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Legal Sidebar

Compensation Programs for Potential COVID-19 Vaccine Injuries

Updated October 20, 2021

More than 200 million Americans have received one or more doses of a Coronavirus Disease 2019 (COVID-19) vaccine, along with billions of people worldwide. The Food and Drug Administration's (FDA's) emergency use authorizations for the Pfizer-BioNTech, Moderna, and Johnson & Johnson COVID-19 vaccines were based on months-long clinical trials (including safety monitoring) of each vaccine, involving tens of thousands of participants. These trials did not identify any safety concerns that would preclude such authorization. (The Pfizer-BioNTech COVID-19 vaccine subsequently received full approval from FDA.) Post-authorization, the COVID-19 vaccines have been subject to safety monitoring requirements by FDA and the Centers for Disease Control and Prevention (CDC) to detect long-term or rare adverse health events. (For more information, see this CRS report.)

The most common side effects of COVID-19 vaccines are mild—such as local pain around the injection side, tiredness, or fever—and usually resolve within a few days. As with most vaccines, however, a very small percentage of inoculated individuals experience serious adverse reactions to a COVID-19 vaccine. For example, approximately two to five people per million receiving mRNA COVID-19 vaccines experience anaphylaxis, a severe allergic reaction, following vaccination. (For this reason, the CDC recommends that all individuals be monitored for at least 15 minutes following their vaccinations, and that all vaccination sites have epinephrine available for treatment of anaphylaxis.) Other serious adverse events reported following vaccination, such as myocarditis and Guillain-Barré Syndrome, are similarly rare and may be associated with COVID-19 vaccines.

Federal law has two distinct compensation regimes that may compensate individuals harmed by adverse reactions to vaccines. In general, the National Vaccine Injury Compensation Program (VICP) may provide compensation for injuries or deaths associated with most vaccines routinely administered in the United States (such as pediatric and seasonal influenza vaccines). During certain public health emergencies, the Countermeasures Injury Compensation Program (CICP) may provide compensation for injuries and deaths resulting from the administration of "covered countermeasures" under the Public Readiness and Emergency Preparedness Act (PREP Act), which may include vaccines.

Under the Secretary of Health and Human Services' (HHS's) PREP Act Declaration for COVID-19 (and its amendments), COVID-19 vaccines are covered countermeasures within the PREP Act's scope. As a result, CICP—and not VICP—will apply to injuries resulting from COVID-19 vaccinations while the

Congressional Research Service
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LSB10584

public health emergency persists and the Declaration remains in force. Compensation through CICP is generally somewhat more limited than through VICP. This Sidebar will review and compare the compensation regimes available for vaccine-related injuries under CICP and VICP, and describe the procedures for injured individuals to obtain compensation under each program. The Sidebar ends with a **Table 1** comparing the two regimes.

The Countermeasures Injury Compensation Program

To encourage expeditious development and deployment of medical countermeasures during a public health emergency, the PREP Act authorizes the Secretary of HHS (the Secretary) to limit legal liability for losses resulting from the administration of medical countermeasures such as diagnostics, treatments, and vaccines. In a declaration effective February 4, 2020 (the PREP Act Declaration), the Secretary invoked the PREP Act and declared COVID-19 to be a public health emergency warranting liability protections for covered countermeasures. Pursuant to the PREP Act Declaration and its subsequent amendments, manufacturers, distributors, and health care providers are generally immune from legal liability (i.e., they cannot be sued for money damages in court) for losses related to the administration or use of covered countermeasures against COVID-19. (For a detailed discussion of the scope of liability immunity under the PREP Act, see this CRS Sidebar.)

In addition to providing immunity from liability, the PREP Act established CICP, a compensation program for individuals seriously injured or killed as a direct result of the administration or use of a covered countermeasure. CICP is a regulatory process administered by HHS's Health Resources and Services Administration (HRSA). HRSA regulations govern CICP's procedures and eligibility determinations.

Covered Vaccines and Injuries

Under the PREP Act and the amended Declaration, covered countermeasures for COVID-19 may include drugs, biological products, and medical devices that the FDA approves, licenses, or authorizes for emergency use "to diagnose, mitigate, prevent, treat, or cure" COVID-19, or used "to limit the harm that COVID-19 . . . might otherwise cause." For example, personal protective equipment (PPE) (e.g., respirators), ventilators, therapeutic drugs (e.g., remdesivir), and monoclonal antibody treatments approved or authorized by FDA to treat or prevent COVID-19 are covered countermeasures under the PREP Act. Notably, FDA-authorized or -approved COVID-19 vaccines—such as those produced by Pfizer, Moderna, and Johnson & Johnson—are covered countermeasures under the PREP Act Declaration.

Under the PREP Act, CICP remedies "shall be exclusive of any other civil action or proceeding" for injuries directly caused by administering covered countermeasures, with limited exceptions. Thus, while the current PREP Act Declaration and public health emergency remain in effect, CICP is the exclusive remedy for claims within the PREP Act's scope, including injuries resulting from COVID-19 vaccinations. (As discussed in detail below, VICP may eventually apply to COVID-19-vaccine injuries after the public health emergency terminates, contingent on certain statutory and regulatory changes.)

CICP compensation is limited to eligible individuals, such as persons injured by countermeasures or their survivors. CICP only provides compensation for death or "serious physical injuries," that is, injuries that warrant hospitalization or lead to a significant loss of function or disability. Thus, individuals who experience only minor side effects from a COVID-19 vaccine—such as soreness, headache, or fatigue—would not be eligible for CICP compensation.

Procedure for Obtaining Compensation

To apply for CICP compensation, a claimant must file a request for benefits within one year of the date the countermeasure was administered. (If the Secretary publishes a new Countermeasure Injury Table, a newly eligible claimant may file within one year after the new table is established.) In addition to the request form, claimants may need to submit medical records and other evidence to establish eligibility. If determined to be eligible, claimants may submit additional documentation to demonstrate the compensation amount. Eligibility and compensation determinations are made by CICP, as the delegate of the Secretary. Claimants may seek reconsideration of an adverse eligibility decision by CICP, but the ultimate decisionmaking authority lies with the Secretary. The PREP Act precludes judicial review of the Secretary's eligibility and compensation decisions.

CICP claimants can prove eligibility for compensation in one of two ways. The first only applies to injuries listed on a Countermeasure Injury Table, which the Secretary must establish by regulation when compelling medical and scientific evidence shows that administration or use of a covered countermeasure directly causes particular injuries. (The table established for the H1N1 pandemic influenza vaccine is one example; no such table has yet been promulgated for COVID-19 vaccines or other COVID-19 countermeasures.) For injuries listed on a Countermeasure Injury Table, if the claimant can show that the countermeasure recipient's injury is listed on the table and was sustained within the relevant time interval (and meets any other requirements set forth in the table), CICP will presume the injury was a direct result of the covered countermeasure. For injuries *not* on a Countermeasure Injury Table (or outside its scope), the claimant must prove the non-table injury was the "direct result" of the countermeasure's administration based on "compelling, reliable, valid, medical and scientific evidence" beyond mere temporal association.

Available Compensation

Compensation under CICP is limited to (1) reasonable medical expenses (e.g., unreimbursed hospitalization costs); (2) loss of employment income (e.g., income lost from inability to work due to disability); and (3) a set death benefit where the death is a direct result of the administration or use of a covered countermeasure. Attorneys' fees and pain-and-suffering damages are not available. CICP awards are also subject to various annual and lifetime limits. For example, annual lost employment income awards are capped at $50,000 per year, and the standard maximum death benefit is the same as that under the Public Safety Officers' Benefits program (currently $370,376).

Given the limited number and scope of past PREP Act declarations, CICP has been used relatively infrequently since the PREP Act's 2005 enactment. The majority of these non-COVID-19 claims were related to the H1N1 influenza vaccine. According to HRSA, for fiscal years 2010 through 2021, CICP received 491 claims unrelated to COVID-19, of which 39 (8%) were determined to be eligible for compensation; 29 claims (6%) have been paid out by CICP, amounting to $6 million in awards.

In light of the COVID-19 pandemic, HRSA has received a larger number of CICP claims than it has received historically. As of September 1, 2021, CICP has received 2,392 claims alleging injury or death relating to COVID-19 countermeasures, of which 1,031 claims (43%) relate to COVID-19 vaccines. CICP has not yet compensated any claims relating to COVID-19 countermeasures; it has denied three claims because the standard of proof for causation was not met and/or a covered injury was not sustained. The remainder of the COVID-19 countermeasure claims (2,389 or 99.9%) are in review or pending CICP review.

Several COVID-19 emergency appropriations allow the Secretary to transfer funds to the Covered Countermeasure Process Fund. Such funds, in addition to prior year fund balances, can be used for CICP compensation awards.

The National Vaccine Injury Compensation Program

After the Secretary terminates the PREP Act Declaration for the COVID-19 pandemic, any injuries or death from COVID-19 vaccines administered after the declaration ends would be addressed in court under tort law unless the COVID-19 vaccines are added to the National Vaccine Injury Compensation Program (VICP; 42 U.S.C. §§ 300aa-10–300aa-44). VICP provides compensation for injuries and deaths caused by certain vaccines that are subject to an excise tax and listed on the Vaccine Injury Table.

VICP was created by the National Childhood Vaccine Injury Act of 1986 (NCVIA) amid concerns that lawsuits against vaccine manufacturers and health care providers alleging vaccine injuries could lead to vaccine shortages and lower immunization rates. Under a typical state tort law framework, the injured person must generally prove that a vaccine caused the injury and that either the vaccine manufacturer is at fault (e.g., negligent, failed to warn adequately) or, under products liability doctrines, that the vaccine was defective. If the person cannot prove one of these elements—for example, if the manufacturer adequately warned of side effects or it is unclear whether the vaccine caused the injury—the claimant receives no compensation. If the vaccine manufacturer is found liable, however, it may be responsible for compensatory damages and potentially punitive damages as determined by a jury. Regardless of the outcome, both sides generally would be responsible for litigation costs.

The NCVIA created a no-fault alternative compensation program for deaths and injuries caused by certain vaccines that are recommended by the CDC for routine administration in children or pregnant women. The program shields manufacturers of certain vaccines from most liability for vaccine-related injuries and deaths, while providing compensation to those injured by vaccines from a trust fund funded by excise taxes paid by the vaccine manufacturers. By limiting liability exposure for vaccine manufacturers, expanding the availability of compensation for injured parties, and lowering the burden of proof, the program reduces uncertainty for both injured persons and vaccine manufacturers. From implementation of the program in 1988 through October 1, 2021, more than 24,441 petitions for compensation have been filed, of which 20,300 have been adjudicated, and 8,353 determined to merit compensation. The program has paid out approximately $4.7 billion in compensation since its inception.

Covered Vaccines and Injuries

To receive compensation, an injured party must show he or she received a "covered vaccine." Not every FDA-approved vaccine is covered by the VICP. The NCVIA included an initial Vaccine Injury Table listing vaccines covered by the program. The statute provides that vaccines can be added to the program by the Secretary amending the Vaccine Injury Table to add vaccines recommended by the CDC for routine administration to children or pregnant women within two years of such a recommendation. To receive compensation through the VICP, the injured person must have received a vaccine that is (1) recommended by the CDC for routine administration to children or pregnant women, (2) listed by the Secretary on the Vaccine Injury Table, and (3) subject to an excise tax that funds the Vaccine Injury Compensation Trust Fund from which compensation is paid. The types of vaccines subject to the excise tax are specified in statute and therefore can only be amended by an act of Congress.

In addition to having received a covered vaccine, the injured party must show either that (1) he or she experienced an injury listed for the vaccine in the Vaccine Injury Table and the first symptom of the onset or significant aggravation of the injury occurred within the time frame specified in the table, or (2) the vaccine caused the injury. The Vaccine Injury Table accordingly allows injured persons to avoid having to prove a vaccine caused their injuries by allowing them instead to show they received an injury that has been associated with the vaccine soon after receiving the vaccine. Nonetheless, injured persons still have the option of directly proving that a vaccine caused their injuries if they experience a less-common injury or the onset or aggravation of the injury is delayed.

Procedure for Obtaining Compensation

To receive compensation through VICP for a vaccine-related injury or death, the injured person (or the estate in the case of a death) files a petition with the U.S. Court of Federal Claims (Claims Court). The petition must generally contain an affidavit and supporting documentation, including relevant medical records, showing the person

- received a vaccine listed in the Vaccine Injury Table;
- sustained an illness, disability, injury, or condition set forth in the Vaccine Injury Table for the particular vaccine, and
    - the first symptom or manifestation occurred within the required time period; or
    - the vaccine caused the injury;
- suffered residual effects or complications that lasted for more than six months or required inpatient hospitalization and surgery, or died; and
- has not collected another award or settlement for the injury or death.

Petitions for vaccine-related injuries must generally be filed within three years of the first symptom or significant aggravation of the injury. Petitions for vaccine-related deaths must be filed within two years of the death and within four years of the first symptom or significant aggravation of the injury from which the death resulted. If the Vaccine Injury Table is amended such that a person qualifies for compensation who previously did not, that person has two years from when the table is revised to seek compensation for injuries or deaths that occurred up to eight years before the table was revised.

When a person files a petition with the Claims Court, the clerk of the court forwards the petition to the chief special master to assign the petition to one of eight special masters. The special master conducts a proceeding to evaluate whether the petition merits compensation under the VICP and, if so, how much. The proceedings resemble trials in allowing the presentation of evidence and submission of testimony, but they operate under more flexible, informal procedures to allow for expeditious resolution. Once a petition is filed, the special master has 240 days to issue a decision that includes factual findings and legal conclusions, though the parties may suspend the proceedings by motion for up to 150 days if necessary.

Following the decision, the petitioner has 30 days to appeal a special master's decision to the Claims Court for review. The court then has 120 days to uphold the decision, issue its own decision, or remand to the special master for further proceedings. Once the court issues its judgment, either because the petitioner does not appeal the special master's decision within 30 days or the court issues a decision after review, the petitioner has 60 days to appeal the judgment to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). If the petitioner chooses not to appeal the decision, the judgment becomes final.

After a final judgment, the petitioner has 90 days to inform the Claims Court whether the petitioner accepts the judgment or will file a civil action for damages in court. A petitioner may also withdraw its petition and file a civil action if the special master fails to act within 240 days or the Claims Court fails to enter the judgment within 420 days, both time frames excluding any suspended time. (Petitioners may opt not to withdraw their petitions if they do not want to risk proceeding in civil court.) Petitioners who neither rejected a judgment nor withdrew their petition due to the court's failure to act in time are barred from filing civil claims.

In addition to limiting the availability of civil actions to parties who have gone through the petition process, the VICP imposes certain limitations on vaccine manufacturers' liability. For example, vaccine manufacturers are not liable for injuries or deaths due to unavoidable side effects from properly prepared vaccines accompanied by proper directions and warnings. Any action that proceeds against a vaccine manufacturer is tried in three stages: (1) liability, (2) general damages, and (3) punitive damages.

Trifurcating the trial in this manner limits the evidence presented to the jury in the first and second stages to the evidence relevant to each stage of the trial.

Available Compensation

The VICP allows individuals to receive compensation for

- actual and reasonably projectable unreimbursable expenses directly related to the vaccine-related injury, including the cost of diagnosis, medical care, rehabilitation, counseling, and vocational training, among others;
- actual and anticipated loss of earnings;
- actual and projected pain and suffering and emotional distress, capped at $250,000;
- vaccine-related death, in the amount of $250,000; and
- reasonable attorneys' fees and other costs associated with proceeding on the petition.

The NCVIA authorized appropriations to compensate individuals injured by vaccines administered before October 1, 1988. Compensation for injuries for vaccines administered after October 1, 1988, is paid out of the Vaccine Injury Compensation Trust Fund (Trust Fund). Vaccine manufacturers pay into the Trust Fund through excise taxes imposed on covered vaccines. The Trust Fund may only be used to pay for vaccine-related injuries from vaccines subject to the excise tax at the time of payment, and for certain government administrative expenses incurred when administering the program. As a result, only vaccines subject to the excise tax are included in the VICP.

Considerations for Congress

The future of the COVID-19 pandemic, the impact of SARS-CoV-2 variants, and the vaccines authorized to prevent COVID-19 remain uncertain. COVID-19 vaccines are currently only authorized and CDC-recommended for individuals 12 years and older or 18 years and older, depending on the vaccine. In addition, the CDC recommends that people who are pregnant receive a COVID-19 vaccine, and recently recommended booster shots of Pfizer's COVID-19 vaccine for some groups. It remains to be seen, however, whether additional inoculations will be needed for the general population on a regular basis as the virus evolves.

Accordingly, it is unknown whether COVID-19 vaccines will be recommended for routine administration after the public health emergency ends, and specifically whether the CDC will recommend any such vaccine for routine administration to children or pregnant women. If so, Congress may consider whether to add COVID-19 vaccines to the excise tax list, which would include them in the VICP. Alternatively, Congress might consider a broader amendment to the excise tax statute to allow any vaccine recommended for routine administration to children or pregnant women to be automatically subject to the excise tax and therefore eligible for the VICP. Or, if Congress decides that COVID-19 injuries should be compensated through VICP even while the public health emergency persists, Congress could amend the PREP Act and NCVIA accordingly.

Congress could also implement an entirely new program specifically addressing compensation for COVID-19 vaccine-related injuries or deaths should it so choose. Or, Congress could opt to leave COVID-19 vaccines out of the VICP and allow the traditional tort system to address any vaccine-related injuries, either now or after the public health emergency ends and CICP no longer applies.

Table 1. Comparison of Vaccine-Injury Compensation Programs: CICP v. VICP

	Countermeasures Injury Compensation Program (CICP)	Vaccine Injury Compensation Program (VICP)
Scope of Coverage	"Covered countermeasures" under the PREP Act, such as pandemic and epidemic products used to treat, mitigate, prevent, or cure COVID-19 (e.g., vaccines, PPE, treatments)	"Covered Vaccines" are those recommended by CDC for routine administration to children or pregnant women, subject to a federal excise tax, and included on the Vaccine Injury Table
Covered Injuries	Death, or serious physical injury that (1) warrants hospitalization or (2) led to a significant loss of function or disability	Death or an illness, injury, or condition that lasted more than six months or required inpatient hospitalization and surgical intervention and was associated with one or more vaccines in the Vaccine Injury Table, unless the cause was an adulterant or contaminant that was intentionally added to the vaccine
Process for Obtaining Compensation	Administrative Process: file request form and supporting documentation with CICP to prove eligibility and compensation amounts	Judicial Process ("vaccine court"): file a petition in the U.S. Court of Federal Claims
Available Benefits	Reasonable medical expenses, lost employment income, and death benefits	Non-reimbursed expenses related to the injury for the diagnosis, medical care, and various rehabilitation and recovery services; lost employment income; pain, suffering, and emotional distress damages; death benefits; attorney's fees
Unavailable Benefits	Attorneys' fees, pain-and-suffering damages, punitive damages	Punitive or exemplary damages
Benefit Caps	$50,000/year for lost employment income (lifetime cap is generally $379,000); standard death benefit of $370,376 for FY2021	$250,000 for death; $250,000 for pain and suffering and emotional distress
Filing Deadlines	Within one year of the administration of the covered countermeasure (or within one year of the issuance of a new Countermeasure Injury Table)	For injuries, within three years of the first symptom; for deaths, within two years of the death and four years of the first symptom
Standard of Proof	Must show the injury (1) meets the requirements on a Countermeasure Injury Table; or (2) was a direct result of the administration or use of a covered countermeasure	Must show the person (1) received a vaccine on the Vaccine Injury Table; (2) sustained or significantly aggravated an illness, disability, injury, or condition, or died; (3) the illness, disability, injury, condition, or death is either listed in the Vaccine Injury Table in association with the vaccine and occurred within a set time period as specified in the table or was caused by the vaccine; (4) suffered the effects for more than six months or required inpatient hospitalization and surgery or died; and (5) has not previously collected an award for the injury or death

Initial Decisionmaker	CICP (as delegate of the Secretary of HHS)	U.S. Court of Federal Claims special master
Appeals & Judicial Review	Claimant may seek reconsideration of CICP decision to a qualified independent panel within 60 days; no further judicial or administrative review	Claimant may seek review of special master decision by U.S. Court of Federal Claims within 30 days of decision; claimant may seek review by the U.S. Court of Appeals for the Federal Circuit within 60 days of final judgment; claimant may accept the judgment or reject it and file a tort claim
Funding Source	Emergency appropriations to Covered Countermeasure Process Fund	Vaccine Injury Compensation Trust Fund based on excise tax of $0.75 per dose on "taxable vaccines"
Number of Claims Processed	Non-COVID-19 claims (2010-2021): 491 claims, of which 452 were determined ineligible and 29 compensated (6%) COVID-19 countermeasure claims (as of September 1, 2021): 2,392 claims, of which 1,031 claims (43%) relate to COVID-19 vaccines; most of these claims (99.9%) remain in or pending review	24,441 petitions as of 10/1/2021, of which 20,300 have been adjudicated, 11,947 were determined ineligible, and 8,353 compensated (41%)
Process for Adding New Vaccines	Scope of "covered countermeasures" is determined by Secretary of HHS's PREP Act declarations (within statutory limits)	Secretary of HHS may add vaccines to the Vaccine Injury Table that are (1) subject to the excise tax; and (2) recommended by the CDC for routine administration to children or pregnant women

Source: HRSA; CRS; 42 U.S.C. §§ 300aa-10–300aa-34; 42 U.S.C. § 247d-6d to -6e; 42 C.F.R. pt. 110.

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