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Legal Sidebar

Vaccine Injury Compensation Program: The Adjudication of Petitions and the 240-Day Deadline

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The Vaccine Injury Compensation Program (VICP) was created by Congress via the National Childhood Vaccine Injury Act of 1986. The VICP is a no-fault compensation program made up of two essential components. First, it allows individuals who suffer vaccine-related injuries or deaths to receive compensation by filing a petition for compensation with the U.S. Court of Federal Claims (Court of Federal Claims) and serving the petition on the Secretary of the U.S. Department of Health and Human Services (HHS). Second, the statute provides a liability shield for vaccine manufacturers and administrators (i.e., individuals who administer vaccines), which generally prevents injured individuals from bringing lawsuits until the VICP process is exhausted. Congress directed the Office of Special Masters (OSM), which adjudicates petitions for compensation, to determine entitlement within 240 days of the filing of the petition. If a petition has not been adjudicated within that time frame, a petitioner may voluntarily dismiss it; this provision is known as the "240-day deadline." Thus, a petitioner may exhaust the VICP remedy either by fully adjudicating a VICP petition, or by withdrawing the petition after the 240-day deadline.

Historically, some individuals who were not entitled to VICP compensation have subsequently sued vaccine manufacturers. In recent years, there has been concern that more petitioners will use the 240-day deadline to exit the program and instead pursue litigation against manufacturers, potentially circumventing the general purpose of the VICP statute. For example, in 2022, hundreds of petitioners filed complaints in federal court that were consolidated into a multidistrict litigation against Merck, the maker of the Gardasil vaccine (*In re Gardasil Products Liability Litigation*). Most, but not all, of those litigants first exhausted their VICP remedy. For the claimants who did not exhaust their VICP remedy, the U.S. Court of Appeals for the Fourth Circuit (Fourth Circuit) ruled in 2025 that *timely* participation in the VICP was necessary before a petitioner could join the multidistrict litigation. In recent years, a growing number of petitions have been dismissed by petitioners after the 240-day deadline, with at least one petitioner claiming that her attorney encouraged her to file a VICP petition only to then use the 240-day deadline to exit the program, even when she wanted to pursue compensation through VICP.

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This Legal Sidebar provides background on the VICP's adjudication process, including the availability of attorney's fees, explains the legislative history of the 240-day deadline, and analyzes the Fourth Circuit's decision in the multidistrict Gardasil litigation. It concludes by exploring potential VICP statutory amendments Congress could consider, if it wished to make changes to the program.

The Adjudication of VICP Petitions

Congress created the VICP to limit the liability of vaccine manufacturers and administrators and to provide a process through which individuals injured by certain routine vaccinations could receive compensation. The statute shields drug manufacturers and administrators from liability for a "vaccine-related injury or death," which is defined as an injury or death associated with one or more vaccines listed on the Vaccine Injury Table (the Table). The VICP's liability shield and the compensation that it provides are both tied to the Table, which currently includes sixteen types of vaccines. Congress included some of these vaccines to the Table when the program was created, while others were added by the HHS Secretary via rulemaking. The statute bars individuals injured by listed vaccines from filing civil claims in excess of $1,000 against a manufacturer or administrator for damages arising from such injuries until after a VICP petition has been filed and judgment entered through the program. The statute also limits the types of civil actions that can be brought against vaccine manufacturers and administrators even after the VICP process is exhausted.

Before a special master may determine whether a VICP petitioner is entitled to compensation, the petitioner must file a full set of medical records, which are then reviewed by representatives of the Secretary. The Health Resources and Services Administration (HRSA), a division of HHS, reviews the medical records to determine if the petitioner has met the medical criteria for compensation. The U.S. Department of Justice then files an official statement of the HHS Secretary's position in the case (known as a "Rule 4 report"). Next, the special master reviews the Rule 4 report and schedules a preliminary status conference with the parties to discuss next steps in the case.

After the Rule 4 report is filed, VICP cases typically proceed in two phases: entitlement and damages. First, the special master determines whether the petitioner is entitled to receive compensation for the alleged injuries. (If the government does not contest causation in its Rule 4 report, then entitlement is presumed and the case proceeds to damages.) Petitioners may demonstrate entitlement to compensation either by showing that they have suffered an injury listed on the Table within the specified onset period (in which case causation is presumed) or by preponderantly proving causation-in-fact for injuries not set forth on the Table via three factors, set out by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) in *Althen v. Secretary of HHS*.

The *Althen* factors require the petitioner to set forth a plausible medical theory of causation, a logical sequence of cause and effect, and a proximate temporal relationship between receipt of the vaccine and onset of the injury. In general, the *Althen* factors are much less burdensome for petitioners to prove than civil tort litigation, which would require a petitioner to prove that the vaccine manufacturer was at fault for the alleged injury, in addition to medical causation. In this way, the VICP makes it easier for litigants to be compensated for injuries caused by vaccines.

If a petitioner is found to be entitled to compensation, the case next proceeds to the damages phase, wherein the special master determines the amount of compensation the petitioner is owed. All damages are awarded by order of the special master, and awards are made out of a trust fund, which is funded by an excise tax paid by manufacturers of the vaccines listed on the Table. In addition to damages, VICP petitioners who are represented by attorneys are generally entitled to an award of reasonable attorney's fees and costs, even if they are found to be ineligible for injury compensation.

VICP Attorney's Fees and Costs

To streamline the process of determining the proper fees award, the special masters use a fee schedule, which contains hourly rates based on each individual attorney's number of years of experience practicing law. OSM first developed schedules for attorney's fees in 2015, and schedules were subsequently adopted by all special masters. In rare cases, a special master may decline to award attorney's fees and costs, if the special master finds that the petition lacked a reasonable basis or was not brought in good faith. For example, in *Stratton v. Secretary of HHS*, the Chief Special Master determined that a petitioner's attorney was not entitled to fees and costs because the case lacked a reasonable basis.

Filed in 2020, the petition in *Stratton* alleged that the Gardasil vaccination caused the petitioner to develop postural orthostatic tachycardia syndrome (POTS). The petitioner dismissed the petition at the 240-day deadline and thereafter joined the multidistrict litigation against Merck over Gardasil. Her attorney then requested more than $10,000 in fees and costs after the dismissal, and the government objected. As part of his analysis of whether the petitioner's attorney was entitled to fees, the Chief Special Master noted that the petition made clear on its face that it was filed only as a formality so that the petitioner could later pursue a claim against Merck. The Chief Special Master also noted that the petition was filed just before the three-year statute of limitations would have run, and the petition stated that petitioner's attorney had not yet reviewed the medical records for objective evidence to support the claim.

The Federal Circuit has stated that in considering a motion for fees, the special master first should make a subjective inquiry into whether the petition was brought in good faith and then undertake an objective evaluation of whether a reasonable basis existed for the claim. The Federal Circuit has directed that reasonable basis should be "more than a mere scintilla [of evidence] but less than a preponderance of proof." Using this inquiry, the Chief Special Master in *Stratton* evaluated whether the petition demonstrated "fundamental substantiating elements" at the time it was filed, including whether the petitioner had received a covered vaccine and the medical records filed in support of her alleged diagnosis.

In denying attorney's fees, the Chief Special Master reasoned that "this matter is one of many initiated by the same [] attorney, who has initiated, then withdrawn, approximately *320 cases from the Program*," so that plaintiffs could sue the manufacturer individually or join the *In re Gardasil* litigation. Given the attorney's experience in the program, the Chief Special Master noted that he may "have had some sense (based on both cases he personally litigated, as well as others)," that HPV claims alleging POTS "were *highly* unlikely to succeed" in the VICP. In addition, upon reviewing the medical records, the Chief Special Master found the record "wholly unsupportive" of petitioner's claim that she developed POTS as a result of Gardasil, because she had been experiencing symptoms *before* she received the vaccine. The Chief Special Master concluded that all cases concerning the HPV vaccine that were withdrawn at the 240-day deadline to join the *In re Gardasil* case "are not automatically properly entitled to, or ineligible for, a fees award," and that each fees request would have to be decided based on its specific facts.

Selected Legislative History of the VICP Statute

Since it was first enacted in 1986, Congress has made several changes to the VICP statute, including changing the timeline for the adjudication of petitions. When the statute was originally enacted, Congress directed special masters to determine entitlement to compensation and any damages within 365 days of the petition's filing. The initial version of the statute also did not contain a deadline allowing petitioners to dismiss their petitions if they were not adjudicated by a certain date.

The legislative history of amendments made to the VICP in 1989 indicate that in the program's initial years of operation, some lawmakers were concerned that the VICP was becoming too formal and adversarial in nature. A House Report that accompanied the 1989 amendments observes that Congress had

wanted the program to be "as swift and uncomplicated as possible," but several avenues for programmatic delay had emerged. The report explained that Congress sought to ensure more timely processing of claims by amending the statute to require that special masters adjudicate petitions and determine damages within 240 days. Along with this change, Congress also included the provision (currently codified at 42 U.S.C. § 300aa-12(g)) that allows the petitioner to dismiss a petition after the 240-day deadline lapses.

In the years since the program's creation, the timeline for adjudicating VICP petitions has stretched well beyond Congress's desired 240-day timeline. A 2014 Government Accountability Office (GAO) study of VICP petitions found that petitions filed since 1999 took an average of five-and-a-half years to adjudicate, but that during this time, approximately 24% of VICP petitions were resolved in two years or less. GAO further noted the increased timeline could be attributed to the omnibus autism proceeding, which took place during the studied 15-year window, and the fact that the HHS Secretary added six new vaccines to the Table. GAO observed that OSM's caseload significantly increased during this time, due to the influx of petitions alleging vaccines caused autism as well as the additional vaccines that were then covered by the program. GAO further found that the average time to adjudicate a non-autism VICP petition during the studied time frame was approximately three-and-a-half years. Finally, GAO noted that while a petitioner may dismiss the petition if it has not been resolved after 240 days, "petitioners rarely exercise this option."

The Fourth Circuit's Decision in *In re: Gardasil Products Liability Litigation*

In 2025, the Fourth Circuit decided an appeal related to the VICP's exhaustion requirement, wherein the court determined that *timely* participation in the VICP is required in order to file a subsequent tort suit, and that a trial court considering such a tort suit could not reconsider a special master's determination that the VICP exhaustion requirement had not been satisfied. The case concerned three petitioners who had joined the multidistrict litigation against Merck regarding Gardasil, but who had not exhausted the VICP process because they had filed their VICP petitions after the statute of limitations had run. (Their petitions were dismissed by the special master for being untimely filed.) In the multidistrict litigation, Merck argued that the petitioners' claims against the company should be dismissed because the petitioners failed to exhaust the VICP remedy and were thus barred from bringing a civil suit. The U.S. District Court for the Western District of North Carolina agreed, and the petitioners appealed the ruling to the Fourth Circuit.

Before the Fourth Circuit, the petitioners argued that a trial court could consider whether a VICP petition was timely and that the special master's timeliness determination had "no force in a tort suit," which the plaintiffs characterized as a "*de novo* civil action." The Fourth Circuit disagreed with the petitioners' first argument, finding that the text of the VICP statute that speaks to the liability shield requires a petition to be filed "in accordance with" the statute, referencing the statute of limitations. Thus, the court reasoned that "the Act requires a claimant to file a *timely* Vaccine Act petition to later be able to bring a tort suit," and that "[a]bsent a timeliness requirement," the filing of a VICP petition would be "a mere technical prerequisite" to filing a civil suit. The court further held that the text of the VICP statute reveals that only the special master and the VICP reviewing courts (i.e., the Court of Federal Claims and the Federal Circuit) are eligible to make or review a timeliness determination.

With regard to petitioner's argument about the de novo nature of a tort action, the Fourth Circuit found that the petitioners "misread what it means for the tort suit to be 'de novo.'" The court held that the "de novo nature of the tort suit" meant only that factual and legal findings of special masters were inadmissible, not that the trial court in a tort suit could "wholly disregard" the VICP proceedings. The Fourth Circuit interpreted the VICP statute's provision regarding the inadmissibility of evidence in "any state of a civil action" as applying only to the three stages of civil actions discussed earlier in the statute:

liability, general damages, and punitive damages. As a result, the court said, the statute "doesn't bar the [special master's] findings of fact and conclusions of law . . . from being considered for other purposes, like determining whether a petition was timely filed."

The effect of the Fourth Circuit's ruling in *In re Gardasil* means that any petitioner who wants to join the multidistrict litigation against Merck, or any other petitioner who wishes to sue a vaccine manufacturer for injuries following vaccination, must first exhaust the VICP remedy. Moreover, once a special master determines that a VICP petition was untimely filed, that decision may only be appealed to the Court of Federal Claims and the Federal Circuit. The Fourth Circuit's decision would preclude a trial court from reaching a different timeliness determination or finding that a petitioner had satisfied the VICP's exhaustion requirement.

Considerations for Congress

Some stakeholders have expressed concern that if petitioners use the 240-day deadline to opt out of the VICP before a determination of entitlement to then file civil suits, this could subvert the general purpose of the program. In response, Congress may consider that there are existing statutory mechanisms that could potentially discourage petitioners from opting out of the VICP if their petition is not adjudicated within 240 days. For example, special masters have recognized that while attorney compensation is not an absolute guarantee, the availability of compensation generally encourages petitioners to retain counsel in their cases, which can help expedite the filing of records and may lead to faster decisions by OSM. However, the VICP statute contains a provision limiting the recovery of attorney's fees and costs to petitions that are filed in good faith and with a reasonable basis. As discussed in *Stratton*, special masters have found instances in which petitioners' attorneys are not entitled to a fee award.

OSM could discourage petitioners' attorneys from using the 240-day deadline to exit the VICP early by denying attorney's fees for petitioners who did not intend to pursue their VICP remedies. As was the case in *Stratton*, if petitioners make clear that they do not intend to pursue their VICP claim after 240 days, this could be a factor in a special master's determination of reasonable basis. If OSM awards fewer fees and costs, it may help curb the influx of case filings. On the other hand, the Fourth Circuit's *In re Gardasil* ruling means that even if a case is likely to be found to lack a reasonable basis, a petitioner must still pursue the VICP remedy before suing the vaccine manufacturer.

If it wished, Congress could balance these and other considerations by making changes to the VICP statute. For example, Congress could consider amending the VICP statute to increase the number of special masters, which is currently capped at eight. Congress could also appropriate additional funding for DOJ and HRSA, both of which also play a role in the VICP process, to facilitate the adjudication of claims. With respect to the 240-day deadline to adjudicate petitions, Congress could amend the statute to give OSM more than 240 days to adjudicate petitions, or it could strike the 240-day deadline from the statute altogether. Eliminating the 240-day deadline may further encourage petitioners to fully adjudicate their VICP claims, which could result in fewer civil tort claims.

If Congress is concerned that the 240-day deadline is being abused by petitioners or their attorneys, it could also amend the VICP statute to deny an attorney's fees award when a petition is dismissed after 240 days, or to deny an attorney's fees award absent a special showing from the petitioner. If Congress wished to alter the balance between encouraging the filing of petitions and not prompting frivolous claims, Congress could also amend the VICP's statutory provisions related to attorney's fees and costs, or it could give the HHS Secretary the authority to modify attorney fee award eligibility criteria via rulemaking. For example, statutory or regulatory clarifications could specify the conditions or factors that must be present in order for an attorney to receive a fee award.

Author Information

Hannah-Alise Rogers
Legislative Attorney

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