

**Testimony Senate Health & Welfare Committee
Wednesday April 22, 2015
H.98**

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Dr. Bark earned her Doctor of Medicine degree from Rush Medical College in 1986. She completed her Pediatric internship at NYU and Pediatric residency at University of Illinois. She trained in rehab medicine and has a Masters Degree in Medical Disaster Preparedness and Response from Boston University Medical School. She is a former Director of the Pediatric Emergency Room at Michael Reese Hospital. Dr. Bark has worked as a medical-legal consultant analyzing injury cases, as well as an expert witness in the federal vaccine court and as an adverse event expert in family courts, here and abroad. She has been in private practice in Chicago, Illinois since 1994.

April 22, 2015

To the Honorable members of the
Vermont Senate Health Committee
Sen. Claire Ayer, Chair
Sen. Virginia "Ginny" Lyons, Vice Chair
Sen. Anthony Pollina
Sen. Dick McCormack
Sen. Brian Collamore, Clerk

Dear Senators,

Thank you for this opportunity to testify before you on the critical and complex issues of vaccines and medical choice.

I am Dr. Toni Bark. I trained as a pediatric intern at New York University (NYU) and did my pediatric residency at the University of Illinois. I have also trained in rehab medicine, have a Masters Degree in Medical Disaster Preparedness and Response from Boston University Medical School and am a former Director of the Pediatric Emergency Room at Michael Reese Hospital in Chicago. I have been in private practice for twenty years and work as a medical-legal consultant analyzing medical cases. I am an expert witness in the federal vaccine court and an adverse event expert in family courts, here and abroad.

Like every trained pediatrician, I never questioned vaccine safety or efficacy. I thought little of vaccine reactions and risks and was furious when parents came to the clinic with children who were not up to date with their vaccines. But after working in the pediatric emergency room, I witnessed repeated patterns of adverse reactions. Children seen in the vaccine clinic would end up in our ER with seizures, respiratory arrest, anaphylaxis, and asthma attacks. I began to see first-hand the risks of vaccines and realized that not all children respond well to vaccination and in fact, some develop life-long debilitating conditions, and some even die.

In my thirty-year experience as a doctor I have found that the *judicious* use of vaccines is essential to maximizing the benefits of this medical procedure. While many people seem to do just fine with vaccination, a small percentage do not. And of this small percentage, the reactions can be severe. Where there is risk, there must be informed consent. According to the National Institutes of Health, informed consent is required for "most vaccines," and means that "you have the right to refuse treatment if you are able to understand your health condition, your treatment options, and the risks and benefits

of each option.”¹ The philosophical exemption is an integral component of informed consent and the right to refuse treatment.

In 1986, Congress granted the pharmaceutical industry liability protection for vaccines, including defects in “design” (as opined by Scalia in the February 2011 SCOTUS ruling), legally ruling vaccines as “unavoidably unsafe.” The National Vaccine Injury Compensation Program (VICP) was established under the Department of Health and Human Services (HHS), which confines vaccine-injury legal cases to a special court. In this court, the 7th amendment, guaranteeing the right to a jury for every American in controversies exceeding \$25, does not pertain, and other fundamental processes afforded by our judicial system, such as discovery, do not exist. In 1990, the HHS set up the Vaccine Safety Datalink (VSD), a collaborative project between CDC’s Immunization Safety Office and nine health care organizations. It continues today in order to monitor safety of vaccines and conduct studies about rare and serious adverse events following immunization. While the HHS may use the Vaccine Safety Database to help them win their cases, claimants are refused access.

Further limitations of the court include a three-year statute of limitations and caps on death awards of \$250,000. There is no jury, no judge, just “special masters” assigned to the courtroom. The court compensates for the conditions listed on the table of injuries (see attached). However, seizure disorders, specifically from MMR and whole cell DPT, or injuries to fetuses, are no longer compensable.

In 2008 the United States Health Resources and Services Administration (HRSA) which oversees the VICP, contracted with the Institute of Medicine (IOM) to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines. As the attached 2011 report summary illustrates, the IOM found “that evidence convincingly supports a causal relationship between some vaccines and some adverse events—such as MMR, varicella zoster, influenza, hepatitis B, meningococcal, and tetanus-containing vaccines linked to anaphylaxis.”²

As you will see from the attachments, of the more than 15,000 cases of vaccine injury filed with VICP between 1989 and 2015, the court has awarded over 3 *billion* dollars to more than 4,000 cases. While these number are high, the government admits it probably only receives ten percent of the adverse events which occur, largely because the vaccine adverse events reporting system is not well known or advertised. And, due to the short statute of limitations, families often are refused filing because the time limit has expired.

I would like to briefly walk you through the attached Vaccine Injury Table. The table lists injuries and conditions “presumed” to be caused by vaccines. As you will see, there are

¹ NIH Informed Consent patient instructions: <http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000445.htm>

² <https://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>

timeframes within which the first symptom must appear to be considered caused by the vaccine. If an injury/condition does not occur within the listed timeframe, proof of harm must be presented based on medical records or opinion, which may include expert witness testimony.

My research into risk/benefit analyses for injury cases in Australia has found that:

- Common adverse reactions to vaccines include symptoms that I recognise as a medical practitioner as possible symptoms of encephalitis or meningitis, even if usually minimal.
- Other adverse reactions to vaccines, that would not be considered trivial, are also reported to occur far more frequently than the risk of any adverse outcome from any of the targeted diseases.
- Serious, debilitating adverse conditions are reported after vaccination, also potentially far more frequently than any serious adverse outcome could occur from the diseases.
- Whilst reported adverse events reported from vaccines and cited on package inserts are not all necessarily causally related, causality assessments that are published by the Australian Government conclude that a sizeable proportion of adverse events are “certainly” or “probably” causally related.
- The procedure, and many of the adverse effects it can cause, is irreversible

In addition to the IOM, the Cochrane Collaboration, an independent international network, considered a gold standard in research, has found repeatedly in its meta-analysis on vaccine studies that further safety and effectiveness studies are needed in order to assess true risk and risk/benefit ratios.

For instance, in 2012 the Cochrane Collaboration found that, “In children under the age of two, the efficacy of inactivated vaccine was similar to placebo. It was not possible to analyse the safety of vaccines from the studies due to the lack of standardisation (sic) in the information given, but very little information was found on the safety of inactivated vaccines, the most commonly used vaccine in young children.”³

Many factors effect how a patient will respond to any drug or vaccine—some are known, others are as of yet unknown. There is emerging science about the genome, proteomics, epigenetics, psychoneuroimmunology, the microbiome and how these might influence vaccine adverse reactions. The single most significant consideration is that **no one drug at one dose is right for everyone**. And vaccines, in their current presentation, are a one-size-fits-all product.

³ T.Jeffersonand others, “Vaccinesforpreventinginfluenzainhealthychildren.”CochraneCollaborative Summaries, August 15, 2012; <http://summaries.cochrane.org/CD004879/vaccines-for-preventing-influenza-in-healthy-children>

Up until 1985, seven diseases in three vaccines were administered to children, but today's infants receive more than that— proposed 2015 schedule has children receiving 53 doses by age 6. There are over 200 new vaccines in the pipeline. Under Vermont vaccine regulations, the phase-in period from when a vaccine moves from recommended to required is generally two years with some State discretion. This creates an increasingly large number of medical procedures for doctors and patients to consider. Without informed consent and the current provision of choice, the doctor-patient relationship is crippled.

Unfortunately medical exemptions are not the answer. My experience with medical exemptions in Illinois is that they are increasingly difficult to be accepted by the state vaccine health official. In 1990, a family history of autoimmunity or adverse reaction to a vaccine was enough to medically exempt a child. But today, many states require the individual child in question to have already experienced a severe vaccine reaction in order to be exempt from that specific vaccine. This means a family cannot decide to spare the next child from a possible reaction. The CDC no longer considers a seizure reaction or death of previous siblings from vaccination to be cause for exemption.

Most parents do not start out questioning the safety and efficacy of vaccines—their stance is changed once they have a child who is permanently and profoundly damaged by a vaccine. They then decide no more for that child and no more for their next children. But surprisingly, because the laws dictating medical exemptions are so limited, these families can not get medical exemptions for their children, nor can others whose children exhibit concerning reactions and/or behavior after vaccines. Medical exemption laws are not preventative, but rather akin to closing-the-barn-door-after-the-horse-has-gone. They do not apply to, and therefore do not protect, many people who need them.

Eliminating non-medical exemptions is a medical mistake. Vaccines have known risks, including life-long devastating conditions. Vermont needs to examine if it wants laws that force people to undergo irreversible medical procedures that are legally classified as “unavoidably unsafe.” Given the national and international recognition of the importance of informed consent, I hope the State will err on the side of medical and personal prudence, where unavoidably unsafe medical procedures cannot be forced on anyone.

Please maintain the right of parent and doctors to implement vaccines judiciously and respect the internationally recognized medical standard of informed consent.

Respectfully,

Toni Bark MD MHEM LEED AP



URL of this page: <http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000445.htm>

Informed consent - adults

You have the right to help decide what medical care is best for you. By law, your health care providers must explain your health condition and treatment choices to you.

Informed consent means:

- You are informed: you have received information about your health condition and treatment options.
- You understand your health condition and treatment options.
- You are able to decide what health care treatment you want to receive and give your consent to receive it.

To obtain your informed consent, your health care provider may talk with you about the treatment. Then you will read a description of it and sign a form. This is written informed consent.

Or, your health care provider may explain a treatment to you. They will ask if you agree to have the treatment. Not all medical treatments require written informed consent.

What treatments need informed consent?

Medical procedures that require you to give written informed consent include:

- Most surgeries, even when they are not done in the hospital.
- Other advanced or complex medical tests and procedures, such as an endoscopy (placing a tube down your throat to look at the inside of your stomach) or a needle biopsy of the liver.
- Radiation or chemotherapy to treat cancer.
- Most vaccines.
- Some blood tests, such as HIV testing (need for written consent varies by state).

What should occur during the informed consent process?

When asking for your informed consent, your doctor or other health care provider must explain:

- If treatment is necessary now or if it can wait
- Your health problem and the reason for the treatment
- What happens during the treatment
- The risks of the treatment and how likely they are to occur
- How likely the treatment is to work
- Other options for treating your health problem
- Unknown risks or possible side effects that may happen later on

You should have enough information to make a decision about your treatment. Your health care provider should also make sure you understand the information. One way a health care provider may do this is by asking you to repeat the information back in your own words.

If you would like more details about your treatment choices, ask your health care provider where to look. There are many trusted websites and other resources your provider can give you.

What is your role in the informed consent process?

You are an important member of your health care team. You should ask questions about anything you do not understand. If you need your provider to explain something in a different way, ask them to do so.

You have the right to refuse treatment if you are able to understand your health condition, your treatment options, and the risks and benefits of each option. Your doctor or other health care provider may tell you they do not think this is the best choice for you. But, your health care providers should not try to force you to have a treatment you do not want to have.

It is important to be involved in the informed consent process. After all, you are the one who will receive the treatment if you give your consent.

Other tips

Informed consent is not needed in an emergency when delayed treatment would be dangerous.

Some people are no longer able to make an informed decision, such as someone with advanced Alzheimer disease or someone in a coma. In both cases, the person would not be able to understand information to decide what medical care they want. In these types of situations, the health care provider would try to obtain informed consent for treatment from a surrogate, or substitute decision-maker.

Even when your health care provider does not ask for your written consent, you should still be told what tests or treatments are being done and why. For example:

- Before they have the test, men should know the pros, cons, and the reasons for a PSA blood test that screens for prostate cancer.
- Women should know the pros, cons, and the reasons for a Pap test, a mammogram, or other tests.
- Anyone who is being tested for an infection that occurs after sexual contact should be told about the test and why they are being tested.

References

Emanuel EJ. Bioethics in the practice of medicine. In: Goldman L, Schafer AI, eds. Goldman's Cecil Medicine. 24th ed. Philadelphia, PA: Saunders Elsevier; 2011:chap 2.

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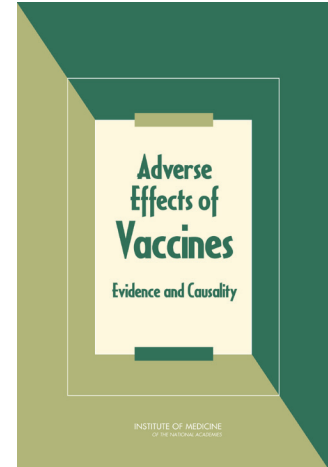
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For more information visit www.iom.edu/vaccineadverseeffects

Adverse Effects of Vaccines

Evidence and Causality



Immunizations are a cornerstone of the nation's efforts to protect people from a host of infectious diseases. As required by the Food and Drug Administration, vaccines are tested for safety before they enter the market, and their performance is continually evaluated to identify any risks that might appear over time.

Vaccines are not free from side effects, or "adverse effects," but most are very rare or very mild. Importantly, some adverse health problems following a vaccine may be due to coincidence and are not caused by the vaccine. As part of the evaluation of vaccines over time, researchers assess evidence to determine if adverse events following vaccination are causally linked to a specific vaccine, and if so, they are referred to as adverse effects. Under the National Childhood Vaccine Injury Act of 1986, Congress established the National Vaccine Injury Compensation Program (VICP) to provide compensation to people injured by vaccines. Anyone who thinks they or a family member—often a child—has been injured can file a claim.

The Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services that administers VICP, can use evidence that demonstrates a causal link between an adverse event and a vaccine to streamline the claim process. As such, HRSA asked the Institute of Medicine (IOM) to review a list of adverse events associated with vaccines covered by VICP and to evaluate the scientific evidence about the event–vaccine relationship. The vaccines covered by VICP include all vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in children. Adults who experience an adverse event following one of these childhood vaccines also are covered by the program. HRSA

As part of the evaluation of vaccines over time, researchers assess evidence to determine if adverse events following vaccination are causally linked to a specific vaccine, and if so, they are referred to as adverse effects.

asked the IOM to review 8 of the 12 covered vaccines. These eight are the varicella zoster vaccine (used against chickenpox); the influenza vaccines (except for the H1N1 influenza vaccine distributed in 2009); the hepatitis B vaccine; the human papillomavirus (HPV) vaccine; the measles, mumps, and rubella (MMR) vaccine; the hepatitis A vaccine; the meningococcal vaccines, and tetanus-containing vaccines that do not carry the whole-cell pertussis component.

Examining the Evidence

The adverse events selected by HRSA for IOM review are ones for which people have submitted claims—successful or not—to VICP. The committee appointed to this study was not asked to assess the benefits or effectiveness of vaccines but only the risk of specific adverse events. Its conclusions reflect the best evidence available at the time. Some of the adverse events the committee examined already are accepted in the medical community, but they are minor or manageable—for example, a sudden allergic reaction called anaphylaxis that can follow the administration of some vaccines.

In its report, the committee explains its process for evaluating the list of adverse events and provides a set of 158 causality conclusions. The committee examined two types of evidence: epidemiologic evidence, which derives from studies of populations, and mechanistic evidence, which draws from biological and clinical studies. The committee evaluated each scientific article for its strengths and weaknesses and then assigned a “weight of evidence” ranking to both the epidemiologic and mechanistic bodies of studies.

The committee considered the weights of evidence and then reached a conclusion about the causal relationship between each vaccine and adverse health problem pairing. The committee began from a position of neutrality, presuming neither causation nor lack of causation, and moved from that position only when the combination of evidence suggested a more definitive assessment regarding causation. The figure pro-

vides an explanation of how the evidence influenced the causality conclusions.

Based on the totality of the evidence, the committee assigned each relationship to one of four categories of causation in which the evidence:

- convincingly supports a causal relationship;
- favors acceptance of a causal relationship;
- favors rejection of a causal relationship; or
- is inadequate to accept or reject a causal relationship.

The committee did not use a category to designate evidence that convincingly supports no causal relationship, because it is virtually impossible to prove the absence of a very rare relationship with the same certainty that is possible to establish the presence of one.

Evidence Convincingly Supports a Causal Relationship

The committee concludes that the evidence convincingly supports a causal relationship between some vaccines and some adverse events.

As a live vaccine, the varicella zoster vaccine is linked to four specific adverse events, all due to infection from the vaccine virus strain:

- Disseminated varicella infection (widespread chickenpox rash shortly after vaccination)
- Disseminated varicella infection with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies
- Vaccine strain viral reactivation (appearance of chickenpox rash months to years after vaccination)
- Vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis (inflammation of the brain)

The MMR vaccine is linked to a disease called measles inclusion body encephalitis, which in very rare cases can affect people whose immune

The committee began from a position of neutrality, presuming neither causation nor lack of causation, and moved from that position only when the combination of evidence suggested a more definitive assessment regarding causation.

systems are compromised and usually occurs within a year of acute measles infection or vaccination. The MMR vaccine also is linked to febrile seizures, which are a type of seizure that occurs in infants and young children in association with fever. Febrile seizures are generally benign and hold no long-term consequences.

Six types of vaccines—MMR, varicella zoster, influenza, hepatitis B, meningococcal, and tetanus-containing vaccines—are linked to anaphylaxis.

The committee also found convincing evidence of a causal relationship between injection of vaccine, independent of the antigen involved, and two types of adverse events, including syncope, or fainting, and deltoid bursitis, or frozen shoulder, characterized by shoulder pain and loss of motion.

Evidence Favors Acceptance of a Causal Relationship

The evidence favors acceptance of four vaccine–adverse event relationships. In these cases, the evidence is strong and generally suggestive, but not firm enough to be described as convincing. These relationships include:

- HPV vaccine and anaphylaxis;
- MMR vaccine and transient arthralgia (temporary joint pain) in female adults;
- MMR vaccine and transient arthralgia in children; and
- certain trivalent inactivated influenza vaccines used in Canada in some recent years

and a mild and temporary oculo-respiratory syndrome, which is characterized by conjunctivitis, facial swelling, and upper respiratory symptoms, including coughing and wheezing.

Evidence Favors Rejection of a Causal Relationship

The evidence favors rejection of five vaccine–adverse event relationships:

- MMR vaccine and autism
- MMR vaccine and type 1 diabetes
- DTaP (tetanus) vaccine and type 1 diabetes
- Inactivated influenza vaccine and Bell’s palsy (weakness of the facial nerve)
- Inactivated influenza vaccine and exacerbation of asthma or reactive airway disease episodes in children and adults

Evidence Inadequate to Accept or Reject a Causal Relationship

For the vast majority, (135 vaccine–adverse event pairs), the evidence is inadequate to accept or reject a causal relationship. In many cases, the adverse event being examined is an extremely rare condition, making it hard to study. In these cases, there was not adequate evidence to determine if the vaccine was or was not causally associated.



Committee to Review Adverse Effects of Vaccines

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Susceptibility

As some of the conclusions suggest, individuals with certain characteristics are more likely to suffer certain adverse effects from particular immunizations. Individuals who have serious immunodeficiencies are clearly at increased risk for specific adverse reactions to live viral vaccines, such as MMR and varicella vaccines. Thus, the committee was able at times to reach more limited conclusions for subgroups of the population.

Conclusion

In applying consistent standards across all the evidence, the committee found that some conclusions were easy to reach: the evidence was clear and consistent or, in the extreme, completely absent. Others required substantial discussion and debate.

The committee was not charged with making recommendations, and it did not pinpoint any particular areas for continued research. Much research already occurs to determine the safety of vaccines for the populations for whom they are recommended. However, there is much to learn about the human immune system, autoimmunity, and the effects of genetic variation, all of which may influence how people respond to vaccines.

Vaccines offer the promise of protection against a variety of infectious diseases. Despite much media attention and strong opinions from many quarters, vaccines remain one of the greatest tools in the public health arsenal. Certainly, some vaccines result in adverse effects that must be acknowledged. But the latest evidence shows that few adverse effects are caused by the vaccines reviewed in this report.

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Adverse Effects of Vaccines

Evidence and Causality

FIGURE

Strength of Evidence that Determined the Causality Conclusions

EPIDEMIOLOGIC ASSESSMENT						MECHANISTIC ASSESSMENT					CAUSALITY CONCLUSION			
High (increased risk)	High (decreased risk or no effect)	Moderate (increased risk)	Moderate (decreased risk or no effect)	Limited	Insufficient	Strong	Inter-mediate	Low-Inter-mediate	Weak	Lacking	Inadequate to Accept or Reject	Favors Rejection	Favors Acceptance	Convincingly Supports
High (increased risk)														Convincingly Supports
						Strong								Convincingly Supports
		Moderate (increased risk)												Favors Acceptance
							Inter-mediate							Favors Acceptance
	High (decreased risk or no effect)*													Favors Rejection
														Inadequate to Accept or Reject
			Moderate (decreased risk or no effect), Limited, or Insufficient**											Inadequate to Accept or Reject
								Low-Intermediate, Weak, or Lacking***						Inadequate to Accept or Reject

* Causality conclusion is favors rejection only if mechanistic assessment is **not** strong or intermediate.

** Causality conclusion is inadequate to accept or reject only if mechanistic assessment is **not** strong or intermediate.

*** Causality conclusion is inadequate to accept or reject only if epidemiologic assessment is **not** high (increased risk), high (decreased risk or no effect), or moderate (increased risk).

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TABLE: Summary of Causality Conclusions

Vaccine	Adverse Event	Causality Conclusion
Varicella	Disseminated varicella infection (widespread chickenpox rash shortly after vaccination)	Convincingly Supports
Varicella	Disseminated varicella infection with subsequent infection resulting in pneumonia, meningitis, or hepatitis	Convincingly Supports ^a
Varicella	Vaccine strain viral reactivation (appearance of chickenpox rash months to years after vaccination)	Convincingly Supports
Varicella	Vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis (inflammation of the brain)	Convincingly Supports
MMR	Measles inclusion body encephalitis	Convincingly Supports ^{a, b}
MMR	Febrile seizures (a type of seizure that occurs in association with fever and is generally regarded as benign)	Convincingly Supports
MMR	Anaphylaxis (a very rare but sudden allergic reaction)	Convincingly Supports
Varicella	Anaphylaxis	Convincingly Supports
Influenza	Anaphylaxis	Convincingly Supports
Hepatitis B	Anaphylaxis	Convincingly Supports ^c
Tetanus Toxoid	Anaphylaxis	Convincingly Supports
Meningococcal	Anaphylaxis	Convincingly Supports
Injection-Related Event	Deltoid bursitis (frozen shoulder, characterized by shoulder pain and loss of motion)	Convincingly Supports
Injection-Related Event	Syncope (fainting)	Convincingly Supports
HPV	Anaphylaxis	Favors Acceptance
MMR	Transient arthralgia (temporary joint pain) in women	Favors Acceptance ^d
MMR	Transient arthralgia in children	Favors Acceptance
Influenza	Oculorespiratory syndrome (a mild and temporary syndrome characterized by conjunctivitis, facial swelling, and upper respiratory symptoms)	Favors Acceptance ^e
MMR	Autism	Favors Rejection
Influenza	Inactivated influenza vaccine and Bell's palsy (weakness or paralysis of the facial nerve)	Favors Rejection
Influenza	Inactivated influenza vaccine and asthma exacerbation or reactive airway disease episodes in children and adults	Favors Rejection
MMR	Type 1 diabetes	Favors Rejection
DT, TT, or aP containing	Type 1 diabetes	Favors Rejection

^a The committee attributes causation to individuals with demonstrated immunodeficiencies.

^b The committee attributes causation to the measles component of the vaccine.

^c The committee attributes causation to yeast-sensitive individuals.

^d The committee attributes causation to the rubella component of the vaccine.

^e The committee attributes causation to two particular vaccines used in three particular years in Canada.

All other causality conclusions are the evidence is inadequate to accept or reject a causal relationship.

National Vaccine Injury Compensation Program Monthly Statistics Report | Updated 03/31/2015

Since the first National Vaccine Injury Compensation (VICP) claims were filed in 1989, 4,022 compensation awards have been made. More than \$2.9 billion in compensation awards has been paid to petitioners and more than \$123.9 million has been paid to cover attorneys' fees and other legal costs.

To date, 9,882 claims have been dismissed. Of those, 4,940 claimants were paid more than \$65.7 million to cover attorneys' fees and other legal costs.

**VICP Adjudication Categories, by Alleged Vaccine,
 For Claims Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006
 Through 12/31/2013**

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2013 (source: CDC)	Compensable			Compensable Total	Dismissed/Non-Compensable Total	Grand Total
		Concession	Court Decision	Settlement			
DT	652,327	1		4	5	4	9
DTaP	75,888,233	12	18	75	105	77	182
DTaP-Hep B-IPV	43,929,797	4	7	18	29	36	65
DTaP-HIB	1,135,474				0	1	1
DTaP-IPV-HIB	39,590,896			7	7	10	17
DTP	0		1	2	3	2	5
DTP-HIB	0				0	1	1
Hep A-Hep B	11,662,755			9	9	2	11
Hep B-HIB	4,796,583	1	1	1	3	1	4
Hepatitis A (Hep A)	124,212,280	4	3	21	28	21	49
Hepatitis B (Hep B)	129,820,136	2	10	40	52	36	88
HIB	83,517,849		1	4	5	4	9
HPV	67,250,524	10		67	75	88	163
Influenza	944,000,000	44	76	862	982	176	1,158
IPV	58,019,052			4	4	2	6
Measles	135,660			1	1		1

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2013 (source: CDC)	Compensable			Compensable Total	Dismissed/Non-Compensable Total	Grand Total
		Concession	Court Decision	Settlement			
Meningococcal	58,412,363	1	2	24	27	4	31
MMR	73,441,556	17	13	56	86	74	160
MMR-Varicella	11,028,270	8		8	16	8	24
Nonqualified	N/A			1	1	21	22
OPV	0	1			1	3	4
Pneumococcal Conjugate	132,932,107		1	5	6	14	20
Rotavirus	70,719,103	1	3	15	19	5	24
Rubella	422,548		1		1		1
Td	55,742,830	5	6	50	61	17	78
Tdap	155,106,848	12	6	86	104	13	117
Tetanus	3,836,052	3		19	22	10	32
Unspecified	N/A	1		2	3	549	552
Varicella	90,425,492	3	6	23	33	10	43
Grand Total	2,236,678,735	131	155	1,404	1,688	1,189	2,877

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2013 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

In addition to the first vaccine alleged by a petitioner, which is the vaccine listed in this table, a VICP petition may allege other vaccines, which may form the basis of compensation.

Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type. Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

"Unspecified" means insufficient information was submitted to make an initial determination. The concession was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s) and the settlements were for multiple vaccines later identified in the Special Master's decisions.

Definitions

Compensable – The injured person who filed a claim was paid money by the VICP. Compensation can be achieved through a concession by the U.S. Department of Health and Human Services (HHS), a decision on the merits of the claim by a special master or a judge of the U.S. Court of Federal Claims (Court), or a settlement between the parties.

- **Concession:** HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision:** A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).

For injury claims, compensable court decisions are based in part on one of the following determinations by the court:

1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
 2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- **Settlement:** The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Claims may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
 - **Non-compensable/Dismissed:** The injured person who filed a claim was ultimately not paid money. Non-compensable Court decisions include the following:
 1. The Court determines that the person who filed the claim did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
 2. The claim was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).
 3. The injured person voluntarily withdrew his or her claim.

**Petitions Filed, Compensated and Dismissed, by Alleged Vaccine,
 Since the Beginning of VICP, 01/01/1988 through 03/31/2015**

Vaccines	Filed			Compensated	Dismissed
	Injury	Death	Grand Total		
DT	69	9	78	25	51
DTaP	379	79	458	180	203
DTaP-Hep B-IPV	62	25	87	30	34
DTaP-HIB	10	1	11	4	3
DTaP-IPV	1	0	1	0	0
DTaP-IPV-HIB	25	17	42	7	11
DTP	3,286	696	3,982	1,270	2,706
DTP-HIB	20	8	28	5	21
Hep A-Hep B	20	0	20	9	2
Hep B-HIB	8	0	8	4	3
Hepatitis A (Hep A)	68	5	73	27	22
Hepatitis B (Hep B)	625	54	679	243	363
HIB	29	3	32	12	14
HPV	266	13	279	75	88
Influenza	1,767	87	1,854	1,049	158
IPV	264	14	278	8	267
Measles	143	19	162	55	107
Meningococcal	40	2	42	28	4
MMR	891	57	948	367	505
MMR-Varicella	31	1	32	16	8
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Nonqualified ¹	85	9	94	1	87
OPV	280	28	308	158	150
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	41	6	47	10	27
Rotavirus	66	1	67	40	17
Rubella	190	4	194	70	123
Td	184	3	187	108	65
Tdap	236	1	237	112	13
Tetanus	99	2	101	43	37
Unspecified ²	5,411	8	5,419	4	4,750
Varicella	79	7	86	51	20
Grand Total	14,704	1,162	15,866	4,026	9,882

¹ Nonqualified petitions are those filed for vaccines not covered under the VICP.

² Unspecified petitions are those submitted with insufficient information to make a determination.

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	216
FY 2002	957
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	503
FY 2014	633
FY 2015	351
Total	15,866

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed. On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	233	295
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	82	121	203
FY 2008	147	134	281
FY 2009	134	231	365
FY 2010	180	293	473
FY 2011	265	1,370	1,635
FY 2012	262	2,439	2,701
FY 2013	366	627	993
FY 2014	368	167	535
FY 2015	204	48	252
Total	4,026	9,882	13,908

Awards Paid

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	\$1,317,654.78	\$54,107.14	0	\$0.00	0	\$0.00	\$1,371,761.92
FY 1990	88	\$53,252,510.46	\$1,379,005.79	4	\$57,699.48	0	\$0.00	\$54,689,215.73
FY 1991	114	\$95,980,493.16	\$2,364,758.91	30	\$496,809.21	0	\$0.00	\$98,842,061.28
FY 1992	130	\$94,538,071.30	\$3,001,927.97	118	\$1,212,677.14	0	\$0.00	\$98,752,676.41
FY 1993	162	\$119,693,267.87	\$3,262,453.06	272	\$2,447,273.05	0	\$0.00	\$125,402,993.98
FY 1994	158	\$98,151,900.08	\$3,571,179.67	335	\$3,166,527.38	0	\$0.00	\$104,889,607.13
FY 1995	169	\$104,085,265.72	\$3,652,770.57	221	\$2,276,136.32	0	\$0.00	\$110,014,172.61
FY 1996	163	\$100,425,325.22	\$3,096,231.96	216	\$2,364,122.71	0	\$0.00	\$105,885,679.89
FY 1997	179	\$113,620,171.68	\$3,898,284.77	142	\$1,879,418.14	0	\$0.00	\$119,397,874.59
FY 1998	165	\$127,546,009.19	\$4,002,278.55	121	\$1,936,065.50	0	\$0.00	\$133,484,353.24
FY 1999	96	\$95,917,680.51	\$2,799,910.85	117	\$2,306,957.40	0	\$0.00	\$101,024,548.76
FY 2000	136	\$125,945,195.64	\$4,112,369.02	80	\$1,724,451.08	0	\$0.00	\$131,782,015.74
FY 2001	97	\$105,878,632.57	\$3,373,865.88	57	\$2,066,224.67	0	\$0.00	\$111,318,723.12
FY 2002	80	\$59,799,604.39	\$2,653,598.89	50	\$656,244.79	0	\$0.00	\$63,109,448.07
FY 2003	65	\$82,816,240.07	\$3,147,755.12	69	\$1,545,654.87	0	\$0.00	\$87,509,650.06
FY 2004	57	\$61,933,764.20	\$3,079,328.55	69	\$1,198,615.96	0	\$0.00	\$66,211,708.71
FY 2005	64	\$55,065,797.01	\$2,694,664.03	71	\$1,790,587.29	0	\$0.00	\$59,551,048.33
FY 2006	68	\$48,746,162.74	\$2,441,199.02	54	\$1,353,632.61	0	\$0.00	\$52,540,994.37
FY 2007	82	\$91,449,433.89	\$4,034,154.37	61	\$1,692,020.25	0	\$0.00	\$97,175,608.51
FY 2008	141	\$75,716,552.06	\$5,191,770.83	73	\$2,511,313.26	2	\$117,265.31	\$83,536,901.46
FY 2009	131	\$74,142,490.58	\$5,404,711.98	36	\$1,557,139.53	28	\$4,241,362.55	\$85,345,704.64
FY 2010	173	\$179,387,341.30	\$5,961,744.40	56	\$1,886,239.95	22	\$1,978,803.88	\$189,214,129.53
FY 2011	251	\$216,319,428.47	\$9,572,042.87	403	\$5,589,417.19	28	\$2,001,770.91	\$233,482,659.44
FY 2012	249	\$163,491,998.82	\$9,104,488.60	1,017	\$8,621,182.32	37	\$5,420,257.99	\$186,637,927.73
FY 2013	375	\$254,666,326.70	\$13,333,179.53	703	\$6,970,278.84	50	\$1,454,851.74	\$276,424,636.81
FY 2014	365	\$202,084,196.12	\$11,973,575.82	505	\$6,801,345.79	38	\$2,493,460.73	\$223,352,578.46
FY 2015	258	\$114,511,261.10	\$6,772,522.65	60	\$1,652,949.24	21	\$1,288,799.60	\$124,225,532.59
Total	4,022	\$2,916,482,775.63	\$123,933,880.80	4,940	\$65,760,983.97	226	\$18,996,572.71	\$3,125,147,213.11

"Compensated" are claims that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/claims are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the claim, whether or not the petition/claim is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Due to the populations receiving vaccines added to the VICP in recent years, the proportion of adults to children seeking compensation has changed. Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult claims related to that vaccine have been filed.

§100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Pub. L. 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Brachial Neuritis	2-28 days.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	72 hours.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Encephalopathy (or encephalitis)	5-15 days (not less than 5 days and not more than 15 days).
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above	Not applicable.

	which illness, disability, injury, or condition arose within the time period prescribed	
IV. Vaccines containing rubella virus (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
V. Vaccines containing measles virus (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7-30 days.
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	6 months.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection	
	—in a non-immunodeficient recipient	30 days.
	—in an immunodeficient recipient	6 months.
	—in a vaccine associated community case	Not applicable.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period	Not applicable.

	prescribed.	
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 hours.
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable.
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines	No Condition Specified	Not applicable.
X. Varicella vaccine	No Condition Specified	Not applicable.
XI. Rotavirus vaccine	No Condition Specified	Not applicable.
XII. Pneumococcal conjugate vaccines	No Condition Specified	Not applicable.
XIII. Hepatitis A vaccines	No Condition Specified	Not applicable.
XIV. Trivalent influenza vaccines	No Condition Specified	Not applicable.
XV. Meningococcal vaccines	No Condition Specified	Not applicable.
XVI. Human papillomavirus (HPV) vaccines	No Condition Specified	Not applicable.
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage *	No Condition Specified	Not applicable.

*Now includes all vaccines against seasonal influenza (except trivalent influenza vaccines, which are already covered), effective November 12, 2013.

(b) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

(1) *Anaphylaxis and anaphylactic shock.* For purposes of paragraph (a) of this section, Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) *Encephalopathy.* For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) *For children less than 18 months of age* who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) *For adults and children 18 months of age or older*, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A “significantly decreased level of consciousness” is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals);
or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) 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 as described above: 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.

(ii) *Chronic Encephalopathy* occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was

caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) [Reserved]

(4) *Seizure and convulsion.* For purposes of paragraphs (b) (2) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(5) *Sequela.* The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(6) *Chronic Arthritis.* (i) For purposes of paragraph (a) of this section, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjögren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction) metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

(iii) Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of paragraph (a) of this section.

(7) *Brachial neuritis.* (i) This term is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities.

(ii) Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(8) *Thrombocytopenic purpura*. This term is defined by a serum platelet count less than 50,000/mm³. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(9) *Vaccine-strain measles viral infection*. This term is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(10) *Vaccine-strain polio viral infection*. This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(c) *Coverage provisions*. (1) Except as provided in paragraph (c)(2), (3), (4), (5), (6), or (7) of this section, the revised Table of Injuries set forth in paragraph (a) of this section and the Qualifications and Aids to Interpretation set forth in paragraph (b) of this section apply to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after March 24, 1997. Petitions for compensation filed before such date shall be governed by section 2114(a) and (b) of the Public Health Service Act as in effect on January 1, 1995, or by §100.3 as in effect on March 10, 1995 (see 60 FR 7678, *et seq.*, February 8, 1995), as applicable.

(2) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, and X of the Table) are included in the Table as of August 6, 1997.

(3) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22, 1998.

(4) Pneumococcal conjugate vaccines (Item XII of the Table) are included in the Table as of December 18, 1999.

(5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1, 2004.

(6) Trivalent influenza vaccines (Item XIV of the Table) are included on the Table as of July 1, 2005.

(7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of the Table) are included on the Table as of February 1, 2007.

(8) Other new vaccines (Item XVII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the FEDERAL REGISTER to announce the effective date of such a tax.

[60 FR 7694, Feb. 8, 1995, as amended at 62 FR 7688, Feb. 20, 1997; 62 FR 10626, Mar. 7, 1997; 63 FR 25778, May 11, 1998; 64 FR 40518, July 27, 1999; 67 FR 48559, July 25, 2002; 73 FR 59530, Oct. 9, 2008; 76 FR 36368, June 22, 2011]