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The National Vaccine Injury Compensation Program and the Office of Special Masters

In 1986, Congress passed the National Childhood Vaccine Injury Act (NCVIA; 42 U.S.C. §§ 300aa-10–300aa-34), which created the National Vaccine Injury Compensation Program (VICP). The VICP is a no-fault compensation program that allows individuals to file a petition (i.e., a claim for money damages) against the Secretary of Health and Human Services (the Secretary) to receive compensation for an injury or death allegedly caused by a covered vaccine. Congress created the Office of Special Masters (OSM), situated within the U.S. Court of Federal Claims, to adjudicate petitions filed under the VICP.

This In Focus describes the OSM’s creation, authority, and unique jurisdiction. It then identifies several issues related to the VICP that may be of interest to Congress.

Jurisdiction and Authority

The OSM has exclusive jurisdiction to adjudicate petitions filed under the VICP. To seek compensation through the VICP, individuals or their designees (also called petitioners) file petitions with the OSM against the Secretary (the respondent). The Secretary is represented by attorneys from the U.S. Department of Justice. Petitioners often retain an attorney to represent them in the proceedings.

The VICP currently covers 16 vaccines that are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children or pregnant women. The list of covered vaccines may be found on the Vaccine Injury Table (the Table). The most current version of the Table may be found on the Health Resources and Services Administration’s (HRSA’s) website: <https://www.hrsa.gov/vaccine-compensation>.

Currently, the VICP does not include any COVID-19 vaccines. Individuals seeking compensation for alleged injuries related to COVID-19 vaccines must instead file a request for benefits under the Countermeasures Injury Compensation Program (CICP), also administered by HRSA.

The Liability Shield

Congress created the VICP to limit the liability of manufacturers and administrators for vaccine-related injuries, while providing a process by which individuals injured by certain vaccines could receive compensation. The Program also addresses the concern that tort lawsuits against vaccine manufacturers could result in vaccine shortages. The NCVIA shields manufacturers and administrators from liability for injuries related to a covered vaccine by generally barring individuals from filing civil claims in excess of \$1,000 against a covered vaccine

manufacturer or administrator for damages arising from a vaccine-related injury or death until after a petition has been filed and judgment entered through the VICP.

Once a claim has been adjudicated through the VICP, judgment is entered, and a petitioner must choose to accept or reject the judgment. If the petitioner accepts the judgment, the petitioner is entitled to any damages awarded by the special master. In return, however, the petitioner is barred from filing a claim in court against a vaccine manufacturer or administrator for the same injury. If the petitioner rejects the judgment, he or she is not entitled to money damages but may sue the manufacturer or administrator in court for the alleged injury or death. The NCVIA limits the types of civil actions that can be brought against manufacturers and administrators; for example, it generally bars claims for damages for unavoidable side effects.

Court Proceedings

Special Masters

A special master is an officer of the court who is appointed by the judges of the U.S. Court of Federal Claims to adjudicate vaccine petitions. The judges appoint special masters for four-year terms and designate a Chief Special Master (CSM). The CSM is responsible for assigning petitions for adjudication by the special masters and for carrying out the OSM’s administrative business. By statute, the OSM is limited to eight special masters. Like the U.S. Court of Federal Claims, it has nationwide jurisdiction and may hear cases in all states and territories.

Special masters function much like judges in adjudicating VICP petitions. In cases where the Secretary contests whether the vaccine caused the alleged injury, the special master may recommend alternative dispute resolution proceedings. Special masters conduct telephonic status conferences between the parties, ensure the record is complete, and hold hearings. The special master may also decide a vaccine petition on the record without a hearing.

Proving Causation

To prevail on a claim, a vaccine petitioner must show that it is more likely than not that the vaccine the petitioner received caused the petitioner’s injuries or death. A petitioner may demonstrate causation by either (1) demonstrating that the petitioner’s injury is on the Table and manifested within the time period specified in the Table; or (2) by demonstrating causation in fact, meaning that the vaccine was the “but for” cause of the petitioner’s injury or death.

For each vaccine, the Table describes the injuries and onset period known to be associated with that vaccine. The Secretary may modify the Table via regulation as outlined in the statute. According to established case law, petitioners may demonstrate causation in fact by providing each of the following: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury.

Damages Awards and Attorney's Fees

A petitioner who prevails on a VICP claim may receive monetary compensation for actual and reasonable projected expenses resulting from the vaccine-related injury or death, including compensation for past and future medical care, pain and suffering, and lost earnings. In the case of a vaccine-related death, the deceased petitioner's estate receives an award of \$250,000. Under the Act, petitioners are not entitled to punitive or exemplary damages, and the OSM may not award them.

The special master may also award the petitioner reasonable attorney's fees and other costs. If a petition is denied, the special master may still award reasonable attorney's fees and costs if the special master finds the petition was brought in good faith and a reasonable basis existed for the claim. Attorneys who receive fees from the program are not permitted to charge their clients any additional fees or costs.

Awards made by the program are paid from the Vaccine Injury Compensation Trust Fund, which is funded by a \$0.75 excise tax on each dose of a covered vaccine. Congress also appropriates VICP-related funds for (1) the OSM and its staff; (2) the Department of Justice, which is tasked with defending VICP cases; and (3) HRSA, which provides medical review of the cases.

A significant percentage of vaccine petitions are resolved via settlements, wherein the Secretary agrees to compensation without conceding that the vaccine was responsible for the petitioner's injuries. Settlements are particularly common for Table injuries.

Appeals

Under the Act, both petitioner and respondent may appeal an OSM decision to the U.S. Court of Federal Claims by filing a motion for review within 30 days of the special master's decision. A party may appeal a decision of the U.S. Court of Federal Claims to the U.S. Court of Appeals for the Federal Circuit by filing a motion within 60 days of the date judgment is entered by the U.S. Court of Federal Claims.

The U.S. Courts of Federal Claims and the Federal Circuit conduct de novo review on questions of law, but they defer to special masters regarding factual findings. The courts typically uphold the special master's findings of fact unless they are arbitrary or capricious.

Recent Caseload Statistics

In FY2021 (October 1, 2020-September 30, 2021), vaccine petition filings increased by 72.9% over FY2020 for a total

of 2,060 filings. As of September 30, 2021, there were more than 4,000 pending vaccine petitions. In FY2021, the OSM disposed of just more than 1,000 vaccine petitions.

Issues for Congress

Expansion of OSM

Congress may consider whether the number of special masters, which is presently capped at eight by statute, is sufficient for the OSM's caseload. The number of vaccine petitions filed in FY2021 (2,060) represented a 433% increase from the number filed 10 years earlier in FY2011 (386). To address the increase in petitions filed in recent years, Congress could amend the Vaccine Act to allow the U.S. Court of Federal Claims to increase the number of special masters who may adjudicate petitions.

COVID-19 vaccine injury claims are currently addressed through the CICP. If the COVID-19 vaccine were added to VICP—which would require an act of Congress in addition to regulatory changes—that may affect VICP's caseload. As of August 2022, there have already been more than 6,000 COVID-19 vaccine injury claims filed in the CICP.

Vaccine Tax

VICP compensation may only be paid for injuries from vaccines subject to the \$0.75 excise tax. When a new vaccine is recommended by the CDC for routine administration to children and/or pregnant women, however, that vaccine is not automatically subject to the \$0.75 excise tax. At that point, Congress would face a decision to amend the Internal Revenue Code in order for the vaccine to be taxed. Any amendment to the Table to add the vaccine is not effective, and the Program may not make compensation awards, until the vaccine becomes subject to the tax. To facilitate the process of adding new vaccines, Congress may consider subjecting to the tax any vaccine recommended for routine administration by the CDC.

Changes to the Vaccine Injury Table

The Secretary has discretion to amend the Table based on evolving science and data, as well as changes in policy. For example, in 2017, the Secretary amended the Table to include shoulder injuries related to vaccine administration (SIRVA). In January 2021, reflecting a change, the Secretary published a final rule removing SIRVA from the Table, stating it is not an injury "associated with" the vaccine, in accordance with the statutory requirements. This action drew public controversy, and the Secretary later rescinded this final rule; SIRVA remains on the Table at this time.

Currently, more than half of the petitions filed in the OSM allege SIRVA and vasovagal syncope (VS). Omitting SIRVA could have a substantial impact on OSM's jurisdiction to review, could affect whether petitioners can recover damages, and could influence public confidence regarding vaccine safety. Future efforts to remove SIRVA and VS from the Table may be challenged in court.

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