APPENDIX D
Vaccine Safety

Appendix D

The Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following receipt of US-licensed vaccines. In recent years, VAERS has received approximately 30,000 US reports annually, most of which describe mild adverse events like fever and injection site reactions. Very rarely, people experience serious adverse events following immunization. By monitoring such events, VAERS can help to identify important new safety concerns.

VAERS is a spontaneous reporting system, meaning that reports about adverse events can be submitted voluntarily by anyone. VAERS has limitations as a surveillance system: data may, and often do, include incorrect and incomplete information. Underreporting, or failure to report events, is another limitation. Serious medical events are more likely to be reported than minor ones. Importantly, VAERS cannot determine cause and effect. The report of an adverse event to VAERS does not indicate that a vaccine caused the event. It only indicates that the event occurred sometime after vaccine receipt. VAERS accepts all reports without judging whether or not the event was caused by the vaccine. More information on the limitations of VAERS data can be found at: http://vaers.hhs.gov/data/index

WHO CAN REPORT? Anyone can submit a VAERS report. Most reports are sent in by vaccine manufacturers and health care providers, but vaccine recipients, parents/guardians, and others may also submit reports.

WHAT SHOULD BE REPORTED? VAERS encourages reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States.

The National Childhood Vaccine Injury Act of 1986 requires health care providers to report:

- Any health event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine,
- Any event listed in the Reportable Events Table that occurs within the specified time period after the vaccination.

A copy of the Reportable Events Table can be found on the following page, or at http://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf.

HOW TO REPORT There are three ways to report to VAERS:

- **Online.** Complete a VAERS online form at https://vaers.hhs.gov/esub/step1. Before you begin, review the Instructions for Completing the VAERS On-Line Form at http://vaers.hhs.gov/esub/help. The VAERS On-Line form must be completed in a single sitting (i.e., you cannot save your work and return later to finish). Information supplied on this form is transmitted securely to VAERS.

- **Fax.** Download a VAERS form at http://vaers.hhs.gov/resources/vaers_form.pdf, or request a form by sending an e-mail to info@vaers.org, by calling 800-822-7967, or by faxing a request to 877-721-0366. Review the Instructions for Completing the VAERS Paper Form at http://vaers.hhs.gov/helpinstructions. Fax the completed form to 877-721-0366.

- **Mail.** Download a VAERS form at http://vaers.hhs.gov/resources/vaers_form.pdf, or request a form by sending an e-mail to info@vaers.org, by calling 800-822-7967, or by faxing a request to 877-721-0366. Review the Instructions for Completing the VAERS Paper Form at http://vaers.hhs.gov/helpinstructions. Mail the completed form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. A pre-paid postage stamp is included on the back of the form.

For more information, visit the VAERS website at http://vaers.hhs.gov .

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VAERS Table of Reportable Events Following Vaccination*

Vaccine/Toxoid	Event and Interval from Vaccination
Tetanus in any combination: DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaPHepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pertussis in any combination: DTaP, DTP, DTP-Hib, Tdap, P, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles, mumps and rubella in any combination: MMR, MR, M, MMRV, R	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (15 days) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rubella in any combination: MMR, MMRV, MR, R	A. Chronic arthritis (42 days) B. Any acute complications or sequelae (including death) of above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles in any combination*:* MMR, MMRV, MR, M	A. Thrombocytopenic purpura (7-30 days) B. Vaccine-strain measles viral infection in an immunodeficient recipient (6 months) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Oral Polio (OPV)	A. Paralytic polio o in a non-immunodeficient recipient (30 days) o in an immunodeficient recipient (6 months) o in a vaccine-associated community case (interval - not applicable) B. Vaccine-strain polio viral infection o in a non-immunodeficient recipient (30 days) o in an immunodeficient recipient (6 months) o in a vaccine-associated community case (interval - not applicable) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Inactivated Polio: IPV, DTaP-IPV, DTaP-IPV/HIB, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Any acute complication or sequelae (including death) of the above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis B in any combination: HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB	A. Anaphylaxis or anaphylactic shock (7 days) B. Any acute complications or sequelae (including death) of the above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hemophilus influenzae type b in any combination (conjugate): Hib, Hib-HepB, DTP-Hib, DTaP-IPV/Hib	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert)
Varicella in any combination: VAR, MMRV	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert)
Rotavirus (monovalent or pentavalent) RV1, RV5	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert)
Pneumococcal conjugate (7-valent or 13-valent) PCV7, PCV13	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert)

The Vaccine Injury Compensation Program (VICP)

The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims. It was established as part of the National Childhood Vaccine Injury Act of 1986, after a rash of lawsuits against vaccine manufacturers and healthcare providers threatened to cause vaccine shortages and reduce vaccination rates.

The VICP is administered jointly by the U.S. Department of Health and Human Services (HHS), the U.S. Court of Federal Claims (the Court), and the U.S. Department of Justice (DOJ). The VICP is located in the HHS, Health Resources and Services Administration (HRSA), Healthcare Systems Bureau, Division of Vaccine Injury Compensation.

Briefly, an individual claiming a vaccine-related injury or death files a petition for compensation with the Court, and may be represented by an attorney. A HHS physician reviews the petition to determine whether it meets the medical criteria for compensation. A recommendation is provided to the Court. The HHS position is presented before a "special master," who makes the decision for compensation under the VICP. A decision may be appealed to a judge of the Court, then to the Federal Circuit Court of Appeals, and eventually to the U.S. Supreme Court.

A petitioner may file a claim in civil court against the vaccine company and/or the vaccine administrator only after first filing a claim under the VICP and then rejecting the decision of the Court.

Who Can File a Claim?

- You may file a claim if you received a vaccine covered by the VICP and believe that you have been injured by this vaccine.
- You may also file a claim if you are a parent or legal guardian of a child or disabled adult who received a vaccine covered by the VICP and believe that the person was injured by this vaccine.
- You may file a claim if you are the legal representative of the estate of a deceased person who received a vaccine covered by the VICP and believe that the person's death resulted from the vaccine injury.
- You may file a claim if you are ***not*** a United States citizen.
- Some people who receive vaccines outside of the U.S. may be eligible for compensation. See the VICP website for more details.
- **In addition**, to be eligible to file a claim, the effects of the person's injury must have:
    1. lasted for more than 6 months after the vaccine was given; or
    2. resulted in a hospital stay **and** surgery; or
    3. resulted in death.

There is no age restriction on who may file a claim. Anyone receiving a vaccine covered by the VICP, no matter their age, can file a claim or have one filed on their behalf.

To learn how to file a claim, see the VICP website at http://www.hrsa.gov/vaccinecompensation/fileclaim.html.

Vaccines covered by VICP are diphtheria, tetanus, pertussis, Hib, hepatitis A, hepatitis B, human papillomavirus, trivalent influenza, measles, mumps, rubella, meningococcal, polio, pneumococcal conjugate, rotavirus, and varicella, in any combination. (Additional vaccines may be added in the future.)

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The **Vaccine Injury Table** makes it easier for some people to get compensation. The Table lists and explains injuries and conditions that are presumed to be caused by vaccines. It also lists time periods in which the first symptom of these injuries and conditions must occur after receiving the vaccine. If the first symptom of these injuries/conditions occurs within the listed time periods, it is presumed that the vaccine was the cause of the injury or condition unless another cause is found. For example, if a patient received the tetanus vaccine and had a severe allergic reaction (anaphylaxis) within 4 hours after receiving the vaccine, then it is presumed that the tetanus vaccine caused the injury, if no other cause is found.

If an injury or condition is not on the Table or if it did not occur within the time period on the Table, the petitioner must prove that the vaccine caused the injury or condition. Such proof must be based on medical records or opinion, which may include expert witness testimony.

A copy of the Vaccine Injury Table is on the following page, or can be found online at http://www.hrsa.gov/vaccinecompensation/vaccinetable.html. A comprehensive explanation of terms used in the table accompanies the online version.

March 2013

For more information, visit the VICP website at http://www.hrsa.gov/vaccinecompensation.

National Childhood Vaccine Injury Act: Vaccine Injury Table

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Brachial Neuritis	2-28 days
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Encephalopathy (or encephalitis)	72 hours
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Encephalopathy (or encephalitis)	5-15 days (not less than 5 days and not more than 15 days
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV. Vaccines containing rubella virus (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
V. Vaccines containing measles virus (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	6 months
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio - in a non-immunodeficient recipient - in an immunodeficient recipient - in a vaccine associated community case	 30 days 6 months Not applicable
	B. Vaccine-Strain Polio Viral Infection - in a non-immunodeficient recipient - in an immunodeficient recipient - in a vaccine associated community case	 30 days 6 months Not applicable
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis or anaphylactic shock B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	4 hours Not applicable
VIII. Hepatitis B vaccines	A. Anaphylaxis or anaphylactic shock B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	4 hours Not applicable
IX. Haemophilus influenzae type B polysaccharide conjugate vaccines	No condition specified	Not applicable
X. Varicella vaccine	No condition specified	Not applicable
XI. Rotavirus vaccine	No condition specified	Not applicable
XII. Pneumococcal conjugate vaccines	No condition specified	Not applicable
XIII. Hepatitis A vaccines	No condition specified	Not applicable
XIV. Trivalent influenza vaccines	No condition specified	Not applicable
XV. Meningococcal vaccines	No condition specified	Not applicable
XVI. Human papillomavirus (HPV) vaccines	No condition specified	Not applicable
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage*	No condition specified	Not applicable

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

July 2014

Countermeasures Injury Compensation Program (CICP)

Overview

The Countermeasures Injury Compensation Program (CICP) is a Federal program that provides benefits to individuals who are seriously injured as a result of the administration or use of a covered countermeasure. CICP also provides death benefits to certain survivors if death directly resulted from receipt of a covered countermeasure. Covered countermeasures may include vaccines, antivirals, drugs, biologics, or medical devices used to prevent, treat, or diagnose an illness that the Secretary of the United States Department of Health and Human Services (the Secretary) declares to be an actual or potential public health emergency. Examples of currently covered countermeasures are pandemic influenza vaccines including the 2009 pandemic H1N1 influenza vaccine, antivirals (e.g., Tamiflu®, Relenza®, peramivir), ventilation assistance devices (e.g., mechanical ventilators), and respiratory protection devices (e.g., N-95 masks) used to treat, diagnose or prevent pandemic influenza. In addition, countermeasures, including vaccines, used to diagnose, treat or prevent smallpox, anthrax, botulism, and acute radiation syndrome are currently covered. Adverse events during pre-licensure testing may be covered as well.

This Program was established by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act), 42 U.S.C. § 247d-6e. The PREP Act also confers broad liability protections covering the manufacture, testing, development, distribution, or use of the designated covered countermeasure.

Filing Deadline and Application and Review Process

Individuals have one (1) year from the date the vaccine or other covered countermeasure was administered or used to request compensation benefits. If their injury is added to a Countermeasures Injury Table, then they may also have one year from the effective date of the Table addition to file. To file a claim, individuals must submit a Request for Benefits Form and the Authorization for Use or Disclosure of Health Information Form to request medical records from each health care provider who treated the injured person. In addition, medical records from one year before the injury to the present time must be submitted. Health care providers should send medical records directly to the Program. All documents should be sent to:
Health Resources and Services Administration
Countermeasures Injury Compensation Program
5600 Fishers Lane, Room 11C-26
Rockville, MD 20857

After an individual has submitted a complete Request for Benefits package, CICP medical staff reviews it to determine if the individual is eligible for compensation. An individual may be eligible for compensation if compelling, reliable, valid, medical and scientific evidence exists demonstrating that the injury for which compensation is sought was caused by the administration or use of a covered countermeasure and no other more likely cause of the injury is found. If an individual is found eligible for compensation, the type and amount of benefits are determined by the Program. If an individual is not eligible for compensation, he/she may request the Associate Administrator of the Healthcare Systems Bureau, HRSA, to reconsider the Program's decision. The Associate Administrator will convene an independent panel to review the Program's decision, make its own findings, and make a recommendation. The Associate Administrator will review this recommendation and make a final decision.

Benefits Available

Eligible individuals may be compensated for reasonable and necessary unreimbursable medical expenses and for lost employment income at the time of the injury. Death benefits may be paid to certain survivors of covered countermeasures recipients who have died as a direct result of the covered countermeasure injury. The U.S. Department of Health and Human Services is the payer of last resort. Therefore, payments are reduced by those of other third party payers.

Contact Information
Website: http://www.hrsa.gov/cicp/
E-mail: CICP@hrsa.gov
Phone: 1-855-266-CICP (2427)

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