Union Calendar No. 575

106th Congress, 2d Session – – – – – – – – – – – House Report 106–977

THE VACCINE INJURY COMPENSATION PROGRAM: ADDRESSING NEEDS AND IMPROVING PRACTICES

SIXTH REPORT

BY THE

COMMITTEE ON GOVERNMENT REFORM

Available via the World Wide Web: http://www.gpo.gov/congress/house
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OCTOBER 12, 2000.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

U.S. GOVERNMENT PRINTING OFFICE

67–173 CC WASHINGTON : 2000

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LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
Washington, DC, October 12, 2000.

Hon. J. DENNIS HASTERT,
Speaker of the House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: By direction of the Committee on Government Reform, I submit herewith the committee's sixth report to the 106th Congress. The committee's report is based on a study conducted by its Subcommittee on Criminal Justice, Drug Policy, and Human Resources.

DAN BURTON,
Chairman.

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106TH CONGRESS, 2d Session } HOUSE OF REPRESENTATIVES { REPORT 106–977

THE VACCINE INJURY COMPENSATION PROGRAM: ADDRESSING NEEDS AND IMPROVING PRACTICES

OCTOBER 12, 2000.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BURTON, from the Committee on Government Reform submitted the following

SIXTH REPORT

On October 5, 2000, the Committee on Government Reform approved and adopted a report entitled, "The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices." The chairman was directed to transmit a copy to the Speaker of the House.

I. SUMMARY

Responding to the complaints of families reporting vaccine injury and pursuant to its authority, the Subcommittee on Criminal Justice, Drug Policy, and Human Resources (the subcommittee) initiated an oversight investigation into the implementation and operation of the National Childhood Vaccine Injury Act of 1986 (the Act) as administered jointly by the Department of Health and Human Services [HHS], the Department of Justice [DOJ] and the U.S. Court of Federal Claims (the Court).

The Act serves three purposes: (1) Provide fair, expedited compensation to those who suffer vaccine injury through the National Vaccine Injury compensation ([VICP] or the Program); (2) Enhance the operation of our system of childhood immunizations; and (3) Protect the Nation's vaccine supply by shielding manufacturers from liability.

The Act has been highly successful in some of its objectives. The vaccine supply is stable and over 1,500 petitioners and their families have been compensated. But the program has received criticism that it does not operate as efficiently or equitably as intended by Congress. Designed as a "no-fault" alternative to litigation against vaccine manufacturers, the program was envisioned by

Congress to compensate "quickly, easily and with certainty and generosity" those individuals who are injured or die as a consequence of our universal vaccination policy.

Based on testimonial and documentary record, the subcommittee finds that the program under the direction of HHS has approved changes that substantially restrict compensation coverage. Furthermore, avoidable, protracted and adversarial litigation of claims has resulted, thereby undermining the remedial nature of the program as intended by the Congress.

Accordingly, recommendations are made to:

- Review the Vaccine Injury Table (the Table) to ensure that it reflects current science and epidemiology;
- Continue developing and implementing speedy and fair informal dispute resolution options and practices; and
- Determine a reasonable alternative standard for non-Table cases.

II. Background

Vaccination is a foundation of modern public health programs and is considered one of the most effective public health initiatives ever undertaken. Since immunization programs began, the number of people contracting vaccine-preventable diseases in the United States has been reduced by more than 95 percent.[1] Morbidity and mortality attributable to smallpox, measles, mumps, rubella, polio, diphtheria, pertussis and tetanus has almost been eliminated.

Over 12 million vaccinations are given to children annually, and many millions of vaccines are given to adults.[2] States now require that virtually all children be vaccinated prior to entering school.

The benefits of vaccination are measured in terms of prevented disease in individuals and in the population to be protected against infectious disease. The risks are measured as potential side effects and injuries. Both are monitored as part of the U.S. public health system. In some instances, the differences in the ways that immune systems react to vaccines on rare occasions may result in severe side effects, including death or disabling conditions requiring lifetime medical care.

Despite these rare instances, it is the overwhelming view of the medical and public health community that the risks of vaccine reactions, both mild reactions and rare serious ones, are far outweighed by the public health benefits of current vaccination practices. Maintaining public support for immunizations is critical for preventing outbreaks of vaccine preventable diseases.

NATIONAL CHILDHOOD VACCINE INJURY ACT

Every year, a number of children are seriously injured by adverse reactions to vaccines. When such a tragedy befalls a family, they are faced with devastating emotional and financial consequences. As the devastation of adverse reactions can lead to paralysis, permanent disability and death, families without adequate insurance can face enormous expenses, including residential care, therapy, medical equipment, and drugs.

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[1] "Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily," GAO/HEHS–00–8 (December 1999), p. 1.

[2] Ibid., p. 4.

Following a nationwide initiative to raise immunization levels among children in the late 1970's, lawsuits in the 1980's stemming from adverse reactions threatened to negatively affect availability, cost and development of vaccines.

Before the VICP was established, families experiencing vaccine related reactions had to rely upon traditional tort litigation. Families were often unable to obtain the scientific and legal resources needed to substantiate vaccine-related injuries in legal proceedings. Scientific studies and medical evidence needed to definitively link vaccines with various medical conditions were often unavailable or insufficient to establish the traditional level of proof required for compensation in the civil tort system. As lawsuits increased, vaccine manufacturers also were burdened with the time and expenses of litigation, as well as the availability and affordability of liability insurance. As the number of vaccine manufacturers fell and prices rose, physicians and public health professionals warned of the potential return of epidemic infectious diseases.[3]

In response, Congress passed the National Childhood Vaccine Injury Act of 1986 (Public Law 99–660) (the Act) to establish a simple system of compensation for children suffering injuries related to routine pediatric immunizations. The Act created a National Vaccine Program and VICP, including advisory committees for each. The Act specifies remedies available to persons suffering vaccine-related injuries, establishes requirements regarding recordkeeping and reporting on vaccine administration and adverse effects, and calls for increased studies of vaccines. The new system for vaccine compensation was intended to be "fair, simple, and easy to administer."[4]

NATIONAL VACCINE INJURY COMPENSATION PROGRAM

Under the Act, the National Vaccine Injury Compensation Program ([VICP] or Program) was created to provide compensation to those who suffer vaccine-related injury or death. The Program is designed as a "no fault" alternative to civil litigation intended to be "fair, simple, and easy to administer" and "to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation to injury."[5]

Vaccines currently covered under the Program include diphtheria, tetanus, pertussis (DTP, DTaP, DT, TT or Td), measles, mumps, rubella (MMR or any components) and polio (OPV or IPV). Hepatitis B, Haemophilus influenza type b (Hib), and varicella (chickenpox) vaccines were added for coverage, effective August 6, 1997. Rotavirus was added effective October 22, 1998. Eight years of retroactive coverage from the effective date is provided for vaccine-related adverse events associated with any vaccine newly added to the Program.

Since enactment, the Program has paid out approximately $1.17 billion in awards for vaccine injuries and attorney's fees. Disbursement for injuries related to vaccines administered after October 1, 1988 are provided by the trust fund supported by an excise tax of 75 cents on every dose of vaccine sold that is covered by the Pro-

[3] "Vaccine Injury Compensation," GAO/HEHS–00–8, pp. 4 and 5.
[4] Ibid., p. 5.
[5] "Vaccine Injury Compensation Program," GAO/HEHS–00–8, p. 5.

gram. Retrospective claims are paid from general fund appropriations.[6]

ADVISORY COMMISSION ON CHILDHOOD VACCINES

The Advisory Commission on Childhood Vaccines [ACCV] is charged with monitoring the VICP and making recommendations to the Secretary of HHS on its implementation. It is composed of nine members appointed by the Secretary for 3-year terms. Three are healthcare professionals, of whom at least two must be pediatricians; three are members of the public, of whom at least two must be parents or guardians of vaccine injured children; and three are attorneys, of whom at least one is counsel to a petitioner and one represents manufacturers. The Commission meets four times a year and is required to submit recommendations on the Program to the Secretary of Health and Human Services.

One of the primary responsibilities of the Commission is advising on modifications to the Table. According to the statute, "The Secretary may not propose changes to the Vaccine Injury Table or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission and allowed the Commission at least 90 days to make such recommendations."

Controversy continues over whether, after reviewing proposed regulations but undergoing a substantial change in membership, the Commission had the opportunity to reconsider fully the final version of the March 1995 regulations to the ACCV prior to their effective date. Critics contend the Commission was unable to address the appropriateness of the amendments, in particular the definitional change of the word "encephalopathy" in the "Aids to Interpretation." Moreover, the ACCV proposed certain additions to the Table that subsequently were rejected by the Secretary. In contrast, HHS argues that the Commission reviewed the change. In 1996, HHS won a legal decision regarding this matter.[7]

NATIONAL VACCINE ADVISORY COMMITTEE

The National Vaccine Advisory Committee [NVAC] has a broad mandate for reviewing and making recommendations concerning vaccine research, production, delivery, safety and efficacy. Recommendations have included ad hoc committee reviews of risks associated with each of the vaccines listed on the injury table.

NVAC is comprised of representatives from State and local health departments, vaccine companies, academia, and consumer groups.[8]

VACCINE INFORMATION STATEMENTS

In an effort to establish adequate risk communication, the Act requires that all healthcare providers who administer vaccines must provide a Vaccine Information Statement [VIS] to the vaccine recipient, their parent or legal guardian prior to each dose. Each VIS contains a brief description of the disease as well as the risks and

[6] Ibid., pp. 3–9.
[7] *O'Connell* v. *Shalala,* 79 F.3d 170 (1st Cir. 1996).
[8] "Vaccine Injury Compensation Program," GAO/HEHS–00–8, p. 13.

benefits of the vaccine. The VIS is developed by the Centers for Disease Control and Prevention [CDC] and distributed to State and local health departments as well as individual providers.

Criticisms have been expressed that the VIS advisements may be incomplete and, in practice, there may be failures to inform recipients of appropriate circumstances for considering modification to the normal vaccination schedule or to opt out of receiving the vaccine. The subcommittee agrees that pediatricians and health care providers should fully inform patients about vaccine risks and benefits.

ASSESSMENTS OF CAUSALITY

Vaccine reactions can be classified by frequency (common, rare), extent (local, systemic), severity (hospitalization, disability, death), causality, and preventability (intrinsic to vaccine, faulty production, faulty administration).

Because of the large number of vaccine exposures, it is clear that temporal associations with adverse outcomes will occur even when there is no causal association. Many health problems in infancy will occur in children who have been vaccinated, and some of these problems will by chance occur in recently vaccinated children.

An adverse event can be causally linked to a vaccine more readily if: 1) the event conforms to a specific clinical syndrome whose association with vaccination has strong biological plausibility (such as anaphylaxis immediately following vaccination); 2) a laboratory result confirms the association (i.e. viral culture and genetic sequencing show virus is a vaccine and not a wild strain); 3) the event recurs on re-administration of the vaccine (positive rechallenge); or 4) a controlled clinical trial or carefully designed epidemiological study shows greater risk of adverse events among vaccinated than control groups.

Because few of the adverse events reported meet any of the first three criteria and clinical trials are almost always too small to provide useful information on serious rare events, epidemiological evidence is the basis for assessing vaccine-relatedness for most serious adverse events that are investigated. Still, much remains unknown about possible adverse events that may be associated with past and present vaccination practices.

CHILDHOOD VACCINE STUDIES

The Act called for the Institute of Medicine [IOM] to review existing studies and medical literature and provide a foundation for recommendations on vaccine injury causation. In reports issued in 1991 and 1994, IOM published several conclusions regarding the scarcity of knowledge about vaccine safety, citing severe limits in data and research capability. Of the 76 adverse events IOM reviewed for a causal relationship, 50 (66 percent) had no or inadequate research.

Specifically, IOM Committees identified the following limitations of existing knowledge: 1) Inadequate understanding of biologic mechanisms underlying adverse events; 2) Insufficient or inconsistent information from case reports and case series; 3) Inadequate size or length of follow-up of many population-based epidemiological studies; 4) Limitations of existing surveillance systems

to provide persuasive evidence of causation, and 5) Few published epidemiological studies.

IOM warned that "if research capacity and accomplishments [are] not improved, future reviews of vaccine safety [will be] similarly handicapped."[9] IOM recommends: "More research could be done on potential long-term adverse effects from vaccines as well as the potential of vaccines to induce or worsen immune disorders." CDC agrees that there remains "uncertainty about estimates of the risk associated with vaccination" and that to "continue research to improve the understanding of vaccine risks is critical."[10]

Despite concerns of IOM, parents, public health authorities and other stakeholders, research needed to develop additional scientific evidence that conclusively addresses many issues of causality has not been completed. Concerns have been expressed that additional research is needed to address the effects of vaccines on chronic diseases, adverse events reporting, the delivery of multiple vaccines and increased rates of childhood vaccinations.[11] While vaccines must be demonstrated to be safe and effective prior to marketing, agencies including NIH, FDA and CDC contend they are constrained by limited resources. However, in part as a response to the concerns of this subcommittee, HHS has recently contracted with IOM to undertake further vaccine safety studies.

COMPENSATION PROCEDURES

An individual claiming injury or death from a vaccine must file a claim or petition with the U.S. Court of Federal Claims (the Court). To qualify, injury claims must be filed within 36 months after initial onset of symptoms, and claims for deaths must be received within 2 years of death and 4 years after the onset of the vaccine-related injury from which the death occurred. The Secretary of HHS, as overall administrator of the Program, is named Respondent on behalf of the government and is represented by the Department of Justice [DOJ].

A physician assigned by HHS has 90 days to review the petition and make a non-binding recommendation as to compensability, based primarily on medical records. This recommendation is then provided to the Court through the DOJ attorney assigned to the case. If the court concurs with an entitlement recommendation, it may obviate the need for a hearing.

Those cases that are not conceded usually proceed to a hearing before an assigned Special Master, who acts in a capacity similar to an administrative law judge. Both the petitioner and the DOJ present testimony, including expert witnesses, and decisionmaking authority is vested in the Court's assigned Special Master.

To expedite proceedings, formal civil discovery and rules of evidence have been relaxed in favor of a more informal process, and timelines have been established. The Special Master is required to issue a judgement within 240 days (exclusive of suspended time) from the date a claim is filed, or the petitioner may withdraw from the Program.

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[9] Research Strategies for Assessing Adverse Events Associated with Vaccines (National Academy Press, 1994).

[10] 1996 IOM Vaccine Safety Forum.

[11] Vaccines—Finding the Balance Between Public Safety and Personal Choice, hearing before the House Committee on Government Reform, 106th Cong., 1st sess., serial No. 106–84 (1999).

The Special Master's decision may be appealed by either party to a judge of the Court, then to the U.S. Federal Circuit Court of Appeals, and then to the U.S. Supreme Court.[12] Following adjudication, if compensation is awarded, damages are negotiated and future needs assessed, typically in consultation with medical professionals, life care planners and other experts. For compensable injuries, awards may take the form of an initial lump sum plus an annuity providing a stream of benefits for lifetime costs of care not covered by insurance. The Program does not pay punitive damages. Successful claims are eligible to receive reasonable compensation for past and future unreimbursable medical, custodial and rehabilitation costs; a $250,000 limit for actual and projected pain, suffering and emotional distress; and lost earnings. A cap of $250,000 was legislated as payment for compensable deaths.

To ensure access, the Program also pays attorneys fees and costs for the petitioner regardless of adjudication, assuming there is a reasonable basis for the petition and it was filed in good faith. While not required, most petitioners do seek legal counsel to help navigate the program's procedures and the need for complex medical evidence.

No petition may be filed under the Program if a civil action is pending for damages related to the vaccine injury, or if damages were previously awarded to the petitioner by a court or in a civil settlement against the vaccine manufacturer or administrator. However, lawsuits may be filed against manufacturers or health care providers under State law in some circumstances, such as when a petition is dismissed or judged noncompensable, or when the vaccine is not covered under the Program, or if the petitioner is not satisfied with the amount of awarded compensation.[13]

Since the program's date of inception, October 1988, approximately 6,000 petitions have been filed, 75 percent involving injury allegations from vaccines administered prior to the law's enactment. Of those cases, more than half (3,500) have resulted in dismissal. To date: 71 percent of the claims are for DTP/DTP-Hib; 2 percent for tetanus/Td/DT; 15 percent for MMR or components, 10 percent for OPV/IPV; and the remaining 2 percent are for new vaccines, vaccines not covered under the VICP, or unspecified vaccines. Awards have ranged from $120.00 to $7.9 million, with the average approximately $800,000.[14]

STANDARDS OF PROOF

Petitioners may become eligible to receive compensation in three ways. First, the claimant must prove, by a preponderance of the evidence, that an injury listed on the Table occurred within the prescribed time.

Second, if the injury is not listed on the Table or did not occur within the prescribed timeframe, pursuant to present adjudication practices, a petitioner is held to traditional and more difficult tort standards, and must prove traditional causation or "causation-in-fact." Congress' guidance on "causation-in-fact" cases is as follows, "Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of sci-

[12] "Commonly Asked Questions About the NVICP," HRSA.
[13] "Vaccine Injury Compensation Program," GAO/HEHS–00–8, p. 5.
[14] "Commonly Asked Questions About NVICP," p. 4.

entific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner."[15] Only a small percentage of claims found not to be covered on the Table receives compensation (only 13 percent).[16]

Finally, the petitioner may receive compensation if he or she demonstrates that the vaccine significantly aggravated a pre-existing condition. Children who do not receive compensation from the fund may be required to rely on other Federal health services that provide limited medical coverage and home health assistance.

VACCINE INJURY TABLE

A unique mechanism is used in the Program to provide petitioners with a rebuttable presumption of causation. This mechanism is the Table of Compensable Events, known as the Vaccine Injury Table (the Table) and its complementary Qualifications and Aids to Interpretation, which provides definitions for injuries and the specific circumstances under which the Table injuries must occur. Originally enacted in 1988 by Congress and subsequently revised by HHS with the advice of experts, the Table identifies serious adverse events that certain experts considered to be caused by vaccines.[17]

The Table serves to eliminate some of the uncertainty caused by gaps in medical knowledge by listing vaccines covered by the program and the injuries, disabilities, illnesses, and conditions (including death) for which compensation may be paid. It also defines the period of time during which the first symptom or substantial aggravation of the injury must appear.

Provided that no "factor unrelated" can be established by the government as the cause of injury, adverse events that occur within the Table are presumed to be related to and caused by the vaccine.

By creating a framework to allow for a presumption of cause and effect to exist for the claimant, the Table is intended to remove much of the burden of proof required in traditional tort proceedings. By contrast, under traditional civil litigation practices, the injured party bears the burden of proving that the vaccine caused injury. This presumptive feature is crucial to the integrity of a no-fault, expedited vaccine injury compensation system, and this approach to vaccine relatedness was intended as a guiding principle for the Vaccine Compensation Program.

Alternative presumptions of cause and effect procedure already exist in other Federal health and benefit programs. For example, the Veterans Health Care Eligibility Reform Act of 1996 (Public Law 104–262) (Veterans Health Care Act) requires the Department of Veterans Affairs [VA] to furnish hospital care and medical services, and may furnish nursing home care to veterans exposed to herbicides in Vietnam. For an Agent-Orange-based claim by a Vietnam veteran for service-connected benefits, the Veterans Health Care Act requires:

- A medical diagnosis of a disease which VA recognizes as being associated with Agent Orange [specified diseases];

[15] House of Representatives Rept. No. 99–908 (1986), p. 5.
[16] "Vaccine Injury Compensation," GAO/HEHS–00–8, p. 12.
[17] "An Overview of Vaccine Safety," CDC.

• Competent evidence of service in Vietnam or offshore in the adjacent waters between 1962 and 1975; and

• Competent medical evidence that the disease began within the deadline (if any).[18]

VACCINE ADVERSE EVENT REPORTING SYSTEM

The Act mandates that all health care providers report certain adverse events following vaccination to the Vaccine Adverse Event Reporting System [VAERS]. VAERS was established by the Food and Drug Administration [FDA] and CDC in 1990 to provide a unified mechanism for the collection and analysis of adverse events associated with vaccines currently licensed in the United States. Reportable vaccine adverse events are defined as health effects that occur after immunization that may or may not be related to the vaccine.[19] 16

VAERS is a passive surveillance system, a repository for voluntarily submitted reports. An active surveillance system, by contrast, would follow all individuals in a defined population to determine their responses to vaccinations. The VAERS reporting form is designed to allow a narrative description of adverse events.

To encourage reporting of any possibly vaccine-induced adverse event, the criteria for reporting to VAERS is nonrestrictive; the system accepts and includes any report submitted, no matter how tenuous the possible connection with vaccination might seem. All persons, including patients, parents and health professionals can report to VAERS with no restrictions on onset intervals or requirements for medical care.

The Act does require that physicians report—directly to VAERS or to the manufacturer—certain categories of serious outcomes defined for regulatory purposes as an event resulting in death, life-threatening illness, hospitalization, prolongation of existing hospitalization, or permanent disability.

VAERS is intended to serve as the "front line" of vaccine safety, since this type of national reporting system can rapidly document possible effects and generate early warning signals that can then be more rigorously investigated in focused studies. VAERS is considered especially valuable in assessing the safety of newly marketed vaccines.

VACCINE SAFETY DATALINK PROJECT

The gaps that exist in the scientific knowledge of rare vaccine side effects prompted the CDC to develop the Vaccine Safety Datalink [VSD] project in 1990. This project involved forming partnerships with four large health maintenance organizations [HMOs] to continually monitor vaccine safety. VSD is an example of a large-linked database [LLDB] and includes information on more than 6 million people.

All vaccines administered within the study population are recorded. Available data includes vaccine type, date, manufacturer, lot number concurrent vaccinations (those given during the same visit) and injection site. Medical records are then monitored for potential adverse events.

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[18] Agent Orange Review, Department of Veterans Affairs, Vol. 16, No. 1 (May 2000).

[19] "An Overview of Vaccine Safety," CDC, p. 4.

The VSD project allows for planned vaccine safety studies as well as timely investigations of hypotheses. At present, the VSD project is examining potential associations between vaccines and 34 serious conditions. The database is also being used to test new vaccine safety hypotheses and issues from the medical literature, VAERS, changes in the immunization schedule or from the introduction of new vaccines.

III. Vaccine Injury Compensation Program Issues

VACCINE INJURY TABLE CHANGES

The Childhood Vaccine Injury Act of 1986 (the Act) established the first Vaccine Injury Table (the Table) as an interim compromise until more scientific information became available, and granted the Secretary rulemaking authority to amend the Table at such time, bringing it more in line with current science. It also called for IOM to assist the Secretary in making changes by conducting a review of medical studies.

HHS exercised its rulemaking authority to amend the Table and the Aids to Interpretation in 1995 and again in 1997, following the publication of IOM studies in 1991 and 1994, respectively. In the reports, IOM identified certain conditions that were 1) consistent or inconsistent with a causal relationship; 2) those that favored or did not favor a causal relationship; and 3) those where evidence was insufficient to indicate the presence or absence of a causal relationship. Most conditions fell in the third category, as IOM concluded there was insufficient medical evidence to prove or disprove a relationship between vaccines and two-thirds of the 75 medical conditions studied.

In conjunction with public policy considerations provided by the ACCV, scientific issues raised by the NVAC, and input from the public, the Secretary added seven injuries and removed three others from the Table while altering definitions in the Aids to Interpretation. These revisions made it easier for some petitioners to obtain compensation, but more difficult for a larger number of petitioners.

Far more claims were associated with the injuries removed from the Table than were associated with the injuries that were added. Prior to the Table revisions, three quarters of the claims alleged injuries on the Table, after the revisions were implemented, more than half of the claims filed were Table injuries. Of note, almost half of past claims awarded compensation were for injuries subsequently removed from the Table.[20]

Under current practices, modifications of the Table largely determine the types of claims for which compensation will be awarded. Historically, injury claims not covered under the Table tend to be approved for compensation far less often than Table injuries, and the compensation amounts are considerably lower.[21] Thus, in administering and refining the Table, HHS defines the parameters of compensation coverage, and is able to limit liability through administrative changes. The justifications for some changes have been

[20] "Vaccine Injury Compensation Program," GAO/HEHS–00–8, p. 13.
[21] "Vaccine Injury Trust Fund," GAO, p. 19.

criticized by some patients, members of the petitioner's bar, and others.

Recently, GAO concluded, "Where science is insufficient to determine causal relationships between a vaccine and injuries, it is not clear that HHS' criteria and approach to making injury table changes are consistent." [22]

Discussing amendments to the Table, HHS cites the following four factors: IOM findings (and subsequent medical studies); biologic plausibility; recommendations from the Advisory Council on Childhood Vaccines [ACCV] and the National Vaccine Advisory Committee [NVAC]; and prevalence of the condition in the population attributable to vaccines. However, GAO findings conclude that: "In communicating its decisions to the public, HHS does not uniformly discuss each of these factors, and the reasons why the relative importance of each factor varies among the decisions is not apparent in all cases." [23] GAO noted:

> The Institute of Medicine (IOM) found that existing scientific evidence favored acceptance of a causal relationship between tetanus vaccines and brachial neuritis, and HHS added that condition to the injury table. On the other hand, the Institute also found evidence of a causal relationship between the tetanus and oral polio vaccines and Guillain-Barre syndrome, but HHS did not add this condition to the injury table.
>
> The IOM found the evidence inadequate to accept or reject a causal relation between vaccines and residual seizure disorder, and HHS removed this condition from the injury table. The Institute also found evidence inadequate to accept or reject a causal relation between the measles and mumps vaccines and encephalopathy, yet HHS left this condition on the injury table.
>
> HHS stated in the Federal Register that decisions not to add injuries, such as Guillain-Barre syndrome, or to remove injuries, such as residual seizure disorder, were based to some extent on the level of risk in compensating an inordinate number of non-vaccine-related cases for the extremely rare vaccine-related case. In applying this criterion, however, HHS' assumptions about the number of potential claims and thresholds for deciding the reasonable level of financial risk for compensating non-vaccine-related injuries were not defined.[24]

Accordingly, criticisms have been expressed that certain procedural actions taken by HHS in revising the Table were inconsistent with the intent of Congress. Some changes have been made to the Table restricting compensation coverage for reasons of both science and policy. It is the view of many in the medical community that the Table, with its near-determinative effect in practice upon compensation, reflects some of the best available scientific and epidemiological research. Finally, current adjudication practices generally assume that the Table reflects existing science and place unduly restrictive causation burdens on petitioners who seek to make

[22] "Vaccine Injury Compensation," GAO/HEHS–00–8, p. 19.
[23] Ibid., p. 22.
[24] "Vaccine Injury Compensation," GAO/HEHS–00–8, p. 15.

claims not covered by the Table. Congress intended that a petitioner be given a reasonable opportunity to present evidence of vaccine injury relatedness even when the injury does not fall within the Table.

COMPENSATION DETERMINATION AND AWARD DELAYS

The compensation process continues to take much longer than Congress intended. The original legislation required a judgement within 1 year and was subsequently amended to require a decision by the Court's Special Master within 240 days. GAO found that 30–40 percent of claims filed each year was processed within 2 years.[25] However, of the more than 5,000 claims filed from October 1, 1988 through February 1999, only about 14 percent received judgment within 1 year, most did not receive judgment within 2 years, and almost a third received judgment in 5 or more years.[26]

Significant delays in adjudication reportedly resulted from the volume of claims received for injuries that occurred prior to October 1, 1988. As the January 31, 1991 deadline to file these retrospective claims drew near, the number of petitions jumped from 125 in 1989 to 3,263 in 1990, creating an immediate and substantial backlog that continues to impact HHS.[27]

Although the number of claims filed since the 1991 deadline has dramatically decreased, the number of claims adjudicated also has declined. The continued procedural delays, which include suspensions at the request of petitioners, reportedly are attributed in some instances to the government's desire to execute a vigorous defense.

According to DOJ, the most common cause of delay is petitioner's inability to provide required medical records that permit a proper review of their claims. HHS data show that more than half of all petitioners were requested to provide supplementary medical records or other information, and most took at least a year to do so. After all the information was received, in most cases, it took the court over another year to reach its decision.[28]

Petitions claiming injuries "off Table," or not listed on the Table, account for some delays. According to the Chief Special Master, whether cases proceed under the Table or as causation-in-fact cases correlates directly to the amount of time, the number of issues presented, and the cost of processing cases. He explains that, prior to the enactment of the Table changes, the vast majority of cases (well over 90 percent) proceeded pursuant to the Table and were resolved quickly. "Causation" cases take longer as more specialized experts are required, more legal and medical issues are presented, hearings are longer, concessions are fewer, and decisions are far more difficult, lengthy and time intensive. The duration of case proceedings and adjudications could increase if the number of non-Table injury cases increases.

ADVERSARIAL PROCESS

As the DOJ has pursued aggressive defenses in compensation cases, entitlement and compensation determinations have been per-

[25] Ibid., p. 9.
[26] Ibid., p. 7.
[27] Ibid., p. 9.
[28] Ibid., p. 10.

ceived by some petitioners as being inappropriately adversarial in nature. According to a GAO report, the availability of more funds has enabled DOJ to "establish a cadre of attorneys specializing in vaccine injury." According to DOJ, there are 16 trial attorneys in the vaccine compensation program. HHS "established an expert witness program" to challenge claims.[29] It is also important to note that Program procedural changes may need approval from the Court.

During our September 28, 1999 hearing, the Subcommittee on Criminal Justice, Drug Policy, and Human Resources (the subcommittee) received testimony from petitioners, their experts and attorneys charging that the governments' defense has, in the words of one witness, "become increasingly stubborn and aggressive, to the point that in its spirit, it is now indistinguishable from the adversarial manner in which some civil lawsuits are conducted."

DOJ asserts that many attorneys in the petitioners' bar speak highly of the compensation process and the cooperative efforts of government counsel. Contrary to DOJ's views, critics cite a number of questionable practices by DOJ, even with the sanction of the Court, appeals resulting in multiple entitlement hearings, aggressive use by government of expert witnesses and investigators, and highly adversarial conduct aimed at impeaching petitioner experts. Other criticisms are noted below:

- DOJ attorneys make full use of the apparently limitless resources available to them. They substitute one expert for another if the opinion rendered by the first is unfavorable or seems not to impress the court, essentially replacing one theory for another, or recruit multiple experts for a single case. Multiple entitlement hearings result. According to DOJ, the Government has only appealed one case to the Federal Circuit Court of Appeals since 1995, and also contends that petitioner's experts are numerous.
- If a Court decision is unfavorable, DOJ may repeat arguments during the Damages Hearing that fail during the entitlement phase, thus making the process of awarding due compensation unnecessarily contentious and burdensome.[30]
- *Marks* v. *Sec. HHS* has been criticized. "In the special master's view, [respondent's] counsel's abrasive, tenacious, obstreperous litigation tactics were inappropriate in a program that is intended to be less adversarial; and hindered greatly a fair, expeditious resolution of the case. In addition, counsel lacks simply tact and compassion. Quite frankly; the special master is embarrassed that respondent's counsel and respondent's life care planner represented the United States Government in this case."[31] DOJ claims this case was highly exceptional, and the attorney's conduct was reviewed.

Finally, DOJ indicated to the subcommittee that no DOJ attorneys handling vaccine injury cases had received formal training in Alternative Dispute Resolution [ADR] techniques and practices prior to the subcommittee hearing on this topic. Since the hearing, DOJ reports that all attorneys assigned to vaccine compensation cases have been trained in ADR and that efforts are underway to

[29] "Vaccine Injury Trust Fund," GAO/HEHS–0067, p. 10.
[30] Hearing statement by Dr. Marcel Kinsbourne.
[31] Decision of Special Master Edwards, *Marks* v. *Sec HHS,* p. 15.

utilize ADR more fully. DOJ also has suggested the addition of a Court rule requiring consideration of voluntary ADR in all cases.

SOVEREIGN IMMUNITY

The doctrine of sovereign immunity generally prevents the Federal Government from being sued without its consent. In interpreting legislation, courts may consider whether there has been a waiver of immunity with respect to a particular type of litigation against the United States.

One canon of statutory construction is that a waiver of sovereign immunity must be definitively and unequivocally expressed. A second one is that the statutory language setting forth a waiver is to be construed strictly in favor of the government. Yet another principle of statutory construction regarding remedial or "welfare" legislation is that courts give a liberal interpretation to further the remedial or humanitarian purposes underlying the statute.

Because the Act authorizes suits and monetary awards against the United States, the doctrine of sovereign immunity has been interpreted and applied by Special Masters. With respect to the Act, which is "remedial" in nature and waives the Federal Government's immunity from suit, the sovereign immunity doctrine has been used to "trump" competing remedial constructions and provide a rationale for restricting compensation awards.[32]

Petitioners' representatives argue that the remedial intent of the Act to provide generous compensation should prevail. Some argue that the waiver of sovereign immunity is not applicable technically since the Secretary simply administers a trust funded through a vaccine tax. Some critics of current practices have called for an express provision to nullify the application of the doctrine of sovereign immunity. The committee is concerned that the doctrine should be applied in an appropriate manner, consistent with the remedial purposes of the Act.

COMPENSATION TRUST FUND

Historically, the vaccine injury compensation trust fund (the Trust fund) has received more in vaccine excise taxes than it has paid out for claims and related administrative costs. Because the fund has spent only about $347 million of the $1.37 billion accrued through fiscal year 1999; the remaining approximately $1 billion was loaned to the Treasury and used for other Federal programs and activities in exchange for Treasury securities. Interest on these securities now totals approximately $435 million. The interest in addition to the $1 billion loaned to the Treasury make up the $1.46 billion balance accrued by the end of fiscal year 1999, representing a very substantial unused reserve.

Unless changes in the administration of the Program are implemented or new scientific research findings become available, this trend of revenue exceeding expenditures could continue, while compensation awards are increasingly difficult. At current rates, the Congressional Budget Office projects that in the next 10 years, the fund will double in size.

The limited number of compensation awards and growing fund balance have become controversial, with various options being con-

[32] Decision of Special Master Hastings in *Childers* v. *HHS,* pp. 3–11.

sidered to address the unused funds. Vaccine manufacturers view the growing balance as an indicator that the excise tax rate is too high and should be lowered. Petitioner families cite the fund as evidence of the government's unwillingness to compensate vaccine injuries and advocate a less restrictive injury table and less burdensome compensation practices. While the administration has not articulated a clear position on this issue, officials from HHS have considered the fund as a potential source of revenue for vaccine-related research or surveillance.[33]

In the 106th Congress, Representative Ron Lewis (R–KY) introduced H.R. 1337, the "Vaccinate America's Children Now Act," a bill to amend the Internal Revenue Code of 1986 to reduce the tax on vaccines to 25 cents per dose. The bill has 66 cosponsors, 40 Republicans and 26 Democrats, of which 27 are members of the Ways and Means Committee. Senator Bunning (KY) introduced the companion bill, S. 85.

While the trust fund contains a significant sum of money, efforts to reduce funding sources raise serious concerns. The worldwide vaccine market is estimated soon to top $7 billion.[34] In the United States alone, there are currently vaccines in development against almost 60 diseases caused by bacteria, viruses, fungi and parasites, including AIDS, malaria and tuberculosis. Coverage for new vaccines could negatively affect the future trust fund balance.[35]

Similarly, changes in the recommended schedule of vaccinations, the increasing use of combination vaccines, and the potential for emerging knowledge linking vaccines to adverse reactions makes risk assessment increasingly difficult. HHS has warned that the fund should not be considered an impenetrable reserve of funds.

Options to control the growth of the trust fund could have revenue and spending implications for the overall Federal budget. The Budget Enforcement Act of 1990 mandates that Congress offset the cost of legislation that reduces revenue or increases spending by establishing new or higher taxes elsewhere or by decreasing spending for other programs.[36]

VACCINE ADVERSE EVENTS REPORTING SYSTEM

Typically, vaccine safety studies that are epidemiological based make inferences from the absence of specific problems. Therefore, it is important to examine and consider surveillance and risk management systems and practices.

While the Vaccine Adverse Events Reporting System [VAERS] may be lauded as the "front line" of vaccine safety, the lack of enforcement provisions and effective monitoring of reporting practices preclude accurate assessments of the extent to which adverse events are actually reported. Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events.

The quality of VAERS data has been questioned. Because reports are submitted from a variety of sources, some inexperienced in completing data forms for medical studies, many reports omit im-

[33] "Vaccine Injury Trust Fund," GAO/HEHS–0067, p. 18.
[34] "When Vaccines Do Harm to Kids: Autism and More," Insight Magazine, Feb. 4, 2000, p. 3.
[35] "Commonly Asked Questions About the NVICP," HRSA, p. 2.
[36] "Vaccine Injury Compensation Fund," GAO report, p. 19.

portant data and contain obvious errors. Assessment is further complicated by the administration of multiple vaccines at the same time, following currently recommended vaccine schedules, because there may be no conclusive way to determine which vaccine or combination of vaccines caused the specific adverse event.

As a database for epidemiological studies, VAERS has serious weaknesses. One major problem is that since unvaccinated people experiencing adverse events are not reported to VAERS, there is no control group to study. Given that over 10,000 reports are filed annually, it is difficult to assure the accuracy and completeness of the database. IOM recognizes that there are limits to the detection and response systems currently in use. In a forum convened on this subject, they concluded: "[E]fforts can be made to improve the quantity, quality, accessibility, and usefulness of VAERS reports."[37]

CONFLICTING ROLES AND RESPONSIBILITIES

Within Congress, there is bipartisan concern over dual responsibilities and potential conflicting interests in HHS drug development and delivery. Regarding vaccines, HHS conducts and encourages vaccine research on the one hand and is the lead agency within the Federal Government for the promotion of vaccination programs. HHS also administers the Vaccine Injury Compensation Program ([VICP] or the Program). Critics charge these responsibilities may conflict.

Under HHS, the CDC Advisory Committee on Immunization Practices [ACIP] makes recommendations for the routine administration of vaccines along with schedules regarding appropriate periodicity, dosage, and contraindications. The ACIP recommends vaccine purchases by CDC. The Food and Drug Administration's Vaccine and Related Biological Products Advisory Committee [VRBPAC] is responsible for supporting applications for licensure of vaccines.

Because of the importance of preserving the public health through the use of safe and effective vaccines, maintaining the highest level of integrity over the entire spectrum of vaccine development and implementation is critical, and opportunities for conflicting roles and interests should be avoided whenever possible.

IV. LEGISLATIVE PROPOSALS

PROPOSALS ENDORSED BY HHS AND DOJ

The Advisory Commission on Childhood Vaccines [ACCV] has recommended that the HHS Secretary propose changes to the Public Health Service Act and the Internal Revenue Code that would improve the VICP. One of these proposals, the elimination of the requirement that claimants must have incurred non-reimbursable expenses in excess of $1,000 to file a petition for compensation, was signed into law on October 22, 1998. The remainder of the recommendations have been incorporated into a bill and sent to the Congress for its consideration. These include:

[37] "Detecting and Responding to Adverse Events Following Vaccination: Workshop Summary," by Cynthia J. Howe, Richard B. Johnston, and Gerald M. Fenichel, editors, November 1995.

- Extend the current statute of limitations from 3 years for injury claims and 2 years for death claims, to 6 years for those claiming injury or death resulting from a covered vaccine.
- Allow for the inclusion of family counseling expenses in VICP awards.
- Add a phrase to specifically allow for the inclusion of reasonable fees and costs associated with the establishment of a guardianship or conservatorship in the definition of "other costs."
- Allow for an interim payment of costs incurred in adjudicating a post-1988 claim under the VICP after a finding as to entitlement is established. Such an interim payment would be made prior to entry of a final judgment and upon a finding that there was good faith and a reasonable basis for the claim.
- Establish a specific method of calculating lost earnings under VICP.
- Eliminate requirement that ACCV meet at least four times annually.
- Change the rulemaking process for amending the Table by reducing the period for public comment from 180 days to 60 days, and eliminating the requirement for a public hearing.
- Clarify the Scope of the term "Factors Unrelated" as it applies to determining eligibility and compensation.
- Expand criteria for one of the two reserved general public seats on the ACCV under Section 2119(a)(1)(B) of the Public Health Service Act to include individuals who have suffered a vaccine-related injury either as children or as adults.
- Allow the U.S. Court of Federal Claims the discretion to provide for a check for attorneys' fees and costs awarded under section 2115(e) to be made payable solely to the attorney for the petitioner.
- Increase to $10,000,000 the limitation on the amount that may be expended for payment of administrative expenses related to the operation of the VICP from the Vaccine Injury Compensation Trust Fund.

The following amendment, which the ACCV did not have the opportunity to review, was added to the Department's proposed bill by the Department of Treasury:

- Allow use of the Vaccine Injury Compensation Trust Fund to pay expenses incurred by the Bureau of the Public Debt in providing financial services to the Trust Fund.

ADDITIONAL PROPOSALS

Among recently recommended legislative reforms brought to the attention of the subcommittee are the following:

Senator Daschle (D–SD) introduced a bill, S. 992, "to provide technical amendments to the Vaccine Injury Compensation Trust Fund." The bill repealed certain mutually conflicting amendments within Public Law 105–277, "Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999." The change eliminates confusion regarding compensability of petitions based on certain administrations of any of the three vaccines added to coverage under the program in 1997. In addition, the bill removes the requirement that at least $1,000 in non-reimbursable expenses be incurred prior to acceptance of the petition for consideration.

Representative Ron Lewis (R–KY) introduced H.R. 1337, "a bill to amend the Internal Revenue Code of 1986 to reduce the tax on vaccines to 25 cents per dose." This is identical to the bill introduced as H.R. 1337, entitled the "Vaccinate America's Children Now Act." This bill has 66 cosponsors, 40 Republicans and 26 Democrats, of which 27 are members of the Ways and Means Committee. Strong support for this proposal also was seen in the 105th Congress within the Ways and Means Committee and the Senate Finance Committee. Senator Bunning (R–KY), introduced a companion bill in the Senate, S. 85, with six cosponsors and more expected.

Representative Marcy Kaptur (D–OH) introduced H.R. 1003, "a bill to amend the Public Health Service Act to revise the filing deadline for certain claims under the National Vaccine Injury Compensation Program." The language in the bill is the same as in the bill she introduced in the 105th Congress as H.R. 3778. Her proposal is to amend the criteria defining the starting point for the time period in which a petition for compensation may be filed. Currently, the timeframe is 36 months beginning with "the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." This bill retains the 36-month time period, but allows the period to commence on the date a diagnosis of vaccine injury is made. Eight other Democrats were added as cosponsors.

Representative Nancy Pelosi (D–CA) introduced H.R. 1274, a bill to "amend the Internal Revenue Code of 1986 to provide a credit for medical research related to developing vaccines against widespread diseases." The "Lifesaving Vaccine Technology Act of 1999" would provide a tax credit equal to 30 percent of the qualified vaccine research expenses for the taxable year. The vaccine research covered would include development of vaccines and microbicides for malaria, tuberculosis, HIV, or any infectious disease (of a single etiology) which, according to the World Health Organization, causes over 1 million human deaths annually. This bill had eight cosponsors, all Democrats, including five members of the Ways and Means Committee.

On May 26, Senator Roth (R–DE) introduced S. 1134, the "Affordable Education Act of 1999." This original measure was reported out of the Finance Committee and placed on the Senate Legislative Calendar under General Orders. Section 410, "Inclusion of Certain Vaccines Against Streptococcus Pneumoniae to List of Taxable Vaccines," would amend Section 4132(a)(1) of the Internal Revenue Code by adding a new subparagraph as follows: "(L) Any conjugate vaccine against streptococcus pneumoniae." The standard excise tax would be collected on all sales of such vaccines on the day after the date on which the Centers for Disease Control and Prevention officially recommends routine administration of this vaccine to children. The vaccine has yet to be licensed by the Food and Drug Administration.

V. Congressional Hearings

Subcommittee Hearings

On May 18, 1999, the Subcommittee on Criminal Justice, Drug Policy, and Human Resources held the first of its two hearings on

vaccines entitled, "Hepatitis B Vaccine: Helping or Hurting Public Health?" The hearing examined the safety of the hepatitis vaccine, the adequacy of disclosure prior to vaccine administration and the efficacy of the FDA's Vaccine Adverse Event Reporting System. The subcommittee heard testimony from Congressman John Joseph Moakley (D–MA) who has experienced hepatitis B, and from other individuals and families claiming vaccine injuries. Witnesses included: Michael Belkin; Judy Converse; Marilyn and Lindsay Kirschner; Barbara Haun; Karen w/ PKIDS; and Betty Fluck. Medical experts included: Dr. Sam Katz, Infectious Disease Society; Dr. Burton Waisbren, Sr., F.A.C.P.; and Dr. Bonnie Dunbar, molecular biologist, Baylor College of Medicine. Advocates of vaccine reform included: Thelma Thiel, chairman and CEO of the Hepatitis Foundation International; and Barbara Loe Fisher, president, National Vaccine Information Center. Representing the government were: Harold Margolis, Chief, Hepatitis Branch, CDC; and Susan Ellenberg, Director of Bio-Statistics and Epidemiology Division, Food and Drug Administration.

On September 28, 1999, the subcommittee convened a hearing entitled, "Compensating Vaccine Injuries: Are Reforms Needed?" The hearing examined the Program's operations including: adversarial procedures, evidentiary and adjudicative standards, and funding. Testimony was received from: petitioners (Michele Clements and Linda Mulhauser); reform advocates (John Salamone, president, Informed Parents Against VAPP, and Cliff Shoemaker, attorney, Shoemaker & Horn); medical experts (Dr. Marcel Kinsbourne, Tufts University, and Dr. Arnold Gale, Stanford University); and government witnesses (Thomas E. Balbier, Jr., Director, National Vaccine Injury Compensation Program, Department of Health and Human Services, and John L. Euler, Deputy Director Torts Branch, Civil Division, Department of Justice).

THE HOUSE COMMITTEE ON GOVERNMENT REFORM HEARINGS

The Committee on Government Reform conducted the following hearings relative to vaccines, which are not discussed in this report:

"Vaccines—Finding the Balance Between Public Safety and Personal Choice," August 3, 1999;

"Defense Vaccines: Force Protection or False Security?" October 12, 1999;

"Autism—Present Challenges, Future Needs—Why the Increased Rates?" April 6, 2000;

"FACA: Conflicts of Interest and Vaccine Development—Preserving the Integrity of the Process?" June 15, 2000; and,

"Mercury in Medicine—Are We Taking Unnecessary Risks?" July 18, 2000.

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