

PROTECTING THE PROMISE

How the Vaccine Injury Compensation Program Sustains Vaccine Access, Affordability, and Innovation

Executive Summary and Key Takeaways

Vaccines remain one of medical innovations greatest success stories, but their availability, affordability, and continued development depend upon deliberate policy design that enable consumer access and public health success. Established nearly forty years ago, the National Vaccine Injury Compensation program stands at the center of that design. Developed in response to a crisis that threatened ongoing access to essential childhood vaccines in America, the no-fault compensation system provided those with vaccine-related injuries with fair and quick compensation, replaced unpredictable litigation with a structured process, and created conditions under which manufacturers would continue investing in vaccine production and innovation.

The evidence that the VICP has delivered is compelling:

- Routine childhood vaccinations during the VICP era have prevented an estimated 508 million illnesses and more than one million deaths, generating \$2.7 trillion in societal savings.
- Vaccine affordability programs, including Vaccines for Children, have helped close vaccination rate gaps for lower-income and uninsured Americans.
- More than 90 new vaccines have received FDA approval since 1986, and the number of manufacturers supplying the U.S. market has grown supporting vaccine access.
- Across more than 5.65 billion doses of covered vaccines distributed between 2006 and 2024, the Vaccine Injury Compensation Program compensated roughly one person per million doses. That a figure that reflects both the extraordinary safety record of modern vaccines and the program's ability to identify and compensate the rare cases where harm occurs.

I. Introduction

Vaccines are among the most powerful tools Americans have affordably preventing disease before it starts, protecting communities from disease outbreaks, and saving individuals and the nation billions in prevented medical costs and lost wages every year. Vaccines and high vaccination rates have nearly eradicated diseases that once killed or disabled hundreds of thousands of Americans each year, and they continue to prevent millions of illnesses, hospitalizations, and deaths annually. Yet the availability of vaccines and their affordability that enables broad access are not automatic. Instead, they are the product of intentional policy design reflective of American values emphasizing our individual and shared interests in preventing illness, protecting vulnerable populations, and enhancing the public's health.



Part of what makes that design necessary is the unusual economics of vaccines as a product. Unlike most medicines, which patients take daily or chronically, vaccines typically require only one or a few doses to confer long-term or lifelong protection. That is their great individual and public health value as well as their fundamental commercial liability. A drug that works so well people rarely need it again generates far less revenue than a treatment taken consistently over time. Combined with the high cost of development, the complexity of biological manufacturing, and the reality that it is governments and public health programs that primarily purchase vaccines, they are far less commercially attractive to develop and produce. Without deliberate policy intervention, the private sector has limited incentive to invest in developing them or to remain in the business of producing them.

At the center of the policy framework encouraging vaccine access and affordability stands the National Vaccine Injury Compensation Program (VICP), a federal no-fault compensation system established under the National Childhood Vaccine Injury Act of 1986. Though perhaps not well known to the public, the VICP is one of America's most consequential pieces of public health infrastructure operating for nearly forty years to provide people injured by covered vaccines with fair compensation while working to ensure the conditions for a stable, innovative, and affordable vaccine market remain in place.

This white paper documents the VICP's track record, examines its role in sustaining vaccine access, affordability, and innovation, and makes the case for its continued and strengthened operation. The evidence is clear: the VICP is not simply a legal mechanism for compensating rare injuries. It is the backbone of a public health compact that, if weakened, would raise costs and narrow access in the short-term while stifling innovation and raising otherwise avoidable costs from vaccine-preventable illnesses longer term.

II. The Problem the VICP Was Built to Solve

The origins of the VICP lie in a genuine market crisis set off, in large part, in 1982 by a documentary and related media coverage that focused on side effects and potential injuries from the DTP (diphtheria-tetanus-pertussis) vaccine. At that time, the vaccine had been used in the U.S. for more than 35 years. Before the DTP vaccine's widespread use started in the 1940s, more than 200,000 cases of pertussis were reported a year.¹ The claims in the documentary ultimately were largely refuted, but in the meantime generated large-scale public fear and an onslaught of legal claims. Lawsuits against manufacturers multiplied to the point that in 1984, the damage amounts claimed in lawsuits were 20 times higher than vaccine sales. A year later, the price of the vaccine had doubled, yet the amount of

¹ Centers for Disease Control and Prevention. "Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." *Morbidity and Mortality Weekly Report*, vol. 67, no. RR-2, 2018, <https://www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm>. Accessed 18 Sept. 2026.



damages claimed in lawsuits were 30 times higher than vaccine sales.² Even defending lawsuits successfully cost millions.³

By 1985, vaccine manufacturers had difficulty obtaining liability insurance at any price. Companies that had produced essential childhood vaccines for decades began to leave the market. The cost of the DTP vaccine skyrocketed, providers bought less, and patient access dropped. By the end of 1985, only one company still manufactured pertussis vaccine in the United States and shortages in supply led to rationing.⁴ The country was at risk of losing access to vaccines that protected children from serious, sometimes fatal illnesses.

Faced with a genuine public health emergency, Congress sought an independent scientific assessment from the Institute of Medicine (IOM). The bipartisan request came directly from Congressman John Dingell (D-MI) and Senator Orrin Hatch (R-UT), who needed credible policy grounding to justify federal intervention in what had become an access and affordability crisis. The IOM responded quickly with its 1985 report: *Vaccine Supply and Innovation*, which not only assessed the challenges but proposed legislative solutions to address them.⁵

The report documented the crisis in precise terms:

- **Rapid lawsuit growth:** Between 1980 and 1983, the number of vaccine injury lawsuits against major manufacturers more than doubled.
- **Dangerous market concentration:** At the time of the study, just one company supplied almost all the nation's polio and DTP vaccines, and only one other supplied all measles, mumps, and rubella vaccines.
- **Supply disruption:** Two of three DTP vaccine manufacturers had withdrawn from the market by 1985, causing a temporary shortage and forcing CDC to recommend rationing by delaying some childhood vaccine doses.
- **Spiraling legal costs:** Legal costs for some manufacturers exceeded millions of dollars in a single year, even when cases were successfully defended.

The IOM committee identified the core problem with unusual clarity: courts were ordering manufacturers to pay large damages not because they had done anything wrong, but because injured individuals had no other place to turn. Judges and juries, faced with a hurt child and no alternative compensation pathway, stretched legal theories to justify awards. As the report notes, “the skeptical lawyer advising a manufacturer could take as the message from the judges: manufacturers are going

2 Pubmed.Ncbi.Nlm.Nih.Gov. <https://pubmed.ncbi.nlm.nih.gov/3486586/>. Accessed 3 Sept. 2026.;

Offit, Paul. “A Dangerous Time for America’s Children: Part II.” Substack newsletter. *Beyond the Noise*, 14 Jan. 2025, <https://pauloffit.substack.com/p/a-dangerous-time-for-americas-children-3bb>;

González, Elizabeth Rasche. “TV Report on DTP Galvanizes US Pediatricians.” *JAMA*, vol. 248, no. 1, 1982, pp. 12–22. [JAMA article](#).

3 *Vaccine Supply and Innovation 1985*. www.nationalacademies.org, <https://www.nationalacademies.org/publications/599>. Accessed 3 Sept. 2026.

4 Centers for Disease Control and Prevention. “Diphtheria-Tetanus-Pertussis Vaccine Shortage—United States.” *Morbidity and Mortality Weekly Report*, 1985. [CDC MMWR article](#)

5 *Vaccine Supply and Innovation 1985*. www.nationalacademies.org, <https://www.nationalacademies.org/publications/599>. Accessed 3 Sept. 2026.



to pay, one way or the other.” The report described the system as a “lottery,” since the outcomes were erratic, slow, and unpredictable for both patients and vaccine manufacturers.

IOM COMMITTEE FINDINGS, 1985

“Those who are injured as an unfortunate consequence of immunization programs should be provided reasonable compensation in a rapid and equitable manner. The common law tort system does not satisfy these requirements.”

“If apprehensions about the current unclear state of the law caused these manufacturers to withdraw, the vaccine supply and immunization programs could be jeopardized, leading to the possible resurgence of these diseases. Also, the apprehensions discussed above are a disincentive to investment in the development of new (or improved) immunizing agents and to competition from new or foreign firms.”

Following the IOM’s findings and recommendations, Congress responded in 1986 with the National Childhood Vaccine Injury Act, which created the VICP. Its purpose was threefold: (1) to provide fair and fast compensation for injured patients; (2) to stabilize the vaccine market by removing the threat of unpredictable litigation; and (3) to preserve accountability for manufacturers who engage in genuine misconduct.

III. How the VICP Works

The VICP operates as a no-fault alternative to the civil tort system. Patients or their families who believe they were harmed by a covered vaccine file a petition with the U.S. Court of Federal Claims, which is adjudicated by a panel of Special Masters. To receive compensation, petitioners must either demonstrate that their injury appears on the Vaccine Injury Table within a specified window of time or prove that the vaccine was the direct cause of the injury. The law preserves the injured person’s ability to sue in traditional courts if dissatisfied with the results. VICP also provides opportunities to appeal claim denials.

Three structural features define the program:

- **The Vaccine Injury Table:** A list of injuries and conditions known to be associated with specific vaccines. For Table injuries, causation is presumed, dramatically reducing the burden of proof and the time to resolution. The HHS Secretary can update the table through an administrative process outlined in federal statutory and regulatory law.⁶
- **The excise tax funding model:** The program is funded by a 75-cent excise tax on every purchased dose of a covered vaccine. For a combination vaccine like MMR, that means a tax of \$2.25 – or 75 cents for each illness covered. The tax spreads the cost of rare injuries across

⁶ Rogers, Hannah-Alise. *The National Vaccine Injury Compensation Program and the Office of Special Masters*. Congressional Research Service, 14 Sept. 2022, IF12213. [Congressional Research Service report](#).



the supply chain, replacing unpredictable and costly lawsuits with a predictable financial obligation to cover compensation. Congress must act to add vaccines to the program.

- **Manufacturer accountability preserved:** The VICP does not protect bad actors. Manufacturers who engage in negligent manufacturing, who falsify safety data, or who otherwise act improperly remain fully liable through the traditional legal system for injuries that result. Only unavoidable injuries from properly manufactured vaccines are covered by VICP.

POINT OF INTEREST • How the VICP Claims Process Works

The VICP was designed to be a faster, fairer system where injured individuals can seek compensation without having to sue a vaccine manufacturer, hire expensive lawyers, or prove that anyone did anything wrong.

Filing a claim. The process begins when an injured party files a claim with the U.S. Court of Federal Claims. Because this is a legal process, most people hire a lawyer. Attorney fees and legal costs are covered by the program as long as the petition is filed in good faith.

Government review. Once filed, HRSA experts review the medical evidence, and the Department of Justice reviews the legal aspects of the claim. Their findings are combined into a report submitted to the court and shared with the person filing the claim.

The Special Master decides. A Special Master, a specialized federal judge who handles only vaccine cases, reviews the evidence and decides whether compensation is warranted and in what amount. The three categories of compensation are medical expenses, lost or future earnings, and pain and suffering. For injuries that appear on the Vaccine Injury Table occurring within a specific timeframe after vaccination, causation is presumed, which speeds up resolution. Injuries not listed on the table or appearing in the timeframe require proof that the vaccine caused the harm.

Resolution and appeals. The petitioner can accept the decision, negotiate a settlement, or appeal, including escalating through the federal courts up to the U.S. Supreme Court if needed.

How long does it take? Congress set a 240-day target for adjudication.⁷ In practice, most claims now take significantly longer to resolve, reflecting the program's growing backlog and need for reform.

⁷ Hannah-Alise Rogers, *Vaccine Injury Compensation Program: The Adjudication of Petitions and the 240-Day Deadline*, Congressional Research Service, Legal Sidebar LSB11428, May 4, 2026.



Since its inception in 1988, the program has covered a growing number of vaccines: rising from 6 vaccines at launch to 16 today. Over that period, more than 29,600 petitions have been filed, with over 11,600 compensated and an estimated \$5.6 billion paid to people filing claims.⁸ Crucially, this compensation has occurred without destabilizing the broader vaccine market, as the IOM and Congress envisioned. More than 5 billion doses of VICP-covered vaccines were distributed between 2006 to 2024 alone and more than 15 new vaccines have been developed since the VICP's establishment (Table 1) with more in the development pipeline aimed at reducing the toll of both infectious and chronic illnesses.

POINT OF INTEREST • Benefits and Challenges of VICP Expansion: Flu Vaccine & Shoulder Injuries

Adding seasonal influenza vaccine to the VICP in July 2005 marked the first time Congress included a vaccine administered primarily to adults. The VICP caseload rose dramatically as a result. The average number of claims filed per year rose from [466 during FY2005–FY2014 to 1,238 per year during FY2015–FY2025](#), driven substantially by flu-related claims.

A second wave followed the 2017 addition of Shoulder Injury Related to Vaccine Administration (SIRVA) to the Vaccine Injury Table. The injury is overwhelmingly associated with improper flu shot administration. SIRVA claims grew from just [10 in 2011 to 711 in 2019, and by 2017–2019 accounted for more than half of all VICP claims filed](#).

These examples highlight both the program's adaptability and structural vulnerability. In both instances, Congress did not adjust the number of Special Masters to hear VICP cases. Expanding VICP coverage without increasing the program's capacity to handle additional cases creates delays and backlogs that undermine the core promise of providing injured people with timely compensation.

IV. The VICP's Role in Vaccine Access and Affordability

One of the most underappreciated aspects of the VICP is its dual purpose of not only compensating people harmed by vaccines, but also to stabilize vaccine access and affordability by keeping vaccines available, keeping manufacturers in the business of making them, and keeping vaccines affordable.

HOW LIABILITY PREDICTABILITY TRANSLATES TO AFFORDABILITY

When manufacturers face unpredictable litigation costs, they respond by raising prices to cover costs, leaving the market, and/or avoiding developing new vaccines. All three outcomes harm access to and

⁸ Health Resources and Services Administration. *National Vaccine Injury Compensation Program: Monthly Statistics Report*. U.S. Department of Health and Human Services, 1 Mar. 2026. [Vaccine Injury Compensation Data | HRSA](#)



affordability of vaccines, raise the prevalence of illnesses, and increase health-related costs from vaccine-preventable illnesses. The VICP addressed these concerns directly by replacing open-ended civil litigation with a structured system funded by a set excise tax on all covered vaccines.

This excise tax model is central to this stability. By funding the compensation system using a per-dose tax, the VICP distributes the cost of rare injuries across the entire vaccine supply chain. The result is a more predictable financial environment in which decisions about vaccine production and investments into new vaccines can be made rationally while providing coverage for vaccine injuries.

COST IS A REAL BARRIER TO VACCINATION

The connection between vaccine affordability and uptake is well documented:

- The Vaccines for Children program (VFC) created in 1994 provides no cost access to all recommended childhood vaccines to children who are Medicaid-eligible, uninsured, or underinsured. The VFC has helped to narrow the gap in vaccination rates between VFC-eligible children and non-VFC-eligible children, but gaps still exist particularly with vaccines requiring multiple doses in a series and costs associated with office visits.⁹
- Adults without health insurance are as much as 10 times less likely to be vaccinated than adults with health insurance.¹⁰
- When out-of-pocket costs are eliminated, uptake rises sharply. For example, after Congress removed cost-sharing for vaccines under Medicare Part D, Tdap vaccine uptake rose by 114 percent and shingles vaccine uptake grew by more than 40 percent in 2023 compared to 2021 when beneficiaries had cost-sharing requirements.¹¹
- Unvaccinated individuals account for nearly 80 percent of the estimated \$9 billion annual economic burden from vaccine-preventable diseases in the U.S.¹²

THE VIRTUOUS CYCLE

Affordable vaccine access drives uptake. Uptake prevents illness. Preventing illness saves money and makes healthcare more affordable overall. In fact, routine childhood vaccinations have prevented approximately 508 million illnesses, 32 million hospitalizations, and over one million deaths among U.S. children born 1994–2023, generating \$540 billion in direct savings and another \$2.7 trillion in societal savings.¹³ These results depend on vaccines remaining accessible. The VICP facilitates affordability programs like the VFC that make broad access possible.

9 Centers for Disease Control and Prevention. "Vaccines for Children." *CDC Vital Signs*, <https://www.cdc.gov/vitalsigns/vaccines-for-children/index.html>. Accessed 18 Sept. 2026.

10 Centers for Disease Control and Prevention. "Adult Vaccination Coverage — United States, 2022." *AdultVaxView*, <https://www.cdc.gov/adultvaxview/publications-resources/adult-vaccination-coverage-2022.html>. Accessed 18 Sept. 2026.

11 U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. *Medicare Part D Enrollee Vaccine Use After Elimination of Cost Sharing for Recommended Vaccines in 2023*. [ASPE fact sheet](#).

12 Ozawa, Sachiko, et al. "Modeling the Economic Burden of Adult Vaccine-Preventable Diseases in the United States." *Health Affairs*, vol. 35, no. 11, 2016, pp. 2124–2132. [Health Affairs article](#).

13 Zhou, Fangjun, et al. "Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program—United States, 1994–2023." *Morbidity and Mortality Weekly Report*, vol. 73, no. 31, 2024, pp. 682–685. [CDC MMWR article](#). <https://doi.org/10.15585/mmwr.mm7331a2>.



KEY DATA POINT

Between 2006 to 2024, more than 5 billion doses of covered vaccines were distributed in the U.S. and just over 14,000 claims were adjudicated within the VICP and more than 10,500 them found to be compensable injuries. Overall, that means, for every 1 million doses of VICP-covered vaccines distributed in the U.S., 1 person received compensation from the VICP.¹⁴

V. The VICP's Role in Vaccine Innovation

Beyond sustaining the existing vaccine supply, the VICP provides the predictable liability environment that manufacturers need to justify the long-term investments required to develop new vaccines and advance the science relating to vaccine safety and efficacy.

The IOM's 1985 analysis identified several economic disincentives unique to vaccines that, made worse by liability risks, were causing companies to abandon vaccine production and research. Vaccines are associated with high R&D costs relative to sales. They have limited market size since vaccines involve a single course of doses eliminate a person's need for the product in the future. Governments purchase in bulk at lower margins. Also, vaccines are biological products that involve sophisticated manufacturing and an unbroken refrigeration distribution chain from factory to patient that adds to costs and complexity. Vaccines also have a shorter shelf-life after production that further complicates manufacturing, distribution, and inventory planning and costs.

The VICP addressed the liability piece directly by replacing unpredictable jury awards and legal costs with a structured, manageable system. This allowed manufacturers to make long-term investment decisions involving vaccine development, manufacturing, and distribution systems enabled by more predictable financial and business models.

Americans have benefitted as a result. Since VICP's establishment in 1988, the number of vaccines available against serious illnesses has more than doubled (Table 1). The technology has also changed from relying on killed or weakened pathogens as was the norm in 1986 to developing recombinant protein vaccines, conjugate vaccines, and mRNA vaccines that are more targeted and effective while reducing the amount of antigen needed in a vaccine to generate a stronger, more durable immune response. Emerging mRNA applications for influenza, personalized cancer treatments,¹⁵ and other diseases represent enormous development investments while holding tremendous promise. Manufacturers will only pursue these if they can plan around known financial risks. A stable liability framework is a prerequisite for a robust development pipeline. The VICP protects vaccine access and affordability today while supporting the conditions that enables vaccine innovation for what comes next.

14 Health Resources and Services Administration. *National Vaccine Injury Compensation Program: National Vaccine Injury Compensation Program Data Report*. U.S. Department of Health and Human Services, 1 Sept.. 2026. [Vaccine Injury Compensation Data | HRSA](#)

15 Lorentzen, Cathrine Lund, et al. "Clinical Advances and Ongoing Trials of mRNA Vaccines for Cancer Treatment." *The Lancet Oncology*, vol. 23, no. 10, 2022, pp. e450–e458. [ScienceDirect article](#). [https://doi.org/10.1016/S1470-2045\(22\)00372-2](https://doi.org/10.1016/S1470-2045(22)00372-2).



TABLE 1: VACCINES DEVELOPED OR EXPANDED SINCE VICP'S ESTABLISHMENT (1986–PRESENT)

Bold = Vaccines in bold are not currently covered by VICP (shingles, COVID-19,¹⁵ RSV).

First FDA approval year noted in parentheses next to name of vaccine or intervention.

DISEASE	FDA APPROVAL DATE(S)	INNOVATION & IMPACT
Haemophilus influenzae type b (Hib) meningitis	1989, 1993, 2009, 2018	Before vaccines, Hib bacterial infections were the main cause of bacterial meningitis and a leading killer of children under age 5. Since routine use, Hib meningitis cases have fallen by about 90% worldwide saving nearly 3 million lives worldwide by 2024. (Meningitis Research Foundation) Several vaccines followed the first Hib vaccine approved in 1987: PedvaxHIB (1989), ActHIB (1993), and Hiberix (2009) protect against Hib-only; and Pentacel (2008) and Vaxelis (2018) combination vaccines offer Hib protection along with diphtheria, tetanus, pertussis, and polio. Vaxelis also protects against hepatitis B. (CDC Hib Vaccines)
Hepatitis B (single & combo vaccines)	1989, 2002, 2017, 2018	Hepatitis B is a liver infection that can become long-term and lead to liver damage or cancer. The first hepatitis B vaccine, Recombivax HB, was approved in 1986; Engerix-B followed in 1989. Both are approved for all ages. For adults, Heplisav-B (2017) reduced the number of doses. Combination vaccines offer fewer shots and multi-illness protection: Twinrix (Hep A & B, 1996), Pediarix (DTaP, Hep B, and polio, 2002), and Vaxelis (DTaP, polio, Hib, and Hep B, 2018). (CDC Hep B Vaccines) Acute hepatitis B cases among people ages 0–19 fell 99%, from 2,180 cases a year to just 13, between 1990 and 2019. (Economic evaluation Hep B)
Chickenpox (Varicella) (single & combo vaccines)	1995, 2005	Chickenpox once infected nearly every U.S. child and could lead to serious skin infections, pneumonia, or brain swelling. Varivax, approved in 1995, remains the only stand-alone chickenpox vaccine. In 2005, ProQuad combined it with the measles-mumps-rubella vaccine into a single shot, cutting the number of injections children need. (Varicella Vaccines) Since 1995, US chickenpox vaccination programs have prevented 91 million cases and saved more than \$23 billion in healthcare costs. (CDC Success vs Chickenpox)
Hepatitis A (single & combo vaccines)	1995, 1996, 2001	Hepatitis A is a highly contagious liver infection spread through contaminated food or water or person-to-person contact with an infected person. Havrix (1995) was the first hepatitis A vaccine in the U.S., followed closely by VAQTA in 1996. In 2001, Twinrix (1996) combined hepatitis A and B protection into a single vaccine for adults. (CDC Hep A) Cases have declined more than 95% since routine vaccination began, preventing an estimated tens of

		thousands of infections every year. Outbreaks still occur. (2023 Viral Hepatitis Surveillance Report 2023 Hepatitis Surveillance CDC)
Pneumococcal disease (innovations adding multiple strain protection)	2000, 2010, 2021	Pneumococcal bacteria cause pneumonia, meningitis, and bloodstream infections, and before vaccines were a major cause of serious illness in young children and older adults. Pneumococcal pneumonia leads to 150,000 hospitalizations in the US each year. (American Lung Association) The first pneumococcal conjugate vaccine, Prevnar (PCV7, 2000), protected against 7 strains of the bacteria. Prevnar 13 expanded that to 13 strains in 2010, and two new vaccines followed in 2021: Prevnar 20, covering 20 strains and Vaxneuvance (PCV15), covering 15 strains including two linked to antibiotic resistance. Overall, these vaccines have prevented more than 282,000 cases of invasive disease and up to 706,000 pneumonia hospitalizations. Vaccines have helped reduce childhood pneumonia hospitalizations by 66–79%. (CDC Public Health Impact)
Seasonal Influenza	2003, 2005, 2007, 2009, 2012, 2013, 2015, 2020, 2024, 2026 (innovations include strain coverage and protection, manufacturing, and administration) (Added to VICP program in 2005)	Millions of Americans contract influenza each year, causing hundreds of thousands of hospitalizations, and thousands of deaths. (CDC Flu burden) Flu vaccines offer protection and diversity in options with innovation allowing for choices based on age and risk factors to provide added protection for vulnerable populations. Innovations include: needle-free, nasal-spray option FluMist (2003; at home option 2024) and jet injector Afluria (2014); Fluzone High-Dose (2009) and Fluvad (2015) providing extra protection for older adults; first widely available subunit vaccine Agriflu (2009) minimized side effects; Flucelvax (2012) and Flublok (2013) involves innovative manufacturing that helps avoid egg-related supply issues. Fluarix Quadrivalent (2012) first to cover four influenza strains (all US flu vaccines now updated to three strains in response to flu strain surveillance). In August 2026, mFlusiva became the first mRNA-based flu vaccine, approved for adults 50 and older. (Flu Vaccine Types ; Ages Covered) During the 2024–2025 flu season, flu vaccination estimated to have prevented 10 million flu-related illnesses, 180,000 hospitalizations, and 12,000 deaths. (CDC Flu Vaccines Work)
Tetanus, Diphtheria & Pertussis or whooping cough (DTaP and Tdap combo vaccines; Td tetanus and diphtheria combo).	1991, 1997, 2002, 2003, 2005, 2008, 2015, 2018	Diphtheria and pertussis spread person to person while tetanus enters the body through cuts or wounds. Pertussis/whooping cough is especially dangerous for infants, and this age group continues to have the highest reported rate of infection. The US experienced a surge in 2024 of more than 35,000 cases. (Whooping Cough Trends) Infanrix (1997) and Daptacel (2002) provide DTaP protection. Other combination vaccines provide DTaP coverage and add protection against polio Kinrix (2008) and Quadracel (2015); polio and hepatitis



		B Pediarix (2002); polio and Hib Pentacel (2008); and polio, Hib, and hepatitis B Vaxelis (2018). (CDC Vaccine Types) Tenivac (2003) covers tetanus and diphtheria for ages 7 and older while Boostrix and Adacel (both 2005) extended pertussis protection to adolescents and adults for the first time. Vaccination during pregnancy is credited with preventing 78% of pertussis cases in infants younger than 2 months old. (Pertussis & Pregnancy)
Shingles	2006, 2017	Shingles is a painful skin rash caused by the same virus as chickenpox reactivating later in life, most often in older adults. Zostavax (2006) was replaced by Shingrix (2017) and is more than 90% effective against shingles and dramatically reduced the burden of shingles in adults 50 and older. Not covered by VICP. (Shingles Vaccine)
Rotavirus	2006, 2008	Rotavirus causes severe diarrhea and dehydration in infants and young children; before vaccination, nearly every U.S. child was infected. RotaTeq (2006) and Rotarix (2008) have helped reduce hospitalizations among U.S. children by about 80%, saving \$121 to \$231 million in health care costs. (Decade review with Rotavirus Vaccination)
HPV (Human Papillomavirus) (expanded to cover different virus types)	2006, 2009, 2014	HPV is a common virus that can cause cervical and other cancers years after infection. Gardasil (2006) was the first HPV vaccine and covered 4 strains; Cervarix (2009) covering 2 different strains; Gardasil 9 (2014) expanded coverage to 9 strains and is now the only HPV vaccine sold in the U.S. (HPV Vaccine) Since HPV vaccine introduction, HPV infection rates have declined by about 90% on average, and cervical precancers among women ages 20–24 fell 80% between 2008 and 2022. (Eliminating Cervical Cancer)
Meningococcal disease	1999, 2005, 2010, 2014 (two vaccines), 2020, 2023, 2025	Meningococcal disease is rare but severe bacterial infection that can cause death in a few hours and leave survivors with permanent disabilities. (Bacterial Meningitis) Available vaccines protect against one or multiple strains of the bacteria that cause meningococcal disease. Conjugate vaccines providing greater protection for children against meningitis became available in 1999. Menactra (2005), Menveo (2010) and MenQuadfi (2020) extended protection to four bacterial strains (MenACWY). Bexsero and Trumenba (2014) offer protection against serogroup B, which is the strain most common among U.S. adolescents and college students. Penbraya (2023) and Penmenvy (2025) protect against all five strains (MenABCWY). (Meningitis Prevention; Available Vaccines)



COVID-19	2021, 2022, 2025	From the 2025–2026 season, COVID-19 vaccination cut risk of COVID-19–related deaths, hospitalizations, and ED/urgent care visits in half. Vaccines include mRNA options Comirnaty (2021), Spikevax (2022), and mNEXSPIKE (2025) and a non-mRNA vaccine, Nuvaxovid (2025). Like the flu vaccine, COVID-19 vaccines are adapted annually to match circulating variants. (COVID-19 Vaccine Effectiveness & Safety) None of these vaccines are covered by VICP; they fall under the separate Countermeasures Injury Compensation Program (CICP).
RSV, adults (vaccines)	2023, 2024	During 2025–2026, RSV (respiratory syncytial virus) caused 170,000 to 340,000 hospitalizations and 9,900 to 25,000 deaths. (RSV Immunization Effectiveness & Safety) Arexvy and Abrysvo (both in 2023) were the first RSV vaccines approved for adults 75 and older and for some younger, at-risk adults. Abrysvo is also approved for use during pregnancy to provide newborn protection. mResvia (2024) approved for adults 60 and older and younger adults at increased risk of illness. (RSV Immunization Effectiveness & Safety) (RSV Recommendations) None of these vaccines are covered by VICP.
RSV, infants (antibody treatments)	2023, 2025	RSV is the leading cause of hospitalization among U.S. infants. Beyfortus (2023) and Enflonsia (2025) are not vaccines, but are monoclonal antibodies given directly to babies whose mothers did not receive the RSV vaccine during pregnancy. With high use of maternal vaccination or one of these antibody treatments, RSV-related infant hospitalizations are estimated to have declined by an estimated 64 to 93%. (RSV Immunization Effectiveness & Safety) Not covered by VICP.

VI. Measuring Success: The VICP's Track Record

The VICP has now operated for nearly forty years with remarkable results.

- Routine childhood vaccinations during the program's era have prevented roughly 508 million illnesses and over 1 million deaths, generating \$2.7 trillion in societal savings.¹⁶
- The Vaccines for Children's program and other vaccine affordability programs have helped to provide low-cost vaccine access that helped close the gap in vaccination rates for lower-income and uninsured Americans and Americans with insurance coverage.

¹⁶ Zhou, Fangjun, et al. "Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program—United States, 1994–2023." *Morbidity and Mortality Weekly Report*, vol. 73, no. 31, 8 Aug. 2024, pp. 682–685. <https://doi.org/10.15585/mmwr.mm7331a2>.



- More than 29,600 petitions have been filed since 1988, of which over 11,600 have been compensated and more than \$5.6 billion paid out.
- Across more than 5.65 billion doses of covered vaccines distributed between 2006 and 2024, the program adjudicated 14,325 petitions and compensated 10,556. That averages out to one injured person compensated per one million doses of vaccines administered.¹⁷
- About 60 percent of the compensation the VICP awards comes from negotiated settlements in which the Department has reviewed the evidence presented but has not concluded that the vaccine at issue caused the claimed injury.¹⁸
- As these results demonstrate, though serious injuries from covered vaccines are rare, the compensation provided when they occur is significant ranging from average payment amounts of \$1.3 million to \$111,500 a year (FY1989–FY2025).¹⁹
- Since VICP's inception, more than 90 new vaccines have received FDA approval in the U.S.²⁰ and the number of manufacturers providing vaccines to U.S. consumers has grown.

The program also promotes public trust. VICP provides a transparent, consistent compensation system that takes injury claims seriously and resolves them fairly while preserving the right to appeal decisions or seek traditional legal recourse. In so doing, the program supports the broader social contract around vaccination. People are more likely to accept recommended vaccines when they believe that, in the rare event of an adverse reaction, they will have their injury claim taken seriously and compensated fairly.

VII. Current Challenges to the Program

Despite its track record, the VICP faces significant administrative and structural pressures that, if unaddressed, will undermine its continuing ability to meet its founding promises.

CASELOAD GROWTH AND ORIGINAL CAPS

The program's most acute problem is structural in that caseload growth has dramatically outpaced resources. For example, more than 2,000 claims were filed in FY2021 compared to 386 ten years earlier.²¹ HRSA 2026 data show that adjudicating a claim now takes two to three years,²² contrary to program goals of fast, fair compensation.

The Eight Special Masters Cap

17 Health Resources and Services Administration. *National Vaccine Injury Compensation Program: Monthly Statistics Report*. U.S. Department of Health and Human Services, 1 Mar. 2026. [Vaccine Injury Compensation Data | HRSA](#)

18 Health Resources and Services Administration. *National Vaccine Injury Compensation Program: Monthly Statistics Report*. U.S. Department of Health and Human Services, 1 Mar. 2026. [Vaccine Injury Compensation Data | HRSA](#)

19 Michaud, Josh, and Jennifer Kates. "Federal Vaccine Injury Compensation Programs: Overview and Current Issues." *KFF*, 15 May 2026. [KFF](#).

20 U.S. Food and Drug Administration. "Vaccines Licensed for Use in the United States." *FDA*, U.S. Department of Health and Human Services, www.fda.gov.

21 Rogers, Hannah-Alise. *The National Vaccine Injury Compensation Program and the Office of Special Masters*. Congressional Research Service, 14 Sept. 2022, IF12213. [Congressional Research Service report](#).

22 Health Resources and Services Administration. *National Vaccine Injury Compensation Program: Monthly Statistics Report*. U.S. Department of Health and Human Services, 1 Mar. 2026. [Vaccine Injury Compensation Data | HRSA](#)



The single most cited structural bottleneck is the statutory cap on the number of Special Masters who adjudicate vaccine petitions. The original law set the number of Special Masters at eight when the program covered six vaccines and served a fraction of today's volume of claims. Efforts to enhance the program must address this issue to ensure that claims are processed efficiently as the program promised.

Original Compensation Caps

Pain-and-suffering awards and death benefits remain capped at \$250,000, the same limit set in 1986 that has never been adjusted for inflation.²³ The gap between the original statutory cap on these damages and inflationary costs through today erode the program's fairness in compensation and preferential alternative to civil litigation.

THE COVERAGE GAP FOR NEW VACCINES

Congress must pass separate legislation to add the excise tax on a new vaccine before it is covered by the VICP. It is a slow, politically contingent process that leaves newly approved vaccines in a liability gap.

Several vaccines now outside VICP coverage (Table 1) represent a meaningful and growing gap. These vaccines collectively target some of the highest-burden conditions among infants and older Americans. Their exclusion leaves millions of vaccinated Americans without the VICP's consumer protections and leaves manufacturers without the market stability that the program provides.

Each of these pressure points directly impact the program's core mission to provide prompt, fair compensation for vaccine-related injuries and market stability that makes affordable vaccine access and continued innovation a reality.

VIII. Recommendations to Strengthen VICP

Addressing the VICP's current challenges requires targeted, constructive reforms that enhance, not dismantle a program that has worked to promote and protect individual and public health. Bipartisan congressional reform efforts like those reflected in the Vaccine Injury Compensation Modernization Act of 2026 are encouraging steps forward to strengthening the program to meet modern demands.

The following recommendations would strengthen the program's capacity to fulfill its founding promise:

- **Expand capacity by raising the number of Special Masters.** Congress should amend the National Childhood Vaccine Injury Act (NCVIA) to raise the Special Masters cap to at least 10, with standing authority to grow further as caseload warrants. Increased appropriations for HRSA medical review staff would also accelerate case adjudication and compensation.

23 Michaud, Josh, and Jennifer Kates. "Federal Vaccine Injury Compensation Programs: Overview and Current Issues." *KFF*, 15 May 2026. [KFF](#).



- **Modernize compensation caps.** Update the \$250,000 ceiling on pain-and-suffering and death benefits to reflect inflation since 1986 and establish an automatic inflation-adjustment mechanism going forward.
- **Automate the excise tax.** Eliminate the requirement for separate congressional action each time a new vaccine is added, replacing it with automatic tax application triggered by addition of vaccines to the Injury Schedule by HHS. This would close the liability gap for newly approved vaccines and streamline the program's ability to grow with the immunization schedule.
- **Develop a backlog reduction plan.** Require HHS and the Department of Justice to submit to Congress a time-bound action plan for eliminating the existing case backlog, with annual progress reporting against defined milestones.
- **Extend VICP coverage to newer vaccines not covered.** Evaluate pathways to bring currently uncovered vaccines such as RSV vaccines under VICP coverage to close the consumer protection and market stability gap.
- **Strengthen transparency and data infrastructure.** Require annual public reporting by Special Masters on caseloads, timelines, and outcomes. Funding data systems that track the program's impact on market stability, vaccine pricing, and population access will increase transparency into the program's impact on goals of vaccine access, affordability, and innovation to supplement reporting on claim volume, processing times, and compensation.

IX. Conclusion

In establishing the VICP, Congress confirmed that vaccines are a public good, immunization programs carry rare and unavoidable risks, and society has a responsibility to compensate those who bear those risks quickly, fairly, and without requiring them to prove fault to recover for their injuries. Since its inception, vaccines have remained accessible and affordable, have spared millions of Americans from serious illness, and have lowered the burden of once widespread illnesses dramatically.

Nearly forty year later, the rationale behind the program remains sound and its success unquestionably shown in the health outcomes of hundreds of millions of Americans and in the \$2.7 trillion in societal savings generated by the vaccines the program helped make possible.

The VICP is the foundation of a public health compact by which manufacturers accept oversight and produce safe vaccines; the government promotes and sometimes requires vaccination; and society, in turn, provides a fair and efficient pathway for those who are harmed. Strengthening the VICP through targeted reforms is not simply a necessary matter of fairness to those injured. It is an investment in the policy foundation that sustains vaccine availability, drives affordability, and provides the market stability that attracts innovators and makes the next generation of vaccines worth pursuing.

ABOUT THE PARTNERSHIP TO FIGHT INFECTIOUS DISEASE

The Partnership to Fight Infectious Disease (PFID) is a coalition of patients, providers, community organizations, academic researchers, business and labor groups, and infectious disease experts working to raise awareness of threats posed by infectious disease, including antimicrobial resistance and the importance of vaccine confidence. For more information, visit www.fightinfectiousdisease.org.

