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Frequently Asked Questions

About the VICP

What vaccine liability protection is afforded to vaccine manufacturers and administrators?

The National Vaccine Injury Compensation Program (VICP) is an alternative to the tort system for resolving vaccine injury petitions. Whether a vaccine manufacturer or administrator is afforded the liability protections of the National Childhood Vaccine Injury Act of 1986, as amended, (the Act) depends upon whether the vaccine is covered under the VICP.

Under the Act, persons with petitions of vaccine-related injuries or deaths resulting from covered vaccines must first exhaust their remedies under the VICP before they can pursue legal actions against vaccine manufacturers or administrators.

To exhaust the remedies available under the VICP and pursue a legal action against a vaccine manufacturer or administrator outside of the VICP, a VICP petitioner must either withdraw his or her petition (if the special master of the U. S. Court of Federal Claims (Court) has failed to issue a decision or the Court has failed to enter judgment within the time provided by the Act) or reject the judgment under the VICP.

Although the Act provides liability protections to vaccine manufacturers and vaccine administrators who administer covered vaccines in many circumstances, these protections are not absolute.

There are instances when a vaccine manufacturer or administrator who gives a covered vaccine is not protected from liability by the Act, such as when an individual files a petition and is requesting damages of $1,000 or less. In this case, a civil suit against a vaccine manufacturer or an administrator may be permitted to be filed in state or federal court without first filing a petition in the VICP.

In addition, if the VICP has paid a petitioner for a vaccine-related injury, the VICP may be able to pursue its own action against a vaccine manufacturer or administrator using its subrogation rights.

Are there legal requirements for vaccine companies to distribute and administer vaccines not licensed in the U.S.?

Vaccines not licensed in the U.S. must be distributed and administered in accordance with all applicable Food and Drug Administration requirements.

For a vaccine company to receive all of the liability protections offered by the National Childhood Vaccine Injury Act of 1986, as amended, the company must comply in all

material respects with all applicable requirements under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (including regulations issued under such provisions).

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Covered vaccines

Will the National Vaccine Injury Compensation Program provide compensation to individuals injured by COVID-19 vaccine?

COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program.

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under a PREP Act declaration. The CICP also may provide benefits to certain survivors of individuals who die as a direct result of the administration or use of such covered countermeasures. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are:

1. any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured:
    - to diagnose, mitigate, prevent, treat, or cure COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or
    - to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause;
2. a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in paragraph (a) above;
3. a product or technology intended to enhance the use or effect of a product described in paragraph (a) or (b) above; or
4. any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, or a respiratory protective device approved by National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary of the Department of Health and Human Services determines to be a priority for use during a public health emergency declared under section 319 of the Public Health Service Act.

The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP and filing a claim are available at the toll-free number 1-855-266-2427 or the Countermeasures Injury Compensation Program (CICP) website.

What is the Vaccine Injury Table?

The Vaccine Injury Table (Table) (PDF - 339 KB) is a listing of covered vaccines and associated injuries that makes it easier for some people to get compensation. The Table

lists and explains injuries and/or conditions that are presumed to be caused by vaccines unless another cause is proven.

The Table's Qualification and Aids to Interpretation (QAI) define some of the injuries and/or conditions listed on the Table.

The Table also lists time periods in which the first symptom of these injuries and/or conditions must occur after receiving the vaccine to receive the Table's presumption.

If the first symptom of an injury and/or condition listed on the Table occurs within the listed time period, and any associated definition(s) included in the QAI are satisfied, it is presumed that the vaccine was the cause of the injury or condition unless another cause is proven.

Example: if you received the tetanus vaccine and had a severe allergic reaction (anaphylaxis) as defined within the QAI within four hours after receiving the vaccine, then it is presumed that the tetanus vaccine caused the injury if no other cause is proven.

In these circumstances, you do not need to show that the vaccine actually caused the anaphylaxis (because meeting the Table's requirement provides a presumption of causation).

If your injury and/or condition is not on the Table or if your injury and/or condition did not satisfy the Table's requirement (e.g., did not occur within the time period listed on the Table or did not meet the QAI), you must prove that the vaccine caused the injury and/or condition.

How are changes made to the Vaccine Injury Table?

The Secretary of Health and Human Services modifies the Table by regulation after consulting with the Advisory Commission on Childhood Vaccines, posting a notice, and soliciting public comment. The Secretary may place injuries or conditions on the Table based on scientific and/or policy reasons.

Do the National Vaccine Injury Compensation Program (VICP) settlements indicate any safety concerns by the Department of Health and Human Services regarding the vaccine alleged to cause the injury?

Conclusions regarding vaccine safety should not be drawn from the fact that cases were settled. Settlements are one way of quickly resolving a petition.

Settlements are an agreement between the respondent (the U.S. Department of Health and Human Services, represented by the U.S. Department of Justice) and the petitioner (the person who filed the vaccine injury petition).

Settlements are not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries.

In settled cases, the United States Court of Federal Claims does not determine that the vaccine caused the injury. Petitions may be resolved by settlement for many reasons, including:

- consideration of prior court decisions;
- a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable;
- a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and/or
- a desire by both parties to resolve a case quickly and efficiently.

If a new vaccine product is licensed, what needs to occur before the vaccine will be covered by the National Vaccine Injury Compensation Program (VICP)?

It depends on whether the vaccine falls within a category of vaccines already covered by the VICP. If the vaccine is in a category of vaccines that is already covered by the VICP, then the new vaccine product is already covered even before the date of licensure.

For example, hepatitis B vaccines are covered under the Program under Category VIII of the Vaccine Injury Table. If a new hepatitis B vaccine is licensed in the U.S., it is already automatically covered under the VICP.

If the licensed new vaccine product is in a category of vaccines that is not covered by the VICP (e.g., yellow fever vaccines), then the new vaccine will not be covered under the VICP until the general category of vaccines is covered.

For a category of vaccines to be covered, the category of vaccines must be recommended for routine administration to children or pregnant women by the Centers for Disease Control and Prevention (e.g., vaccines that protect against seasonal influenza), subject to an excise tax by federal law, and added to the VICP by the Secretary of Health and Human Services.

Are vaccine-related injuries or deaths related to vaccines that are not yet licensed in the U.S. compensable under the National Vaccine Injury Compensation Program (VICP)?

Vaccine-related injuries or death related to vaccines not yet licensed in the U.S. are compensable as long as other eligibility requirements are satisfied. An otherwise eligible person who receives a vaccine that is under a category of vaccines covered by the VICP within the applicable time limits would be entitled to apply for compensation under the VICP even if the vaccine is not licensed in the U.S.

Are all pneumococcal vaccines covered by the National Vaccine Injury Compensation Program (VICP)?

No, all pneumococcal vaccines are not covered by the VICP.

There are two types of pneumococcal vaccines given in the U.S.:

- The pneumococcal conjugate vaccine (PCV13)--administered routinely to infants and children up to age 5; and
- The pneumococcal polysaccharide vaccine (PPV23)--given to adults age 65 and older and individuals of varying age with certain medical conditions making them at higher risk for pneumococcal infection.

The VICP covers only the pneumococcal conjugate vaccine (PCV13). Pneumococcal conjugate vaccines have been covered under the VICP since December 18, 1999.

Are all formulations of meningococcal vaccine, including those that are not licensed in the United States and are under Investigational New Drug application (IND), covered under the VICP?

Yes. Individuals thought to be injured by any meningococcal vaccine may be eligible for compensation from the National Vaccine Injury Compensation Program (VICP) as of February 1, 2007.

To be eligible for compensation, claims must be filed within the applicable filing deadlines, discussed above.

An otherwise eligible person who receives any meningococcal vaccine in the U.S. would be entitled to apply for compensation under the VICP. This is true even if the vaccine

administered is not licensed in the U.S. and was distributed under an IND (including an expanded access IND).

While VICP materials sometimes describe coverage for conjugate and polysaccharide meningococcal vaccines, all other categories of meningococcal vaccines, such as vaccines produced by recombinant DNA technology, are also covered under the VICP in otherwise eligible individuals.

Meningococcal vaccines administered under an IND on or after November 2013 at colleges and/or universities in the United States in connection with an outbreak are covered under the VICP.

Are maternal immunizations (vaccines administered to pregnant women) covered by the National Vaccine Injury Compensation Program (VICP) and are related injury claims eligible for compensation in the VICP?

Section 3093(c) of the 21st Century Cures Act (Public Law 114-255) (PDF) expanded the VICP's coverage to include vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in pregnant women and subject to an excise tax.

Vaccine-injury claims may be filed for both:

- Injuries alleged to have been sustained by women receiving any VICP-covered vaccine during pregnancy; and
- Injuries alleged to have been sustained by live-born children who were in utero at the time those women were administered such vaccines.

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Who can file

Are there age restrictions on who may receive compensation from the National Vaccine Injury Compensation Program (VICP)?

There are no age restrictions on who may receive compensation in the VICP. Petitions may be filed on behalf of infants, children and adolescents, or by adults receiving VICP-covered vaccines. Other legal requirements, such as the statute of limitations for filing an injury or death petition, must be satisfied in order to receive compensation.

Can an individual who suffered a serious injury after receiving both the seasonal flu vaccine, which is covered by the National Vaccine Injury Compensation Program (VICP), and the 2009 H1N1 vaccine, which is covered by the Countermeasures Injury Compensation Program (CICP), file a petition with both programs?

People who believe they have been injured after receiving vaccines covered by the VICP and the CICP may file a petition with either program or with both programs. Depending on the circumstances, however, petitioners may not be eligible to receive compensation under both programs or under either program.

Is eligibility to receive compensation under the National Vaccine Injury Compensation Program (VICP) affected by whether a covered vaccine, such as Tdap, is administered off-label or against Advisory Committee on Immunization Practices or Centers for Disease Control and Prevention (CDC) administration recommendations?

The VICP is a no-fault compensation program. Generally, petitioners need only show that the injured person received a vaccine set forth in the Vaccine Injury Table (PDF - 339 KB) (a

"covered" vaccine); and sustained an injury that is set forth on the Table, significantly aggravated a pre-existing condition or that the injury was caused by the vaccine (if the injury is not listed on the Table).

To be a covered vaccine, a vaccine must be recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children or pregnant women, subject to an excise tax by federal law, and added to the VICP by the Secretary of Health and Human Services.

There are no requirements that the petitioner show that the vaccine was used pursuant to Food and Drug Administration labeling or specific Advisory Committee on Immunization Practices or Centers for Disease Control and Prevention administration recommendations, or otherwise was administered pursuant to any standard of care.

Are individuals who receive a covered vaccine outside of the U.S. eligible to file a petition with the National Vaccine Injury Compensation Program (VICP)?

If a person received a vaccine covered by the VICP outside of the U.S. (or its trust territories), the person may be eligible for compensation if:

1. the person was, at the time of vaccination, a U.S. citizen serving abroad as a member of the Armed Forces or as an employee of the U.S., or a dependent of such a citizen; or
2. the vaccine's manufacturer was located in the U.S. and the person returned to the U.S. within 6 months after the date of vaccination.

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Disclaimer

The content of this website reflects the current thinking of the United States Department of Health and Human Services on the topics addressed and does not create or confer any rights for or on any person and does not operate to bind the Department or the public. The ultimate decision about the scope of the statutes authorizing the VICP is within the authority of the United States Court of Federal Claims, which is responsible for resolving petitions for compensation under the VICP.

If you have additional questions, call: 1-800-338-2382 or email: vaccinecompensation@hrsa.gov.

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