CONGRESS.GOV

H.R.5546 - National Childhood Vaccine Injury Act of 1986

99th Congress (1985-1986)

Sponsor: Rep. Waxman, Henry A. [D-CA-24] (Introduced 09/18/1986)
Committees: House - Energy and Commerce; Ways and Means | Senate - Labor and Human Resources
Committee Reports: H.Rept 99-908 Part 1
Latest Action: Senate - 10/18/1986 Read twice and referred to the Committee on Labor and Human Resources. (All Actions)
Tracker: Introduced **Passed House**

Summary(2) Text Actions(11) Titles(3) Amendments(0) Cosponsors(23) Committees(3) Related Bills(1)

There are 2 summaries for H.R.5546. Passed House amended (10/14/1986) ▼

Bill summaries are authored by CRS.

Shown Here:
Passed House amended (10/14/1986)

(Measure passed House, amended)
National Childhood Vaccine Injury Act of 1986 - **Title I: Vaccines - Subtitle 1: National Vaccine Program** - Amends the Public Health Service Act to establish in the Department of Health and Human Services a National Vaccine Program to: (1) direct vaccine research and development within the Federal Government; (2) ensure the production and procurement of safe and effective vaccines; (3) direct the distribution and use of vaccines; and (4) coordinate governmental and nongovernmental activities. Requires the Director of the Program to report to specified congressional committees.

Establishes the National Vaccine Advisory Committee to recommend: (1) ways to encourage the availability of an adequate supply of vaccines; and (2) research priorities.

Authorizes appropriations for FY 1987 through 1991.

Subtitle 2: National Vaccine Injury Compensation Program - **Part A: Program Requirements** - Establishes the National Vaccine Injury Compensation Program as an alternative remedy to judicial action for specified vaccine-related injuries.

Prescribes the contents of any petition for compensation.

Grants U.S. district courts authority to determine eligibility and compensation. Requires the district court in which the petition is filed to designate a special master to serve as an adjunct to the court. Sets forth the responsibilities of the court.

Lists factors to be considered when determining the amount of a compensation award. Sets forth a table of injuries deemed vaccine-related for compensation purposes. Permits the Secretary of Health and Human Services to: (1) promulgate regulations to revise such table; and (2) recommend changes to the vaccines covered by the table.

Provides that compensation awarded under the Program shall be paid out of the National Vaccine Injury Compensation Trust Fund. Limits awards for actual and projected pain and suffering and emotional distress to $250,000. Prohibits awards for punitive damages.

Establishes the Advisory Commission on Childhood Vaccines to: (1) advise the Secretary on the implementation of the Program; (2) recommend changes to the Vaccine Injury Table; and (3) recommend research priorities.

Part B: Additional Remedies - Sets forth procedures under which the person who filed a petition for compensation under the program may elect to file a civil action for damages.

Provides that no vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death: (1) resulting from unavoidable side effects; or (2) solely due to the manufacturer's failure to provide direct warnings. Provides that a manufacturer may be held liable where: (1) such manufacturer engaged in the fraudulent or intentional withholding of information; or (2) such manufacturer failed to exercise due care. Permits punitive damages in such civil actions under certain circumstances.

Part C: Assuring a Safer Childhood Vaccination Program in the United States - Requires each health care provider who administers a vaccine listed in the Vaccine Injury Table to record certain information with respect to each such vaccine. Requires each health care provider and vaccine manufacturer to report certain information to the Secretary.

Requires the Secretary to develop certain vaccine information materials for distribution to the legal representatives of any child receiving a vaccine listed in the Vaccine Injury Table.

Directs the Secretary to promote the development of safer childhood vaccines.

Sets forth recordkeeping and reporting requirements for vaccine manufacturers. Imposes civil and criminal penalties for destroying, altering, or concealing any such report or record.

Part D: General Provisions - Allows any person to commence a civil action against the Secretary where the Secretary allegedly has failed to perform a duty under this Act. Provides for judicial review of the Secretary's regulatory actions in a court of appeals of the United States.

Allows the Secretary to provide licensing for unpatented vaccines for naturally occurring human infectious diseases under certain circumstances.

Requires the Secretary to conduct studies on pertussis, rubella, and radiculoneuritis vaccines and publish the results of such studies.

Directs the Secretary to study the risks to children associated with each vaccine listed in the Vaccine Injury Table and establish guidelines respecting the administration of such vaccines. Directs the Secretary to periodically review and revise such guidelines.

Directs the Secretary to review the warnings, use instructions, and precautionary information presently used by manufacturers of vaccines listed in the Vaccine Injury Table. Directs the Secretary to require manufacturers to revise and reissue any warning, instruction, or information found inadequate.

Grants the Secretary recall authority with respect to any licensed virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other licensed product which presents a danger to public health. Establishes civil penalties for recall violations.

Directs the Secretary to make annual reports to specified congressional committees on the impact this Act has on the supply of vaccines.

Title II: Miscellaneous - Provides that certain Federal provisions designed to reduce paperwork shall not apply to information required to carry out this Act.