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Congress of the United States
House of Representatives
Washington, DC 20515

March 4, 2019

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Mark Zuckerberg
Chairman and Chief Executive Officer
Facebook, Inc.
1 Hacker Way
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IF VACCINES DO NOT CAUSE INJURIES, WHY HAS THE VACCINE INJURY TRUST FUND PAID OUT $4,061,322,557.08 FOR VACCINE INJURIES?

Dear Mr. Zuckerberg:

I am supportive of childhood vaccinations and believe that parents should have their children vaccinated against vaccine preventable illnesses. I also respect the right of parents to make fully informed medical decisions including those regarding vaccinations. Decisions about vaccinations, like all medications, should be decided based on the family's medical history including allergies and history of auto-immune diseases as well as other factors.

I also agree with our nation's public health officials and federal agencies that vaccines can have life-threatening and debilitating effects on some children and adults. The number of serious adverse reactions may be small on a population level, but to children who suffer life-long debilitation and the families that care for them it is no small matter. It is something they live with every day. It is life-altering and often life-consuming.

A media report[1] suggests that Facebook is considering limiting the free speech of Americans who present safety concerns about vaccinations online including on Facebook and within Facebook groups. I have some questions about this matter and would also like to provide some facts regarding blatantly false information you received in a February 14th letter (enclosed) from my colleague Rep. Adam Schiff. The letter states, *"There is no evidence to suggest that vaccines cause life-threatening or disabling diseases."* The Institute of Medicine, the Centers for Disease Control, and manufacturers all acknowledge that vaccines can cause harm to infants, children and adults. The vaccine injury table listing a wide range of more than 50 adverse reactions for recommended/mandated vaccines is available at https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf (enclosed). I have serious concerns that Facebook, based on false statements and similar ill-informed assertions, may initiate limits on the free speech of Americans who enjoy the community sharing of information and ideas online through Facebook.

[1] https://www.bloomberg.com/news/articles/2019-02-14/facebook-says-it-may-remove-anti-vaccine-recommendations

There is likely not a more contentious topic in medicine today than vaccinations. As a legislator who has monitored these safety concerns while serving in the Florida legislature and since entering Congress in 2008, I know there are many layers to this issue including concerns about the fidelity of some of the safety studies conducted in the last 20 years.

Vaccines, like every medication, have risks and benefits that are taken into consideration by the Food and Drug Administration (FDA) in the licensing process. One of the most valuable resources available online from the manufacturer and the FDA is the package insert from each vaccine. The package insert is the FDA approved statement about the product, the ingredients, the known risks and benefits as well as information about contraindications. It is speculated that serious reactions are rare, but they do exist. The National Library of Medicine[2] for instance acknowledges that the Measles-Mumps-Rubella (MMR) vaccine can cause seizures, deafness, brain damage and very rarely death. In fact, a February 4, 2019, U.S. Department of Health and Human Services Report, notes that the federal government has compensated over 440 children for MMR-related injury claims.[3]

Because vaccine injuries do occur, now retired Congressman Henry Waxman (D-CA) spearheaded bipartisan legislation creating the National Vaccine Injury Compensation Program (NVICP) in the 1980s which was signed into law by President Ronald Regan. The NVICP was designed as a no-fault alternative to the traditional tort system to compensate those who suffer serious injury from the covered vaccines while providing liability protection to the vaccine manufacturers and the medical personnel who administer vaccines.

According to the most recent NVICP report, since its inception, over $4 billion has been paid to more than 6,300 people for their vaccine injuries including between 500 and 700 individuals in each of the last four years.[4] The number of children and adults compensated for vaccine injuries is 400% higher than it was a decade ago and 600% higher than it was in 1999.

Vaccines hold a unique place in our society. They are the only medications mandated by state governments, based on federal recommendations while also having liability protections for manufacturers and those administering the vaccine. As such it is critically important for the public to have access to open and honest dialogue. It is also critically important that we remain ever vigilant to ensure that everything is done to make vaccines as safe as possible, particularly since government is mandating that they be given to perfectly healthy children.

As you know medical science is not stagnant. One has simply to look at the progress in brain research in areas such as neuroplasticity as well as the current research on the microbiome and depression to understand that our scientific knowledge is always evolving. In the 1960s through the 1990s, we used an oral polio vaccine in the United States. Because it was a live virus vaccine that at times transmitted the polio virus through virus shedding, the Centers for Disease Control and Prevention (CDC) stopped recommending its use in the United States and now only

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[2] https://medlineplus.gov/druginfo/meds/a601176.html
[3] https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-february-2019.pdf
[4] https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/monthly-stats-february-2019.pdf

recommends the injected polio vaccine.[5] In 1999 the newly introduced Rotashield vaccine was recalled after ten cases of intussusception, a serious adverse event, were reported in infants.[6] Experts in the field created a new field of study known as vaccine adversomics.[7] [8] We are just scratching the surface of understanding who is at a higher risk for vaccine adverse reactions. The compensation of Hannah Poling in the NVICP highlighted that mitochondrial dysfunction may be a risk factor for the development of "autism-like" features according to past CDC Director Julie Gerberding.[9]

The word of mouth discussion such as that on Facebook is one of the ways common elements of vaccine injuries become known and can be addressed within the medical-public health environment.

I have refrained from portraying the parents and groups who talk about vaccines as 'anti-vaccine' because that is a bullying-tactic being used by individuals online and in the media rather than an accurate reflection of the thousands of parents who are expressing concerns about safety and asking federal public health authorities to conduct higher quality research to reduce the risks of seizures, brain injury, and other life altering adverse events. In fact, some of the parents engaged in such discussions believe that a particular vaccination may have contributed to the decline and adverse health outcomes of their children.

Addressing vaccine safety issues that have persisted decades is best addressed not by silencing or bullying one side or the other, but rather by engaging in a robust vaccine safety research program by truly independent researchers that will make vaccines safer and develop a better understanding of particular risk factors for infants, children and adults.

I appreciate Rep. Schiff's question and have a few of my own as well:

1. Do you as the CEO of Facebook believe in free speech?
2. Do you as the CEO of Facebook see the role of Facebook as a forum for open dialogue on topics of interest by the public?
3. If Facebook should decide to begin judging the medical accuracy of a statement posted by the public and by organizations, what will be the standards utilized? (For example, the letter written by U.S. Rep. Adam Schiff includes blatantly false information – would Facebook ban his letter from being posted?)
4. Does Facebook accept paid advertising from (a) pharmaceutical companies that produce vaccinations and are offered product liability protection through the VICCA program, (i.e. Merck, Glaxo, Pfizer, etc.) (b) medical associations that promote vaccinations (i.e. the American Academy of Pediatrics, the American Medical Association, etc.), recipients of grants from government agencies or pharmaceutical companies to promote immunizations, (Every Child By Two, etc..), or government organizations promoting vaccines such as the CDC or a state public health agency?

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[5] https://www.cdc.gov/mmwr/PDF/rr/rr4905.pdf
[6] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5334a3.htm
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4630804/pdf/nihms732579.pdf
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3752773/pdf/nihms-473716.pdf
[9] http://content.time.com/time/health/article/0,8599,1721109,00.html

5. What action has Facebook taken to address the bullying of individuals who discuss vaccine injury by individuals paid to promote vaccine policies sometimes referred to online as 'trolls'?
6. Recent news articles have suggested that Facebook has a deboosting code? Is that true, and if so, has Facebook deployed, or are you considering deploying deboosting code to limit pages whose owners discuss vaccine safety and related issues?
7. Reports also indicate Facebook may label some individuals as "trolls"? Is this true? And, if so, has a troll designation been assigned in relation to the vaccine safety discussions?

I look forward to a prompt response to this important topic.

Sincerely,

Bill Posey
Member of Congress

Enclosures

PERMANENT SELECT
COMMITTEE ON INTELLIGENCE
CHAIRMAN

COMMITTEE ON APPROPRIATIONS
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ADAM B. SCHIFF
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February 14, 2019

Mark Zuckerberg
Chairman and Chief Executive Officer
Facebook Inc.
1 Hacker Way
Menlo Park, CA 94025

Dear, Mr. Zuckerberg:

As more Americans use the Internet and social media platforms as their primary source of information, it is important that we explore the quality of the information that they receive, particularly on issues that directly impact the health and well-being of Americans, as well as the billions who use your site around the world. Accordingly, I am writing out of my concern that Facebook and Instagram are surfacing and recommending messages that discourage parents from vaccinating their children, a direct threat to public health, and reversing progress made in tackling vaccine-preventable diseases.

The scientific and medical communities are in overwhelming consensus that vaccines are both effective and safe. There is no evidence to suggest that vaccines cause life-threatening or disabling diseases, and the dissemination of unfounded and debunked theories about the dangers of vaccinations pose a great risk to public health. In fact, the World Health Organization listed vaccine hesitancy – the reluctance or refusal to vaccinate despite the availability of vaccines – as one of the top threats to global health in 2019. In a dramatic demonstration of the dangers, Washington state declared a public health emergency due to a measles epidemic in Clark County, signaling the resurgence of a potentially fatal disease that was effectively eliminated from the United States decades ago by vaccines.

There is strong evidence to suggest that at least part of the source of this trend is the degree to which medically inaccurate information about vaccines surface on the websites where many Americans get their information, among them Facebook and Instagram. As I have discussed with you in other contexts, and as you have acknowledged, the algorithms which power these services are not designed to distinguish quality information from misinformation or misleading information, and the consequences of that are particularly troubling for public health issues. I acknowledge that it may not always be a simple matter to determine when information is medically accurate, nor do we ask that your platform engage in the practice of medicine, but if a concerned parent consistently sees information in their Newsfeed that casts doubt on the safety or efficacy of vaccines, it could cause them to disregard the advice of their children's physicians and public health experts and decline to follow the recommended vaccination schedule. Repetition of information, even if false, can often be mistaken for accuracy, and exposure to anti-vaccine content via social media may negatively shape user attitudes towards vaccination.

Additionally, even parents and guardians who seek out accurate information about vaccines could unwittingly reach pages and videos with misinformation. A report by the Guardian[1] found that on both Facebook and YouTube, suggested searches related to vaccines often led users to pages or groups

[1] https://www.theguardian.com/media/2019/feb/01/facebook-youtube-anti-vaccination-misinformation-social-media

providing medically and scientifically inaccurate information. Finally, I am concerned by the report that Facebook accepts paid advertising that contains deliberate misinformation about vaccines.

As a Member of Congress who is deeply concerned about declining vaccination rates around the nation, I am requesting additional information on the steps that you currently take to provide medically accurate information on vaccinations to your users, and to encourage you to consider additional steps you can take to address this growing problem. I was pleased to see YouTube's recent announcement that it will no longer recommend videos that violate its community guidelines, such as conspiracy theories or medically inaccurate videos, and encourage further action to be taken related to vaccine misinformation.

Specifically, I request that you provide answers on the following questions:

- Does content which provides medically inaccurate information about vaccines violate your terms of service?
- What action(s) do you currently take to address misinformation related to vaccines on your platforms? Are you considering or taking additional actions?
- Do you accept paid advertising from anti-vaccine activists and groups on your platforms? How much has been spent in the past year on advertising on this topic?
- What steps do you currently take to prevent anti-vaccine videos or information from being recommended to users, either algorithmically or as a suggested search result?

I appreciate your timely response to these questions and encourage you to consider what additional steps you can take to address this growing problem. As more Americans rely on your services as their primary source of information, it is vital that you take that responsibility with the seriousness it requires, and nowhere more so than in matters of public health and children's health. Thank you for your attention to this important topic.

Sincerely,

Adam B. Schiff
Member of Congress

Vaccine Injury Table

Applies Only to Petitions for Compensation Filed under the National Vaccine Injury Compensation Program on or after March 21, 2017

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS 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. Paragraph (b) of this section sets forth additional provisions 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. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

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 B. Brachial Neuritis	≤4 hours. 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.
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, MM, MMRV)	A. Anaphylaxis B. Encephalopathy or encephalitis	≤4 hours. 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.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
IV. Vaccines containing rubella virus (*e.g.*, MMR, MMRV)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus (*e.g.*, MMR, MM, MMRV)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive	≤12 months.
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.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
IX. Haemophilus influenzae type b (Hib) 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	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive	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. Seasonal influenza vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
	D. Guillain-Barré Syndrome	3-42 days (not less than 3 days and not more than 42 days).
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.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
	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) *Provisions that apply to all conditions listed.* (1) Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed in paragraph (a) of this section (and defined in paragraphs (c) and (d) of this section) qualifies as a Table injury under paragraph (a) except when the definition in paragraph (c) requires exclusion.

(2) In determining whether or not an injury is a condition set forth in paragraph (a) of this section, the Court shall consider the entire medical record.

(3) An idiopathic condition that meets the definition of an illness, disability, injury, or condition set forth in paragraph (c) of this section shall be considered to be a condition set forth in paragraph (a) of this section.

(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 is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequela. 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.

(2) *Encephalopathy.* A vaccine recipient shall be considered to have suffered an encephalopathy if an injury meeting the description below of an acute encephalopathy occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) *Acute encephalopathy.* (A) For children less than 18 months of age who present:

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

(*2*) Following a seizure, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that 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 (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.

(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) *Exclusionary criteria for encephalopathy.* 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 it is shown that the encephalopathy was caused by:

(A) An underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, 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.

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

(i) *Acute encephalitis.* Encephalitis is indicated by evidence of neurologic dysfunction, as described in paragraph (c)(3)(i)(A) of this section, plus evidence of an inflammatory process in the brain, as described in paragraph (c)(3)(i)(B) of this section.

(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; abnormal 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 paragraph (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)/mm^3 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 Fahrenheit);

(*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) *Exclusionary criteria for encephalitis.* 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 it is shown that the encephalitis 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; or

(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.* (i) For purposes of paragraph (a) of this section, intussusception means the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered to be a Table intussusception:

(A) Onset that occurs with or after the third dose of a vaccine containing rotavirus;

(B) Onset within 14 days after an infectious disease associated with intussusception, including viral disease (such as those secondary to non-enteric or enteric adenovirus, or other enteric viruses such as Enterovirus), enteric bacteria (such as Campylobacter jejuni), or enteric parasites (such as Ascaris lumbricoides), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;

(C) Onset in a person with a preexisting condition identified as the lead point for intussusception such as intestinal masses and cystic structures (such as polyps, tumors, Meckel's diverticulum, lymphoma, or duplication cysts);

(D) Onset in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal

hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Scholein purpura, hematoma, or hemangioma); or

(E) Onset in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease).

(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; and

(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 idiopathic arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/determatomyositis, fibromyalgia, necrotizing vasculitis 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.

(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 or on the side opposite the injection. It is sometimes bilateral, affecting both upper extremities. A vaccine recipient shall be considered to have suffered brachial neuritis as a Table injury if such recipient manifests all of the following:

(i) Pain in the affected arm and shoulder is a presenting symptom and occurs within the specified time-frame;

(ii) Weakness;

(A) Clinical diagnosis in the absence of nerve conduction and electromyographic 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 weakness is limited to muscles supplied by 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/mm^3 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, 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. However, if culture or serologic testing is performed, and the viral illness is attributed to the vaccine-strain measles virus, the presumption of causation will remain in effect. 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 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 a vaccine intended for intramuscular administration in the upper arm. 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 intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time-frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular 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 viral disease.* Disseminated varicella vaccine-strain viral 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, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. 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, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. 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 sequela. 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 sequela of an episode of syncope meeting the Table requirements.

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

(15) *Guillain-Barré Syndrome (GBS).* (i) GBS is an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.

(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP, AMAN, and AMSAN requires:

(A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;

(B) A monophasic illness pattern;

(C) An interval between onset and nadir of weakness between 12 hours and 28 days;

(D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,

(E) The absence of an identified more likely alternative diagnosis.

(iii) Fisher Syndrome (FS), also known as Miller Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDP may be seen with limb weakness. The diagnosis of FS requires:

(A) Bilateral ophthalmoparesis;

(B) Bilateral reduced or absent tendon reflexes;

(C) Ataxia;

(D) The absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP, AMAN, or AMSAN);

(E) A monophasic illness pattern;

(F) An interval between onset and nadir of weakness between 12 hours and 28 days;

(G) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau);

(H) No alteration in consciousness;

(I) No corticospinal track signs; and

(J) The absence of an identified more likely alternative diagnosis.

(iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with

a total CSF white blood cell count below 50 cells per microliter. Both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

(v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness.

(vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, critical illness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.

(d) *Glossary for purposes of paragraph (c) of this section*—(1) *Chronic encephalopathy.* (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 first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis.

(ii) Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months from the first symptom or manifestation of onset or of significant aggravation of an 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, intradermal, or subcutaneous needle administration of a vaccine.

(3) *Sequela* means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(4) *Significantly decreased level of consciousness* is indicated by the presence of one or more of the following clinical signs:

(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* 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.

(e) *Coverage provisions.* (1) Except as provided in paragraph (e)(2), (3), (4), (5), (6), (7), or (8) of this section, this section applies only to petitions for compensation under the program filed with the United States Court of Federal Claims on or after February 21, 2017.

(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 (Included in item XIV of the Table) are included on the Table as of July 1, 2005. All other seasonal influenza vaccines (Item XIV of the Table) are included on the Table as of November 12, 2013.

(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.