Exhibit A

(Cite as: H.R. REP. 99-908, 1986 U.S.C.C.A.N. 6344)

**6344 P.L. 99-660, HEALTH PROGRAMS
DATES OF CONSIDERATION AND PASSAGE
Senate August 12, October 18, 1986
House October 17, 1986

Senate Report (Labor and Human Resources Committee) No. 99-380,
Aug. 6, 1986 [To accompany S. 1744]
Cong. Record Vol. 132 (1986)
Related Reports:
Senate Report (Labor and Human Resources Committee) No. 99-225,
Dec. 18, 1985 [To accompany S. 1848]
Senate Report (Governmental Affairs Committee) No. 99-506,
Sept. 30, 1986 [To accompany S. 1209]
House Report (Energy and Commerce Committee) No. 99-908,
Sept. 26, 1986 [To accompany H.R. 5546]
House Report (Energy and Commerce Committee) No. 99-903,
Sept. 26, 1986 [To accompany H.R. 5540]
House Report (Energy and Commerce Committee) No. 99-154,
June 3, 1986 [To accompany H.R. 2417]
Senate Report (Labor and Human Resources Committee) No. 99-229,
Jan. 22, 1986 [To accompany S. 1762]

Much of Title III of this Public Law was derived from H.R. 5546. House
Report (Energy and Commerce Committee) No. 99-908, Sept. 26, 1986 [to
accompany H.R. 5546] is set out:

HOUSE REPORT NO. 99-908
September 26, 1986

*1 The Committee on Energy and Commerce, to whom was referred the bill (H.R.
5546) to amend the Public Health Service Act to establish a National Vaccine
Program for the development of new vaccines and the improvement of existing
vaccines and a program to compensate the victims of vaccine-related injuries and
deaths, and for other purposes, having considered the same, report favorably
thereon with amendments and recommend that the bill, as amended, do pass.

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*3 PURPOSE AND SUMMARY

H.R. 5546, the 'National Childhood Vaccine Injury Act of 1986', creates a new
system for compensating individuals who have been injured by vaccines routinely
administered to children. The system consists of two separate, but related parts
and concerns only the actions of those injured by specified childhood vaccines and
the manufacturers of such vaccines.

Part A of the system amends the Public Health Service Act to establish a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity. All individuals injured by a vaccine administered after the date of enactment of the legislation are required to go through the compensation program. Judgments and awards entered under the compensation program must be expressly rejected before other remedies may be pursued. Funding for the program is provided through a tax to be placed on designated childhood vaccines.

Part B of the system deals with the additional remedies that are available to vaccine-injured persons should they elect to reject a judgment and award made under the compensation program and to take action directly against a vaccine manufacturer. Under such circumstances, an individual may file a civil action for damages relating to a vaccine injury just as he or she may have done prior to the enactment of the legislation. Under Part B of the system, however, *4 several new substantive and procedural requirements are established for the recovery of these damages.

H.R. 5546 contains several other provisions not pertaining to the issue of compensation for vaccine-injured persons, but very much linked to the related questions of vaccine development, safety, and effectiveness. The bill makes mandatory—for the first time—the reporting of injuries resulting from routine childhood vaccines to Federal officials. It requires the Secretary to develop and distribute parent information materials on these vaccines and on the diseases **6345 they prevent. Vaccine manufacturers are required to keep records on the production, testing, and handling of their products and to report any potential problems to appropriate Federal agencies within a 24-hour period. A new authority to recall hazardous vaccines is provided for the Secretary. Finally, the legislation requires the Secretary to perform a number of studies on various childhood vaccines and on the sufficiency of their warnings and labels.

The bill also establishes a National Vaccine Program to oversee and carry out Federal vaccine-related research, testing, licensing, production, and distribution activities concerning all vaccines. The purpose of this program is to provide needed focus and direction at the Federal level on the development of both new and improved vaccines that can be used in this country and around the world. Under such a program, the Committee expects that a greater number of manufacturers will enter the vaccine market and that a greater number of vaccine products will become available to prevent disease, reduce reactions, and otherwise improve public health.

BACKGROUND AND NEED FOR LEGISLATION

Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken. Use of vaccines has prevented thousands of children's deaths each year and has substantially reduced the effects resulting from disease. Billions of medical and health-related dollars have been saved by immunizations. And, through the development of vaccines to prevent childhood diseases, significant scientific progress has been made in the
development of vaccines to prevent other types of diseases. In brief, the Nation's efforts to protect its children by preventing disease have been—by every measure—a success.

In recent years, however, the Nation's ability to maintain this level of success has come into question. Previously unrecognized injuries associated with vaccines have become more widely known. While most of the Nation's children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured. These children are often without a source of payment or compensation for their medical and rehabilitative needs, and they and their families have resorted in greater numbers to the tort system for some form of financial relief.

At least in part as a result of this increase in litigation, the prices of vaccines have jumped enormously. The number of childhood vaccine manufacturers has declined significantly. In certain areas, the level of immunization against some preventable diseases has decreased while the incidence of those diseases has increased. *5 All of this has led to the Committee's re-evaluation of all current vaccine and vaccine-related activities and, in turn, to a real concern about the future of Federal immunization initiatives.

H.R. 5546 is the result of the Committee's re-evaluation. It reflects five principal findings (the basis for which are discussed below) made by the Committee during its study of this issue:

**6346 (1) The availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities.

(2) The Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries.

(3) Private or non-governmental activities have proven inadequate in achieving either of these goals.

(4) Current economic conditions have resulted in an unstable and unpredictable childhood vaccine market, making the threat of vaccine shortages a real possibility.

(5) Because of their cost-effectiveness, the Federal government has an interest in the development, distribution, and use of vaccines, including those designed to prevent non-childhood diseases.

Childhood Diseases and Immunization Programs

Since the early days of this Nation's history, the Federal government has had the responsibility to prevent the spread of infectious diseases from other countries into the United States and between States within its own borders. In meeting this responsibility, the Federal government has assumed—for more than a generation now—a leadership role in providing immunizations against childhood diseases. Through Federal support, State and local health agencies are able to plan, develop, and conduct programs to immunize children against polio, measles, mumps, rubella (German measles), diphtheria, pertussis (whooping cough), and tetanus. This role, repeatedly reaffirmed by the Congress, assures that the country maintains a consistent national policy in protecting our children against
preventable diseases. (For a more detailed description of the Federal
government's historical involvement with childhood immunization programs, see Part
II, Childhood Immunizations, a report prepared by the staff of the Subcommittee on
Health and the Environment (Comm. Print 99- LL.).)

Over the years, State government has become an important adjunct in carrying out
the Federal government's responsibility to prevent the spread of infectious
diseases. Today, State immunization laws require that virtually all children be
vaccinated against each of the seven common childhood diseases before they enter
school. Near-universal compliance with these laws has resulted in the dramatic
reduction in the incidence of these diseases. Indeed, polio, diphtheria, and
tetanus have essentially been eradicated as childhood diseases in this country.
Great progress has been made in eliminating measles as a native disease and
efforts have been intensified to hasten the elimination of the other childhood
diseases as well.

Compensation for vaccine-related injuries

In the past, the medical problems that can be associated with the vaccines that
are given to children have sometimes been overlooked. More recently, however,
information has become available about the potential hazards of these vaccines and
about the serious--and sometimes deadly--consequences they can have. This is
particularly true with regard to the pertussis vaccine which is most commonly
administered as part of a series of immunizations known as DPT (diphtheria,
pertussis, tetanus). Severe reactions to the other vaccines have been reported as
well.

While it is true that some children, because of their physical condition, are
more likely to react to a vaccine, vaccine reactions are not completely
foreseeable. There is today no 'perfect' or reaction-free childhood vaccine on the
market. A relatively small number of children who receive immunizations each year
have serious reactions to them. But it is not always possible to predict who they
will be or what reactions they will have. And since State law requires that all
children be immunized before entering school, most parents have no choice but to
risk the change--small as that may be--that their child may be injured from a
vaccine.

Despite these possibilities, public health officials, private physician groups,
and parent organizations have repeatedly stated that it is safer to take the
required shots than to risk the health consequences of contracting the diseases
immunizations are designed to prevent. As a result and in light of the overall
success of immunization programs, the Federal government continues to support
States and local efforts to provide immunizations to children and States continue
to require that children be vaccinated as a condition for entering school.

But for the relatively few who are injured by vaccines--through no fault of
their own--the opportunities for redress and restitution are limited,
time-consuming, expensive, and often unanswered. Currently, vaccine-injured
persons can seek recovery for their damages only through the civil tort system or
through a settlement arrangement with the vaccine manufacturer. Over time,
neither approach has proven satisfactory. Lawsuits and settlement negotiations
can take months and even years to complete. Transaction costs—including attorneys' fees and court payments—are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met.

This approach has also been ineffective for the manufacturers of childhood vaccines. This has become especially true in more recent years as the number of lawsuits—particularly those concerning the DPT vaccine—has increased. (For a more detailed discussion of the litigation experience of manufacturers, see Part IV of the Subcommittee's report, Childhood Immunizations, which presents the results of the Subcommittee's survey of the manufacturers on this subject.) Manufacturers have become concerned not only with the problems of time and expense, but with the issue of the availability of affordable product liability insurance that is used to cover losses related to vaccine injury cases. Whether current problems with liability insurance arise from a crisis in the tort system or from a particularly bad downturn in the business cycle of the insurance industry has been and remains a matter of great controversy. Nevertheless, there is little doubt that vaccine manufacturers face great difficulty in obtaining insurance. This lack of insurance was the stated reason for one manufacturer to withdraw temporarily from the vaccine market in 1984. Others have suggested that they may follow a similar course of action. This factor, coupled with the possibility that vaccine-injured persons may recover substantial awards in tort claims, has prompted manufacturers to question their continued participation in the vaccine market.

The loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country. Currently, there is only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the DPT vaccine. Two States, Michigan and Massachusetts, produce their own DPT vaccine. Despite Congressional support, Federal vaccine stockpiles maintained by the Centers for Disease Control (CDC) have never reached CDC's recommended level of six-months' supply. Thus, the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases.

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Thus, two overriding concerns have led to the development of this legislation: (a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market. As further outlined below, H.R. 5546 establishes a new system for vaccine injury compensation which the Committee believes is fair, simple, and easy to administer. Just as important, the Committee believes that once this system is in place and manufacturers have a better sense of their potential litigation obligations, a more stable childhood vaccine market will evolve.

In establishing this new system, however, the Committee recognizes the need for additional measures to help ensure that the Nation is able to maintain safe and
reliable childhood vaccination programs and to continue these programs' great successes of the past. H.R. 5546 contains, therefore, a number of provisions concerning vaccine safety, production, and information. In addition, the bill calls for several studies to be completed on specified vaccines. These provisions, together with the new compensation system, should produce a much improved national childhood immunization initiative.

In light of the significant public health advances that have been made as a direct result of the development and use of childhood vaccines, the Committee believes that more emphasis should be placed on the research and production of other vaccines. Accordingly, H.R. 5546 establishes a National Vaccine Program to make better use of the scientific opportunities offered by both public and private vaccine research. It is the Committee's expectation that under this program substantial progress will be made toward the development and distribution of vaccines that will further enhance the public health of this country as well as countries around the world.

**6349 #8 SECTION--BY-SECTION ANALYSIS AND DISCUSSION

Section 1--Short Title and Table of Contents

TITLE I--VACCINES

Section 101--Amendment to the Public Health Service Act

Section 101 adds a new title, numbered Title XXI, to the Public Health Service Act. The following references (through Section 2133) refer to the provisions of that title.

TITLE XXI--VACCINES

Subtitle 1--National Vaccine Program

In March of 1985, the Oversight and Investigations Subcommittee conducted a hearing on vaccine development, in the context of a series of hearings on biotechnology. Witnesses described advances in biotechnology that could lead to the production of new and improved vaccines, as well as the lack of organization at the Federal in the promotion and use of vaccines.

In response to these hearings and other Subcommittee and Congressional activity, on March 6, 1986, Chairman John D. Dingell of this Committee and Chairman Orrin G. Hatch of the Senate Committee on Labor and Human Resources wrote to Dr. Samuel O. Thier, President of the Institute of Medicine (IOM) to seek assistance in formulating a new policy on vaccines. In that letter, the two chairmen requested that the IOM examine questions of research development, testing, supply, and use of vaccines.

The IOM responded by convening a national conference of 70 leading experts on vaccines and immunization. The conference proceedings were summarized in a paper prepared for the use of the Committee and published as Committee Print 99-II.
Working groups discussed problems and policy alternatives in seven areas: research; development; clinical trials; licensing and quality control; production and procurement; distribution and use; and surveillance and monitoring.

Among the researchers at the IOM conference, the discussion focused on the continuing inadequacy of government and industrial investment in this extraordinarily cost beneficial area of preventive medicine. Despite a strong history of the Government assigning high priority to vaccines, based on analyses of the cost-effectiveness of immunization, these researchers were not sanguine that their work would be carried through to its public health application.

The participants in the IOM conference reported that many potentially promising research results are never developed as products. Clinical trials are expensive and thus potentially limit vaccine development. The U.S. system of licensure is not linked to the public health goal of preventing human infectious disease. Decisions to manufacture and sell vaccines are often based on the small U.S. vaccine market rather than a response to the public health need.

Federal programs have probably had their greatest effect on the distribution and use of vaccines in the U.S., but the number of vaccines and their use is far from optimal. Adult vaccines, which are **6350 *9 not mandated by school attendance statutes in the States, are poorly used in the U.S. There was agreement that improved surveillance of vaccine use and effectiveness would improve all aspects of vaccine and immunization programs.

At the close of the IOM conference, the current chairman of an interagency working group in the Public Health Service responded that further collaboration and cooperation between the Centers for Disease Control, the National Institutes of Health, and the Food and Drug Administration would be productive. There has been coordination of the effort to develop an improved pertussis vaccine and to stabilize the supply of the current vaccine. However, there has been neither time nor resources to do similar planning on other vaccine issues.

The National Vaccine Program established in subtitle I is a response to a broadly accepted need to make better use of the scientific opportunities offered by vaccine research. Both industry and government can enhance their efforts through coordination and collaboration.

Section 2101—Establishment

This section mandates the Secretary of Health and Human Services to create a National Vaccine Program, to be administered by a Director, selected by the Secretary. The purpose of the Program is to achieve optimal prevention of naturally occurring human infectious diseases through immunization and to achieve optimal prevention of the adverse reactions to vaccines. The program is not intended to address infectious diseases that might be caused by manmade biological warfare agents.

Section 2102—Program Responsibilities

Subsection (a).—This provision spells out the elements of the national Vaccine Program. These program responsibilities are implemented through the plan.
described in Section 2103 (discussed below), and by the Director and the small
staff funded by an appropriation authorized by Section 2106(a) (discussed below).
The responsibilities are as follows:

(1) Vaccine Research.--The National Vaccine Program Director shall, by
providing direction to and coordinating the research activities of Federal
agencies, assure that Federal resources used for vaccine research have the
most beneficial effect in preventing human infectious diseases. The vaccine
research referred to in this section includes those activities intended to enhance
our fundamental knowledge about diseases, pathogens, vectors, adjuvants, and host
responses and thus make safe vaccine development possible. Such research is
currently conducted by or for the National Institutes of Health, the Centers for
Disease Control, the Food and Drug Administration, the Department of Defense, and
the Agency for International Development.

(2) Vaccine Development.--Vaccine development activities of Federal agencies
are to be coordinated by, and receive direction from, the National Vaccine
Program. Vaccine development entails research on particular vaccines to produce
them in test batches for clinical trials and, if these are successful, to address
the engineering problems of industrial level production. An understanding of
the role of private research and private development activities will be
essential for the National Vaccine Program to operate effectively.

(3) Safety and Efficacy Testing of Vaccines.--Clinical trials to establish
safety and efficacy are now required for all vaccines. Difficulty in organizing
clinical trials and their cost may deter the development of important vaccines.
The National Vaccine Program will assure that clinical testing of vaccines
proceeds efficiently, so that the basic public health goals of immunization
programs can be met. The Director of the Program will provide direction for,
and coordinate, the testing activities conducted and supported by Federal agencies.
Information about private testing activities will be essential to improve the
effectiveness of Federal programs.

(4) Licensing of Vaccine Manufacturers and Vaccines.--The Food and Drug
Administration, under Section 351, now licenses vaccine manufacturers and
vaccines. The National Vaccine Program will, by coordinating these licensure
activities with other Federal agencies that are engaged in research, development,
and clinical testing, seek to make the licensure program responsive to the public
health priorities of immunization. The National Vaccine Program will assist the
Food and Drug Administration to assign resources to vaccine licensure activities,
so that these activities may best contribute to rapid licensure of important
vaccines.

(5) Production and Procurement of Vaccines.--The National Vaccine Program will
be responsible for determining the vaccine supply needs of the United States. The
Program will attempt to coordinate agency activities to assure that an adequate
supply of vaccines is produced by the public and private sectors and that the
Federal agencies will have the resources needed to procure the vaccines needed to
supplement state and local, public and private purchases to achieve optimal
immunization of the Nation's population. In addition, the Program will coordinate
and monitor the United States continued contribution to the United Nations'
immunization program and assistance of other countries through foreign aid.
International immunization activities have always resulted in public health and financial benefits for U.S. citizens. Through the plan and resources available under Section 2100(b) (discussed below) the National Vaccine Program will ensure adequate vaccine production and procurement.

(6) Distribution and Use of Vaccines.—The Centers for Disease Control is the agency charged with Federal responsibility for vaccine distribution and use. By providing direction to the Centers for Disease Control and coordinating its activities with other Federal agencies under the Plan, the National Vaccine Program can enhance the effectiveness of immunization programs. The programs of assistance to State and local health departments and to health practitioners in distributing vaccine and encouraging public acceptance of immunizations and avoiding misuse of vaccines leading to adverse reactions would be coordinated with other Federal activities.

(7) Evaluating the Need for and the Effectiveness and Adverse Effects of Vaccines and Immunization Activities.—In addition to the five Federal agencies regularly involved in immunization activities, the surveillance and monitoring activities envisioned in Section **6352 *11 2102(a)(7) would involve the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, the Health Care Financing Administration, and the Veterans' Administration. By coordinating and providing direction to these agencies and cooperating with private institutions, the National Vaccine Program would create a national program of monitoring and surveillance of vaccines and immunization activities.

(8) Coordinating Governmental and Non-Governmental Activities.—The National Vaccine Program would constitute the central focus in the Federal government for gathering and analyzing information about non-government vaccine and immunization activities. Because of the success of immunization efforts, including vaccine research and development, is dependent on close collaboration and cooperation between government, industry, universities, and others, the National Vaccine Program will encourage the investment of non-government resources in a manner that they will complement government activities.

(9) Funding Federal Agencies.—Because effective cooperation between Federal agencies under the National Vaccine Plan depends on each agency's meeting goals set in the Plan, the Director is authorized under Section 2106 (discussed below) to make funds available for activities described under the Plan, to supplement funds otherwise available to such agencies for activities under the Plan. These funds would be made available during the year that the Plan is in force to make sure that the failure of one agency to meet an objective does not cripple the whole national vaccine effort.

Subsection (b).—In carrying out this Section the Director shall consult with each and every Federal agency with a role in vaccine or immunization activity. The Committee expects that the Director will choose to create an interagency committee to enhance communication and to facilitate this kind of consultation.

Section 2103—Plan

The National Vaccine Plan, which is to produced by January 1, 1987, and updated
annually, will describe all vaccine and immunization activities of the Federal government. It will establish priorities for research, development, testing, licensing, production, procurement, distribution and effective use of vaccines. It will describe an optimal use of resources to carry out the priorities, and describe how each of the various department and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with the Plan's priorities.

The annual production of the Plan is to be an optimal use of resources to the ongoing process for coordinating and providing direction to collaborating agencies.

Section 2104--Report

So that the appropriate House and Senate committees may perform their oversight function with regard to the National Vaccine Program, the Director is to submit an annual report on the implementation of the program and the Plan. This Plan will provide Congress with information on progress in vaccine research, development, testing, licensing, production and procurement, distribution *12 **6353 and use, and monitoring and surveillance. Information about these activities from many agencies should be assembled in this report so that the Congress can understand the progress being made on vaccines and immunizations against human infectious diseases.

Section 2105--National Vaccine Advisory Committee

This section creates a national advisory committee to advise the Director of the Program. Recognizing the longstanding role of the National Academy of Sciences' Institute of Medicine in vaccine policy development, the Committee intends that the Director consult with the Academy in appointing the Advisory Committee. The Director shall select the Committee's membership from among a broad and representative range of individuals concerned with vaccines.

The Advisory Committee will make recommendations in four areas:

1. How to assure the supply of safe and effective vaccines.
2. Research priorities to enhance vaccine safety and efficacy.
3. Implementation of the Program and content of the Plan and report.
4. Important areas for government and non-government cooperation to be included in the Program, Plan or report.

Section 2106--Authorizations

This section makes two annual authorizations for five years. The first is for funds to support staff for the Program and to support its activities, including the Advisory Committee. The second is for funds to be made available to programs under the Plan, which during a fiscal year, require additional funding to meet the objectives spelled out in the Plan.

Subtitle 2--National Vaccine Injury Compensation Program

Part A--Program Requirements

The bill establishes a compensation system for those persons injured by routine pediatric vaccines. The system is intended to be expeditious and fair. It is also intended to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective.

While the bill does not prohibit a vaccine-injured person who has completed compensation proceedings from going on to court, the system is intended to lessen the number of lawsuits against manufacturers. Toward this end, the bill requires that a person with an injury resulting from a vaccine that was administered after the enactment of this legislation file a compensation petition and go through the compensation program before proceeding with any litigation against a manufacturer.

If, however, after compensation proceedings are complete, a vaccine-injured person elects to reject the system's findings and award and go on to court, he or she is free to do so.

**6354 *13** The Committee anticipates that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation.

The Committee also recognizes that because of many States' standards of proof of liability, many vaccine-injured persons are presently without legal remedy under current tort law. The Committee anticipates that many of these persons will be compensated for their injuries under the compensation system.

Section 2110--Program Established

Section 2110 establishes the National Vaccine Injury Compensation Program ('the Program') for the administration of payments awarded to vaccine-injured persons. The Program is to be administered by the Secretary of the Department of Health and Human Services (HHS). The section also establishes that it is the ethical duty of an attorney consulted on matters of vaccine-injury to advise his or her client or potential client of the availability of compensation under the program.

Section 2111--Petitions for Compensation

Subsection (a)--General Rule.--Under the bill, a compensation proceeding is initiated by the filing of a petition for compensation with the U.S. district court for the district in which the petitioner resides or in which the injury occurred. This petition is also to be served upon the Secretary of HHS.

In its establishment of eligibility for compensation and its establishment of proceedings that must be completed before entering litigation, the bill divides vaccine-injured persons into three general groups: 1) those who were injured by a vaccine more than eight years before enactment of the legislation; 2) those who were injured by a vaccine that was administered before the enactment of the legislation, but less than eight years before; and 3) those who are injured by a
vaccine that is administered after the enactment of the legislation.

Group One: As described below in Section 2116, those persons in the first group are not eligible for compensation under the system. As further described in Section 2122, the bill makes no changes from current law in such persons' legal rights or remedies.

Group Two: Those persons in the second group (i.e., those injured less than eight years ago but by a vaccine administered before enactment of the legislation) are eligible for compensation but are not required to enter the compensation system before pursuing tort litigation.

If such a person has pursued a civil action against a manufacturer before enactment of the legislation and no damages were awarded or the action was dismissed, he or she may file for compensation. The ability to make such an election under this Section is not intended to permit such a person to bring a civil action that would be barred by such State doctrines as res judicata, laches, or collateral estoppel. It is not intended that such a claimant would be permitted to file a new civil action upon completion of the compensation proceedings; rather, this permissive entry is provided only to **6355 *14 give these persons the opportunity for compensation under the no-fault system.

If a person in the second group has a tort action against a manufacturer pending at the time of enactment, he or she may elect to maintain such an action or may, within two years of enactment or before judgment in the action (whichever comes first), elect to withdraw the action without prejudice and enter the compensation system. If such a person elects to maintain the civil action, he or she is permanently barred from entering the compensation system. If such a person elects to withdraw the civil action within the specified time, he or she may enter the system and may, at the conclusion of the compensation proceedings, elect to pursue whatever tort remedies may be available (although if a second civil action is to be filed, he or she must, of course, first reject the compensation findings and award).

If a person in the second group initiates a civil action against a manufacturer after the enactment of this legislation without first completing the compensation system, he or she may not enter the compensation system.

If a person in the second group has been awarded damages or has received a settlement for a civil action against a manufacturer, he or she may not enter the compensation system.

Group Three: Persons in the third group must complete the compensation proceeding and reject its judgment and its award before pursuing a civil action against a manufacturer for vaccine injury. This limitation does not apply to claims for under $1,000.

The bill also prohibits the act--by impleader, cross-claim, or separate suit or any other practice--of making a vaccine manufacturer a party to any civil action brought by a person in the third group before that person has completed a compensation proceeding.

If a civil action is initiated by a person in group three who has not completed the compensation proceeding and rejected its judgment and award, that civil action is to be dismissed. This dismissal of a civil action does not affect the person's ability to bring another civil action after completing the compensation proceeding.
and rejecting its judgment and award.

If a civil action is initiated and dismissed as described in the preceding paragraph, and if a petition for compensation is filed thereafter, the date of the filing of the civil action is to be considered the date of the filing of the petition for purposes of the time limitations set forth below in Section 2116. Such a petition must be completed within one year.

Subsection (b)--Petitioners.--A petition may be filed by any person (or his or her legal representative) who has been injured by a vaccine listed in the Vaccine Injury Table ('the Table,' discussed in Section 2114 below). Only one petition may be filed with respect to each administration of a vaccine. While this provision allows for the possibility of a separate recovery for each shot in a series of inoculations with the same vaccine, the Committee intends that such multiple awards be made only under the unusual circumstances in which separate and distinct injuries occur from individual administration. In most circumstances in which a vaccine has been given on more than one occasion and injuries have resulted, the Committee intends that a single petition encompass all requests for compensation and that the limits of available compensation apply to this petition and that only in the most unusual circumstances should a petitioner be allowed to make more than one recovery and exceed the limitations on pain and suffering payments.

Subsection (c)--Petition Content.--A petition must contain a variety of materials necessary to make a finding that compensation is to be made. These materials include evidence that the person on behalf of whom the petition is filed (hereinafter referred to as 'the petitioner')--

received a vaccine listed in the Table or contracted polio from a recipient or oral polio vaccine;

met certain citizenship or location restrictions;

sustained or had significantly aggravated an injury listed in the Table;

sustained or had aggravated the injury within the time periods specified in the Table;

suffered residual effects for more than one year or died or incurred unreimbursable expenses of greater than $1,000; and

has not previously collected an award or settlement for the injury.

The petition should also contain all available relevant medical records and identification of any unavailable records. In addition, the petition should include documents necessary for the determination of the amount of the compensation award.

If the petitioner sustained or had significantly aggravated an injury not listed in the Table, he or she may petition for compensation. If the petitioner sustained or had significantly aggravated an injury listed in the Table but not within the time period set forth in the Table, he or she may petition for compensation. In both of these cases, however, the petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. (Such a finding of causation is deemed to exist for those injuries listed in the

Table which occur within the time period set forth in the Table.) The Committee does not intend, however, to suggest that variance from the Table should act as a presumption against the petitioner but rather only that such a petitioner is not to be deemed to be eligible for compensation without further showings of causation.

'Significant aggravation' is defined below in Section 2133. The Committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g. a child with monthly seizures who, after vaccination, has seizures on a daily basis). The Committee also intends that the time periods set forth in the Table apply to the significant aggravation in order for causation to be deemed to exist (e.g., a significant deterioration of a **6357 *16 seizure disorder after DTP vaccination must first become manifest within three days of the vaccination).

Section 2112--Court Jurisdiction

Subsection (a)--General Rule.--The district courts are to have jurisdiction over the compensation proceedings and such orders as are necessary to assure payment of awards.

Subsection (b)--Parties.--The Secretary of HHS is to be named as the respondent to all petitions for compensation. No other persons may intervene or otherwise be made a party to the compensation proceeding.

Within 30 days of receiving the petition, the Secretary is to publish a notice of the petition in the Federal Register. Upon such publication, any person may submit relevant, written information relating to evidence of other causes of the injury for which compensation is sought. If the petition is brought for an injury which is not listed in the Table or for an injury which is listed in the Table but which did not occur within the time period set forth in the Table, any person may submit relevant written information relating to the injury and its causation.

The Committee has endeavored to create a swift, uncomplicated compensation system and it is the Committee's intent that the submission of relevant evidence on these limited points be the sole self-initiated participation of persons other than the petitioner or the Secretary. While the Special Master may, as described below in Subsection (c), require the submission of evidence or require testimony, outside persons may not enter into the proceeding on their own.

Subsection (c)--Special Masters.--After the receipt of a petition, the district court is to designate a Special Master to serve as an adjunct to the court. The Master may require any evidence, require the submission of any information, require any testimony, conduct hearings, and prepare proposed findings of fact and conclusions of law and submit these findings to the court.

Information submitted to the Master may not be disclosed to anyone other than the petitioner or the Secretary without the express, written consent of the person who submitted the information. It is the Committee's intent that, in order to
guarantee full cooperation with the Master, all materials remain confidential and
that the parties themselves not redisclose individually identifiable materials
shared with them as part of the proceedings. However, nothing in this section is
intended to affect or modify any of the rules of discovery governing civil actions
for damages should the petitioner decide to pursue his or her claim in tort after
completion of the compensation proceeding.

Other than the discovery specifically described as the prerogative of the
Master, there is to be no other discovery in a compensation proceeding. In order
to expedite the proceedings, the power of the Special Master is intended to
replace the usual rules of discovery in civil actions in Federal courts. Because
the only issues relevant to the compensation proceeding are whether the petitioner
suffered a compensable injury and, if so, the extent of compensable damages, there
should be no need for a wider inquiry, which might be appropriate in a civil
action raising other issues. Thus, while the **6358 ** Special Master may compel
any testimony or appearance, neither party is given power to cross-examine
witnesses, file interrogatories, or take depositions. In this regard, the
Committee expects the Special Master to be vigorous and diligent in investigating
factual elements necessary to determine the validity of the petitioner's claim.

Subsection (d)--Action by the Court.--If either party objects to the proposed
findings of fact and conclusions of law of the Special Master, or if the court
choose to do so on its own motion, the district court is to review the record of
the proceedings and may order a remand or make a de novo determination.

If no objection is filed and if the court chooses not to review the proceeding,
the court is to adopt the findings of the Special Master and is to render judgment
on these findings. The entire proceeding--from date of filing through Special
Master proceedings and court review--is to take place as expeditiously as possible
and, in no case, should take more than one year. The Committee notes that much of
the equity in limiting compensation and limiting other remedies arises from the
speed and reliability with which the petitioner can expect judgment; without such
quick and certain conclusion of proceedings, the compensation system would work an
injustice upon the petitioner.

Subsection (e)--Administration of Award.--As described below in Section 2115,
awards are to be made on a periodic basis and for specific purposes. The award is
to be administered by the Program, which is to audit the payment of compensation.
A petitioner awarded compensation is to notify the Program of any changes which
significantly affect the compensation to be paid. Thus, the petitioner has an
affirmative duty to disclose to the Program if elements of compensation are no
longer needed or if actual expenses are less than projected for that period.

Subsection (f)--Revision of the Award.--If a petitioner has been awarded
compensation for projected unreimbursable expenses and he or she finds, during the
period for which the payment was made, that the award is insufficient to meet
these expenses, he or she may request the court to review the award and to
increase the award or to revise the payment schedule or both. Thus, if medical
costs rise more quickly than expected or if the petitioner's injury becomes more
serious, he or she may ask for increased and more frequent payment.

Conversely, if the petitioner discloses a smaller need then projected or if the
audit by the Program discloses that an item of compensation is no longer required

or that compensation has been used improperly, the Program is to petition the court to revise the award.

The Committee does not anticipate that frequent adjustments or frequent audits will be necessary nor does the Committee intend the Program to become a free-for-service, third-party payor (i.e., an agency to reimburse only for direct and individual charges incurred on behalf of the petitioner) for future medical and rehabilitation services. Rather the Program should serve, within broad general guidelines of stewardship, as an administrator of the Fund, ensuring that awards are used as the Special Master and court judge find appropriate.

**6359 *18 Subsection (g)--Appeals.--The judgment of the court is to be the final determination of the compensation petition, except that either the petitioner or the Secretary may request a review of the judgment by the court of appeals for the circuit in which the district court is located. If such an appeal is requested, the request is to be delivered to the other party within 60 days.

Section 2113--Determination of Eligibility and Compensation

Subsection (a)--General Rule.--Compensation is to be awarded if the court determines on the basis of the record as a whole that (1) the petitioner has demonstrated those matters required by Section 2111 above (e.g., receipt of vaccine, citizenship, time of initial onset of injury, etc.) and (2) there is not a preponderance of the evidence that the injury was caused by factors unrelated to the vaccine. The court may not make such a finding on the basis of the petitioner's claims alone, without other medical records or opinion.

In its determination that the injury was not caused by factors unrelated to the vaccine, the court may rely on evidence of other infections, traumas, or conditions but is not to include speculative or hypothetical matters or explanations. If the injury is not demonstrated to have been caused by other defined illnesses or factors and the injury is demonstrated to have met the other requirements of Section 2111 and the Table, the injury is to be deemed to be vaccine-related.

The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary or the Advisory Commission on Childhood Vaccines (discussed below in Section 2119) may propose to revise the Table, as provided below in Section 2114. Until such time, however, the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.

Subsection (b)--Matters to be Considered.--In its determination of the petitioner's eligibility for compensation, the court is to consider all relevant medical and scientific evidence in the record, including medical records and
tests. None of this evidence is binding on the court, and the court should, of course, exercise its best judgment in evaluating whether the record satisfies the requirements for compensation. The court is specifically authorized to find that the record demonstrates that the time restrictions of the Table have been met even if some pieces of evidence omit references to time or incorrectly record them.

Subsection (c)--Record Defined.--The record refers to the compensation proceeding record.

**6360 *19 Section 2114--Vaccine Injury Table

Subsection (a)--Initial Table.--The Vaccine Injury Table sets forth a list of vaccines, injuries, and time periods of initial onset of injuries. If a listed injury is first manifest within the time period specified in the Table following the administration of the vaccine listed in the Table, the injury is to be considered compensable (unless there is other evidence to the contrary, as described above in Section 2113).

Each portion of the Table also includes a provision for complications or sequelae of listed injuries which occur within the specified time periods. Thus, for example, if an anaphylactic shock occurs within 24 hours of the administration of a DTP vaccine (i.e., within the specified time period), that injury is compensable if other conditions are met. If kidney failure occurs as a complication of that injury, it too is compensable, regardless of when the initial onset of kidney failure occurs. If, however, anaphylactic shock occurs 48 hours after administration of the vaccine (i.e., outside the specified time period) and kidney failure follows, neither injury is compensable unless a demonstration of causation can be made (as provided above in Section 2111(c)(1)(C)(ii)). These provisions are added to emphasize that compensation is available not just for the acute vaccine reactions listed but also for those conditions which result from these reactions. These provisions are not intended to expand the filing periods specified below in Section 2116, and if a petition for compensation for the original listed injury is not filed within the time limits specified in that section, a petition for compensation for a complication may not be filed after that period. If an award has been made on a petition for a listed injury, a later complication may not supersede the prohibition of multiple petitions (described above in Section 2111(b)); rather a petitioner should petition for revision of the award under the provisions of Section 2112(f) (discussed above).

Subsection (b)--Qualifications and Aids to Interpretation.--Subsection (b) provides various descriptions and definitions that the Committee intends be used in interpreting the meaning of the Table. In addition, the subsection also restates in specific terms the general rule described in Section 2113 and provides that if the cause of an encephalopathy is an infection or another condition not related to the vaccine, the encephalopathy is not to be considered compensable. If, however, the court is unable to determine the cause of an encephalopathy, the encephalopathy is to be considered compensable if other conditions (including specified time of initial onset) are met.

Subsection (c)--Administrative Revision of the Table.--The Secretary is authorized to promulgate regulations making administrative revisions of the Table.
Such regulations may add injuries to be compensated to the Table or may delete listed injuries from the Table. Such regulations may also modify the time periods set forth in the Table during which initial symptoms of an injury must occur. In promulgating such regulations the Secretary must provide for public hearing and comment.

In addition, the Advisory Commission on Childhood Vaccines (discussed below in Section 2119) or any other person may request **6361 *20 the Secretary to propose regulations to revise the Table. Unless clearly frivolous, requests by persons other than the Commission shall be referred by the Secretary to the Commission for its recommendations. Following receipt of the Commission's recommendations or within 180 days of receipt of the request, the Secretary is to conduct a rulemaking proceeding on the request or publish reasons for not conducting such a proceeding.

Any modification made to the Table is to apply only to petitions filed after the modification is made.

Subsection (d)--Role of Commission.--In making revisions of the Table, the Secretary is to provide notice to and to consult with the Advisory Commission on Childhood Vaccines (described below in Section 2119).

Subsection (e)--Recommendation.--The Secretary is authorized to recommend to the Congress revisions of the Table to change the vaccines covered by the Table. As new vaccines are developed, licensed, or required by State law, the Committee intends that the Secretary make recommendations of modification as soon as possible. The Committee is especially interested at this time in receiving the Secretary's recommendations as to compensation regarding the Haemophilus influenzae vaccine, the Hepatitis B vaccine, and other vaccines in current use.

Section 2115--Compensation

Subsection (a)--General Rule.--Compensation awarded under the Program is to be paid from the Trust Fund (described below in Title II). In general, potential compensation is divided into four types--(1) medical and rehabilitative care, (2) death benefits, (3) lost earnings, and (4) pain and suffering benefits. Payment for projected medical and rehabilitative care is to be made on a periodic basis, not less frequently than annually; payment for all other forms of compensation may be made in a lump sum.

(1) Medical and Rehabilitative Care. Compensation may be awarded for a wide range of medical and rehabilitative care, ranging from diagnosis to special nutritional needs, from custodial care to clothing for incontinence or physical protection. The Committee recognizes that injured children often have special or unusual health care and education needs and has attempted to provide flexibility in compensation awards by its broad description of compensable care.

Subject to the limits of Section 2116 (described below) compensation may be made for actual past unreimbursed expenses, for actual unreimbursable expenses incurred from the time of judgment to the time of award, and for reasonable projected unreimbursable expenses. In dealing with already incurred expenses, the Committee intends that the Program pay only demonstrated, actual costs for which reimbursement cannot be obtained. Interest and inflation adjustments are not
authorized for past expenses.

In dealing with prospective payments, as mentioned above, the Committee does not intend for the Program to become a fee-for-service, third-party payor for future medical and rehabilitation services. Flexibility for projected expenses and periodic payment is intended.

**6362 *21 (2) Death Benefits. Allowable death benefits for a vaccine-related death are set a level of $250,000.**

(3) Lost Earnings. In the case of an adult who sustains a vaccine injury and whose earning capacity is impaired by the injury, the level of compensation for lost earnings is to be determined in accordance with accepted actuarial principles.

In the case of a child who sustains a vaccine injury, compensation for lost earnings is to be made only after the child attains the age of 18. At the age of 18, if the earning capacity of the injured person is determined to be impaired, the award is to be adjusted to include lost earnings up to the level of the average weekly earnings of workers in the private, non-farm sector, with appropriate, specified offsets. If the earning capacity of the injured person improves, the petitioner is obligated (as provided in Section 2112, discussed above) to notify the Program and the lost earnings component of the award is to be reduced or eliminated. The Committee does not intend that the award be reduced because of other government benefits for which the injured person might be eligible.

(4) Pain and Suffering. Awards for pain, suffering, and emotional distress are authorized to be made at a level not to exceed $250,000 for each petition. As contrasted with the fixed death benefit, the award for pain and suffering is to be set at the discretion of the Master and of the court. The Committee does not intend that all petitions for which compensation is awarded be given this maximum level but rather that the Master consider the individual pain and suffering of the injured person, as well as the benefits conferred by other forms of compensation within the legislation.

Subsection (b)--Residential and Custodial Care and Service.--Any compensation award for residential and custodial care and service expenses is to be sufficient to allow the compensated person to remain living at home. This provision is not intended to prevent injured persons from receiving appropriate institutional care if they and their families request such services; neither is it intended to provide for the payment of family living expenses, the purchase of a home, or the construction of a major addition. The Committee intends that this provision allow for in-home medical, rehabilitative, and custodial care, and such modifications to existing physical facilities (such as bathroom facilities) as are necessary to ensure that injured persons are not required to be institutionalized for purely economic reasons.

Subsection (c)--Types of Compensation Prohibited.--Compensation under the Program may not include punitive or exemplary damages or any form of compensation (other than death benefits or lost earnings) that is not for the health, education, or welfare of the injured person.

Subsection (d)--Attorneys' Fees.--If the court awards compensation on a petition, the compensation is to include an amount to provide for reasonable
attorneys' fees and other costs incurred in proceedings on the petition. If the
court does not award compensation on a petition, it may, in its discretion,
nonetheless make such an award for attorneys' fees and costs if it determines that
the action was brought in good faith and that there was a reasonable basis for the
claim for which the action was brought.

**6363 *22 If, at the time of enactment of this legislation, a petitioner had a
civil action pending and elected under the provisions of Section 2111 (described
above) to withdraw the action and petition for compensation, the court may make an
award for attorneys' fees and costs incurred in that action before enactment.
No attorney may charge a fee for services in connection with a petition other
than the amount authorized by this section.

Matters to be demonstrated before compensation can be awarded are relatively
narrow and well-defined. Traditional discovery, cross-examination, pleadings, and
trial are not allowed in the proceeding on a petition. Because of the
straightforward nature of the petition and the proceedings, the Committee does not
anticipate that reasonable attorneys' fees will be large. (For example,
attorneys' fees in a similar compensation program for black lung disease have
proven to be well below those that might be expected in litigation and have, in
almost all cases, been less than $15,000 in total.)

Conversely, however, the Committee does not intend that the limitation of fees
to those included in the award act to limit petitioners' ability to obtain
qualified assistance and intends that the court make adequate provision for
attorneys' time and that the court exercise its discretion to award fees in
non-prevailing, good-faith claims.

Subsection (e)--Payment of Compensation.--Except for ongoing medical and
rehabilitative expenses, compensation may not be paid until an election is made
under Section 2121 (described below) to accept the compensation and to waive the
right to bring a civil action against a vaccine manufacturer. Compensation for
unreimbursable actual expenses for medical and rehabilitative care is to be paid
from the date of judgment on a petition and is to cease if an election is made
under Section 2121 (described below) to reject the compensation and to bring a
civil action. Payment of compensation is to be exempt from Federal reduction
orders.

Subsection (f)--Program Not Primarily Liable.--Payment of compensation is not to
be made for items or services for which payment has been made or can be expected
to be made by other public or private entities. Thus, if an insurance program or
a health maintenance organization pays or is obligated to pay for health care
services, the Program is not to pay for these same services.

Subsection (g)--Liability of Health Insurance Carriers, Prepaid Health Plans and
Benefit Providers.--No health insurance policy may make benefits secondary to
benefits under the Program. Similarly, no State or pre-paid health plan may make
benefits secondary to benefits under the Program. Thus, the elimination of
vaccine-related injuries from an insurance program or a health maintenance
organization which would cover similar injuries or conditions which are not
vaccine-related is not allowed.

Section 2116--Limitation of Actions
Subsection (a)--General Rule.--As described in Section 2111 (above), the bill divides vaccine-injured persons into three general groups: 1) those who were injured by a vaccine more than eight years before enactment of the legislation; 2) those who were injured by a vaccine that was administered before the enactment of the legislation but less than eight years ago; and 3) those who are **6364 *23 injured by a vaccine that is administered after the enactment of the legislation.

Persons in the first group are not eligible to receive compensation.

Persons in the second group must file a petition within two years of promulgation of regulations implementing the Program.

Persons in the third group who are seeking an award for injury must file a petition within three years of the first manifestation of the illness. Persons in the third group who are seeking an award for a death must file a petition within two years of the death or within four years of the first manifestation of the illness, whichever is earlier.

Subsection (b)--Effect of Revised Table.--If the Table is revised (as described above in Section 2114) and the effect of the revision is to make an individual eligible for compensation, that individual must file a petition within two years of the effective date of the revision. No compensation is to be provided, however, for an injury or death that occurred more than eight years before the date of the revision.

Subsection (c)--State Limitations of Actions.--If a petition is filed under the Program, the State statute of limitations is to be stayed with respect to a civil action for a vaccine-related injury or death. If, for example, a State law provides that a civil action must be brought within three years of the onset of an injury and if a petition is filed two and a half years after the onset of a vaccine-related injury and if--following the compensation proceedings--a petitioner then elects to initiate a civil action, the State limitation of actions is to be stayed for the duration of the compensation proceedings and the petitioner, in this example, would have six months after the judgment on compensation in which to initiate a civil action under the State law. If, however, the State statute of limitations makes special provisions for minors such that actions need not be brought before the age of 18 and if the petitioner files for compensation at age three and, at age four, elects to reject the compensation judgment and initiate a civil action, then the State statute of limitations is unaffected and the civil action may be brought until the age of 18.

Section 2117--Subrogation

Subsection (a)--Generally Rule.--The Vaccine Injury Compensation Trust Fund (described below in Title II) is to be subrogated to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation is paid. This right of subrogation does not, however, allow the Fund to recover an amount greater than the compensation paid. The court may refer the record of a compensation proceeding to the Secretary and to the Attorney General with recommendations as to subrogation.

While the Committee recognizes that other similar authorities of subrogation of rights of recovery are often unexercised, the Committee anticipates that the

Secretary, in an effort to ensure the solvency of the Fund and to lower the surcharge necessary to continue the Fund, will vigorously pursue the rights of the government in this instance.

**6365 624** Subsection (b)--Disposition of Amounts Recovered.--Amounts recovered under this authority are to be deposited in the Fund.

Section 2118--Increase for Inflation

The compensation set for death benefits and for maximum awards for pain and suffering under Section 2115 (described above) are to be increased to account for inflation. The civil penalty authorized under Section 2128 (described below) is to be similarly increased. This provision is adopted in an attempt to maintain these provisions at meaningful levels, rather than allowing them to become token amounts.

Section 2119--Advisory Commission on Childhood Vaccines

Subsection (a)--Establishment.--The Advisory Commission on Childhood Vaccines is to be established and is to be composed of nine members appointed by the Secretary. These members are to be health professionals, members of the general public, and attorneys. The Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control, the Commissioner of Food and Drugs are to be ex officio members.

Subsection (b)--Term of Office.--Members are to be appointed for three year terms, although initial members are to be appointed to staggered terms.

Subsection (c)--Meetings.--The Commission is to meet four times a year and at the call of the chair.

Subsection (d)--Compensation.--Standard compensation provisions are made for Commission members.

Subsection (e)--Staff.--The Secretary is to provide appropriate staff to the Commission.

Subsection (f)--Functions.--The Commission is established to advise the Secretary on the implementation of the Program, the modification of the Table, the improved safety of vaccines, and the gathering of information on vaccine-associated injuries. The Commission to the Director of the National Institutes for Health on research on vaccine safety.

Part B--Additional Remedies

Part B modifies the requirements for the pursuit of remedies beyond the system for a vaccine injury or death. Should a petitioner choose to reject the judgment and award of the Special Master and the court, he or she is free to pursue whatever additional remedies may be available under applicable law. In so doing, however, the petitioner must proceed in accordance with specific trial procedures outlined below. Manufacturers defending against such actions may, in turn, raise certain presumptions and standards of liability, also outlined below.
Section 2121--Authority to Bring Actions

Subsection (a)--Election.--The provision sets forth the options available to the petitioner once the judgment of the district court regarding the petition for compensation has become final. At any point not later than 90 days from the date that a final judgment **6366 *25 has been entered, the petitioner may file an election in writing either to accept the court's judgment (whether it awarded compensation or not) or to file a civil action for damages for the vaccine-related injury or death.

The election must be filed in writing even if the court has refused to award compensation. In the event that the petitioner fails to file an election in writing within the 90-day period, he or she will be deemed to have accepted the court's judgment.

If a petitioner elects to receive compensation or is deemed to have accepted the court's judgment, he or she may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered.

Subsection (b)--Limitation of Actions.--After the petitioner has completed a proceeding for compensation and has made a timely election in writing not to accept the compensation award (or the judgment of the court denying compensation), the statute of limitations governing the filing of an action for damages arising from the vaccine-related injury or death will be that which is set forth in applicable State law. Under this provision, the petitioner must elect in writing within 90 days whether or not to accept the court's final judgment regarding compensation.

Should the petitioner properly elect to file a civil action for damages, he or she must then look to State law to determine the period within which such an action for damages must be filed. A number of States have statutes of limitations that are stayed during the period in which one is a minor. Except for the requirement (where applicable) that one file a petition for compensation within the proper time period as a prerequisite to filing a civil action for damages and the provision in Section 2116(c) (discussed above) that stays the statute of limitations during the pendency of a petition for compensation, nothing in this legislation is intended to affect these statutes of limitations--or any other provisions of State statutes of limitations--with respect to the filing of civil actions for damages for a vaccine-related injury or death.

Section 2122--Standards of Responsibility

Subsection (a)--General Rule.--This section establishes certain standards of responsibility with respect to civil actions brought for damages for vaccine-related injuries or death. In some cases, the standards will be the same or similar to existing State law; in others, the standards will change most State laws. The Committee believes that the establishment of these standards of responsibility is appropriate in light of the availability of a comprehensive and fair compensation system. However, the establishment of these standards are the only new requirements that affect State law regarding actions for vaccine-related
injuries or death; all other aspects of State law remain unchanged.

Subsection (b)--Unavoidable Adverse Side Effects; Direct Warnings.--This provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even through the vaccine was **6367 *26 properly prepared and accompanied by proper directions and warnings.

The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding 'unavoidably unsafe' products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system. The vaccines addressed in this legislation certainly present the hardest case for the application of Comment K. In such a case, the plaintiff is almost invariably a young child, often badly injured or killed, and free from wrongdoing. And, even if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtedly will find it difficult to rule in favor of the 'innocent' manufacturer if the equally 'innocent' child has to bear the risk of loss with no other possibility of recompense.

The Committee believes that this bill offers another, better, alternative. Part A establishes a no-fault compensation system that goes far beyond even the most expensive ruling issued by in a court in a vaccine case. Under this compensation system, vaccine-injured persons may obtain a full and fair award for their injuries even if the manufacturer has made as safe a vaccine as possible. Petitioners are compensated because they suffered harm from the vaccine--even a 'safe' one--not because they demonstrated wrongdoing on the part of the manufacturer.

Given the existence of the compensation system in this bill, the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should pursue recompense in the compensation system, not the tort system.

For purposes of this subsection, a vaccine is presumed to be accompanied by proper directions and warnings where the manufacturer demonstrates that it complied in all material respects with relevant Federal law governing the approval and labeling of the vaccine. This presumption may be overcome, however, but only upon a showing that the manufacturer engaged in fraudulent conduct or intentional and unlawful withholding of information in obtaining premarket approval for the vaccine from the Food and Drug Administration; or upon a showing that the manufacturer intentionally and wrongfully withheld information relating to the vaccine's safety or efficacy after it was approved; or upon a showing, by clear and convincing evidence, that the manufacturer failed to exercise due care notwithstanding its compliance with relevant Federal law.

In establishing this presumption, the Committee intends to make clear its view that only those significant failures to warn or provide directions that clearly
pertain to vaccine safety and that clearly arise from substantial wrongdoing on the part of the manufacturer ought to result in liability.

**6368 *27 Subsection (c) --Direct Warnings.--Subsection (c) addresses a line of cases in which vaccine manufacturers have been held liable for their failure to provide warnings directly to the injured party. (See, e.g., Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977), Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974) and Davis v. Wyeth Laboratories, 399 F.2d 121 (9th Cir. 1968).) Its purpose is to establish the principle that no vaccine manufacturer is to be held liable for damages arising from a vaccine-related injury or death solely due to its failure to provide direct warnings to the injured party (or the injured party's legal representative). If the manufacturer provides an adequate warning and adequate directions to an intermediary such as a doctor, nurse, or pharmacist who can be expected to know about the product and its risks, and who is responsible for informing the ultimate recipient of a vaccine (or the recipient's legal representative), the manufacturer should not be held liable for any failure to warn or provide directions directly to a person (or a person's legal representative) who is injured from the vaccine. Thus, once the manufacturer provides adequate warnings and directions to such professionals, the manufacturer meets the requirements of this provision and fulfills its obligations under the law with respect to its duty to warn of potential vaccine risks or hazards.

Subsection (d) --Construction.--The provisions relating to an election made under Section 2121(a), as discussed above, are not intended to permit a petitioner to bring a civil action that would be barred by State doctrines of res judicata or collateral estoppel. Section 2111(a)(4) (above) permits a petitioner who received an adverse ruling from a court in a civil action brought against a vaccine manufacturer before the date of enactment of the legislation to file a petition for compensation. Nothing in this legislation, however, is intended to permit the filing of a new civil action upon completion of the proceeding for compensation if a final judgment denying recovery was entered in a previous civil action.

Subsection (e) --Preemption.--State statutes that effectively foreclose individuals from bringing civil actions from vaccine-related injuries or deaths or pre-empted by this subsection. The Committee intends for this preemption to apply even where a State has established a compensation system as an alternative to filing civil actions. It does not intend, however, to preempts states limitations or other provisions of State law and practice that regulate the time or manner in which civil actions in general may be brought or maintained. Similarly, the Committee does not intend to preempt State statutes that limit damages, such as those that establish limitations or 'caps' on awards for pain and suffering and mental anguish, in actions for personal injury or death.

Section 2123 --Trial

Subsection (a) --General Rule.--Section 2123 provides for the tridurcation of civil actions against vaccine manufacturers for damages from a vaccine-related injury or death associated with the administration of a vaccine after the date of enactment of this subtitle which is not barred by any of the limitations contained

in Section 2111(a)(2) (above).

**6369** *28 The purpose of this Section is not to bar in any way the introduction of otherwise admissible evidence concerning a vaccine-related injury or death in civil actions. Rather, its purpose is to establish rules for the timing of the introduction of such evidence in order to prevent irrelevant and prejudicial factors from unfairly influencing the outcome of trials. Thus, the legislation establishes three stages for the conduct of such civil actions.

Subsection (b)--Liability.--In the first stage of a trial for damages arising from a vaccine-related injury or death, the question of liability for such injury or death is to be determined separately, i.e., before any consideration of damages may be given to the issues of damages, either general or punitive. Accordingly, this subsection requires that the court make a determination of liability before proceeding to consider questions of damages. Regardless of the court's evidentiary rulings under applicable law in this regard, the Committee urges courts to be diligent in addressing liability issues in a manner as free as possible from irrelevant and prejudicial factors (such as inflammatory material or documentation whose emotional impact can be expected to overshadow necessary factual determinations).

Subsection (c)--General Damages.--Should the question of liability be decided against the defendant, the second stage of a civil action is to be held to determine the amount of damages, other than punitive damages, the defendant should be required to pay. In separating punitive damages from the first and second stages of a trial, the Committee intends to prevent the introduction of evidence relating to the financial position of the vaccine manufacturer from these stages.

In establishing three separate stages of trial, the Committee does not intend, however, to bar the introduction of evidence respecting the defendant that is relevant either to the establishment of liability or the determination of damages simply because such evidence would establish the grounds for punitive damages as well. In establishing liability, for example, a plaintiff may demonstrate that the manufacturer produced a defective vaccine through clearly criminal behavior if that is what the evidence shows. The Committee also does not intend to limit plaintiffs to establishing liability by a preponderance of the evidence if they go further and can establish liability beyond a reasonable doubt.

Subsection (d)--Punitive Damages.--The third stage of a trial be held solely for the purpose of determining punitive damages where such damages are sought by the plaintiff and permitted by State law. Under this subsection, punitive damages are not to be awarded in cases arising from injuries or death associated with a vaccine if a determination is made that a vaccine manufacturer has complied with those specified provisions of the Public Health Service Act and the Food, Drug and Cosmetic Act relevant to vaccine safety. The Committee believes that punitive damages should be assessed only where particularly reprehensible, conscious behavior is involved. Where a manufacturer has attempted in good faith to comply with a government standard-- even if the standard provides inadequate protection to the public--the manufacturer should not be assessed punitive damages absent evidence that it engaged in reprehensible behavior that directly resulted in the establishment of **6370** *29 maintenance of the standard's inadequacy. Section 2123(d)(2) sets forth the types of reprehensible behavior that would result in the
imposition of punitive damages.

Subsection (e)—Evidence.—This provision bars the introduction into evidence in any civil action against a vaccine manufacturer of the existence of the Vaccine Injury Table (discussed in Section 2114 above), any finding of the district court or the Special Master appointed by the court, and the final judgment of the district court. Compensation standards, evidence, and proceedings are sufficiently different from civil proceedings in tort that the findings made in compensation are not likely to be based on the more rigorous requirements of a tort proceeding and might confuse such civil actions.

Part C—Assuring a Safer Childhood Vaccination Program in the United States

The legislation mandates a number of procedures that must be followed for the maintenance of the safest and most effective childhood vaccination programs possible. While some of these procedures are already in place, others are not. Moreover, because current practices are not mandatory, Federal officials may not be receiving all of the information that is needed to evaluate the safety and effectiveness of the various childhood vaccines.

Section 2125—Recording and Reporting of Information

Health care providers who administer the vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above) to keep permanent medical records on the administration of these vaccines, including information on the specific vaccine that was given. Both health care providers and vaccine manufacturers are also required to report to the Secretary on the occurrence within a 7-day period of any event set forth in the Table as well as the occurrence of any contraindicating reactions to the vaccine that are specified within the vaccine manufacturer's package insert. The reporting of these events is to begin within 90 days after the enactment of this legislation. Information concerning the nature of the reactions reported to the Secretary is to be made available to the public.

Section 2126—Vaccine Information

The Secretary must develop and disseminate within one year after the enactment of this legislation, information materials on the vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above). Such materials are to include information on the diseases these vaccines are designed to prevent, the potential adverse reactions to the vaccines, and the reporting mechanisms that should be followed when adverse reactions do occur. The materials are to be developed under a rulemaking procedure that includes sufficient opportunity for public comment. The Secretary is to disseminate the materials to health care providers who, in turn, are to distribute the information (or its equivalent) to the legal representatives of children receiving vaccines prior to the time such vaccines are administered.

**6371 *30 Section 2127—Mandate for Safer Childhood Vaccines

The Secretary has the responsibility to promote the development and use of improved, safer childhood vaccines. In carrying out this mandate, the Secretary is to make appropriate use of each of the authorities concerning vaccine development, distribution, and use, including those relating to the activities of the Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control, as well as the provisions of this legislation. Within two years after the date of enactment of this legislation, the Secretary is to report to the Congress on the actions that have been taken during this period to comply with this mandate.

Section 2128—Manufacturer Recordkeeping and Reporting

This section specifies the recordkeeping information that manufacturers are to prepare and maintain on the vaccines they produce as well as the reporting procedures they must follow upon the development of significant vaccine safety problems. These requirements are applicable both to the manufacturers of vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above) and to the manufacturers of any other vaccines which are mandated for use under State law. Section 2128 also provides for sanctions that are to be imposed on manufacturers and individuals who intentionally destroy, alter, falsify, or conceal the information that is to be provided under these requirements.

Part D—General Provisions

Section 2131—Citizens' Actions

Subsection (a)—General Rule.—Section 2131 provides standing to any person to bring an action in a district court of the U.S. against the Secretary where the Secretary has failed to perform any act or duty under this subtitle.

Subsection (b)—Notice.—Before bringing such an action under this Section, the person claiming a failure on the part of the Secretary to perform his or her duty must give written notice of intent to commence such an action. The purpose of requiring such notice is to permit the Secretary to come into compliance with this subtitle. Courts should consider the Secretary's good faith efforts to take substantial steps to come into compliance with this subtitle in issuing any final order against the Secretary.

Subsection (c)—Costs of Litigation.—In issuing any final order under this Section, a court may award costs of litigation (including reasonable attorney and expert witness fees) to any party (plaintiff or defendant) when appropriate. The Committee urges the courts to be judicious in awarding costs under this provision. Courts should be reluctant to give such awards to a plaintiff simply because he or she has demonstrated a technical violation of the law having little impact on any of its major purposes. Courts should, however, be reluctant to assess damages against unsuccessful plaintiffs where they have sought in good faith to compel the Secretary to perform his or her obligations under the law.

**6372 *31 Section 2132—Judicial Review

A petition for review of a regulation under this subtitle may be filed in a court of appeals within 60 days from the date of the promulgation of regulations or after such date if such petition is based solely on grounds arising after such 60th day.

Section 2133--Definitions

This section sets forth definitions that apply in Subtitle 2 of the legislation. Subsection (1) defines the term 'health care provider.' Subsection (2) defines the term 'legal representative.' Because most individuals injured by vaccines are children, the Committee anticipates that legal representatives will be parties in the filing and processing of most petitions for compensation.

Subsection (3) defines the term 'manufacturer.' This section makes clear that the term is intended to be applied broadly to include public and private groups that manufacture, import, process, or distribute under their own label vaccines set forth in the Vaccine Injury Table (discussed in Section 2114 above). For purposes of recordkeeping and reporting (as well as the imposition of sanctions) under Section 2128 (above), the term includes any manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any state.

Subsection (4) defines the term 'significant aggravation.'

Subsection (5) defines the term 'vaccine-related injury or death.'

Subsection (6) defines the terms 'Advisory Commission on Childhood Vaccines,' 'Vaccines Injury Table,' and 'National Vaccine Injury Compensation Trust Fund,'

Section 102--Related Studies

Subsection (a)--Review of Pertussis Vaccines and Related Illnesses and Conditions.--Within three years of the date of enactment of this legislation, the Secretary must complete a review of all relevant medical and scientific information on the nature, circumstances and extend of the relationship between vaccines containing pertussis and a specified list of illnesses and conditions.

Subsection (b)--Findings with Respect to Pertussis.--Within three years of the date of enactment of this legislation, the Secretary must make and publish in the Federal Register specific findings regarding the illnesses and conditions set forth in subsection (a) (above).

Subsection (c)--Revision of Table with Respect to Pertussis Vaccines.--At the time the Secretary publishes the findings required in subsection (b) (above), the Secretary must also propose such regulations as may be necessary to change the Vaccine Injury Table (discussed in Section 2114 above) in accordance with the findings made pursuant to subsection (b). The Secretary must promulgate such regulations no later than 42 months after the date of enactment of this legislation after providing an opportunity for a public hearing.

Subsection (d)--Review of MMR Vaccines and Related Illnesses and Conditions.--Within three years of the date of enactment of this legislation, the Secretary will complete a review of all relevant **6373 *32 medical and scientific

information on the nature, circumstances and extent of the relationship between vaccines containing rubella (including vaccines intended to prevent or confer immunity against measles, mumps, the rubella) and radiculoneuritis. Within this same time period, the Secretary is to make and publish in the Federal Register any findings regarding the relationship between rubella vaccines and radiculoneuritis.

The Secretary is also required to propose such regulations as may be necessary to change the Vaccine Injury Table (discussed in Section 2114 above) in accordance with the Secretary's findings.

Subsection (e)—Pertussis and MMR Studies.—The Secretary is to arrange for studies with respect to vaccines containing pertussis and vaccines containing rubella (including MMR) in order to assist the Secretary in making the findings required in subsections (b) and (d) (above). The results of the studies are to be submitted to the House Committee on Energy and Commerce and the Senate Committee on Labor and Human Resources within 32 months of the date of enactment of this legislation. The studies must be made available to the public at the time they are submitted to the Secretary.

Section 103—Study of Other Vaccine Risks

Subsection (a)—Study.—Within three years of the date of enactment of this legislation, the Secretary is to arrange for a study of risks not studied under Section 102 (above) that are associated with the vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above). In addition, the Secretary is to establish guidelines respecting the administration of such vaccines including the circumstances under which such vaccines should not be administered, the circumstances under which administration of the vaccines should be delayed, as well as the groups, categories, or characteristics of potential recipients of such vaccines who may be at significantly higher risk of major adverse reactions to such vaccines than the general population of potential recipients.

Subsection (b)—Revision of Guidelines.—Not less than every three years, the Secretary is to review and revise the guidelines issued pursuant to subsection (a) (above). Should the Secretary find on the basis of such periodic reviews that no revision of the guidelines is necessary at that particular time, the Secretary shall publish that finding in the Federal Register.

Subsection (c)—Factors Affecting Guidelines.—This provision sets forth several factors that the Secretary must consider in establishing guidelines under subsection (a) (above).

Subsection (d)—Dissemination.—The Secretary is required to disseminate widely the guidelines establish under subsection (a) (above).

Section 104—Review of Warnings, Use Instructions, and Precautionary Information

Within one year of the date of enactment of this legislation, the Secretary is to review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above) and is to determine, by rule, whether such warnings, instructions 6374 33 and information adequately warn health care providers of
the nature and extent of dangers posed by such vaccines. If the Secretary should
determine that any such warnings, instructions, or information is inadequate for
this purpose, the Secretary must require the appropriate manufacturer or
manufacturers to revise and reissue such warnings, instructions, or information as
expeditiously as practical, but not later than 18 months after the date of
enactment of this legislation.

Section 105--Recall Authority

Section 105 provides specific authority for the Secretary to seek the recall of
any batch, lot or other quantity of a vaccine licensed under subsection (d) of
Section 351 of the Public Health Service Act upon the Secretary's determination
and issuance of an order (pursuant to Section 554 of the Administrative Procedure
Act) indicating that the quantity of vaccine presents an imminent or substantial
hazard to the public health.

The Committee understands that most recalls conducted by the Food and Drug
Administration have been conducted on a voluntary basis even where no formal
statutory authority for recall exists. The Committee does not intend this
 provision to displace existing voluntary procedures which have proven successful
in protecting the public.

TITLE II--AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1954

Part I--National Vaccine Injury Compensation Trust Fund

Section 201--Establishment of National Vaccine Injury Compensation Trust Fund

Subsection (a)--In General.--The National Vaccine Injury Compensation Trust Fund
('the Fund') is established in the Treasury of the U.S. to include appropriated
and credited amounts. There are appropriated to the Fund in amounts equal to the
excise taxes of the vaccines covered by the Program (described below in Section
211) and to the amounts recovered by the Program in its rights of subrogation
(described above in Section 2117). Expenditures from the Fund are for the
purposes of the Program (described above in Title I, Subtitle 2, Part A).

Repayable advances to the Fund are authorized to be appropriated. These
advances are, in essence, a loan to the Fund to carry out the Program. Such
advances are to be repaid, with interest, to the general fund of the Treasury when
the Secretary determines that the Fund has sufficient resources to do so.

The liability of the Federal government is limited to funds available in the
Fund. Nothing in Title I of the bill is to be construed as authorizing the
payment of any claim from any other source than the Fund. If at any time the Fund
has insufficient funds to pay all claims payable, the claims shall be paid in full
in the order in which they were determined.

Subsection (b)--Appropriation for Initial Funding of Trust Fund.--There is
appropriated, as a repayable advance, $40 million for the initial establishment of
the Fund, to remain available until expended.

**6375** *34 Subsection (c)--Clerical Amendment.--This subsection provides for an

amendment to the table of sections.

Subsection (d)--Effective Date.--Except for subsection (b), the amendment made by this Section is to take effect on January 1, 1987. The amendment made by subsection (b) is to apply to fiscal year 1987.

Part II--Revenue Sources for National Vaccine Injury Compensation Trust Fund

Section 211--Manufacturers Excise Tax on Childhood Vaccines

Subsection (a)--In general.--A tax is to be imposed on the sale of childhood vaccines. A table of tax rates is included. Using current assumptions as to numbers of doses of vaccine that will be sold, the taxes set forth in the tax table should generate approximately $40 million in the first year. The taxes are set to generate sufficient annual income for the Fund to cover all costs of compensation and to allow for gradual repayment of the initial repayable advance for capitalization.

The taxes are set at different rates among vaccines to reflect the currently accepted views regarding the relative reactogenicity of vaccines. Thus, because it is generally agreed that pertussis vaccine causes a disproportionately large number of reactions--estimated to be 77 percent of all serious vaccine injuries--the excise tax on the five-shot series of pertussis vaccines will account for approximately 77 percent of the total excise tax funding of the Fund. Inactivated polio vaccine is considered to cause very few reactions, and the excise tax on that vaccine will account for only a nominal portion of the total tax funding of the Fund.

The tax and assumed income for vaccines that are distributed in large numbers in the U.S. are as follows:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Tax</th>
<th>Number of doses distributed (in millions)</th>
<th>Revenues generated (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D+T+P ..</td>
<td>$1.56</td>
<td>20.0</td>
<td>$31.2</td>
</tr>
<tr>
<td>D+T ......</td>
<td>.02</td>
<td>1.0</td>
<td>0.02</td>
</tr>
<tr>
<td>M+M+R ......</td>
<td>1.52</td>
<td>5.0</td>
<td>7.6</td>
</tr>
<tr>
<td>OPV ........</td>
<td>.10</td>
<td>17.1</td>
<td>1.71</td>
</tr>
</tbody>
</table>

In future years, the excise tax is to be adjusted to account for inflation in medical care costs, the indicator most reflective of the costs of compensation under the Program.

Subsection (b)--Certain Exemption from Manufacturers Excise Taxes Not to apply to Vaccine Tax.--This provision requires that all purchasers of vaccine are to pay the excise taxes.

Subsection (c)--Sales to United States Not Exempt from Tax.--This provision requires that the U.S. and its possessions pay the excise taxes for purchase of
vaccines.

Subsection (d)—Clerical Amendment.--This provision amends the table of contents.

Subsection (e)—Effective Date.--The amendments made by this Section are to take effect on January 1, 1987.

**6376 *35 TITLE III--MISCELLANEOUS

This title waives certain regulatory requirements in the implementation of this legislation. The title also provides that if any provision of the legislation is found to be invalid on Constitutional grounds, the entire Act is to be considered invalid.

The title also specifies that if, at any time, the Fund becomes insolvent for a continuous period of six months, all of the Compensation Program and changes in other remedies made by Subtitle 2 of Title XXI of the Public Health Service Act (described above) will cease to be effective. Subtitle 2 is to remain ineffective until sufficient funds to restore the Fund to solvency. The amendment was adopted to ensure that petitioners would not be forced to proceed with petitions which could not, in fact, receive awards and that vaccine-injured persons would not be restricted from bringing civil actions if the compensation system was, in practical terms, not available. The Committee notes that once sufficient funds become available again, Subtitle 2 will become effective. A short period of ineffectiveness caused by this section should not have any continuing effect on petitions or lawsuits once the subtitle again becomes applicable, except to stay the filing requirements for the period of ineffectiveness.

HEARINGS

The Committee's Subcommittee on Health and the Environment held one day of hearings on the related bill H.R. 5184 on July 25, 1986. Testimony was received from nine witnesses, representing public health organizations, parent organizations, and vaccine manufacturers, with additional material submitted by five individuals and organizations. Hearings were also held by the Subcommittee on legislation and issues related to vaccine injury compensation on September 10, 1984 and December 19, 1984 (Serial No. 98-183).

COMMITTEE CONSIDERATION

On September 17, 1986, the Subcommittee on Health and the Environment met in open session and ordered reported the related bill H.R. 5184 as amended by a voice vote, a quorum being present. On September 18, 1986, the Committee met in open session and ordered reported the bill H.R. 5546 with amendments by voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(1)(3)(A) of Rule XI of the Rules of the House of
Representatives, the Subcommittee held oversight hearings and made findings that are reflected in the legislative report.

COMMITTEE ON GOVERNMENT OPERATIONS

Pursuant to clause 2(1)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

**6377 *36 COMMITTEE COST ESTIMATE

In compliance with clause 7(a) of rule XIII of the Rules of the House of Representatives, the Committee believes that the cost incurred in carrying out H.R. 5546 would be as follows:

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Outlays</td>
<td>25.0</td>
<td>56.0</td>
<td>38.0</td>
<td>16.0</td>
<td>18.0</td>
</tr>
</tbody>
</table>

The Congressional Budget Office estimates of the cost of the program are significantly higher because of two fundamental assumptions with which the Committee disagrees: the number of vaccine-injured persons to be compensated and the projected costs of attorneys' fees for the compensation proceeding.

CBO estimates that 'as many as 1,500 people may have suffered qualifying injuries over the past 8 years.' CBO goes on to estimate that 'an additional 185 new cases would result each year. . . .' This assumption is based on methodology used by the American Academy of Pediatrics in 1983. In more recent studies done for the Academy as part of its submissions to the Subcommittee, however, it has been estimated that the incidence of chronic injury or death from vaccines is 79 cases per year for the period of 1963 to 1985 and 71 cases per year at present. The Committee has used this estimate of incidence in projecting the costs of the legislation and estimates that approximately 640 persons are eligible to apply for vaccine injuries which occurred over the past 8 years and that 80 new cases of vaccine injury will be eligible for compensation each year under the Program. As CBO notes, 'Costs will be proportionately lower if fewer people receive awards.'

(This lower estimate is bolstered by the Committee's results of a survey of vaccine manufacturers, included as part of its report, Childhood Immunizations (Comm. Print 99-LL). In that survey, manufacturers reported a total of 252 cases filed against manufacturers over approximately five years. While the Committee does expect that many people who might not be able to recover damages under the more rigorous requirements of tort action will be compensated, the Committee does not expect that number to grow by as much as four times. The Committee also notes that the vast majority of vaccine suits have arisen from relatively recent inoculations and that the number of compensation petitions from persons who were
injured at an earlier time will be predictably smaller than those filing for recent injuries.)

CBO also estimates that the legal costs and attorneys' fees will be $50,000 per case in the compensation system. The Committee has assumed that costs under a no-fault, non-adversarial system will be significantly lower. With most evidentiary requirements specified in the legislation, with prohibitions on traditional discovery and courtroom procedure, and with no obligations to demonstrate negligence or product defectiveness, the costs of legal services will more closely approximate those incurred in such systems as the Black Lung benefits program or workers' compensation programs. In these systems, legal costs rarely rise above $10,000 per case. The Committee has, therefore, assumed that legal costs may be as much as $15,000 per case in the compensation Program.

Using such projections and assuming that CBO's estimates for Trust Fund revenue are accurate, the Committee would expect that the Trust Fund balance would be as follows:

<table>
<thead>
<tr>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance</td>
<td>+1.0</td>
<td>-18.0</td>
<td>-20.0</td>
<td>+6.0</td>
<td>+33.0</td>
</tr>
</tbody>
</table>

CONGRESSIONAL BUDGET OFFICE ESTIMATE

U.S. CONGRESS,

CONGRESSIONAL BUDGET OFFICE,


Hon. JOHN D. DINGELL,
Chairman, Committee on Energy and Commerce, House of Representatives,
Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for H.R. 5546, the National Childhood Vaccine Injury Act of 1986, as ordered reported by the House Committee on Energy and Commerce on September 18, 1986.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,

Sincerely,

JAMES BLUM

(For Rudolph G. Penner).

CONGRESSIONAL BUDGET OFFICE--COST ESTIMATE

3. Bill status: As ordered reported by the House Committee on Energy and Commerce on September 18, 1986.
4. Bill purpose: To establish a national vaccine program for the development of new vaccines and the improvement of existing vaccines and a program to compensate the victims of vaccine-related injuries and deaths, and for other purposes.
5. Estimated cost to the Federal government:

[By fiscal year, in millions of dollars]

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>National Vaccine Injury Compensation Trust Fund:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budget authority</td>
<td>75</td>
<td>168</td>
<td>115</td>
<td>42</td>
<td>45</td>
</tr>
<tr>
<td>Outlays</td>
<td>75</td>
<td>168</td>
<td>115</td>
<td>42</td>
<td>45</td>
</tr>
<tr>
<td>Revenues, gross</td>
<td>26</td>
<td>38</td>
<td>40</td>
<td>42</td>
<td>45</td>
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<tr>
<td>Income tax offset</td>
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<td>-9</td>
<td>-10</td>
<td>-10</td>
<td>-11</td>
</tr>
<tr>
<td>Revenues, net</td>
<td>20</td>
<td>29</td>
<td>30</td>
<td>32</td>
<td>34</td>
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<tr>
<td>Net budget impact (increase in deficit)</td>
<td>55</td>
<td>139</td>
<td>85</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Estimated authorizations:</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>National Vaccine Program</td>
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<tr>
<td>Federal agency funds</td>
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<tr>
<td>Advisory Commission</td>
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<td>1</td>
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<td>1</td>
</tr>
<tr>
<td>Vaccine information</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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</tr>
<tr>
<td>Recordkeeping and reporting</td>
<td>( [FN-1] )</td>
<td>(1)</td>
<td>(1)</td>
<td>(1)</td>
<td>(1)</td>
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<tr>
<td>Studies</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>(1)</td>
<td>(1)</td>
</tr>
<tr>
<td>Total estimated authorization level</td>
<td>26</td>
<td>29</td>
<td>31</td>
<td>33</td>
<td>36</td>
</tr>
<tr>
<td>Estimated outlays</td>
<td>19</td>
<td>25</td>
<td>29</td>
<td>31</td>
<td>35</td>
</tr>
<tr>
<td>Bill total:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budget authority/estimated authorization level</td>
<td>101</td>
<td>197</td>
<td>146</td>
<td>75</td>
<td>81</td>
</tr>
<tr>
<td>Estimated outlays</td>
<td>94</td>
<td>193</td>
<td>144</td>
<td>73</td>
<td>80</td>
</tr>
<tr>
<td>Revenues, net</td>
<td>20</td>
<td>29</td>
<td>30</td>
<td>32</td>
<td>34</td>
</tr>
<tr>
<td>Net budget impact (increase in deficit)</td>
<td>74</td>
<td>164</td>
<td>114</td>
<td>41</td>
<td>46</td>
</tr>
</tbody>
</table>

FN1 Less than $500,000. Details may not add due to rounding.

**6379 Basis of estimate**

National Vaccine Injury Compensation Trust Fund.--H.R. 5546 would establish a program to compensate those who have sustained severe injuries from childhood vaccines. Revenues from taxes levied on each vaccine dose, as specified in the bill, would be appropriated to the proposed National Vaccine Injury Compensation Trust Fund. These revenues are estimated by multiplying the tax per vaccine dose specified in the bill by the projected number of doses distributed. In addition, the bill would authorize the appropriation to the trust fund of repayable advances from the Treasury needed to carry out the purpose of the fund. Compensation payments authorized in the bill would be made from the fund. CBO estimates payments from the trust fund will exceed trust fund revenues by about $250 million for the first three years the program is in operation. The resulting net increase in the deficit would be funded by borrowing from the Treasury. This estimate assumes any necessary funding in the form of repayable advances from the Treasury is fully appropriated.

Outlays from the trust fund are larger in beginning years since payments to persons injured within the past eight years will be made in the first three years.

Over the five-year projection period, annual outlays from the trust fund are composed largely of compensation for pain and suffering and attorney fees. CBO expects outlays to begin to increase significantly in ten to twenty years as payments then will be composed largely of compensation for lost earnings. Most children receive vaccines before the age of five, and, if injured, would not be eligible for lost earnings compensation until reaching age eighteen.

In general, compensation would be paid to vaccine-injured persons for any unreimbursed past costs incurred and any projected future costs for medical care and rehabilitation services and for actual and anticipated lost earnings. Compensation would also cover payments for pain, suffering and emotional distress, payments in the event of death, and reasonable attorney fees. Payments for pain, suffering and emotional distress and for death would be made in the year of the court's approval of a petition for compensation. Payments for unreimbursed past costs, actual lost **6380** earnings and attorney fees would also be made in a lump sum in the year a petition is approved. All other payments would be made periodically thereafter, assumed in this estimate to be on an annual basis.

The bill would allow anyone who may suffer certain severe vaccine-related injuries in the future to file a petition for compensation. The bill would also provide some retroactive coverage, allowing anyone who suffered such injuries in the last 8 years to file for compensation. CBO estimates as many as 1,500 people may have suffered qualifying injuries over the past 8 years. We estimate an additional 185 new cases would result each year from adverse reactions to those vaccinations covered in the bill. We assume all those eligible for compensation would file for, and receive awards. Costs would be proportionately lower if fewer people receive awards.

The estimated number of projected severe adverse reactions to vaccines is based on the methodology used in a study by the American Academy of Pediatrics (AAP) entitled 'Estimate of the Costs of Major Program Alternatives in Design of a National Program to Reimburse the Medical and Rehabilitation and Other Costs of
Persons Severely Injured by Immunizations' (April 23, 1983). The estimated number of severe adverse reactions in 1978 has been multiplied by the ratio of the projected number of vaccine doses expected to be distributed in the 1987-1991 period to the number of doses distributed in 1978. Estimates for the number of injuries resulting in past years were similarly calculated. CBO estimates for medical and rehabilitation costs are also based on the AAP study.

Estimates for lost earnings are based on projected average gross weekly earnings of workers in the private sector adjusted for appropriate tax and insurance offsets, as specified in the bill. Since compensation for lost earnings is only to begin after a person reaches age 18, eligibility for payments was estimated by creating an age distribution of those having adverse reactions to vaccines.

Compensation for pain, suffering, and emotional distress is capped in the bill at $250,000 for fiscal year 1987. The number and amount of pain and suffering awards that might be made is uncertain, and would be left to the discretion of special masters designated to render judgement on vaccine injury cases. For purposes of this estimate, CBO assumes half the amount allowed would be paid to all awardees or alternatively, the maximum amount for pain and suffering would be paid to half the awardees, yielding the same cost figures. This amount is allowed to increase for inflation in future years, as stated in the bill. Payments for pain and suffering would make up the majority of annual costs in the first years of program operation. If the maximum amount were awarded to all those estimated to have vaccine-related injuries, the costs of this bill would be $300 million higher over the five year period.

Compensation in the case of a vaccine-related death is set in the bill at $250,000. Based on the incidence of adverse reactions to vaccines calculated by CBO, an estimated five deaths following vaccination could occur each year. Payments to estates would total $1.25 million annually. These payments are also allowed to increase for inflation, as stated in the bill.

Compensation for reasonable attorney fees and other costs associated with the proceedings would also be included as part of the **6381** award. Attorney fees may also be paid, at the court's discretion, in cases where an award is not made if the case is brought in good faith. Projected attorney fees under the new system of compensation are difficult to estimate. In general, attorney receive fees equal to a percentage of the net present value of a court award. One attorney who handles vaccine injury cases testified in Senate proceedings on vaccine compensation that his fees range between 33 and 40 percent of the net present value of the final award. In addition, litigation expenses run about $100,000 per case under the current tort system. CBO expects both attorney fees and legal expenses to be lower under the new system, since proceedings should be less adversarial and manufacturer negligence and vaccine defectiveness need not be demonstrated. CBO assumes attorney fees and other legal costs to be about $50,000 per case.

Other authorizations

The authorization levels for vaccine research, development, safety and efficacy testing, and manufacturer licensing and for additional funding for federal
agencies is stated in the bill. All other authorization levels are estimated. We assume all authorized amounts are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates calculated by CBO on the basis of similar program data. All authorizations are subject to subsequent appropriations action.

The bill would establish a nine member Advisory Commission on Childhood Vaccines. The Commission would be responsible for several scientific studies and surveys. We estimate compensation, travel and per diem for Commission members and salary and overhead for a full-time staff of ten to be about $1 million in each fiscal year. Costs could be higher or lower depending on the actual number of staff hired.

The bill would require the Secretary of Health and Human Services (HHS) to provide information to parents on adverse reactions to be distributed by health care providers administering vaccines. The development, printing and dissemination costs for these materials are expected to be about $1 million each year.

The bill would make it mandatory for physicians and vaccine manufacturers to report adverse reactions to the Secretary of HHS. Both the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) currently collect some of this information, but expect this provision would increase their workloads. CBO estimates additional personnel would be needed at CDC and FDA to process the additional reports at a total cost of about $400,000 each year.

Finally, the bill would require several studies on various vaccine related topics: whether or not a casual relationship exists between pertussis vaccines, measles, mumps, and rubella vaccines, and certain illnesses; the risks to children associated with certain vaccines; and a biennial study of the impact of this bill on vaccine supply. CBO expects costs for these studies to be about $2 million in 1987 and 1988, declining as some studies are completed to $1 million in 1989, and less than $500,000 in 1990 and 1991.

**6382-41 6. Estimated cost to State and Local Government: The budgets of state and local governments would not be affected directly by the enactment of this bill.

7. Estimate comparison: None.
8. Previous CBO estimate: None.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(1)(4) of rule XI of the Rules of the House of Representatives, the Committee makes the following statement with regard to the inflationary impact of the reported bill:

The Committee believes that the proposed legislation will have a significant anti-inflationary effect. Recent increases in vaccine prices have been as high as 500 percent over a two-year period. The Committee believes that the proposed legislation will go far to restrain such sudden and erratic price increases and
may, indeed, result in lower costs in the future. Moreover, the Committee would note that vaccines are among the most cost-effective of health care programs and that maintenance of high immunization levels is essential to restraining the increase in health care costs.

AGENCY VIEWS

No agency views were received on H.R. 5446.

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*78 DISSenting VIEWS ON H.R. 5546--NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986

We agree completely that Congress should act to develop a program to compensate children who have been injured by mandatory childhood vaccines and to ensure the continuation of our crucial National Childhood Immunization Program. There are several reasonable legislative proposals that address these problems. H.R. 5546 is not one of those proposals. H.R. 5546 establishes new taxing authority, further erodes the concept of compensating victims of negligent acts, and provides authority for the establishment of several unnecessary and dulcative advisory councils and commissions.

H.R. 1780, a bill with over 40 House cosponsors, including five Committee Chairmen, is much more reasonable and fiscally responsible. H.R. 1780 requires minimal involvement of the Federal Government. All compensation would be paid through private liability insurance not out of a federal trust fund. There would be generous, but limited, liability for health care providers and manufacturers, striking an appropriate balance between the needs of the general public in having a steady, affordable vaccine supply and the needs of the very few individuals injured by mandatory vaccines.

H.R. 1780 would establish at minimal government expense a fast, reliable, no-fault compensation system for those injured by vaccines. It would assure continued vaccine availability by establishing **6383 liability ceilings which would enable insurers to predict the potential liability associated with manufacturing and administering a vaccine. The bill would also encourage the development of safer vaccines by keeping existing companies in business, bringing old companies back in, establishing a single advisory commission on childhood vaccines and a program to provide incentives for safer vaccines.

H.R. 1780 establishes independent panels under the auspices of the Department of Health and Human Services (HHS) to hear claims of vaccine injury. The hearing panel would enter a binding award for damages, not to exceed $1,000,000 per claim. If a claimant rejected this administrative award, he would be allowed to file a civil action but the $1,000,000 ceiling would remain.

H.R. 5546, in contrast, imposes an unnecessarily bureaucratic process. The federal government would have to fund awards and manage other activities which can be handled through already established mechanisms.

We must address the growing crisis facing our childhood vaccine program, but we
must do it in an efficient, reasonable and fiscally responsible manner.

BILL DANNEMEYER.

JACK FIELDS.

HOWARD C NIELSON.

DAN SCHAEFER.


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