



UNIVERSITY OF CALIFORNIA LAW
SAN FRANCISCO

The National Vaccine Injury Compensation Program: Continuity and Change

Dorit R. Reiss, Professor of Law



Disclosures:

- Stock ownership in GSK.
- All relevant financial relationships have been mitigated.



Learning Objectives:

3

- Discuss why no-fault systems are used for compensating vaccine harms.
- Describe the creation and structure of the vaccine injury compensation program.
- Identify potential reforms of the vaccine injury program.



Smallpox vaccine side effects

- Common: sore arm, fever, body aches.
- 1000 in million toxic or allergic reaction at site of injection – virus can spread, no treatment needed.
- 14-52 per million potentially life threatening reactions – encephalitis, eczema vaccinatum, more.
- 1-2 out per million died.



Vaccine v. disease risks

Table. Comparison of the effects of diseases and the side effects of vaccines on the National Immunisation Program

Disease	Effect of disease	Side effect of vaccine
Diphtheria - <u>bacteria</u> spread by respiratory droplets; causes severe throat and breathing difficulties.	Up to 1 in 7 patients die. The <u>bacteria</u> release a toxin that can paralyse nerves and cause heart failure.	About 1 in 10 has swelling, redness or pain at the injection site, or fever (DTPa/dTpa vaccine). Booster doses of DTPa may occasionally be associated with <u>extensive limb swelling</u> , but this resolves completely within a few days. Serious adverse events are very rare.
Hepatitis A - <u>virus</u> spread by contact or ingestion of faecally contaminated water or food, or by contact with the faeces of a person infected with hepatitis A.	At least 7 in 10 adult patients develop <u>jaundice</u> (yellowing of the skin and eyes), fever, anorexia (decreased appetite), nausea, vomiting, liver pain and malaise (tiredness).	About 1 in 5 has swelling, redness or pain at the injection site. Serious adverse events are very rare.
Hepatitis B - <u>virus</u> spread mainly by blood, sexual contact or from mother to newborn baby; causes acute hepatitis (liver <u>infection</u>) or <u>chronic infection</u> .	About 1 in 4 people with <u>chronic infection</u> will develop cirrhosis or liver cancer.	About 1 in 20 has swelling, redness or pain at the injection site, and 2 in 100 have fever. Anaphylaxis occurs in about 1 in 1 million. Serious adverse events are very rare.



Tenuto v. Lederle Labs





No fault systems:

7

- **Do not show:**
 - Negligence
 - Product defect
 - Other fault
- **Show:**
 - Causation
 - Damages

Global landscape analysis of no-fault compensation programmes for vaccine injuries: A review and survey of implementing countries

Randy G. Mungwira , Christine Guillard, Adiela Saldaña, Nobuhiko Okabe, Helen Petousis-Harris, Edinam Agbenu, Lance Rodewald, Patrick L. F. Zuber

Published: May 21, 2020 • <https://doi.org/10.1371/journal.pone.0233334>

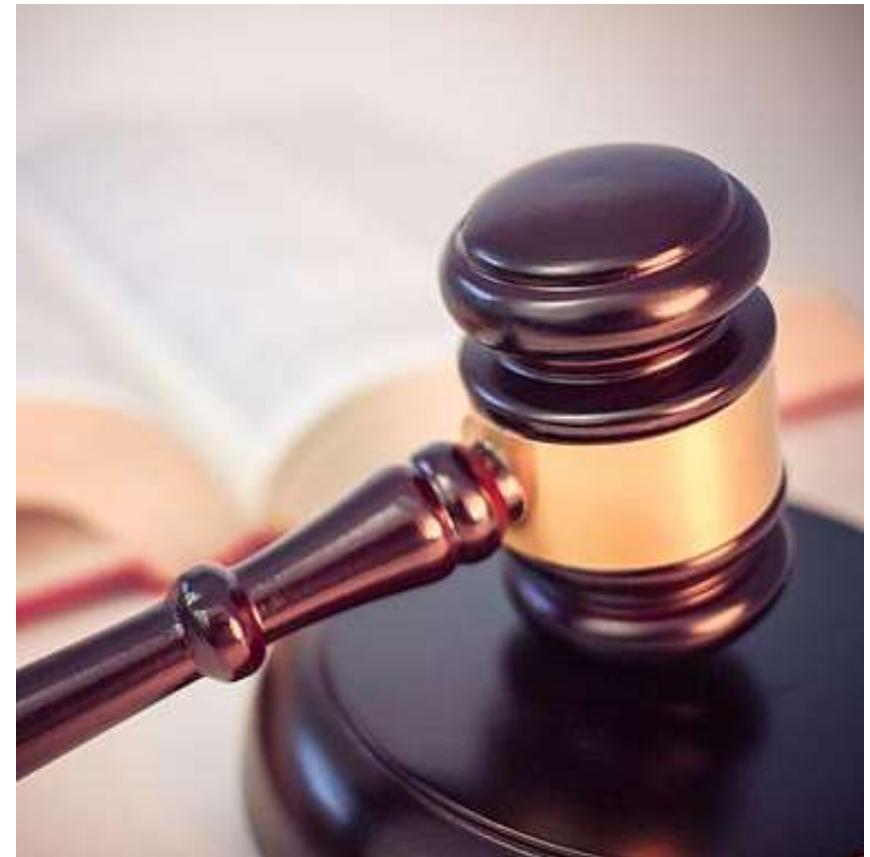
Article	Authors	Metrics	Comments	Media Coverage	Peer Review
▼					



Why no fault for vaccines?

8

- Easier compensation.
- Fairness: public benefit.
- Increase vaccine confidence.
- Concerns: accountability and legal tools.



What is an important difference between regular civil litigation and a no fault system?

A. In a no fault system you do not need to show causation.

0%

B. In a no fault system you have to meet higher proof requirements.

0%

C. In a no fault system you do not need to show a product defect, negligence, fraud or other problematic conduct.

0%

D. No fault systems do not give full damages.

0%



10

VACCINE INJURY COMPENSATION PROGRAM



VICP: A spot of history

11

- In the 1980s, concerns that the DPT(Diphtheria, pertussis, tetanus) vaccine caused brain damage led to low uptake and lawsuits.
- Manufacturers were leaving the market.
- Plaintiffs were unhappy with the difficulty of compensation.



National Childhood Vaccine Injury Act of 1986

- “The Vaccine Act;”
- Created VICP.
- Goals:
 - Protect the vaccine supply.
 - Provide individuals an exclusive, swift, flexible, and less adversarial alternative to traditional civil tort litigation.
- Original focus was children (6 covered vaccines).





Current covered vaccines:

compensation/covered-vaccines

[https://www.hrsa.gov/vaccine-](https://www.hrsa.gov/vaccine-compensation/covered-vaccines)

13

- Diphtheria (e.g., DTP, DTaP, Tdap, DT, Td, TT)
- Haemophilus influenza type b polysaccharide conjugate vaccines (e.g., Hib)
- Hepatitis A (e.g., HAV)
- Hepatitis B (e.g., HBV)
- Human papillomavirus (e.g., HPV)
- Seasonal influenza (e.g., Flu)
- Measles (e.g., MMR)
- Mumps (e.g., MMR, MR, M)
- Meningococcal (e.g., MCV4, MPSV4, MenB-FHbp, MenB-4C)
- Pertussis (e.g., DTP, DTaP, Tdap)
- Pneumococcal conjugate (e.g., PCV)



Relatively Recent Changes:

14

- 2005: influenza vaccines added to table:
 - Increased number of cases.
 - Majority of cases are now from adults.
 - Increase in SIRVA cases. (Shoulder Injury Related to Vaccine Administration).
- 2009-2010: dismissal of OAP (Omnibus Autism Proceeding) claims.
- 2017: rulemaking revisiting table.



The United States Court of Federal Claims

(Source:
<https://www.uscfc.uscourts.gov/frequently-asked-questions>)

15

- Congress renamed the Claims Court to U.S. Court of Federal Claims in 1992;
- 16 active judges nominated by President and confirmed by Senate.
- Nominated for 15 years terms; can be reappointed.
- President appoints Chief Justice.
- Jurisdiction: “Claims for money against the federal government.





The Special Master

16

- Appointed by the court of federal claims for four years.
- Appointment can be renewed – they usually stay.
- Makes legal and factual determinations, including:
 - Entitlement to damages;
 - Quantifying damages; and
 - Award of attorneys' fees and costs.
- Similar authority to administrative law judge in running hearing.
- Other issues (discovery, admissibility, case management, and resolution by hearing/dispositive motion) within Special Master's discretion;
- Special Masters perform an “inquisitorial” function.



Funding:

- Excise tax paid by manufacturers into Vaccine Injury Compensation Trust Fund;
- Current tax: \$0.75 per dose.
- Present value of Vaccine Fund = **\$4,247,079,343.**

17





VICP payments (Report from September 2025):

18

Category	Amount
Vaccines doses given 2006- 2023	5,347,310,532
Compensated Awards	12,262
Total Adjudications	25,593
Amount awarded	\$4,867,749,112,46
Attorneys Fees Paid	\$380,249,141.68
Attorney fees for Dismissed cases	\$135,947,454.23



Process:

https://www.myvaccinelawyer.com/vaccine-injury-lawyer/resources/vaccine/vicp/?utm_source=adwords&utm_medium=ppc&utm_term=vicp&utm_campaign=2019-2020+Vaccine+Campaign&hsa_acc=6279629756&hsa_kw=vicp&hsa_grp=179622247634&hsa_net=adwords&hsa_src=g&hsa_ad=739458714957&hsa_mt=b&hsa_ver=3&hsa_cam=6548094361&hsa_tgt=kwd-341440681&gad_source=1&gad_campaignid=22352095387&gbraid=0AAAAADLwlw9aV19kmIM7QJ_M7dhhnBG69&gclid=CjoKCQjwzOvEBhDVARIsADHfJJR7fNvQIiY4m3_07HYDJ36yTLJKD3ciH_mpnviOCVyJyCVzaUesZNEaArFMEALw_wcB

19



An individual files a petition with the U.S. Court of Federal Claims.



The U.S. Department of Health and Human Services (HHS) medical staff reviews the petition, determines if it meets the medical criteria for compensation and makes a preliminary recommendation.



The parties may begin settlement discussions at this time, or HHS could choose to defend the case if they believe it does not qualify for compensation.



If HHS chooses to defend the case, sometimes the parties will retain medical experts to support their side, and in a rare case, petitioners can go to a hearing in front of a Special Master.



If the case is decided in favor of the petitioner, the Court orders the U.S. Department of Health and Human Services to award compensation.



The special master's decision may be appealed and petitioners who reject the decision of the court (or withdraw their petitions within certain timelines) may file a claim in civil court against the vaccine company and/or the health care provider who administered the vaccine.



Limits:

- Covered vaccine.
 - ACIP (Advisory Committee of Immunization Practices) recommended for Children or Pregnant persons.
 - Added to table by secretary.
- Within statute of limitations:
 - 36 months.
 - Death: 24 months/48 months after first symptom.
- Severe condition for six months, or hospitalization, or death.



What do petitioners need to show?

21

- Causation.
- Damages.
- Lawyer fees.





Causation:

22

Two ways to show causation:

- Table injury.

<https://www.hrsa.gov/sites/default/files/hrsa/vicp/vaccine-injury-table-01-03-2022.pdf>

- Off-table injury: Althen.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis	≤4 hours.
	B. Brachial Neuritis	2-28 days (not less than 2 days and not more than 28 days).
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	≤72 hours.
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.



Althen v. Secretary of Health and Human Services (2005)

“[show] by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury”



Damages:

24

Included:

- Non-reimbursable medical expenses;
- Lost wages;
- Pain & suffering (capped at \$250,000);
- Death Benefit (\$250,000) *and* incurred expenses;
- Reimbursement of related Medicaid Lien.
- Reasonable attorney fees and cost (even if lost).

Not included:

- Punitive damages
- Lost wages or pain and suffering for anyone but the injured person.
- Expenses for others (except for parents of an injured child).



Lawyer fees and costs:

25

- “Reasonable” fees and costs.
- Even if lose, if reasonable basis to bring.
 - What’s unreasonable?
 - Timing
 - Content of case

Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
\$54,107.14	0	\$0.00	0	\$0.00	\$1,371,761.92
\$1,379,005.79	4	\$57,699.48	0	\$0.00	\$4,689,215.73
\$2,364,758.91	30	\$496,809.21	0	\$0.00	\$98,842,061.28
\$3,001,927.97	118	\$1,212,677.14	0	\$0.00	\$98,752,676.41
\$3,247,634.04	274	\$2,517,092.07	0	\$0.00	\$125,402,993.98
\$3,571,179.67	335	\$3,166,527.38	0	\$0.00	\$104,889,607.13
\$3,870,328.44	219	\$2,258,578.45	0	\$0.00	\$110,014,172.61
\$3,116,678.57	214	\$2,343,676.10	0	\$0.00	\$105,885,679.89
\$3,898,284.77	142	\$1,879,418.14	0	\$0.00	\$119,397,874.59
\$3,985,674.78	123	\$1,952,669.27	0	\$0.00	\$133,484,353.24
\$2,799,910.85	117	\$2,306,957.40	0	\$0.00	\$101,024,548.76
\$4,112,369.02	80	\$1,724,451.08	0	\$0.00	\$131,782,015.74
\$3,336,798.81	58	\$2,103,291.74	0	\$0.00	\$111,318,723.12
\$2,653,598.89	50	\$656,244.79	0	\$0.00	\$63,109,448.07
\$3,147,755.12	69	\$1,545,654.87	0	\$0.00	\$87,509,650.06
\$3,079,328.55	69	\$1,198,615.96	0	\$0.00	\$66,211,708.71
\$2,694,664.03	71	\$1,790,587.29	0	\$0.00	\$59,551,048.33
\$2,441,199.02	54	\$1,353,632.61	0	\$0.00	\$52,540,994.37
\$4,034,154.37	61	\$1,692,020.25	0	\$0.00	\$97,175,608.51
\$5,191,770.83	74	\$2,531,394.20	2	\$117,265.31	\$83,556,982.40
\$5,404,711.98	36	\$1,557,139.53	31	\$4,241,362.55	\$85,345,704.64
\$5,961,744.40	59	\$1,933,550.09	22	\$1,978,803.88	\$189,261,439.67
\$9,572,042.87	403	\$5,589,417.19	29	\$1,931,698.29	\$233,412,586.82
\$9,141,518.25	1,020	\$8,591,967.64	46	\$5,420,257.99	\$183,743,453.69
\$13,543,099.70	704	\$7,012,615.42	63	\$1,423,851.74	\$267,784,815.47
\$12,115,885.64	508	\$8,824,566.68	50	\$2,493,460.73	\$222,455,029.14
\$14,464,063.71	119	\$3,567,660.32	62	\$3,089,497.66	\$225,259,101.93
\$16,298,140.59	103	\$2,761,910.68	72	\$3,398,557.26	\$252,598,859.73
\$22,045,785.00	133	\$4,513,355.82	69	\$3,363,464.24	\$282,168,537.84
\$16,689,908.68	116	\$5,190,318.37	71	\$4,999,766.30	\$226,468,000.39
\$18,991,247.55	105	\$5,329,568.03	84	\$5,449,290.58	\$225,987,813.80

Page 8



Access to state courts:

26

- Petitioner can go to state courts if time limits not met.
- Petitioner can reject decision and then file in state courts.
- Except for design defect claims: program is the only recourse for those.



Resolutions

<https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-06-01-25.pdf>

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	447
FY 2011	386
FY 2012	402
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	1,238
FY 2019	1,282
FY 2020	1,192
FY 2021	2,057
FY 2022	1,029
FY 2023	1,167
FY 2024	1,185
FY 2025	841
Total	28,673

Out of the **28,673** petitions filed since the program's inception, VICP has disposed of **25,026**.

- 12,019 were declared compensable;
- 13,007 were dismissed.

- Updated to: June 2025.

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed. On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	88	174
FY 2002	104	104	208
FY 2003	56	100	156
FY 2004	62	247	309
FY 2005	60	229	289
FY 2006	69	193	262
FY 2007	82	136	218
FY 2008	147	151	298
FY 2009	134	257	391
FY 2010	180	330	510
FY 2011	266	1,742	2,008
FY 2012	265	2,533	2,798
FY 2013	369	651	1,020
FY 2014	370	194	564
FY 2015	521	146	667
FY 2016	700	187	887
FY 2017	696	203	899
FY 2018	545	202	747
FY 2019	641	182	823
FY 2020	710	217	927
FY 2021	754	260	1,014
FY 2022	939	271	1,210
FY 2023	882	323	1,205
FY 2024	1,179	286	1,465
FY 2025	621	157	778
Total	12,019	13,007	25,026



Resolutions

<https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-06-01-25.pdf>

28

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed. On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	88	174
FY 2002	104	104	208
FY 2003	56	100	156
FY 2004	62	247	309
FY 2005	60	229	289
FY 2006	69	193	262
FY 2007	82	136	218
FY 2008	147	151	298
FY 2009	134	257	391
FY 2010	180	330	510
FY 2011	266	1,742	2,008
FY 2012	265	2,533	2,798
FY 2013	369	651	1,020
FY 2014	370	194	564
FY 2015	521	146	667
FY 2016	700	187	887
FY 2017	696	203	899
FY 2018	545	202	747
FY 2019	641	182	823
FY 2020	710	217	927
FY 2021	754	260	1,014
FY 2022	939	271	1,210
FY 2023	882	323	1,205
FY 2024	1,179	286	1,465
FY 2025	621	157	778
Total	12,019	13,007	25,026

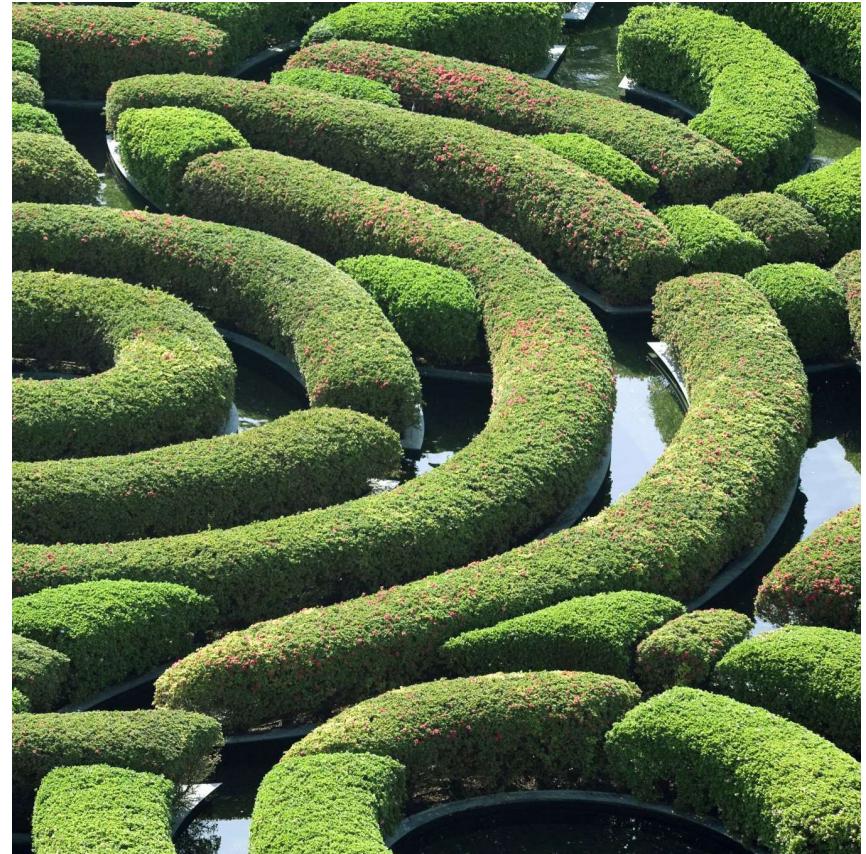
Which of these is a real change in VICP since its start?

- A. Most compensations in recent times were made to adults, not children. 0%
- B. The rate of cases compensated dropped dramatically in the past decade. 0%
- C. VICP no longer covers lawyer fees. 0%
- D. Maximum compensation for death increased dramatically. 0%



Problems with VICP:

- Needs more special masters.
- Caps need to be raised.
- Statute of limitations.
- Delays?
- Reducing adversarialism?





Health Resources & Services Administration

Bureaus and Offices | Newsroom | Contact HRSA

HRSA
Health Resources & Services Administration

Home Grants ▾ Loans & Scholarships ▾ Data Warehouse ▾ Training & TA Hub ▾ About HRSA ▾

[Home](#) » Countermeasures Injury Compensation Program (CICP)

CICP Home

Covered Countermeasures

Who Can File for Benefits?

CICP Filing Process

Occasionally, public health emergencies and security dangers threaten our country.

31

COUNTERMEASURES INJURY COMPENSATION PROGRAM (CICP)



Public Readiness and Emergency Preparedness Act of 2005 (PREP Act)

- Authorizes the Secretary of U.S. Department of Health and Human Services to issue PREP Act Declarations
- Declarations provide immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency.



CICP Process

33

1. Submit a Request for Benefits Package.
2. CICP medical staff reviews to determine whether the requester is eligible for program benefits.
3. If eligible, the requester is asked to submit additional documentation to determine the type and amount of compensation the requester may be entitled to receive.
4. Can ask the Associate Administrator of the Healthcare Systems Bureau of HRSA to reconsider the program's eligibility or benefits determination. A qualified panel, independent of the program, is convened to review the program's determination.
5. The panel makes its recommendation to the Associate Administrator who makes a final determination.



CICP Criteria for Compensation

34

- A covered injury is a direct result of a covered countermeasure;
- Causation standard: “compelling, reliable, valid, medical and scientific evidence” that the injury:
 - Meets the requirement of an injury table; or
 - Is the direct result of administering a covered countermeasure (including aggravation).
- Statute of limitation: one year.
- Cannot go to state courts, except:
 - Willful misconduct.



Issues:

- CICP standard is hard to meet.
- No alternative.
- No review.
- Need to find an alternative for COVID-19 vaccines.

Which is not different between VICP and CICP?

A. The standard for showing causation.

0%

B. How long is the statute of limitations.

0%

C. When you can take your case to the civil courts.

0%

D. Whether you need to show causation.

0%



By
<https://reformparty.org/>, Fair use,
<https://en.wikipedia.org/w/index.php?curid=78755882>



37

REFORMS TO COME?



Changes:

- Representative Paul Gosar: bill to remove immunity/statute of limitations.

38

Home > Legislation > 119th Congress > H.R.4668

[Citation](#) [Subscribe](#) [Print](#)

H.R.4668 - End the Vaccine Carveout Act
119th Congress (2025-2026) | [Get alerts](#)

BILL Hide Overview [X](#)

Sponsor: [Rep. Gosar, Paul A. \[R-AZ-9\]](#) (Introduced 07/23/2025)
Committees: House - Energy and Commerce
Latest Action: House - 07/23/2025 Referred to the House Committee on Energy and Commerce. ([All Actions](#))
Tracker: [Introduced](#) → Passed House → Passed Senate → To President → Became Law

Summary (0) **Text (1)** Actions (2) Titles (2) Amendments (0) Cosponsors (29) Committees (1) Related Bills (0)

Text: H.R.4668 — 119th Congress (2025-2026) [View Text](#)

[Print](#) [Email](#) [Share](#)

≡ Listen ►

More [Committees](#) [CBO Cost](#) [Subject](#) [Health](#) [Give Feedback](#) [Contact Congress](#)



Changes:

- Secretary Kennedy's reform?
 - Details not announced.
Some points:
 - Discovery.
 - Delays.
 - “System broken”?
 - Changes to ACIP relevant.
 - Rumor: will add autism to table somehow.
 - Question: COVID-19 vaccines.
 - Lawsuit dismissed.

39





Thank you!

Questions? Comments?

reissd@uclawsf.edu

415-5654844