Vaccine Injury Compensation Programs

An Effective Balance of Public Health and Personal Remedy

The U.S. government created a generous compensation program in 1986 for people claiming harm after vaccination and, in exchange, limited their ability to sue manufacturers. A similar program for public-health emergency medical countermeasures was enacted in 2005. To help policy-makers understand the background and facts behind this liability program, Immunize.org developed this educational document, based in part on legal analysis by Dorit Rubinstein Reiss, JD, PhD, professor, University of California Hastings College of Law, and the book Vaccine Court: The Law and Politics of Injury, *by Anna Kirkland, 2016.*

Background: The Situation in the 1980s

Vaccines are exceedingly safe but, like any medication, they have side-effect profiles. Vaccines are the safest of medications. Before FDA licensing, vaccines are studied in larger populations than are other drugs. Once licensed and put to use, **multiple layers of safety surveillance** continue as long as the vaccines are distributed.

The Vaccine Injury Compensation Program (VICP) is **a no-fault alternative** to the traditional legal system for resolving petitions claiming injury after vaccination. (www.hrsa.gov/vaccine-compensation/index.html)

In the 1980s, **lawsuits** against vaccine companies and healthcare providers **threatened to cause vaccine shortages and reduce U.S. vaccination rates**. By the end of 1984, only one manufacturer of diphtheria-tetanus-pertussis (DTP) vaccine remained. Reduced vaccination rates could have caused a resurgence of serious diseases that routine vaccination can prevent (e.g., diphtheria, tetanus, pertussis, poliomyelitis, measles, mumps, rubella).

In the 1980s, people claiming vaccine injuries were not satisfied with a liability situation where **the path to compensation was arduous and uncertain**.

The U.S. Congress responded with the National Childhood Vaccine Injury Act (NCVIA) of 1986 (42 U.S.C. §§300aa-1 to 300aa-34). The program **balances liability protections for manufacturers with a clearer pathway for petitioners**.

Any individual, of any age, who received a covered vaccine, and believes he or she was injured as a result, **can file a petition**. Parents, legal guardians and legal representatives can file on behalf of children, disabled adults, and individuals who are deceased.

The Vaccine Injury Compensation Program (VICP) is widely considered **a success in balancing society's need to protect its children from serious infections** through an ample vaccine supply with an **easier compensation mechanism** to provide remedies in cases of adverse events that could have been caused by a vaccine.[1]

The Vaccine Injury Compensation Program (VICP) Details

The VICP program is **funded by an excise tax** on each dose of specified vaccine as it is purchased.

The VICP is **administered jointly by the U.S. Department of Health & Human Services, the Department of Justice, and the U.S. Court of Federal Claims**. Citizen input is provided by the Advisory Commission on Childhood Vaccines (ACCV).

Adverse events listed in a Vaccine Injury Table are presumed to have been caused by the vaccine cited in the list. Such claims are processed in a streamlined, no-fault fashion. Claims for other adverse events not included in the Table can also be considered.

The VICP has **paid out more than $4.9 billion to petitioners over 30+ years**. The no-fault character of this program means that being awarded compensation does not necessarily mean a vaccine caused an alleged injury.

Between 2006 to 2021, **over 4 billion doses of vaccines covered** by VICP were distributed in the U.S., with 7,075 petitions or claims receiving compensation under VICP.[2]

Comparison of VICP to Litigation in Civil Courts

Petitioners do not have to provide evidence of a defect in a vaccine's design, or any defect.

Causation standards are more lenient than in civil courts.

The **rules of evidence are relaxed** – petitioners can use non-experts and bring in materials (e.g., personal diary) that would not be allowed in regular courts.

Fees and costs are covered even if petitioners lose. When they win, they pay no contingency fee to attorneys representing them; the whole award goes to the petitioner.

But there are some disadvantages to petitioners. **Discovery is limited, and the statute of limitations is 3 years.**

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Petitioners can appeal in civil court if they do not prevail under VICP, but few do because it is widely considered harder for a petitioner to win in civil court.

Recent Events

In 2011, a case before the U.S. Supreme Court (Bruesewitz v. Wyeth, 562 U.S. 223) examined the scope of VICP liability protections.[3] In a 6:2 decision, the Supreme Court interpreted the NCVIA to preempt design-defect claims. For those claims, the only available forum is VICP, per this ruling.

The Food and Drug Administration (FDA) regulations that regulate the drug-manufacturing process formed a clear part of the Supreme Court's reasoning. The Justices wrote:

> "…the FDA's regulations – more than 90 of them – that pervasively regulate the manufacturing process, down to the requirements for plumbing and ventilation systems at each manufacturing facility. Material noncompliance with any one of them, or with any other FDA regulation, could cost the manufacturer its regulatory-compliance defense."
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> "And of course whenever the FDA concludes that a vaccine is unsafe, it may revoke the license."

Some people seek to overturn the Bruesewitz decision through legislation.

- The Bruesewitz decision does not take away petitioners' rights to have claims considered within the VICP process.
- Both the States and the federal government have multiple statutes limiting liability for policy reasons. No one has an absolute right to sue.

As a matter of balanced public policy, the federal government created a generous compensation program for people claiming harms from vaccines, and in exchange, limited their ability to sue manufacturers.

How does vaccine compensation in the U.S. compare to other countries, such as in Europe?

In general, the European social-services net is more extensive than in the U.S., reducing the need to litigate to cover basic needs and costs.

- European tort law differs from U.S. law in ways that discourage litigation. In many European countries, there are no contingency fees – making lawsuits harder for those with less means, though there may be legal aid available.
- There is no general European law on liability for vaccine injuries. Some European states have partial or full liability protections. In France, some claims of vaccine injuries do go to the courts, but others are compensated by the government without access to court.

The PREP Act of 2005 and Countermeasures Injury Compensation Program (CICP)

The Public Readiness & Emergency Preparedness Act (PREP Act, 42 U.S.C. §§247d to 6d) authorizes the Secretary of Health & Human Services to issue a declaration that provides immunity from liability (except for willful misconduct) for claims of loss resulting from administration or use of countermeasures to diseases, threats and conditions determined to constitute a present, or credible risk of a future public-health emergency. This limited immunity from liability applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. PREP Act declarations have been issued for various anthrax, botulism, COVID-19, smallpox, and other medical countermeasures. The PREP Act and the NCVIA, discussed on page 1, are similar in balancing liability protections for manufacturers with a clearer pathway for petitioners. For more information, see www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

The PREP Act also authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits in case of physical injury due to covered countermeasures. With CICP, benefits must be requested within 1 year from the date of administration or use of the covered countermeasure alleged to have caused the injury. Examples of covered countermeasures in the case of the COVID-19 pandemic include specified diagnostic tests, treatments, and vaccines. For more information, see www.hrsa.gov/cicp.

REFERENCES

1 Kirkland, Anna. *Vaccine Court: The Law and Politics of Injury*. New York: New York University Press; 2016. www.universitypressscholarship.com/view/10.18574/nyu/9781479876938.001.0001/upso-9781479876938

2 Health Resources & Services Administration (HRSA). Vaccine Injury Compensation Data www.hrsa.gov/vaccine-compensation/data/index.html

3 www.supremecourt.gov/opinions/10pdf/09-152.pdf.