

VIA EMAIL AND FEDEX

March 20, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary, U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
[REDACTED]

Re: *Petition Pursuant to 42 U.S.C. § 300aa-14(c)(2) to Amend the Vaccine Injury Table and Notice of Ongoing Statutory Violation Pursuant to 42 U.S.C. § 300aa-31*

Dear Secretary Kennedy:

On behalf of the Informed Consent Action Network (“**ICAN**”), and numerous individuals injured by childhood vaccines (collectively with ICAN, the “**Petitioners**”), we write to petition you, as the Secretary of Health and Human Services (“**the Secretary**”), to amend the Vaccine Injury Table (“**Table**”) pursuant to the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-14, and to provide notice pursuant to 42 U.S.C. § 300aa-31 that the current Table constitutes an ongoing violation of federal law.

I. Background and Purpose of the Vaccine Injury Compensation Program

Congress enacted the National Childhood Vaccine Injury Act (the “**Act**”) of 1986 which created the Vaccine Injury Compensation Program (“**VICP**”) with the express intent of providing “fair, expedited compensation” to individuals injured by covered vaccines.¹ In exchange for access to what was supposed to be a streamlined compensation system, injured parties relinquish significant rights—including the right to a jury trial, adjudication before an Article III judge, meaningful discovery, contingency-based attorneys’ fees to attract counsel, and having an adversary with limited resources, instead of being adversarial to HHS and the Department of Justice.

To implement this framework, and to provide a trade-off for the loss of these rights, Congress required the creation of a Vaccine Injury Table identifying those injuries, disabilities, illnesses, conditions, and deaths “associated with” covered vaccines and for which compensation may be awarded when the statutory criteria are met. Notably, Congress deliberately used the term “associated with,” rather than “caused by,” to define the scope of the injuries included on the Table. *See* 42 U.S.C. § 300aa-14(e). That choice was intentional. It reflects Congress’s recognition that vaccine science evolves and that definitive causal determinations may lag behind observed clinical associations. Accordingly, the statute directs that the Table “shall” include the “injuries, disabilities, illnesses, conditions, and deaths associated with” covered vaccines. 42 U.S.C. §300aa-14(e)(1)(B); 42 U.S.C. § 300aa-14(e)(2)(B).

¹ <https://www.congress.gov/committee-report/106th-congress/house-report/977/1>.

The statutory design ensures that, where evidence supports an association between a covered vaccine and an adverse condition, the Secretary must initiate rulemaking to amend the Table to add the adverse condition. The VICP was structured to operate in circumstances where scientific certainty is incomplete—not to delay Table inclusion until causation has been conclusively established. In that regard, the conditions detailed herein, including those identified in the Appendix, have been shown to be “associated with” the relevant vaccines, as reflected in findings and acknowledgments by the CDC, FDA, HRSA, other federal health authorities, and the vaccine manufacturers themselves.

II. Legal Authority and Statutory Framework

Under 42 U.S.C. § 300aa-14(c)(1), the Secretary is authorized to promulgate regulations modifying the Table through notice-and-comment rulemaking. Section § 300aa-14(c)(2) further provides that any person—including members of the public—may petition the Secretary to propose amendments to the Table. Unless a petition is clearly frivolous, it must be referred to the Advisory Commission on Childhood Vaccines (“**Commission**”) for its recommendations. Upon receipt of the Commission’s recommendation—or 180 days after referral, whichever occurs first—the Secretary shall either initiate a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for declining to do so.

The statute contains an additional mandatory directive. When the CDC recommends a vaccine for routine administration to children after August 1, 1993, the Secretary shall amend the Table within two years to include that vaccine and the injuries, disabilities, illnesses, conditions, and deaths associated with it. *See* 42 U.S.C. § 300aa-14(e)(2)(A)-(C). The statutory language is unequivocal: amendment is not discretionary. The obligation to amend the Table must be implemented through the rulemaking framework established by Congress.

III. Federal Health Authorities Have Evaluated and Identified Vaccine-Injury Associations That Are Not Currently on the Vaccine Injury Table

In 2009, HHS and HRSA contracted with the Institute of Medicine (“**IOM**”) to convene a committee of experts to review the epidemiologic, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by the VICP. The IOM was expressly charged by HHS and HRSA, and partially funded by CDC, with studying vaccine-injury pairs expressly identified by these agencies as being “associated with” one or more childhood vaccines, including evaluating the biological mechanisms that underlie specific theories for how a vaccine is related to a specific adverse event.

The resulting IOM report, published in 2012, studied approximately 158 vaccine-injury pairs that these agencies had identified as being associated and categorized them based on the strength of the available evidence, including findings of causal relationship, evidence favoring rejection of causal relationship, and instances in which the evidence was inadequate to accept or reject causation. In many instances, the IOM identified evidence consistent with association or biologic plausibility while acknowledging limitations in available studies.

The fact that federal health authorities identified what vaccines were associated with what injuries, and then commissioned, conducted, and relied upon this evaluation reflects official

recognition that these vaccine-injury pairs meet the statutory framework: these vaccines were recommended for routine use by CDC and these injuries are associated with these vaccines. Thus, where the federal government has acknowledged associations relevant to covered vaccines, those findings bear directly on the Secretary's obligation to amend the Table under 42 U.S.C. § 300aa-14.

Importantly, although not relevant to the determination as to whether they should be added to the Table, the IOM was unable to reach a causality conclusion for the vast majority of these vaccine-injury pairs—not because evidence showed a lack of association, but because the studies had not been done.

The IOM ruled out only five vaccine-injury pairs—including MMR and autism—because some studies have been done which the IOM used to rule out a causal relationship for those five specific pairs. Thus, this petition does not seek those injuries' inclusion on the Table. For the remaining vaccine-injury pairs, no such showing has been made. Federal law therefore requires that the Secretary add these injuries, which HRSA already expressly stated were associated with one or more vaccines, to the Table through rulemaking consistent with 42 U.S.C. § 300aa-14.

As the IOM Report itself states in its Preface:

The Institute of Medicine (IOM) was charged by Congress when it enacted the National Childhood Vaccine Injury Act in 1986 with reviewing the literature regarding **the adverse events associated with vaccines** covered by the program, a charge which the IOM has addressed 11 times in the past 25 years. Following in this tradition, the task of this committee was to assess dispassionately the scientific evidence about whether eight different vaccines cause adverse events (AE), a total of 158 vaccine-AE pairs, the largest study undertaken to date, and the first comprehensive review since 1994.²

The Memorandum of Agreement between HRSA and the IOM,³ executed in 2009, reflects that the IOM was charged with investigating “adverse health events associated with” vaccines—language that directly mirrors the statutory standard.⁴ The final report by the IOM recognizes this in its “Charge to the Committee:” “In 2009 the IOM entered into a contract with the Health Resources and Services Administration (HRSA)⁵ to convene a committee of experts to review the epidemiologic, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by the VICP.”

² See 2012 Institute of Medicine Report, “Adverse Effects of Vaccines, Evidence and Causality,” available at <https://www.nationalacademies.org/read/13164> at ix (emphasis added).

³ See <https://childrenshealthdefense.org/wp-content/uploads/01-11-MOAs-for-the-2011-IOM-Report.pdf>.

⁴ <https://childrenshealthdefense.org/wp-content/uploads/01-11-MOAs-for-the-2011-IOM-Report.pdf>.

⁵ “The CDC and the National Vaccine Program Office also provided funds for the project via the contract with HRSA.” (footnote in original source).

The IOM report reflects the committee’s expectation that “...the report will provide the scientific basis for review and adjudication of claims of vaccine injury by the VICP.”⁶

Thus, HHS, CDC, HRSA, and the National Vaccine Program Office are thus on record commissioning multiple studies to assess already-identified vaccine-injury associations, and yet have still failed to add those conditions to the Table. These federally commissioned findings underscore that the government has long recognized the relevance of association-based analysis under the Act.

Similarly, in 2021, the Agency for Healthcare Research and Quality (“AHRQ”) conducted an updated review of the same vaccine-injury pairs previously examined by the IOM.⁷ The report “was limited to a safety assessment and focuses on reported **adverse events associated with vaccines**” and the report’s “Strengths and Limitations” section stated: “Our review of the literature was extensive and designed to capture available evidence on the presence and absence of **adverse events associated with vaccines** currently in use in the United States for routine immunization.”⁸ Critically, the fact that AHRQ looked at these associated injury pairs again—years after the IOM Report—reflects a recognition and acknowledgement that not only are these injuries associated with vaccines, but there is reason to continue examining these associations.⁹

To be clear, HHS, CDC, HRSA, AHRQ, and the National Vaccine Program Office have publicly and continuously recognized numerous injuries as “associated with” vaccines and yet these injuries have not been added to the Table in violation of federal law.

IV. The Secretary’s Failure to Act Constitutes an Ongoing Statutory Violation

These conditions are mandated to be included on the Table pursuant to 42 U.S.C. § 300aa-14. Section 300aa-14(e) provides that the Table “shall” be amended to include “the injuries, disabilities, illnesses, conditions, and deaths associated with” covered vaccines within two years of those vaccines having been recommended for routine use. When the “associated with” standard is met, amendment must occur pursuant to 42 U.S.C. § 300aa-14(e).¹⁰

Federal health authorities have for years identified and acknowledged associations between specific vaccines and adverse health events. Where such associations have been recognized, the continued failure to amend the Table is inconsistent with the obligations imposed by 42 U.S.C. § 300aa-14.

⁶ See 2012 Institute of Medicine Report, “Adverse Effects of Vaccines, Evidence and Causality,” available at <https://www.nationalacademies.org/read/13164> at 2.

⁷ See AHRQ, CER-244, Safety of Vaccines Used for Routine Immunization in the United States (2021), available at <https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-244-safety-vaccines.pdf>.

⁸ *Id.* at 9 and ES-8 (emphasis added).

⁹ See also https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/vaccine-safety_research.pdf.

¹⁰ Injuries associated with vaccines routinely recommended before August 1, 1993 should have been added to the table no later than August 1, 1995. See 42 U.S.C. § 300aa-14(e)(1). Injuries associated with vaccines routinely recommended after August 1, 1993 should have been added within two years of the date of routine recommendation. See 42 U.S.C. § 300aa-14(e)(2).

This letter therefore serves as:

- (1) A formal petition pursuant to 42 U.S.C. § 300aa-14(c)(2) requesting referral to the Commission and initiation of rulemaking proceedings to amend the Table; and
- (2) Notice pursuant to 42 U.S.C. § 300aa-31 that the Secretary's failure to act concerning these acknowledged associations constitutes noncompliance with the mandatory statutory obligations under 42 U.S.C. § 300aa-14(e) and the procedural requirements of 42 U.S.C. § 300aa-14(c).

V. Identification of Vaccine-Injury Pairs (Appendix)

Attached hereto as “**the Appendix**” is a chart identifying specific vaccine-injury pairs that federal health authorities have previously acknowledged and recognized in various official publications to be associated with covered vaccines within the meaning of 42 U.S.C. § 300aa-14(e). The chart compiles findings and acknowledgements reflected in the 2012 IOM report commissioned and/or funded by HHS, HRSA, CDC, and the National Vaccine Program Office; the 2021 AHRQ report; CDC materials; and FDA-approved vaccine manufacturer package inserts.

The purpose of the Appendix is not to relitigate scientific questions, but to identify vaccine-injury pairs that the federal government itself has already recognized as associated. In numerous instances, federal authorities have expressly used the language of “association,” “correlation,” “relationship,” or biological plausibility in discussing these adverse events. Under the statutory standard, which refers to injuries “associated with” covered vaccines, such acknowledgements are legally sufficient to trigger the Secretary's obligation to evaluate their inclusion on the Table.

The Appendix further identifies, where applicable, each federal entity and/or manufacturer that has acknowledged the association as well as the source document reflecting that acknowledgment. This compilation is intended to assist the Secretary in discharging his statutory responsibilities by providing a consolidated reference to injuries already recognized within federal health literature as “associated with” certain vaccines.

Petitioners respectfully request that the Secretary review each vaccine-injury pair identified in the Appendix and forthwith initiate proceedings to amend the Table forthwith consistent with the requirements of 42 U.S.C. § 300aa-14(c)(2) and (e).

VI. Petition and Requests

Pursuant to 42 U.S.C. § 300aa-14(c)(2) and the citizens' petition provision of the statute, Petitioners respectfully request that the Secretary:

1. Refer this petition to the Commission in accordance with 42 U.S.C. § 300aa-14(c)(2);
2. Initiate notice-and-comment rulemaking to evaluate amendment of the Table with respect to the vaccine-injury pairs identified in the Appendix;

3. Include in any such rulemaking all injuries, disabilities, illnesses, conditions, and deaths associated with covered vaccines where federal health authorities—including HHS, HRSA, CDC, AHRQ, the National Vaccine Program Office, and FDA—or vaccine manufacturers (as reflected in FDA-approved package inserts) have acknowledged evidence of association;
4. Ensure that any amendments to the Table reflect all associations acknowledged in federal health literature—including through the IOM commissioning process, AHRQ reports, CDC recommendations, FDA approvals, and FDA-approved vaccine manufacturer package inserts—consistent with the statutory standard that an “association,” rather than causation, triggers inclusion on the Table; and
5. Comply with the mandate of 42 U.S.C. § 300aa-14(e)(2) to amend the Table to include all vaccines routinely recommended by the CDC after August 1, 1993, along with their associated injuries, disabilities, illnesses, conditions, and deaths.

VII. Conclusion

The VICP was designed to provide a safety net for vaccine-injured individuals—a promise to the American public in exchange for the significant legal rights they surrendered. That promise has not been kept, and as such, the VICP’s statutory objectives have not been realized. Congress employed mandatory language and established specific procedural safeguards to ensure that the Table would be amended when appropriate. For more than a decade, federal health authorities have acknowledged associations between vaccines and injuries while simultaneously failing to add those injuries to the Table, leaving affected individuals without access to compensation the statute was designed to provide.

To avoid litigation, Petitioners respectfully petition and urge the Secretary to act immediately to fulfill the statutory mandate, strengthen and clarify the administration of the VICP consistent with congressional intent, and ensure that all vaccine-injured Americans receive the compensation they are owed. At a minimum, that includes adding to the Table the injuries that have already been admitted by federal health agencies to be associated with one or more vaccines, as detailed in the Appendix to this letter.

We stand ready to provide any additional information, data, or briefing that would assist the Secretary in taking the required action. Thank you for your deep and abiding commitment to make HHS transparent and accountable, and to correcting its longstanding failures and deficiencies. We appreciate your sacrifice and work toward those critical goals on behalf of the American people.

Very truly yours,



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Elizabeth A. Brehm, Esq.
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APPENDIX – VACCINE INJURIES TO ADD TO VACCINE INJURY TABLE

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	Acute Disseminated Encephalomyelitis (ADEM)	X	X	X	X	X			IOM
	Apnea						X	X	Infanrix
	Arthralgia						X	X	Boostrix
	Arthropathy	X	X	X	X	X			IOM
	Arthus hypersensitivity						X	X	Adacel
	Ataxia	X	X	X	X	X			IOM
	Autism	X	X	X	X	X			IOM
	Bronchitis						X	X	Infanrix
	Cellulitis						X	X	Daptacel, Infanrix
	Chronic Inflammatory Disseminated Polyneuropathy	X	X	X	X	X			IOM
	Chronic Urticaria	X	X	X	X	X			IOM
	Convulsions (with and without fever)	X	X	X	X	X	X	X	IOM, Boostrix, Adacel, Daptacel
	Cyanosis						X	X	Daptacel, Infanrix
	Encephalitis	X	X	X	X	X	X	X	IOM, Boostrix
	Encephalopathy	X	X	X	X	X	X	X	IOM, Infanrix
	Extensive swelling of the injected limb						X	X	Boostrix, Daptacel, Adacel
	Facial palsy	X	X	X	X	X	X	X	IOM, Adacel, Boostrix
	Fibromyalgia	X	X	X	X	X			IOM
	Guillain-Barré syndrome						X	X	Adacel
	Henoch-Schönlein purpura						X	X	Boostrix
	Hypotonic-Hyporesponsive Episode (HHE)						X	X	Daptacel
	Hypersensitivity						X	X	Daptacel, Infanrix, Adacel
	Hypoesthesia						X	X	Adacel
	Hypotonia						X	X	Daptacel, Infanrix
	Loss of consciousness						X	X	Boostrix
	Multiple Sclerosis Onset in Adults	X	X	X	X	X			IOM
Multiple Sclerosis Relapse in Adults	X	X	X	X	X			IOM	
Multiple Sclerosis Relapse in Children	X	X	X	X	X			IOM	

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
	Myelitis						X	X	Adacel
	Myocarditis	X	X	X	X	X	X	X	IOM, Adacel, Boostrix
	Myositis						X	X	Adacel
	Opsoclonus Myoclonus Syndrome	X	X	X	X	X			IOM
	Optic Neuritis	X	X	X	X	X			IOM
	Paresthesia						X	X	Adacel, Boostrix
	Pruritus						X	X	Infanrix
	Respiratory tract infection						X	X	Infanrix
	Serum Sickness	X	X	X	X	X			IOM
	Sudden Infant Death Syndrome	X	X	X	X	X	X	X	IOM, Infanrix
	Syncope						X	X	Daptacel, Infanrix, Adacel, Boostrix
	Thrombocytopenia	X	X	X	X	X	X	X	IOM, Infanrix
	Transverse Myelitis	X	X	X	X	X			IOM
	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)	Acute Disseminated Encephalomyelitis (ADEM)	X	X	X	X	X		
Apnea							X	X	Infanrix
Arthralgia							X	X	Boostrix
Arthropathy		X	X	X	X	X			IOM
Arthus hypersensitivity							X	X	Adacel
Ataxia		X	X	X	X	X			IOM
Autism		X	X	X	X	X			IOM
Bronchitis							X	X	Infanrix
Cellulitis							X	X	Daptacel, Infanrix
Chronic Inflammatory Disseminated Polyneuropathy		X	X	X	X	X			IOM
Chronic Urticaria		X	X	X	X	X			IOM
Convulsions (with and without fever)		X	X	X	X	X	X	X	IOM, Boostrix, Adacel, Daptacel
Cyanosis							X	X	Daptacel, Infanrix
Extensive swelling of the injected limb							X	X	Boostrix, Daptacel, Adacel
Facial palsy		X	X	X	X	X	X	X	IOM, Adacel, Boostrix
Fibromyalgia		X	X	X	X	X			IOM
Guillain-Barré syndrome							X	X	Adacel
Henoch-Schönlein purpura						X	X	Boostrix	

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
	Hypotonic-Hyporesponsive Episode (HHE)						X	X	Daptacel
	Hypersensitivity						X	X	Daptacel, Infanrix, Adacel
	Hypoesthesia						X	X	Adacel
	Hypotonia						X	X	Daptacel, Infanrix
	Loss of consciousness						X	X	Boostrix
	Multiple Sclerosis Onset in Adults	X	X	X	X	X			IOM
	Multiple Sclerosis Relapse in Adults	X	X	X	X	X			IOM
	Multiple Sclerosis Relapse in Children	X	X	X	X	X			IOM
	Myelitis						X	X	Adacel
	Myocarditis	X	X	X	X	X	X	X	IOM, Adacel, Boostrix
	Myositis						X	X	Adacel
	Opsoclonus Myoclonus Syndrome	X	X	X	X	X			IOM
	Optic Neuritis	X	X	X	X	X			IOM
	Paresthesia						X	X	Adacel, Boostrix
	Pruritus						X	X	Infanrix
	Respiratory tract infection						X	X	Infanrix
	Serum Sickness	X	X	X	X	X			IOM
	Sudden Infant Death Syndrome	X	X	X	X	X	X	X	IOM, Infanrix
	Syncope						X	X	Daptacel, Infanrix, Adacel, Boostrix
	Thrombocytopenia	X	X	X	X	X	X	X	IOM, Infanrix
	Transverse Myelitis	X	X	X	X	X	X	X	IOM
III. Vaccines containing measles, mumps, and rubella virus or any of its components (e.g., MMR, MM, MMRV)	Acute disseminated encephalomyelitis (ADEM)	X	X	X	X	X	X	X	IOM, MMRII
	Acute hemorrhagic edema of infancy						X	X	MMRII
	Afebrile Seizures / Afebrile Convulsions	X	X	X	X	X	X	X	IOM, Priorix, MMRII
	Arthralgia						X	X	MMRII, Priorix
	Arthropathy in Men	X	X	X	X	X			IOM
	Ataxia	X	X	X	X	X	X	X	IOM, MMRII
	Atypical measles						X	X	MMRII
	Brachial Neuritis	X	X	X	X	X			IOM
	Bronchial spasm						X	X	MMRII
	Cerebellitis						X	X	Priorix

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
	Chronic Arthralgia in Women	X	X	X	X	X			IOM
	Chronic Arthropathy in Children	X	X	X	X	X			IOM
	Chronic cutaneous granulomas with rubella vaccine virus detected by biopsy						X	X	MMRII, Priorix
	Chronic Fatigue Syndrome	X	X	X	X	X			IOM
	Chronic Inflammatory Disseminated Polyneuropathy	X	X	X	X	X			IOM
	Epididymitis						X	X	MMRII
	Erythema multiforme						X	X	MMRII, Priorix
	Febrile Seizures	X	X	X	X	X	X	X	IOM, MMRII
	Fibromyalgia	X	X	X	X	X			IOM
	Guillain-Barré syndrome	X	X	X	X	X	X	X	IOM, MMRII, Priorix
	Hearing Loss (nerve deafness and sensorineural deafness)	X	X	X	X	X	X	X	IOM, MMRII, Priorix
	Hepatitis	X	X	X	X	X			IOM
	Leukocytosis						X	X	MMRII
	Measles inclusion body encephalitis (MIBE)	X	X	X	X	X	X	X	IOM, MMRII
	Measles-like illness						X	X	Priorix
	Meningitis						X	X	Priorix
	Multiple Sclerosis Onset in Adults	X	X	X	X	X			IOM
	Multiple Sclerosis Onset in Children	X	X	X	X	X			IOM
	Mumps-like illness						X	X	Priorix
	Ocular palsies						X	X	MMRII
	Opsoclonus Myoclonus Syndrome	X	X	X	X	X			IOM
	Optic neuritis						X	X	MMRII
	Orchitis						X	X	MMRII
	Otitis media						X	X	MMRII
	Pancreatitis						X	X	MMRII
	Panniculitis						X	X	MMRII
	Papillitis						X	X	MMRII
	Paresthesia						X	X	MMRII
	Parotitis						X	X	MMRII
	Peripheral neuritis						X	X	Priorix
	Pneumonia						X	X	MMRII
	Pneumonitis						X	X	MMRII
	Polyneuritis						X	X	MMRII
	Polyneuropathy						X	X	MMRII
	Henoch-Schönlein Purpura						X	X	MMRII

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
	Retinitis						X	X	MMRII
	Subacute sclerosing panencephalitis (SSPE)						X	X	MMRII
	Syncope						X	X	MMRII, Priorix
	Thrombocytopenia						X	X	MMRII, Priorix
	Transverse Myelitis	X	X	X	X	X	X	X	IOM, MMRII, Priorix
	Vasculitis						X	X	MMRII, Priorix
VII. Vaccines containing polio inactivated virus (e.g., IPV)	Arthralgia						X	X	Ipol
	Convulsion						X	X	Ipol
	Paresthesia						X	X	Ipol
	Syncope						X	X	Ipol
VIII. Hepatitis B vaccines	Acute Disseminated Encephalomyelitis	X	X	X	X	X			IOM
	Apnea						X	X	Engerix-B
	Apparent hypersensitivity syndrome (serum sickness-like)						X	X	Engerix-B
	Arthritis	X	X	X	X	X	X	X	IOM, Engerix-B, Recombivax HB
	Brachial Neuritis	X	X	X	X	X			IOM
	Bronchospasm including asthma-like symptoms						X	X	Engerix-B, Recombivax HB
	Chronic Inflammatory Disseminated Polyneuropathy	X	X	X	X	X			IOM
	Eczema						X	X	Engerix-B, Recombivax HB
	Encephalitis/Encephalopathy	X	X	X	X	X	X	X	IOM, Engerix-B, Recombivax HB
	Erythema multiforme including Stevens-Johnson syndrome						X	X	Engerix-B, Recombivax HB
	Erythema nodosum						X	X	Engerix-B
	First Demyelinating Event in Adults	X	X	X	X	X			IOM
	First Demyelinating Event in Children	X	X	X	X	X			IOM
Guillain-Barré syndrome	X	X	X	X	X	X	X	X	IOM, Recombivax

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
									HB, Engerix-B
	Herpes zoster						X	X	Engerix-B, Recombivax HB
	Hypoesthesia						X	X	Engerix-B, Recombivax HB
	Keratitis						X	X	Engerix-B
	Lichen planus						X	X	Engerix-B
	Lupus-like syndrome						X	X	Recombivax HB
	Meningitis						X	X	Engerix-B
	Migraine						X	X	Engerix-B, Recombivax HB
	Multiple sclerosis	X	X	X	X	X	X	X	IOM, Recombivax HB, Engerix-B
	Multiple sclerosis, exacerbation	X	X	X	X	X	X	X	IOM, Recombivax HB, Engerix-B
	Muscle weakness						X	X	Recombivax HB
	Neuritis						X	X	Engerix-B
	Neuromyelitis Optica	X	X	X	X	X			IOM
	Optic neuritis						X	X	Engerix-B, Recombivax HB
	Paralysis						X	X	Engerix-B
	Paresis						X	X	Engerix-B
	Paresthesia						X	X	Engerix-B
	Peripheral neuropathy including Bell's palsy						X	X	Recombivax HB, Engerix-B
	Petechiae						X	X	Recombivax HB
	Polyarteritis Nodosa, Onset or Exacerbation	X	X	X	X	X	X	X	IOM, Recombivax HB
	Purpura						X	X	Engerix-B
	Radiculopathy						X	X	Recombivax HB
	Seizures	X	X	X	X	X	X	X	IOM, Recombivax HB, Engerix-B

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
	Serum-sickness						X	X	Recombivax HB
	Syncope						X	X	Engerix-B, Recombivax HB
	Systemic Lupus Erythematosus, Onset or Exacerbation	X	X	X	X	X	X	X	IOM, Recombivax HB
	Tachycardia						X	X	Engerix-B, Recombivax HB
	Thrombocytopenia						X	X	Engerix-B, Recombivax HB
	Tinnitus						X	X	Engerix-B, Recombivax HB
	Transverse Myelitis	X	X	X	X	X	X	X	IOM, Recombivax HB, Engerix-B
	Type 1 Diabetes	X	X	X	X	X			IOM
	Uveitis						X	X	Recombivax HB
	Vasculitis, Onset or Exacerbation	X	X	X	X	X	X	X	IOM, Recombivax HB, Engerix-B
	Visual disturbances						X	X	Recombivax HB
IX. Haemophilus influenzae type b (Hib) vaccines	Anaphylaxis						X	X	Hiberix
	Apnea						X	X	Hiberix
	Convulsions (with or without fever)						X	X	Hiberix, ActHIB
	Extensive limb swelling						X	X	ActHIB, Hiberix
	Febrile seizures						X	X	PedvaxHIB
	Hypotonic-hyporesponsive episode						X	X	Hiberix
	Peripheral edema						X	X	ActHIB
	Syncope						X	X	Hiberix
X. Varicella vaccines	Acute Disseminated Encephalomyelitis	X	X	X	X	X			IOM
	Arthropathy, Onset or Exacerbation	X	X	X	X	X			IOM
	Aplastic anemia						X	X	Varivax
	Aseptic meningitis						X	X	Varivax
	Ataxia	X	X	X	X	X	X	X	IOM, Varivax
	Bell's palsy						X	X	Varivax

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
	Cerebrovascular accident						X	X	Varivax
	Encephalopathy / Encephalitis	X	X	X	X	X	X	X	IOM, Varivax
	Erythema multiforme						X	X	Varivax
	Guillain-Barré syndrome	X	X	X	X	X	X	X	IOM, Varivax
	Henoch-Schönlein purpura						X	X	Varivax
	Herpes zoster (wild-type or vaccine strain)						X	X	Varivax
	Meningitis						X	X	Varivax
	Necrotizing retinitis (in immunocompromised individuals)						X	X	Varivax
	Paresthesia						X	X	Varivax
	Peripheral edema						X	X	Varivax
	Pneumonia/pneumonitis						X	X	Varivax
	Secondary bacterial infections of skin and soft tissue						X	X	Varivax
	Seizures	X	X	X	X	X	X	X	IOM, Varivax
	Stevens-Johnson syndrome						X	X	Varivax
	Syncope						X	X	Varivax
	Thrombocytopenia	X	X	X	X	X	X	X	IOM, Varivax
	Transverse Myelitis	X	X	X	X	X	X	X	IOM, Varivax
XI. Rotavirus vaccines	Anaphylactic reaction						X	X	RotaTeq
	Gastroenteritis with vaccine viral shedding in infants with SCID						X	X	Rotarix, RotaTeq
	Hematochezia						X	X	RotaTeq, Rotarix
	Idiopathic thrombocytopenic purpura						X	X	Rotarix
	Kawasaki disease						X	X	Rotarix, RotaTeq
	Transmission of vaccine virus strains from vaccine recipient to non-vaccinated contacts						X	X	RotaTeq
XII. Pneumococcal conjugate vaccines	Anaphylactic/anaphylactoid reaction including shock						X	X	Prevnar 13
	Apnea						X	X	Prevnar 13
	Cyanosis						X	X	Prevnar 13
	Erythema multiforme						X	X	Prevnar 13
	Hypotonia						X	X	Prevnar 13
XIII. Hepatitis A vaccines	Acute Disseminated Encephalomyelitis	X	X	X	X	X			IOM
	Anaphylaxis	X	X	X	X	X	X	X	IOM, Havrix
	Autoimmune Hepatitis	X	X	X	X	X			IOM
	Bell's Palsy	X	X	X	X	X			IOM
	Cerebellar ataxia						X	X	Vaqta
	Chronic Inflammatory Disseminated Polyneuropathy	X	X	X	X	X			IOM

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)	
	Congenital anomaly						X	X	Havrix	
	Convulsion						X	X	Havrix	
	Encephalitis / Encephalopathy						X	X	Vaqta, Havrix	
	Erythema multiforme						X	X	Havrix	
	Guillain-Barré syndrome	X	X	X	X	X	X	X	IOM, Vaqta, Havrix	
	Hepatitis						X	X	Havrix	
	Hyperhidrosis						X	X	Havrix	
	Hypoesthesia						X	X	Havrix	
	Jaundice						X	X	Havrix	
	Multiple Sclerosis	X	X	X	X	X	X	X	IOM, Havrix	
	Myelitis						X	X	Havrix	
	Neuropathy						X	X	Havrix	
	Paresthesia						X	X	Havrix	
	Serum sickness–like syndrome						X	X	Havrix	
	Syncope						X	X	Havrix	
	Thrombocytopenia						X	X	Havrix, Vaqta	
	Transverse Myelitis	X	X	X	X	X	X	X	X	IOM
	Vasculitis							X	X	Havrix
XIV. Seasonal influenza vaccines	Abdominal pain or discomfort						X	X	Fluarix	
	Abnormal gait						X	X	FluLaval	
	Acute Disseminated Encephalomyelitis	X	X	X	X	X			IOM	
	Arthritis						X	X	FluLaval	
	Arthropathy, Onset or Exacerbation	X	X	X	X	X			IOM	
	Asthenia						X	X	FluLaval, Fluarix, Fluzone	
	Asthma Exacerbation or Reactive Airway Disease Episodes	X	X	X	X	X	X	X	IOM, Fluarix	
	Brachial Neuritis	X	X	X	X	X	X	X	IOM, Fluzone	
	Bronchospasm						X	X	FluLaval, Fluarix	
	Cellulitis and large injection site swelling						X	X	Afluria, FluLaval	
	Chest pain						X	X	Fluzone, FluLaval, Fluarix	
	Chronic Inflammatory Disseminated Polyneuropathy	X	X	X	X	X			IOM	
	Conjunctivitis						X	X	Fluarix	
	Convulsions (including febrile seizures)						X	X	Afluria, Fluarix,	

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
									Fluzone, FluLaval
	Dysphagia						X	X	FluLaval
	Dysphonia						X	X	FluLaval
	Encephalitis	X	X	X	X	X			IOM
	Encephalomyelitis						X	X	Afluria, Fluarix
	Encephalopathy	X	X	X	X	X	X	X	IOM, FluLaval, Afluria
	Erythema multiforme						X	X	Fluarix
	Exacerbation of symptoms of mitochondrial encephalomyopathy (Leigh syndrome)						X	X	FluMist
	Extensive swelling of injected limb						X	X	Flucelvax
	Facial palsy (Bell's palsy)						X	X	Fluzone, Flublok, Fluarix, FluMist, FluLaval
	Facial paresis						X	X	Fluarix
	Fibromyalgia	X	X	X	X	X			IOM
	Henoch-Schönlein purpura						X	X	Fluarix
	Hypoesthesia						X	X	FluLaval, Fluarix
	Hypokinesia						X	X	FluLaval
	Influenza-like illness						X	X	Afluria, Fluarix, FluLaval
	Insomnia						X	X	FluLaval
	Laryngitis						X	X	FluLaval
	Limb paralysis						X	X	FluLaval
	Meningitis (including Eosinophilic meningitis)						X	X	FluMist
	Multiple Sclerosis Onset or Relapse in Adults	X	X	X	X	X			IOM
	Muscle weakness						X	X	FluLaval
	Myelitis (including encephalomyelitis and transverse myelitis)						X	X	Fluzone, Fluarix
	Myocardial Infarction	X	X	X	X	X			IOM
	Neuralgia						X	X	Afluria
	Neuritis or neuropathy						X	X	Afluria, Fluarix
	Neuromyelitis Optica	X	X	X	X	X			IOM
	Ocular hyperemia						X	X	Fluzone
	Optic neuritis/neuropathy						X	X	Fluzone

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
	Paresthesia						X	X	Fluzone, Afluria, FluLaval, Flucelvax, Fluarix
	Pericarditis						X	X	FluMist
	Photophobia						X	X	FluLaval
	Polyarteritis Nodosa	X	X	X	X	X			IOM
	Respiratory distress						X	X	Fluarix
	Serum sickness						X	X	Fluarix
	Small Fiber Neuropathy	X	X	X	X	X			IOM
	Stevens-Johnson syndrome						X	X	Fluzone, Fluarix
	Stridor						X	X	Fluarix
	Stroke	X	X	X	X	X			IOM
	Syncope and presyncope						X	X	Afluria, Flublok, Fluzone, FluLaval, Flucelvax, Fluarix
	Systemic Lupus Erythematosus, Onset or Exacerbation	X	X	X	X	X			IOM
	Tachycardia						X	X	Fluarix
	Thrombocytopenia						X	X	Fluzone, Afluria
	Tonsillitis						X	X	Fluarix
	Transverse Myelitis	X	X	X	X	X	X	X	IOM, Afluria
	Tremor						X	X	FluLaval
	Vaccine-associated encephalitis						X	X	FluMist
	Vasculitis, Onset or Exacerbation	X	X	X	X	X	X	X	IOM, Fluarix, Afluria, Fluzone
	Vertigo						X	X	Fluarix
XV. Meningococcal vaccines	Acute Disseminated Encephalomyelitis	X	X	X	X	X			IOM
	Arthralgia						X	X	Menveo
	Balance disorder (including vestibular disorder)						X	X	Menveo
	Bell's palsy						X	X	Menveo
	Chronic Headache	X	X	X	X	X			IOM
	Chronic Inflammatory Disseminated Polyneuropathy	X	X	X	X	X			IOM
	Convulsion						X	X	MenQuadfi, Menveo
	Encephalitis / Encephalopathy	X	X	X	X	X			IOM
	Eyelid ptosis						X	X	Menveo

Table Category	Injury	HHS	HRSA	CDC	National Vaccine Program Office	AHRQ	FDA	Manufacturer	Source (vaccine names refer to package insert for that product)
	Febrile seizure						X	X	MenQuadfi
	Guillain-Barré syndrome	X	X	X	X	X			IOM
	Head injury						X	X	Menveo
	Hearing impaired						X	X	Menveo
	Multiple Sclerosis	X	X	X	X	X			IOM
	Skin exfoliation						X	X	Menveo
	Syncope						X	X	MenQuadfi, Menveo
	Transverse Myelitis	X	X	X	X	X			IOM
XVI. Human papillomavirus (HPV) vaccines	Acute disseminated encephalomyelitis	X	X	X	X	X	X	X	IOM, Gardasil 9
	Amyotrophic Lateral Sclerosis	X	X	X	X	X			IOM
	Arthralgia						X	X	Gardasil 9
	Asthenia						X	X	Gardasil 9
	Autoimmune diseases						X	X	Gardasil 9
	Autoimmune hemolytic anemia						X	X	Gardasil 9
	Brachial Neuritis	X	X	X	X	X			IOM
	Bronchospasm						X	X	Gardasil 9
	Cellulitis						X	X	Gardasil 9
	Chronic Inflammatory Disseminated Polyneuropathy	X	X	X	X	X			IOM
	Deep venous thrombosis						X	X	Gardasil 9
	Guillain-Barré syndrome	X	X	X	X	X	X	X	IOM, Gardasil 9
	Hypercoagulable States	X	X	X	X	X			IOM
	Idiopathic thrombocytopenic purpura						X	X	Gardasil 9
	Motor neuron disease						X	X	Gardasil 9
	Multiple Sclerosis	X	X	X	X	X			IOM
	Neuromyelitis Optica	X	X	X	X	X			IOM
	Pancreatitis	X	X	X	X	X	X	X	IOM, Gardasil 9
	Paralysis						X	X	Gardasil 9
	Pulmonary embolus						X	X	Gardasil 9
Seizures						X	X	Gardasil 9	
Syncope						X	X	Gardasil 9	
Thromboembolic Events	X	X	X	X	X			IOM	
Transverse Myelitis	X	X	X	X	X	X	X	IOM, Gardasil 9	

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