May 27, 2026

VIA EMAIL AND FDA DOCKET

Members, Vaccines and Related Biological
Products Advisory Committee
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852
CBERVRBPAC@fda.hhs.gov
FDA-2026-N-3962-0001

Re: *Docket No. FDA-2026-N-3962 for Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—United States (U.S.) 2026-2027 Formula for COVID-19 Vaccine Composition*

Dear VRBPAC Members:

We write on behalf of Informed Consent Action Network ("**ICAN**") and React19, in advance of VRBPAC's (the "**Committee**") May 28, 2026 meeting, during which the committee will make recommendations on the 2026-2027 formula for Covid-19 vaccines. We write to bring to your attention numerous deeply troubling issues concerning Covid-19 vaccines, including the treatment of individuals injured by Covid-19 vaccines in the United States—a crisis of institutional neglect that has been laid bare by congressional investigations, extensive documentation of regulatory failures, and years of hard-fought litigation to obtain safety data that federal agencies sought to conceal from the public. These issues should not and cannot be ignored in any conversation or decision-making concerning additional recommendations.

The Staggering Rate of Injury Following Covid-19 Vaccination Has Been Ignored

Since the Covid-19 pandemic, tens of thousands of individuals have contacted our firm alone reporting Covid-19 vaccine-related injuries. Separately, React19 is a network of 40,000 individuals seriously injured by a Covid-19 vaccine. The attached letter from React19 to our firm ("**React19 Letter**") contains profiles of a handful of those injured and describes the pattern of abandonment these individuals have endured.

The scale of Covid-19 vaccine injuries is also reflected in the government's own data. CDC launched V-safe, a smartphone-based monitoring system, simultaneously with the rollout of the first Covid-19 vaccine in December 2020.[1] Approximately 10 million Americans enrolled in V-

[1] https://web.archive.org/web/20220101081450/https:/www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

safe, most of whom were no doubt vaccine enthusiasts who signed up to participate in the rollout, not to report problems.[2]

When the data was finally obtained—after over two years of legal demands and federal litigation—it revealed that **7.7% of V-safe users reported needing medical care after a Covid-19 vaccine**, and **an additional 25% of users reported missing school or work or being unable to perform normal daily activities** after injection.[3] On average, each person seeking medical care sought it 2 to 3 times, and approximately 75% of those medical care visits were reported as urgent care, emergency room visits, or hospitalizations.[4]

These are not fringe figures—this is CDC's own data, from its own surveillance system, which CDC tried to hide from the public. CDC published over 40 studies on Covid-19 vaccines and when V-safe data was used, it only reported on the first week of health impact data while suppressing the full picture that showed an alarming rate of injury. The pattern of concealment extended well beyond V-safe: when ICAN submitted approximately twenty Freedom of Information Act requests to FDA and CDC on June 30, 2022, seeking the agencies' own safety signal analyses of Covid-19 vaccines, both agencies stonewalled, denied, and obstructed—forcing ICAN to file multiple federal lawsuits to obtain records that should have been readily available to the public.[5]

The System is Designed to Fail the Injured by Pretending They Don't Exist

The treatment of the Covid-19 vaccine injured in America is not merely inadequate—it is a system designed to deny them recognition, care, and compensation at every turn. Rather than receiving proper medical care, individuals who claim injury from a Covid-19 vaccine are often disparaged by the very medical community they trusted, with many doctors refusing to acknowledge their injuries. Those who dare share their experience of Covid-19 vaccine injury are often labeled anti-science and anti-vaxxers by many parts of the medical community despite having been vaccinated. For example, the case of Maddie de Garay exemplifies this pattern. Maddie is one of the injured profiles in the attached React19 letter. She was a healthy 12-year-old Pfizer clinical trial participant who ended up in a wheelchair with a feeding tube after receiving Pfizer's COVID-19 vaccine.[6] Her injuries were initially reported to FDA as merely "functional abdominal pain"—effectively a stomachache—despite the devastating reality of her condition.[7]

When the medical community learns that a child's brain may be swelling from a virus, they rush to provide treatment. But, for those who claim their child's brain is swelling from a vaccine,

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[2] https://icandecide.org/v-safe-data/ (https://perma.cc/F26E-EUY7).

[3] *Id.*

[4] *Id.*

[5] https://icandecide.org/press-release/icans-two-lawsuits-so-far-for-cdc-and-fdas-vaers-safety-signal-analyses-set-to-blow-lid-off-their-misconduct/.

[6] https://www.sirillp.com/wp-content/uploads/2024/04/FDA-emails-with-Pfizer-about-M.-deGaray-c6f24607aa9781481eae01d0d073b684.pdf (https://perma.cc/2P5B-45YV).

[7] *Id.*

they will likely be sent home and some disparaging note will be left in the child's medical record. This double standard is unconscionable—and it is compounded by the legal reality facing these individuals.

Legal Abandonment and the CICP: No Recourse for the Covid-19 Vaccine Injured

Those injured by Covid-19 vaccines face a uniquely cruel legal reality. Because, as you know but often ignore, Covid-19 vaccines have been and continue to be shielded by the PREP Act, and thus, injured individuals are barred from filing lawsuits against the manufacturers and administrators of these vaccines. And unlike recipients of fully licensed vaccines—who can at least access the Vaccine Injury Compensation Program ("**VICP**")—those injured by Covid-19 vaccines are funneled into the Countermeasures Injury Compensation Program ("**CICP**"), a program that was never designed to handle claims at this scale and that offers no hearing, no judicial review, and no meaningful due process.

The CICP has proven to be a virtual dead end—the program's denial rate has been staggering—leaving the vast majority of claimants without any compensation whatsoever.[8] To date, a total of 14,135 COVID-19 requests for benefits have been filed with CICP.[9] Of those, only 7,168 have been issued decisions and, of those, 7,066 have been denied—that is a 98.6% denial rate. There are still 6,967 requests pending review.[10] Since the pandemic, only 56 COVID-19 related vaccine injury claims have been compensated.[11] Excluding three very large outliers,[12] the average payout is a mere $7,038.90 per person for their life changing injuries[13]—this is wholly inadequate.

For these reasons and more, our firm has a current federal lawsuit that challenges the constitutionality of the CICP.[14] The lawsuit details the egregious due process violations of those injured by Covid-19 vaccines.

If the Product is Safe, Why Does it Need Immunity?

Perhaps if the CICP were a robust system that was adequately, fairly, and timely compensating all of those who were injured by Covid-19 vaccines, the issue of PREP Act immunity might not be nearly as problematic or urgent. That is not the reality. And thus, there is

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[8] https://www.ronjohnson.senate.gov/services/files/4DF802C8-DE9B-46C7-B470-37DD85569A76; 2023-09-05 RHJ to HHS re CICP follow up.pdf.

[9] HRSA, Countermeasures Injury Compensation Program (CICP) Data, (May 1, 2026), https://www.hrsa.gov/cicp/cicp-data.

[10] *Id.*

[11] HRSA, Countermeasures Injury Compensation Program (CICP) Data, Table 4 CICP Claims Compensated (Fiscal Years 2010 – 2026) as of May 1, 2026, (May 1, 2026), https://www.hrsa.gov/cicp/cicp-data.

[12] The outliers are $5,942,538.84, $370,376.00, and $370,376.00. The first outlier is a trust that is set up for a severely injured individual and the other two, with matching amounts, appear to be death benefits paid out.

[13] The range is $638.95 (min) and $5,942,538.84 (max).

[14] https://www.sirillp.com/wp-content/uploads/securepdfs/2026/05/TX-CICP-AMENDED-COMPLAINT.pdf.

a simple question that demands an honest answer: if the Covid-19 vaccines are truly safe, why do their manufacturers require complete immunity from liability?

For every other product in America, it is the mere potential of liability that drives companies to carefully evaluate product safety before going to market and to actively monitor and improve the product's safety thereafter. Companies that are financially liable for injuries want robust pre-licensure studies to avoid post-licensure liability. In contrast, companies that are not financially liable for injuries caused by their products have no financial interest in identifying safety issues pre-licensure—and that disincentive continues post-licensure.

Pfizer conducted multi-year, placebo controlled clinical trials for its most profitable drugs, because it is liable for injuries those drugs cause. But for its Covid-19 vaccine—shielded by the PREP Act—there was no such incentive.[15] The reasonable conclusion is that immunity is needed precisely because these products could be made safer and because risks are not being fully disclosed. After all, if vaccines are so safe, why do pharmaceutical companies—almost of all whom have been forced to pay out billions of dollars for misconduct related to drug products—need legal protection for injuries that vaccines will supposedly not cause?

Until this perverse incentive structure is corrected—until manufacturers are willing to stand behind the safety of their product without the shield of the PREP Act—there should be no further mandates, no further coercion, no further administration, and no further recommendation from VRBPAC or FDA of these products. If pharmaceutical companies have confidence in the safety of these vaccines, they should demonstrate that confidence by accepting liability for the injuries they cause. Until then, further distribution and recommendations should be paused pending a full accounting of the harms already inflicted and meaningful reform of the compensation system available to the injured.

The safety concerns underlying these arguments are not theoretical—they were evident from the earliest stages of the Covid-19 vaccine program.

Deaths in the Covid-19 Vaccine Clinical Trials

The problems with Covid-19 vaccines were apparent from the very beginning—in fact, they were apparent from the clinical trials themselves. In Pfizer's pivotal clinical trial, the placebo group and the vaccinated group had approximately the same number of participants, with the placebo group having slightly more participants.[16] If the vaccine prevented deaths, there should have been more deaths in the placebo group. If it had no impact on mortality, the deaths should have been roughly equal. And if the vaccine caused deaths, there should have been more deaths in the vaccinated group.

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[15] https://moneyinc.com/the-five-highest-selling-pfizer-drugs-of-all-time/ (https://perma.cc/4CBU-3JZF); https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html (https://perma.cc/7PAK-DRCV); https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states; https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases.

[16] https://www.fda.gov/media/151733/download.

Notably, the official FDA documentation states that there were 21 deaths in the vaccinated group and 17 deaths in the placebo group. **More people died in the group that received the vaccine than in the group that did not**. One would expect this finding to have raised an alarm. Instead, FDA allowed Pfizer to explain away each individual death as unrelated to the vaccine, rather than requiring a statistical comparison between the groups.[17]

When it came to evaluating whether the vaccines reduced symptoms, FDA permitted Pfizer to conduct a straightforward statistical comparison: 162 positive cases in the placebo group versus 8 in the vaccinated group—yielding the widely touted 95% efficacy rate. This statistical comparison was permitted even though there were 3,410 additional "suspected" but unconfirmed cases that were excluded from the calculation. But when the vaccinated group had more deaths than the placebo group—a result that did not fit the narrative—no such statistical comparison was permitted. Instead, Pfizer's paid researchers were allowed to use their subjective judgment to dismiss each death individually.[18]

The case of Maddie de Garay, mentioned above and referenced in the React19 letter, makes the consequences of this approach clear. Maddie was one of only 1,131 vaccinated participants in the clinical trial to authorize Pfizer's Covid-19 vaccine for children ages 12 to 15. She entered the trial as a perfectly healthy child. Within hours of her second dose, she was rushed to the emergency room and suffered cascading medical issues that left her in a wheelchair, dependent on a feeding tube, and suffering from numerous other serious health conditions.[19] When FDA learned—through others, not Pfizer—about the true severity of Maddie's condition, Pfizer's paid principal investigator simply stated he did not "feel" her injuries were consistent with a vaccine related adverse event.[20] FDA accepted this conclusion without further investigation.[21]

Dr. Peter Marks and the Suppression of Safety Signals

Perhaps nothing illustrates the institutional indifference to the vaccine injured more starkly than the conduct of Dr. Peter Marks, who led FDA's Center for Biologics Evaluation and Research (CBER)—the very unit responsible for Covid-19 vaccine safety and surveillance. What Senator Johnson's report and ICAN's litigations have now revealed is that the suppression of safety signals was not a passive failure but an active choice at the highest levels of the agency.[22]

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[17] *Id.*

[18] *Id.*

[19] https://www.sirillp.com/wp-content/uploads/securepdfs/2025/08/Ltr-to-Dr.-Paul-Richards-FDA-re-Maddie-de-Garay-dated-2022-3-8.pdf.

[20] https://www.sirillp.com/wp-content/uploads/2024/04/FDA-emails-with-Pfizer-about-M.-deGaray-c6f24607aa9781481eae01d0d073b684.pdf (https://perma.cc/2P5B-45YV).

[21] *Id.*

[22] https://icandecide.org/press-release/icans-two-lawsuits-so-far-for-cdc-and-fdas-vaers-safety-signal-analyses-set-to-blow-lid-off-their-misconduct/; https://icandecide.org/press-release/breaking-ican-acquires-critical-fda-safety-reports-concerning-covid-19-vaccines-after-years-of-litigation/.

When Dr. Ana Szarfman, a senior FDA medical officer and safety data mining developer, identified dozens of statistically significant safety signals for adverse events associated with the Covid-19 vaccines using an updated signal detection methodology, 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.[23]

Dr. Szarfman's methodology—developed in collaboration with Dr. William DuMouchel, the inventor of the algorithm underlying FDA's existing data mining system—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.[24] Subsequent analyses revealed safety signals for acute myocardial infarction, non-site specific embolism and thrombosis, dementia, and even death and sudden death associated with the Moderna and Pfizer vaccines.[25]

Rather than investigating these signals, Dr. Marks took action against the scientists who found them. In September 2021, Dr. Marks informed the former CDER Director, Dr. Cavazzoni, that Dr. Szarfman has "been asked to cease and desist" conducting her data analyses, complaining that her work had "become a major distraction."[26] Most damningly, Marks warned that Dr. Szafman's data mining could "create erroneous conflicts that feed into anti-vaccination rhetoric."[27] In other words, the concern was not whether the Covid-19 vaccines were harming people, but whether acknowledging that fact might undermine public confidence in the vaccine program.

This is the same Dr. Peter Marks who told representatives of React19 that FDA was simply not seeing the signals being asked about. (*See* React19 Letter).[28] Yet internal FDA records now make clear that his own agency was detecting these signals, and that officials under his direction were actively suppressing them, restricting access to safety data largely for "data security reasons" and ultimately ceasing the distribution of weekly data mining reports entirely.[29] As one CDC official candidly admitted, "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."[30]

The Masking Problem: Hidden Signals, Hidden Harm

FDA's existing data mining system suffered from a well-known statistical phenomenon called "masking," which according to Dr. Szarfman's peer-reviewed research, "is roughly eight

[23] https://www.ronjohnson.senate.gov/services/files/4DF802C8-DE9B-46C7-B470-37DD85569A76 at 2.

[24] *Id.*

[25] *Id.* at 2-3.

[26] *Id.* at 10.

[27] *Id.* at 3.

[28] *See also* www.therealpetermarks.com.

[29] https://www.ronjohnson.senate.gov/services/files/4DF802C8-DE9B-46C7-B470-37DD85569A76 at 10-11.

[30] *Id.* at 11.

times more likely to occur with Covid-19 vaccines than with other vaccines."[31] This means that the very system relied upon by FDA to detect safety signals was structurally incapable of detecting many of them during the Covid-19 vaccination campaign—precisely when detecting them mattered most.

Dr. Szarfman offered a solution: a "state of the art" algorithm that demonstrated "superior" performance in detecting hidden signals.[32] Yet FDA officials refused to adopt it. Instead, as one official later admitted, "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…data mining we use for all vaccines…rather than take an experimental approach."[33] The result: countless safety signals remained hidden from view while hundreds of millions of Americans received these products.

This likely explains why FDA has, to this day, refused to disclose records related to its Empirical Bayesian data mining. In fact, ICAN submitted a FOIA request to FDA for records, including communications, concerning Empirical Bayesian data mining on June 30, 2022 (approaching **four years** ago). FDA denied the request in full in August 2022. ICAN appealed that and never received a response to its appeal. Thus, ICAN sued on January 25, 2023.[34] FDA moved for an 18-month stay on September 14, 2023 and despite the fact that far more than 18 months have passed, that stay is still in place by the District Court of DC and FDA—to date—still has not produced all responsive records. This is the opposite of transparency and accountability and until FDA makes public all relevant records, VRBPAC should not vote to recommend additional Covid-19 vaccines.

Against this backdrop of suppressed safety data and institutional resistance to transparency, the Committee's own record warrants scrutiny.

Committee Bias

The public record reveals a pattern of statements by current and former Committee members that, taken together, demonstrate a deeply entrenched presumption in favor of Covid-19 vaccination—a presumption that persisted even as evidence of serious harm mounted. Consider the following:

[31] *Id*. at 4.

[32] *Id*. at 9

[33] *Id.* at 30.

[34] https://icandecide.org/press-release/icans-two-lawsuits-so-far-for-cdc-and-fdas-vaers-safety-signal-analyses-set-to-blow-lid-off-their-misconduct/.

In a December 2021 interview, Arnold Monto, MD—who served on the Committee during the pandemic and frequently serves as Acting Chair declared, "We never expected our vaccines to be so good, so effective."[35] He added unequivocally, "The data are clear: this is a safe vaccine."[36]

At the December 17, 2020 VRBPAC meeting, Hayley Gans, MD—who currently sits on the Committee—was asked by Dr. Monto whether the benefits of the Moderna vaccine outweighed its risks. Her answer was unqualified:

> I would say that the evidence that has been studied in great detail on this vaccine highly weighs any of the issues that we've seen. And I think it really supports us being able to, with the pandemic in the background, really move forward and finally provide a safe and effective way to get to herd immunity. Again, understanding that this is for 18 years and older and that obviously we need to be able to provide this to all of our population to get there, but it's a first step.[37]

In September 2021, Anna Durbin, MD, asserted that the Covid-19 "[v]accines provide protection without any of the morbidities you can get with a natural Covid-19 protection"[38]—a claim that is flatly contradicted by the tens of thousands of vaccine injury reports filed with VAERS and the lived experience of those who suffered serious adverse events.

Perhaps most striking, former Committee member Tina Tan, MD, told the public—before the first Covid-19 vaccine was even authorized—that "[s]afety should not be a legitimate concern."[39] This statement, made in the absence of any long-term safety data, exemplifies the predetermined conclusion that characterized the Committee's approach.

Taken together, these statements reveal not mere optimism but a fixed institutional conviction—one that foreclosed genuine safety inquiry and left no room for the possibility that these products could cause serious harm. It was this very "safe and effective" narrative, repeated by the Committee members entrusted with independent scientific oversight, that led millions of Americans to accept vaccination without informed consent regarding its true risks. Those who were subsequently injured were not merely harmed by a medical product; they were misled by the people responsible for evaluating it. Therefore, we ask that you each recognize and acknowledge

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[35] Jessica Glenza, *Head of US FDA's advisory group: 'We never expected Covid vaccines to be so good, so effective,'* The Guardian, (Dec. 25, 2021), https://www.theguardian.com/society/2021/dec/25/us-fda-vaccine-advisory-group-covid-vaccines-flu.

[36] *Id.*

[37] VRBPAC Committee Meeting, (Dec. 17, 2020), https://www.fda.gov/media/145466/download at 354.

[38] Katie Pearce, *Vaccines beat natural immunity in fight against COVID-19*, John Hopkins, (Sept. 10, 2021), https://hub.jhu.edu/2021/09/10/infection-from-covid-vs-vaccines/.

[39] Kristin Samuelson, *Should a COVID-19 vaccine be mandated?*, Northwestern Now (Nov. 17, 2020) https://news.northwestern.edu/stories/2020/11/should-a-covid-19-vaccine-be-mandated/ (https://perma.cc/K5TV-5G3N).

any biases you may have concerning these products. That is owed to every American who trusts and follows your recommendations.

Conclusion

The Covid-19 vaccine injured have been failed at every turn by the very institutions entrusted with their protection. The government's own surveillance data reveals alarming rates of injury that were actively concealed from the public. Clinical trial results raised mortality concerns that were dismissed without rigorous statistical analysis. Internal FDA safety signals were suppressed at the direction of senior officials. The compensation program designed to provide recourse has denied the overwhelming majority of claims. And the manufacturers of these products continue to enjoy complete immunity from liability—removing any financial incentive to review or improve safety or transparency.

The years that have passed have not mooted or diluted any of these issues; in fact, time has only brought more to light. As VRBPAC convenes to consider the 2026-2027 Covid-19 vaccine formula, we urge you to confront these realities rather than perpetuate the institutional indifference that has defined the response to date. At a minimum, no further formulations should be recommended without a full and transparent accounting of the safety signals identified to date, meaningful reform of the compensation system, and the removal of liability protections that eliminate manufacturers' incentive to prioritize safety.

ICAN, React19, our firm, and many others have not forgotten the vaccine injured, and they will not stop reminding each of you of your duties and responsibilities to the American public. It is your professional, moral, and ethical duty to understand, take seriously, and rectify the critical issues identified above. The vaccine injured (and the future vaccine injured if you continue to recommend these vaccines) deserve recognition, not silence—and we look forward to seeing that commitment reflected in your upcoming meeting.

Very truly yours,

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Enc.: React19 Letter
Cc:
Robert F. Kennedy, Jr., Secretary, HHS - [redacted]
Jay Bhattacharya, MD, PhD, Acting Director, CDC / Director, NIH - [redacted]
Kyle Diamantas, J.S., Acting Commissioner, FDA - [redacted]

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May 26, 2026
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Re: Request for Legal Representation on Behalf of the COVID-19 Vaccine Injured

Dear Mr. Siri,

I write to you in my capacity as a co-founder of React19, a nonprofit organization built by and for individuals who suffered serious adverse reactions following COVID-19 vaccination. Our 40,000 members did what our country asked and were vaccinated. We trusted the institutions built to protect us, and when things went terribly wrong, those institutions turned away.

That said, both the PREP Act and the 1986 National Childhood Vaccine Injury Act include numerous provisions ostensibly designed to not only benefit those currently suffering from vaccine injuries, but also to minimize the frequency and severity of similar future harms. These provisions impose clear obligations on federal health authorities that they have blatantly failed to undertake.

These obligations include duties to investigate and publicly disclose vaccine safety signals, maintain and act upon an effective adverse-event reporting system, update vaccine labeling and provider guidance as new risks emerge, conduct and support meaningful post-market safety research, and provide accurate risk information to the public.

To write this plainly, we are not reaching out because we are injured, but rather because of the events that occurred after our injuries.

These events describe a pattern of abandonment over the past five years that can be summarized in two acts. Beginning in early 2021, federal health officials at the NIH, FDA, and CDC privately acknowledged COVID vaccine injuries while publicly denying them. The NIH launched a COVID vaccine injury study in January, treated patients onsite with therapies it withheld from the broader medical community, and asked the injured to stay quiet until findings were publicized. They never were. The FDA was internally aware of dozens of masked safety signals while Dr. Peter Marks told React19 there were *"no signals."* By September 2021, the same month federal vaccine mandates were announced, the NIH had withdrawn from the injured community without notice and denied any study had occurred. The FDA scientist alerting superiors of the masking was ultimately silenced. For REACT19, three years of meetings with the FDA followed. Signals and significant masking of signals were acknowledged internally, but never publicly disclosed. 2023-2024 included internal communications clearly stating the FDA knew the system would mask signals significantly even before COVID. Still absolutely nothing said publicly about their system's own limitations.

It is clear that there was temporal overlap between React19's independent reporting to the FDA, the NIH's study findings, external medical research findings conducted through the CAALM citizen's petition and concerns by Dr. Szarfman regarding the masking of serious adverse events by the faulty data mining procedures surfacing at the FDA. Neuropathic and autonomic disorders, pulmonary embolism, sudden cardiac death, autoimmune conditions, deaths: the same emerged from three independent sources, all in 2021.

The second act began in early 2025, when the new administration brought reassurances, hopes of CICP reform, proper disclosure of COVID vaccine adverse events, a vaccine injury clinic at the NIH, ACIP recommendations, and research funding. None have materialized. HHS CICP reform was quickly abandoned. FDA's investigations into child deaths were "leaked" without full disclosure. A promised further investigation by FDA head Makary in cardiac and neuro-immune complications abruptly halted. FDA reviews for expanded use for time-critical access to therapeutics with FDA's CDER Director, Dr. Tracey Beth Hoeg ended with her firing. In a clear change in direction, a promised February 2026 ACIP meeting to review COVID vaccine injury was cancelled, rescheduled, and then cancelled again. Ultimately the committee was disbanded entirely. No public statements have been made on the condition nor public commitments, no roundtables, no committees to evaluate the condition and fund research initiatives.

The pattern of private acknowledgment and public silence has continued, under different leadership, unchanged. **More details can be found under Appendix I.*

The NIH researchers clearly stated that early recognition and intervention are key for these serious adverse events. It doesn't take a data scientist to see the problem: you can't find what you're not looking for, and you can't see what you're willfully blind to.

We are asking you to consider a possible cause of action based on these unacceptable statutory violations. Attached to this letter, you will find a list of current React19 members we believe have been egregiously harmed by the government's continuing failure to honor these obligations – their conditions were made significantly worse resulting in unnecessary death, permanent disability, avoidable bankruptcy, homelessness, and avoidable years of additional pain and suffering. Each of these individuals has volunteered to serve as a plaintiff, not only for their own benefit, but also for the thousands of other similarly situated Americans in desperate need of relief.

As noted above, we remain grateful for your past efforts on behalf of the vaccine injured. Should you have any questions regarding our current request, please do not hesitate to let me know.

With urgency and hope,

Co-Founder | REACT19
[redacted]

PROFILES OF THE INJURED

5.5 years later, help has never come.

16-year-old male, TX - Five days after a single Pfizer dose, he collapsed in front of his best friend while running across a parking lot to play basketball. He passed away from sudden heart failure. His autopsy reports high levels of inflammation in his heart, liver, and other organs. An FDA investigation was carried out in 2025, but the findings were never disclosed. His father, who had sole custody of his son, is struggling daily trying to continue to live without his son. (Ernesto Ramirez JR) https://youtu.be/XNUba1k7kew?si=EZSJHKUy5zwZg0ur

18-year-old male, PA – High school student. Within 2 days of his 2nd shot, he was admitted to the ER for concerning symptoms, while there he then had sudden cardiac failure. He was life-flighted to a bigger hospital and by the time he landed, he was in multiple organ failure. He died just one week after his high school graduation. Medical providers discouraged an autopsy or post mortem investigation be conducted. His mother has testified to the US House, and her senators for help, with no substantive response. "Nobody could understand why an 18 year old boy would be in cardiac arrest." (Roman) https://rumble.com/v3t4ai8-laurie-kumontis-mother-of-roman-rep-smucker-house-briefing-oct-17-2023.html

19-year-old male, MN - At 15 years old, thriving star swimmer, mandated to compete. Diagnosed with POTS, MCAS, hypermobility spectrum disorder, chronic fatigue syndrome, and chronic sinusitis post 2 Pfizer vaccines. Previously healthy and no medical conditions or concerns. Athlete with college aspirations now struggles with severe fatigue and brain fog, chemical and environmental sensitivities, gastrointestinal problems, dehydration, dizziness, exercise intolerance. (mother Susan Snyder) https://youtu.be/KffKxgqZ1hc?si=3dGI_DvGrqKWjoYj

26-year-old male, PA – Talented composer and college student now permanently disabled due to flaccid paralysis, severe spasticity. Now has to be under supervision 24/7, care provided by his single mother and his brother who has also put his life on hold to ensure he is safe and cared for. His mother testified to the US House and to her home senator, with her disabled son next to her in a broken wheelchair, while no response or help was given. The staff left his family in the room with the broken wheelchair in the Senate buildings. His young now severely disabled condition has maxed out all the resources of the family, but they continue to stay by his side. (Andre Cherry, mother Judith Cherry) https://rumble.com/v3srls0-andre-cherry-react19-rep-smucker-house-briefing-oct-17-2023.html

26-year-old male, FL - Antiphospholipid syndrome and six strokes since 2021.
He was offered life saving/rescue Eculuizumab treatment as he developed life threatening complications despite Rituxumab and IVIG treatment- which he awaited four years- but the hospital and his attending hospital hematologist will not proceed without vaccines- including additional dose of COVID vaccine, despite previous life-threatening reaction.. He has now requested hospice. His mother is rallying him to keep his will to fight going. (Cody Hudson, mother Heather Hudson) https://rumble.com/v367yzb-cody-hudson.html

34-year-old male, TX – Young father of a 6-year-old son, diagnosed with ALS a fatal neurodegenerative disease. His brother championed his brother's case doing everything he could to help improve his brother's life including a trip to the NIH where he was studied with several servicemembers who also were suffering with ALS after vaccination. His brother helped him be the recipient of the Neuralink that is helping him a bit. His champion passed away unexpectedly, leaving him without his greatest support, left with extremely limited financial resources. Most importantly this illness has robbed him of time, those precious years with his son. (Jake Schneider) https://www.youtube.com/watch?v=rx0apNO9Deg

34-year-old male, WA - Was healthy and active tech executive with no significant medical history. He received his first Pfizer COVID-19 vaccine on April 20, 2021. Six days later he shared that he was experiencing a severe headache that persisted for several days. He passed away shortly after from a thoracic aortic dissection. His mother shared his story with Peter Marks (FDA) in 2022. No follow-up was provided by the FDA. (Victor Simoes, mother Henrietta Castillo-Simoes) https://rumble.com/v250fak-react19-reveals-severe-vaccine-side-effects-that-the-fda-is-hiding.html?start=62

36-year-old male, WA - After his second covid vaccine he experienced 20 cardiac arrests within 18 hours and is now effectively crippled. 5 years later that number is now 39. His heart continues to have extreme failure, despite a defibrillator internally placed. He wants to believe "Persistence is Key" but without any competent care or help, his life-threatening condition continues to decline. He needs serous intervention to stop the sudden cardiac failure that severely impacts his quality of life. (Sean Ryan) https://youtu.be/p19atQmEq1o?si=1FuwHQyLBKtjqJrx

36-year-old female, TN – Physical therapist, used to be the busy mom of three active kids. She has been life-flighted seven times, buried in medical expenses from multiple hospital stays and surgeries. Wheelchair-bound and using her skills as a PT to push beyond, and a permanent breathing tube to combat the constant barrage of spasms that constrict her airway. She wants to continue to live to see her three children grow up, despite the many government barriers that continue to make it extremely difficult for her to get financial and medical support. (Nikki Holland, DPT) https://rumble.com/v3srg76-dr.-nikki-holland-react19-rep-smucker-house-briefing-oct-17-2023.html

42-year-old male, MN – Young father and active duty military veteran. Severe GBS after Pfizer, medically induced coma, woke up not being able to move. His baby boy was put on his chest in the hospital, as a motivator to fight for his life. ICU for weeks, followed by months of intensive rehab. Lost all financial resources. Permanently disabled but doing everything he can to have a few more moments with his son. No CICP compensation, no help from senators. (Drew Jameson) https://youtu.be/-G3jGGKI5ns?si=iGEePCKKvDmAsuUQ

46-year-old female, OH – Registered nurse and young mom, working in hospice home care during pandemic. Threatened benefits reduction along with incoming mandate. Transverse myelitis left her severely permanently disabled, no federal compensation, no NIH support. Requires oxygen and can only ambulate very short distance with a walker. Without any federal guidance, due to continued failure of body systems including cardiovascular, respiratory and immune , doctors had also gave up on her, referring her to hospice/palliative care in 2024, to make her comfortable until she dies. REACT19 intervened and helped her get therapies that were previously given by the NIH. With

those therapies there is no longer a need for hospice as an option. Condition rapidly declines when current medical and federal regulations interfere with access to those therapies. Treatment and medication costs over $200k per year just to keep her alive. (Danielle Baker) https://youtu.be/eAsloiHQwXs?si=iGbWspAW7qrlv-3n

60-year-old male, NY – Totally healthy newly retired. First shot triggered a TIA. Second shot resulted in multiple hospitalizations revealed swollen lymph nodes, an enlarged spleen, low platelets, and rapid weight loss, but no cancer was detected. Despite extensive testing and treatment, including steroids, chemo, and blood transfusions, his condition deteriorated. HLH was suspected. He ultimately passed away after suffering severely without help over 6 months. His wife and family are devastated. After providing an update to VAERS on his death, the family was sent annual reminders to update VAERS on his condition. "He's dead." She told them over and over. The notices for updates on his health from VAERS kept coming. (Daniel Brown, wife Elizabeth) https://rumble.com/v2hlxrg-dearly-discarded-21-liz-brown.html

69-year-old female, CA - retired physician developed tremors, twitching, brain fog, severe burning neuropathy, Mast Cell Activation Syndrome, POTS, pericarditis, post exertional malaise, tinnitus, double vision following one dose of the Pfizer Covid vaccine over 5 years ago and continues to suffer to this day with many debilitating symptoms. She communicated extensively with the FDA and NIH starting in late December of 2020 on behalf of herself and many others injured by the vaccines. Her pleas for help fell on the deaf ears of Peter Marks, Janet Woodcock, Anthony Fauci, Avindra Nath, Rochelle Walensky and others. She was one of 23 vaccine injured studied by the NIH and then abandoned by them. Their promises to her to notify the public of these vaccine injuries never happened. She continues to advocate for the injured and fight for the truth about Covid vaccine injuries. (Dr. Danice Hertz) https://youtu.be/tyHkW59LeWc?si=6eAjpKaFFqyjTT5d

13-year-old male, NC – Developed severe disabling neurological and systemic symptoms following Covid-19 vaccination, eventually becoming partially paralyzed, wheelchair dependent, and largely bedbound with profound weight loss and physical decline. The illness was initially treated as psychological, including admission to a psychosomatic/psychiatric unit, despite continued deterioration. After extensive medical treatment, including IVIG and later surgery, the patient gradually stabilized and regained significant function. (Anonymous)

14-year-old female, NY - Previously an honor student and varsity soccer athlete. Loved many different competitive sports. Wanted to be a doctor. Now… utterly disabled. Diagnoses include severe POTS, ME CFS, MCAS, PANS which has caused debilitating psychiatric symptoms, polyneuropathies causing numbness and tingling, cognitive decline requiring cognition / memory therapy, insomnia. Currently relies upon a wheelchair because POTS is physically debilitating. Unable to work/play and requires help. (mother Kristen)

14-year-old female, NJ - Severe debilitating tinnitus, migraines, anxiety, hearing loss needing the use of hearing aids, hyperacusis, and insomnia. Hearing aids are not covered by NJ insurance. Under a neurologist's care, medications do not help. Failed cries for help to the government. This has taken her future, her happiness, all our financial resources, and ultimately hope that any relief will come. (anonymous)

16-year-old female, PA – at 12 years old just to begin 7th grade, now disabled called CRPS (Chronic Regional Pain Syndrome). "Nothing really helps. the pain is always there and never goes away. It is a horrible stabbing burning pain. Somedays her pain is low, like a level 2, and others, usually right before a viral infection it shoots up to an 8 or 9 and we have to rush her to the hospital where they will give her morphine." (S J)

17-year-old, female, ME - POTS, menstrual irregularities, extreme fatigue, peripheral neuropathy, severe sudden onset OCD, to name some of the issues. Family is in dire need of interventions and financial assistance to return child to previous healthy condition. Previously high functioning, now trying to hold on but incapable of living without constant supervision and assistance. "The worst is the severe sudden onset OCD (PANS-like illness) which has ripped our family apart, ripped our finances to shreds, made our daughter think she will never be free of the illness. She has gone through hell." (father, Mike)

17-year-old female, FL - CIDP, wheelchair-dependent, severe reaction in the clinical trial. After years of struggling to get adequate treatment, with no help at all from the drug company, government or the children's hospital that administered the shot, she ultimately underwent a high-risk surgery, leaving her on a battery of anti-spasmodic medications, and botox to reduce painful severe muscle spasms and cramps. She has told her mother she is done with the doctors. Mother is devastated after 5 years of trying to get her daughter even standard medical care, and has been begging the government for help for years. Asks why the government continues to not do anything to help her daughter. (anonymous)

18-year-old female, CA - At age 13 at time of injury in June 2021. Reduced total lung capacity restrictive type, daily nerve pain throughout body, vertigo, reactive airway disease, exercise intolerance, heart palpitations, bilateral leg fatigue and discomfort, and chronic fatigue. Countless visits to Emergency Departments and to many medical specialists. Her CICP claim was denied in 2024, and the detailed VAERS report dated December 2021 is no longer available on the VAERS public database. "I have gotten no response when I've inquired about the disappearance of the report. I also completed V-safe reports on my daughter's behalf, with responses each time in the free response fields detailing continuing adverse effects." (Amanda Greco)

20-year-old female, TX – 16 year old high school student now with autoimmune encephalitis, pure autonomic failure, autoimmune autonomic neuropathy, CFS (chronic fatigue syndrome), dysautonomia, POTS (postural orthostatic tachycardia syndrome), autoantibodies, blurry vision. Lives at home with parents who support financially. Her entire adult life will be affected by her overwhelming health issues. "I often wonder what damage has really been done, and am I past the point of healing damage is so bad, it is not curable, and I will live a life of chronic pain?" (Sutton, mother Brandi)

23-year-old male, TN – Young, healthy and thriving college student. Suffered from cardiac arrest and brain damage, likely caused by blood clots. He remained in a vegetative state until his passing on August 24, 2023, with his death certificate noting a reaction to the vaccine as a contributing factor. His parents, share their very tragic story in hopes that their loss will help others see more clearly and that we might all get a glimpse of their beloved son's sweet soul. (Trent, mother Kimberly Aveyah, father Andy Lieffring)

24-year-old female, CO – Nursing student, mandated by her program, suffered severe neurological and immunologic attack that ultimately put her in the ICU. She was put on life support and passed away before Christmas 2021. VAERS report was filed, but no follow-up provided to the family, nor was there any avenue for compensation through the CICP. Her mother continues to seek answers for the tragic loss of her daughter who had her entire life ahead of her. (Alexis Budzon, mother Holly Budzon)

26-year-old female. VA - College graduate about to start her career. Now she is mostly bed bound, in constant pain due to small fiber neuropathy, severe insomnia and is unable to eat. She can no longer cook, clean or drive. She is completely dependent on her parents financially. Multiple ER visits continue, hospital stays. Five years of medical interventions have not made a significant difference in her quality of life. (anonymous)

28-year-old female, IN – Young and healthy woman with T1 diabetes. She died at home less than 48 hours after the Moderna injection. Injection was on 01/19/21 at approximately 11:15am and she died on 01/21/21 at approximately 1:00am.
Her new husband and her mother are both devastated and will never ever be the same without her. They wished these severe responses would have been appropriately communicated by the FDA so those with conditions like hers would know to take an extra watchful eye after the vaccination is administered. (Haley link, mother Shauna Link)

28-year-old female, NC – Healthy athlete and US Coast guard service member. Neurologic symptoms, extreme fatigue, tremors and seizure-like episodes, vision disturbances, chronic pain, and debilitating post-exertional exhaustion. By April 2023 her health had declined so severely that they became largely bedridden for months. Despite seeking government help, her savings and other resources have been completely depleted. She wants to heal and get back to living her life. (Lindy Ayers)

31-year-old male, FL - received two doses of the Moderna COVID-19 mRNA vaccine. He experienced a severe adverse reaction after each dose, consisting of intense pain in his legs, back, and shoulders. Eleven weeks after the second dose, on December 28, 2021, he suffered a massive thrombosis in his left anterior descending coronary artery, resulting in a fatal heart attack while en route to the hospital. Upon arrival, emergency room staff attempted to resuscitate him, but he was pronounced dead approximately 20 minutes later. The grief has been crippling for the family. “It has been very difficult for us, and it hasn’t gotten easier with time,” shared the family. (Chris Goodrich, father Jim Goodrich)

32-year-old male, IL - severe insomnia, hyperacusis, tinnitus, and ME/CFS that requires wheelchair assistance, muscle wasting since 2021. “I’ve drained my savings of both my parents and myself as well and my medical expenses totals more than 80k out of pocket. I have accepted I will be dead soon. I have spent 5 years thinking about “offing” myself to make a statement to bring attention to the topic to force the govt to help other vax injured and not sweep us under the rug. If I do not get compensation or any symptom relief, I plan to go to Switzerland to do Pegasos program for assisted suicide at 33 years old. I used to have dreams what I wanted to do with my life, now I am just waiting to die so I’m not a burden to my family.” (Justin Prince)

35-year-old female, AZ – Physically fit and active marketing director now permanently disabled, diagnosed with Myocarditis, Pericarditis, Hyperandrogenic POTS, Mast Cell Activation Syndrome, hEDS/Hypermobility Syndrome, Ventricular Tachycardia, Dysautonomia, Chronic Fatigue, Chronic Pain, recurring Lactic and Metabolic Acidosis. The financial devastation has been equally crushing. With no family financial support, "I live in constant fear of losing my home, medical care, and the ability to even afford to feed and sustain myself. Every single day I grieve the total destruction of my life, my career, my future, and all my hopes and dreams, reduced to a hollow shell of who I once was. I am no longer truly living, but merely surviving each and every day in despair. I have come to believe that this unimaginable suffering will only end when my life itself is finally over." (Anonymous)

35-year-old female, AZ - Dysautonomia, SFN, widespread joint and nerve pain, head pressure, flu-like symptoms, and other systemic neurological symptoms. Have found no specialist who would acknowledge or document vaccine injury, or offer any legitimate treatment options. Everything that has helped I've discovered through v injury groups (hydroxychloriquine, LDN, CNS regulation). Still disabled and physically limited, but have made improvements since 2021 thanks to online help and support. (Eva Vracar)

39-year-old female, Iowa - Mandated despite working remotely, or lose the healthcare that was keeping my 2 year old son alive. Within 24 hours of her dose of Moderna, severe neurological and immune injuries , including vision loss, hearing loss, brain lesions/inflammation, chronic pain, cardiac symptoms, and debilitating fatigue. Five years later, spike protein still remains in my body and I have confirmed DNA/RNA damage. After being denied compensation and repeatedly dismissed by the medical system, I am continuing to deteriorate physically and financially. (Erica Samp)

42-year-old male, TX - Severe myalgic encephalomyelitis and autoimmune encephalitis marked by extreme sensitivity to lights and sounds, tinnitus, insomnia, severe PENE/PEM, and intense, constant brain burning sensations. He could not tolerate screens, sounds, and could not work for nearly 4 years. Rendered completely bedbound, barely able to eat and drink, communicate, unable to shower/groom, and unable to care for himself. He lost his life after dramatic continued decline as a result of one Pfizer shot in early 2026. (Eric Hauser)

42-year-old male, TX - Tinnitus in quiet environments; the condition became severely reactive, progressing to hyperacusis/noxacusis with sound-induced pain and escalating tinnitus. "I have been homebound for four years. I was forcibly placed in a mental ward, where sound exposure, stress, and medication significantly worsened my condition. This misattribution caused further injury instead of treatment. I am now severely disabled. I am living in continuous, extreme physical torture, yet I love my life and do not want to die. If medical euthanasia were legally available, I would choose it solely to escape the unrelenting physical suffering, not because of depression or lack of will to live. The failure to recognize and treat this condition has resulted in loss of my home, career, assets, and independence." (Travis Scott Henry)

42-year-old female, GA - Documented as top 5% of the "world's healthiest population" from life insurance policy before being administered two covid vaccines (Moderna). Neurologic symptoms,

Central Nervous System overhauled, extreme fatigue, brain micro adenoma on pituitary gland, severe micro-clotting, confirmed pericarditis fat inflammation with degenerative heart valves, confirmed on-going degenerative nerve/ muscle condition with atrophy, chronic pain, small fiber neuropathy confirmed via biopsy, bouts of random paralysis from the neck down (up to 8 hours per episode), gastroparesis, tremors, chronic debilitating migraines. Medically and legally determined to be fully disabled. Requires very expensive treatment and maintenance that includes at home care with a traveling nurse. (Lindsay Paul)

44-year-old female, AZ - Saddle anesthesia/ castration, inflammatory polyneuropathy, celiac, POTS, dysautonomia, EBV reactivation and Hashimoto's since 2021. Remission from autoimmune encephalitis since IVIG 2023-2024. In $30K medical debt for past treatments. Could no longer afford IVIG since 2024. Went to Switzerland for INUSpheresis. Currently in ovarian failure, getting routine CTs for a kidney lesion, and awaiting an echocardiogram from debilitating chest pains. My children were 5mo, 7yo and 9yo when I got injured, they forgot who I was before this. Still no answers or help from the government. (Kelli Menaker)

48-year-old male, PA – Criminal defense attorney and father of three. Neurologic symptoms including severe nerve pain, debilitating fatigue, cognitive impairment, muscle weakness, and migraine headaches. Fully disabled since March of 2021 and will likely never practice law again. Currently receives three full day IVIG infusions every third week to slow symptom progression. (Chris Dreisbach)

48-year-old male, PA - Endurance athlete, Ironman. 1 dose of J&J, ended up in the ER with bells palsy, Lhermitte's sign, optic pain in both eyes, severe head pain. Filed report with VAERS, CICP and sent letter after letter to J&J. "I now have MS, severe depression, can't walk more than a few minutes with extreme bad balance, internal tremors, I burn from the waist down 24/7 along with horrible chronic fatigue. Ther vaccine has ruined the man I was, the father I was and definitely the husband I was. My social life is nonexistent. Nobody should ever have to experience this life sentence, there is not a day goes by I don't think of ending the pain myself." (Michael Tokar)

48-year-old male, PR – Previously healthy and active. Developed progressive difficulty walking following two doses of Moderna's COVID-19 vaccine. MRI imaging later led to a diagnosis of Multiple Sclerosis (MS), a demyelinating disease of the central nervous system. Symptoms progressed to severe disability, leaving him bedridden, unable to work, and dependent on his mother for daily care. Doctors continue to deny relation. "Still bedridden and deteriorating day by day." (Victor Medina)

49-year-old male, PA – No prior health issues. Eight hospitalizations and three emergency heart surgeries in the twelve weeks following Pfizer vaccination. Complete heart block, pacemaker (later removed), pericarditis, cardiac tamponade, DVT and clots, left leg and foot drag, burning full body neuropathy, tinnitus, occipital neuralgia, corneal scarring with vision loss, full body tremors and spasms, severe pain and weakness in legs, Bedridden or housebound for the past five years. "Have spent all of my retirement savings in medical expenses. Went from making a six figure salary to barely able to walk or feed myself most days, unable to work, and about to lose my home. Need assisted care from girlfriend and family for basic needs and travel to medical appointments." (Robert Fusaro)

52-year-old male, NC - Healthy bank executive. In his words: "Dear Senator Burr, I have been severely injured by the Pfizer vaccine. I've been diagnosed with POTS/Dysautonomia, Stiff Person Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), and have full body small fiber neuropathy (SFN). I'm in chronic pain… life has been ruined physically and financially. Can you please help us so that we can attempt to regain some quality of life?" After receiving no response from any government agency, including his letter that was personally delivered to his US Senator, Michael felt he had no choice other than to end his own suffering. He flew to Switzerland, and ended his life. His final words were sent in detail to the FDA via React19. Nothing was investigated. (M Tilaro)

52-year-old male, LA - Loss of speech, facial and body paralysis, brain lesions, blindness, AFIB and blood clots. Diagnosed with optic neuritis, dysautonomia, heart blockage and demyelination in CNS after third dose of Pfizer's Covid shot in December of 2021. Prior history of gout and high cholesterol. Ongoing medical treatments IVIG, autoimmune suppressants and blood thinners for life. Currently severely disabled unable to walk without assistance with power chair, legally blind and continues to decline with treatments. (Chris Pigott)

55-year-old male, TX - Previously started/ran a national wellness company on the Inc. 500 list, is now living with severe progressive neurological and systemic illness, including Multiple System Atrophy, dysautonomia/POTS, severe micro clotting complications, and Alpha-synucleinopathy with reported frontal lobe white matter changes. He is now 95% bedridden and fully homebound, requiring extensive daily assistance. He underwent two spinal surgical interventions and spent his life savings on treatments intended to restore function, but his condition has continued to decline. His wife has asked that his story not be forgotten. (Dan Van Ackeren)

57-year-old, male NY – Myositis, an autoimmune condition where my immune system is attacking the muscles, and Anti-Jo-1AB that attacks my connective tissues. Resulted in severe atrophy and nerve pain body-wide. I was a healthy, productive marine electrician working on U.S. Navy ships, and I am now disabled with no quality of life from the pain and suffering. Facebook due to it's cruel and unjust White House directed censorship has me alienated/embarrassed from my family and friends when I needed their support the most. (Charlie T. Bell)

57-year-old male, NJ – After the AstraZeneca clinical trial vaccine he suffered two heart attacks, then a catastrophic hemorrhagic stroke. "I lost full use of my left side and most of the vision in my left eye. My family physician contacted both the FDA, but no meaningful follow-up was provided. My CICP application was rejected. Now disabled, my wife was forced to close her business in order to care for me full-time. She now assists me daily with basic activities such as dressing and mobility. While she does so without complaint, it is deeply difficult for me to see the burden she carries." (Stephen P DeMitri)

57-year-old female, MD - Previously very fit and active Mom to two young girls. 2 Moderna shots in Jan & Feb 2021. Didn't feel well after the 1st dose but was assured this was "normal". After 2nd dose, her health quickly deteriorated. 5 trips to the ER in 9 days with high heart rate, high BP, internal tremors, severe burning sensation on skin, intense electrical bursts in her extremities, inability to swallow food (lost 17 lbs in 2 weeks from 140 to 123 lbs). Liver enzymes and ferritin levels soared.

After several months and many different drs, a neurologist referred her to Dr. Avindra Nath at NIH where her vaccine injury was confirmed. She participated in their small study from June 2021 - March 2022. Ultimately, never heard from them again and was abandoned to navigate her injury alone. (Debbie)

57-year-old Female, NH, She "had a wonderful, balanced life." Evaluated for stroke and cardiac conditions . Still suffers with uncontrolled blood pressure and heart rate, vision issues brain fog, PEM, migraines severe neck and lie back pain. She remains disabled, with mounting medical bills, struggling to find even a single doctor who will recognize her injury. Resources continue to go to care.Lost and unsure what will come next? (Cathleen Roy-Dwelley)

58- year-old male, TX - Suffered two rare cerebellum strokes in 2021 at the age of 59, three weeks after Pfizer covid shot. Was in excellent health. 80 days in hospital, underwent emergency brain surgery to save life. Battled double pneumonia, had to have tracheotomy and feeding tube installed. Have permanent damage to vocal cords, aphasia and left side movement degeneration. Survived but lost career as pilot. "The impact on my family has been immense, I now fully depend on those who use to depend on me." (Tim McAdams)

58-year-old female, UT. Healthcare worker now suffering permanent disability with severe head pressure, tinnitus, POTS, Lyme, EBV, neuropathy, and severe body pain. Simple things most people take for granted are now gone. Multiple ambulance calls, ER visits, iron infusions, countless doctor appointments, and tried numerous treatments, all in hopes of regaining even a small part of my life. Sadly, nothing has brought relief. (E. Andria Anderson)

61-year-old female, GA - Severe immune-mediated neuropathy since 2021. Financially depleted after years without meaningful medical support. Told us she will pursue suicide within 60 days, her husband is supportive of her plan. Her pain and the strain on the family has reached its breaking point. Could not talk her out of it. (Anonymous)

63-year-old male, NJ — Pulmonary embolism, heart attack, and B-cell lymphoma diagnosed January 2022, following two Moderna doses in August/September 2021. Hospitalized for one month. No prior history of disease. Ongoing sequelae includes persistent foot numbness (resulting in five pulled teeth and two separate incidents of broken ribs), severe dry mouth, and significant emotional toll. "I continue to keep a brave face but I find myself crying out loud a lot." Physicians refuse to discuss possible vaccine causation. Continues to face the decline alone. (Tim Bensel)

Appendix I

Timeline of events between REACT19 and Federal health authorities, internal FDA communications, and external experts:

January 11, 2021 – NIH began a study on COVID vaccine injuries. Shortly after in **March 2021**, seriously COVID-19 vaccine-injured patients were flown to NIH headquarters for extensive testing and evaluation, and treatment. Study participants received credible diagnoses, including "post-vaccine neuropathy" and specialized treatments that participants say saved their lives.

On **March 1, 2021** – FDA began reviewing internal reports of safety signal "masking" indicating several safety signals were being suppressed by their existing surveillance systems. One analysis identified "49 examples of extreme masking," including approximately 25 statistically significant safety signals.

March 2021 – Dr. Ana Szarfman, a senior FDA medical officer who helped develop the agency's data mining system, alerted Dr. Peter Marks and other senior FDA officials that a known limitation in FDA's existing surveillance system was actively *masking* adverse event signals. She provided a superior methodology that adjusted for the masking.[1]

Dr. Szarfman's analyses using the superior methodology identified 49 examples of extreme masking, including approximately 25 statistically significant safety signals not previously detected.

March 17, 2021 – The NIH (Drs. Nath and Safavi), the FDA (Drs. Woodcock and Marks), the CDC (Dr. Walensky), confirmed that more than 1,000 neurological complications had been reported. The communication to the vaccine-injured continued with promises:

> *"I promise you we will report your issue and other cases that are reviewing now and I really appreciate if you kindly give us 1-2 weeks to collect comprehensive information before publicizing it."* [2]

That was the foundation on which the community held its silence. The NIH reinforced it in **April 2021**, telling injured Dr. Danice Hertz: *"I am working really hard to prepare this information in the organized fashion to inform the medical community."* [2]

April 28, 2021 – Behind closed doors, NIH staff informed Francis Collins and Anthony Fauci about the injury study sharing, *"NINDS has not yet determined if they will do proactive press materials on this paper."* (source email available with REACT19)

May 7, 2021 – Drs. Menschik, Narayan Nair, instructing her to *"please hold off on creating and sending data mining reports and analyses using COVID-19 vaccine [adverse event] data."* [9]

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[1] U.S. Senate Permanent Subcommittee on Investigations, Majority Staff Report, *"Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals"* (April 29, 2026), https://www.ronjohnson.senate.gov/services/files/4DF802C8-DE9B-46C7-B470-37DD85569A76

[2] The Real Peter Marks, Danice Hertz email with Peter Marks, p5 https://static.therealpetermarks.com/assets/2021-03-17_hertz-emails-03-17-2021.pdf

May 24, 2021 – React19 submits original letter/petition to the FDA about Covid-vaccine injuries.[4]

June 2021 – the NIH then asked participants to remain quiet during in-person evaluation visits, until they disclosed the study themselves. The participants complied, holding onto the promise that "help is coming" for the many others nationwide. Dr Nath also specifically expressed that injuries should be recognized and treated early, to prevent serious outcomes. The NIH spent the rest of the summer privately advising patients and doctors on testing and treatments.

July 12, 2021 – Dr. Szarfman warned FDA officials in writing that her and Dr. DuMouchel's methodology had detected *"an increased mortality signal with the COVID-19 vaccines,"* using a method that *"automatically unmask[s] signals that remain hidden by other data mining methodologies."*[9]

July 20, 2021 – CDC's vaccine director Tom Shimbukuro responds to his team asking what to say to an external vaccine-injured scientist who identified tinnitus as a safety signal, *"Thank him for his email and cut him off."* (source email with REACT19)

July 23, 2021 – External experts at CAALM, the Coalition Advocating for Adequately Labeled Medicines, submit a citizen's petition warning FDA officials of methodology had detected *"an increased mortality signal with the COVID-19 vaccines,"* and pulmonary embolism, sudden cardiac death, sperm concentration, heavy menstrual bleeding and detection of vaccine mRNA in breastmilk. In refusing to add these adverse events to the label, the FDA invokes the strictest of standards (demonstrating causality), contradicting federal law that calls for using the "some basis to believe" standard. [3]

September 2021, NIH researchers abruptly withdrew from patient support groups. Follow-up appointments were cancelled. The NIH began turning patients away. Subsequent inquiries about the NIH study were met with curt denials and refusal to discuss any involvement by the NIH.

September 15, 2021 – Dr. Marks wrote that Dr. Szarfman *"has been asked to cease and desist,"* and warned that her data mining could ***"create erroneous conflicts that feed in to anti-vaccination rhetoric."*** [1]

September 16, 2021 – Dr Marks wrote Brianne Dressen ***"****The Vaccine Adverse Event Reporting System (VAERS) has not identified any potential safety signal for the adverse experiences you provided both in your letter and at the meeting."* Referenced letter: [4]

September 22, 2021 – Dr. Menschik (FDA) wrote internally acknowledging the masking limitation in language drafted for a forthcoming safety paper: *"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."* This language describing the limitation appeared in two October 2021 preprints of the 6-month mRNA

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[3] We tried to improve COVID vaccine labeling — the FDA said 'no thanks'; Doshi, Wastila; The Hill; https://thehill.com/opinion/healthcare/4037145-we-tried-to-improve-covid-vaccine-labeling-the-fda-said-no-thanks/

[4] Original REACT19 petition to FDA and CDC - https://www.react19.org/files/pdfs/originalreact19petition-2021.pdf

vaccine safety review, but was removed before the paper's final publication in *The Lancet* in March 2022. [1]

The injured study participants then shifted their efforts to the FDA, meeting with Peter Marks from **October 2021 through December 2022,** seeking acknowledgement of commonly reported vaccine side effects.

October 2021 – Dr. Marks met with React19 and asked for specific signals indicating vaccine injury. REACT19 narrowed the universe to tinnitus, neuropathy, POTS, MIS, paraesthesias, a long-COVID-like syndrome, and handed over 88 VAERS terms for neuropathy alone. Dr. Marks committed to review.

December 15, 2021 – Dr. Avindra Nath (NIH) wrote to Brianne Dressen denying that any clinical trial had ever existed and directing the injured to "*receive care from their local physicians,"* physicians who, because the NIH had never publicized what it knew, had no way to recognize or treat what the NIH had been treating privately for nine months. (source email available with REACT19)

January 2022 – Dr. Woodcock wrote to REACT19: *"Yes it does seem that long COVID and some of these other symptoms seem similar, I have noticed that myself in people I know."* And the following day: *"I agree about the need for physician awareness since treatment is available. I will consult with the Center for Biologics on this immediately."* The Center for Biologics is Dr. Marks's center. Whatever was consulted, nothing was disclosed. (source email available with REACT19)

May 2022 – The first meeting with REACT19 after Dr. Robert Califf took over as FDA Commissioner, Dr. Marks shifted the language. There was *"no signal, but still not denying it is happening."* Then: *"there IS a signal for neuropathy but not strong enough."* Asked how many charts the FDA had evaluated to identify neuropathy, the FDA could not answer. React19 mentioned paraesthesias as the precursor for neuropathy, and asked to evaluate this signal. Asked about MIS-V in pediatric cases, Dr. Marks suggested it *"may go on the label."* It did not.

September 2022 – the FDA met virtually with REACT19 instead of in-person in Washington DC. Dr. Marks informed 20 participants that there still were no signals, but that *"nobody's denying that these issues aren't real."* First-hand testimonies of injury were presented, including an injured child's mother who shared that her doctors could not help her, ultimately committing her injured 8 year old to a psych ward. With REACT19's help she received treatment her daughter needed. Dressen stated to Dr Marks, *"If it were up to the government, this 8 year old girl would still be in diapers in a wheelchair…. The only reason she walked back into school last fall as if nothing had ever happened to her, is because she found people on the internet who happened to have the secrets from the NIH."* Dr. Marks replied, *"There are no secrets here."* [5]

November 26, 2022 – FDA and CDC officials discussed internally limiting distribution of FDA's weekly data mining reports on COVID-19 vaccines. One CDC official wrote: *"I think that because of the FOIAs we may have asked FDA to stop sending these weekly data mining outputs."*

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[5] FDA / REACT19 DC meeting: https://rumble.com/v250fak-react19-reveals-severe-vaccine-side-effects-that-the-fda-is-hiding.html

December 2022 –The FDA admitted to REACT19 there was a *slight signal* for small fiber neuropathy in women aged 30–50. It was not disclosed to the public, nor was paraesthesias.. React19 also disclosed issues with 1 in 3 VAERS reports not being available for public review and requested an audit. No audit was carried out. FDA ceased communication, continued to deny the existence of these serious safety concerns to the public. [1]

January 2023 – External experts at CAALM, the Coalition Advocating for Adequately Labeled Medicines, submit a 2nd petition to the FDA requesting that the FDA, "amend current product labeling. Incomplete, inaccurate, or misleading labeling of any medical product can negatively impact the health and safety of Americans, with global ramifications considering the international importance of FDA decisions." They requested the following adverse events be added: multisystem inflammatory syndrome (MIS) in children; pulmonary embolism [Pfizer only]; sudden cardiac death; neuropathic and autonomic disorders. [6] FDA issued response to petition stating that the vaccines are "Safe Pure and Potent" and no vaccine label changes are needed. [7]

June 13, 2023 – Acting CDC Director, Dr Rochelle Walensky under sworn testimony to the US House of Representatives stated, "We at CDC have a responsibility to comb through every single one of them to review the medical charts and to see if they are related." [8] REACT19 confirmed several death reports that were not investigated. One case review by REACT19 physicians confirmed only 1 out of 9 death reports to VAERS were followed up on. Inquiries to FDA on these reports were ignored.

October 27, 2023 – Dr. Narayan Nair (FDA) wrote internally to colleagues at FDA and CDC acknowledging the same surveillance limitation Dr. Szarfman had identified more than two years earlier: *"We were aware of this limitation before and during the pandemic."* The email proposed addressing the limitation in academic papers, either by acknowledging it as a footnote or by omitting data mining findings entirely. Public disclosure was not among the options considered.[9]

March 15, 2024 – Dr. Nair acknowledged the same limitation again, *"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. Do you know if there is a public reference that discusses this limitation?."* FDA colleague Dr. David Menschik confirmed in response: *"I understood we provided CDC language for this limitation for the 6 month safety review of mRNA vaccines (and I could share that language if helpful) but in looking at the*

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[6] CAALM Petition #2 submitted to FDA (2023) - https://www.react19.org/files/pdfs/caalmcitizenpetitioin2023-fda-2023-p-0360-0001.pdf

[7] FDA response to CAALM Petition (2023) - https://www.react19.org/files/pdfs/fdaresponse-fda-2023-p-0360-0191.pdf

[8] June 13, 2023 "Oversight of CDC Policies and Decisions During the COVID-19 Pandemic" Witness: 1) Dr. Rochelle Walensky Director U.S. Centers for Disease Control and Prevention

[9] Email from Narayan Nair (FDA) to John Su (CDC) and Samaneh Bazel (FDA), cc Tom Shimabukuro (CDC), "RE: [EXTERNAL] RE: FDA coauthor for tinnitus paper" (October 27, 2023). Released as part of U.S. Senate Permanent Subcommittee on Investigations, Records Release Part 1 (April 29, 2026), https://www.ronjohnson.senate.gov/services/files/412001C8-1358-4D68-B886-3EED43FBE4B6

published article, it now appears that they took it out before publication. I'm not aware of such language included in another publication."

A full three years after the limitation was first flagged internally, the FDA had still not disclosed it publicly, and now its own division director was internally confirming that draft language describing the limitation had been removed before publication of a major mRNA vaccine safety review.

2023 – Nath (NIH) researcher published a commentary on vaccine adverse events, recommending once again *the importance of early recognition and intervention*, better research measures into mechanisms and treatments. [10] Press release or notification of the NIH's findings were never disclosed by the NIH.

February 15, 2024 — HRSA Director George Reed Grimes testified before the US House Select Subcommittee on the Coronavirus Pandemic that CICP had only four staff when the pandemic began and a backlog of over 10,000 claims. At the current rate of 90 claims resolved per month, the backlog would take nearly a decade to clear. *(SSCP Final Report, p. 362)*[11]

March 21, 2024 — Dr. Renée Gentry, Director of GWU's Vaccine Injury Litigation Clinic, testified before the Select Subcommittee that CICP provides "little more than the right to file and lose," and that dismissing the vaccine injured as "anti-vax" "creates and bolsters vaccine hesitancy in those individuals who were previously vaccinated and are pro-vaccine." *(SSCP Final Report, pp. 361, 364–365)* [11]

May 13, 2024 — Former FDA Acting Commissioner Janet Woodcock testified under oath before the Select Subcommittee that COVID vaccine recipients experienced "uncommon but serious and life-changing reactions beyond those described by federal agencies," including brain fog, fatigue, and neurological symptoms. She testified that patients "were told it's all in your head." When asked whether others at FDA took the issue as seriously as she did, she answered: ***"No."*** *(SSCP Final Report, pp. 354–355)* [11]

December 4, 2024 — The Select Subcommittee on the Coronavirus Pandemic issued its Final Report, finding formally: *"The federal government mandated [COVID-19 vaccines] without an adequate system in place to adjudicate the inevitable injuries they cause." (SSCP Final Report, p. 363)* [11]

January 2025 – Reassurances that the new administration cared about vaccine injuries began to come into React19 by HHS, FDA, CDC, NIH.

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[10] Nath A. Neurologic Complications With Vaccines: What We Know, What We Don't, and What We Should Do. Neurology. 2023 Oct 3;101(14):621-626. doi: 10.1212/WNL.0000000000207337. Epub 2023 Apr 25. PMID: 37185124; PMCID: PMC10573146.

[11] Select Subcommittee on the Coronavirus Pandemic Committee on Oversight and Accountability U.S. House of Representatives https://oversight.house.gov/wp-content/uploads/2024/12/12.04.2024-SSCP-FINAL-REPORT.pdf

Work began **in early 2025** to provide reasonable recommendations to HHS to reform the failing CICP and VICP compensation schemes. React19 was informed that the CICP will not be addressed, and subsequent follow-up ceased.

October 2025 – Two vaccine-injured and bereaved members met with FDA head Marty Makary and Tracey Beth-Hoeg. Commitment to investigate and publicize child vaccine deaths, ended in a vague leaked document. Commitment to investigate serious cardiac vaccine injuries, no follow-up done, no public acknowledgement or report made. Both officials are no longer with the FDA.

February 2026 – A public meeting finally to review mechanisms of COVID vaccine injury, and recommendations for better safety monitoring, provider education and research by way of CDC's ACIP, was cancelled reportedly by the White House, to be subsequently rescheduled and then cancelled again. The committee has ultimately been disbanded, no further commitments to address COVID vaccine injuries have taken place.

March 2026 – REACT19 met with Dr Hoeg (FDA) to work through expediting "right to try" or "expanded use" or "off-label" for IVIG, and other therapies, showing immediate need for better coverage for this medication for patients. Further work was committed to explore expanding use for new, poorly understood conditions.

March 2026 – REACT19 participated in a formal meeting at the CDC to introduce a COVID vaccine adverse event code for formal review. This review remains open until October 2026, at which point REACT19 hopes it is formally approved.

February 2026 – Promises made to REACT19 for a vaccine injury clinic at the NIH, reinstatement of the autonomic lab, implementation of patient voices through respective research committees, agreed to by NIH director Jay Bhattacharya. After multiple follow-ups by REACT19, a subsequent email from NIH admin in May of 2026, assures REACT19 the clinic is in a plan. No other commitments were addressed, nor are any follow-up meetings scheduled.

May 2026 – Dr. Makary and Dr. Beth-Hoeg leave FDA, by forced resignation and firing, putting a halt to much needed investigation of complications after COVID vaccination.

Appendix II

Review of failures to comply within the statutes set forth in the PREP act and NCVIA of 1986:

Reasonable Alternative Remedy for Legal Liability
(PREP Act, 42 U.S.C. § 247d-6e — provides CICP as the exclusive compensation pathway for covered countermeasures, granted in exchange for liability immunity under § 247d-6d)
13,000 CICP claims remain to be adjudicated; a small number of awards make it beyond a 97.5% rejection rate, with an average payout of $4,000.[12] Unlike VICP (42 U.S.C. §§ 300aa-10 to 300aa-34), CICP offers no attorney fee provision, a one-year filing deadline (versus three years under VICP), no right to judicial review, and no injury table — placing the entire burden of proof on the claimant.
The Select Subcommittee on the Coronavirus Pandemic formally concluded in its Final Report: *"The federal government mandated [COVID-19 vaccines] without an adequate system in place to adjudicate the inevitable injuries they cause."* [11]

Post-Market Surveillance
(NCVIA, 42 U.S.C. § 300aa-25(b) — adverse event reporting and review; PREP Act, 42 U.S.C. § 247d-6d(b)(1) — active pharmacovigilance of covered countermeasures)
The FDA is statutorily required to follow up on all death reports; this obligation was not met. Serious and fatal reports to V-safe went unreviewed and not followed up on. Likewise, VAERS reports continued to go without follow-up, with one in ten records being deleted.[13],[14]

The combined record, internal acknowledgment paired with external denial; suppressed data mining analyses; the documented prioritization of public messaging (*"anti-vaccination rhetoric"*) over disclosure of statistically significant signals including death; the abandonment of an active research study, then lying about the existence of the study; the direction to a senior FDA scientist to *"hold off"* and *"cease and desist"* on her safety analyses, directly satisfies the *"knowingly without legal or factual justification"* and *"disregard of a known or obvious risk"* prongs of the statutory standard. The October 27, 2023 internal email from Dr. Narayan Nair compounds this analysis: the FDA confirmed in writing that it *"was aware of this limitation before and during the pandemic,"* knew of a remediation tool, and chose to continue using a system it knew could not detect class-wide adverse events.[15] **Public disclosure was not proposed. As of this writing, the limitation has never been disclosed to the public.** Instead mandates were implemented paired

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[12] HHS HRSA CICP Compensation Reform Table: https://www.hrsa.gov/cicp/cicp-data (April 2026)

[13] React19 VAERS Audit, (Nov 2022): https://react19.org/science-and-research/reviews-surveys-studies/react19-research-vaers-audit

[14] "Is the US's Vaccine Adverse Event Reporting System broken?" *BMJ* 2023;383, doi: https://doi.org/10.1136/bmj.p2582

[15] Email exchange between Narayan Nair (FDA), "RE: Data mining question" (2023). Released as part of U.S. Senate Permanent Subcommittee on Investigations, Records Release (April 2026). https://www.ronjohnson.senate.gov/services/files/4DF802C8-DE9B-46C7-B470-37DD85569A76

with "misinformation" campaigns that included the White House,[16] HHS,[17] and even medical boards.[18][19] The pattern is reinforced again on March 15, 2024, when Dr. Nair searched internally for *any* public reference to the limitation and Dr. David Menschik confirmed that language describing it had been removed before publication of the 6-month mRNA vaccine safety review.

Three years after the FDA was first alerted to the masking problem, three years after the agency declined to use a tool that would have corrected it, three years after senior officials prioritized concerns about *"anti-vaccination rhetoric"* over disclosure of statistically significant signals including death, the FDA still had not informed the public. The limitation had been kept from the published scientific record. [1]

Safety Signals
(NCVIA, 42 U.S.C. § 300aa-27(a)(2) — dissemination of adverse reaction information; FDA labeling authority, 21 C.F.R. § 601.12 and 21 U.S.C. § 355(o)(4))
-Timely communications on emerging possible adverse events failed to emerge.
-COVID vaccine adverse events remain without public acknowledgement for highly reported conditions like sudden cardiac failure, stroke, pulmonary embolism, autoimmunity, GBS, MIS, death, neuropathies, and long COVID-like multisystem disorders.
- Despite FDA's postmarketing scientists detecting a statistical signal for pulmonary embolism, and CDC/FDA co-authored research calling for "enhanced pharmacovigilance" for MIS in children.[20]
- Both inside and outside FDA experts alerted specific signals that went unheeded and were ultimately suppressed.[1] - Dr. Szarfman's internal data mining identified extreme signal masking; she was directed to cease and desist. CAALM's external scientists identified the same signals in formal petitions; both were denied. In all cases, the governing statutory standard, "some basis to believe" a causal relationship exists (21 C.F.R. § 201.57(c)(7)), was not applied.

Refusal to Apply the Correct Statutory Standard for Label Updates
(21 C.F.R. § 201.57(c)(7) — FDA labeling regulation defining adverse reactions; 21 C.F.R. § 201.56(a)(2) — duty to update labeling when new information renders it inaccurate) FDA labeling regulations require that warnings be added to a drug or biologic label whenever there is *"reasonable evidence of a causal association"* with an adverse reaction, explicitly noting that *"reasonable evidence of a causal association does not require proof of a causal relationship."*

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[16] Dressen v. Flaherty, Censorship Legal Complaint (2023): https://nclalegal.org/wp-content/uploads/2023/08/Dressen-Complaint-Filed-5.22.23.pdf
[17] HHS.gov; Confronting Health Misinformation (2021): https://www.hhs.gov/sites/default/files/surgeon-general-misinformation-advisory.pdf
[18] ABIM COVID vaccine Misinformation Notice (2021): https://www.abimfoundation.org/blog-post/joint-statement-on-dissemination-of-misinformation
[19] FSMB Misinformation Warning (2021): https://www.newswise.com/articles/fsmb-spreading-covid-19-vaccine-misinformation-may-put-medical-license-at-risk
[20] Fujisawa, A., Kodama, S., Konishi, N. et al. Characterizing persistent Post-COVID-19 vaccination symptoms using MedDRA system organ class and preferred term classifications. *Sci Rep* 16, 12366 (2026). https://doi.org/10.1038/s41598-026-43949-z

When CAALM, React19, and outside scientists and pharmacovigilance experts formally petitioned FDA, in July 2021 and January 2023, to add adverse events to COVID-19 vaccine labeling, including pulmonary embolism, sudden cardiac death, MIS-C, neuropathic and autonomic disorders, paraesthesias, decreased sperm concentration, heavy menstrual bleeding, and detection of vaccine mRNA in breastmilk, the FDA denied both petitions. Both denials were signed by Dr. Peter Marks. In the 2023 denial, FDA invoked the strictest possible standard, demonstration of causality, to refuse each requested label addition. This standard does not appear in 21 C.F.R. § 201.57(c)(7), which requires only that there be "some basis to believe" a causal relationship exists. FDA applied this elevated standard selectively: it had already added myocarditis warnings to the same labels under a lower evidentiary threshold. Meanwhile, FDA's own scientists had authored various papers on various signals like pulmonary embolism, MIS-V, and mandated boosters, that FDA cited as insufficient for labeling, and Dr. Marks was simultaneously telling React19 members in private meetings that "there are no safety signals" but that he was "not denying these injuries are real."

The regulation FDA was bound to apply, 21 C.F.R. § 201.56(a)(2), further requires that labeling be updated whenever new information causes it to be inaccurate or misleading. That obligation was not met.[21]

Adverse Reaction Research and Publication
(NCVIA, 42 U.S.C. § 300aa-27(a)(1) — duty to research vaccine adverse reactions and disseminate findings; PREP Act, 42 U.S.C. § 247d-6d(b)(7) — duty to evaluate countermeasure risks)
-The NIH vaccine injury study launched January 11, 2021 was never published. Participants were flown to NIH headquarters, received credible diagnoses including *"post-vaccine neuropathy,"* and were treated onsite with therapies the NIH withheld from the broader medical community. FOIA-produced emails confirm that NIH leadership, including communications copied to Dr. Francis Collins and Dr. Anthony Fauci, declined to issue press materials, with NINDS staff acknowledging the choice in writing: *"NINDS has not yet determined if they will do proactive press materials on this paper."* (see REACT19 for document, FOIA by Surya Arby)
-NIH was also receiving numerous emails from desperate injured individuals also needing help, flagging safety concerns and more.
-NIH consistently lied to the public and reporters about the study's existence.

Clinical Guidance and Provider Education
(NCVIA, 42 U.S.C. § 300aa-27(a)(2) — duty to disseminate adverse reaction information to healthcare providers)
The diagnostic and treatment protocols the NIH developed and used privately on study participants, including identification of immune-mediated small fiber neuropathy and dysautonomia, and treatment with high-dose corticosteroids and IVIG, were never disseminated to the broader medical community. Physicians across the country, uninformed, gave psych diagnoses,

[21] Specific requirements on content and format of labeling for human prescription drug and biological products described in § 201.56(b)(1). https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201/subpart-B/section-201.57

denied medical exemptions, and allowed treatable conditions to progress. An 8-year-old child was committed to a psychiatric ward for an immune-mediated condition the NIH already knew how to treat; she achieved remission only when React19 secured IVIG independently using the NIH's private guidance.[22] At least one injured patient was killed when his physician, in good faith and total ignorance, administered methotrexate. [23]
In 2022, In at least two instances of correspondence with CHD after the FOIA request was filed, NIH claimed that it had no knowledge of "adverse vaccination reaction reports." [24]

Vaccine Recipient Information Accuracy
(NCVIA, 42 U.S.C. § 300aa-26 — duty to provide accurate Vaccine Information Statements to recipients prior to administration)
COVID-19 vaccine recipient fact sheets and public-facing information were not updated when adverse event signals were internally evaluated. Public messaging campaigns, including agency-amplified PSAs, categorized real vaccine reactions as *"misinformation."*[17] HHS directed designated *"medical disinformation,"* a designation that, in the absence of public disclosure, was applied to physicians who recognized vaccine injury.

Triennial Reporting to Congress
(NCVIA, 42 U.S.C. § 300aa-27(c) — Secretary's obligation to report to Congress on vaccine safety activities)
The Secretary's reports to Congress regarding COVID-19 vaccine safety activities cannot have accurately represented the state of the agencies' knowledge, given the contemporaneous internal record of suppressed signals, withheld research, and undisclosed clinical findings now documented in FOIA productions and the April 2026 PSI Majority Staff Report.

Willful Misconduct: The Sole Exception to PREP Act Immunity
(PREP Act, 42 U.S.C. § 247d-6d(c)(1)(A); § 247d-6d(d)(1))
PREP Act immunity is broad but conditional. The sole statutory exception is *"willful misconduct,"* defined as an act or omission taken *"(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit."*

In 2021 and 2023, CAALM formally petitioned FDA to add pulmonary embolism, sudden cardiac death, neuropathic and autonomic disorders, and MIS-C to COVID-19 vaccine labeling, supported by an FDA-authored study and an NIH study. Both petitions were denied by Dr. Peter Marks, applying a causality standard stricter than the law requires. The governing regulation, 21 C.F.R. § 201.57(c)(7), requires only *"some basis to believe"* a causal relationship exists, the same standard FDA had already used to add myocarditis to the same labels. While denying those petitions, FDA's own response letters declared the vaccines *"Safe, Pure, and Potent"* under 42 U.S.C. §

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[22] FDA – REACT19 testimony of mother of 8 year old to Peter Marks (2022) https://rumble.com/v250fak-react19-reveals-severe-vaccine-side-effects-that-the-fda-is-hiding.html

[23] Children's Health Defense FOIA. (2023) https://childrenshealthdefense.org/defender/chd-nih-lawsuit-foia-covid-vaccine-injury/

[24] Children's Health Defense FOIA. (2023) https://childrenshealthdefense.org/defender/chd-nih-lawsuit-foia-covid-vaccine-injury/

262(a)(2)(C)(i)(I), the identical statutory language used to mandate public confidence in those products. These same signals that were in parallel identified by the FDA's scientist and suppressed and silenced.
The full record, internal signals suppressed, a senior scientist silenced, two petitions denied under an unlawfully elevated standard, public declarations of safety made while injuries went unlabeled, and a congressional finding that the compensation system was never adequate, satisfies all three prongs of willful misconduct under 42 U.S.C. § 247d-6d(c)(1)(A): intentional action toward a wrongful purpose, knowing disregard of legal obligation, and disregard of a known and obvious risk.

*** Complex new conditions can be acknowledged and in a timely fashion. For example, Long COVID:*