National Vaccine Injury Compensation Program
Strategic Plan

April 2006

Prepared by the
Division of Vaccine Injury Compensation

Acknowledgements

The Division of Vaccine Injury Compensation (DVIC), Healthcare Systems Bureau, Health Resources and Services Administration thanks the National Vaccine Injury Compensation Program Strategic Planning Workgroup (the Workgroup) for its valuable time, commitment, and diligent efforts in gathering data for and developing this Strategic Plan. The list of Workgroup members is included in Appendix C. DVIC would also like to thank all of the stakeholders who were able to participate in the Retreat (Appendix D), and who contributed to the development of the Strategic Plan (Appendix E). In addition, DVIC would to thank the attorneys at the Department of Justice, Civil Division, Torts Branch, Vaccine Litigation and the Department of Health and Human Services, Office of the General Counsel, Public Health Division for their review of this plan. This plan was made possible by the dedication of the Workgroup and stakeholders.

The National Vaccine Injury Compensation Program (VICP) Strategic Plan

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Acronyms/Abbreviations

Act	National Childhood Vaccine Injury Act of 1986, as amended
ACCV	Advisory Commission on Childhood Vaccines
CDC	Centers for Disease Control and Prevention
Court	U.S. Court of Federal Claims
DVIC	Division of Vaccine Injury Compensation
DOJ	Department of Justice
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IOM	Institute of Medicine
NIH	National Institutes of Health
NPI	National Partnership for Immunization
NVPO	National Vaccine Program Office
Retreat	VICP Strategic Planning Retreat
Secretary	Secretary of Health and Human Services
Table	Vaccine Injury Table
Trust Fund	Vaccine Injury Compensation Trust Fund
VICP	National Vaccine Injury Compensation Program
Workgroup	VICP Strategic Planning Workgroup

Executive Summary

In the early 1980s, reports of harmful side effects following the DTP (diphtheria, tetanus, pertussis) vaccine posed major liability concerns for vaccine companies and health care providers, and caused many to question the safety of the DTP vaccine. Many parents began filing lawsuits against vaccine companies and health care providers. The dilemma facing the Nation was so great that Congress created the National Vaccine Injury Compensation Program (VICP). The VICP, which went into effect on October 1, 1988, is a "no-fault" alternative to the traditional tort system for resolving certain vaccine injury claims.

Within the Executive Branch of the Federal Government, the VICP is administered by the Department of Health and Human Services (HHS), and the Department of Justice (DOJ). The HHS component of the VICP is located organizationally in the Health Resources and Services Administration (HRSA), Healthcare Systems Bureau (HSB), Division of Vaccine Injury Compensation (DVIC). The DOJ, Civil Division, Torts Branch, Vaccine Litigation represents the Secretary of HHS in proceedings before the U.S. Court of Federal Claims (Court). The Court decides which claims will be compensated.

The ***mission*** of the VICP is to process claims expeditiously and fairly utilizing current vaccine safety research to determine injuries thought to be caused by vaccines, and raise awareness about the existence of the VICP. Since its inception, the VICP has been a key component in stabilizing the U.S. vaccine market by providing liability protection to both vaccine companies and health care providers. Not only does it provide a more streamlined and less adversarial alternative to the traditional tort system for resolving claims, the VICP encourages research and development of new and safer vaccines.

Following are the critical issues facing the VICP over the next five years (2005-2010):

- dramatic shift in claims from nearly all alleging a Vaccine Injury Table (Table) condition to the majority now alleging a non-Table (or off-Table) condition, which creates a more difficult burden for petitioners and raises questions as to how the current causation standard is applied to VICP claims;
- the claims process is difficult for stakeholders to understand; and
- many parents, the general public, attorneys, and health care professionals are not aware of the existence of the VICP.

To address these critical issues, the VICP developed a 5-year Strategic Plan. Over the next 5 years, the VICP will implement the following strategic goals to work toward achieving its vision. The ***vision*** of the VICP is to fairly compensate individuals injured by covered vaccines quickly, easily and with certainty, and create an environment that fosters the production and use of existing vaccines and the development of new, safe and effective vaccines.

Strategic Theme 1

- Examine alternative approaches for adjudication of off-Table claims.

Strategic Theme 2

- Assure that the VICP is responsive to evolving science, medicine and policy actions.

Strategic Theme 3

- Assess and streamline the claims process to make it quicker, more user-friendly, and fair to all parties.

Strategic Theme 4

- Increase knowledge about the VICP among all stakeholders.

The VICP will develop a plan to implement its strategic goals and objectives. This Strategic Plan will be updated periodically.

Introduction

In the early 1980s, reports of harmful side effects following the DTP (diphtheria, tetanus, pertussis) vaccine posed major liability concerns for vaccine companies and health care providers, and caused many to question the safety of the DTP vaccine. Many parents began filing lawsuits against vaccine companies and health care providers. This, in turn, caused many of the companies that developed and produced vaccines to leave the marketplace, creating significant vaccine shortages and a real threat to the Nation's health.

The dilemma facing the nation was so great that Congress acted. A coalition of parents, physician groups, and policy makers participated in the development of a solution. The National Vaccine Injury Compensation Program (VICP), which went into effect on October 1, 1988, is a "no-fault" alternative to the traditional tort system for resolving certain vaccine injury claims.

Within the Executive Branch of the Federal Government, the VICP is administered by the Department of Health and Human Services (HHS), and the Department of Justice (DOJ). The HHS component of the VICP is located organizationally in the Health Resources and Services Administration (HRSA), Healthcare Systems Bureau (HSB), Division of Vaccine Injury Compensation (DVIC). The DOJ, Civil Division, Torts Branch, Vaccine Litigation represents the Secretary of HHS in proceedings before the U.S. Court of Federal Claims (Court) and reviews petitions to determine whether they meet the legal requirements for compensation. The Court also has a role in administering the VICP. The Court has two primary functions: 1) claims management, which involves overseeing the collection of information and setting time frames for its submission; and 2) decision making, which involves determining the types of proceedings necessary for presenting the relevant evidence, and ultimately, weighing the evidence in rendering a final determination on whether petitioners are entitled to an award, and if so, how much will be paid in individual claims.

Since its inception, the VICP has been a key component in stabilizing the U.S. vaccine market by providing liability protection to both vaccine companies and health care providers. Not only does it provide a more streamlined and less adversarial alternative to the traditional tort system for resolving claims, the VICP encourages research and development of new and safer vaccines. The VICP covers all vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. The vaccines currently covered include: **diphtheria, tetanus, pertussis** (DTP, DTaP, Tdap, DT, TT or Td), **measles, mumps, rubella** (MMR or any components), **polio** (OPV or IPV), **hepatitis B, *Haemophilus influenza* type b** (Hib)**, varicella**, **rotavirus, pneumococcal conjugate, hepatitis A** and **influenza (trivalent).**

VICP Mission Statement

To process National Vaccine Injury Compensation Program (VICP) claims expeditiously and fairly utilizing current vaccine safety research to determine injuries thought to be caused by vaccines, and raise awareness about the existence of the VICP.

VICP Vision Statement

To fairly compensate individuals injured by covered vaccines quickly, easily and with certainty, and create an environment that fosters the production and use of existing vaccines, and the development of new, safe and effective vaccines.

VICP Values

Accountability
We strive to ensure the financial integrity of the Vaccine Injury Compensation Trust Fund.

Collaboration
We strive to work harmoniously with our immunization partners.

Communication
We strive to promote the availability of the VICP.

Compassion
We strive to compensate individuals with sensitivity and in consideration of the situation of each petitioner.

Fairness
We strive to adjudicate claims fairly and efficiently.

Improvement
We strive to work with all of our stakeholders to improve the VICP.

Protecting Public Health
We strive to create an environment to stabilize vaccine supply and foster vaccine research and development by protecting vaccine administrators and companies from liability for vaccine-related injuries and deaths.

Science-based
We strive to review claims based on all available scientific evidence.

Timeliness
We strive to process claims, and compensate individuals expeditiously.

Vaccine Safety Research
We strongly encourage continued research to ensure the safety of current and future vaccines.

Critical Issues Facing the VICP

Following are the critical issues facing the VICP over the next five years:

- dramatic shift in claims from nearly all alleging a Vaccine Injury Table (Table) condition to the majority now alleging a non-Table (or off-Table) condition, which creates a more difficult burden for petitioners and raises questions as to how the current causation standard is applied to VICP claims;
- the claims process is difficult for stakeholders to understand; and
- many parents, the general public, attorneys, and health care professionals are not aware of the existence of the VICP.

VICP Strategic Goals and Objectives

Strategic Theme 1

- Examine alternative approaches for adjudication of off-Table claims.

  Objectives:
  1.1 Identify alternative approaches for adjudication of off-Table claims.
  1.2 Evaluate these approaches.
  1.3 Obtain a consensus on the best approach(es) to pursue.

Strategic Theme 2

- Assure that the VICP is responsive to evolving science, medicine and policy actions.

  Objectives:
  2.1 Request the Institute of Medicine (IOM) or other appropriate body to review possible vaccine adverse events and make recommendations to the Secretary of Health and Human Services periodically.
  2.2 Update the Table using findings from vaccine adverse event research. Revise the Table periodically after considering the recommendations of the Advisory Commission on Childhood Vaccines (ACCV).
  2.3 Evaluate the viability of recommendations to cover additional categories of vaccines under the VICP.

Strategic Theme 3

- Assess and streamline the claims process to make it quicker, more user-friendly, and fair to all parties.

Objectives:

3.1 Evaluate the current claims process to ensure continuous process improvements.

3.2 Obtain and assess feedback from petitioners and their attorneys about making improvements to the claims process.

3.3 Ensure that the claims processing requirements of the Act are implemented and followed, such as submitting medical records at the same time that the claim is filed.

3.4 Consider additional proposals for making improvements to the VICP after consultation with the ACCV and appropriate stakeholders.

Strategic Theme 4

- Increase knowledge about the VICP among all stakeholders. Communication about the existence of the VICP, while necessary, can be frightening to people. It is vitally important to communicate to the public the message that, while vaccines are safe, the VICP's goal is to compensate the small number of people who suffer rare, but serious adverse events related to covered vaccines.

Objectives:

4.1 Evaluate current VICP communications and outreach materials, and simplify and improve their effectiveness.

4.2 Develop and implement a marketing plan to increase awareness of the VICP among stakeholders.

4.3 Create communications materials that are easily understood by the public, health care providers, and attorneys.

Long Term and Annual Performance Measures and Data

A Program Assessment Rating Tool (PART) review of the VICP was conducted for the Fiscal Year 2007 Budget. HRSA and DOJ went through the PART process jointly. The VICP received an overall rating of Adequate. During this review, the VICP developed a new set of performance measures that support the mission, visions and values of the VICP. These measures focus on the timely adjudication of vaccine injury claims and award settlements.

Long-Term and Annual Measure 1: Percentage of cases in which judgment awarding compensation is rejected and an election to pursue a civil action is filed

Explanation: Once a determination has been made that petitioners are eligible for compensation, they are able to reject an award and pursue a traditional civil lawsuit. This measure tracks the number of individuals who pursue civil litigation following a determination that they are eligible for compensation. This is a measure of petitioners' satisfaction with the VICP and the VICP's ability to protect vaccine companies from civil action. The actual data for this measure will be collected and reported by DOJ.

Fiscal Year	**Target**	**Actual Data**
2002	Historical	0%
2003	Historical	1.5%
2004	Baseline	0%
2005	0%	0%
2006	0%	
2007	0%	
2008	0%	

Long Term and Annual Measure 2: Average claim processing time

Explanation: The measure tracks the average length of time from the date a claim is filed until payment is authorized for compensable cases and the date of filing to judgment for dismissed cases. This measure encompasses total claim processing time, which is influenced by all program participants. These program participants (particularly petitioners, petitioners' counsel, and the Special Masters) do influence the speed with which VICP proceedings take place and impact the program's ability to achieve success under this measure. * Longer processing times reflect the expectation that over 5,000 cases currently pending in several omnibus proceedings will begin to be resolved in the coming years. As these cases are finally resolved, they will increase significantly the average processing time for all cases completed during these years. The actual data for this measure will be collected and reported by the HRSA.

Fiscal Year	Target	Actual Data
2002	Historical	995 days
2003	Historical	1021 days
2004	Baseline	738 days
2005	990 days	894
2006	1005 days*	
2007	1213 days*	
2008	1433 days*	

Annual Measure 3: Percentage of cases where the deadline for the Rule 4(b) report is met once the case has been deemed complete

Explanation: A Rule 4(b) report is similar to the government's "answer" in a traditional civil lawsuit. Its purpose is to explain the government's position as to why an award should or should not be granted, provide a medical analysis of petitioner's claims, and assert any applicable legal arguments. The actual data for this measure will be collected and reported by DOJ.

Fiscal Year	Target	Actual Data
2004	Baseline	75.3%
2005	78%	83.7%
2006	80%	
2007	83%	
2008	86%	

Annual Measure 4: Percentage of cases in which case settlements are completed within the court-ordered 15 weeks

Explanation: This measure tracks the percentage of claims in which settlements are completed within 15 weeks from the date of a tentative agreement between the parties and the settlement proposal is submitted to petitioner for his/her concurrence. This measure is calculated by determining the amount of time between a tentative agreement between the parties and the date on which the settlement stipulation is approved by appropriate officials at HRSA and DOJ. The actual data for this measure will be collected and reported by DOJ.

Fiscal Year	Target	Actual Data
2002	Historical	80%
2003	Historical	92%
2004	Baseline	80%
2005	85%	95%
2006	90%	
2007	92%	
2008	92%	

Annual Measure 5: Median time to process an award for damages

Explanation: Once a petitioner has been found eligible for compensation, whether by decision or order of a special master or by the Federal government's concession of a claim, the amount of damages must be determined. The measure tracks the median time it takes to complete this process. The actual data for this measure will be collected and reported by DOJ.

Fiscal Year	Target	Actual Data
2002	Historical	533 days
2003	Historical	564.5 days
2004	Baseline	529.5 days
2005	529.5 days	483.9 days
2006	500 days	
2007	485 days	
2008	475 days	

Annual Measure 6: Decrease the average time settlements are approved from the date of the receipt of the DOJ settlement proposal

Explanation: Approving settlements for petitioners as efficiently as possible will help to ensure they are satisfied with the processing of their claim. HRSA is unable to reduce the average time any further because of factors inherent in the approval system, such as the necessary legal review and opinion by the Department of Health and Human Services Office of the General Counsel. Therefore, for FY 2008 and beyond, the annual target will be to maintain the program performance at 10.0 days. The actual data for this measure will be collected and reported by HRSA.

Fiscal Year	Target	Actual Data
2002	Historical	16 days
2003	Historical	15 days
2004	Baseline	11 days
2005	10 days	18 days
2006	10 days	
2007	10 days	
2008	10 days	

Annual Measure 7: Decrease the average time that lump sum only awards are paid from the receipt of a DOJ clearance letter

Explanation: Paying petitioners as efficiently as possible will help to ensure they are satisfied with the processing of their claim. HRSA is unable to reduce the average time any further because of factors inherent in the payment system, such as obtaining petitioner's social security numbers which are required by the

U.S. Department of Treasury to issue a payment, as well as approvals and payment authorization procedures. Therefore, for FY 2008 and beyond, the annual target will be to maintain the program performance at 5.0 days. The actual data for this measure will be collected and reported by HRSA.

Fiscal Year	Target	Actual Data
2002	Historical	7 days
2003	Historical	6 days
2004	Baseline	6 days
2005	5 days	11 days
2006	5 days	
2007	5 days	
2008	5 days	

Appendices

Appendix A: The Planning Process

In 2002, the Workgroup was formed and conducted its first meeting in May of that year. The Workgroup represents key stakeholders with interest in the VICP. The eight Workgroup members, guided in the process by staff from Vantage Inc. (a training consulting company under contract with HRSA), gathered data and developed draft documents (e.g., vision and mission statements). These data and documents were discussed at the Retreat held in October 2002.

Participants in the Retreat included a larger representative sample of stakeholders with interest in the VICP. The draft Strategic Plan was presented to participants at the Retreat for their review and comments. Stakeholders unable to attend the Retreat provided their review and comments to the strategic planning process in writing and through phone interviews conducted by members of the Workgroup. Based on these comments, the draft documents developed by the Workgroup were used by the Division of Vaccine Injury Compensation staff to develop the Strategic Plan, Communications Plan, and Implementation Plan.

All of the stakeholders, including the Workgroup, who participated in the development of the Strategic Plan were free to express their independent views, experiences and opinions. (A list of the Workgroup members and Vantage staff is included in Appendix C, and the list of Retreat attendees is included in Appendix D.) The Strategic Plan was completed in June 2004.

Appendix B: Stakeholders of the VICP

Stakeholders are significantly affected by any changes to the VICP. Stakeholders are allowed to participate in the decision making process that affects the operations of the VICP, and participate in the development of new ideas for the VICP. The stakeholders of the VICP are listed below:

Department of Health and Human Services (HHS), Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation;

Department of Justice, Civil Division, Torts Branch, Vaccine Litigation;

U.S. Court of Federal Claims;

U.S. Department of the Treasury (collects the excise tax on childhood vaccines, administers the Trust Fund, and makes payments as authorized by the VICP);

Advisory Commission on Childhood Vaccines (see Appendix F for a description of the responsibilities);

Petitioners;

Parents and legal guardians of injured children;

Petitioners' attorneys;

Vaccine companies;

Healthcare providers;

Centers for Disease Control and Prevention;

National Institutes of Health;

Food and Drug Administration;

National Vaccine Program Office;

HHS Office of the General Counsel;

Congress; and

State and local health departments.

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Appendix F: Summary of Major VICP Statutory Responsibilities

The VICP strives to compensate vaccine-injured individuals quickly, easily, and fairly. The three means by which a petitioner may qualify for compensation are: 1) proof that an injury listed on the Table occurred within the specified timeframe; 2) proof that the vaccine significantly aggravated a pre-existing condition; or 3) proof that the vaccine caused the injury.

The Table lists specific injuries or conditions and the time frames in which they must occur after vaccine administration. The Table is a legal mechanism for defining complex medical conditions, and allows a statutory "presumption of causation." The Table serves as the basis for presumptions of causation for vaccines covered under the VICP. It is much easier to demonstrate a Table injury than to prove that the vaccine caused the condition. However, if an adverse event is not listed on the Table, an individual may still file a claim, but must prove that the vaccine did "in fact" cause the alleged injury. Compensation may not be awarded if the Court determines that the injury or death was due to an alternative cause unrelated to the vaccine, even if a Table injury is demonstrated.

The VICP promulgates revisions of the Table as appropriate.

The VICP compiles and disseminates information about the VICP.

The VICP promotes safer childhood vaccines.

The VICP awards compensation.

The Court adjudicates VICP claims.

The ACCV has the following responsibilities: advises the Secretary on the implementation of the VICP; recommends changes in the Table; advises the Secretary in implementing the Secretary’s responsibilities regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveys Federal, state and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines; and recommends to the Director of the NVPO research related to vaccine injuries needed to implement the VICP.

The Act specifies the level of administrative funding for the VICP. Funding is provided by an excise tax on each "dose" (disease prevented) of covered vaccine purchased. Under rules authorized by the Department of Treasury, 75 percent of excise tax collections are deposited into the Trust Fund, which is used to pay compensation for vaccine-related injuries and death.

The VICP authorizes payments from the Trust Fund.

Appendix G: Expectations of VICP by Stakeholders

The development of safe and effective vaccines against diseases represents one of the major success stories of public health. Vaccines prevent thousands of deaths and associated illnesses each year in the United States. With that success comes the reality that vaccines can result in rare, but serious adverse events, perhaps even death, in those who receive them.

Childhood immunization comprises the largest portion of our National immunization program. Vaccines are unique in that they are administered to healthy individuals to prevent disease, not only in the recipient, but also in society as a whole. When a vaccine is given to a healthy individual, there is less tolerance of adverse events, especially when a child is affected. Since state governments mandate that children be vaccinated for school or daycare entry, it is believed that society has an obligation to care for those relatively few individuals who are injured by vaccines.

When individuals are injured by vaccines, they or their legal guardians expect that injuries will be identified quickly and treated appropriately. They also expect to be informed about the VICP so that they may file a timely claim.

The legislative history of the VICP states that compensation is to be provided "quickly, easily and with certainty and generosity." Individuals injured by vaccines or their legal guardians, Congress and other stakeholders have different opinions about what this statement means. In addition, all stakeholders expect the VICP staff to be compassionate when delivering services.

Vaccine companies play a key role in ensuring a steady supply of vaccines. The increase in the number of individuals pursuing litigation against vaccine companies could drastically reduce the supply of vaccines, as well as increase the cost of vaccines. Such a situation would negatively affect the Nation's immunization rates and public health.

Society expects to be free from the threat of vaccine-preventable diseases by having a readily available supply of safe, cost-effective vaccines and ongoing vaccine research and development. Society also expects to be adequately informed of the risks of vaccines, as well as the benefits.

Society expects that the Trust Fund will be used for the purpose it was intended - to compensate individuals injured by vaccines covered by the VICP.

The medical and scientific communities expect that the latest available science will be applied when deciding if a specific injury or death is vaccine-related.

Health officials expect that the VICP, by providing adequate, fair and efficient compensation to the few individuals injured by vaccines, will continue to play a critical role in ensuring high immunization rates for recommended childhood

vaccines, thus preventing the spread of vaccine-preventable diseases and associated morbidity and mortality.

Healthcare providers who administer vaccines to children and vaccine companies expect that they will be protected against lawsuits when vaccines are administered in accordance with currently accepted standards. They also expect to have a continued adequate supply of vaccines.

The Office of Special Masters of the Court, attorneys representing petitioners, and HHS expect that, in each case, complete documentation and evidence will be presented. Completed documentation permits prompt and fair evaluation of the merits of each claim, and when appropriate, allows a determination to be made as to the amount of compensation to be awarded to each petitioner.

In short, every segment of our society has come to expect the benefits of successful immunization efforts. Society now expects resolution to the problems and concerns associated with the few, but sometimes serious adverse events resulting from vaccines.

Appendix H: Strengths, Weaknesses, Opportunities and Threats (SWOT) Analysis

The Workgroup conducted an analysis of the current strengths and weaknesses of the VICP which were recognized as follows.

Strengths

- The Act provides the VICP with a clear mission.
- The VICP personnel are passionate about and dedicated to the VICP's mission, enabling outcomes that consistently meet or exceed expectations for both quality and volume.
- The VICP is generally well-regarded as a program that compensates those injured by vaccines.
- The VICP endeavors to be science-based in its assessment of claims.
- The VICP usually processes claims in a timely manner.
- Funding of the VICP through the excise tax, coupled with restrictions on the use of funds, provides financial stability to the VICP.
- The ACCV oversight of the VICP and the Trust Fund affords additional protection and stability.
- Reversionary trust agreements further ensure financial stability.
- Comprehensive data are available concerning case adjudication and compensation.
- The Expert Witness Program provides the VICP with an excellent source of evidence-based, objective medical and scientific opinion. It has also proven itself a valuable resource in related public health programs (*e.g.* Anthrax Vaccine Expert Committee).
- The VICP pays petitioner attorneys' fees and costs regardless of outcome as long as the claim was reasonable and brought on a good faith basis; and thus, enhancing access to the VICP.
- The Table relieves the burden of having to prove that the vaccine caused an injury.
- The VICP collaborates with other health agencies, such as the CDC, FDA, NIH and NVPO, as well as the U.S. Department of Defense.

- The VICP has been instrumental in stabilizing the vaccine market.

- The VICP is a generous, expeditious and more certain alternative to the civil court system.

- The special masters are perceived as fair.

- The VICP has the ability to make changes to the Table through the regulatory process, instead of the legislative process.

Weaknesses

- The VICP's standards for deciding off-Table cases need to be reviewed and possibly made less burdensome to petitioners.

- The VICP's procedures need modification and improvement, as recommended by the ACCV and others. Some of the improvements suggested by various stakeholders include: allowing interim payment of attorneys' fees and costs so that petitioners can make timely payments to experts; refining and shortening the life care planning process; extending the statute of limitations from 3 to 6 years; and possibly allowing flexibility when compensation can be given to a petitioner, such as permitting a partial payment after entitlement, but before the life care planning process is complete.

- Efforts to educate the public about the VICP are inadequate.

- The public's lack of understanding of science and medicine, coupled with the frequent dissemination of inaccurate information by the media and special interest groups, results in the formation of opinions lacking a basis in science.

- The decisions of the Court are inconsistent.

- There is the perception that the VICP is responsible for delays in the processing of claims when, in many instances, the delays result from meeting the needs of the petitioner.

- Petitioners and attorneys lacking experience with the VICP must confront experienced government attorneys, fostering the view of "government as enemy."

- The very existence of the VICP communicates a mixed message that while vaccines are beneficial and safe, they may, in rare instances, cause injury or death.

- The VICP lacks enforcement authority to ensure that awards are used for their intended purposes.

- Some petitioners perceive the Act, or its interpretation, as too rigid.

- The VICP data have potential public health applications, but are underutilized for this purpose.

- The acceptance by the Court of experts who testify using non-evidence based opinions undermines the credibility of the VICP.

- The number of claims filed varies from year to year; and thus, it is a challenge to plan for adequate resources to process claims.

- Individuals and families filing claims with the VICP do not have access to a support system to help them navigate through the claims process.

- The Act has loopholes which some people believe allows claims alleging injuries from vaccines and components of licensed vaccines to be filed in civil courts before first being filed with the VICP.

- There is no formal mechanism for petitioners to provide feedback on their perspectives of the VICP at the end of the adjudication process.

Similarly, the Workgroup assessed the VICP's potential opportunities, as well as threats, posed by both internal and external factors. These opportunities and threats were recognized as follows.

<u>Opportunities</u>

- The VICP could be instrumental in influencing the adoption of new legal and medical standards for determining entitlement to compensation for off-Table claims, which represents an increasing proportion of newly filed claims.

- The VICP could assume a leadership role in public education about vaccine safety by clearly communicating the benefits and risks of immunization.

- The VICP can continue to provide protection from tort liability to vaccine companies and healthcare providers that administer vaccines.

- The VICP could enhance vaccine safety research.

- In the face of the potential threat of bioterrorism, the VICP could serve as a model for the compensation of those injured by vaccines administered in response to, or anticipation of, biological weapons.

- The VICP has the potential to serve as a model for the broad reform of medical malpractice and civil litigation.

- The VICP could be expanded to cover all vaccines, such as adult vaccines.

- The VICP could develop new and more effective methods to raise awareness about the existence of the VICP, and educate petitioners, attorneys and health care providers about the process of filing a claim with the VICP.

Threats

- The introduction of newer, safer vaccines results in fewer claims alleging Table injuries and more claims for off-Table injuries which creates conflict. Adjudicating off-Table claims is more adversarial or litigious than adjudicating Table injuries because the burden of proof that the vaccine caused the injury is higher.

- Relaxed standards for assessing causation of vaccine-related injury could jeopardize the public's trust of, and reliance upon, vaccines as the first line defense against serious infectious diseases. The relaxed standard may lead to more claims being compensated; and therefore, the public may think that vaccines are not safe.

- Confidence in the VICP may be eroded by uninformed, misinformed or politically-motivated negative opinions of the VICP expressed by public figures.

- Not unlike other Federal programs, the VICP is affected by the public's mistrust of the Federal government.

- The dramatic increase of thimerosal-related litigation in the civil courts, as well as the VICP, may call into question the purpose and value of the VICP and overly utilize program resources and funding.

- The VICP is threatened generally by the public's relative lack of education in science, medicine, and law. As a corollary, if the VICP is not firmly grounded in evidence-based science, the respect and support of the scientific and medical communities will be threatened.

- The public's unwillingness to accept even a small degree of risk threatens its level of immunity against serious infectious disease, and, hence, threatens the VICP. Because of successful vaccination programs, society has not experienced the morbidity associated with vaccine-preventable diseases which plagued previous generations. Therefore, society, as a

whole, seems less willing to accept the risk of an adverse event resulting from a vaccine given to a healthy child.

- Since the balance in the Trust Fund is currently over $2 billion, various stakeholders want to use these funds for purposes other than compensating individuals injured by vaccines. This results from a lack of understanding of the need for risk reserves.

Appendix I: Glossary

Adjudication - hearing and settling a case by judicial procedure

Causation-in-fact- standard of proof which relies on a factual determination that a vaccine actually caused an injury or death

Covered vaccine - a vaccine which is eligible for compensation under the VICP

Factor unrelated - a medical condition that is not linked to the vaccine and is the cause of the injury that is alleged to be vaccine-related

Off-Table c*laims* - claims alleging injuries which are not on the Vaccine Injury Table, or fall outside the prescribed time intervals

Reversionary trust agreements - A reversionary trust is a secure, economical mechanism for the receipt, management, investment, and disbursement of a vaccine injury award on behalf of the injured party. A trust provides protection of the award by a private corporate trustee from mismanagement, dissipation or premature exhaustion of award proceeds. Unlike a guardianship or conservatorship, a reversionary trust is the tax-free accumulation of income, which inures to the benefit of the beneficiary. If unused funds remain in the trust upon the death of the beneficiary, the funds "revert," or are returned to the Vaccine Injury Compensation Trust Fund for disbursement to future claimants.

Expert witness program - VICP medical experts who testify at vaccine injury hearings on behalf of HHS

Special master - A special attorney similar to a judge that is appointed by the U.S. Court of Federal Claims to preside over vaccine injury cases

Stakeholder - “one who has a share or an interest, as in an enterprise” according to the *American Heritage Dictionary*. Stakeholders include individuals and organizations with an interest in and/or who have direct involvement with the VICP (e.g., parents and legal guardians of injured children, petitioners’ attorneys, vaccine companies, healthcare providers).

Vaccine Injury Compensation Trust Fund - the funding source for compensating claims for a vaccine-related injury or death filed after October 1, 1988 and is funded by a $.75 tax on each “dose” (disease prevented) contained in a covered vaccine

Vaccine Injury Table - lists specific injuries or conditions and the time frames in which they must occur after vaccine administration and is a legal mechanism that allows a statutory "presumption of causation" for vaccines covered under the VICP