100.3 Vaccine Injury Table.

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)), paragraph (a) sets forth 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. Paragraph (b) of this section sets forth additional conditions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the Qualifications and Aids to Interpretation for the terms used in the Table and in paragraph (b) of this section. Conditions and injuries that do not meet the terms of the Qualifications and Aids to Interpretation are not within the Vaccine Injury Table. Paragraph (d) of this section sets forth a glossary of terms used in subparagraphs (a), (b), and (c).

(a) Vaccine Injury Table

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	≤4 hours
	B. Brachial Neuritis	2-28 days (not less than 2 days and not more than 28 days)
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
	Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed	(this wording is in every line of this table and thus has been moved to bottom of the Table under section (b) as provision that applies to all vaccines listed)
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	≤4 hours
	B. Encephalopathy or encephalitis	≤72 hours
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour

III. Vaccines containing measles, mumps, and rubella virus or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis	≤4 hours
	B. Encephalopathy or encephalitis	5-15 days (not less than 5 days and not more than 15 days)
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
IV. Vaccines containing rubella virus (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days)
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
V. Vaccines containing measles virus (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days)
	B. Vaccine-Strain Measles Viral Disease infection in an immunodeficient recipient	6 months
	--Vaccine-strain virus identified --If strain determination is not done or if laboratory testing is inconclusive	Not applicable ≤12 months
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
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
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis	≤4 hours

	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
IX. Haemophilus influenzae type b conjugate vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour
X. Varicella vaccines	A. Anaphylaxis	≤4 hours
	B. Disseminated varicella vaccine-strain viral disease	
	--Vaccine-strain virus identified --If strain determination is not done or if laboratory testing is inconclusive	Not applicable 7-42 days (not less than 7 days and not more than 42 days)
	C. Varicella vaccine-strain viral reactivation	Not applicable
	D. Shoulder Injury Related to Vaccine Administration	≤48 hours
	E. Vasovagal syncope	≤1 hour
XI. Rotavirus vaccines	A. Intussusception	1-21 days (not less than 1 day and not more than 21 days)
XII. Pneumococcal conjugate vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour
XIII. Hepatitis A vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour
XIV. Trivalent influenza vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours

	C. Vasovagal syncope	≤1 hour
XVI. Human papillomavirus (HPV) vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
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.	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1hour

(b) *Provision that applies to all vaccines listed.* (moved here from each row of the Table) Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed in subparagraph (a) (and defined in subparagraphs (c) and (d)) qualifies as a Table injury under subparagraph (a) except when the definition in subparagraph (c) requires exclusion.

(c) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to, define and describe the scope of, and be read in conjunction with paragraphs (a), (b), and (d) of this section:

(1) *Anaphylaxis.* Anaphylaxis and anaphylactic shock is an acute, severe, and potentially lethal systemic allergic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. 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. There are no specific pathological findings to confirm a diagnosis of anaphylaxis. 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 the Vaccine Injury Table, A vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period if an injury meeting the description below of an acute encephalopathy occurs within the applicable time period and results in a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) 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:

(*1*) without an associated a seizure event, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" that lasts at least 24 hours,

(*2*) following a seizure shall be viewed as having, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that persists beyond lasts at least 24 hours and cannot be attributed to a postictal state –from a seizure or a medication.

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

(*1*) A significant change in mental status that is not medication related specifically(such as a confusional state, delirium, or 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.

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

Significantly decreased level of consciousness definitions and chronic encephalopathy section MOVED to glossary section

(C) The following clinical features in themselves 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, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia.

(D) Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy and in the absence of other evidence of an acute encephalopathy seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy.

(ii) Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, an encephalopathy shall not be considered to be a condition set forth in the Table if after evaluating the entire medical record, the preponderance of evidence shows that it was caused by:

(A) an underlying condition or systemic disease (such as autoimmune disorder, malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, metabolic disturbance, prenatal or perinatal central nervous system (CNS) injury), or

(B) an acute event shown to be unrelated to the vaccine such as a head trauma, stroke, transient ischemic attack, complicated migraine, drug use (illicit or prescribed) or an infectious disease.

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.

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

Definitions of seizure and sequela moved to the Glossary section

(3) *Encephalitis.* A vaccine recipient shall be considered to have suffered an encephalitis if an injury meeting the description below of an acute encephalitis occurs within the applicable time period and results in a chronic encephalopathy.

(i) *Acute encephalitis.* Encephalitis is indicated by evidence of neurologic dysfunction, as described in subparagraph (A) below, plus evidence of an inflammatory process in the brain, as described in subparagraph (B) below.

(A) Evidence of neurologic dysfunction consists of either:

(1) one of the following neurologic findings referable to the CNS: focal cortical signs (such as aphasia, alexia, agraphia, cortical blindness); cranial nerve abnormalities; visual field defects; presence of primitive reflexes (such as Babinski's sign or sucking reflex); or cerebellar dysfunction (such as ataxia, dysmetria, or nystagmus); or

(2) an acute encephalopathy as set forth in subparagraph (c)(2)(i) of this section.

(B) Evidence of an inflammatory process in the brain (central nervous system or CNS inflammation) must include cerebrospinal fluid (CSF) pleocytosis (>5 white blood cells (WBC)/mm3 in children >2 months of age and adults; >15 WBC/mm3 in children <2 months of age); or at least two of the following:

(*1*) Fever (temperature ≥ 100.4 degrees Farenheit);

(*2*) Electroencephalogram findings consistent with encephalitis, such as diffuse or multifocal nonspecific background slowing and periodic discharges; or

(*3*) Neuroimaging findings consistent with encephalitis, which include, but are not limited to brain/spine magnetic resonance imaging (MRI) displaying diffuse or multifocal areas of hyperintense signal on T2-weighted, diffusion-weighted image, or fluid-attenuation inversion recovery sequences

(ii) Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in the Table if, after evaluating the entire medical record, the preponderance of evidence shows that it was caused by:

(A) an underlying malignancy that led to a paraneoplastic encephalitis,

(B) an infectious disease associated with encephalitis, including a bacterial, parasitic, fungal or viral illness (such as herpes viruses, adenovirus, enterovirus, West Nile Virus, or human immunodeficiency virus), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;

(C) acute disseminated encephalomyelitis (ADEM). Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen but is a minor component); or

(D) other conditions or abnormalities that would explain the vaccine recipient's symptoms.

(4) *Intussusception.* : [Defined in separate rotavirus NPRM]

(5) *Chronic Arthritis.* Chronic arthritis is defined as persistent joint swelling with at least two additional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months.

(i) 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) 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 idiopathic arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/ dermatomyositis, fibromyalgia, necrotizing vascultitis and vasculopathies and Sjogren'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, blood disorders, or arthralgia (joint pain) or joint stiffness without swelling. Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

(6) *Brachial neuritis.* This term is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is typically followed in days or weeks by weakness in the affected upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. Atrophy of the affected muscles may occur. 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. 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).

A vaccine recipient shall be considered to have suffered a brachial neuritis as a Table injury if such recipient manifests, within the applicable period, all of the following:

(i) Pain in the affected arm and shoulder is a presenting symptom;

(ii) Weakness;

(A) Clinical diagnosis in the absence of nerve conduction and elecromyographic studies requires weakness in muscles supplied by more than one peripheral nerve.
(B) Nerve conduction studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus are required before the diagnosis can be made if muscle weakness is limited to a single peripheral nerve.

(iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and
(iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.

(7) *Thrombocytopenic purpura.* This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm3 with normal red and white blood cell indices. 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. Thrombocytopenic purpura does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura 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, 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.

(8) *Vaccine-strain measles viral* infection is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests *disease.* This term is defined as a measles illness that involves the skin and/or another organ (such as the brain or lungs). Measles virus must be isolated from the affected organ or histopathologic findings characteristic for the disease must be present. Measles viral strain determination may be performed by methods such as polymerase chain reaction test and vaccine-specific monoclonal antibody. If strain determination reveals wild-type measles virus or another, non-vaccine-strain virus, the disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur within 12 months after vaccination.

(9) *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.

(10) *Shoulder Injury Related to Vaccine Administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of an injected vaccine. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine administration;
(ii) Pain occurs within the specified time frame;
(iii) Pain and reduced range of motion are limited to the shoulder in which the vaccine was administered; and
(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

(11) *Disseminated varicella vaccine-strain virus disease.* Disseminated varicella vaccine-strain virus disease is defined as a varicella illness that involves the skin beyond the dermatome in which the vaccination was given and/or disease caused by vaccine-strain varicella in another organ. For organs other than the skin, disease, not just mildly abnormal laboratory values, must be demonstrated in the involved organ. If there is involvement of an organ beyond the skin, and no virus was identified in that organ, the involvement of all organs must occur as part of the same, discrete illness. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur 7– 42 days after vaccination.

(12) *Varicella vaccine-strain viral reactivation disease.* Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster with or without concurrent disease in an organ other than the skin. Zoster, or shingles, is a painful, unilateral, pruritic rash appearing in one or more sensory dermatomes. For organs other than the skin, disease, not just mildly abnormal laboratory values, must be demonstrated in the involved organ. There must be laboratory confirmation that the vaccine-strain of the varicella virus is present in the skin or in any other involved organ, for example by oligonucleotide or polymerase chain reaction. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table.

(13) *Vasovagal syncope.* Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequelae. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent syncope occurring after the applicable time period are not considered to be sequelae of an episode of syncope meeting the Table requirements.

(d) *Glossary for purposes of sections (b) and* (c)

(1) *Chronic encephalopathy.* (moved here from encephalopathy section)

(i) A chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy or encephalitis, persists for at least 6 months from the date of vaccination.

(ii) Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within 6 months of their acute encephalopathy or encephalitis 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 or encephalitis.

(2) *"Injected"* refers to the intramuscular or subcutaneous needle administration of a vaccine.

(3) "*Immunodeficient recipient*" is defined as an individual with an inherited or acquired disorder resulting from an identifiable defect in the immunological system which impairs the body's ability to fight infections. The identifiable defect, such as absent T lymphocytes in severe combined immunodeficiency or decreased CD4 cell counts in acquired immunodeficiency syndrome, must be demonstrated in the medical records.

(4) "*Significantly decreased level of consciousness*" is indicated by the presence of one or more of the following clinical signs: (moved here from encephalopathy section)

(i) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
(ii) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
(iii) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(5) *Seizure*. (moved here from encephalopathy section) The term "seizure" includes myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures, but not absence (petit mal), or pseudo seizures. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(6) *Sequela*. (moved here from encephalopathy section) The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.