National Vaccine Information Center

www.NVIC.org

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Dear Ms. Garvey:

As you gather information for your review of the federal Vaccine Injury Compensation Program (VICP) created under the 1986 National Childhood Vaccine Injury Act (Public Law 99-660) at the request of the Chairman of the U.S. House Committee on Oversight and Government Reform, thank you for contacting the National Vaccine Information Center (NVIC) to inquire about our perspective. We appreciated the opportunity to discuss our concerns about operation of the VICP with you and your colleagues last week by telephone and, as promised, following is a referenced written follow-up.

In order to fully explain our answers to your specific questions regarding operation of the VICP, it is necessary to put them in context by reviewing events that are part of the history of the 1986 Childhood Vaccine Injury Act and it's subsequent implementation because they have impacted operation of the VICP. These events, which include actions by federal agencies before and after the law was passed in 1986, have shaped the way the federal vaccine injury compensation program is working today and how it is perceived by petitioners filing claims.

NVIC WORKED WITH CONGRESS ON THE 1986 NATIONAL CHILDHOOD VACCINE INJURY ACT

NVIC co-founders Jeffrey Schwartz, Barbara Loe Fisher and Kathi Williams worked with parents of DPT vaccine injured children and Congress on the 1986 law after we were contacted by congressional legislative staff and asked to participate in the spring of 1982, shortly after we founded the non-profit charity, Dissatisfied Parents Together (DPT) that is known today as the National Vaccine Information Center (NVIC). The mission statement of our non-profit charity in 1982 was "to prevent vaccine injuries and deaths through public education" and that remains our primary mission today, as well as defending the ethical principle of informed consent. [1]

The participation of NVIC co-founders, who were parents of DPT vaccine injured children, during the legislative process creating the 1986 National Childhood Vaccine Injury Act [2] was to ensure that it would be a law that balanced ***prevention*** of vaccine injury and deaths with ***compensation*** for vaccine injury and deaths.

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Among the unique contributions that NVIC parent co-founders made to the Act was to:

(1) secure vaccine safety provisions requiring pediatricians and all vaccine providers to:

- give parents adequate vaccine benefit and risk information *before* children are vaccinated;
- record serious health problems following vaccination in the child's permanent medical record and keep a permanent record of the vaccine manufacturer's name and lot number; and
- report vaccine adverse events to a centralized federal vaccine adverse event reporting system (VAERS).

(2) secure a provision in the Act that Congress would ask the Institute of Medicine of the National Academy of Sciences to review and make reports on scientific evidence related to vaccine adverse events; and

(3) secure the participation of parents of vaccine injured children and other members of the public on vaccine advisory committees.

Vaccine Injury Table: Making the VICP Less Burdensome. NVIC co-founders also worked on developing a Vaccine Injury Table (VIT) that included symptoms of vaccine reactions and injuries and other administrative mechanisms in the VICP that would ensure the federal program was operated as a "no-fault, non-adversarial" ***alternative*** to a civil court action. Although Congress expressed the intent to protect the vaccine supply by reducing liability for vaccine manufacturers, the Childhood Vaccine Injury Act was also characterized as an historic effort to provide families of children, who were brain damaged or died after receipt of one or more of the then-seven federally recommended and state mandated vaccines, with an "expeditious and fair" less expensive, less time-consuming and less traumatic alternative to taking legal action against pharmaceutical corporations.

Many of the children in need of vaccine injury compensation have experienced a long-recognized serious complication of vaccination: acute encephalopathy with or without brain inflammation (encephalitis, encephalomyelitis). [3] [4] [5] In some cases, brain inflammation or acute encephalopathy – irrespective of the cause - can lead to chronic encephalopathy (permanent neurological dysfunction). [6] [7] [8] [9]

Families caring for vaccine injured children with severe brain injury have little money, time or physical and emotional energy to spend on expensive and drawn out legal proceedings and the VIT was one mechanism for making the VICP a less burdensome legal alternative for petitioners.

VICP Created As A Legal Alternative*.* Parents working with Congress during the legislative process in the early 1980's were repeatedly assured that the proposed federal compensation program would be an ***alternative*** to a civil lawsuit and that access to the tort system would not be cut-off. [10] From parents' perspective, this was important for two reasons:

- The proposed VICP designated the Secretary of DHHS to serve as the defendant and for Department of Justice to provide attorneys to argue for the Secretary's position during adjudication by the U.S. Court of Claims in DHHS-contested vaccine injury claims. Because both DHHS and the Department of Justice had ***publicly opposed*** creation of a federal vaccine injury compensation program, [11] continued access to the tort system by plaintiff's who were denied or offered too little compensation was a compelling incentive for DHHS and Justice to

operate the VICP fairly and be "expeditious" and generous in awarding compensation to children injured by federally recommended vaccines.

- Preserving access to the tort system for product liability claims when there was evidence that a drug company could have made a vaccine less reactive would serve as an economic incentive for drug companies to make their products as safe as possible. [12]

VICP Funding: A Trust Fund. The proposed funding mechanism for the VICP was a federally operated Trust Fund, into which all parents giving their children federally recommended vaccines in a private pediatrician's office would contribute money through a surcharge (excise tax) placed by the vaccine manufacturer on each vaccine dose purchased by pediatricians for administration to children. Likewise, the federal government would pay a surcharge for each dose of vaccine purchased for administration to underinsured children in public health clinics.

Effectively, the surcharge on each dose of vaccine paid by parents and the federal government, which provides money for the Trust Fund, functions as a type of self-insurance program for families. The Trust Fund was designed to provide a financial safety net for children, who were injured by government recommended and mandated vaccines, and for their parents caring for them. The Trust Fund pays for VICP awards, plaintiff attorney fees and costs for administration of the VICP by DHHS, Department of Justice and U.S. Court of Claims.

The Department of Treasury collects the excise tax monies from vaccine manufacturers and manages the Trust Fund's investments. As of June 30, 2014, the surcharge on each dose of vaccine is 75 cents [13] and there is about $3 billion remaining in the Trust Fund. [14]

Presumption of Causation in VICP to Avoid Adversarial Proceedings. The key to creating a no-fault, non-adversarial federal compensation alternative to a lawsuit in the proposed 1986 legislation was that the VICP would avoid compelling most plaintiff's to prove "causation in fact," which is the standard used in personal injury and product liability lawsuits filed in the tort system. During the legislative process, the VICP was characterized practically and ethically as a political solution for a complex and controversial public health policy issue:

- the federal government recommends and state governments mandate that children receive certain vaccines, which carry a risk of injury or death that can be greater for some than others;

- when children are left with permanent vaccine injuries or die after receipt of government recommended and mandated vaccines, government has a legal and ethical duty to offer financial support for those children.

There was to be a "presumption" of causation in the absence of a more biologically plausible explanation for the child's brain injury or death following vaccination in order for (1) parents to want to select the no-fault, non-adversarial federal compensation alternative as the preferred legal option for obtaining compensation for their vaccine injured children, thereby reducing product liability and malpractice lawsuits; and (2) to make the VICP less burdensome than a long, contentious, expensive and emotionally draining lawsuit for families caring for a severely vaccine injured child.

NVIC HAS MONITORED AND REPORTED ON IMPLEMENTATION OF THE VICP

Since the Vaccine Injury Act was passed in 1986, NVIC has monitored and reported publicly on the law's implementation, including to Congress and in public comment and presentations to the National Vaccine Advisory Committee (NVAC) and the Advisory Commission on Childhood Vaccines (ACCV).

In 1999, NVIC Co-founder and President Barbara Loe Fisher testified in Congress and also submitted written testimony outlining concerns about the operation of the VICP. [15] [16] In 2008, after DHHS requested that the Institute of Medicine conduct another review of the medical literature related to vaccine adverse events, she gave a presentation to the Advisory Commission on Childhood Vaccines (ACCV) entitled "Vaccine Injury Compensation Program: A Failed Experiment in Tort Reform?" [17] In the past few years, NVIC Executive Director Theresa Wrangham has been monitoring ACCV meetings and offering public comment on behalf of NVIC that reinforce our long standing criticism of the way that the VICP is being operated. [18] [19]

TOO MANY CHILDREN DENIED VACCINE INJURY COMPENSATION

Steps taken over the past three decades by the Department of Health and Human Services, [20] Department of Justice [21] and special masters in the U.S. Court of Claims [22] have resulted in unjust limitation of the numbers of children receiving vaccine injury compensation after receipt of federally recommended or state mandated vaccines. **Three out of four VICP petitioners are denied awards.** Since 1988, there have been 15, 269 claims filed; 9,786 claims dismissed, and 3,645 compensated as of July 1, 2014. [23]

It is both shocking and telling that in a federal program created by Congress to provide financial assistance to children injured by government recommended and mandated vaccines, today only 20% of the total number of compensation awards are made to children while 80% are for adults. [24] ***Currently, there are twice as many adult plaintiffs filing petitions for federal vaccine injury compensation than child plaintiffs.*** [25]

Having worked hard to protect the legal rights of vaccine injured children and their parents when Congress took action in the early 1980's to "protect the vaccine supply" after drug companies threatened to stop making childhood vaccines if they were not given liability protection, we are extremely disappointed by the failure of the 1986 law to fulfill the promises made to parents during the legislative process. We are deeply troubled by what has happened to a program that was sold to the American people as a no-fault, non-adversarial *alternative* to a civil product liability or malpractice lawsuit involving drug companies marketing federally recommended and state mandated childhood vaccines and pediatricians administering those vaccines to children in the U.S.

RECOMMENDED CHILD VACCINE SCHEDULE VERY DIFFERENT TODAY

Federal vaccination recommendations for children today are very different from what they were when the Childhood Vaccine Injury Act was passed by Congress. In 1986, the CDC recommended that pediatricians give 23 doses of seven vaccines (DPT, MMR, OPV) to infants and children between two months and six years of age. [26] At the time, most states mandated that children receive those seven vaccines prior to entering kindergarten. Since 1981, there has been a 95% plus vaccination rate for those seven vaccines among children entering kindergarten, which continues today. [27] [28]

CDC officials now direct pediatricians to give children 69 doses of 16 vaccines beginning on the day of birth through age 18, with 49 doses of 14 vaccines given by age six. [29] This represents a tripling of the numbers of doses of federally recommended vaccinations given to children.

The 2014 federally recommended child vaccine schedule also represents a doubling of the number of vaccines that have been added to the list of vaccines covered under the VICP since 1986. Yet, significantly, very few signs and symptoms of vaccine reactions and injuries related to the new vaccines have been added to the Vaccine Injury Table.

In addition to a tripling of the numbers of federally recommended vaccinations since 1986, there have been concomitant increases in federal funding of financial incentives for state governments to achieve high coverage rates with all federally recommended vaccines through congressionally appropriated Section 317 grants. [30] [31] States with higher vaccine coverage rates receive "bonus" awards from the incentive grants as a reward and, according to a 2000 Institute of Medicine report, some state health officials have indicated they are being "punished" financially when their vaccine coverage rates are lower than those of other states. [32]

These federally initiated financial incentives, rewards and sanctions have encouraged state health officials to mandate or lobby legislatures to add every new federally recommended vaccine to state mandates. Vaccine mandates for children have more than doubled in most states since 1986. [33]

ELIMINATION OF VACCINE CONTRAINDICATIONS AND EXEMPTIONS: POTENTIAL EFFECT ON THE VICP

In the past decade, federal health officials have also recommended that adults be legally required to receive federally recommended vaccines, such as annual influenza vaccinations, as a condition of employment.[34] Further, public health officials [35] [36] and medical trade associations [37] are now aggressively advocating for the elimination or restriction of vaccine exemptions in state vaccine laws, including religious and conscientious or philosophical belief exemptions,[38] even though there is evidence that restrictiveness of non-medical vaccine exemptions in states does not have a significant impact on lowering infectious disease rates. [39]

At the same time, federal health officials and medical trade groups have narrowed or eliminated many medical contraindications to vaccination in the absence of scientific evidence defining biological, genetic and environmental risk factors for individuals more susceptible to suffering vaccine injuries. Today, very few medical conditions qualify as a reason to defer or withhold vaccines,[40] [41] even for the immunocompromised,[42] while some "no exceptions" mandatory vaccination proponents are also calling for a restriction of legal medical exemptions to vaccination, as well. [43]

One adverse effect of "no exceptions" implementation of one-size-fits-all vaccine policies for both children and adults is to increase vaccine risks for susceptible individuals, which will also increase the numbers of petitioners filing petitions for federal vaccine injury compensation in the future.

VACCINE PRICES HAVE INCREASED SINCE 1986 DESPITE EXISTENCE OF VICP

In pressing Congress for a liability shield in 1986, which prompted Congress to give the pharmaceutical industry a liability shield and create the VICP, drug companies marketing vaccines in the U.S. told Congress that if product liability litigation costs were reduced, childhood vaccine prices also would be reduced and contained. Just the opposite has occurred in the past three decades since the VICP was created under the 1986 Childhood Vaccine Injury Act.

In 1986, it cost $80 for a child to receive all federally recommended childhood vaccines in a private pediatrician's office. [44] By 2013, that cost had risen to $2,300 per child. [45] According to the CDC, the cost to vaccinate one child with every recommended vaccine at federal contract prices also skyrocketed 2500% between 1990 and 2012, escalating from $70 to $1,700 per child. [46]

Although much of this per child cost increase reflects the growing list of new vaccines federally recommended for children (as well as increases in total numbers of doses of vaccines recommended)

since the Childhood Vaccine Injury Act became law, even the per dose costs for purchase of the seven vaccines (DPT, MMR, polio) originally covered by the VICP in the 1986 law have continued to rise.

DHHS congressional budget requests for CDC childhood immunization expenditures increased from $1 billion in 1997 [47] to $4.8 billion in 2014. [48] Since 1993, congressional appropriations for the Vaccines for Children (VFC) program created under the Childhood Immunization Act of 1993 have been earmarked for CDC to purchase vaccines from drug companies for administration to Medicaid-eligible and uninsured or underinsured children. Today the VFC program constitutes nearly half of the CDC's $11 billion dollar annual budget. [49]

The federal government has become the single biggest purchaser of vaccines from drug companies and a number of state governments have also become direct purchasers of vaccines for both adults and children from drug companies at federal contract prices for all vaccines administered in the state. [50] This has the effect of securing advance commitments for vaccine manufacturers while significantly cutting their direct marketing costs to doctors, pharmacies, insurers and other providers and distributors of vaccines in the state. Under the Affordable Health Care Act (ACA) insurance companies are required to provide federally recommended vaccines to children and adults without deductibles or co-pays. [51]

The creation of a federal vaccine injury compensation program, along with the liability shield given to the pharmaceutical industry by Congress in 1986 and by the U.S. Supreme Court in 2011, has ensured that vaccine manufacturing and marketing in the U.S. is profitable for drug companies [52] [53] [54] [55] but has not led to a reduction or containment of health care costs for vaccine purchase. [56] [57]

VICP NOW AN "EXCLUSIVE" LEGAL REMEDY

Against this backdrop of increasing vaccine recommendations, increasing vaccine costs and restriction of vaccine contraindications and exemptions, today the VICP is no longer an ***alternative*** to a civil lawsuit for injuries or deaths caused by government recommended and mandated vaccines like it was when the 1986 law was passed by Congress. In a split decision for *Bruesewitz v Wyeth*, on Feb. 22, 2011 the U.S. Supreme Court referred to vaccines as "unavoidably unsafe" and effectively made the VICP the *exclusive legal remedy* for all Americans experiencing life-altering or fatal injuries from use of *any* vaccine that is *federally licensed and recommended for children.* [58]

This "unavoidably unsafe" product liability protection now extends to companies even when plaintiffs have evidence that an FDA licensed and CDC recommended vaccine was defective in design and could have been made less harmful by the company. In an insightful dissenting opinion, Justice Sonia Sotomayor was joined by Justice Ruth Bader Ginsburg in accurately describing and interpreting the legislative history of the 1986 National Childhood Vaccine Injury Act.

In the *Bruesewitz v. Wyeth* dissenting opinion conclusion, Justice Sotomayor warned:

> ***"The majority's decision leaves a regulatory vacuum in which no one – neither the FDA nor any other federal agency, nor state and federal juries – ensures that vaccine manufacturers adequately take account of scientific and technological advancements. This concern is especially acute with respect to vaccines that have already been released and marketed to the public. Manufacturers, given the lack of robust competition in the vaccine market, will often have little or no incentive to improve the designs of vaccines that are already generating significant profit margins. Nothing in the text, structure or legislative history remotely suggests that Congress intended that result."*** [59]

Currently, all that is required for a pharmaceutical corporation to secure a liability shield for a newly licensed vaccine is to persuade public health officials at the Centers for Disease Control (CDC) to add the vaccine to the growing list of federally recommended vaccines for children which, in most cases, are now also recommended for adults. As a result, *almost every pharmaceutical corporation* marketing government licensed, recommended and mandated vaccines in the U.S. today is shielded from product liability and accountability in the civil justice system.

It is important to note that a number of vaccines recommended, mandated and added to the VICP since 1986 are for infectious diseases that do not meet the "compelling state interest" public health policy standard applied to the first government recommended and mandated vaccine, smallpox. Smallpox was a publicly communicable disease with a significant rate of complications and morbidity while, for example, varicella (chickenpox), rotavirus (infant diarrhea) and hepatitis A (diarrhea related to poor sanitation) [60]rarely cause injury or death in the U.S. and other diseases, such as hepatitis B and HPV, [61] cannot easily be transmitted in public.

FUTURE NEW VACCINES WILL BE AUTOMATICALLY ADDED TO VICP

Since 2001, the financial public-private partnerships that have been created between federal health and defense agencies and pharmaceutical corporations selling vaccines [62] [63] has led to the construction of new vaccine production facilities for drug companies [64] and the creation of hundreds of experimental vaccines.[65] Many of these new viral and bacterial vaccines are genetically engineered using novel cell substrates and adjuvants for production, which have the potential to raise known but also unknown risks for individuals, communities and the environment. [66] [67]

Most newly licensed vaccines will be recommended by the CDC for "universal use" by all children and some may be fast tracked to licensure by FDA with altered standards for proof of safety and effectiveness prior to licensure. [68] [69] If most vaccines currently in development are federally recommended for children in the future and most are also recommended for adults, then the VICP becomes the only legal remedy for *all* Americans suffering vaccine injuries and deaths after newly licensed vaccines are put on the market, even if there is evidence demonstrating that a drug company could have made a vaccine less harmful.

There is no other for-profit and publicly traded manufacturing industry in America that enjoys this kind of blanket liability protection for products, which not only carry a risk of injury or death but also are recommended and mandated by government.

THE BAR HAS BEEN RAISED FOR FEDERAL AGENCIES AND U.S. COURT OF CLAIMS AND LEGALLY AND ETHICALLY IT MUST BE MET

In light of the fact that pharmaceutical corporations selling federally recommended and state mandated vaccines used by hundreds of millions of Americans are not legally liable in the tort system for injuries or deaths that occur from use of their products – even if there is evidence they could have made the product safer - the bar for those responsible for operating the VICP has been raised substantially to adhere to the spirit and intent of the 1986 law. That bar is exponentially raised every time a new vaccine is licensed by the FDA and recommended by the CDC for universal use by all children in the absence of scientific knowledge about exactly who is individually more susceptible to suffering harm from use of the vaccine.

For the past two decades, officials in the U.S. Department of Health and Human Services (DHHS), attorneys in the Department of Justice and special masters in the U.S. Court of Claims rendering judgments about vaccine injuries and deaths have too often failed to operate the VICP in a way that

adheres to the spirit and intent of the National Childhood Vaccine Injury Act. This is a betrayal of trust that parents of vaccine injured children placed in the legislative process in the 1980's and, today, it is having profound implications for all Americans required to adhere to federal vaccine policies that affect their ability to obtain an education, health insurance, medical care and employment.

The failure of federal agencies and the U.S. Court of Claims to implement the federal vaccine injury compensation program in a way that adheres to the original spirit and intent of the National Childhood Vaccine Injury Act is a betrayal of all Americans for whom the risks of using government recommended and mandated vaccines turns out to be 100 percent.

BIODIVERSITY, INDIVIDUAL SUSCEPTIBILITY BEING IGNORED

The fact that the VICP has become the *exclusive remedy* and not a legal *alternative* to the tort system gives vaccine manufacturers, policymakers and providers a free pass whenever individuals are injured or die after receiving federally recommended vaccines, including individuals with high risk factors that make them more vulnerable to suffering harm from vaccines. Lack of rigorous scientific investigation by vaccine manufacturers into defining *prior to licensure* the biological mechanisms and individual high risk factors for vaccine injury and death places susceptible individuals at great risk whenever they receive federally recommended and state mandated vaccines. [70] [71]

In this regard, the Institute of Medicine (IOM) pointed out in a series of published reports between 1991 and 2013 that there are known and unknown risk factors, which increase an individual's susceptibility to suffering vaccine reactions that may lead to permanent injury or even death. However, most of these high risk factors are not identified prior to vaccination in part due to significant gaps in scientific knowledge about the biological mechanisms for complications of vaccination and the reasons for why responses to vaccination differ between individuals.

1991 IOM REPORT ON PERTUSSIS AND RUBELLA VACCINES

Between 1991 and 1994, the Institute of Medicine published the first of three reports about the adverse effects of federally recommended childhood vaccines as directed by Congress in the 1986 National Childhood Vaccine Injury Act. The first report, *Adverse Effects of Pertussis and Rubella Vaccines,* confirmed that DPT and rubella vaccines are associated with serious side effects. [72]

The 1991 IOM Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines found enough quality scientific evidence to conclude that:

- "Evidence is consistent with a **causal relation between DPT vaccine and acute encephalopathy and shock and 'unusual shock-like state;**
- "Evidence indicates **a causal relation between DPT vaccine and protracted, inconsolable crying;**
- "Evidence is consistent with a **causal relation between rubella vaccine and chronic arthritis"**
- "Evidence indicates **a causal relation between rubella vaccine and acute arthritis."**

Insufficient Scientific Studies to Make Causation Conclusions: However, the IOM committee was unable to make a determination about *whether or not* DPT vaccine can cause 10 other reported adverse events, including:

- aseptic meningitis;
- chronic neurological damage;
- erythema multiforme or other rash;
- Guillain-Barre syndrome;
- hemolytic anemia;
- juvenile diabetes;
- learning disabilities and attention deficit disorder;
- peripheral mononeuropathy; and
- thrombocytopenia

This inability to make a causation conclusion was due to the fact that the Committee found insufficient "relevant evidence" in the medical literature "to indicate *whether or not* a causal relation exists" between a particular vaccine and reported adverse effect. [This "insufficient evidence" determination in the 1991 report was misinterpreted and continued to be misinterpreted in subsequent IOM reports by some as evidence for "no causation" when, in fact, it is an acknowledgement that there is either a complete absence of or too few biological mechanism and methodologically sound epidemiological studies examining the relationship between the vaccine and a particular adverse health outcome.]

Encephalopathy Defined. Significantly, the 1991 IOM committee identified a causal relationship between DPT vaccine and acute encephalopathy and went into great detail when describing scientific definitions of encephalopathy. In the report, the committee noted that "acute or subacute encephalitis, encephalomyelitis and encephalopathy" were used in various published studies to describe a "constellation of symptoms and signs reflecting a generalized disturbance in brain function" that may include:

- altered levels of consciousness;
- confusion;
- irritability;
- headaches;
- changes in behavior;
- screaming attacks;
- neck stiffness;
- sudden onset of convulsions;
- visual, auditory or speech disturbances;
- motor and sensory deficit;
- other neurological abnormality of the brain.

Many Gaps in Scientific Knowledge. The 1991 IOM report also for the first time pointed out to the medical community and the public that there is a serious lack of quality basic science research and methodologically sound epidemiological studies evaluating the mechanisms and frequency of vaccine adverse events. This knowledge gap hampered the IOM committee's investigation into reported serious health problems associated with the two federally recommended childhood vaccines (DPT, rubella). The committee stated:

> ***"In the course of its review the committee found many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines. Such***

shortcomings relate, for example, to pathologic mechanisms of specific infectious agents, the molecular basis for vaccine injury, and the natural history of conditions such as encephalopathy, mental retardation and chronic arthritis." [73]

The IOM committee went on to issue a prophetic warning:

"Many of the reports of case series suffer from inadequate or inconsistent case definitions, variable details about cases, inclusions of non-representative case groups and failure to consider potential confounding variables or biases. In addition, existing surveillance systems of vaccine injury have limited capacity to provide persuasive evidence of causation. Many of the population-based epidemiologic studies are too small or have inadequate lengths of follow-up to have a reasonable chance of detecting true adverse effects, unless these effects are large or occur promptly and consistently after vaccination. ***If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped."***

1993: DHHS MOVES TO REVISE VICP TABLE, LIMIT VACCINE INFORMATION

In 1993, DHHS officials lobbied for federal legislation that would make substantial changes to vaccine compensation and safety provisions in the 1986 Childhood Vaccine Injury Act. Notably, the Comprehensive Child Immunization Act of 1993 created:

- the Vaccines for Children (VFC) program;
- established state vaccine tracking registries;
- required states to establish child immunization rate goals; and
- authorized financial grants to states that exceeded those goals.

However, the Comprehensive Child Immunization Act of 1993 also changed requirements for DHHS to revise the VICP Vaccine Injury Table. [74] Also in 1993 DHHS supported the Preventive Health Amendments (PL 103-183) that weakened vaccine safety provisions in the 1986 law by reducing the amount of information about vaccine risks contained in vaccine information materials published by CDC for pediatricians to provide to parents. [75]

1994 IOM REPORT ON ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES

The Institute of Medicine issued two important reports in 1994 and both fell within the congressional vaccine research mandate under the 1986 law for IOM to review the relevant scientific and medical literature for evidence there are health risks to children associated with federally recommended vaccines. The first 1994 IOM report *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality* examined scientific evidence related to seven federally recommended childhood vaccines: diphtheria, tetanus, measles, mumps, polio, hepatitis B and H. influenza type b (Hib) vaccines, including:

- circumstances under which administration of these vaccines increases the risk of an adverse event;
- characteristics of groups known to be at increased risk of an adverse event; and
- timing of vaccination that increases the risk of an adverse event.

In *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality,* the IOM again acknowledged that federally recommended vaccines for children can cause serious reactions which

can result in permanent brain and immune system dysfunction or death for some individuals. [76] Among the causation findings, the IOM Vaccine Safety Committee stated:

- "The evidence favors acceptance of a **causal relation between DT and Guillain-Barre syndrome (GBS) and brachial neuritis**;
- " The evidence favors acceptance of a **causal relation between oral polio vaccine and Guillain-Barre syndrome (GBS);**
- "The evidence establishes a **causal relation between measles vaccine and vaccine-strain viral infection;**
- "The evidence establishes a **causal relation between measles-mumps-rubella vaccine and thrombocytopenia**;
- "The evidence establishes a **causal relation between oral polio vaccine and poliomyelitis and death from polio vaccine-strain viral infection**.

However, for more than 30 reported serious brain and immune system problems associated with the seven federally recommended vaccines under examination, the committee was unable to come to a conclusion about *whether or not* there was a causal relationship. Once again, an IOM committee was frustrated by gaps in vaccine safety science and made statements such as:

> ***"For the vast majority of vaccine-adverse event relations studied, the data came predominantly from uncontrolled studies and case reports."*** [77]

This 1994 report echoed concerns expressed in the 1991 IOM report about lack of scientific knowledge about vaccine adverse events and why there is individual susceptibility to suffering vaccine harm:

> **"*The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meetings indicated that many parents and physicians share this concern….The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not. When it is clear that a vaccine can cause a specific adverse event, research should be encouraged to elucidate the factors that put certain people at risk for that adverse reaction."*** [78]

In a concluding chapter "Need for Research and Surveillance," the committee pointed out one vaccine safety science gap that is a barrier to making causality conclusions, a science gap which has been echoed by parents of vaccine injured children seeking information about potential differences in health outcomes between children who do and do not receive one or more federally recommended vaccines:

> ***"The committee found that a judgment regarding causality was often limited by the absence of background data for the occurrence of the pathologic condition (the putative adverse event) in apparently normal individuals not recently exposed to the vaccine."*** [79]

This lack of background data for the occurrence of chronic brain and immune system disorders in unvaccinated children or those receiving fewer vaccines, such as learning disabilities, ADD/ADHD and

other developmental delays; seizure disorders; asthma; severe food allergies and other chronic health problems, continues to hamper causality conclusions about vaccine adverse events.

1994 IOM REPORT ON DPT & CHRONIC NERVOUS SYSTEM DYSFUNCTION

The second report issued by IOM in 1994, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* was groundbreaking. [80] This report affirmed the conclusions of the *National Childhood Encephalopathy Study (NCES)* published by the British government in 1981. [81]

More than three decades after *NCES* was published, it remains the largest well-conducted prospective, case controlled study of neurological disorders in children. The *NCES* included evaluation of cases of acute and chronic encephalopathy that developed after children received DPT or measles vaccines and, in 1981, *NCES* authors concluded that receipt of DPT vaccine was causally related to the development of acute encephalopathy (encephalitis, encephalomyelitis) and permanent brain damage in some previously healthy children enrolled in *NCES*, as well as those with underlying brain or metabolic disorders after the DPT vaccine "triggered" expression of the underlying disorder.

Attributable risk estimates in for participants in *NCES* were that:

- **1 in 110,000 DPT shots was followed by an acute encephalopathy within seven days of administration of the vaccine**; and

- **1 in 310,000 DPT shots was followed by persistent neurological damage one year later.**

It is notable that in 1981, the same year that the *NCES* was published confirming that DPT vaccine can cause acute and chronic encephalopathy, an FDA-sponsored case controlled study conducted at UCLA was published reporting the results of a head-to-head comparison of the reactivity of whole cell DPT vaccines and DT vaccines. [82] That U.S. study found that DPT vaccine was far more reactive than DT vaccine and estimated that **1 in 1,750 DPT shots was followed by a convulsion or a hypotonic-hyporesponsive episode (HHE**).

In 1993, *NCES* authors published a 10-year follow up of the children, who had developed an acute encephalopathy after DPT vaccination during the study. [83] They found that many of the children were continuing to suffer clinical symptoms of neurologic, behavioral, educational, motor, sensory and self care dysfunctions, including:

- low scores for global educational abilities assessed by intelligence, vocabulary, spelling, reading and arithmetic tests;
- epilepsy/seizure disorder;
- tremor;
- fine or gross motor incoordination;
- muscle weakness or spasticity in one or more limbs;
- hearing and vision problems;
- behavioral dysfunction (problem, hyperactive or unsociable behavior);
- lack of bladder or bowel control.

The *NCES* authors said:

> ***"Our results provide good evidence that illnesses such as those studied in the national childhood encephalopathy study, including a variety of encephalopathies***

and severe convulsions, both febrile and afebrile, can have lasting sequelae as measured by various indices of brain function. This seems to be true for cases associated in time with diphtheria, tetanus and pertussis immunization as for other cases." [84]

The 1994 IOM Committee to Study New Research on Vaccines reviewed the 10-Year follow up of *NCES* and determined that, in addition to the evidence about acute and chronic encephalopathy they had collected for the 1991 IOM report on DPT vaccine, there was compelling scientific evidence to conclude that children with or without underlying brain or metabolic abnormalities can experience an acute encephalopathy within 7 days after receipt of DPT vaccine and go on to suffer chronic neurological dysfunction.

The IOM committee stated:

"The NCES data are consistent with the possibility that some children without underlying brain or metabolic abnormalities might experience serious acute neurologic illness within 7 days after receiving DPT and that acute illness could have chronic nervous system sequelae. The NCES data are also consistent with the possibility that some children with underlying brain or metabolic abnormalities (which foster a "triggering" by DPT of an acute neurologic illness) might go on to develop chronic neurological dysfunction due to a DPT-triggered acute illness. Therefore, the committee concludes that the balance of evidence is consistent with a causal relation between DPT and the forms of chronic nervous system dysfunction described in the NCES in those children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccine." [85]

1995: DHHS INVOKES RULE MAKING AUTHORITY TO WEAKEN VACCINE INJURY TABLE AND MAKE OBTAINING COMPENSATION MORE DIFFICULT

When the Vaccine Injury Table (VIT) was included in the VICP legislation in 1986, there were only seven federally recommended and state mandated childhood vaccines: diphtheria, tetanus, pertussis (DTP); measles, mumps, rubella (MMR); and oral polio vaccine (OPV). The Table was created to include clinical symptoms of vaccine complications and time periods within which those symptoms were most often manifested to serve as a guide for awarding no-fault, non-adversarial, expedited vaccine injury compensation.

The VIT was the centerpiece of the federal compensation system alternative to a civil lawsuit: there was to be a *presumption of causation* by DHHS and Justice in the absence of a more biologically plausible explanation when plaintiff's presented evidence for an "on-Table' vaccine injury.

Despite scientific evidence by 1995 that vaccines can cause acute and chronic encephalopathy and other kinds of brain and immune system disorders even though significant gaps in scientific knowledge about all of the potential biological mechanisms of vaccine injury and death remained, in 1995 the then-Secretary of DHHS moved to wield "discretionary authority" and substantially revise the Vaccine Injury Table. This action served to make the VICP process more adversarial and substantially reduce compensation awards.

On Feb. 8, 1995, the Final Rule was published in the *Federal Register.* [86] Among the major changes DHHS made to the Vaccine Injury Table, which changed the VICP from a non-adversarial to an adversarial proceeding was:

- The removal of seizure disorder and hypotonic/hyporesponsive episodes (HHE) from the Table;
- The re-writing of the definition of encephalopathy.

In particular, the re-writing of the definition of encephalopathy for the purpose of disqualifying many children from receiving "no-fault, non-adversarial" federal vaccine injury compensation - children who had experienced classic symptoms of acute and chronic encephalopathy following vaccination - was seen as a betrayal of trust by parents who had participated in creation of the Childhood Vaccine Injury Act.

Encephalopathy: The Most Serious Compensable Event. The centerpiece of the Vaccine Injury Table was a list of clinical symptoms associated with acute and chronic encephalopathy. Not only can acute encephalopathy give evidence for brain inflammation (encephalitis, [87] [88]encephalomyelitis [89]) but chronic encephalopathy can result in the most serious manifestations of brain injury, which range from minimal brain dysfunction, such as multiple learning disabilities and ADHD, to medication resistant seizure disorders, developmental and behavior disorders and profound mental retardation. [90]

Three long-recognized neurological symptoms of acute encephalopathy in the scientific literature are sudden onset of convulsions (seizures); high pitched screaming *(cri encephalique*) that is a manifestation of cerebral irritation and altered state of consciousness. A long-recognized neurological symptom of chronic encephalopathy in the medical literature is chronic brain inflammation that may include residual seizure disorder, which over time leads to irreversible brain damage. This kind of catastrophic brain damage in a child can render the child incapable of functioning independently in society as an adult, requiring lifelong economic support.

While the original definition of encephalopathy in the VIT when the 1986 law was enacted was defined as "*any acute or chronic significant acquired abnormality of, or injury to, or impairment of function of, the brain,"* the new VIT definition of acute encephalopathy re-written by DHHS in 1995 became "*a significantly decreased level of consciousness lasting for at least 24 hours."* And DHHS went further: the Table now specifically excluded clinical signs and symptoms of acute encephalopathy that have been reported in the medical literature to be associated with encephalopathy for a century, including a sign of brain inflammation (encephalitis) that had, by 1991, been acknowledged by the Institute of Medicine as being causally associated with DPT vaccine: protracted inconsolable crying (includes high pitched screaming or *cri encephalique*).

Since 1995, the DHHS-altered Vaccine Injury Table states:

> "*The following clinical features alone or in combination do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy."*

Under rule making authority, the action by DHHS in 1995 to remove long recognized symptoms of acute and chronic encephalopathy, including seizures, from the Vaccine Injury Table was the first in a series of actions that DHHS and Department of Justice (DOJ) took after the 1991 and 1994 IOM reports that signaled a return to the position both agencies took before Congress passed the 1986 law. **Before and after the 1986 law, DHHS and DOJ have been opposed to government acknowledgement of vaccine injuries and deaths that would require awarding of federal vaccine injury compensation.**

A Radically Changed and More Adversarial VICP. Commenting on the 1995 VIT changes by DHHS and the effect on operation of the VICP, George Washington University law professor Peter Meyers wrote in 2011:

> *"According to former Chief Special Master Gary J. Golkiewicz, the 1995 rule change did produce a tremendous change in the nature of the vaccine claims litigated in the program." In the first few years, practically all cases involved only satisfying the Table requirements and adjudicating whether another factor unrelated to the vaccine was the likely cause of the injury. With the changes in the Table and the subsequent addition of many new vaccines without any Table injuries, the focus of vaccine case adjudication is now dramatically different.*
>
> *Ninety percent of vaccine cases are now causation-in-fact cases." The Table was intended to be a crucial innovation, a key to the quick, hospitable, and less adversarial Vaccine Act proceedings. It is now central to only a small minority of cases. The Table has little significance in resolving the overwhelming majority of vaccine cases that come before the court today. The recent focus on causation-in-fact cases has also generated other major changes in the nature of the Vaccine Injury Program.*
>
> *First, the cases are substantially more difficult and complex to litigate. The special masters have much more challenging scientific disputes to resolve in these cases than they do for Table claims. Second, both sides need to locate experts in cutting-edge areas, where substantial uncertainty still exists.*
>
> *For the old Table injuries, a neurologist would testify whether a petitioner's injury did or did not meet the definition of encephalopathy listed in the Table, and its Qualifications and Aides to Interpretation, and whether the onset of the injury did or did not occur within the time period required by the Table. In off-Table cases, the experts now have to present much more complex testimony concerning whether the vaccine was the likely cause of the problems that the petitioner subsequently experienced.*
>
> *The complex off-Table cases that now predominate in the Vaccine Compensation Program also proceed more slowly than the simpler Table injury cases, and typically result in more adversarial litigation than Table cases because the parties and their experts usually begin from polar opposite positions. The relatively easy question of determining whether an injury satisfies the Table criteria has become the much more difficult question of whether a vaccine in fact caused an injury.*
>
> *These changes have encouraged the type of adversarial litigation that the Vaccine Injury Act was designed to minimize."*

Since the 1995 Vaccine Injury Table changes were made by DHHS, dozens of doses of eight new vaccines have been added to list of federally recommended vaccines for children, which are now compensable under the VICP, but there have been very few compensable vaccine injuries or symptoms of vaccine reactions added to the VIT.

1995-2005: MORE IOM REPORTS AND CONTROVERSY

After 1995, as the VICP became more adversarial and new childhood vaccines were added to the federally recommended childhood vaccine list to prevent infectious diseases that were either (1) not highly endemic among children in the U.S. or (2) easily communicable in a public setting (hepatitis B) or

(3) did not cause a high rate of significant complications and mortality (chickenpox), more parents began asking questions about federal vaccine policy recommendations and vaccine safety science.

IOM Vaccine Safety Forum (1995-1998). In 1995, DHHS (National Vaccine Program Office) contracted with IOM in the first of a series of public engagement initiatives that would bring vaccine stakeholders together to discuss vaccine safety issues. The IOM Vaccine Safety Forum was established in 1995 "to examine critical issues relevant to the safety of vaccines used in the United States and to discuss methods for improving the safety of vaccines and vaccination programs."

Individuals appointed to the Vaccine Safety Forum included representatives from federal agencies responsible for regulating vaccines and implementing vaccine policies; vaccine manufacturers; physicians; academic researchers and parent or consumer groups with an interest in vaccines. The members of the IOM Vaccine Safety Forum, which included NVIC co-founder Barbara Loe Fisher, worked together between 1995 and 1998 to coordinate public workshops that culminated in published reports on vaccine safety, research and risk communication topics. [91] [92] [93]

IOM Immunization Safety Reviews (2001-2004). In 2001, DHHS (CDC and NIH) contracted with Institute of Medicine to establish an Immunization Safety Review Committee to evaluate available evidence on a number of vaccine safety concerns being publicly discussed that impacted on implementation of federal vaccine policies. For each vaccine adverse event hypothesis examined, the IOM committee was charged by DHHS with assessing the scientific evidence and significance of the issue for society.

This charge by DHHS to IOM was different than those made to previous IOM Committees conducting congressionally mandated reviews of vaccine safety science under the 1986 Childhood Vaccine Injury Act. DHHS directed the IOM to examine epidemiological and clinical evidence regarding an hypothesis for a possible causal relationship between the vaccine and an adverse event, along with "experimental evidence for any biological mechanisms relevant to the hypothesis." DHHS simultaneously charged the IOM committee with making a "significance assessment" addressing the burden of health risks associated with the vaccine-preventable disease and with the adverse event in question, as well as the level of public concern about the safety issue.

The meshing together of a request for impartial evaluation of the scientific evidence regarding vaccine adverse events essentially viewed through a prism of DHHS concerns about federal vaccine policy implementation was perceived as conflicting and political by the informed public. Young parents with children who had regressed after vaccination into chronic poor health, including those considering filing a petition in the VICP, were especially concerned. In 2001, many more parents were asking questions about whether there is a relationship between increases in the numbers of federally recommended vaccines for children and increases in the numbers of children suffering with vaccine-related chronic health problems. [94]

The IOM Immunization Safety Review Committee published a series of eight reports between 2001 and 2004 examining a range of vaccine safety questions from the relationship between Thimerosal-containing vaccines and neurodevelopmental disorders [95] or MMR vaccines and autism [96] to hepatitis B vaccine and demyelinating neurological disorders [97] and influenza vaccines and neurological complications. [98] Some of the report conclusions were very controversial and generated public debate, particularly the last report published in 2004 on vaccines and autism that suggested no further research into the relationship between autism and vaccines should be funded. [99]

2005 IOM Report on Vaccine Safety Research, Data Access and Public Trust. In 2004, DHHS (CDC) requested that IOM establish a committee to review the design and implementation of the CDC's

new Vaccine Safety Datalink Sharing Program to assess compliance with current standards of practice for data sharing in the scientific community and make recommendations for any needed modifications.

The Vaccine Safety Datalink (VSD) was created in 1990 by CDC in affiliation with private managed care organizations, including Kaiser Permanente. It is a large linked database that includes non-personally identifying medical information and vaccination histories on more than five million Americans enrolled in eight private health maintenance organizations (HMO). Since 1991, CDC officials and physicians associated with the private managed care organizations providing information on HMO participants that populates the VSD database have utilized retrospective analyses of VSD data to make conclusions about vaccine safety in a number of published studies. [100]

Some of the studies utilizing VSD data, which have been conducted by the CDC or individuals affiliated with participating HMO's, have been questioned by parent groups. By 2002, several independent researchers seeking access to the VSD database for the purpose of replicating published studies utilizing VSD data alleged that they were being unfairly denied access to the VSD database.

In 2005, the IOM Committee on the Review of the National Immunization Program's Research Procedures and Data Sharing Program published a report, *Vaccine Safety Research, Data Access, and Public Trus*t. [101] The IOM Committee concluded that:

> ***"There are legitimate concerns about the independence and fairness of the implementation of review procedures applied to VSD data sharing proposals and of determination about the release of preliminary findings from VSD analyses. The lack of transparency of some of the processes also affects the trust relationship between the National Immunization Program Office (NIP) and the general public."***

Among other recommendations, the 2005 IOM Committee said that:

> **"*to give the full array of stakeholders an opportunity to provide input into the VSD research plan priority-setting process and to ensure that the process is as transparent as possible, an independent group should be used to review and provide advice on the VSD research plan."* [102]**

2002-2009: OMNIBUS AUTISM PROCEEDING IN U.S. COURT OF CLAIMS FLAWED

The 1995 changes to the Table of Compensable Events has forced most vaccine injury cases "off-Table," where there is no presumption of causation but a requirement to prove causation in what amounts to a trial without a jury in the U.S. Court of Claims. This has increased the power of special masters in the U.S. Court of Claims, who were at the outset simply making decisions about whether or not an individual child's vaccine injury or death was or was not eligible for federal compensation under the 1986 law.

However, by the late 1990's, the Office of the Special Masters had expanded its authority and created the concept of an "omnibus proceeding" where special masters made the decision to evaluate multiple vaccine injury claims sharing similar characteristics and adverse health outcomes and made scientific judgments about causation that affected disposition of all the cases. An omnibus proceeding was held in the U.S. Court of Claims in 1992-1993 on whether rubella vaccine can cause chronic arthritis and another omnibus proceeding was organized by the special masters in 2006 focusing on whether hepatitis B vaccine can cause demyelinating disorders..

In 2002, the Office of Special Masters, DHHS, Department of Justice and plaintiff's lawyers agreed to hold an Omnibus Autism Proceeding (OAP) that examined three biological mechanism hypotheses forwarded by plaintiff attorneys that:

- MMR vaccines and Thimerosal-containing vaccines can combine to cause autism;
- Thimerosal-containing vaccines alone can cause autism;
- MMR vaccines alone can cause autism.

The Autism Omnibus Proceeding involved more than 5,000 petitions filed in the VICP on behalf of children, most of whom were healthy and then regressed and developed a constellation of symptoms labeled by doctors as "autism" after receipt of MMR or Thimerosal-containing vaccines.

During the legislative process leading to development of the 1986 law, there was no public discussion among parents and other participants about the holding of omnibus proceedings by special masters in which the petitions of individual children with different genetic, biological and environmental histories, who were given different vaccines using different vaccine schedules, and who manifested different clinical signs of vaccine reaction symptoms and subsequent chronic brain and immune system dysfunction, would be lumped into a what was characterized as a homogeneous group and have their cases argued using novel biological mechanism hypotheses for the purpose of awarding or denying compensation to them.

In fact, there is no explicit authority in the Childhood Vaccine Injury Act for "omnibus" proceedings. The 1986 law was supposed to offer each individual child filing a vaccine injury claim with either (1) non-adversarial compensation for "on-Table" injuries or (2) a day in the U.S. Court of Claims to argue for why federal compensation should be awarded to that individual child based on a unique set of facts relevant to that child's vaccine reaction, despite opposition from DHHS and Justice.

In 2009, the U.S. Court of Claims declared that the plaintiff's lawyers had not proven the biological plausibility of the three novel biological mechanism vaccine injury hypotheses they had argued was the cause of autism for more than 5,000 children. The U.S. Court of Claims ruling was publicly characterized as an infallible finding of a global scientific truth [103] and, yet, that was not the authoritative role that the special masters or U.S. Court of Claims judges were qualified for or given by Congress in the 1986 Childhood Vaccine Injury Act.

It was a miscarriage of justice when the vaccine injury petitions of thousands of children with vaccine related brain and immune dysfunction labeled by doctors as "autism" were dismissed or petitioners were encouraged to withdraw their claims [104] - not based on consideration of unique evidence in each individual child's case - but based on special masters judging the merits of three narrow biological mechanism hypotheses. The fact that (1) vaccines can and do cause acute and chronic encephalopathy involving a number of known – and potentially as yet unknown – biological mechanisms and (2) the fact that a number of VICP awards have been made when vaccines other than MMR or those that are Thimerosal-containing have caused encephalopathy and subsequent neurological damage, was ignored in the conclusions of the autism omnibus proceeding. [105] [106]

Whatever the reasons for the omission of other vaccines and proven biological mechanisms for vaccine-induced chronic brain and immune system dysfunction from consideration and inclusion in the autism omnibus proceeding, it was a fatal error in judgment not to do so. The thousands of children suffering with vaccine-related autism should not be excluded from having their individual day in vaccine court and obtaining federal vaccine injury compensation because of an error in judgment.

2012 IOM REPORT ON ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY

Two decades after the first congressionally mandated 1991 Institute of Medicine (IOM) report was published, in 2012, the IOM published a report *Adverse Effects of Vaccines: Evidence and Causality* [107] again reviewing the medical literature for scientific evidence that vaccines can cause brain and immune system dysfunction that involved a total of 158 vaccine-adverse event reported associations. This time, IOM examined the following vaccines federally recommended for children: varicella zoster (chickenpox) vaccine; influenza vaccines; hepatitis B vaccine; human papillomavirus vaccine (HPV); tetanus toxoid-containing vaccines other than those containing the whole cell pertussis component; measles, mumps and rubella vaccines; hepatitis A vaccine; and meningococcal vaccines.

In 2009, the Health Resources and Services Administration (HRSA) had contracted with IOM to conduct what would become the largest assessment of epidemiologic, clinical and biological mechanism evidence about vaccine adverse event outcomes conducted by IOM since the 1986 Childhood Vaccine Injury Act became law and IOM published the 1991 and 1994 reports requested by Congress under the Act. The CDC and National Vaccine Program Office (NVPO) also contributed funding for the 2012 IOM study.[108]

The stated purpose of the 2012 study was to provide scientific basis for review and adjudication of claims of vaccine injury by the VICP. At the study outset, HRSA presented a list of specific adverse events for the committee to review, which HRSA indicated represented the majority of adverse events listed in VICP petitioner claims. During the course of its review of the medical literature, the IOM committee added to the report the following adverse events for which epidemiological studies or case reports were identified:

- all cause mortality and seizures following influenza vaccine;
- optic neuritis following MMR, influenza, hepatitis B and DTaP vaccines;
- neuromyelitis optica following MMR vaccine;
- erythema nodosum following hepatitis B vaccine;
- stroke and small fiber neuropathy following varicella vaccine.

The 2012 IOM Committee to Review Adverse Effects of Vaccines concluded that "the evidence convincingly supports" or "favors acceptance of" a causal relationship between:

- varicella vaccine and Oka varicella zoster vaccine reactivation;
- MMR vaccine and measles inclusion body encephalitis;
- MMR vaccine and febrile seizures;
- Anaphylaxis and MMR, varicella, influenza, hepatitis B, meningococcal, HPV and tetanus toxoid vaccine;
- MMR vaccine and transient arthralgia in female adults and children;
- Any of the vaccines and syncope (sudden loss of consciousness)
- Any of the vaccines and deltoid bursitis;

***Significantly, for 135 (85%) [109]of serious adverse health outcomes associated with one or more of the federally recommended vaccines under examination, there was either an absence of or too little biological mechanism evidence and/or methodologically sound epidemiologic studies related to the vaccine and reported serious adverse health outcome for the committee to make a causation conclusion*.** This lack of enough scientific evidence to make a vaccine causation determination included a wide range of brain and immune system disorders, such as:

- Encephalitis; encephalopathy; acute disseminated encephalomyelitis (ADEM); meningitis; traverse myelitis; optic neuritis; chronic inflammatory disseminated polyneuropathy; Bell's palsy; small fiber neuropathy; Guillain Barre Syndrome GBS); afebrile seizures; infantile spasms; opsoclonus/myoclonus syndrome; ataxia; first demyelinating event in children and adults;

- Onset or exacerbation of vasculitis, lupus, rheumatoid arthritis, juvenile idiopathic arthritis and psoriatic arthritis; fibromyalgia; chronic fatigue syndrome;

- Multiple sclerosis and chronic arthritis in children and adults;

- Stroke, myocardial infarction (heart attack); type 1 diabetes; pancreatitis;

- Serum sickness; chronic urticaria; sudden infant death syndrome (SIDS); autoimmune hepatitis;, amyotrophic lateral sclerosis (ALS); and

- Autism.

Like the previous IOM committees, this committee was unable to come to conclusions about causation for the majority of vaccine-related adverse health outcomes because of continuing gaps in scientific knowledge about the biological mechanisms for vaccine adverse effects. Chapter 3 "Evaluating Biological Mechanisms of Adverse Events" is a thoughtful description of the outstanding biological mechanism questions that need to be answered before there can be a better understanding of how and why vaccines can cause acute and chronic brain and immune system dysfunction and death.

Among the vaccine knowledge gaps the report highlighted was a lack of understanding of biological, genetic and other high risk factors, which increase an individual's susceptibility to vaccine reactions:

> ***"Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a pre-existing susceptibility. These predispositions can exist for a number of reasons – genetic variants (in human or microbiome DNA), environmental exposures, behaviors, illness or developmental stage, to name just a few, all of which can interact. Some of these adverse reactions are specific to the particular vaccines, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine; others, at least with current technology and practice, are not."*** [110]

In the Preface of the published 2012 study, the IOM committee chair, Ellen Wright Clayton, M.D., stated that the committee "had a herculean task, requiring long and thoughtful discussions of our approach to analyzing the studies culled from more than 12,000 peer-reviewed articles." She said "some issues simply cannot be resolved with current available epidemiological data" and emphasized that scientific conclusions about cause and effect relationships between vaccines and reported adverse events requires a combination of biological mechanism and epidemiological evidence, particularly when it comes to identifying individual susceptibility risk factors:

> ***"Even very large epidemiologic studies may not detect or rule out rare events. Subgroup analysis or more focused epidemiologic studies, informed by as yet incomplete knowledge of the biological mechanisms of vaccine-induced injury, may be required….The value of dialogue between both epidemiologic and mechanism approaches cannot be overstated. Epidemiologic studies can identify particular high risk groups, who can then be examined with more in depth testing to explore***

predisposing factors. The findings of such studies can then inform more focused epidemiologic research as well as efforts to reduce risks. These conversations between different types of research can be difficult, but the results are worth it."

In their concluding remarks, the committee once again reminded readers to accurately interpret the IOM's "evidence is inadequate to accept or reject" causality conclusion for the majority of the vaccine-related adverse events examined in the study:

"For the majority of adverse events the committee was asked to examine, the committee concludes that the evidence is inadequate to accept or reject a causal relationship. Some might interpret that to mean either of the following statements:

- *Because the committee did not find convincing evidence that the vaccine **does** cause the adverse event, the vaccine is safe;*
- *Because the committee did not find convincing evidence the the vaccine does **not** cause the adverse event, the vaccine is unsafe;*

Neither of these interpretations is correct. "Inadequate to accept or reject" means just that – inadequate. If there is evidence in either direction that is suggestive but not sufficiently strong about the causal relationship, it will be reflected in the weight-of-evidence assessments of the epidemiologic or the mechanistic data. However suggestive those assessments might be, in the end the committee concluded that the evidence was inadequate to accept or reject a causal association." [111]

2013 IOM REPORT ON CHILDHOOD IMMUNIZATION SCHEDULE AND SAFETY

In 2012, DHHS contracted with the IOM to establish a committee to review and report on:

- scientific findings and stakeholder concerns related to the safety of the recommended childhood immunization schedule; and

- identify potential research approaches, methodologies, and study designs that could inform this question, considering strengths, weaknesses, as well as the ethical and financial feasibility of each approach.

During 2012, the IOM Committee on the Assessment of Studies of health Outcomes Related to the Recommended Childhood Immunization Schedule held a series of public meetings with vaccine stakeholders to gather information for its report. [112]

Relevant Background: This most recent research request by DHHS to IOM was in part generated by a vaccine stakeholder public engagement process that the National Vaccine Program Office (NVPO) initiated in 2008 through the National Vaccine Advisory Committee (NVAC) [113] to discuss development of the CDC's Immunization Safety Office (ISO) vaccine research agenda. That 2008 DHHS initiative was connected to the 2005 IOM report on *Vaccine Safety Research, Data Access and Public Trust,* [114] in which the IOM committee reviewing the transparency and researcher access to information in the CDC-operated Vaccine Safety Datalink (VSD) called for vaccine stakeholder input into creation of the national vaccine safety research agenda that utilizes the VSD to conduct vaccine safety studies.

On Feb. 27, 2009, an NVAC Vaccine Safety Writing Group composed of vaccine stakeholders from government, industry, medical trade and consumer groups, including representatives from NVIC, met in

Salt Lake City. The goal was to identify potential vaccine research gaps and comment on options for development of federal vaccine safety research priorities.[115] Importantly, during this meeting participants broadly discussed vaccine safety research priorities and potential study designs that were not confined to DHHS and its private HMO corporation partners using the VSD to conduct those vaccine safety studies.

Facilitated by The Keystone Center, a draft consensus recommendation was created by stakeholder participants at the 2009 Salt Lake City meeting, which stated in part: [116]

> *"Public and stakeholder engagement activities have identified a strong desire to study the health impact of the immunization schedule, potentially through a "vaccinated vs. unvaccinated study…. Given public and stakeholder interest in this topic, we recommend an external expert advisory group with broad expertise assess this issue. This expert panel should be convened under the auspices of a well-respected independent body. Particularly, this review should consider strengths and weaknesses, ethical issues and feasibility including timelines and cost of various study designs and report back to the NVAC; consideration should be given to broad biomedical research including laboratory studies, and animal studies;* ***consideration should also be given to study designs comparing children vaccinated by the standard immunization schedule with unvaccinated children (by parental intention), and possibly partially vaccinated children or children vaccinated by alternative immunization schedules; outcomes to assess include biomarkers of immunity and metabolism, and outcomes including but not limited to neurodevelopmental outcomes, allergies, asthma, immune-mediated diseases, and learning disabilities****."*

Additionally, an NVAC meeting in Washington, D.C. was held on Mar. 16 to obtain additional comments from the public. [117]

Federally Recommended Childhood Vaccine Schedule Not Fully Evaluated. When the IOM published the 2013 report on *Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence and Future Studies*, [118]the committee acknowledged that scientific evaluation of adverse health outcomes associated with the federally recommended childhood vaccine schedule was difficult because of vaccine safety research gaps:

> ***"In summary, few studies have comprehensively assessed the association between the entire immunization schedule or variations in the overall schedule and categories of health outcomes, and no study has directly examined health outcomes and stakeholder concerns in precisely the way that the committee was charged to address in its statement of task. No studies have compared the differences in health outcomes that some stakeholders questioned between entirely unimmunized populations of children and fully immunized children. Experts who addressed the committee pointed not to a body of evidence that had been overlooked but rather to the fact that existing research has not been designed to test the entire immunization schedule. The committee believes that although the available evidence is reassuring, studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted."*** [119]

The committee concluded that the federally recommended vaccine schedule for children between birth and six years of age had not been fully scientifically evaluated and that significant gaps in scientific knowledge about vaccine safety, particularly for children who may be biologically at higher risk for experiencing vaccine reactions, remain. The committee stated:

- ***"The concept of the immunization "schedule" is not well developed in the scientific literature.*** *Most vaccine research focuses on the health outcomes associated with single immunizations or combinations of vaccine administered at a single visit. Even though each new vaccine is evaluated in the context of the overall immunization schedule that existed at the time of review, individual elements of the schedule are not evaluated once it is adjusted to accommodate a new vaccine. Key elements of the immunization schedule—for example, the number, frequency, timing, order, and age at the time of administration of vaccines—have not been systematically examined in research studies."*

- *"**The second major issue that the committee encountered during the review of the scientific literature was uncertainty over whether the scientific literature has addressed all health outcomes and safety concerns**. The committee could not determine whether its list of health outcomes was complete or whether a more comprehensive system of surveillance might identify other outcomes of potential safety significance. In addition, the conditions of concern to some stakeholders, such as immunological, neurological, and developmental problems, are illnesses and conditions for which the etiology, in general, is not well understood. Further research on these conditions may clarify their etiologies."*

- ***"Finally, the committee found that evidence from assessments of health outcomes in potentially susceptible subpopulations of children who may have an increased risk of adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited*** *and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes. Most children who experience an adverse reaction to immunization have a preexisting susceptibility. Some predispositions may be detectable prior to vaccination; others, at least with current technology and practice, are not (IOM, 2012, p. 82)."* [120]

The 2013 IOM Committee was able to find *fewer than 40 scientific studies* evaluating the safety of the federally recommended child vaccine schedule and that there is not enough scientific evidence to determine if the vaccine schedule is or is not causally associated with development of the following brain and immune system disorders prevalent among children today:

- Asthma;
- Atopy;
- Allergy;
- Autoimmunity;
- Autism;
- Learning disorders;
- Communication disorders;
- Developmental disorders;
- Intellectual disability;
- Attention deficit disorder;
- Disruptive behavior disorder;
- Tics and Tourette's syndrome;
- Seizures;
- Febrile seizures;
- Epilepsy.

IOM Call for Vaccine Safety Research Using VSD Criticized. Although the 2013 IOM Committee pointed out continuing significant gaps in vaccine safety science, including lack of methodologically sound studies evaluating the safety of the federally recommended child vaccine schedule and risks factors for individual susceptibility for vaccine injury, the committee recommended that DHHS utilize the Vaccine Safety Datalink (VSD) database to conduct vaccine safety studies.

Parent groups, such as NVIC, questioned the IOM recommendations suggesting that prospective clinical trials, including cohort trials, are not useful for examining the safety of the child vaccine schedule. They opposed the committee's recommendation that future vaccine safety research be conducted by DHHS exclusively using CDC operated closed database systems, such as the VSD, and cited vaccine safety research conflicts of interest for federal agencies developing and patenting new vaccines, regulating vaccines and making vaccine policy. [121]

THE GOOD SCIENCE MUST BE DONE TO INFORM VICP PROCEEDINGS BUT NOT WITH TRUST FUND MONEY AND NOT BY DHHS

It is clear that the long standing significant gaps in vaccine science – both with regard to knowledge about the biological mechanisms of vaccine injury and death and identification of genetic, biological and environmental risk factors which make some individuals more susceptible to suffering harm from vaccination – must be filled. Without that science, the special masters and judges in the U.S. Court of Claims will continue to make judgments regarding awarding or denial of vaccine injury compensation in the VICP in a vacuum of knowledge.

The methodologically sound science must be done but for the public to have trust in the conclusions of studies evaluating vaccine adverse events, it must be conduced by researchers who are free from financial ties to industry and the federal government. In addition, there must be a public oversight mechanism on the research that is comprised of vaccine stakeholders, including representatives from non-profit consumer groups, such as the National Vaccine Information Center, which have been independently monitoring vaccine safety for many years.

The National Vaccine Information Center has long pointed out that there are inherent conflicts of interest in allowing legal responsibility for vaccine development, regulation, policymaking, promotion and vaccine safety oversight to exist within the same federal agency (DHHS). The fact that DHHS is also responsible for operating the VICP and acknowledging vaccine injuries and deaths is even more problematical when it comes to evaluating vaccine safety science.

Calls for Improved Vaccine Safety System. In 2010, NVIC representatives participated in a public engagement initiative coordinated by the National Vaccine Advisory Committee (NVAC) to review and describe infrastructure needs for the federal vaccine safety system. At an NVAC-sponsored meeting of vaccine stakeholders in Salt Lake City on Apr. 11-13, 2010, the group identified objectivity, transparency and evidence-based decision making as highly prioritized attributes of a robust vaccine safety system. Participants agreed that an improved internal assessment system is important and that an external assessment of the vaccine safety system is either essential or acceptable. [122]

NVIC submitted public comments critical of NVAC's draft report on improvement of the vaccine safety system and called for the creation of an independent vaccine safety oversight mechanism outside of DHHS modeled after the National Transportation Safety Board (NTSB) or Consumer Product Safety Commission, which are independent executive branch entities outside the Cabinet Department structure that obtain funding from Congress. [123]

Trust Fund Must Be Protected. On multiple occasions, DHHS officials have suggested that Trust

Fund money could be used to conduct studies to close long-standing vaccine safety science gaps.[124] However, as necessary as vaccine safety research is to help prevent vaccine injuries and deaths and to inform special masters and judges in the U.S. Court of Claims, the funds collected with an excise tax on vaccines purchased and sold in the U.S. must not be used for any other purpose than awarding vaccine injury compensation as the 1986 Act stipulated.

The Trust Fund cannot be raided and used for any other purpose because that money has been collected for the sole purpose of awarding federal vaccine injury compensation to those harmed by government recommended and mandated vaccines. The fact that three out of four petitioners filing for vaccine injury compensation are turned away empty handed [125] and there is $3 billion remaining in the Trust Fund reinforces the need for the VICP to do a better job of both informing the public about the existence of the VICP and awarding non-adversarial compensation to the vaccine injured.

Congress appropriates billions of dollars to NIH and CDC every year to develop new vaccines and promote the use of federally recommended vaccines. There is more than enough money that can be carved out of those vaccine development and promotion budgets to fund vaccine safety science research that is conducted by independent researchers without financial ties to industry or government.

NVIC ANSWERS TO GAO SPECIFIC QUESTIONS

The Petitioner's Experience

1. ***Has NVIC collected or is NVIC aware of any data regarding the experience of petitioners who have filed VICP claims (for example, petitioners' understanding of the process and timeframes?) If so, please direct us to any reports or other documentation.***

In NVIC's 1999 congressional testimony about the VICP and the statement to the Advisory Commission on Childhood Vaccines (ACCV) in 2008,[126] there is a description of VCIP petitioners experiences that reflect views quantified in a 2007 survey conducted by the Altarum Institute for DHHS entitled "Petitioners Satisfaction Survey." The goal of the federal survey was to assess how happy or unhappy petitioners were after having gone through the VICP process.

Summary results of this survey were presented to the ACCV in June 2009 and the transcript for the June 4-5, 2009 ACCV meeting and ACCV meeting minutes[127] can be accessed online. However, the final report has not been released to the public by DHHS yet.

Following is a description of survey results of VICP petitioner satisfaction that are reflected in the June 4-5, 2009 ACCV meeting transcript and minutes:

- 716 petitioners were contacted by 265 individual attorneys, who represented the petitioners in the VICP;
- Only 107 petitioners responded for a 23% response rate, which made the survey underpowered;
- 50% of the vaccine injured plaintiffs were five years old or younger and 25% were under six months of age, with the remaining between six and 60 years of age;
- Over 50% of the vaccine injured plaintiffs or their parents had college degrees and family incomes over $60,000;

- About 75% of respondents found out about the VICP from the Internet or parents, friends, health care providers or their attorneys;

- 35% said that getting information about the existence of the VICP was easy, while 32% found it difficult;

- About 17% of respondents said that finding an attorney was easy while 25% said it was very difficult;

- About 30% of respondents said the VICP claims filing process was "more or less easy" and 40% said it was "more or less difficult," while the rest were neutral;

- About 30% of respondents were satisfied with the hearing process; slightly more than 30% were dissatisfied; 64% of respondents said the process was "too long;"

- Of those who responded, about 40% received an award; 60% did not receive an award; 51% stated that the compensation that was awarded was inadequate;

- There a statistically significant correlation between "satisfaction" and receipt of an award;

2. What information has NVIC obtained or heard about petitioners' experiences (both positive and negative) in the VICP claims process?

At this point, what we hear from most parents with vaccine-injured children is that they view the vaccine injury claims process as confusing, time-consuming and traumatic. They feel like they are fighting an uphill battle on an uneven playing ground and that it is unlikely they will be compensated. In other words, they feel that the deck is stacked against them.

- Some have difficulty finding attorneys to take their case;

- Others have missed the statute of limitations, which is only two years from date of death and three years from first symptom of a vaccine injury. Many parents, whose pediatricians failed to inform them about how to monitor their children after vaccination for signs and symptoms of a vaccine reaction, do not know that their child's chronic brain and immune system problems may have been causally related to vaccination until it is too late to file a claim in the VICP.

- A lot of parents, whose children have vaccine-related brain and immune system dysfunction labeled by doctors as "autism," believe they have no hope of obtaining an award in the VICP because of the 2009 Omnibus Autism Proceeding ruling so they do not file a claim;

- Others, who have secured an attorney and filed a claim by the deadline are waiting years to have their claims adjudicated if they do not have an on-Table injury and DHHS and the Department of Justice oppose awarding compensation;

- Many have had their claims dismissed because their medical records are incomplete or plaintiff's attorneys cannot find expert witnesses to testify in the case; or have been

- Forced to settle for less that what it will cost them to take care of their child or themselves for throughout life.

3. ***What can you tell us about petitioners who filed on-Table injuries as compared to off-Table injuries? Specifically, does NVIC have, or can NVIC point us to any information on how their experiences differ, if at all?***

In addition to the information contained in the first 25 pages of NVIC's written response to these questions, George Washington University Professor Peter Meyers published an excellent analysis in 2011 of the difficulty of successfully arguing and obtaining compensation for off-Table injuries compared to on-Table injuries in *Administrative Law Review.* [128]

4. ***Are there any groups or associations you could refer us to who could discuss petitioners' experiences, including petitioners or health care providers?***

Attorneys who handle petitioner claims are the best resource for personally contacting petitioners for information about their experiences with the VICP. The Vaccine Injured Petitioners Bar Association established in 2010 has more information. [129]

Efforts to Inform the Public of VICP

5. ***Has NVIC collected or is NVIC aware of any data on HHS's effort to inform the public of VICP?***

As mentioned in the first 25 pages of NVIC's written response to these questions, DHHS was strongly opposed to the passage of the 1986 National Childhood Vaccine Injury Act and it has been our experience that DHHS has done little to inform the public about the existence of the VICP. Although HRSA maintains a website and publishes information about VICP awards, as does the U.S. Court of Claims, there is little public promotion of the existence of the VICP by DHHS and both websites are difficult to navigate.

Parent awareness about the VICP through federal information materials is mostly through mention of the VICP at the end of the Vaccine Information Statement (VIS) published by the CDC and on the form used by vaccine providers to report a vaccine injury to the federal Vaccine Adverse Events Reporting System (VAERS).

There has been an historic reluctance for DHHS to promote public awareness about the VICP because the existence of a vaccine injury compensation program is acknowledgement that vaccines can and do cause injury and death. Millions of advertising dollars are spent every year by CDC to promote vaccine use of all federally recommended vaccines and to advocate for strict adherence to the federally recommended vaccine schedule but there does not appear to be a lot of enthusiasm at DHHS for spending advertising dollars to make the public aware of the VICP.

There is also lack of transparency with regard to informing the public about the details of federal vaccine injury compensation awards. NVIC has requested a higher degree of transparency that includes posting information about vaccine injury and death awards (without personally identifiable information) that is broken down by year. [130]

We have also requested that information is made available on the numbers of doses of a particular vaccine that are distributed annually in the U.S. Currently only information on numbers of vaccine administered is made available.

6. ***What is NVIC's perspective on HHS's efforts to inform the public of VICP?***

NVIC agrees with many of the points made in a June 2010 report commissioned by the Health Resources Services Administration (HRSA) entitled *The National Vaccine Injury Compensation Program: Awareness, Perception and Communication Considerations.*[131] Referred to as the "Banyan Report," it was a focus group survey of about twenty parents and twenty health care professionals on public awareness and perceptions of the VICP. The report also included a review of medical literature that mentions the VICP, but authors found a "dearth" of literature specifically addressing public awareness and perception of the VICP.

Authors reported that parents and health care professionals were unaware that there was a federal vaccine injury compensation program. They also found that:

- health care professionals (vaccine providers) are not complying with the vaccine safety informing provision of the 1986 law, which requires the CDC's Vaccine Information Statement (VIS) to be given to parents of minor children *before* vaccination takes place and to adults receiving vaccines;

- one study revealed that health care professionals did not the authors' review of literature found a study suggesting the majority of health care professionals did not discuss the VICP during patient visits.

Health care providers administering vaccines, who were aware of the VICP, were reluctant to discuss the existence of a vaccine injury compensation program for fear that parents would decide not to give their children vaccines. Vaccine providers expressed the opinion that the existing VICP information brochure and booklet that discussed the program were too wordy and negative for consumers to understand.

However, contrary to health care provider fears, the survey found that the parent group did not change their intent to vaccinate after they read VICP information materials (brochure and booklet) on the VICP. Consumers said that information contained in VICP brochure and booklet were well written and understandable but that the "tone" could be improved.

Younger consumers were found to be more likely to research vaccine information outside of advice given by their health care provider, especially when it came to the topic of vaccine risks and injury. The survey also found that consumers did not think the VICP website was well organized.

The website has changed little since the Banyan report was published and continues to be difficult to navigate. In addition, the VICP brochure no longer appears to be on the VICP website.

Consumer and health care provider recommendations for promoting the VICP included:

- Improve VICP website design and information;
- Advertise the VICP online;
- Provide brochures and flyers on the VICP at health fairs, waiting rooms and pharmacies;
- Include notices about the VICP in insurance statements and health care invoices;
- Conduct CME courses on the VICP for health care providers;
- Partner with NGO's in making the public aware of the VICP;
- Promote the VICP in TV and print ads, infomercials and PSAs.

NVIC was not contacted for input as a Subject Matter Expert (SME) on the Banyan report, even though others with "subject matter expertise" were consulted. The report did mention that NVIC is a source for VICP information.

It does not appear that the Banyan report recommendations for making the public aware of the VICP were implemented by DHHS, although many of the recommendations appear to have been used by CDC to promote increased vaccine uptake.

a. Do you have any information on how the public generally becomes informed of the availability of VICP?

Since the VICP became operational in the late 1980's, NVIC has promoted the existence of the program on the NVIC website at **NVIC.org** and in NVIC **publications**, [132] **brochures** [133] press releases and videos. NVIC is likely the most well-known and easily accessible non-federal agency online resource for information on the VICP.

Parents also become aware of the VICP by word of mouth from other parents of vaccine-injured children, who have gone through the VICP claims process. However, for most parents – especially those who are not computer literate and do not know how to search the Internet for information - it is very difficult to find information on the VICP.

If parents to do not know there is a VICP and their doctors have either not informed them about vaccine risks or denied that a serious health problem following vaccination may be related to the vaccines a child received, parents do not know that they can apply for vaccine injury compensation for their child and many miss deadlines for filing.

b. What efforts by HHS, to inform the public of VICP, are you aware of?

See our answers to questions # 5 and #6.

c. Are there any efforts you would like to see HHS do or improve upon to inform the public of the availability of the program?

NVIC recommends that DHHS make the public aware of the VICP through special publications, brochures, press releases, videos and advertising online and in television, magazine and billboard advertising. There should also be specific promotion to health care providers who give vaccines and VICP awareness should be included in medical education courses in colleges.

CDC has substantial congressional appropriations to spend on vaccine promotion efforts and should spend some of it on making the public aware of the VICP. DHHS spending to make the public more aware of the existence of a federal vaccine injury compensation program should be on par with DHHS spending to promote public adherence to federal vaccine use policies.

CDC should strive to be more balanced in the language they use when messaging about vaccine benefits and risks. The informed public wants and expects vaccine benefit and risk information to be anchored with accurate facts and presented in a way that is neutral and not biased.

Vaccine Injury Table

7. Does NVIC have any comments on the changes made in the vaccine injury table and the criteria for changing the table?

As discussed in the first 25 pages of this written statement regarding the 1995 Vaccine Injury Table changes, continuing gaps in scientific knowledge about the biological mechanisms of vaccine injury and the Omnibus Autism Proceeding.

It is unfortunate that DHHS has used two decades of IOM reports evaluating vaccine adverse events - in which IOM has continually been unable to make definitive causation conclusions for the majority of serious health disorders reported following receipt of federally recommended vaccines – as a reason to deny compensation rather than to presume causation and compensate. When the "evidence is inadequate to accept or reject" causation for a frequently reported adverse health outcome after receipt of a particular vaccine, DHHS, the Department of Justice and the U.S. Court of Claims special masters should live up to the spirit and intent of the National Childhood Vaccine Injury Act and award compensation in the absence of a biologically plausible alternative explanation.

The erosion of public trust in the federal vaccine injury compensation program is partly due to an historic unwillingness by those making federal vaccine policy and operating the VICP to acknowledge the reality of vaccine injuries and deaths and treat those suffering complications from vaccination with the same respect and compassion that is accorded to those suffering complications from infectious diseases.

VICP Claims Processing

8. Has NVIC conducted or is NVIC aware of any analysis identifying factors associated with differences in VICP claims processing timeframes (i.e., longer or shorter timeframes)?

a. If so, who conducted the analysis and what factors were identified? Please provide copies if available or a link to a website if it is available on-line.

NVIC (and the public) do not have direct access to this information. However, according to the US Department of Justice, in the past year, VICP claims are being settled more rapidly. In a June 2014 report to ACCV, Department of Justice Deputy Director of Torts Vincent Matanoski said that about 80% of VICP claims are now being settled within three years.[134] However, DOJ presentations have also shown that some compensation awards have taken nearly 12 years to finalize.

According to information released by DOJ:

- About 80% of claims now filed within the VICP are for adult vaccine-related injuries;
- About 80% of settlements are for adult injuries;
- Two-thirds of settlements are for influenza vaccine injuries and GBS is the leading injury being compensated;
- On-Table injuries theoretically resolve more quickly than off-Table injuries. The acknowledged gaps in vaccine safety research by the Institute of Medicine has resulted in the majority of claims being relegated to an off-table process, which can be lengthy;

- According to the VICP, about 57% of the claims since 2006 have been compensated: some 82% were settlements; 10% were decisions made by the U.S. Court of Claims special masters; and just over 7% were concessions by DHHS.

b. What factors do you believe may contribute to longer claims processing timeframes?

Clearly, the fact that DHHS has gutted the Vaccine Injury Table and generally does not want to acknowledge vaccine injury and death with the payment of VICP awards, has made the VICP both adversarial and time consuming.

It is NVIC's perspective that today petitioners may be under pressure to "settle" claims because there are so few on-table compensable injuries listed and the burden is on petitioners to prove causation for an off-table injury. There is a sense that plaintiffs are afraid that if attorneys pursue litigation with DHHS and the Department of Justice in the U.S. Court of Claims, they will lose or get less compensation.

This is very reminiscent of the strategy that pharmaceutical corporations selling vaccines employed in the 1980's to persuade parents of vaccine injured children to settle on the courthouse steps before a jury trial. The drug companies, like DHHS and DOJ had deep pockets and an unlimited amount of time to mount a defense and the plaintiff's had little money or time to do the same. So cases were settled on the courthouse steps for a couple of hundred thousand dollars, far too little to care for a profoundly brain injured child for life.

Conclusion

Effective operation of the VICP in accordance with the spirit and intent of the 1986 Childhood Vaccine Injury Act becomes more urgent with every newly licensed and federally recommended vaccine for children and with every revision of federal vaccine policy recommendations for children and adults. For example, the Advisory Commission on Childhood Vaccines (ACCV) is currently discussing proposed revisions to the Vaccine Injury Table to add fetal injuries following administration of federally recommended vaccines (currently Tdap and influenza vaccines) to pregnant women during any trimester.[135]

There are complex scientific, legal, ethical and public policy issues that intersect with regard to implementation of vaccine safety and compensation provisions in the 1986 law and operation of the VICP by federal agencies and the U.S. Court of Claims, which require urgent attention. New vaccines being developed by federal agencies and the pharmaceutical industry that are federally recommended for universal use by all Americans in the future may carry risks that are not well defined prior to licensure. As the only existing legal remedy for those suffering vaccine harm, questions about vaccine safety and the VICP will continue to be asked by the public.

Thank you, again, for the opportunity to speak with you and submit these written comments for your consideration as you review the operation of the federal Vaccine Injury Compensation Program (VICP). Please contact us if you have further questions.

Sincerely,

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Co-founder and President

Kathi Williams

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References:

[1] NVIC.org. About National Vaccine Information Center (NVIC).

[2] NVIC.org. National Childhood Vaccine Injury Act of 1986.

[3] Huynh W, Cordato DJ, Kehdi E et al. Post-vaccination encephalomyelitis: Literature review and illustrative case. *Journal of Clinical Neuroscience* 2008; 15: 1315-1322.

[4] Tunkel AR, Glaser CA, Block KC et al. The Management of Encephalitis: Clinical Practice Guidelines of the Infectious Diseases Society of America. *Clinical Infectious Diseases* 2008; 47(3): 303-327.

[5] Pellegrino P, Carnovale C, Perrone V et al. Acute Disseminated Encephalomyelitis Onset: Evaluation Based on Vaccine Adverse Events Reporting System. *PLOS One* Oct. 18, 2013.

[6] Institute of Medicine Vaccine Safety Committee. Adverse Effects of Pertussis and Rubella Vaccines. Chapter 4: Encephalopathy (pp. 86-88). Washington, DC. *The National Academies Press* 1991.

[7] Institute of Medicine Committee to Study New Research on Vaccines. DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis. Executive Summary (pp.1-2) Washington, D.C. *The National Academies Press* 1994.

[8] Weibel RE, Caserta V, Benor DE, Evans G. Acute Encephalopathy Followed by Permanent Brain Injury or Death Associated with Further Attenuated Measles Vaccines: A Review of Cases Submitted to the National Vaccine Injury Compensation Program. *Pediatrics* 1998; 101(3): 383-387.

[9] LaRoche SM. Seizures and Encephalopathy. *Semin Neurol* 2011; 31(19): 194-201.

[10] Holland MS, Krakow RJ. Brief of Amici Curiae National Vaccine Information Center, Its Co-Founders and 24 other organizations in support of petitioners. In: *Bruesewitz v. Wyeth* filed with Supreme Court of the United States June 1, 2010.

[11] Mariner WK. Innovation and Challenge: The First Year of the National Vaccine Injury Compensation Program. Report prepared for Administrative Conference of the United States 1991.

[12] Vernick JS, Mair JS, Tenet SP, Sapsin JW. Role of Litigation in Preventing Product-related Injuries. *Epidemiol Rev* 2003; 25(1): 90-98.

[13] Health Resources Services Administration (HRSA). National Vaccine Injury Compensation Program: Vaccine Injury Compensation Trust Fund. (Accessed July 6, 2014.)

[14] Dept. of Treasury. Vaccine Injury Trust Fund Trial Balance (Unaudited) June 1, 2014 – June 30, 2014.

[15] Oral testimony of Barbara Loe Fisher, NVIC Co-founder and President. *Criminal Justice, Drug Policy and Human Resources Subcommittee, House Government Reform Committee* May 18, 1999.

[16] Written testimony of Barbara Loe Fisher, NVIC Co-founder and President. *Criminal Justice, Drug Policy and Human Resources Subcommittee, House Government Reform Committee*. Sept. 28, 1999.

[17] Fisher BL. The Vaccine Injury Compensation Program: A Failed Experiment in Tort Reform? Presented to Advisory Commission on Childhood Vaccines Nov. 18, 2008.

[18] Wrangham T. NVIC Public Comment to Advisory Commission on Childhood Vaccines (ACCV). June 14, 2012.

[19] Wrangham T. NVIC Public Comment to Advisory Commission on Childhood Vaccines Sept. 5, 2013.

[20] DHHS. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table Final Rule. *Federal Register* Feb. 8, 1995; 60(26): 7678-7696.

[21] Oral and written testimony of Marcel Kinsbourne, M.D., Medical Expert, Tufts University. *Hearing of Criminal Justice, Drug Policy and Human Resources Subcommittee, House Government Reform Committee* Sept. 28, 1999. (pp. 51-61).

[22] Daniels M. Special Masters in the National Vaccine Injury Compensation Program: Placing a Heightened Burdon on Vaccine Program Petitioners by Straying from Precedent and Congressional Intent. *Journal of Health and Biomedical Law* 2010; 6: 79-107.

[23] Health Resources Services Administration (HRSA). Claims Filed and Compensated or Dismissed by Vaccine – July 1, 2014.

[24] Health Resources Services Administration (HRSA). Advisory Commission on Childhood Vaccines (ACCV) Transcript: Comments of Vince Matanoski, Deputy Director, Torts Branch, Dept. of Justice (pp. 25-26) Sept. 5, 2013.

[25] Matanoski VJ. Report from the Department of Justice: Vaccine Injury Compensation Program Petitions Filed May 16, 2012 – Aug 15, 2014 (Slide 2). *Advisory Commission on Childhood Vaccines (ACCV)* Sep. 6, 2012.

[26] Centers for Disease Control (CDC). Recommended schedule for active immunization of normal infants and children. *DHHS* 1983.

[27] Hinman AR, Orenstein WA Schuchat A. Vaccine Preventable Diseases, Immunization and MMWR 1961- 2011. *MMWR* 2011; 60(04): 49-57.

[28] CDC. Vaccination Rates Among Children in Kindergarten – United States, 2012-2013 School Year. *MMWR* Aug. 2, 2013; 62(30): 607-612.

[29] Centers for Disease Control (CDC). Recommended Immunization Schedules for Persons Aged 0 Through 18 Years - United States, 2014. *DHHS* Jan 1, 2014.

[30] Hinman AR, Orenstein WA, Rodewald L. Financing Immunizations in the United States. *Clin Infect Dis* 2004; 38(10: 1440-1446.

[31] Frieden TR. DHHS Report to Congress on Section 317 Immunization Program. *U.S. Senate Appropriations Committee* 2014.

[32] Institute of Medicine Committee on Immunization Finance Policies and Practices. Calling the Shots: Immunization Finance Policies and Practices. Chapter 5: Infrastructure Investments and Immunization

Programs and Federal Finance Practices (pp. 175-180). Washington D.C. *The National Academy Press* 2000.

[33] Immunization Action Coalition (IAC). State Information: State Immunization Mandates. June 4, 2014.

[34] Fisher BL, Wrangham TK. NVIC Public Comment to National Vaccine Program Office (NVPO) on Draft Recommendations of the Health Care Personnel Influenza Vaccine Subgroup of the National Vaccine Advisory Committee (NVAC) Jan. 16, 2012.

[35] Association of State and Territorial Health Officials (ASTHO). Immunization Resource Guide. 2013.

[36] Association of Immunization Managers (AIM). Position Statement on Personal Belief Exemptions from State Vaccination Mandates. Jan. 21, 2014.

[37] American Academy of Family Physicians (AAFP). Pediatric Infectious Diseases Society Rejects 'Personal Belief' Immunization Exemptions. *AAFP News* May 4, 2011.

[38] NVIC. National Vaccine Information Center Calls for U.S. Vaccine Policy and Law Reform to Protect Human and Civil Rights. *Business Wire* May 21, 2014.

[39] Yang YT and Debold V. A Longitudinal Analysis of the Effect of Nonmedical Exemption Law and Vaccine Uptake on Vaccine-Targeted Disease Rates. *American Journal of Public Health* February 2014;104(2): 371-377.

[40] CDC. Conditions Commonly Misperceived as Contraindications to Vaccination. Oct. 19, 2013.

[41] CDC. Chart of Contraindications and Precautions to Commonly Used Vaccines for Childhood Vaccines. Mar. 6, 2014.

[42] Rubin LG, Levin MJ, Lyungman P et al. 2013 Infectious Diseases Society of America (IDSA) Clinical Practice Guideline for Vaccination of the Immunocompromised Host. *Clin Infect Dis* Dec. 4, 2013.

[43] Stadlin S, Bednarczyk RA, Omer SB. Medical Exemptions to School Immunization Requirements in the United States – Association of State Policies with Medical Exemption Rates (2004-2011). *J Infect Dis* Aug 29, 2012.

[44] CDC. 1986 Vaccine Price List formerly posted and accessed on CDC website in March 2014 but no longer posted on CDC's Vaccine Price List Archives pages revised July 1, 2014.

[45] CDC. Archived CDC Vaccine Price List - Nov. 18, 2013. (Accessed July 6, 2014).

[46] Schuchat A. Vaccine Management: Cost to Vaccinate One Child with Vaccines Universally Recommended 1990, 2000, 2012. Page 16. *National Vaccine Advisory Committee* June 6, 2012.

[47] Shalala DE. Testimony by Secretary of Department of Health and Human Services on FY97 Labor, HHS, Education Appropriations. *U.S. Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies* June 6, 1996.

[48] DHHS. FY2015 Budget in Brief. CDC Budget Overview: Immunization and Respiratory Diseases (pp. 30-33). *DHHS* June 2014.

[49] Ibid.

[50] Orenstein DG, Weidenaar K. Alternative State Vaccination Funding Models. *The Network for Public Health Law, Robert Wood Johnson Foundation* May 2012.
[51] CMS.gov. Affordable Care Act Implementation FAQs: Limitations on Cost-Sharing under the Affordable Care Act Coverage of Preventive Services.

[52] Drug Discovery & Development. Vaccine Market A Refuge for Big Pharma. January 13, 2011.

[53] Transparency Market Research. U.S. Vaccine Market Is Expected to Reach USD 17.4 Billion by 2018. *PR Newswire* Sept. 13, 2012.

[54] Palmer E, Bryant A. Top 5 Vaccine Companies by Revenue. *Fierce Vaccines* Mar. 14, 2013.

[55] Staton T. Analysts see $1.5B boost for Pfizer on 'better than expected' Prevnar 13 data. *Fierce Pharma* Mar. 13, 2014.

[56] CDC. Vaccines for Children Program (VFC): CDC Vaccine Price List (July 1, 2014).

[57] Silverman E. Sticking Point: Why Do Vaccine Costs Keep Rising? Ask Pfizer. *Wall Street Journal* July 3, 2014.

[58] Supreme Court of the United States. *Bruesewitz v. Wyeth* No. 09-152. Justice Scalia delivering opinion Feb. 22, 2011.

[59] Supreme Court of the United States. *Bruesewitz v. Wyeth* No. 09-152. Justice Sotomayor with whom Justice Ginsberg joins, dissenting Feb. 22, 2011.

[60] Barclay L. Recommendations Updated for Universal Administration of Hepatitis A Vaccination in US Children. *Medscape Medical News* July 5, 2007.

[61] Rabin R. A New Vaccine for Girls, But Should It Be Compulsory? *New York Times* July 18, 2006.

[62] National Institutes of Health. NIH Technology Licenses to Merck for HPV Vaccine. *NIH Office of Technology Transfer*. Press Release.

[63] National Institutes of Allergy and Infectious Disease (NIAID). Partnering with NIAID: Technology Transfer Collaborations. Sept. 21, 2011.

[64] DHHS. A milestone in protection from influenza. *DHHS Press Release* June 17, 2014.

[65] National Institutes of Health (NIH). Clinical Trials – Vaccines. *Clinical trials.gov* Accessed July 6, 2014.

[66] DHHS. Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications. *Food and Drug Administration* February 2010.

[67] DHHS. Draft Guidance for Industry: Detecting the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products. *Food and Drug Administration* July 3, 2014.

[68] FDA. Gardasil HPV Quadrivalent Vaccine: Background Document. *Vaccines & Related Biological Products Advisory Committee (VRBPAC).* May 18, 2006.

[69] Fisher BL. Public Comment: Licensure Pathways for Pandemic Influenza Vaccines. *FDA Vaccines and Related Biological Products Advisory Committee Meeting* Feb. 29, 2012.

[70] HRSA. Vaccine Injury Awards Paid. (June 2, 2014). (Accessed July 6, 2014). using Internet Archive Wayback Machine – U.S. Court of Claims has recently eliminated vaccine injury case details of VICP awards on the new U.S. Claims in the vaccine injury cases on their new VICP information website.).

[71] U.S. Court of Federal Claims. Vaccine Cases (Published). Accessed July 6, 2014 using Internet Archive Wayback Machine – U.S. Court of Federal Claims recently eliminated vaccine injury case details about VICP awards on the new U.S. Court of Federal Claims website).

[72] Institute of Medicine Vaccine Safety Committee. Adverse Effects of Pertussis and Rubella Vaccines. Washington, DC. *The National Academies Press*. 1991.

[73] Ibid. Afterword on Research Needs. (p. 206).

[74] Congress.gov. Comprehensive Child Immunization Act of 1993 – Summary.

[75] Public Law 103-183. Preventive Health Amendments (pp. 223-225). Dec. 14, 1993.

[76] Institute of Medicine Vaccine Safety Committee. Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality. Washington, D.C. *The National Academies Press* 1994.

[77] Ibid. Executive Summary (p. 17).

[78] Ibid. Need for Research and Surveillance. (pp. 305 & 307).

[79] Ibid. Risk-Modifying Factors (p. 307).

[80] Institute of Medicine Committee to Study New Research on Vaccines. DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis. Washington, D.C. *The National Academy Press* 1994.

[81] Miller DL, Ross EM Alderslade R et al. Pertussis immunization and serious acute neurological illness in children. *BMJ* 1981; 282: 1595-1599.

[82] Cody CL, Baraff LJ, Cherry JD et al. Nature and rates of adverse reactions associated with DTP and DT immunizations in infants and children. *Pediatrics* 1981; 68: 650-660.

[83] Miller D, Madge N, Diamond J et al. Pertussis immunization and serious acute neurological illnesses in children. *BMJ* 1993; 307: 1171-1176.

[84] Ibid. Discussion (p. 1175).

[85] Institute of Medicine Committee to Study New Research on Vaccines. DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis. Conclusion (p. 15). Washington, D.C. *The National Academy Press* 1994.

[86] DHHS. Final Rule: National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table. *Federal Register* Feb. 8, 1995; 60(26): 7678-7695.

[87] Medline Plus. Encephalitis: Symptoms (Infants) and Emergency Symptoms. Aug. 1, 2012.

[88] HealthGrades. What Is Encephalitis? Aug. 9, 2013.

[89] National Institute for Neurological Disorders and Stroke (NINDS). What Is Acute Disseminated Encephalomyelitis? Feb. 14, 2014.

[90] See References #3-9.

[91] Fisher, BL. Vaccine Safety Research Needs: Perspective from Parents. *Institute of Medicine Vaccine Safety Forum Public Workshop* Apr. 1, 1996.

[92] Institute of Medicine Vaccine Safety Forum. Howe CJ, Johnston RB, Fenichel GM, Editors. Summaries of Two Workshops. Washington, D.C. *The National Academy Press* 1997.

[93] Institute of Medicine Vaccine Safety Forum. Evans G, Bostrom A, Johnston RB, Fisher BL, Stoto MA, Editors. Risk Communication and Vaccination Workshop Summary. Washington, D.C. *The National Academy Press* 1997.

[94] Fisher BL. Presentation on vaccine safety research needs to Institute of Medicine Immunization Safety Review Committee. *National Academy of Sciences* Jan. 22, 2001.

[95] IOM Immunization Safety Review Committee. Thimerosal-Containing Vaccines and Neurodevelopmental Disorders. Washington, D.C. *National Academy Press* 2001.

[96] IOM Immunization Safety Review Committee. Measles-Mumps-Rubella Vaccines and Autism. Washington, D.C. *National Academy Press* 2001.

[97] Immunization Safety Review Committee. Hepatitis B Vaccine and Demyelinating Neurological Disorders. Washington, D.C. *National Academy Press* 2002.

[98] IOM Immunization Safety Review Committee. Influenza Vaccines and Neurological Complications. Washington, D.C. *National Academy Press* 2003.

[99] IOM Immunization Safety Review Committee. Vaccines and Autism. Washington, D.C. *National Academy Press* 2004.

[100] CDC. Vaccine Safety Datalink (VSD) Project Publications. June 18, 2014.

[101] Institute of Medicine Committee on the Review of the National Immunization Program's Research Procedures and Data Sharing Program. Vaccine Safety Research, Data Access and Public Trust. Washington, D.C. *The National Academies Press* 2005.

[102] Ibid. Executive Summary: Independent Review of Vaccine Safety Datalink Activities. (p. 6).

[103] Rubin R. Court rules autism not connected to vaccines. *USA Today* Feb. 13, 2009.

[104] U.S. Court of Federal Claims. Omnibus Autism Proceeding: Guidance to Petitioners on How to Exit the Vaccine Program. Oct. 10, 2012.

[105] Attkisson S. Vaccine Case: An Exception or A Precedent? *CBS News* Mar. 6, 2008.

[106] U.S. Court of Claims. *Bailey Banks V. Secretary of DHHS.* No. 02-0738V. Conclusion in favor of entitlement. July 20, 2007.

[107] Institute of Medicine Committee to Review Adverse Effects of Vaccines. Adverse Effects of Vaccines: Evidence and Causality. Washington, D.C. *The National Academies Press* 2012.

[108] Ibid. Summary.

[109] ACCV Presentation - Updating the Vaccine Injury Table following the 2011 IOM Report on Adverse Effects of Vaccines. Rosemary Johann-Liang, M.D.
Chief Medical Officer, National Vaccine Injury Compensation Program (NVICP)
Mar. 8, 2012

[110] Institute of Medicine Committee to Review Adverse Effects of Vaccines. Evaluation of Biologic Mechanisms of Adverse Effects: Increased Susceptibility. (p. 82). Washington, D.C. *The National Academies Press* 2012.

[111] Ibid. Concluding Comments (p. 632-633).

[112] Fisher BL. Vaccine Safety Research Needs: A Public Perspective. IOM Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule Meeting. Feb. 9, 2012.

[113] Fisher BL. Vaccine Safety Research Priorities: Engaging the Public. Oral presentation. *National Vaccine Advisory Committee Vaccine Safety Working Group* Apr. 11, 2008.

[114] Institute of Medicine Committee on the Review of the National Immunization Program's Research Procedures and Data Sharing Program. Vaccine Safety Research, Data Access and Public Trust. Washington, D.C. *The National Academies Press* 2005.

[115] May H. Should federal officials study vaccine schedule? *Salt Lake Tribune* Mar. 3, 2009.

[116] Kirby D. US Health Officials Back Study Idea on Vaccinated vs. Unvaccinated Children – Will Media Take Note? *Huffington Post* Mar. 2, 2009.

[117] Fisher BL. Talking Vaccine Science with Government: Why Do It? *NVIC Newsletter* Mar. 12, 2009.

[118] Institute of Medicine Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule. The Childhood Immunization Schedule and Safety Stakeholder Concerns, Scientific Evidence and Future Studies. Washington, D.C. *The National Academies Press* 2013.

[119] Institute of Medicine Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule. The Childhood Immunization Schedule and Safety Stakeholder Concerns, Scientific Evidence and Future Studies. Summary (p. 5-6). Washington, D.C. *The National Academies Press* 2013.

[120] Ibid. Summary of Scientific Findings. (pp. 129-130).

[121] Business Wire. National Vaccine Information Center Supports Three of Five Recommendations of New IOM Repot on U.S. Childhood Immunization Schedule Safety and Calls for Transparency. NVIC Press Release Jan. 16, 2013.

[122] The Keystone Center Team. Memo to NVAC Vaccine Safety Work Group and Interested Stakeholders. *The Keystone Center* Apr. 13, 2010.

[123] Fisher, BL. Wrangham TK. NVIC Public Comment on VSWG Draft Report Recommendations on the Federal Vaccine Safety System. June 6, 2011.

[124] DHHS. Transcript of Advisory Commission on Childhood Vaccines (ACCV) Meeting Mar. 9, 2012. (pp. 99-101).

[125] Health Resources Services Administration (HRSA). Claims Filed and Compensated or Dismissed by Vaccine – July 1, 2014.

[126] Fisher BL. The Vaccine Injury Compensation Program: A Failed Experiment in Tort Reform? Presented to Advisory Commission on Childhood Vaccines Nov. 18, 2008.

[127] Swamy N. Altarum Institute Petitioners Satisfaction Survey Presentation to the Advisory Commission on Childhood Vaccines. *ACCV Meeting Minutes* Jun 4, 2009

[128] Meyers P. Fixing the Flaws in the Federal Vaccine Injury Compensation Program. *Administrative Law Review* 2011; 63(4).

[129] The Vaccine Injured Petitioner's Bar Association.

[130] Wrangham TK. NVIC Public Comment at Advisory Commission on Childhood Vaccine meeting Sept. 5, 2013.

[131] The National Vaccine Injury Compensation Program: Awareness, Perception, and Communication Considerations. Presented Oct. 2010 by Banyan Communications and Altarum Institute to the Advisory Commission on Childhood Vaccines in June 2010. Provided by NVIC to GAO staff July 2014.

[132] NVIC. If You Vaccinate, Ask Eight Questions.

[133] NVIC. Know the Facts to Stay Healthy This Flu Season.

[134] Matanoski V. Department of Justice Report on VICP (May 16, 2013 – Aug. 15, 2013). Advisory Commission on Childhood Vaccines Transcript Sept. 5, 2013.

[135] Fisher BL, Wrangham TK. NVIC Public Comment on Draft NVAC Maternal Immunization Working Group Recommendations on Maternal Immunizations. Apr. 25, 2014.