A Review of the Vaccine Injury Compensation Program - Is Justice Being Served?

May 2012

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The Unique Positions of Vaccine Policies in the United States

In late 1999, the Centers for Disease Control and Prevention (CDC) declared vaccinations as the top achievement in public health for the 20th century. (Centers for Disease Control and Prevention) In the early 1900s the major health threats to Americans were associated with the lack of clean water and proper sewage treatment, poor nutrition, and infectious diseases. The development of antibiotics and vaccinations as well as improvements in sanitation, nutrition and public education about hygiene and preventing the spread of infectious disease have all worked together to see the leading causes of death in the United States shift from infectious diseases to chronic diseases. Many of the policies in place in 2012 grew out of policies developed to increase vaccination rates for smallpox, polio and measles.

The Only Drugs Mandated by Government

Vaccines hold a unique position in public health. They are the only medications required by a government as a prerequisite for participation of children in schools, day cares facilities, and to receive federal assistance such as food stamps. School and day care mandates technically come from the state governments (and, at times, local jurisdictions). These state mandates are based on federal recommendations made through the Advisory Committee on Immunization Practices (ACIP) and CDC. The Federal government requires that all children under age five years be up to date on their immunizations for their families to receive food stamps and other federal assistance. Medicaid is the only exemption to this requirement. Penalty for non-compliance includes a possible monetary fine each month there is non-compliance or a discontinuation of federal assistance services.

Massachusetts was the first state to mandate a vaccination in 1809 (smallpox). Forty-six years later the state would link mandatory vaccination to school participation. (Hinman, 2007)

Because of this unique position in public health, the importance of insuring that individuals who suffer serious adverse reactions from a vaccine retain an avenue to seek compensation is vital. Additionally, constant attention is required to insure that vaccines are made safer as knowledge and science advance. Vaccinations are the only medical treatment widely given to healthy children and, as such, the standards of safety for vaccinations must be very high to ensure that the benefits of their use to outweigh the risks.

The Coalition for Safeminds was founded in 2000 with a focus on ending the use of all forms of mercury and other neurotoxicants in medical products, including vaccines.

Brief History of the Vaccine Injury Compensation Program

In the 1980s, pharmaceutical companies were facing increased litigation from families whose children suffered serious adverse events from their vaccines. According to the National Vaccine Information Center, in the early 1980s, four companies were making and selling vaccines for children in the United States – Merck, Wyeth, Lederle, and Connaught. (National Vaccine Information Center) At the time, three vaccines for seven diseases were being given. The oral Polio vaccine (OPV) manufactured by Lederle, the Measles Mumps Rubella (MMR) vaccine manufactured by Merck; and the Diphtheria, Pertussis, Tetanus (DPT) vaccine produced by Wyeth (which was owned by American Home Products); Lederle (which was owned by American Cyanamid); and Connaught. Injuries associated with the oral polio vaccine and the whole cell pertussis portion of the DPT reesulted in more than 2000 lawsuits. Most were settled prior to court. At least 52 families were compensated a combined total of more than $16 million for their child's injury by the manufacturers. In 1984, a jury awarded $1.4 million to Kevin Toner in *Toner v Lederle* for the paralysis he suffered from developing transverse myelitis. The jury's decision was confirmed by the appellate court.

In the mid 1980s, the pharmaceutical industry came to Congress with a threat to get out of the vaccine manufacturing business unless they were provided product liability protection by the government. The fear of a resurgence of polio or measles if vaccines were in short supply spurred Congress to act and on October 1, 1988, the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the National Vaccine Injury Compensation Program (VICP). According to Congressman Henry Waxman, the Original Co-sponsor of the legislation:

"The purpose of the program was threefold. First, to be a no-fault program to compensate people from the rare but sometimes serious side effects of vaccines. Let me underscore that. When you immunize large numbers of people, there are going to be some rare cases of adverse consequences, very serious adverse consequences. And we have to acknowledge that reality there. In that case, we decided that we must compensate those people. We mandate the vaccinations, for the most part, for all the children in this country, as a public health preventative. So if somebody's injured, we ought to make sure that person is compensated. We don't take away their right to sue. But we have a compensation system that offers them an alternative to going into court. Our second objective was to lower the number of lawsuits against vaccine companies in order to encourage these companies to stay in the business. And of course, to ensure that we had a healthy domestic supply of vaccines. And the third purpose of the bill was to allay parents' concerns about vaccine safety so that parents would continue to have their children vaccinated." (Committee on Government Reform, United States House of Representatives)

In addition to vaccine manufacturers being provided liability protection, those who deliver vaccines are also protected under the Act.

Vaccine Manufacturers Do Not Contribute to Injury Compensation

The VICP is administered by the Department of Health and Human Services, with the Department of Justice representing the US Government in the US Court of Federal Claims. Management of the program resides at the Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation. The Department of the Treasury oversees the collection of an excise tax of $0.75 per disease in a dose of vaccine which funds the Vaccine Injury Compensation Trust Fund. So, for example, the MMR is taxed at $2.25, while the Hepatitis B is taxed at $0.75.(Department of Health and Human Services).

The vaccine manufacturers provide no financial contribution towards injury compensation. In 2004, the House Committee on Ways and Means Report on the American Job Creation Act which included provisions to include coverage of the Hepatitis A and Influenza vaccines on the list of covered vaccines in the program confirmed that it is the purchaser of the vaccine rather than the manufacturer of the vaccine that pays the excise tax which funds the Vaccine Injury Compensation Trust Fund.

"Medicaid is a major purchaser of vaccines through the Vaccines for Children program, administered through the Centers for Disease Control and Prevention (CDC). Medicare is a major purchaser of the vaccines for the elderly. [Congressional Budget Office] CBO estimates that Medicaid and Medicare pay for approximately half of the hepatitis A and influenza vaccines sold annually. Based on estimates provided by[Joint Committee on Taxation] JCT, CBO expects that implementing the bill would cost the Medicaid and Medicare programs about $10 million in 2004 and $556 million over the 2004–2014 period." (Committee on Ways and Means, US House of Representatives)

The federal government is the largest single purchaser of vaccines and thus government is taxing itself to pay for the Vaccine Injury Compensation Program. Safeminds believes that manufacturers should bear at least part of the financial burden of funding the VICP Trust Fund, rather than the taxpayer. SafeMinds also recommends that the Vaccine Adverse Event Reporting System be made mandatory for all physicians and that there be ongoing monitoring of vaccine safety data such that manufacturers of vaccines with greater reported adverse events bear a greater proportion of the cost of the program. This would create a financial incentive for vaccine manufacturers to make the safest possible vaccines.

In October 2000, the Committee on Government Reform issued a report based on a study conducted by its Subcommittee on Criminal Justice, Drug Policy, and Human Resources entitled, The Vaccine Injury Compensation Program:

Addressing Needs and Improving Practices" chaired by Congressman John Mica. (Committee on Government Reform, US House of Representatives) The report provided a comprehensive review of the program's operation and reiterated its 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.

It went on to detail that in the first 12 years of VICP, approximately 6,000 petitions were filed. Three-quarters of the cases filed involved injury allegations prior to 1988. More than 50 percent were dismissed. The report provided that "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 at the time ranged from $120.00 to $7.9 million, with the average approximately $800,000."

The report states: "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." And concluded: "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." The recommendations from the report were:

- 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.

Vaccines are Acknowledged to Have Risks

There is no question as to whether or not vaccines may cause injury. This is acknowledged by all parties – manufacturers, regulators and legislators.

There is a balance that the US government seeks with all medications – the risk benefit ratio.

Balancing the Risk Benefit Ratio of Vaccines

The approval, regulation and oversight of vaccines, like all medications, include a balance of the risk-benefit ratio. Do the benefits of the product outweigh the risks of possible injury from its use? Vaccines, like all medications, have risks associated with them, some known and expected and others not yet known. One of the reasons the federal government has post-marketing surveillance is to identify adverse events as quickly as possible. All drugs including vaccines contain a package insert, which is carefully reviewed and requires approval by the Food and Drug Administration (FDA). Within these package inserts are warnings and lists of reported adverse reactions.

Using the **M-M-R II** insert (Merck) as an example, the following information is provided as warnings to both medical personnel and parents:

Hypersensitivity: Hypersensitivity to any component of the vaccine, including gelatin. Anaphylactic or anaphylactoid reactions to neomycin or chicken eggs (vaccine contains chick embryo)

Medical Contraindication: Do not give M-M-R II:

- To pregnant females; the possible effects of the vaccine on fetal development are unknown at this time. (A recommendation not to become pregnant within 3 months of immunization is included in the document)
- During Febrile respiratory illness or other active febrile infection.
- To patients receiving immunosuppressive therapy.
- To individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
- To individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.
- To individuals with current thrombocytopenia who may develop more severe thrombocytopenia following vaccination.

Known Adverse Reactions: For M-M-R II include:

- atypical measles
- fever
- syncope
- headache
- dizziness
- malaise
- irritability
- Vasculitis
- Pancreatitis
- Diarrhea
- Vomiting
- Parotitis
- Nausea
- Diabetes mellitus
- Arthritis
- Arthralgia
- Myalgia
- Chronic joint symptoms
- Encephalitis
- Encephalopathy
- Measles inclusion body encephalitis (MIBE)
- Subacute sclerosing panencephalitis (SSPE)
- Guillain-Barré Syndrome (GBS)
- febrile convulsions
- afebrile convulsions or seizures
- ataxia
- polyneuritis
- polyneuropathy
- ocular palsies
- paresthesia
- Thrombocytopenia
- Pneumonia
- Stevens-Johnson syndrome
- erythema ultiforme
- urticaria; rash; measles-like rash; pruritis
- Ear Nerve deafness; otitis media
- Eye Retinitis; optic neuritis
- Panniculitis (Inflammation of the subcutaneous fat, especially of the abdominal wall.)
- Transmission of rubella live virus to infant through mother's breast milk

The M-M-R-II package insert also includes information about what is theorized or not known.

Theoretical Risks: Transmission of live virus (measles and mumps) to susceptible (immune compromised family member [i.e. cancer, HIV, RA].

Unknown Risks:

- M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.
- Animal reproduction studies have not been conducted with M-M-R II. It is also not known whether M-M-R II can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.
- Safety and effectiveness of measles vaccine in infants below the age of 6 months have not been established.
- Safety and effectiveness of mumps and rubella vaccine in infants less than 12 months of age have not been established.

The package insert for one brand of **Hepatitis B Vaccine** (Engerix-B) (Glaxo Smith Kline) includes the following known adverse reactions:

- Apnea in premature infants
- Dizziness
- Upper Respiratory Track Illnesses
- Anorexia
- Lymphadenopathy
- Agitation
- Insomnia
- Somnolence
- Tingling
- Hypotension
- Flushing
- Arthralgia
- back pain
- myalgia
- pain/stiffness in arm, shoulder, or neck
- Encephalitis, encephalopathy
- Migraine
- Multiple sclerosis
- neuritis, neuropathy including hypoesthesia
- paresthesia
- Guillain-Barré syndrome and Bell's palsy
- optic neuritis
- seizures, syncope, transverse myelitis
- visual disturbances
- tinnitus, vertigo.
- Palpitations, tachycardia.
- Vasculitis
- asthma-like symptoms.
- Dyspepsia.
- Alopecia, angioedema
- Eczema
- erythema multiforme including Stevens-Johnson syndrome
- Arthritis, muscular weakness.
- Abnormal liver function tests

SafeMinds Calls for Safer Vaccines

SafeMinds is not 'anti-vaccine' as has at times been stated by individuals with differing opinions. Rather, Safeminds believes that a decision to use any medication including a vaccine is a decision that is best made by parents who are fully informed of benefits and risks, in collaboration with medical professionals and taking into account the unique health and family history of a child. SafeMinds supports personalized medicine and believes that universal

immunization policies can address personal medical needs without putting herd immunity at risk.

It should be noted that the Special Masters have not allowed the attorneys for petitioners to submit the package insert for the vaccine.as evidence to the program despite its having been approved by the FDA based on body of evidence available to the agency including adverse event reports, and scientific evidence.

The Management Structure of the VICP

Four Federal government organizations have a role in the VICP:

- the U.S. Department of Health and Human Services (HHS);
- the U.S. Department of Justice (DOJ); and
- the U.S. Court of Federal Claims (the Court)
- the U.S. Department of the Treasury

The VICP is located in the HHS, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation. (HRSA). Special Masters within the U. S. Court of Federal Claims decides who will be compensated. At HHS, the program is managed at the Health Resources and Services Administration (HRSA), Healthcare Systems Bureau, Division of Vaccine Injury Compensation.

The Vaccine Injury Compensation Trust Fund provides funding for the National Vaccine Injury Compensation Program to compensate vaccine-related injury or death claims for covered vaccines administered on or after October 1, 1988. The Department of Treasury collects the excise taxes and manages the Fund's investments.

Management Concerns and Legislative Recommendations

In 2002, Stanley P. Kops, Esq wrote, "Though the Congressional intent was to create a victim-friendly statute which provided just and fair compensation quickly and without the uncertainties and proof problems inherent in civil actions, frequent practitioners under the Act are in virtually universal agreement that the program, as it has evolved during the past decade and a half, is a perversion of the Congressional intent." (Stanley P. Kops, 2002)

SafeMinds believes that the VICP urgently needs to be improved to function as it was intended, or that Congress needs to eliminate the program and restore the Constitutional rights of thousands of vaccine injured to seek legal recourse.

The Last Big Legislative Effort – HR 3471 (107th Congress)

During the 107th Congress, a bipartisan group of legislators introduced, HR 3471 The National Vaccine Injury Compensation Program Improvement Act of 2002 which included provisions to:

1. **Lost Earnings Method Codified:** Codify the currently used method for calculating the lost future earnings that may be included in a compensation award when the injured individual is a child. It specifies a particular calculation annually performed by the Bureau of Labor Statistics, and allows the Secretary of Health and Human Services [the Secretary] to substitute a different but similar method by regulation. (Recommended by the Administration.)

2. **Family Counseling and Expense of Guardianship/Conservatorship:** Added two items to the categories of expenses that may be compensated under the program: (1) the expense of counseling for the family of the injured person, when such counseling pertains to the vaccine-related injury, and (2) the expenses of establishing a guardianship or conservatorship for the injured individual. (Recommended by the Administration.)

3. **Interim Attorneys Fees and Expenses:** While the government has an extensive budget to immediately compensate their experts and to collect information, petitioner's council have been expected since the inception of the program to cover all expenses bringing the case to its conclusion without reimbursement. Even if the program were swift as intended, this creates an uneven playing field for petitioners, and in cases that drag on for a decade, it is an impossible burden to bear for most lawyers, who are typically in smaller law firms. HR 3471 included a provision to allow a special master or the court to award interim costs for reasonable attorney's fees, costs, including expert witnesses and medical records. Once a case is determined to be legitimate, attorney's fees and costs will be reimbursed even if the petitioner is not awarded compensation. (Recommended by the Administration.)

4. **Once Court Determines Compensation is Due, Payment of Unreimbursed Medical Fees:** When the VICP has determined that the petitioner is entitled to compensation, provisions that allow for immediate payment for unreimbursed medical expenses. This is important as the life care plan process can take years, and too often families are suffering financial distress in their attempt to provide the needed medical services.

5. **Increase State of Limitations:** Expanding the statute of limitations to six years for both injury and death cases and to 8 years on claims based on revisions to the Table of Injuries. (Extended the statute to six years for injury cases and the expansion of the statute of limitations on for table changes was recommended by the Administration).

6. **Increasing Parent participation on ACCV:** Change the requirement for just 1 to 2 of the 3 members of the general public to the Advisory Commission on Childhood Vaccines be legal representatives of children who have suffered a vaccine-related injury or death. It also adds that 1 other be a representative of a child who has suffered a vaccine-related injury or death or an individual who has personally suffered a vaccine-related injury. (Recommended by the Administration.)

7. **Conforming Amendment:** Included a conforming amendment to the Vaccine Injury Compensation Trust Fund Provision of the Internal Revenue Code of 1986, so as to allow use of the Trust Fund for elements of compensation that are added or expanded by this bill. (Necessary for implementation of the amendments.) (Recommended by the Administration.)

8. **Increase Limit of Administrative Expenses:** Two changes to the Trust Fund provision of the Tax Code to (a) resolves a conflict between two simultaneous amendments made by the Omnibus Consolidated and Emergency Supplement Appropriations Act of 1999, P.L. 105-277, to that provision. One of the amendments would have allowed use of the Trust Fund to pay administrative expenses of the VICP only up to $9,500,000 per year, the other amendment would have allowed use of the Trust Fund for such purposes without a cap. Subsection (a) will allow use of the Trust Fund up to a cap of $10,000,000. Subsection (b) will allow use of the Trust Fund to pay expenses incurred by the Bureau of the Public Debt, of the Treasure Department in providing financial services to the Trust Fund.

Vaccine Injury Compensation Act — As Written by Parents —June 10, 2003

Nine years ago, a group of parents laid out the concepts of what would be a truly fair and equitable vaccine injury compensation program.

1. VICA is an alternative rather than a replacement remedy. Therefore, VICA shall not compromise any substantive right, regulations, procedural or evidentiary right that is afforded to claimant under color of any state's law.

The original intent of VICA was to be a low cost, non-adversarial alternative to suing in civil court. It has veered far from the original intent. If it is to exist, it needs to be restored to its original intent. Also, just because you miss the VICA three year, or six year statute, doesn't mean you cannot sue in your state under their existing laws for minors.

2. If the Vaccine-Injured must enter the VICA program before going to civil court, then the Vaccine Injured want a full look back to Oct. 1988 with NO Statute of Limitations time constraints and a full opt-out to go to civil court after 240 days with no final judgment and only one extension of 60 days for a total of 300 days.

If a vaccine is found to have a causal relationship to the injuries the injured claims, then the injured should be able to file a claim in VICA with no time constraints. Many vaccines were made with viruses that are now called "slow viruses." Their full extent may not be known for years. i.e. SV 40 virus from the Polio Vaccine of the early 1960s is being found in 40-somethings with brain tumors. Their SV 40 virus is being traced to their polio vaccine given to them at the time, known as hot batches. Also the mercury-poisoned children of the 1990s were misdiagnosed. Their parents are only now finding out, and science is catching up, to these injuries. No one should be barred for these reasons.

3. Two recommendations for the Table of Injuries. 1) If an injury meets the preponderance of evidence in a VICA or a civil court claim that the injury was caused by vaccines, then the injury must be added to the VICA Table of Injuries immediately and the VICA administrator must inform all claimants previously denied for the same or similar injury that their claim is now recognized as a compensable event. Injured has one year to file their claim from date of notice. Notice shall be by certified mail, return receipt requested. 2) The advisory panel that evaluates and adds to the Table of Injuries will be constituted of 30% parents/vaccine injured. See the NIH policy that provides for 30% of public participation on advisory committees.

The Table is the heart of VICA. We have heard of endless stories from people who have had clear injuries from vaccines and yet the injuries are not on the

Table despite the preponderance of evidence that the injury is clearly recognized as an injury from vaccines. We believe that the Table should be directed by science and the preponderance of evidence. And we want parents of injured children or injured adults to comprise at least 30% of the panel that oversees the Table of Injuries. This helps to keep the balance that VICA desperately needs.

4. If the claimant gets a VICA award, then they will be entitled to any post judgment interest calculated using current interest rates at the time. Said interest shall be tax free.

Many times after judgment, a case is appealed time after time. Parents have testified that they believe it is to drag the case out over many years, some even believe, until the child dies. We have even spoken with one claimant that won their case two years ago and have not yet seen a dime of VICA money. This is unacceptable. We believe if the government had to pay interest on a claim after a positive judgment, it would encourage things to move along as they should.

5. VICA program will approve any claim based upon the medical records in lieu of a hearing. If the claimant's medical evidence substantiates an injury that meets the requirements on the Table of injuries, claimant must be approved without hearing, further discovery or delay. Said review must occur within 120 days of receipt of all necessary medical records in accordance with HIPAA - HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT.

This would make VICA the true no-fault, non-adversarial program it was intended to be.

6. VICA is prohibited from paying for studies with money allotted to VICA to fund vaccine injury judgments. Research money will come from NIH or other government agencies for any studies to determine causation for Table Injuries. Studies to be conducted will be determined every six months by Congressional Committee with oversight over VICA.

We have heard that this is happening and it is reprehensible. We can present information that this indeed happened when "seizures within 14 days of a vaccine as a table injury" was reduced to 3 days. There were other changes made to the table in the 1990s as well. VICA money was used to pay for one-sided studies to be able to turn away claims.

7. Every two years fair and open public hearings into the vaccine-neurodevelopmental disorder connections will be conducted by the IOM. Unbiased, independent experts will be called that are approved

by the advisory panel noted in #3 above. Researchers chosen will not get any funding from stock, patents or have any other appearance of a conflict of interest. A report from the Commission will be delivered to the Special Masters with conclusions impacting the Table of Injuries.

This is to keep up with science and hold vaccines to a government standard using the data we have available on an on-going basis.

8. Raise the death claim to $1,000,000 and pay without limitation, medical, physical/occupational therapy, rehabilitation, medical monitoring, special diets, supplements, educational/tutorial therapy expenses incurred from injury to death.

There have been reports (to the Government Reform Committee) that some vaccine injured children cost their parents hundreds of thousands of dollars over many years – some as many as 10 years. VICA kept dragging these cases out, but when the child died, they paid a death claim of $250,000 but NONE of the other money owed that had added up over time for treatments, loss of income due to one parent staying home, loss of consortium, etc.

9. Delete the pain and suffering cap of $250,000 and insert that there is no cap on pain and suffering. Monetary award will be determined on a case by case basis.

Obviously, some cases deserve more than others.

10. Parents with an injured child may file a separate loss of consortium claim though the VICA program. Said filing by injured claimant shall toll federal and state statutes of limitation and repose for any available loss of consortium.

Many parents with an older child, just finding out their child is, and has been, mercury-poisoned have passed their ability to file loss of consortium claims in their state due to statute of limitations. They couldn't file in their state because they didn't know the reason for the injury. Now that they know, they have lost their ability to file. They should be able to file in VICA. If the child's injury is deemed vaccine-related, this is precisely where these cases need to reside.

11. The vaccine injured may file a punitive damage claim with no caps. Monetary award will be determined on a case by case basis.

Once again, all cases differ. If it is proven, as it was with tobacco, that companies hid information about thimerosal's detrimental effects, parents certainly, under the law, should be able to file a case for punitive damages. VICA should address this.

12. Compensatory damages will include, but not be limited to: past, present and future medical treatments, drugs or devices for said injury, physical/occupational therapy, rehabilitation, medical monitoring, special diets, supplements, educational/tutorial therapy and any other treatments/medical/therapy needs as deemed by the treating physician.

We have spoken with many parents who have won in VICA only to have Justice Department attorneys with endless time, money and energy, deny claim after claim, even when claims are made by reputable physicians. Paying for supplements to help children digest their food or to compensate for mineral imbalances in their bodies, chelating and implementing diets, like the ones for autism/mercury poisoning, costs a great deal of money to implement. The child would not have been on such supplements and diet, and would not be chelating, if the injuries didn't happen, therefore VICA should be responsible, especially if documented by the child's physician.

13. Change of condition procedures. If the claimant has a new condition that requires a new medical treatment, drug or device then said claimant may petition to modify the judgment for additional compensation, award or payment due to said medical condition or availability of new therapy. The causation of said additional medical injury shall be by the treating physician's statement.

We spoke to a father of a child that won in VICA for damage due to the polio vaccine. He has also testified before the Government Reform Committee. The child got polio from the vaccine and was affected from the waist down. Even though the injury took only days after the vaccine to manifest, and the family promptly filed in VICA, the case still took seven years. At 8 ½ years old, the child was finally compensated in VICA. However, three years later, the child began to develop hand tremors that he had not had before. This was documented by several physicians at reputable DC area hospitals as developing due to his ongoing battle to fight the virus, the prior neurological damage, etc. VICA has denied all claims for the child's occupational therapy for his hands claiming that it wasn't due to the vaccine because it took until he was 11 years old to manifest. This lack of vision and judgment must stop. These positions in the Justice Department need to be filled with reasonable people and we must give them the laws to be able to carry out reasonable treatments for the vaccine-injured.

14. Regarding allotment of funds once a claim is won in VICA – Abolish experimental and medical necessity defenses in reasons for denial in making a decision on how judgment should be spent. Defer to treating physician. If the treating physician says that any said medical treatment,

therapy, drug, supplement, diet, etc. is needed for the vaccine injured health or well-being, then it is approved. Parents do not have to have the burden of proof to obtain coverage for their child's needs.

Another parent we spoke to had four doctors tell VICA that her daughter (who was DPT injured and won in VICA) should begin IVIG treatments in order to help her with her immune system problems and horrible infections she was having. The child, in additional to being severally disabled, was very sickly. VICA denied time after time, finding their experts to go up against the child's own physicians. VICA's experts said she didn't need the treatments, therefore VICA would not pay. The child, at 16, did not get the very expensive treatments and is now near death.

15. Rent, clothing and food shall not be counted in any asset determination or as a qualification of determining availability of any Federal, State or Benefit program. VICA should provide the amount of any judgment.

"Public confidence in the integrity of the Government is indispensable to faith in democracy; and when we lose faith in the system, we have lost faith in everything we fight and spend for."

—Adlai Stevenson

The Autism-Vaccine Omnibus Proceedings

With almost 5,000 cases of vaccine injury linked to the onset of autism filed in the National Vaccine Injury Compensation Program (VICP), an Omnibus Proceedings was organized within the program, eventually ruling against all of the cases except for one - Hannah Poling. The government conceded that Hannah Poling's vaccine injury was real and that she should be compensated in the VICP.

Hannah's case was originally scheduled to be one of the three test cases in the Omnibus proceedings arguing a link between thimerosal, the mercury preservative, in vaccines and autism. By plucking Hannah's case out of the Omnibus proceeding, the hundreds of other families whose children's injuries are identical or almost identical to Hannah's have been denied justice. The official concession provides that the five vaccinations for nine diseases she received on July 19, 2000, "significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder." Since that time, the government has stated that her mitochondrial disorder is 'rare'. Again, what the government is stating to the public is not entirely accurate. While her mitochondrial disorder may be

rare in the general population, there is increasing evidence that between 10 and 20 percent of children who regress into autism may have this same 'rare' mitochondrial disorder. The description of Hannah's health status before and after vaccination mirrored the story of most families who filed in the program.

The entire controversy over the autism-vaccine link and omnibus proceedings was avoidable. Had the VICP management team monitored and tracked the cases filed and compensated within the VICP, it would have been clear that children do suffer brain injury from vaccines that lead to the onset of autism or autism symptoms. There were over1300 cases over 20 years in which vaccine-induced brain injury was conceded. In at least 21 cases discovered by investigators who published a paper in May 2011 in the *Pace Environmental Law Review* the terms "autism or autism-like symptoms" were found in the court records.

The same staff at HHS have been involved in the VICP from the outset. They would have been involved in the first series of IOM investigations in which autism originally was brought up in the early 1990s, would testify before Congress, and be involved in the subsequent IOM inquiry. These same government officials involved in the VICP told the world the Hannah Poling concession was the first time the VICP had compensated an individual whose vaccine injury led to the onset of autism.

SafeMinds can draw two conclusions from the way the autism-vaccine issue has been handled – there is either incompetence or an active cover up. It is inconceivable that staff signed off on 21 cases of brain injury in which autism was noted and did not recall that when testifying before Congress, or in managing other cases. In addition to the 21 cases mentioned above, when the investigators reached out to 150 of the 1300 families, of the ones that would participate in the study, they found another 62 cases of confirmed autism in individuals whose vaccine-induced brain injury was financially compensated by the government. The 5,000 cases filed in the VICP would best have been settled by an administrative procedure in which medical records were submitted and reviewed, not through a multi-year omnibus proceedings in which most of the cases were never actually reviewed. One can only conclude that for the families in this omnibus proceeding that justice has not been provided.

VICP is Not Working as Congress Intended

Congress created the VICP to be a compensation program that would be easy to traverse, swift, fair, non adversarial and when there was a close call, to rule in favor of the vaccine-injured petitioner. While the immunity given to drug companies and health professionals in the 1986 National Childhood Vaccine Injury Act has resulted in a massive expansion of our vaccine schedule, it has

become increasingly difficult for families to be compensated when a vaccine injury occurs.

The program remains a David Versus Goliath process in which, too often, David is unsuccessful no matter how solid the case because the government has deep pockets and the upper hand with the court. While most of the conversation in the VICP is on children, half of the cases currently in the program are of adults who have been injured.

Inefficiencies and inequalities that need to be addressed:

1. The Vaccine Injury Table needs to be updated more routinely and include the injuries noted on the package insert for each vaccine.
2. Full discovery from the manufacturer should be allowed. (This was promised to the Autism Omnibus proceeding, but was not provided.)
3. Full discovery from the government should also be allowed.
4. Attorneys for petitioners should be able to refer to other cases in the program.
5. Ex Parte conversations between the government and Special Masters should not occur.
6. More transparency is needed in cases that are not 'published' or are settled through alternative means.
7. The VICP needs to track and publish all of the vaccine injuries that are compensated.
8. Parents of children who have been compensated should not be threatened to have the annuity curtailed if they talk about their experience in the program.
9. A review of the use of a small cadre of brokers to set up the annuities cries out for oversight.
10. Greater expediency is needed to compensate families. The life-care planers hired by the government need to work with more efficiency and speed. (It should not take two years.)
11. Expert Witnesses for petitioners should be compensated at the same time and at the same rate as government expert witnesses. (Government witnesses are paid immediately while petitioners' witnesses often wait a decade for payment, and may be compensated at a lower rate.)

    A review of the behavior of Special Master's on the bench to determine if they are too closely aligned with the government, if they treat counsel, experts and families fairly.

Congress needs to re-engage in oversight and do so every Congressional session to insure the program works as intended. SafeMinds stands ready to work with Congress to provide information relevant to oversight of the VICP.