- Niu responds to Menschik in two separate emails, writing first, "[n]o, I haven't requested anything from Ana. I am only passively passing on her data mining runs when she sends them to me."[154] She then quickly sends the second email stating that she is "not working on anything with [Szarfman]."[155]
- The same day, Niu also sends Menschik her previous conversation with Szarfman, in which Niu told Szarfman that she cannot collaborate with Szarfman.[156]

- **May 6, 2021:** Szarfman circulates an analysis run by DuMouchel to Norman Stockbridge and another CDER official, showing that MGPS had undervalued the safety signals for acute myocardial infarction for both the Pfizer and Moderna COVID-19 vaccines.[157] DuMouchel's RGPS method appeared to yield much higher signals compared to FDA's MGPS method.[158]

- **May 7, 2021:**
  - Following Szarfman's multi-month efforts advocating for FDA to change its data mining system in order to unmask statistically significant safety signals associated with the COVID-19 vaccines, Menschik, Nair, and Zinderman draft a lengthy email to Szarfman.[159]
  - The final draft of the email, which Zinderman eventually sends to Szarfman that same day, directs her to "please hold off on creating and sending data mining reports and analyses using COVID-19 vaccine [adverse event] data."[160]
  - In the email to Szarfman, the FDA officials attempt to downplay her findings writing that, "we are already screening and reviewing reports, such as [acute myocardial infarction], [thrombocytopenia syndrome], Thromboembolic events, and other forms of coagulopathy."[161] The email concludes by reiterating the directive to Szarfman to "hold off" on continuing her efforts.[162]
  - Szarfman replies to Zinderman that from now on, "I will only deliver analyses when I am specifically requested to do so[.]"[163] She reiterates, however, "[w]e are testing a new data mining methodology, and given the circumstances, it will be good for all to understand its performance with such important data. **This is a method that also strongly reduces confounding**, so it may be helpful in certain future circumstances."[164]

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[153] *Id.*
[154] *Id.*
[155] PSI-HHS-000008258190.
[156] PSI-HHS-000008258271.
[157] PSI-HHS-000002208944-45.
[158] *Id.* (using the RGPS methodology, ER05 notification signals were significantly higher than the previously running EB05 of MGPS).
[159] PSICOVID_00017246; PSI-HHS-000008251530; PSI-HHS-000008251912-13; PSI-HHS-000001195617-19; PSI_HHS-000008253450-51; PSI-HHS-000001175745-47; PSI-HHS-000001148712-14.
[160] PSICOVID_00017246-47.
[161] *Id.*
[162] *Id.*
[163] PSICOVID_00017245.
[164] *Id.* (emphasis added).

- Zinderman forwards Szarfman's response to Menschik and Niu.[165]

- **May 10, 2021:** FDA expands EUA for Pfizer's COVID-19 mRNA vaccine for ages 12-15.[166]

- **June 4, 2021:** Szarfman receives clearance from Stockbridge to publish a paper she co-authored with DuMouchel and others at Oracle, entitled "Masking Associated with Early COVID-19 Vaccine Safety Surveillance."[167] Szarfman encloses a draft version of her paper that "demonstrates the potential utility of a new signal detection methodology called RGPS that can address masking and confounding effects that cannot be properly controlled by conventional signaling methodologies."[168]

- **June 11, 2021:**
  - Following apparent conversations between the CDC and FDA regarding "myocardial events and the lack of signals in VAERS[,]" Szarfman writes to her FDA colleagues, resending DuMouchel's analysis that she initially sent one month prior that uncovered statistically significant safety signals for acute myocardial infarction.[169] Referring to the FDA and CDC's discussion on myocardial events, Szarfman writes, "**I am not astonished that MGPS was unable to detect these signals.**"[170] Once again, she reiterates the strength of her and DuMouchel's new data mining system, noting that one month ago, "we documented that RGPS signals [acute myocardial infarction]."[171]
  - Szarfman eventually alerts Forshee, a high-ranking CBER official, about her findings relating to statistically significant safety signals for acute myocardial infarction and invites him to collaborate with her on her upcoming paper about masking.[172] It is unclear whether Forshee responds.[173]

- **July 9, 2021:** Szarfman calls Forshee to discuss increased risk of mortality following COVID-19 vaccination.[174]

- **July 12, 2021:** Following her July 9 phone call, Szarfman writes Forshee, "As we talked over the phone, I became aware last Fri[day] that scientists from Cornell are concerned of an increased mortality signal with the COVID-19 vaccines."[175] **Szarfman encloses DuMouchel's earlier RGPS analysis, showing statistically significant safety signals for "death and sudden death" associated with the Pfizer and Moderna COVID-19**

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[165] *Id.*
[166] COVID-19 Timeline, Centers for Disease Control and Prevention, https://www.cdc.gov/museum/timeline/covid19.html.
[167] PSI-HHS-000001640809; PSI-HHS-000001622854-55.
[168] PSI-HHS-000001622854; PSI-HHS-000001639129-34 at 33.
[169] PSI-HHS-000002208944-45.
[170] PSI-HHS-000002208944.
[171] *Id.*
[172] *Id.*
[173] *Id.*
[174] PSI-HHS-000002199145-46; PSI-HHS-000004592364-65 (with attachment).
[175] PSI-HHS-000004592364-65 (with attachment).

vaccines.[176] She writes that the method DuMouchel used "automatically unmask[s] signals that remain hidden by other data mining methodologies, including MGPS[,]" FDA's current data mining methodology.[177]

- **July 13, 2021:** Forshee documents his contact with Szarfman and forwards her email and DuMouchel's analysis to Marks, noting that, "**she and Bill DuMouchel had found an increased risk of mortality following COVID-19 vaccination using data mining methods.**"[178] Forshee writes that he is "very concerned" with how Szarfman and DuMouchel may be interpreting their findings.[179] Marks thanks Forshee for "documenting this" and tells Forshee that he "will follow up appropriately."[180]

- **Aug. 11, 2021:** Menschik informs CDC officials that FDA will limit its distribution of its data mining reports "largely for data security reasons."[181]

- **Aug. 12, 2021:** Szarfman attends a call with Commonwealth, the contractor that runs FDA's data mining system, and apparently raises concerns about the current methodology.[182] Szarfman reportedly tells the contractor that "'the 20-year-old MGPS model could potentially mask signals.'"[183] Baer, who participated on the call, reports Szarfman's comments to Zinderman and Menschik and informs them that she told Szarfman that Zinderman and Menschik are aware of her considerations.[184]

- **Aug. 23, 2021:** FDA approves the Biologics License Application ("BLA") for Pfizer's Comirnaty COVID-19 vaccine for ages 16 and older.[185]

- **Sept. 3, 2021:**
    - Commonwealth employees, Brian Hendrix and James Sydnor, follow up with Szarfman from an earlier conversation, informing her that for questions regarding data mining runs, she needs to speak with Menschik or Baer directly.[186] Szarfman subsequently clarifies her masking concerns with the contractors, writing, "[t]herefore the background will only be for covid-19 vaccines, instead of for other vaccines. **Therefore, masking covid-19 vaccine signals that are common with these vaccines,** but not common across other types of vaccines."[187]

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[176] *Id.* (emphasis added).
[177] *Id.* That same day, Forshee forwards Szarfman's email and DuMouchel's analysis to Anderson. PSI-HHS-000004590546-47 (with attachment).
[178] PSI-HHS-000004588545-46 (with attachment); PSI-HHS-000004592364-65 (with attachment).
[179] PSI-HHS-000004588545-46.
[180] PSI-HHS-000002199145.
[181] PSI-HHS-000005524064.
[182] PSICOVID_00017545.
[183] *Id.*
[184] *Id.*
[185] BLA approval, Food and Drug Admin., Aug. 23, 2021, https://www.fda.gov/media/151710/download?attachment; COVID-19 Timeline, Centers for Disease Control and Prevention, https://www.cdc.gov/museum/timeline/covid19.html.
[186] PSI-HHS-000008254473-74.
[187] PSI-HHS-000008254472 (emphasis added).

- Hendrix responds to Szarfman, adding Menschik and Baer to the email chain for their awareness.[188] Szarfman replies directly to Menschik, reiterating the advantages of RGPS compared to MGPS.[189] She explicitly writes, "**RGPS is much, much better at unmasking signals than MGPS.** It automatically identifies and corrects for confounders. **This is an important function to have, given the pandemic situation.**"[190]

- **Sept. 8, 2021:** Menschik and Zinderman draft a response to Szarfman's previous email, and Menschik sends it to her.[191] In his email to Szarfman, Menschik underscores that VAERS data mining is CBER's responsibility and must be only conducted through that office (Szarfman is a CDER employee, not a CBER employee).[192] However, Menschik appears to acknowledge a limited issue with MGPS, separate from masking, that he plans to review further within CBER.[193] He also writes, "[**a**]**ny further discussion on VAERS data mining methods/findings outside my chain of command will have to be offline and in general terms**, as well as without reference to any specific VAERS [adverse events]."[194]

- **Sept. 14, 2021:**
  - Anderson and Nair draft an email regarding Szarfman's data mining activities that Anderson eventually send to Marks.[195]
  - In the email, Anderson takes issue with Szarfman's efforts and access to CBER data "given that she is a CDER employee."[196] He notes, "we have concerns about her communicating data mining findings using CBER VAERS data to CBER and non-CBER personnel."[197] Anderson requests that Szarfman "refrain[s] from using her FDA email or communicating data mining findings using CBER VAERS data[.]"[198]
  - Anderson appears to acknowledge the masking issue Szarfman has previously raised.[199] Rather than take immediate steps to adjust FDA's system to address Szarfman's concerns, Anderson suggests taking a "retrospective approach" to determine if safety signals were missed only after receiving reports of adverse events through active surveillance systems.[200] Given that FDA failed to detect the

[188] *Id.*
[189] PSI-HHS-000008254471.
[190] *Id.* (emphasis added).
[191] PSI-HHS-000008253098; PSI-HHS-000008253959; PSI-HHS-000008252951; PSI-HHS-000008253958; PSI-HHS-000008267103; PSI-HHS-000008254470.
[192] PSI-HHS-000008254470.
[193] *Id.*
[194] *Id.* (emphasis added).
[195] PSICOVID_00014054-55; PSI-HHS-000002213753-54.
[196] PSI-HHS-000002213753-54.
[197] *Id.*
[198] *Id.*
[199] *Id.*
[200] *Id.*

safety signal for myocarditis months earlier, it is unclear what further evidence was needed to trigger a reevaluation of FDA's current data mining system.[201]

- **Sept. 15, 2021:**
  - Marks forwards Anderson's write-up concerning Szarfman's data mining efforts to CDER Director Patrizia Cavazzoni, to whom Szarfman reports, and writes, "I really am sorry to bother you with this, but issue is [*sic*] become a major distraction. . . . **Ana Szarfman[] has decided on her own to do vaccine analysis using VAERS** as part of her work at FDA. She is, however, not doing this in collaboration with our CBER statisticians, and quite to the contrary, **has been asked to cease and desist,** because the strategy that she is using **could create erroneous conflicts that feed in to anti-vaccination rhetoric.**"[202]
  - CDER Office of New Drugs Director Peter Stein replies to Marks, "[T]hanks for flagging this – we've made it clear to her that she should not be discussing or providing internal analyses externally, and needs to focus on her assigned work." He closes his email, "Hopefully, you won't have further surprises…."[203]

- **Sept. 22, 2021:**
  - Menschik writes to John Su, a CDC official and member of the Vaccine Safety Team and Vaccine Safety Technical Work Group, and appears to identify limitations within FDA's data mining system.[204] Menschik describes the masking effect, the exact data limitation that Szarfman had been raising for months at FDA.[205] Although Menschik does not credit Szarfman, he echoes her concerns in draft language Menschik shares with Su for an article reviewing the safety of the COVID-19 vaccines.[206]
  - Menschik's draft language notes that FDA's current data mining system "has multiple limitations," including that, "**disproportionately scores** . . . **can be muted by COVID-19 vaccine reports contributing substantially to the comparator group,** particularly if both mRNA COVID-19 vaccines are associated with the same adverse event."[207] Menschik tells Su that he is "happy" to discuss further by phone.[208]
  - Su acknowledges the concern in a response email, noting that signal detection with VAERS data "has always been tricky business" and that those who work with VAERS frequently are "mindful of those limitations[.]"[209]

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[201] See Chairman Ron Johnson, Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination, Permanent Subcomm. on Investigations, May 21, 2025, https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-toWarn.pdf.
[202] PSI-HHS-000002213753 (emphasis added).
[203] PSI-HHS-000002213752-53 (ellipses in original).
[204] PSI-HHS-000008268909.
[205] *Id.*
[206] *Id.*
[207] *Id.* (emphasis added).
[208] *Id.*
[209] *Id.*

- **Oct. 29, 2021:** FDA expands EUA for the Pfizer COVID-19 vaccine for children ages 5-11.[210]

- **Jan. 3, 2022:** FDA grants EUA for Pfizer COVID-19 boosters for children ages 12-15 and a third primary series dose for children ages 5-11 who are immunocompromised.[211]

- **Jan. 31, 2022:** FDA fully approves Moderna COVID-19 vaccine for individuals ages 18 and older.[212]

- **Feb. 18, 2022:**
    - Following FDA's apparent decision "not to reconsider authorization" of Moderna's COVID-19 vaccine EUA for adolescents ages 12-17, FDA official Sarah Walinsky sends an invitation for a virtual meeting to Marks and other FDA officials to discuss how to respond to Moderna's appeal.[213] Walinsky attaches several items to the meeting invitation including a recent email between FDA officials discussing how to respond to Moderna and whether FDA should push Moderna "towards a BLA submission instead of an EUA submission."[214] One FDA official notes that FDA's current draft response to Moderna appears to justify its decision to not authorize the vaccine because "there is not an emergency need for the Moderna vaccine for this pediatric population, especially given the data suggesting an increased myocarditis risk compared to the currently available vaccine for this population (Pfizer)."[215]
    - Walinsky also attaches a preprint version of Szarfman's forthcoming paper, "Signaling COVID-19 Vaccine Adverse Events" (which appears to be a finalized version of the earlier draft titled, "Masking Associated with Early COVID-19 Vaccine Safety Surveillance"), which discusses the increased detection of the myocarditis signal for the COVID-19 vaccines when using the RGPS method.[216] It is unclear why Walinsky circulated the preprint and whether the meeting took place.

- **June 17, 2022:** FDA issues EUAs for the Moderna COVID-19 vaccines to all children as young as 6 months old and the Pfizer COVID-19 vaccines to children ages 6 months to 4 years old.[217]

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[210] FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age, Food and Drug Admin., Oct. 29, 2021, https://web.archive.org/web/20211029200859/https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age.
[211] COVID-19 Timeline, Centers for Disease Control and Prevention, https://www.cdc.gov/museum/timeline/covid19.html.
[212] *Id.*
[213] PSI-HHS-000001617192-93; PSI-HHS-000001626344-45; PSI-HHS-000001626448-49.
[214] PSI-HHS-000001626344-45.
[215] *Id.*
[216] PSI-HHS-000001627327-77.
[217] Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age, Food and Drug Admin., June 17, 2022,

- **June 23, 2022:** Authors including Szarfman and DuMouchel, publish their paper on masking titled "Signaling COVID-19 Vaccine Adverse Events" in the journal *Drug Safety*.[218]

- **July 8, 2022:** FDA approves supplemental BLA for the Pfizer COVID-19 vaccine, authorizing its use for children ages 12 to 15 years old.[219]

- **July 12, 2022:** Zinderman sends a weekly data mining report to his colleagues at FDA, including Menschik and Nair, and to a limited number of senior CDC officials, including Tom Shimabukuro and John Su.[220] Based on records reviewed by the Subcommittee, this appears to be the final weekly data mining report FDA distributes for the COVID-19 vaccines.

- **July 17, 2022:** Szarfman emails her paper entitled "Signaling COVID-19 Vaccine Adverse Events" to then-FDA Commissioner Robert Califf, noting that it describes "advances in the data mining (DM) methodology, especially the capacity to unmask hidden signals due to previously unaccountable confounders[.]"[221] Upon receipt of this and another article, Califf simply replies, "Thanks. These are good."[222]

- **Aug. 5, 2022:** In response to an FDA official's question regarding sending COVID-19 vaccine data mining to CDC, Menschik confirms to his FDA colleagues, "[W]e are no longer routinely sending COVID data mining to CDC[.]"[223] Menschik notes that Nair had previously discussed this decision with CDC official Shimabukuro.[224]

- **Aug. 31, 2022:** Forshee writes to Marks and Anderson, notifying them about Szarfman being a co-author on "Signaling COVID-19 Vaccine Adverse Events."[225] He references that they are discussing best ways to address "a number of issues with the paper and its findings[.]"[226] Forshee references Szarfman's earlier efforts in 2021, where she raised concerns about FDA's current data mining system.[227]

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https://web.archive.org/web/20220617140937/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children?utm_medium=email&utm_source=govdelivery.

[218] Rave Harpaz et al., Signaling COVID-19 Vaccine Adverse Events, Drug Safety (2022), https://link.springer.com/article/10.1007/s40264-022-01186-z.

[219] COVID-19 Timeline, Centers for Disease Control and Prevention, https://www.cdc.gov/museum/timeline/covid19.html; Supplement BLA approval, Food and Drug Admin., July 8, 2022, https://www.fda.gov/media/159727/download?attachment.

[220] PSI-HHS-000001217046 (with attachment).

[221] PSI-HHS-000004461747-48.

[222] *Id.*

[223] PSI-HHS-000008266854.

[224] *Id.* After Menschik informs his colleagues that FDA is no longer routinely sending the data mining to CDC, one FDA official responds, "I was also hoping we would stop doing that at some point!" *Id.*

[225] PSI-HHS-000004594929; Forshee attaches Marks' September 2021 email to Szarfman's supervisors Cavazzoni and Stein. PSI-HHS-000004604858-59.

[226] PSI-HHS-000004594929.

[227] *Id.*; PSI-HHS-000004604858-59.

- **Sept. 30, 2022:** Nair writes to his FDA colleagues that he suggested to CDC earlier that summer that "we discontinue the routine regular [weekly data mining] emails."[228] Nair adds, "[t]his was intended as a timesaving measure and to reduce email traffic."[229] He informs his colleagues that FDA decided to end its weekly reporting email because "it had been some time that we had had a data mining alert that required further evaluation, CDC agreed with this approach."[230] Nair pointed out, however, that "FDA is still regularly conducting data mining for all approved/authorized vaccines."[231]

- **Nov. 26, 2022:** CDC officials discuss how they no longer receive weekly data mining reports from FDA.[232] One official notes, "**I think that because of the FOIAs [Freedom of Information Act requests] we may have asked FDA to stop sending these weekly data mining outputs.**"[233] A CDC official eventually writes to Menschik requesting the most recent data mining report.[234]

- **Nov. 28, 2022:**
    - Menschik emails Nair about how to respond to CDC's request.[235] Menschik notes that FDA has "concerns about sharing our data mining output externally given history including **over reliance on data mining output[.]**"[236]
    - Menschik warns that the data mining results may be "misconstrued" because the detection of "signals," or lack thereof, could lead to a false conclusion.[237] Because of these issues in addition to the masking limitations, Menschik argues against sharing the data that CDC requested and states that FDA's "standard practice" relies on "assigned reviewers" to evaluate potential safety findings "in the context of other available data" prior to sharing any safety signal information.[238]

- **Dec. 1, 2022:** Nair responds to the CDC official, incorporating many of Menschik's points that appear to downplay FDA's reliance on EB data mining.[239] Nair writes, "Results from data mining are considered hypothesis generating and do not, by themselves, demonstrate causal associations."[240] He adds that little can be attained from the presence of a safety signal, or lack thereof, and notes that even the use of the terms

[228] PSI-HHS-000001160286.
[229] *Id.*
[230] *Id.*
[231] *Id.*; Per Chairman Johnson's March 23, 2026 highlighting the FDA's detection of ischemic stroke following COVID-19 vaccination, it appears FDA did regularly conduct data mining runs. Letter from Sen. Ron Johnson, Permanent Subcomm. on Investigations to Robert Kennedy, Secretary, Dep't of Health and Human Services, March 23, 2026, https://www.ronjohnson.senate.gov/services/files/CA500350-195E-472C-9F26-BE93B290B9D9.
[232] PSI-HHS-000002480132.
[233] *Id.* (emphasis added).
[234] PSICOVID_00015642-43.
[235] *Id.*
[236] *Id.* (emphasis added).
[237] *Id.*
[238] *Id.*
[239] PSICOVID_00014435.
[240] *Id.*

"signal and/or safety signal have certain connotations and may trigger actions so we try not [*sic*] conflate data mining alerts with signals."[241]

- **Oct. 27, 2023:** Nair responds to concerns about masking in FDA's data mining system raised by Judy Maro, a Harvard professor working with FDA and CDC officials.[242] In his response, he writes, "**We were aware of this limitation before and during the pandemic.** There are many data mining tools and **there was some discussion about utilizing a novel tool to adjust for this.** However, we thought it would be problematic to use a brand new, possibly unvalidated tool in the context of an EUA. We ended up using the same EBGM [Empirical Bayes Geometric Mean] data mining we use for all vaccines and has a long history of use rather than take an experimental approach."[243]

- **March 15, 2024:**
    - Approximately three years after Szarfman raised concerns about the masking limitation in FDA's data mining system as a result of the large number of COVID-19 vaccine reports, FDA officials including Nair, Menschik, and Zinderman discuss the masking effect.[244] Nair writes, "I know in the past we have discussed one of the possible limitations of data mining currently is the vast number of VAERS reports from the COVID vaccines may limit our ability to detect statistical alerts because disproportionality scores may be driven towards the null."[245] Nair asks his colleagues if they know of any publications discussing the masking limitation of data mining.[246]
    - In response to Nair, Zinderman writes, "I recall Anna [*sic*] talking about masking in the few interactions we had with her, but I don't remember there being references."[247]
    - Following Zinderman's email, Baer writes to Menschik only and attaches the "Signaling COVID-19 Vaccine Adverse Events" paper coauthored by Szarfman, DuMouchel.[248] She attaches the paper for Menschik's consideration because she believes it could be relevant to Nair's request for public references to the masking limitation.[249] She follows up later that day providing two specific examples of articles cited in Szarfman's and DuMouchel's paper but ultimately defers to him on whether to share with Nair as resources.[250]
    - Later, Menschik responds to Nair's original email and recalls providing the CDC with language addressing the masking issue for a draft safety article, but "it now appears that they took it out before publication."[251] This is likely a reference to the draft language Menschik previously shared with CDC official Su on Sept. 22,

[241] *Id.*
[242] PSI-HHS-000001136460-64.
[243] PSI-HHS-000001136460 (emphasis added).
[244] PSI-HHS-000008261793-94.
[245] *Id.*
[246] *Id.*
[247] PSI-HHS-000008261793.
[248] PSI-HHS-000008263353.
[249] *Id.*; PSI-HHS-000008261793.
[250] PSI-HHS-000008261793.
[251] PSI-HHS-000001152913.

2021.[252] It is unclear whether Menschik provides the articles Baer sent to him.

- **Sept. 26, 2024:**
  - Following a discussion about data mining with Oracle contractors, Baer writes to Menschik about the RPGS algorithm.[253] Baer notes that when she compared results of the RGPS and MGPS models for the Gardasil vaccine, she found that the RGPS model yielded "significantly higher" numbers than the MGPS model for certain adverse events.[254] She also found that the RGPS numbers were higher than MGPS numbers for certain adverse events associated with the Pfizer COVID-19 bivalent vaccine.[255]
  - Baer also mentions Szarfman's 2022 paper about the masking limitation in data mining and appears to acknowledge that the lower numbers from the MGPS model were a result of masking.[256] She writes, "I understand the theory behind masking and trying to adjust for it, but I feel that comprehending the details of the approach and, importantly, which approach is 'better,' is beyond my training and experience. I think someone with more data mining expertise would have to be involved in that decision."[257]
  - In response to Baer, Menschik appears to concur with Baer's finding and writes that "in general the [RGPS model] appears way more sensitive in that its scores are generally higher than corresponding [MGPS model] scores when sampling different [adverse events]."[258] Despite his apparent acknowledgment that RGPS addresses the masking limitation of MGPS, Menschik appears to express his preference for continuing to use MGPS.[259]

[252] PSI-HHS-000008268909.
[253] PSI-HHS-000008253424.
[254] *Id.* It is unclear what adverse events Baer reviewed that were associated with the Gardasil vaccine.
[255] *Id.* It is also unclear what adverse events Baer reviewed that were associated with the Pfizer COVID-19 bivalent vaccine.
[256] *Id.*
[257] *Id.*
[258] *Id.*
[259] *Id.*

III. Glossary

Key Figures

Anderson, Steven—Director, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, FDA.

Baer, Bethany—Division of Pharmacovigilance, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, FDA.

Califf, Robert—Commissioner, FDA (Feb. 2022-Jan. 2025).

Cavazzoni, Patrizia—Director, Center for Drug Evaluation and Research, FDA.

DuMouchel, William—Chief Statistician, Oracle.

Forshee, Richard—Associate Director for Research/Acting Deputy Director and later Deputy Director, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, FDA.

Hendrix, Brian—Empirica Signal system, Contractor, Commonwealth Informatics.

Marks, Peter—Director, Center for Biologics Evaluation and Research, FDA.

Maro, Judy—Associate Professor, Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute.

Menschik, David—Associate Director for Surveillance Informatics, Division of Pharmacovigilance, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, FDA.

Nair, Narayan—Division Director, Division of Pharmacovigilance, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, FDA.

Niu, Manette—Acting Branch Chief, Division of Pharmacovigilance, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, FDA.

Shimabukuro, Tom—Deputy Director and later Director, Immunization Safety Office, CDC; and later, Deputy Director, Influenza Division, Center for Immunization and Respiratory Diseases, CDC.

Sydnor, James—Empirica Signal system, Contractor, Commonwealth Informatics.

Stein, Peter—Director, Office of New Drugs, Center for Drug Evaluation and Research, FDA.

Stockbridge, Norman—Division Director, Division of Cardiology and Nephrology, Center for Drug Evaluation and Research, FDA.

Su, John—Immunization Safety Office, CDC; and later Deputy Director and Acting Director, Immunization Safety Office, CDC.

Szarfman, Ana—Medical Officer, Safety Data Mining Developer and Medical Informatics Analyst, Division of Cardiology, Hematology, Endocrinology, and Nephrology, Center for Drug Evaluation and Research, FDA.

Walinsky, Sarah—Acting Chief of Staff, Center for Biologics Evaluation and Research, FDA.

Weber, Robert—Product Management Director and Head of Signal Detection and Management Working Group, Oracle.

Zinderman, Craig—Associate Director for Medical Policy, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, FDA.

Key Terms

Empirica Signal—Oracle's software platform, which utilizes EB data mining, used by FDA for data mining.[260]

Empirical Bayesian ("EB") Data Mining—The data mining method utilized by federal health agencies to identify statistical associations between products and adverse events.[261]

Masking—Sometimes referred to as "muting," masking is a statistical phenomenon in which the volume of adverse event reports from a similar drug or vaccine product drowns out reports from other drug or vaccine products, thus distorting the baseline group being compared to the drug or vaccine of interest being screened.[262] This may result in safety signals for adverse events going undetected.[263]

Multi-item Gamma Poisson Shrinker ("MGPS")—The EB data mining algorithm used by FDA. MGPS was originally developed by William DuMouchel in 1999.[264]

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[260] User Guide and Online Help, "About the Oracle Empirica Signal Application," Oracle, April 1, 2025, https://docs.oracle.com/en/industries/life-sciences/empirica/2025.4.01/userguide/empirica-signal-application.html.
[261] Data Mining at FDA – White Paper, Food and Drug Admin., Aug. 20, 2018, https://www.fda.gov/science-research/data-mining/data-mining-fda-white-paper.
[262] Rave Harpaz et al., Signaling COVID-19 Vaccine Adverse Events, Drug Safety, June 23, 2022, https://link.springer.com/article/10.1007/s40264-022-01186-z.
[263] *Id.*
[264] William DuMouchel, Bayesian Data Mining in Large Frequency Tables, With an Application to the FDA Spontaneous Reporting System, Am. Stat., (Aug. 1999), https://www.researchgate.net/publication/254331086_Bayesian_Data_Mining_in_Large_Frequency_Tables_with_an_Application_to_the_FDA_Spontaneous_Reporting_System_Reply; See also Emeri Potter et al., FDA Adverse Event Reporting System (FAERS) Essentials: A Guide to Understanding, Applying, and Interpreting Adverse Event Data Reported to FAERS, Clin. Pharmacol. Ther., May 19, 2025, https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.3701.

Regression-Adjusted Gamma Poisson Shrinker ("RGPS")—First outlined in a 2012 Oracle white paper by William DuMouchel, RGPS is an update to MGPS that controls for masking effects.[265]

[265] William DuMouchel and Rave Harpaz, Regression-Adjusted GPS Algorithm (RGPS), Oracle, Nov. 2012, https://docs.oracle.com/health-sciences/empirica-signal-811/ESIUG/Regression-Adjusted_GPS_Algorithm.pdf; Rave Harpaz et al., Signaling COVID-19 Vaccine Adverse Events, Drug Safety, June 23, 2022, https://link.springer.com/article/10.1007/s40264-022-01186-z.

IV. Appendix – Chairman Johnson's Oversight of COVID-19 Vaccines

Timeline of Chairman Johnson's Relevant COVID-19 Vaccine Adverse Event Oversight

- **April 27, 2021**: During a meeting with then-National Institutes of Health ("NIH") Director Dr. Francis Collins, Sen. Johnson asks him about the alarming number of adverse event reports in VAERS, particularly the more than 2,900 deaths worldwide reported within 30-days of vaccination, **Collins responded "Senator, people die**."[266]

- **June 28, 2021**: Letter from Sen. Johnson and Sen. Mike Lee to CDC Director Dr. Rochelle Walensky and FDA Acting Commissioner Dr. Janet Woodcock raising concerns about several hundred individuals who reported experiencing an adverse event after receiving a COVID-19 vaccine.[267]

- **July 13, 2021**: Letter from Sen. Johnson to Collins, Walensky, and Woodcock regarding vaccine safety monitoring systems described in the October 2020 VRBAC meeting. Sen Johnson, writes, "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**."[268]

- **Nov. 2, 2021**: Sen. Johnson holds a panel discussion on vaccine mandates featuring doctors, medical researchers, and vaccine injured.[269]

- **Oct. 14, 2021**: Letter from Sen. Johnson to Collins, Walensky, Woodcock, Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research at FDA, and Dr. Tom Shimabukuro, Deputy Director of the Immunization Safety Office at CDC regarding federal health agencies' safety surveillance systems and reports of adverse events following COVID-19 vaccination.[270]

- **Dec. 29, 2021**: Letter from Sen. Johnson to Woodcock and Walensky regarding specific "hot lots" of COVID-19 vaccines associated with increased reports of adverse events.[271]

- **Jan. 24, 2022**: Sen. Johnson leads a roundtable entitled, "COVID-19: A Second Opinion." At the event, Sen. Johnson documents 1.05 million adverse events, and 22,000 deaths connected to the COVID-19 vaccines.[272]

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[266] Available at https://www.ronjohnson.senate.gov/services/files/17788FED-A947-4143-8C1B-95C59E60EE87 at 2.
[267] Available at https://www.ronjohnson.senate.gov/services/files/EB95C952-175D-405C-8247-AD40FB742DEF.
[268] Available at https://www.ronjohnson.senate.gov/services/files/17788FED-A947-4143-8C1B-95C59E60EE87.
[269] Available at https://www.ronjohnson.senate.gov/vaccine-side-effects-and-mandates.
[270] Available at https://www.ronjohnson.senate.gov/services/files/7EC06E87-9F6F-4E22-8877-8D519CF25A32.
[271] Available at https://www.ronjohnson.senate.gov/services/files/F564153D-89FD-40C9-A1B1-8663C22D2F0A.
[272] Available at https://www.ronjohnson.senate.gov/vaccine-side-effects-and-mandates.

- **March 1, 2022**: Letter from Sen. Johnson to Walensky reiterating outstanding requests for information on COVID-19 including data on adverse events and vaccine lot variation data.[273]

- **March 23, 2022**: Letter from Sen. Johnson to HHS Secretary Xavier Becerra, FDA Commissioner Dr. Robert Califf, National Institute of Allergy and Infectious Diseases Director Dr. Anthony Fauci, and Walensky highlighting the over 1 million reports of adverse events on VAERS and what steps are being taken to address these reports. Sen. Johnson writes, "As of March 18, 2022, VAERS has received 1,183,495 worldwide reports of adverse events and 25,641 death reports. Of those deaths, 7,382 (28.8%) occurred on day 0, 1, or 2 following vaccination."[274]

- **June 23, 2022**: Letter from Sen. Johnson to Walensky requesting CDC provide vaccine safety data, including any EB data mining analyses, created as part of its vaccine safety monitoring efforts.[275]

- **July 25, 2022**: Letter from Sen. Johnson to Walensky reiterating request for June 23, 2022 request for vaccine safety data, including EB data mining analyses.[276]

- **Sept. 12, 2022:** Letter from Sen. Johnson to Walensky in response to CDC producing only public Proportional Reporting Ratio analyses and failing to respond to requests for EB data mining analyses.[277]

- **Dec. 7, 2022**: Sen. Johnson leads a roundtable entitled, "COVID -19 Vaccines: What They are, How they Work, and Possible Causes of Injuries." At the event, Sen. Johnson documents 1.47 million adverse events, and 32,000 deaths connected to the COVID-19 vaccines.[278]

- **Jan. 10, 2023**: Letter from Sen. Johnson to Walensky reiterating requests for EB data mining analyses and other vaccine safety data first requested in June 2022.[279]

- **April 20, 2023**: Letter from Sen. Johnson to Becerra and Carole Johnson, Administrator of the Health Resources and Services Administration regarding Countermeasures Injury Compensation Program claims by individuals for COVID-19 vaccine injuries.[280]

- **Sept. 5, 2023**: Letter from Sen. Johnson to Califf requesting FDA produce all EB data mining analyses related to the COVID-19 vaccines.[281]

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[273] Available at https://www.ronjohnson.senate.gov/services/files/018E3CF9-DCE9-4F0D-836B-DC4DD9866FF2.
[274] Available at https://www.ronjohnson.senate.gov/services/files/08942E5E-4220-48A9-B989-9D5947C10BB4.
[275] Available at https://www.ronjohnson.senate.gov/services/files/9914278B-A73B-4434-8349-91091138E18B.
[276] Available at https://www.ronjohnson.senate.gov/services/files/D48FBED6-BDF3-4FB7-8B24-D52A2EDCE39E.
[277] Available at https://www.ronjohnson.senate.gov/services/files/0CBE044E-4F2C-47F2-8272-4DB4F14D3359.
[278] Available at https://www.ronjohnson.senate.gov/vaccine-side-effects-and-mandates.
[279] Available at https://www.ronjohnson.senate.gov/services/files/AB68101B-CDA4-49F1-8174-4274DDEB0120.
[280] Available at https://www.ronjohnson.senate.gov/services/files/A80C5322-F694-4803-BC15-BE3B0D4708D1.
[281] Available at https://www.ronjohnson.senate.gov/services/files/0E2CC41F-6202-4124-A7F6-8491E864FB23.

- **Sept. 5, 2023**: Letter from Sen. Johnson to Becerra reiterating requests for information on CICP claims by individuals reporting vaccine injuries following a COVID-19 vaccine.[282]

- **Oct. 25, 2023**: Letter from Sen. Johnson to Califf, Becerra, CDC Director Dr. Mandy Cohen, and NIH Acting Director Lawrence Tabak reiterating earlier requests for vaccine safety information and requesting additional vaccine safety information, including information on myocarditis and pericarditis after vaccination.[283]

- **Dec. 21, 2023**: Letter from Sen. Johnson to Becerra, Califf, and Cohen highlighting that the deaths per million doses of COVID-19 vaccines are approximately **55 times greater than for deaths per million doses of flu vaccines** and requesting all Proportional Reporting Ratio and EB data mining analyses for the COVID-19 vaccines.[284]

- **Jan. 12, 2024**: Letter from Sen. Johnson to Califf and Cohen highlighting the issue of higher rates of adverse events connected to specific manufacture lots of COVID-19 vaccine and reiterating requests from December, including the request for all EB data mining analysis on COVID-19 vaccines.[285]

- **Feb. 26, 2024**: Sen. Johnson leads a roundtable entitled, "Federal Health Agencies and the COVID Cartel: What are They Hiding?"[286]

- **Sept. 4, 2024**: Letter from Sen. Johnson to Califf and Cohen regarding a study finding increased all-cause mortality following receipt of the Moderna mRNA COVID-19 vaccine and requesting mortality data related to COVID-19 vaccines from federal health agencies.[287]

- **Nov. 19, 2024**: Letter from Sen. Johnson to Becerra, Califf, and Cohen highlighting heavily redacted records released through the Freedom of Information Act ("FOIA") connected to federal health agencies knowledge of the risks of myocarditis and pericarditis following an mRNA COVID-19 vaccine and requesting unredacted copies of these records.[288]

- **Dec. 5, 2024**: Letter from Sen. Johnson to Becerra, Califf, and Cohen highlighting additional heavily redacted FOIA records connected to federal health agencies' knowledge of the risks of myocarditis and pericarditis following an mRNA COVID-19 vaccine and requesting unredacted copies of these records.[289]

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[282] Available at https://www.ronjohnson.senate.gov/services/files/241E701E-A91E-4B82-B4A8-FF233A3C5C98.
[283] Available at https://www.ronjohnson.senate.gov/services/files/8989A37B-49B7-4E87-827F-9BE74D00D06A.
[284] Available at https://www.ronjohnson.senate.gov/services/files/0D09CBFB-7A6E-426F-813D-F89DFC4E2EFD.
[285] Available at https://www.ronjohnson.senate.gov/services/files/603DE6AC-5F83-4226-8A69-0BB5DCDA6841.
[286] Available at https://www.ronjohnson.senate.gov/2024/2/icymi-sen-johnson-leads-roundtable-discussion-federal-health-agencies-and-the-covid-cartel-what-are-they-hiding.
[287] Available at https://www.ronjohnson.senate.gov/services/files/32B052BE-2606-4118-9833-BD0F255867C0.
[288] Available at https://www.ronjohnson.senate.gov/services/files/00AAFB3D-72EE-475F-94D5-66708B4AA86D.
[289] Available at https://www.ronjohnson.senate.gov/services/files/CCEF4C60-FA50-4A57-804B-D4CA2F835C41.

- **Jan. 28, 2025**: Chairman Johnson subpoenas HHS for records connected to COVID-19 vaccines, including EB data mining and vaccine safety monitoring.[290]

- **May 21, 2025**: PSI releases its interim report titled, "Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination," detailing how federal health officials knew about the risks of myocarditis and pericarditis after an mRNA COVID-19 vaccine and failed to properly alert the public to those risks.[291]

- **Dec. 15, 2025**: Letter from Sen. Johnson to Secretary of HHS Robert F. Kennedy, Jr. regarding Dr. Vinay Prasad's, the Director of the Center for Biologics Evaluation and Research, memorandum on deaths of children following a COVID-19 vaccine.[292]

- **March 23, 2026**: Letter from Sen. Johnson to Secretary of HHS Robert F. Kennedy, Jr. detailing findings that in late 2022, federal health officials identified, and subsequently ignored and downplayed, a risk of ischemic stroke in individuals age 65 years and older who received the Pfizer COVID-19 bivalent booster and raising concerns about masking in EB data mining used to monitor COVID-19 vaccine safety.[293]

[290] Available at https://www.ronjohnson.senate.gov/services/files/8FAB9531-F799-4067-BA1C-AB8CA182D100.
[291] Available at https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-to-Warn.pdf.
[292] Available at https://www.ronjohnson.senate.gov/services/files/AFDAD3A2-D789-46ED-B895-16341762156A.
[293] Available at https://www.ronjohnson.senate.gov/2026/3/psi-chairman-johnson-reveals-further-evidence-of-biden-administration-downplaying-covid-19-vaccine-safety-risk.