

# 'No-Fault' Federal Liability Coverage for Health Care Providers

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**VACCINES GIVEN TO INFANTS AND YOUNG CHILDREN** over the past 2 decades will prevent 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the course of their lifetimes, according to the CDC.<sup>1</sup>

It is indisputable that vaccines save lives. The National Vaccine Injury Compensation Program (VICP) is in place to maintain vaccine supply and immunization rates (**FIGURE 1**).

## HISTORY OF THE VICP

In the 1980s, suspicion arose regarding the safety of the childhood diphtheria, tetanus, pertussis vaccine because of news reports of serious adverse effects. During this time, lawsuits were filed against manufacturers and health care providers. In response, the manufacturers and health care providers threatened to decrease vaccine supplies and reduce vaccination rates. As a result, citizens were at an increased and unnecessary risk of contracting communicable vaccine-preventable diseases.

To balance society's benefit to individual risk, a group of civilians, manufacturers, practitioners, and public health organizations lobbied for Congress to enact a law that would protect all parties involved: health care providers, manufacturers, and patients injured by childhood vaccines. On October 1, 1988,

the National Childhood Vaccine Injury Act of 1986 established the VICP.<sup>2</sup>

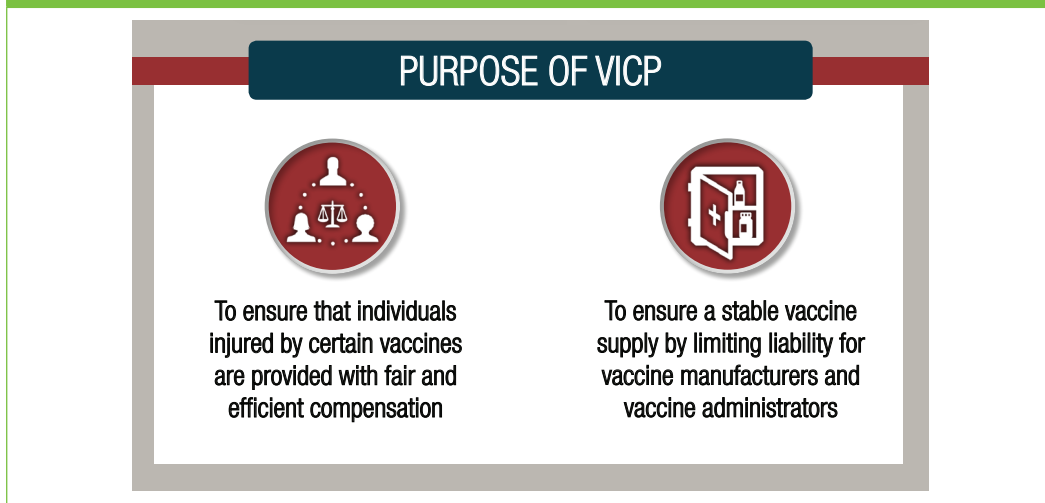
Since its origination, 19,361 petitions for compensation have been filed with the VICP. Thirty-one percent (5999) of those were defined as compensable, totaling more than \$3.8 billion in payouts. The average payout has been \$633,439.<sup>3</sup>

## LOGISTICS OF THE VICP

The VICP is defined as a no-fault alternative to the traditional legal system for resolving vaccine injury petitions.<sup>3</sup> It is administered by the US Department of Health and Human Services, while the US Department of Justice and the US Court of Federal Claims also have roles. The program is funded by a \$.75 excise tax on vaccines recommended by the CDC for routine administration to children.<sup>2</sup>

The Vaccine Injury Table was implemented in accordance with the VICP to aid in determining compensation eligibility. **FIGURE 2** lists covered vaccines; the illnesses, disabilities, injuries, and conditions included for each; and the respective time periods for the first symptom, or manifestation of onset, after vaccine administration. For example, anaphylaxis caused by the varicella vaccine must occur no more than 4 hours after receiving the immunization to be considered.

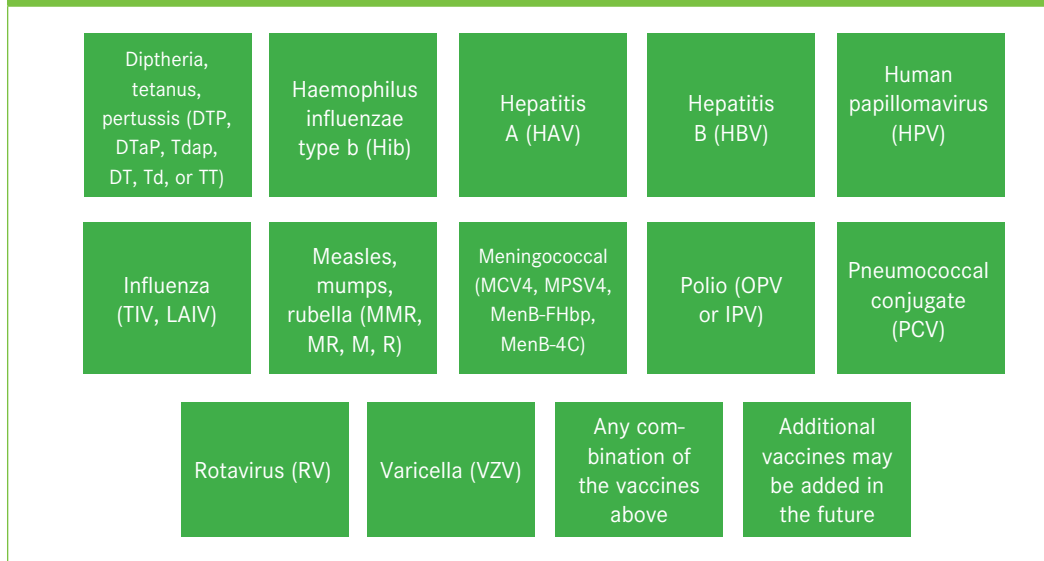
**FIGURE 1. PURPOSE OF VICP<sup>2</sup>**



Source: Health Resources & Services Administration

FOR REFERENCES, GO TO  
[PHARMACYTIMES.COM/  
LINK/144](https://www.pharmacytimes.com/link/144).

**FIGURE 2. VACCINES COVERED BY THE VICP**



Source: The National Vaccine Injury Compensation Program

To be awarded compensation, the petitioner must prove one of the following:

- The injured person received a vaccine listed on the Vaccine Injury Table, and the first symptom of the injury/condition on the table occurred within the period listed on the Vaccine Injury Table
- The vaccine caused the injury; or
- The vaccine caused aggravation of an existing illness.

In addition, the court must rule out any other possible causes that resulted in the death or injury of a patient.<sup>3</sup>

### HEALTH CARE PROVIDERS AND THE VICP

For health care providers to receive liability protection for covered vaccines under the VICP, 3 requirements must be met. Fortunately, these are already considered best practices and do not add steps or documentation to the immunization process. First, the patient's permanent medical record must specify the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the qualified immunizer. Second, the patient must be given the most up-to-date version of the relevant vaccine information statement. The version number and the date distributed should be documented. Third, if any adverse events occur, they should be recorded in the patient's record and reported to the Vaccine Adverse Event Reporting System. This program monitors the safety of vaccines and is jointly administered by the CDC and the FDA.<sup>4</sup>

Although the VICP provides a significant amount of no-fault liability coverage, there are a few circumstances under which a health care provider may be sued through the traditional legal system. Perhaps most evident, this situation can occur if the vaccine is not covered under the VICP (ie, Pneumovax [for pneumonia]). The petitioner may also take action against the immunizer if he or she is requesting damages of \$1000 or less, if the petition has been dismissed under the VICP, or if the

compensation awarded is declined.<sup>5</sup>

In summary, creation of the VICP under the National Childhood Vaccine Injury Act of 1986 possibly averted the resurgence of vaccine-preventable diseases. Almost 30 years later, it is still successfully serving its 2 original purposes: to ensure that individuals injured by certain vaccines are provided with efficient and fair compensation and to ensure a stable vaccine supply by limiting liability for vaccine manufacturers and administrators. Ideally, additional vaccines will be added to the Vaccine Injury Table to provide further protection to both individuals and the public. ♦

### REFERENCES

1. Szabo L. CDC: vaccines save hundreds of thousands of lives. *USA Today*. April 24, 2014 [usatoday.com/story/news/nation/2014/04/24/cdc-vaccine-benefits/8094789/](http://usatoday.com/story/news/nation/2014/04/24/cdc-vaccine-benefits/8094789/). Published Accessed July 3, 2018.
2. Health Resources & Services Administration. National Vaccine Injury Compensation Program. HRSA website. [hrsa.gov/vaccine-compensation/index.html](http://hrsa.gov/vaccine-compensation/index.html). Updated April 2018. Accessed July 3, 2018.
3. Tanzi MG. Two federal programs compensate for vaccine-related injuries. American Pharmacists Association website. [pharmacist.com/article/two-federal-programs-compensate-vaccine-related-injuries](http://pharmacist.com/article/two-federal-programs-compensate-vaccine-related-injuries). Published January 12, 2016. Accessed July 3, 2018.
4. Human Resources & Services Administration. National Vaccine Injury Compensation Program. [in.gov/isdh/files/VICP.pdf](http://in.gov/isdh/files/VICP.pdf). Accessed July 3, 2018.
5. CDC. Vaccine recommendations and guidelines of the ACIP: vaccination records. CDC website. [cdc.gov/vaccines/hcp/acip-recs/general-recs/records.html](http://cdc.gov/vaccines/hcp/acip-recs/general-recs/records.html). Updated April 20, 2017. Accessed July 3, 2018.