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Cite this as: *BMJ* 2022;377:e0919<http://dx.doi.org/10.1136/bmj.0919>

Published:

VACCINE INJURY

Covid-19: Is the US compensation scheme for vaccine injuries fit for purpose?

Patients and lawyers say that America's system for covid vaccine injury claims is costly, opaque, and yet to issue a single payout. **Maryanne Demasi** reports

Maryanne Demasi *investigative reporter*

"My toes move constantly, 24 hours a day, uncontrollably back and forth," says Chris Dreisbach, a 44 year old attorney who was admitted to hospital with debilitating neurological symptoms after a second dose of Pfizer's mRNA vaccine in March 2021. "I often spend at least four hours a day in my bathtub, because a hot bath is the only way I can turn down this electrical sensation that pulses through me. The cognitive issues are worse. I used to pride myself on being able to get up in a courtroom and think on my feet. Now, I have this brain fog. It's embarrassing."

From his hospital bed Dreisbach began researching compensation schemes, only to discover that the US's national Vaccine Injury Compensation Program (VICP) was not available to people injured by covid-19 vaccines. Instead he was forced to lodge a claim with a more costly, opaque, and less generous system that has yet to pay out on a single claim for covid vaccines. Senators, lawyers, doctors, and others such as Dreisbach are questioning why patients injured by vaccines are being routed into a scheme they view as inferior.

Two different schemes

The VICP was established as the result of a federal law known as the National Childhood Vaccine Injury Act of 1986, designed to provide compensation in the rare instances where an injury results from vaccination, while also shielding manufacturers from liability so that they continue to make the products. Funded by a \$0.75 excise tax on each dose, this law is thought to have contributed to historically high levels of vaccine uptake in the US.¹ It covers the majority of vaccines including routine childhood immunisations, but it is not available to people injured by covid vaccines.

When the US secretary of the Department of Health and Human Services declared a public health emergency in early 2020² this triggered the 2005 Public Readiness and Emergency Preparedness Act, meaning that any injuries arising from covid countermeasures—including ventilators, antivirals, and vaccines—would instead have to be filed with the Countermeasures Injury Compensation Program (CICP).

Critics say that the CICP is inferior to the VICP in terms of its payouts and the way claims are assessed. Only the most serious injuries and death are compensated, claims have to be made within a year after vaccination, and it has a higher burden of proof

than the VICP. Loss of income under the CICP is limited to \$50 000 (£38 250; €45 900) a year, and no compensation is included for pain or emotional distress. Under the VICP, payouts for lost wages are not capped, and compensation for pain and suffering is awarded up to \$250 000.³

Since 1988 compensation has been awarded in 36% of the 24 909 claims filed under the VICP, with around \$4.7bn paid out.⁴ In contrast, compensation has been awarded for just 0.4% of the 7547 claims filed under the CICP, with around \$6m paid out.⁵ The vast majority (93%) of the claims handled by the CICP have been filed during the covid pandemic, of which 4097 relate to injuries or deaths from covid vaccines and 2959 relate to other covid countermeasures.

To date, only one of the covid claims has been deemed compensable,⁵ although no money has been paid yet. In contrast, Thailand's National Health Security Office reports compensating over 14 000 people around \$50m to settle covid vaccine injury claims through a process that promises quick financial assistance.⁶

Critics also say that the CICP is less transparent. The CICP is a "horrible programme," says Peter Meyers, emeritus professor at George Washington University Law School in Washington, DC. "You basically submit your application for compensation, it's then dealt with secretly, and you don't have a right to have a lawyer paid for by the programme. You don't have a right to a hearing. We have no idea how these cases are being processed . . . There is such a lack of transparency in this programme that it's frightening."

Unlike CICP claims, which are resolved by an administrative process, VICP claims are resolved by a judicial process. Meyers says, "Those are open proceedings: you have a right to a hearing before an independent special master [adjudicator], the court will pay for your lawyer, the court will pay for an expert witness to support you, and if you don't like the result of that decision you can appeal to a court with judges—none of which you can do in the CICP."

The CICP also has a higher burden of proof than the VICP. There must be "compelling, reliable, valid, medical and scientific evidence" that the vaccine directly caused the injury. As an attorney, Dreisbach knows that meeting this standard is virtually unattainable, especially as he has not received a definitive diagnosis. "If we don't know what my medical condition exactly is, there is no possible way

that I can prove that vaccination caused an unknown,” he says.

While Pfizer and Moderna’s covid vaccines are now both fully approved by the US Food and Drug Administration, the Public Readiness and Emergency Preparedness Act governing the CICIP does not distinguish between the vaccines that are fully approved and those authorised only for emergency use, says Katharine Van Tassel, professor of law at Case Western Reserve University in Cleveland, Ohio. Covid vaccine injury claims will be considered under the VICP only after the secretary of the Department of Health and Human Services declares an end to the public health emergency—and by then it will be too late for many people, she says.

Structural racism is built into the system, Van Tassel adds. “The majority of essential workers, who had to be vaccinated quickly, were individuals with low income, people of colour, your most vulnerable populations—and they are the very people who will not have access to the VICP,” she says.

The BMJ contacted the US Department of Health and Human Services and the Health Resources Administration for a response to these criticisms, but neither has responded.

Campaign for reform

A small group of US senators has been working towards reforming the CICIP. On 11 March 2022 Senator Mike Lee introduced the Countermeasure Injury Compensation Amendment Bill co-sponsored by Senators Mike Braun, Ron Johnson, and Cindy Hyde-Smith. It suggests reforming the CICIP so that its processes and payouts are comparable to the VICP. It also proposes creating a commission to identify injuries caused directly by a covid countermeasure and to allow previously rejected claims to be resubmitted.⁷

However, Van Tassel believes that a simpler solution exists: to route all covid vaccine injury claims through the existing VICP system. Meyers agrees, having called for a reform of the CICIP for over a decade.

“It’s a mess, in my opinion,” he says. “I think the best thing that could happen is to transfer all the covid-19 cases out of the CICIP and put them in the vaccine court [VICP], which is far superior, and add to the number of special masters who are deciding these cases to deal with the inevitable backlog of cases.”

Even with a move to the VICP, some argue that it will take considerable time for the system to function smoothly. Cody Meissner, professor of Paediatrics at Tufts University School of Medicine in Boston and former chair of the federal advisory committee that provides oversight of the VICP, calls it a “wonderful programme” but is concerned that it may become clogged with claims that ultimately are not vaccine related.

“Poorly understood but unrelated adverse events may occur after any vaccine administration,” he explains. “Many post-vaccine events are not related to the vaccine and occur simply by coincidence.”

Usually, when vaccines are added to the VICP it relies on a body of literature about known adverse events to decide on compensation, says Meissner, adding, “I don’t know that we’re there yet with covid-19 vaccines.”

He also worries that lawyers with conflicts of interest are behind the push to move covid vaccine claims to the VICP, for their fees can be paid under the programme even if the claim is denied.

Still, Dreisbach is hoping for change. He is campaigning as a board member of React 19, a non-profit organisation creating a network of patients, doctors, and scientists to research the underlying causes

of vaccine injury and advocate for legislative changes to achieve fair compensation for vaccine injury.⁸

“The covid vaccines have been fully approved by the FDA, recommended for children as young as 5 by the CDC [Centers for Disease Control and Prevention], and mandated by employers across the country,” he says. “It’s past time for our elected lawmakers to support the covid vaccine injured, just as they have those injured by other routine vaccinations covered by the VICP.”

“The system is broken”

After being vaccinated with the Johnson & Johnson covid vaccine on 14 March 2021 Michelle Zimmerman (fig 1), from Seattle, developed severe pain, loss of movement in her left arm, and problems with her cognition, memory, speech, and eyesight. Different specialists gave a primary diagnosis of a “severe vaccine reaction” (fig 2).



Fig 1 | Michelle Zimmerman

Unable to return to work as a high school leader, teacher, and education researcher and aided by parents who were taking care of her, she submitted medical reports to her insurance company. The insurer granted her claim, agreeing that the evidence proved that her disability began on the day she was vaccinated.

Zimmerman then prepared to apply for compensation through the CICIP. Before submitting, she called administrators for clarity on what standards of proof were needed to show that her injuries were vaccine related. The CICIP was unable to provide an answer, she tells *The BMJ*. “So, that was the first part that really concerned me,” she says. “If you don’t have a high level education or, like me, are going through severe cognitive vision problems, it’s incredibly excruciating and difficult to try to even get through the instructions of how you would establish proof—what would count and what doesn’t count.”

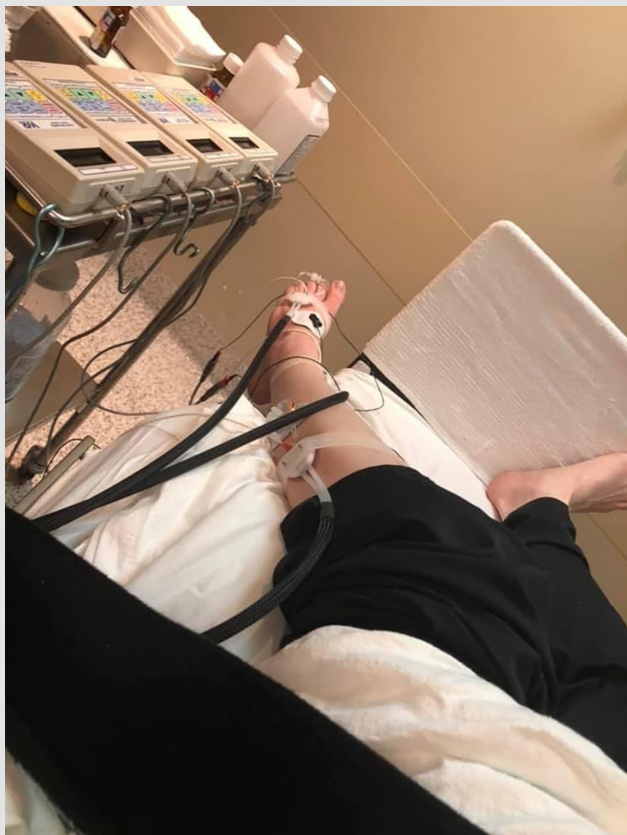


Fig 2 | Zimmerman in hospital after vaccination

No record

Zimmerman submitted her application on 1 October 2021 and received an automatic confirmation email. She then emailed administrators to get written confirmation of her submission, but she says that she was then left in limbo because the CICIP does not provide a timeline for when claimants should expect to hear a response. After calling repeatedly to check the status of her claim, in November she received a phone call from a CICIP administrator who told her that there was no record of her application.

She was horrified. As a researcher and author, she knew the importance of good governance around people's medical records. "You don't just lose things like that," she says. She was told that it was not possible to talk to any supervisors and that the only route available was to resubmit her application.

But the CICIP has a time limit: it accepts claims only if filed within a year of receiving a covid vaccine. "Had I not called and written so often, I would not have known that they lost all record of me until it was too late to resubmit," she says. She has still not received a case number or written confirmation of her submission.

The experience has left her with little confidence in the system and with concern for others, especially disadvantaged groups. "If I can't navigate the system with a PhD, what hope is there for someone else?" she asks. "You have no resources for attorney support. You have no one who has expertise who can go through medical journals for you. If I didn't have disability insurance, I don't know what I would do."

Zimmerman believes that the system is "broken" and is calling for covid vaccines to be added to the VICP. She says, "So many of us who are injured received vaccines to protect others, for civic duty, and to decrease load on medical professionals, and now we are being called collateral damage because the CICIP is not a functioning safeguard."

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Competing interests: None declared.

Provenance and peer review: Commissioned; externally peer reviewed.

the **bmj** | *BMJ* 2022;377:e0919 | doi: 10.1136/bmj.o919