Children's Health Defense

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The Honorable Ron Johnson
Chairman

The Honorable Richard Blumenthal
Ranking Member

Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
United States Senate

Please find below my, Dr. Karl Jablonowski, written testimony for the U.S. Permanent Subcommittee on Investigations hearing titled, "Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals."

Introduction

My research at Children's Health Defense has been focusing on bringing about an end to childhood epidemics. In its course I have gained insight into the promise, pitfalls, and failings of pharmacovigilance systems that the United States relies upon to effectuate pharmaceutical safety in the population.

A vaccine clinical trial phase 1 and 2 involve up to a few hundred very healthy people, to make sure it's safe enough for phase 3, involving a few thousand very healthy people. All of it orchestrated by the pharmaceutical company that stands to profit. By the time it is FDA approved, if a bad reaction is uncommon we're not going to see it in a few-thousand person study - but, like how not every single cigarette causes cancer, the dangers are still real. We simply do not know what adverse events will look like in a diverse large population until vaccines are administered to a diverse large population. In essence, the clinical trial never ends, it's just that the population becomes the subjects of the uncontrolled experiment. We had better be watching awfully closely - that is pharmacovigilance.

Our knowledge of the safety of the mRNA vaccine prior to the issuance of the Emergency Use Authorization was poor. Pfizer did not perform a drug-drug interaction study, so they had no idea if the vaccine would interact with another drug and have an effect. Pfizer also did not

perform a cardiovascular toxicity study, or a central nervous system toxicity study, or evaluate the toxicity of other organs like the liver, kidneys, or even blood toxicity. They did not perform a genotoxicity study to see if DNA would be affected or a carcinogenicity study to see if the vaccine may cause cancers. Technically they did a reproductive toxicity study[1], but not one that followed good laboratory practices and would not normally be accepted for approval considerations. Animal and in vitro studies are not sufficient to substantiate health-related claims, and neither are poorly tracked mandated population-wide vaccines.

Pharmacovigilance behind-closed-doors should give everyone pause. It is simply too important to not do it correctly and timely. Lapses can be, and were, catastrophic.

The Promise of the Vaccine Adverse Event Reporting System

VAERS was instituted and administered jointly by the FDA and the CDC as a result of the National Childhood Vaccine Injury Act of 1986[2]. The impetus of passing the Act was the large number of our nation's children being vaccine injured by the childhood DTP vaccine.

There are two major successes of VAERS.

Wyeth-Lederle's (acquired by Pfizer) RotaShield® was approved in August 1998 as the first vaccine to prevent rotavirus infections in infants[3]. It was recommended as a 3-dose series at 2-months, 4-months, and 6-months of age. There was a higher than expected number of reports for intussusception, a life-threatening bowel obstruction, to VAERS. This initiated a multi-state investigation that concluded an increase 20-30 times over expected risk 2-weeks following the first dose and 3-7 times over expected risk 2-weeks after the second dose. Pre-licensure trials included 5 intussusception cases of the 10,054 vaccinated (all after second or third dose), and 1 of the 4,633 placebo recipients. Though this represents a higher odds ratio, it was not deemed statistically significant (unadjusted OR 2.30 (95%CI: 0.27-19.73, p-value=0.446)[4]). RotaShield® was suspended in July 1999 and fully withdrawn from the U.S. market in October 1999[5].

Lederle Laboratory was the primary manufacturer in the 1990s of the Oral Polio Vaccine (OPV), recommended at 2-months, 4-months, and 6-months of age. It is a live-virus vaccine. The wild-type poliovirus is grown in non-human primate (monkey) kidney cells at cold temperatures. This selects for mutations that allow the virus to replicate well in cooler temperatures, such as cell cultures or the human gut. The human brain is about 2-degrees celsius warmer than the core temperature in healthy adults, and the cold-adapted vaccine strain is less likely to thrive in neural tissue. There is, however, the risk of mutations reverting the virus lineage to a neurovirulent form, resulting in Vaccine-Associated Paralytic Poliomyelitis (VAPP). By the mid-1990s, the only polio paralysis cases in the U.S. were vaccine related[6]. In January 1997,

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[1] Christopher J Bowman et al., "Lack of Effects on Female Fertility and Prenatal and Postnatal Offspring Development in Rats with bnt162b2, a mRNA-Based COVID-19 Vaccine," *Reproductive Toxicology* 103, (2021): 28–35, doi: 10.1016/j.reprotox.2021.05.007

[2] https://www.congress.gov/bill/99th-congress/house-bill/5546

[3] https://archive.cdc.gov/www_cdc_gov/vaccines/vpd-vac/rotavirus/vac-rotashield-historical.htm

[4] https://www.medcalc.org/en/calc/odds_ratio.php

[5] CDC, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5334a3.htm accessed April 26, 2026

[6] https://www.cdc.gov/mmWR/preview/mmwrhtml/00045949.htm

the ACIP changed the recommendation surrounding the poliovirus vaccine based partly on VAERS reports. The new recommendation excluded OPV in favor of Inactivated Polio Virus (IPV) vaccine for infants at 2-months and 4-months of age.

The Pitfalls of the Vaccine Adverse Event Reporting System

VAERS is a passive volunteer-based surveillance system. Anyone may submit a VAERS report, and for any degree of suspicion that an adverse event is related to a vaccine. VAERS reporting is available to all, and is not limited to the discretion of medical care givers.

Its design may be considered appropriate in 1986, with 1986 technology, where the primary transmission of documents was the U.S. Postal Service or telefacsimile. In the information-age there is an unacceptable disconnect between a VAERS report and the medical records of the affected person.

Biases are inherent in the passive volunteer-based surveillance system, and New Hampshire is a good example of this. According to VAERS, New Hampshire has the highest per-capita infant mortality rate in the country[7]. According to national statistics New Hampshire sits at the second lowest infant mortality rate in the country. It is reasonable to interpret these seemingly contradictory statements as both: New Hampshire does a good job in keeping their infant population healthy, and New Hampshire reports infant deaths to VAERS.

Revealed in Part 5[8] of the Honorable Ron Johnson's data release on March 25th, 2026[9] is an estimation of how much time is dedicated to each report. On page 8 of the document and slide 8 of Dr. Narayan Nair's presentation titled "Artificial Intelligence and Division of Pharmacovigilance" is an estimate of "~20,000 serious reports/reviewer (~385 per week)". This indicates that a reviewer of serious reports processes an estimated 20,000 per year or an estimated 385 per week. Assuming a 40-hour work week, this translates into one serious report every 6 minutes 14 seconds. Dr. Nair notes on the next line, all boldface, "~28-fold increase in serious adverse events" from pre-Covid era. In a contract between the CDC and General Dynamics Information Technology (GDIT), the CDC predicted that the "total number of reports received during periods of peak activity (which are not expected to reflect sustained activity) is expected to be 1,000 reports per day, with up to 40% of the reports serious."[10] According to monthly status reports from GDIT, in January 2021, the number of incoming reports rose to over 2,500 per day[11]. The bottleneck of processing and the magnitude of reports to be processed

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[7] https://rumble.com/v58lqpp-ep.6-right-on-point-podcast-w-wayne-rohde-karl-jablonowski-phd.html?start=783

[8] https://www.ronjohnson.senate.gov/services/files/32FB3363-DFD1-453C-88FC-BE53E324F93E

[9] https://www.ronjohnson.senate.gov/2026/3/psi-chairman-johnson-reveals-further-evidence-of-biden-administration-downplaying-covid-19-vaccine-safety-risk

[10] Children's Health Defense, https://childrenshealthdefense.org/wp-content/uploads/CDC.GDIT-Contract-Summer-2020.pdf accessed April 25, 2026

[11] Children's Health Defense, https://childrenshealthdefense.org/wp-content/uploads/CDC.GDIT-Status-reports.pdf accessed April 25, 2026

created a lag-time of several months between report date and input date[12]. Those months were the most important several months in pharmacovigilance history.

The largest pitfall of VAERS is that the CDC, which co-administers it, doesn't even take it, or the human suffering each report represents, seriously. Of mortalities associated with the COVID-19 vaccine it wrote, one of the worst lines CDC has ever written, in the Lancet - Infectious Disease, "The concentrated reporting of deaths on the first few days after vaccination follows patterns similar to those observed for other adult vaccinations. This pattern might represent reporting bias because the likelihood to report a serious adverse event might increase when it occurs in close temporal proximity to vaccination."[13] All of VAERS is a collection of adverse events "in close temporal proximity to vaccination." Though no critical reader would have the take-away, the paper was cited by at ACIP's meeting of May 19, 2022 as supporting "[n]o unusual clustering of causes of death associated with U.S. authorized COVID-19 vaccines"[14].

The Failing of the Vaccine Adverse Event Reporting System

A failed Standard Operating Procedure:

According to the Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021)[15], section 2.3.1 Proportional Reporting Ratio (PRR)[16], "CDC will perform PRR data mining on a weekly basis or as needed." The CDC chose to ignore their own Standard Operating Procedure and not run the distinct analysis during the early months of the vaccine rollouts.

PRR represents a rudimentary level of sophistication, and is described in Table 4[17]. As Dr. Tom Shimabukuro puts it, "PRR is a simple (maybe overly simplistic) mathematical calculation. There are no technical limitations to doing PRR, it's easy, and there are plenty of data in VAERS to do PRR whenever we want to and on whichever vaccines we choose."[18] In response to a Children's Health Defense FOIA request, the CDC revealed PRR analysis from March 25, 2022 through July 31, 2022. The above e-mail demonstrates that the CDC Immunization Safety Office members, Dr. Tom Shimabukuro and Dr. John Su, were seemingly unaware that CDC had been running PRR analysis for 90 days, and would continue to run it for another 38 days.

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[12] Rose J. Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System?. Science, Public Health Policy and the Law. 2021 Oct 01; v3.2019-2024
https://publichealthpolicyjournal.com/critical-appraisal-of-vaers-pharmacovigilance-is-the-u-s-vaccine-adverse-events-reporting-system-vaers-a-functioning-pharmacovigilance-system/

[13] Rosenblum, H. G., Gee, J., Liu, R., Marquez, P. L., Zhang, B., Strid, P., Abara, W. E., McNeil, M. M., Myers, T. R., Hause, A. M., Su, J. R., Markowitz, L. E., Shimabukuro, T. T., & Shay, D. K. (2022). 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. Infectious diseases*, *22*(6), 802–812. https://doi.org/10.1016/S1473-3099(22)00054-8

[14] https://www.youtube.com/watch?v=Zhod_rH2Kw8&t=4763s

[15] 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

[16] *Id.* p.16

[17] *Id.* p.16

[18] Part 8, p.144,
https://www.ronjohnson.senate.gov/services/files/9F5B0145-6120-4DC7-8451-FB6D31BB0D3F

In response to Children's Health Defense FOIA request, the CDC stated "[t]he results of the PRR analysis within the time period mentioned above were generally consistent with empirical Bayesian data mining, revealing no additional unexpected safety signals."[19] This statement is hard to reconcile given PRR analysis produced 743 clinically relevant signals and EB data mining produced 3[20].

A Standard Operating Procedure that is "dynamic and subject to change without notice"[21] is a failed Standard Operating Procedure.

Failure of Empirical Bayesian Data Mining:

Rosenblum et al.:

Rosenblum et al.[22] (Rosenblum) is a study of the first 6 months of the US COVID-19 vaccination program, utilizing VAERS and v-safe. The study has 14 CDC authors, most of whom are in the Immunization Safety Office. It was originally[23] to include two from the FDA - specifically contributing EB data mining results - showing nothing of interest as an attestation of safety of the mRNA vaccines. It was cleared by both CDC (and their Office of Science) and the FDA before being submitted for publication at The Lancet Infectious Disease. The Lancet's editor reviewed it and passed it along to 6 reviewers, an end-product of "the most extensive safety analysis in U.S. history."[24] Not a single person in this chain questioned the appropriateness of EB data mining…until, and only, Reviewer #5. They wrote "[f]or the disproportionality analysis we have no information on the dataset. What were the vaccines included in the dataset? What was the proportion of COVID-19 vaccines?...If this proportion is over 90% the possibility of identifying a signal was likely close to zero."[25]

That is: the Immunization Safety Office at the CDC, the people who should know something about the safety of vaccines, and the EB data mining team at the FDA, the only people running a surveillance report on VAERS, just tried to get "the most extensive safety analysis in U.S. history" published and were stopped by Reviewer #5…the only person in this entire chain who

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[19] Children's Health Defense, https://childrenshealthdefense.org/wp-content/uploads/CDC-letter-re-PRR-v.-EB-Mining.pdf accessed April 26, 2026

[20] Jablonowski, K., Evans, R., Hooker, B., 2025. The Pharmacovigilance Betrayal of the COVID-19 Era. Medical Research Archives, 13(5). https://doi.org/10.18103/mra.v13i5.6505

[21] Children's Health Defense, https://childrenshealthdefense.org/wp-content/uploads/CDC-letter-re-PRR-v.-EB-Mining.pdf accessed April 26, 2026

[22] Rosenblum, H. G., Gee, J., Liu, R., Marquez, P. L., Zhang, B., Strid, P., Abara, W. E., McNeil, M. M., Myers, T. R., Hause, A. M., Su, J. R., Markowitz, L. E., Shimabukuro, T. T., & Shay, D. K. (2022). 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. Infectious diseases*, *22*(6), 802–812. https://doi.org/10.1016/S1473-3099(22)00054-8

[23] Part 9, p.179-216, https://www.ronjohnson.senate.gov/services/files/7DD643F9-BF66-4923-B791-7766870C8856

[24] https://www.cdc.gov/vaccine-safety-systems/monitoring/covid-19.html

[25] Part 9, 1.131, https://www.ronjohnson.senate.gov/services/files/7DD643F9-BF66-4923-B791-7766870C8856

seemed to think the limitations of EB data mining means the absence of a signal does not mean the absence of a hazard.

Because of Reviewer #5, EB data mining and the two FDA authors, were stripped out of this paper. Dr. David Menschik was one of the FDA authors, and wrote to the first-author "[w]e acknowledge this in the limitations and understand that there is a considerable bias towards the null when using our data mining methods in this current, unprecedented situation."[26]

The FDA is saying the only system monitoring VAERS doesn't work in this "unprecedented situation" - meaning the pathetically tested COVID vaccines pushed onto the country generated a half-million VAERS reports in the first few months - far outpacing all reports over the last 30 years. This isn't a blind-spot, the FDA was completely blind to COVID-19 vaccine adverse events. The CDC chose to ignore their own Standard Operating Procedure and not run a distinct monitoring program, in favor of the FDAs. It was figuratively, the blind leading the blind and dressed up as "the most extensive safety analysis in U.S. history."

Dr. Menschik knew of the limitations prior to publication. In an email to Dr. John Su, he wrote "disproportionately [sic] scores…can be muted…particularly if both mRNA COVID-19 vaccines are associated with the same adverse event", and warned of not putting "excess value on the absence of a signal"[27]. He's probably alluding to myocarditis, which never flagged in the EB data mining system. To which Dr. John Su responded "[s]ignal detection with VAERS data has always been tricky business."[28]

The first-author, to make sure she got it right, e-mailed Dr. Menschik "...you're saying that the sheer volume of COVID-19 vaccine reports basically washes out the possibility of finding disproportionality…"[29] to which Dr. Menschik responded "I think you've got the main point...data mining has blind spots…"[30] Again, this isn't a blind-spot, the FDA was completely blind to COVID-19 vaccine adverse events. And the CDC wasn't even looking.

Dr. Menschik was actually the individual who ran the weekly reports and sent them out. In weekly EB data mining emails to Dr. John Su and Dr. Tom Shimabukuro (both also authors on the paper). It included attached slides[31] that discuss the limitations, the same slides every single week. Those limitations are, essentially just because we don't see it, doesn't mean it's not there, and the entire system can be used for screening and hypothesis generation only.

Failure to pass the scrutiny of Reviewer #5 is an indication that the only system monitoring VAERS fails to monitor for safety. The FDA authors withdrawing their contribution to the study is an admission, acknowledging that the multimillion dollar per year pharmacovigilance system isn't working.

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[26] *Id.* p.126
[27] *Id.* p.178
[28] Part 3, p.6, https://www.ronjohnson.senate.gov/services/files/70DB86AF-8620-49A3-ABE2-18FFA3C57968
[29] Part 9, p.120-121, https://www.ronjohnson.senate.gov/services/files/7DD643F9-BF66-4923-B791-7766870C8856
[30] *Id.* p.120
[31] Part 10, p160, https://www.ronjohnson.senate.gov/services/files/F92FBB0A-CCFD-412A-A02D-243AA1844D6E

Yih et al.:

In October of 2023 CDC asks the FDA if they would like to be co-authors on a tinnitus paper utilizing EB data mining, Yih et al.[32] (Yih).

After reading their plan Dr. Judith Maro, Associate Professor at Harvard, was blunt: "It will be mostly useless to try to make statements about the COVID vaccines because the database will have so many COVID reports that you can't create a comparator."[33]

Dr. John Su responded privately, "I don't know the methods well enough to address Judy's comments"[34]. A co-author, Dr. Nair, wrote "[w]e could report our data mining findings and just acknowledge this as a limitation (this is what we have done in other papers)."[35] And that is what they did. Yih was published in the American Journal of Otolaryngology, concluding "these findings do not support an increased risk of tinnitus following COVID-19 vaccination" and includes EB data mining, for which one of the authors - Dr. Judith Maro, has already said "it will be mostly useless to try to make statements about COVID vaccines".

Co-author, Dr. Brian Hooker, and I have submitted a letter to the editor of the publishing journal. In it we highlight the authors' dismissive consideration of the masking effect inherent in EB data mining of COVID-19 vaccines in VAERS. We conclude that the fact-pattern is meritorious of a review concerning retraction, in part or in whole, of the study. As of this writing, the editor of the journal has sent it for peer review.

Failure to learn:

The overall theme, not only does CDC not understand the limitations of EB data mining, they are not learning. Before Rosenblum was written, on myocarditis, Shimabukuro wrote on June 3rd 2021: "This stuff is kind of like a foreign language to me. I get it conceptually, but I can't explain the mathematical details."[36] Later (June 22nd), in a direct message to Dr. Frank DeStefano: "I'm perplexed that myocarditis isn't alerting for either of the mRNA vaccines. I'm wondering if it's getting washed out in the half million reports."[37]

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[32] Yih, W. K., Duffy, J., Su, J. R., Bazel, S., Fireman, B., Hurley, L., Maro, J. C., Marquez, P., Moro, P., Nair, N., Nelson, J., Smith, N., Sundaram, M., Vasquez-Benitez, G., Weintraub, E., Xu, S., & Shimabukuro, T. (2024). Tinnitus after COVID-19 vaccination: Findings from the vaccine adverse event reporting system and the vaccine safety datalink. *American journal of otolaryngology*, *45*(6), 104448. https://doi.org/10.1016/j.amjoto.2024.104448

[33] Part 4, p109-110, https://www.ronjohnson.senate.gov/services/files/6102048F-D934-4511-8CA4-DFFB06DE6F8E

[34] Id. p.108-109

[35] Id. p.108

[36] Id. p.104

[37] Part 9, p118, https://www.ronjohnson.senate.gov/services/files/7DD643F9-BF66-4923-B791-7766870C8856

Why then use EB data mining as an attestation of safety in Rosenblum, or Yin, or an MMWR report on the safety in adolescents aged 12-17 years[38], or on pregnancy adverse events in the journal of Vaccine[39]?

Failure to learn the limitations of EB data mining is disturbing. The Immunization Safety Office of the CDC has been taught the limitations by: the failure to detect myocarditis in 2021[40]; Reviewer #5 of Rosenblum in 2022[41]; Dr. Judith Maro in 2023[42]. The office still continues to publish into 2024 utilizing the lack of EB data mining signal as an attestation of safety.

A simple explanation of EB data mining begins with a Proportional Reporting Ratio, just like the one the CDC chose not to produce. That will have a lot of false positives, because high ratios can be driven by very few numbers. So a shrinker is applied that shrinks the high ratios with few numbers - that method is dependent upon the distribution across the entire database. The Geometric mean of the posterior distribution is the shrunken estimate of the relative reporting ratio, for which you flag as a signal if the lower 5th percentile is above 2.

The first limitation is highlighted by Reviewer #5 of Rosenblum. The expected count is based on a tiny fragment, as VAERS was grossly under-reported over the preceding 30 years. The observed is based on a huge number of reports, as the pathetically tested COVID-19 vaccines were pushed onto the country resulting in so many reports that the reporting system ground to a halt. Prior distributions across the entire dataset is going to dilute everything, or as Reviewer #5 put it, “the possibility of identifying a signal was likely close to zero.”[43]

The second limitation is that if the sudden surge of VAERS reports was from two vaccines of the same platform, like mRNA experimental gene therapy, have the same adverse events, as Dr. Menschik put it “disproportionately [sic] scores…can be muted”.[44]

The scientific community performs self-correction with varying degrees of success. If it is performed well in this context, all papers that lean on the lack of a COVID vaccine EB data mining signal to support safety will be retracted.

Failure in duty:

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[38] Hause AM, Gee J, Baggs J, et al. COVID-19 Vaccine Safety in Adolescents Aged 12–17 Years — United States, December 14, 2020–July 16, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1053-1058. DOI: http://dx.doi.org/10.15585/mmwr.mm7031e1

[39] Moro, P. L., Olson, C. K., Clark, E., Marquez, P., Strid, P., Ellington, S., Zhang, B., Mba-Jonas, A., Alimchandani, M., Cragan, J., & Moore, C. (2022). Post-authorization surveillance of adverse events following COVID-19 vaccines in pregnant persons in the vaccine adverse event reporting system (VAERS), December 2020 - October 2021. *Vaccine*, *40*(24), 3389–3394. https://doi.org/10.1016/j.vaccine.2022.04.031

[40] Part 9, p118, https://www.ronjohnson.senate.gov/services/files/7DD643F9-BF66-4923-B791-7766870C8856

[41] Part 9, 1.131, https://www.ronjohnson.senate.gov/services/files/7DD643F9-BF66-4923-B791-7766870C8856

[42] Part 4, p109-110, https://www.ronjohnson.senate.gov/services/files/6102048F-D934-4511-8CA4-DFFB06DE6F8E

[43] Part 9, 1.131, https://www.ronjohnson.senate.gov/services/files/7DD643F9-BF66-4923-B791-7766870C8856

[44] Part 9, 1.178, https://www.ronjohnson.senate.gov/services/files/7DD643F9-BF66-4923-B791-7766870C8856

Pharmacovigilance over the past several years has been insulting, and many people are injured. To add more insult to that injury, the e-mail[45] that Dr. Nair wrote to Drs. Su and Shimabukuro "We could report our data mining findings and just acknowledge this as a limitation", before that he wrote "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." He's saying that the brand new vaccines can't be monitored with a brand new tool.

That statement is made so much worse by knowing what position Dr. Nair once held, Director and Chief Medical Officer of the Division of Injury Compensation Programs, which administers the Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program. Injuries are only compensated if they can be identified as such.

Dr. Nair ends the email with "You could develop another tool that would compensate for the greater number of COVID vaccine reports. I am not sure how to do this but you would need a statistician with DM [data mining] experience. This would be beyond our capabilities at FDA." He is describing the work of Dr. Ana Szarfman (who collaborated with Dr. William DuMouchel, the inventor of EB data mining). He is describing the qualifications of Dr. Ana Szarfman. Dr. Ana Szarfman has already co-developed the tool, is amply qualified, has sent out numerous comparable analyses showing uncompensated and compensated signals, and is (at the time) employed by the FDA.

Failure that became a Betrayal:

The population of the United States is around 340,000,000[46]. A VAERS search for COVID-19 vaccine adverse event reports for the 50 states and the District of Columbia yields 853,031 (data current as of March 27th, 2026)[47]. This equates to roughly 1-in-400 Americans filing a VAERS report of having a VAERS report filed on their behalf.

Filing a VAERS report is an act of hope, and selfless hope at that. Too late for the injured, it is the hope that the knowledge of one person's injury and suffering may avert the affliction of another person's.

The culmination of those many acts of selfless hope amounted to enough evidence for a statistically significant signal of myocarditis in young males as early as the week of February 19th, 2021[48]. That was a week before even Dr. Roee Singer, Deputy Director, Division of

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[45] Part 4, p109-110, https://www.ronjohnson.senate.gov/services/files/6102048F-D934-4511-8CA4-DFFB06DE6F8E

[46] https://www.census.gov/popclock/

[47] United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 03/27/2026, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Apr 25, 2026 10:47:32 AM

[48] Delayed Vigilance: A Comment on Myocarditis in Association with the COVID-19 Injections. (2022). *International Journal of Vaccine Theory, Practice, and Research* , *2*(2), 651.1-651.4. https://doi.org/10.56098/ijvtpr.v2i2.61

Epidemiology, Israel Ministry of Health contacts the CDC stating "From the Israel vaccine adverse event monitoring team: We are seeing a large number of myocarditis and pericarditis cases in young individuals soon after [sic] Pfizer COVID-19 vaccine. We would like to discuss the issue with a relevant expert at CDC."[49] That was months before the citizens of the United States were made aware of the risk posed by the novel vaccines.

For all its EB data mining efforts, the FDA found merely 3 clinically significant signals for mRNA vaccines: a rash (mechanical urticaria), exposure via breast milk, and drug ineffective[50]. CDC did run a PRR analysis for 4-short months[51], and when they did they discovered 743 clinically significant safety signals including stroke, heavy menstrual bleeding, myocarditis, cardiac arrest, and death. "For 5-to-11 year-olds, the analysis flagged 56 symptoms, of which 20 are serious, including myo- and pericarditis. For 12-to-17 year-olds, the analysis flagged 95 symptoms, of which 45 are serious, also including myo- and pericarditis."[52]

This is *the* betrayal of our time, so vast that we cannot even count its casualties.

The Promise of V-Safe

V-safe is a smart-phone application that prompts users for health check-ins. It constitutes an active volunteer surveillance system, as it actively engages with the around 10 million volunteers who agreed to participate with the system. V-safe allows for the surveillance of subclinical indications of health outcomes associated with vaccination. The vast 10 million volunteers were distributed demographically and geographically, with the acceptable limitation of participation dependent upon smart-phone usage circa 2021.

The Pitfalls of V-Safe

V-safe's protocol document[53] from January 28, 2021 describes 10-check-box options for minor transient conditions (chills; headache; joint pain; muscle or body aches; fatigue or tiredness; nausea; vomiting; diarrhea; abdominal pain; rash, not including the immediate are around the injection site), 1-check-box for none, and a free-text field for "other". This is a system designed to collect inconsequential data. In the extreme hypothetical, if every one of the 10 million users checked every one of the 10 boxes every time they were prompted, would it have changed the multibillion dollar rollout of the emergency use authorized vaccines? My opinion is "no".

Dr. Renata Engler is distinguished in the study of vaccine-induced myocarditis among U.S. military members. Amid the possibility of biological warfare in the early 2000s the smallpox

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[50] Jablonowski, K., Evans, R., Hooker, B., 2025. The Pharmacovigilance Betrayal of the COVID-19 Era. Medical Research Archives, 13(5). https://doi.org/10.18103/mra.v13i5.6505
[51] Id.
[52] Children's Health Defense, https://childrenshealthdefense.org/defender/emails-chd-foia-government-covid-vaccine-injury-reports/ accessed on April 25, 2026
[53] p.43, https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-to-Warn.pdf

vaccine was administered to service personnel. Dr. Engler is among the researchers who characterized the myocarditis outcome of those vaccinations in a clinical review[54], a follow-up[55], a prospective study[56], and a comparative observational cohort study[57]. Dr. Engler gave a presentation to CDC on April 12, 2021[58]. For not including myocarditis into V-safe she had this to ask: "If you do not ask, you will not see it, but does that mean it does not exist?" Dr. Engler's paper "Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military"[59] was accepted for publication 50 days later on June 1, 2021. Over the next years she would have several more publications on our military's and nation's newfound myocarditis epidemic, including: case definition[60], cardiac adverse events[61], and relapsing myocarditis[62].

The Failing of V-Safe

V-safe succeeded in collecting inconsequential data, which in itself is a failure of pharmacovigilance. Among its first uses was in Rosenblum[63] study of the first 6 months of the

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[58] p.45, https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-to-Warn.pdf

[59] Montgomery, J., Ryan, M., Engler, R., Hoffman, D., McClenathan, B., Collins, L., Loran, D., Hrncir, D., Herring, K., Platzer, M., Adams, N., Sanou, A., & Cooper, L. T., Jr (2021). Myocarditis Following Immunization With mRNA COVID-19 Vaccines in Members of the US Military. *JAMA cardiology*, *6*(10), 1202–1206. https://doi.org/10.1001/jamacardio.2021.2833

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US COVID-19 vaccination program. It included a mortality assessment, dismissing "[t]he concentrated reporting of deaths on the first few days after vaccination" as "reporting bias". Instead, they chose to populate the paper with clinically inconsequential findings. The only figure of the paper is a time series analysis of both Moderna's and Pfizer-BioNTech's COVID-19 vaccine, for both dose 1 and dose 2, of: injection-site pain, fatigue, headache, myalgia, chills, and joint pain.

Though no signal for myocarditis was ever attributed to V-safe, it is with horror that we find 366 individuals typed "myocarditis" in the "other" free-text field[64], a condition requiring a medical diagnosis. The horror is amplified by the nearly 50,000 registrants who typed "chest pain" into the "other" free-text field.

Children's Health Defense contractor Thomas Yengst performed a pregnancy analysis on V-safe data. Of the 10 million participants, 104,556 women checked the pregnant box. Of those, 11,037 (or 10.6%) indicated a pregnancy difficulty. Women who checked the pregnant box and contributed free-text information numbered 36,981 (or 35.4%) of whom 3,691 (or 10.0%) indicated a miscarriage. Ten percent miscarriage rate is the upper-bound of pregnancy outcome before the woman is aware of the pregnancy. That rate drops dramatically after the fetal heart begins to function. These findings do not, by themselves, constitute a failure to warn, as the numbers as presented are explainable. These findings do, however, present V-safe's failure to explain. The CDC's and FDA's preliminary findings[65] left Americans with more questions than answers, questions still unanswered.

The Promise of the Vaccine Safety Datalink

The Vaccine Safety Datalink (VSD) is a collaboration of 13 integrated healthcare organizations covering over 15.5 million people[66]. It can detect near-real-time safety issues as they arise and most frequently use a Rapid Cycle Analysis, for example the first 21 days after vaccination compared to the subsequent 21 days could detect an adverse event of rapid onset. Its use is intended to "allow the CDC to adequately monitor vaccine safety in a scientifically rigorous manner."[67]

The datalink includes: birth date, gender, medicaid status, enrollment, immunizations, vaccine type/manufacturer/lot-number/date-of-administration, hospitalization and outpatient (date, length of stay, diagnosis code, diagnosis type), gestational age, child's weight, Apgar score, race, birth

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observational study of reports to the Vaccine Adverse Event Reporting System and v-safe. *The Lancet. Infectious diseases*, *22*(6), 802–812. https://doi.org/10.1016/S1473-3099(22)00054-8

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[65] Shimabukuro, T. T., Kim, S. Y., Myers, T. R., Moro, P. L., Oduyebo, T., Panagiotakopoulos, L., Marquez, P. L., Olson, C. K., Liu, R., Chang, K. T., Ellington, S. R., Burkel, V. K., Smoots, A. N., Green, C. J., Licata, C., Zhang, B. C., Alimchandani, M., Mba-Jonas, A., Martin, S. W., Gee, J. M., … CDC v-safe COVID-19 Pregnancy Registry Team (2021). Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *The New England journal of medicine*, *384*(24), 2273–2282. https://doi.org/10.1056/NEJMoa2104983

[66] p.6, https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

[67] Part 8, p.157, https://www.ronjohnson.senate.gov/services/files/9F5B0145-6120-4DC7-8451-FB6D31BB0D3F

geography, mother's date of birth, underlying cause of death, date of death, and patient's zip code[68].

The Pitfalls of the Vaccine Safety Datalink

Rapid Cycle Analysis is designed to detect adverse events of rapid onset. If the adverse event has a delayed onset, with a median onset near or beyond the risk interval, Rapid Cycle Analysis will negate it. Other options that would not be subject to delayed onset negation are rarely utilized in CDC's VSD analyses. These include vaccinated vs. unvaccinated direct comparison and pre-post (medical utilization for the same individual before vaccination and after vaccination). Both of these types of analyses would require the well-practiced extra-step of considering differences in healthcare seeking behavior.

The VSD, by nature, can only analyze clinically recognized outcomes, and, by its distribution, is made up of approximately 50% from California residents.

The largest pitfall of the VSD is not in its design, data, or mode of analysis, but in who is allowed access. This many million-dollar taxpayer funded resource is not available to any scientist outside of the 13 Managed Care Organizations (MCO) or the federal government without 13 independent IRB applications approved by all 13 MCOs, an estimated $250,000 per project. Transparency is simply unattainable, and allows for the poor practice of science free rein over vaccine safety.

The Failing of the Vaccine Safety Datalink

A true accounting of poor-quality science derived from the VSD, where the skeptical researcher may not access, would fill volumes. For expediency, it is appropriate to demonstrate from example.

Eriksen et al.[69] (Eriksen) is a study entitled "Lack of Association Between Hepatitis B Birth Immunization and Neonatal Death". It includes the notable author Dr. Frank DeStefano, at the time a medical epidemiologist at the CDC and appointed acting chief of the Immunization Safety Branch of the National Immunization Program. The study was recently cited by the ironically named Vaccine Integrity Project[70] and former CDC Director Dr. Rochelle Walensky[71] in the

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[68] *Id.* p.154

[69] Eriksen, E. M., Perlman, J. A., Miller, A., Marcy, S. M., Lee, H., Vadheim, C., Zangwill, K. M., Chen, R. T., DeStefano, F., Lewis, E., Black, S., Shinefield, H., & Ward, J. I. (2004). Lack of association between hepatitis B birth immunization and neonatal death: a population-based study from the vaccine safety datalink project. *The Pediatric infectious disease journal*, *23*(7), 656–662. https://doi.org/10.1097/01.inf.0000130953.08946.d0

[70] Ironically named Vaccine Integrity Project, Center for Infectious Disease Research and Policy, University of Minnesota, https://www.cidrap.umn.edu/sites/default/files/searchable-download/Universal%20Hepatitis%20B%20Vaccination%20at%20Birth%202Dec2025.pdf accessed April 25, 2026

[71] Ulrich, A. K., Fleming, D. F., Smith, E. A., Anderson, C. J., Mehr, A. J., Redepenning, S. G., Stoddart, C. J., Moat, L. E., Walensky, R. P., & Lackritz, E. M. (2026). Hepatitis B Vaccination at Birth: Safety, Effectiveness, and Public Health Benefit. *Pediatrics*, 10.1542/peds.2025-075783. Advance online publication. https://doi.org/10.1542/peds.2025-075783

journal of the American Academy of Pediatrics as supporting, “[n]o increase in infant deaths attributed to HepB vaccination”.

Eriksen is a publication utilizing the VSD, specifically the MCOs of both “Southern and Northern California Kaiser Permanente Health Plans of more than 350,000 live births from 1993 to 1998 and ascertained all deaths occurring under 29 days of age.” The authors compared vaccinated and unvaccinated neonates who died in the first 29 days, matched on a few characteristics, and concluded “no significant difference”.

The authors failed to match on gestational age or birthweight. The unvaccinated had a median gestation of 28 weeks (extreme prematurity) while the vaccinated had 39 weeks of gestation (full term). The unvaccinated had a median birth weight of 3 pounds while the vaccinated had a median birth weight of 6.8 pounds. It is inappropriate to consider this a vaccinated and unvaccinated study, as it is in practice a comparison between full term neonates and extreme premature and low birthweight neonates.

There are plenty of poor quality studies out there, and this is one of them with an abysmal conclusion, “[n]o increase in infant deaths attributed to HepB vaccination”, which is an untenable summary given the study’s design. What I find difficult to reconcile is that Walensky, the former CDC director, leans on it to assert the safety of the Hepatitis B birth dose. At best she never read it. Much worse she did and stands by it.

This was her initiative to demonstrate the scientific community is well-functioning, and that it establishes the Hepatitis B birth dose to be safe. She failed miserably, and in that failing actually demonstrates the counterpoints. The scientific community is NOT well-functioning surrounding vaccinations, and that the Hepatitis B birth dose has never been shown to be safe.

Conclusions

No serendipity:

The COVID-19 mRNA vaccines were, by honest accounting, pathetically tested. Prior to EUA many safety studies (drug-drug interactions, cardiovascular toxicity, central nervous system toxicity, other organ toxicity, blood toxicity, genotoxicity, carcinogenicity) were skipped. Had they turned out to be actually safe, it would have been serendipitous, a happy accident. Luck is not a pillar of public health.

Failure to look:

The largest pharmaceutical rollout in human history was the CDC’s time to shine. More so, America needed the CDC to shine. When we needed them the most, the CDC chose to ignore their own SOP and defer to the FDA.

Failure to fix the broken warning system:

The last several years is littered with examples of knowledge that the EB data mining system was incapable of effectuating pharmacovigilance. With full knowledge of its failures and

limitations, the lack of a hypothesis generating signal was still presented as an attestation of safety.

Failure to protect:

Even if public health institutions had overcome the pharmacovigilance failures and managed to warn, a warning of an approved product would be insufficient to protect the citizenry. With professional membership medical organizations (AAP, AMA, ACOG, IDSA, etc.) spinning narratives of safety, efficacy, and necessity, there is no assurance a warning would be heeded.

The landscape of freedom of choice drastically changed on September 9, 2021[72]. The most powerful threat to freedom originated domestically from the highest office of the United States government. Then President Joe Biden proclaimed the vaccines to be "safe", described "a pandemic of the unvaccinated", stated the obvious "this is not about freedom or personal choice", and then threatened everyone who would think otherwise with "our patience is wearing thin." Public health institutions needed to, and didn't, counter the coercion under extreme duress.

What's a freedom for?:

The Freedom of Information Act evasion is uncomfortably well-practiced throughout the documents produced by the subcommittee. "[M]any considerations not suited to email..."[73] and "I think that because of the FOIAs we may have asked FDA to stop sending these weekly data mining outputs"[74] are overt deprivations of Americans' freedom.

In the backdrop of evasion, even potentially honest mistakes could also potentially be practiced evasion. On May 24th, 2021 Dr. Peter Marks forwards an email from Dr. Steve Anderson on a CMS signal for pulmonary embolism and immune thrombocytopenia to Dr. Rochelle Walensky, but does so to her non-government email address[75]. Mistake or evasion is unclear. Why would the Director of CBER email the Director of CDC to her non-government email address? Why would he even have that email address?

FOIA evasion is not conduct becoming of a democratic republic, it is conduct of a government that believes it is beyond oversight of the governed. "Instituted among Men, deriving their just powers from the consent of the governed"[76] depends upon the governed to be able to give consent. The governed cannot give consent if they are being deceived; not even if they wanted to - because it wouldn't be called "consent" it would be called "submission" or "subjugation".

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[72] Miller Center, https://millercenter.org/the-presidency/presidential-speeches/september-9-2021-remarks-fighting-covid-19-pandemic accessed April 25, 2026
[73] PSI-HHS-000008251979
[74] PSI-HHS-000002480132.
[75] Children's Health Defense, https://childrenshealthdefense.org/wp-content/uploads/s_r_23-00756-FDA-Equity-Modified.pdf accessed APril 25, 2026
[76] U.S. Declaration of Independence. (1776). https://www.archives.gov/founding-docs/declaration-transcript

History's lesson:

Our understanding of signal detection was catapulted forward after the first time a U.S. military radar detected an enemy aircraft, it was ignored. Those aircraft went on to bomb Pearl Harbor. America and Congress really needed to know why our navy was destroyed while docked and our aircraft were destroyed on the ground. The ensuing investigations and growth in understanding signal detection were needed to ensure Americans would not again be put in harm's way by the failure to warn. But 79 years later, it happened again.

All mistakes made are repeatable. Time is allowing for the escape of accountability and diminishing our opportunity to learn. Either we learn the lessons we need to in order to fix our flaws from the last pandemic, or a future one. The COVID-19 pandemic created over 100 billionaires in the United States[77] and over 1,000 billionaires around the world[78]. Anything that profitable is going to repeat.

Sincerely,

Karl Jablonowski, PhD
Director of Science and Research
Children's Health Defense

[77] https://nchstats.com/billionaires-in-united-states/
Archived at http://archive.today/2026.04.25-023739/https://nchstats.com/billionaires-in-united-states/
[78] https://www.equals.ink/p/its-a-great-time-to-be-a-billionaire
Archived at
http://archive.today/2026.04.25-023636/https://www.equals.ink/p/its-a-great-time-to-be-a-billionaire

Pharmacovigilance is absolutely necessary. Our knowledge is limited, even of a vaccine that passes clinical trials of a few thousand healthy individuals. We simply do not know what adverse events look like for a diverse large population until vaccines are administered to a diverse large population. We had better be watching very closely, which is pharmacovigilance.

The vaccines were, by honest accounting, pathetically tested. Pre-EUA no studies on drug-drug interactions, cardiovascular toxicity, central nervous system toxicity, other organ toxicity, blood toxicity, genotoxicity, carcinogenicity. Had they turned out to be actually safe, it would have been serendipitous, a happy accident. Luck is not a pillar of public health.

Pharmacovigilance behind closed doors should give everyone pause. It is simply too important to not do it correctly. Lapses can be, and were, catastrophic.

That vigilance heavily depended upon three sources of data: the passive surveillance of VAERS, the active surveillance of v-safe, and the VSD, an active system linked to medical records.

V-safe was designed to collect inconsequential data. One of the first papers to publish the results was a mortality and adverse event study. The only figure of the paper was a time-series comparison from both Moderna and Pfizer, for both dose one and dose two of adverse events no one cares about: injection-site pain, fatigue, headache, myalgia, chills, and joint pain.

Dr. Renata Engler is distinguished in the study of vaccine-induced myocarditis among the U.S. military with 4 publications on the smallpox vaccine. On the CDC not including myocarditis in V-safe she asked: “If you do not ask, you will not see it, but does that mean it does not exist?” Within 50 days of that meeting Dr. Engler would start adding 4 more publications on COVID-19 vaccine associated myocarditis. The CDC already had Israel’s slides in hand.

The V-safe system had 10 million volunteers, about one-third entered free-text. Perhaps there is some horror found in the 366 individuals who typed in “myocarditis”, a condition requiring medical diagnosis. That is amplified by the nearly 50,000 registrants who typed in “chest pain”.

The Vaccine Safety Datalink is a collaboration of 13 healthcare organizations covering over 15.5 million people. It can detect safety issues within weeks and most frequently uses a Rapid Cycle Analysis, which can miss delayed onset events. Better and timely options like vaccinated vs. unvaccinated and pre-post are rarely used, and would need the well-practiced extra-step of considering differences in healthcare seeking behavior.

By the time the CDC’s webpage was updated to warn of "inflammation of the heart” 313 million doses had been administered to 173 million people in the United States, and it had just been authorized for the most vulnerable 12-15 year olds. I don’t see vigilance at work.

With VAERS, the CDC chose to ignore its own Standard Operating Procedure and not run Proportional Reporting Ratios in favor of the FDA’s, what Walensky calls “more robust” and

Shimabukuro calls “the gold standard”. VAERS had been grossly under-reported over the first 30 years, maxing out at 58,000 reports per year. In its 31st year alone VAERS logged 18-times that number. Because of this disproportionality, the FDA’s disproportionality analysis was washed out. Since both dominant vaccines were of the same platform and similar adverse events, the comparison was muted. This isn’t a blind-spot. The FDA was completely blind to adverse events and the CDC wasn’t even looking.

There was a savior in the ranks of the FDA, who: correctly identified the problem; appropriately worked with the inventor of EB data mining to create a solution; communicated the fix to everyone who would listen. The problem is, no one listened.

Luck was not on our side. The CDC failed to look. The FDA failed to fix a broken system that the CDC touted as “the gold standard”. The HHS failed to protect us, especially after freedom of choice was assaulted by the President threatening us all with “our patience is wearing thin”. FOIA evasion was well practiced, and discovered - obviously - not through a FOIA.

Simply put, during the largest pharmaceutical roll-out in human history, pharmacovigilance did not exist. That is *the* betrayal of our time, so vast that we cannot even count its casualties.