



National Childhood Vaccine Injury Act of 1986

[BY NVIC.ORG](https://www.nvic.org)



Preface

This Digital PDF Series includes information about the 1986 Act. It is pertinent to understand this act in relation to liability and accountability.

(Please note that this information comes from [NVIC.org](https://www.nvic.org), and that I, therefore, do not take credit for their words.)

The National
Childhood
Vaccine Injury
Act passed by the
99th Congress in
1986 was
acknowledgement
by the U.S.
government that:

1. federally licensed and recommended vaccines mandated by states for children to attend school can and do cause injury and death;
2. vaccine safety should be a priority for health agencies, vaccine manufacturers, doctors and other vaccine administrators;
3. individuals injured by government recommended and mandated childhood vaccines should have access to a federal vaccine injury compensation program administrative alternative to filing a vaccine injury lawsuit in civil court, and should have access to the civil court system when:
 - federal compensation is denied or is inadequate;
 - there is evidence a pediatrician or other vaccine administrator negligently administered a vaccine;
 - a vaccine manufacturer engaged in criminal fraud or negligence; or
 - a vaccine manufacturer could have made a vaccine less harmful (design defect).

The co-founders of Dissatisfied Parents Together (DPT) and the National Vaccine Information Center (NVIC) worked with Congress on the Act between 1982 and 1986. It was and is the position of DPT/NVIC that vaccine injured persons or their parents/legal guardians should be allowed to make a choice between filing a vaccine injury lawsuit in civil court or applying for compensation in a non-adversarial, expedited, less traumatic and less expensive vaccine injury compensation program alternative to a lawsuit.

1986 Act Did Not Eliminate All Liability for Vaccine Makers or Administrators

The National Childhood Vaccine Injury Act passed by the 99th Congress in 1986 did not completely shield doctors or other vaccine administrators from vaccine injury lawsuits. Although vaccine product liability for manufacturers was restricted, it was not eliminated, and manufacturers continued to be liable for design defect. In 1987, medical trade organizations successfully lobbied for inclusion of a one-sentence amendment in an Omnibus funding bill that broadened liability protection for pediatricians and other vaccine administrators but did not broaden liability protection for vaccine manufacturers when there was evidence the company could have made a vaccine less harmful.

U.S. Supreme Court Removed Vaccine Product Liability in 2011

Twenty-five years later, a 2011 split decision in *Bruesewitz v. Wyeth* by the U.S. Supreme Court blocked the legal right of vaccine injured persons to hold drug companies liable for design defect and failing to improve an FDA licensed vaccine to make it less harmful. Justices Sonia Sotomayor and Ruth Bader Ginsberg wrote a strong dissent, objecting to the majority's inaccurate interpretation of the law and its legislative history.

However, the majority ruling in this Supreme Court case means that, today, even if a drug company could have improved a government licensed and mandated vaccine to make it less reactive, a vaccine injured person cannot sue the company in a civil court in front of a jury of peers.

Additionally, between 1987 and 2016, Congress allowed amendments and broad rule making authority granted to the Department of Health and Human Services (DHHS) to alter and weaken the original Act. The Act's safety and research provisions, which parents fought hard to secure in the original Act to help prevent vaccine injuries and deaths, have been seriously compromised. Neglect and lack of congressional oversight on the Act for more than 30 years has enabled DHHS and the Department of Justice to turn what was supposed to be a non-adversarial, expedited, less expensive, fairer and more predictable federal vaccine injury compensation program, which Congress promised parents in 1986, into a highly adversarial, lengthy, traumatic and unpredictable imitation of a lawsuit in front of a one person jury.

National Tort Reform Changed U.S. Medical Malpractice and Product Liability Laws

In addition, product liability and personal injury tort reform legislation enacted by Congress and state legislatures since the 1970s has severely restricted class action, medical malpractice and product liability lawsuits in federal and state courts. Wealthy corporations and insurance companies have successfully lobbied to restrict the amount of awards or block the right to a jury trial for ordinary citizens so that the legal rights of corporations and government often prevail over the legal rights of individuals. This national tort reform trend to shield industry and medical trade organizations from financial accountability in civil courts for harm caused to individuals was reflected in the 2011 Supreme Court majority decision to, in effect, create new vaccine product liability law instead of correctly interpreting existing law in the 1986 Act.

NVIC Does Not Support Total Repeal of the 1986 Act.

In recognition of current personal injury and product liability lawsuit restrictions in U.S. courts and the nearly unanimous passage of the 21st Century Cures Act by Congress in 2016, which further lowered FDA licensing and informed consent standards, NVIC does not support a campaign to totally repeal the 1986 Act. **Not only is it not politically viable, but it would also give industry, medical trade organizations and federal agencies exactly what they want: another opportunity to lobby Congress to amend the Act to make it worse.**

Repeal of the Act would:

- eliminate the government's historic acknowledgement that FDA licensed and CDC recommended vaccines can and do cause injury and death;
- eliminate the legal duty of doctors and medical workers administering vaccines to provide written information about disease and vaccine risks to those being vaccinated or their legal representatives before vaccines are given;
- eliminate the legal duty of doctors and medical workers administering vaccines to record serious health problems following vaccination in a person's permanent medical record;
- eliminate the legal duty of vaccine manufacturers and vaccine administrators to record and report vaccine reactions, injuries and deaths to the federal Vaccine Adverse Event Reporting System (VAERS);
- eliminate the publicly accessible online VAERS, which has recorded 650,000 reports of vaccine reactions, injuries and deaths since 1990, although that number represents only one to 10 percent of what has occurred because mandatory reporting required by the Act has not been enforced;^{18 19 20} and
- eliminate the legal requirement for federal health agencies to conduct vaccine safety research to prevent vaccine injuries and deaths.

Repeal of the Act would also end the federal vaccine injury compensation program (VICP). Even though Congress has allowed the VICP to be systematically weakened by amendments and federal agency rule making, the program has awarded almost \$4 billion to nearly 6,000 vaccine victims and their attorneys, financial compensation that likely would not have been matched in the tort system.

Government Has Broken the Social Contract with Americans

During three decades of congressional amendments to the Act and abuse of authority by federal agencies, the government has broken the social contract with Americans being required to purchase and use FDA licensed and CDC recommended vaccines.

The U.S. government has assumed liability for harm caused by government licensed and mandated vaccines, but government officials cannot be sued in a civil court in front of a jury for failing to warn and protect the people from unsafe vaccines. The reality today is that nobody developing, manufacturing, selling, licensing, recommending, mandating or giving vaccines in the U.S. has real incentive to prevent vaccine injuries and deaths.

Flexible Vaccine Exemptions Must Be Secured and Protected

The federal government is encouraging adoption and enforcement of “no exceptions” vaccination laws, which require use of federally recommended vaccines and severely restrict or eliminate flexible medical, religious and conscientious belief vaccine exemptions. Forcing people to use products that can cause injury and death without voluntary informed consent is a violation of basic human rights, including autonomy and freedom of thought, conscience and religious belief.

The federal government has systematically betrayed the public’s trust by failing to keep the promise made to parents in the 1986 Act. It is NVIC’s position that flexible medical, religious and conscientious belief vaccine exemptions must be secured and protected in all public health policies and laws so that Americans have the legal right to make voluntary decisions about vaccination and protect their health and the health of their children.

About NVIC

About NVIC: *Founded in 1982 by parents of vaccine injured children, the National Vaccine Information Center (NVIC) is a non-profit charity dedicated to preventing vaccine injuries and deaths through public education. NVIC defends the human right to autonomy and freedom of thought, speech, conscience, religious belief and informed consent to medical risk taking. NVIC opposes “no exceptions” mandatory vaccination laws and advocates for the inclusion of flexible medical, religious and conscientious belief vaccine exemptions in public health policies and laws. Learn more at [NVIC.org](https://www.nvic.org). Take action at [NVICAdvocacy.org](https://www.nvicadvocacy.org).*

A book, [The Promise and Reality of the 1986 National Childhood Vaccine Injury Act](#), by NVIC Co-founder and President Barbara Loe Fisher will be published in 2019 with supporting documents and references available on [NVIC.org](https://www.nvic.org).

References

- [1](#) Public Law 99-660. Title III – [National Childhood Vaccine Injury Act of 1986](#). 42 USC 300aa. Nov. 14, 1986.
- [2](#) Fisher BL. [Statement of National Vaccine Information Center: Compensating Vaccine Injuries: Are Reforms Needed?](#) U.S. House Subcommittee on Criminal Justice, Drug Policy and Human Resources Hearing Sept. 28, 1999.
- [3](#) Fisher BL. [The Vaccine Injury Compensation Program: A Failed Experiment in Tort Reform](#). Advisory Commission on Childhood Vaccines Nov. 18, 2008.
- [4](#) U.S. Congress. [Omnibus Budget Reconciliation Act of 1987 \(Public Law 100-203\). Subtitle D – Vaccine Components. Sec. 4306. Vaccine Administrators](#). Pg. 224. Dec. 22, 1987.
- [5](#) Supreme Court of the United States. [Bruesewitz v. Wyeth](#) No. 09-152. Justice Scalia delivering opinion Feb. 22, 2011.
- [6](#) Supreme Court of the United States. [Bruesewitz v. Wyeth](#) No. 09-152. [Justice Sotomayor with whom Justice Ginsberg joins, dissenting](#) Feb. 22, 2011.
- [7](#) NVIC. [National Vaccine Information Center Cites ‘Betrayal’ of Consumers by US Supreme Court Giving Total Liability Shield to Big Pharma](#). NVIC Press Release Feb. 23, 2011.
- [8](#) 42 USC Chapter 6A, Subchapter XIX: Vaccines. Public Health Service. [National Childhood Vaccine Injury Compensation Act of 1986 with amendments](#).
- [9](#) H.R. 2202. [Preventive Health Amendments of 1993. Section 708: Simplification of Vaccine Information Materials](#). Sponsor: Rep. Henry Waxman (D-CA).
- [10](#) DHHS. [Final Rule: National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table](#). *Federal Register* Feb. 8, 1995; 60(26): 7678-7695.
- [11](#) Department of Health and Human Services. Notice of Proposed Rule Making. 42CFR Part 100; RIN0906-AB14. [National Vaccine Injury Compensation Program: Adding the Category of Vaccines for Pregnant Women to the Vaccine Injury Table](#). *Federal Register* Apr. 4, 2018.
- [12](#) Fisher BL, Williams K, Wrangham TK. NVIC Response to Government Accountability Office (GAO) inquiry on [History and Implementation of the National Childhood Vaccine Injury Act](#). July 11, 2014.
- [13](#) Fisher BL, Wrangham TK. Public Comment to DHHS Health Resources Services Administration (HRSA) [Opposing Changes to the Vaccine Injury Table](#). Jan. 25, 2016.
- [14](#) Hubbard FP. [The Nature and Impact of the ‘Tort Reform’ Movement](#). *Hofstra Law Review* 2006; 35:437-538.
- [15](#) Palazzolo J. [We Won’t See You in Court: The Era of Tort Lawsuits Is Waning](#). *Wall Street Journal* July 24, 2017.
- [16](#) Fisher BL. [Here Comes the 21st Century Cures Act: Say Goodbye to Vaccine Safety Science](#). *National Vaccine Information Center* July 21, 2015.
- [17](#) Hiltzik M. [The 21st Century Cures Act: A huge handout to the drug industry disguised as a pro-research bounty](#). *LA Times* Dec. 5, 2016.
- [18](#) MedAlerts. [Vaccine Adverse Event Reporting System \(VAERS\) searchable database: total number of vaccine adverse events reported to U.S. government since 1990](#).
- [19](#) Rosenthal S, Chen R. [The reporting sensitivities of two passive surveillance systems for vaccine adverse events](#). *Am J Public Health* 1995; 85: pp. 1706-9.
- [20](#) Ross L. [Electronic Support for Public Health Vaccine Adverse Event Reporting System \(ESP: VAERS\)](#). *Agency for Healthcare Research and Quality (AHRQ)* 2011.
- [21](#) Department of Health and Human Services. [National Vaccine Injury Compensation Program \(VICP\) Data and Statistics](#). *Health Resources Services Administration (HRSA)* May 1, 2018.
- [22](#) National Vaccine Information Center. [State Vaccine Legislation in America: 2015-2017](#). Oct. 25, 2017.
- [23](#) Fisher BL. [Parents Deserve to Know More Than School Vaccination Rates](#). *National Vaccine Information Center* Sept. 8, 2015.
- [24](#) Fisher BL. [From Nuremberg to California: Why Informed Consent Matters in the 21st Century](#). *National Vaccine Information Center* Oct. 24, 2017.