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SUMMARY

Compensation for COVID-19 Vaccine Injuries

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More than 260 million Americans, and billions of people worldwide, have received one or more doses of a vaccine to protect against COVID-19. Studies estimate that COVID-19 vaccinations have prevented millions of deaths from the disease.

Most common side effects of COVID-19 vaccines are mild and generally resolve in a few days. In rare instances, COVID-19 vaccines can cause serious adverse events. Individuals who believe they have been injured by a COVID-19 vaccine may seek compensation for those injuries and associated harms or costs. Absent an applicable federal law, individuals allegedly injured by a vaccine might seek redress by filing a state tort law claim against the vaccine manufacturer. However, federal law has two distinct compensation regimes that limit legal liability for vaccine manufacturers and provide potential compensation—without requiring a showing of fault—for individuals harmed by adverse reactions to vaccines.

For injuries and deaths associated with most vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in the United States, the National Vaccine Injury Compensation Program (VICP) may provide compensation. During public health emergencies declared under the Public Readiness and Emergency Preparedness Act (PREP Act), the Countermeasures Injury Compensation Program (CICP) may provide compensation for injuries and deaths resulting from the administration of "covered countermeasures," which may include vaccines.

The VICP and CICP regimes are similar in some ways, but the programs serve distinct purposes. Compensation through CICP is generally less comprehensive than compensation through VICP. CICP is a regulatory process administered by the Health Resources and Services Administration (HRSA), a division of the U.S. Department of Health and Human Services (HHS). CICP compensation is available only for death or serious injuries resulting from a covered countermeasure. A claimant must generally file a request form and associated documentation with HRSA within one year of the date that the covered countermeasure was administered. For injuries not listed by the Secretary of HHS on a Countermeasure Injury Table, the claimant must demonstrate that the injury was a direct result of the countermeasure's administration based on compelling medical and scientific evidence. HRSA makes decisions regarding eligibility and compensation; judicial review is not available. CICP compensation is limited to reasonable medical expenses, loss of employment income, and a death benefit when the claimant's death is a direct result of the administration of a covered countermeasure.

Under the Secretary of HHS's current PREP Act Declaration for COVID-19, FDA-authorized or -licensed COVID-19 vaccines are covered countermeasures. While a PREP Act declaration is in effect, CICP is the sole remedy available for injuries related to covered countermeasures, so CICP—and not VICP—will apply to injuries resulting from COVID-19 vaccinations while the Declaration remains in effect.

When coverage under the PREP Act Declaration for COVID-19 ends, COVID-19 vaccine injuries could be compensated through VICP, contingent on additional regulatory and statutory changes. For a vaccine to be included in VICP, (1) the vaccine must be recommended by the CDC for routine administration to children or pregnant women (which the CDC did in 2023); (2) the vaccine must be made subject by an act of Congress to the excise tax that funds VICP; and (3) the Secretary of HHS must add the vaccine to the Vaccine Injury Table, which lists injuries and conditions associated with vaccines covered by VICP. If the remaining two changes occur, COVID-19 vaccines would be covered by VICP.

To receive compensation through VICP for a vaccine-related injury or death, the injured person or their estate must file a petition with the U.S. Court of Federal Claims, generally within three years of the onset of the first symptom or significant aggravation of the injury, or within two years of death or four years of the first symptom resulting in death. To receive compensation, petitioners must either show that they experienced an injury listed in the Vaccine Injury Table within the time frame specified in the Table, or prove that the vaccine was the "but-for" cause of their injury. Special masters determine eligibility and compensation; their decisions may be appealed to the U.S. Court of Federal Claims and the U.S. Court of Appeals for the Federal Circuit. Successful petitioners may receive medical expenses, lost income, a set death benefit, and reasonable attorneys' fees and costs. Petitioners who are dissatisfied with the compensation they receive, or whose claims are delayed, may opt to pursue civil actions in court, subject to certain limitations on vaccine manufacturer liability.

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More than 260 million Americans, along with billions of people around the world, have received one or more doses of a COVID-19 vaccine.[1] Studies estimate that these vaccinations have prevented hundreds of thousands of deaths in the United States[2] and millions of deaths worldwide.[3]

Currently, vaccines produced by Pfizer-BioNTech, Moderna, and Novavax are licensed or authorized by the U.S. Food and Drug Administration (FDA) for use to prevent COVID-19.[4] (The FDA formerly authorized a COVID-19 vaccine produced by Janssen Pharmaceuticals, a subsidiary of Johnson & Johnson, but the manufacturer voluntarily withdrew the emergency use authorization in 2023.[5]) The FDA based its authorization of these vaccines on clinical trials involving tens of thousands of participants; these trials did not identify any safety concerns that precluded authorization.[6] The vaccines are subject to continuing safety monitoring requirements by the FDA and the Centers for Disease Control and Prevention (CDC) to track the incidence of side effects and detect long-term, rare, or unexpected adverse medical events.[7]

The most common side effects of COVID-19 vaccines are mild—such as local pain around the injection site, fatigue, or fever—and usually resolve within a few days.[8] As with most vaccines, however, a small percentage of inoculated individuals experience serious adverse reactions to a

[1] *Understanding Vaccination Progress*, JOHNS HOPKINS UNIVERSITY, https://coronavirus.jhu.edu/vaccines/us-states (last updated Mar. 10, 2023); *More Than 12.7 Billion Shots Given: Covid-19 Tracker*, BLOOMBERG, https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/ (last updated Oct. 6, 2022).

[2] *See, e.g.*, Molly K. Steele et al., *Estimated Number of COVID-19 Infections, Hospitalizations, and Deaths Prevented Among Vaccinated Persons in the US, December 2020 to September 2021*, JAMA NETWORK OPEN, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793913 (July 6, 2022) (finding that COVID-19 vaccinations prevented 1.6 million hospitalizations and 235,000 COVID-19-associated deaths in the United States over a ten-month period); Virat Agrawal, Neeraj Sood & Christopher M. Whaley, *The Impact of the Global COVID-19 Vaccination Campaign on All-Cause Mortality*, NAT'L BUREAU OF ECON. RSCH., https://www.nber.org/papers/w31812 (working paper) (Oct. 2023), at 16 (finding that the first eight months of the global vaccination campaign averted over 400,000 deaths in the United States).

[3] *See, e.g.*, Agrawal et al., *supra* note 2 (finding that the first eight months of the global vaccination campaign averted about 2.4 million excess deaths worldwide); Oliver J. Watson et al., *Global Impact of the First Year of COVID-19 Vaccination: A Mathematical Modelling Study*, 22 THE LANCET INFECTIOUS DISEASES 1293 (June 23, 2022), https://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2822%2900320-6/fulltext (estimating that the COVID-19 vaccines ultimately prevented 14.4 million deaths worldwide).

[4] *See COVID-19 Vaccines for 2024–2025*, FDA, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines-2024-2025 (last updated Sept. 3, 2024). Specifically, the Moderna vaccine (SPIKEVAX) and Pfizer vaccine (COMIRNATY) are licensed for use for people aged twelve and older. *See SPIKEVAX*, FDA, https://www.fda.gov/vaccines-blood-biologics/spikevax (last updated Jan. 1, 2025); *COMIRNATY*, FDA, https://www.fda.gov/vaccines-blood-biologics/comirnaty (last updated Oct. 11, 2024). FDA has authorized the Moderna and Pfizer vaccines for emergency use in children aged six months to eleven years. *See COVID-19 Vaccines for 2024–2025*, *supra*. The Novavax vaccine is authorized for emergency use for people aged twelve and older. *Id.*

[5] *See Janssen COVID-19 Vaccine*, FDA, https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/janssen-covid-19-vaccine (June 2, 2023).

[6] *See* Letter from FDA to Pfizer Inc., at 1–2 (May 10, 2021), https://www.fda.gov/media/144412/download; Letter from FDA to ModernaTX, Inc., at 7 (Aug. 22, 2024), https://www.fda.gov/media/144636/download; Letter from FDA to Novavax, Inc., at 3–4 (Aug. 30, 2024), https://www.fda.gov/media/159902/download?attachment.

[7] *Ensuring COVID-19 Vaccine Safety in the US*, CDC, https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/vaccines/safety.html (last updated Dec. 22, 2022) ("COVID-19 vaccines are monitored by the most intense safety monitoring efforts in U.S. history."); *see generally* CRS Report R46593, *Vaccine Safety in the United States: Overview and Considerations for COVID-19 Vaccines*, by Kavya Sekar and Agata Bodie (2021).

[8] *Coronavirus Disease 2019 (COVID-19) Vaccine Safety*, CDC, https://www.cdc.gov/vaccine-safety/vaccines/covid-19.html (last updated Jan. 31, 2025).

COVID-19 vaccine.[9] For example, approximately five people per million receiving mRNA COVID-19 vaccines experience anaphylaxis, a severe allergic reaction, following vaccination.[10] Other serious adverse events reported following vaccination, such as myocarditis and Guillain-Barré Syndrome (GBS), are similarly rare but are associated with some COVID-19 vaccines in some populations.[11]

Federal law has two distinct compensation regimes for 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).[12] 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," which may include vaccines, under the Public Readiness and Emergency Preparedness Act (PREP Act).[13]

Under the Secretary of Health and Human Services' (HHS's) PREP Act Declaration for COVID-19, issued in March 2020 and subsequently amended many times, COVID-19 vaccines are covered countermeasures within the PREP Act's scope.[14] As a result, CICP—and not VICP—currently applies to injuries resulting from COVID-19 vaccinations while the PREP Act Declaration remains in force.[15] Compensation through CICP is generally somewhat more limited than through VICP.[16]

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[9] *Id.*

[10] *Id.* ("Anaphylaxis occurs at a rate of approximately 5 cases per one million vaccine doses administered."); *accord* Tom T. Shimabukuro, Matthew Cole & John R. Su, *Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US: December 14, 2020–January 18, 2021*, 325 JAMA 1101–02 (Feb. 12, 2021), https://jamanetwork.com/journals/jama/fullarticle/2776557 (reporting rates of 2.5 to 4.7 cases of anaphylaxis per million doses of mRNA COVID-19 vaccines administered).

[11] *See Coronavirus Disease 2019 (COVID-19) Vaccine Safety*, CDC, https://www.cdc.gov/vaccine-safety/vaccines/covid-19.html (last updated Jan. 31, 2025); *see also* Hannah G. Rosenblum et al., *Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices—United States, July 2021*, 70 MMWR 1094–99 (Aug. 13, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e4.htm (estimating rates of Guillain-Barré Syndrome, myocarditis, and other serious adverse events per million vaccine doses administered); Matthew E. Oster et al., *Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021*, 327 JAMA 331 (Jan. 25, 2022) (estimating rates of myocarditis per million vaccine doses administered).

[12] *National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN. (HRSA), https://www.hrsa.gov/vaccine-compensation/index.html (last updated Apr. 2025); *Covered Vaccines*, HRSA, https://www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html (last updated Apr. 2025) ("The National Vaccine Injury Compensation Program (VICP) covers most vaccines routinely given in the U.S.").

[13] *See Countermeasures Injury Compensation Program (CICP)*, HRSA, https://www.hrsa.gov/cicp/ (last updated Jan. 2023); Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, div. C, 119 Stat. 2818 (2005).

[14] *See* 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99875, 99880 (Dec. 11, 2024); *Public Readiness and Emergency Preparedness Act*, U.S. DEP'T OF HEALTH & HUMAN SERVS. HHS OFF. OF THE ASST. SEC. FOR PREPAREDNESS & RESPONSE (HHS ASPR), https://aspr.hhs.gov/legal/PREPact/pages/default.aspx (last visited Apr. 10, 2025) (links to the COVID-19 PREP Act Declaration and its twelve amendments).

[15] *Frequently Asked Questions*, HRSA, https://www.hrsa.gov/cicp/faq (last visited Apr. 10, 2025) ("COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program (VICP).").

[16] *See Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP)*, HRSA, https://www.hrsa.gov/cicp/cicp-vicp (last updated Sept. 2023); *see also infra* "Appendix. Comparison of Vaccine-Injury Programs: CICP vs. VICP."

This report reviews and compares the compensation regimes available for vaccine-related injuries under CICP and VICP, and describes the procedures for injured individuals to obtain compensation under each program. The report concludes with an **Appendix** that compares the two regimes.

The Countermeasures Injury Compensation Program (CICP)

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.[17] In a declaration effective February 4, 2020 (the PREP Act Declaration), the Secretary invoked the PREP Act and declared the spread of COVID-19 to be a public health emergency warranting liability protections for covered countermeasures (e.g., drugs, biologics, and medical devices used to diagnose, treat, or prevent COVID-19).[18] Pursuant to the PREP Act Declaration and its subsequent amendments,[19] 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.[20]

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.[21] CICP is a regulatory process administered by the Health Resources and Services Administration (HRSA).[22] HRSA regulations govern CICP's procedures and eligibility determinations.[23]

Covered Vaccines and Injuries

Under the PREP Act and the amended PREP Act Declaration, covered countermeasures for COVID-19 may include drugs, biologics, 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."[24] For example, personal protective

[17] 42 U.S.C. § 247-6d(a)–(b).

[18] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020). Although the initial declaration was issued on March 10, 2020, it was retroactively made effective beginning on February 4, 2020. *Id.* at 15198.

[19] *See Public Readiness and Emergency Preparedness Act*, HHS ASPR, https://aspr.hhs.gov/legal/PREPact/pages/default.aspx (last visited Mar. 5, 2025).

[20] *See* 42 U.S.C. § 247d-6d(a); *see generally PREP Act Questions and Answers*, HHS ASPR, https://aspr.hhs.gov/legal/PREPact/Pages/PREP-Act-Question-and-Answers.aspx (last visited Apr. 10, 2025). For a detailed discussion of the scope of liability immunity under the PREP Act, see CRS Legal Sidebar LSB10443, *The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures*, by Kevin J. Hickey (2022), and CRS Legal Sidebar LSB10730, *The PREP Act and COVID-19, Part 2: The PREP Act Declaration for COVID-19 Countermeasures*, by Kevin J. Hickey (2025).

[21] 42 U.S.C. § 247d-6e; *Countermeasures Injury Compensation Program (CICP)*, HRSA, https://www.hrsa.gov/cicp/ (last updated Jan. 2023).

[22] *See Frequently Asked Questions*, HRSA, https://www.hrsa.gov/cicp/faq (last visited Apr. 10, 2025).

[23] *See* 42 C.F.R. pt. 110.

[24] 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99875, 99880 (Dec. 11, 2024); 42 U.S.C. § 2476d-6d(i)(7).

equipment (PPE) (e.g., respirators), antiviral drugs (e.g., Paxlovid), and monoclonal antibody treatments authorized by the FDA to treat or prevent COVID-19 are covered countermeasures under the COVID-19 PREP Act Declaration.[25] Notably, FDA-authorized or -licensed COVID-19 vaccines—such as those produced by Pfizer, Moderna, and Novavax—are covered countermeasures under the current 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 a single, limited exception for claims of "willful misconduct").[26] Thus, so long as COVID-19 vaccines remain covered under the current PREP Act Declaration, CICP is the exclusive remedy for claims within the PREP Act's scope, including injuries allegedly resulting from COVID-19 vaccinations.[27] As discussed below in "Possible Transition of COVID-19 Vaccines from Coverage Under CICP to VICP," COVID-19-vaccine-related injuries may eventually be compensable through VICP (or through tort suits) after the PREP Act Declaration no longer applies, depending on certain statutory and regulatory changes.

CICP compensation is limited to eligible individuals, such as persons injured by countermeasures or their survivors.[28] CICP provides compensation only for death or "serious physical injuries"—that is, injuries that warrant hospitalization or lead to a significant loss of function or disability.[29] Individuals who experience only minor, short-term side effects from a COVID-19 vaccine—such as mild soreness, headache, or fatigue—would not be eligible for CICP compensation.[30]

Procedure for Obtaining Compensation

To apply for CICP compensation, a claimant generally must file a request for benefits within one year of the date the countermeasure was administered.[31] (If the Secretary publishes a new Countermeasure Injury Table, a newly eligible claimant may file within one year after the new Table is established.[32]) In addition to the request form, claimants may need to submit medical

[25] *Emergency Use Authorization*, FDA, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov (last updated Dec. 23, 2024) (listing FDA emergency use authorizations for vaccines, drugs, biologics, and medical devices for use against COVID-19). PREP Act coverage for some COVID-19 countermeasures has expired, but COVID-19 vaccines currently remain covered through the end of 2029. *See* 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99875, 99882–83 (Dec. 11, 2024); *see generally* CRS Legal Sidebar LSB10730, *The PREP Act and COVID-19, Part 2: The PREP Act Declaration for COVID-19 Countermeasures*, by Kevin J. Hickey (2025).

[26] *See* 42 U.S.C. §§ 247d-6e(d)(4) ("The [CICP] remedy . . . shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for [claims of willful misconduct]."); 42 U.S.C. 247d-6d(d)(1) ("[T]he sole exception to the immunity from suit and liability of covered persons [under the PREP Act] shall be [willful misconduct claims].").

[27] *See id.*; *see also Frequently Asked Questions*, HRSA, https://www.hrsa.gov/cicp/faq (last visited Apr. 10, 2025) ("COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program (VICP).").

[28] *See* 42 C.F.R. § 110.10.

[29] *See id.* § 110.3(z); 42 U.S.C. § 247d-6e(e)(3).

[30] *See Coronavirus Disease 2019 (COVID-19) Vaccine Safety*, CDC, https://www.cdc.gov/vaccine-safety/vaccines/covid-19.html (last updated Jan. 31, 2025) (describing temporary arm soreness, muscle pain, fatigue, fever, and other "common side effects" of COVID-19 vaccines).

[31] 42 C.F.R. § 110.42(a).

[32] *Id.* § 110.42(f).

records and other evidence to establish eligibility.[33] If determined to be eligible, claimants may submit additional documentation to demonstrate the compensation amount.[34] Eligibility and compensation determinations are made by HRSA (exercising power delegated by the Secretary).[35] Claimants may seek reconsideration of an adverse eligibility decision by HRSA, but the ultimate decisionmaking authority lies with the Secretary.[36] The PREP Act precludes judicial review of the Secretary's eligibility and compensation decisions.[37]

CICP claimants can prove eligibility for compensation in one of two ways.[38] The first applies only 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.[39] (The Table established for pandemic influenza vaccines is one example;[40] no such table has yet been promulgated for any COVID-19 countermeasure, including COVID-19 vaccines.) 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.[41] 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, [and] valid" medical and scientific evidence beyond mere temporal association.[42]

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 when the death is a direct result of the administration or use of a covered countermeasure.[43] Attorneys' fees and pain-and-suffering damages are not available under CICP.[44] CICP awards are also subject to various annual and lifetime limits. For

[33] *See id.* § 110.50–110.53; *see also Criteria to Demonstrate That a Covered Injury Occurred*, HRSA, https://www.hrsa.gov/cicp/injury-occurred (last updated Sept. 2023).

[34] *See* 42 C.F.R. § 110.60–110.63; *see also Countermeasures Injury Compensation Program (CICP) Filing Process*, HRSA, https://www.hrsa.gov/cicp/filing-benefits (last updated Sept. 2023).

[35] *See* 42 C.F.R. § 110.72–110.74.

[36] *See id.* §§ 110.90 (process to request reconsideration of eligibility determinations), 110.91 ("[T]he Secretary may, at any time, on her own motion or on application, review any determination made under this part [and] may affirm, vacate, or modify the determination in any manner the Secretary deems appropriate.").

[37] *See* 42 U.S.C. § 247d-6e(b)(4) (incorporating 42 U.S.C. § 239a(f)(2)); 42 C.F.R. § 110.92 ("[N]o judicial review of the Secretary's actions concerning eligibility and benefits determinations under [CICP] is permitted.").

[38] *See* 42 C.F.R. § 110.20(b)–(c).

[39] 42 U.S.C. § 247d-6e(5)(A).

[40] 42 C.F.R. § 110.100.

[41] *See id.* § 110.20(b).

[42] *See id.* § 110.20(c).

[43] *Id.* § 110.2(a).

[44] *See Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP)*, HRSA, https://www.hrsa.gov/cicp/cicp-vicp (last updated Sept. 2023) ("Attorneys' fees and costs are not paid by [CICP]."); Nicholas M. Pace, Lloyd Dixon & Bethany Saunders-Medina, *The Compensation System for Potential Side Effects Is an Important Part of a COVID-19 Vaccine Campaign*, THERANDBLOG (Dec. 18, 2020), https://www.rand.org/blog/2020/12/the-compensation-system-for-potential-side-effects.html ("The CICP does not provide any compensation for pain, suffering, emotional distress, or similar damages . . . .").

example, annual lost employment income awards are capped at $50,000 per year,[45] and the standard maximum death benefit is the same as that under the Public Safety Officers' Benefits program (currently $448,575).[46]

Status of Pending CICP Claims for COVID-19 Countermeasures

Given the limited number and scope of past PREP Act declarations, CICP has been used relatively infrequently since the PREP Act's 2005 enactment and prior to the COVID-19 pandemic.[47] Before 2020, fewer than 600 CICP claims had been filed, and only a few dozen had been compensated,[48] potentially due to the limited use of PREP Act declarations and the higher burden of proof in CICP.

Following the COVID-19 PREP Act Declaration and the widespread use of COVID-19 vaccines, the number of CICP claims received by HRSA has risen dramatically, with HRSA receiving over 13,000 claims in the last few years.[49] Almost 96% of all CICP claims *ever* filed with HRSA relate to COVID-19 countermeasures,[50] and a large majority of those COVID-19 countermeasure claims (over 77%) allege injuries or deaths from COVID-19 vaccines.[51] Because the HHS Secretary has not issued a Countermeasure Injury Table for any COVID-19 countermeasure, these claimants must prove causation directly. HRSA reports that as of April 2025, it had reached a decision with respect to 4,111 (29.9%) out of 13,764 total COVID-19 countermeasure claims, denying 4,044 claims (98.4%) and finding 67 claims eligible for compensation (1.6%).[52]

The National Vaccine Injury Compensation Program (VICP)

After the Secretary terminates the PREP Act Declaration for the COVID-19 pandemic, COVID-19 vaccine manufacturers would no longer enjoy liability protections, unless the COVID-19 vaccine were added to VICP. Without CICP's or VICP's liability protections, COVID-19 vaccine manufacturers could be sued in state courts under tort law theories alleging that their vaccines caused injury or death.[53] If Congress added the COVID-19 vaccines to VICP, however,

[45] 42 C.F.R. § 110.81(c)(2).

[46] *Id.* § 110.82(b)(1); *Benefits by Year: Public Safety Officers' Benefits Program*, U.S. DEP'T OF JUSTICE BUR. OF JUST. ASSISTANCE, https://psob.bja.ojp.gov/knowledge-base/benefits-by-year/ (last visited Apr. 10, 2025).

[47] *See* Pace et al., *supra* note 44 ("The NVICP has handled more than 20,000 vaccine injury claims since its inception, while the CICP, as far as can be determined, has processed about 500 since the law that created the program was enacted in 2005 [and prior to COVID-19].").

[48] *See id.* According to HRSA, CICP compensated only 30 non-COVID-19 claims between fiscal years 2010 and 2025; almost all of these were claimed injuries from the 2009 H1N1 influenza vaccine. *See* HRSA, *Table 4. CICP Claims Compensated (Fiscal Years 2010–2025)*, https://www.hrsa.gov/cicp/cicp-data/table-4 (last updated Apr. 1, 2025). Over the history of the program, CICP has received around 574 non-COVID-19-related claims in total. *See* HRSA, *Countermeasures Injury Compensation Program (CICP) Data*, https://www.hrsa.gov/cicp/cicp-data (last updated Apr. 1, 2025) (reporting 14,338 CICP claims ever filed, and 13,764 that relate to COVID-19 countermeasures).

[49] HRSA, *Countermeasures Injury Compensation Program (CICP) Data*, https://www.hrsa.gov/cicp/cicp-data (last updated Apr. 1, 2025) (reporting 13,764 claims relating to COVID-19 countermeasures).

[50] *Id.* (reporting 14,338 total CICP claims).

[51] *See id.* (reporting 10,651 claims alleging COVID-19 vaccine injuries or deaths out of 13,764 total COVID-19 countermeasure injury claims).

[52] *See id.*

[53] 42 U.S.C. §§ 300aa-10–300aa-44; 26 U.S.C. §§ 4131, 4132, 9510; 42 U.S.C. § 247d-6e(d)(4). *See also National*
(continued...)

manufacturers of the vaccines would once again be protected from state court civil suits. In addition, VICP provides compensation to individuals for injuries and deaths associated with vaccines that are listed on the Vaccine Injury Table and subject to an excise tax.[54]

Congress created VICP via the National Childhood Vaccine Injury Act of 1986 (NCVIA) amid concerns that lawsuits against vaccine manufacturers and health care providers alleging vaccine injuries could deter pharmaceutical innovation, lead to vaccine shortages, and lower immunization rates.[55] Under a typical state tort law framework, an injured person must generally prove that a vaccine caused the injury and that either the vaccine manufacturer is at fault (e.g., was negligent, failed to warn adequately) or, under products liability doctrines, that the vaccine was defective.[56] 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 judge or jury.[57] Regardless of the outcome, both sides generally would be responsible for their own litigation costs.[58]

In contrast to the state tort law framework, VICP is a no-fault alternative compensation program for deaths and injuries caused by certain vaccines that are recommended by the CDC for routine administration to children or pregnant women.[59] The Program was designed to shield vaccine manufacturers from most tort liability for vaccine-related injuries and deaths, while providing compensation to those injured from a trust fund funded by excise taxes paid by the vaccine manufacturers.[60] 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 February 1, 2025, 28,292 petitions for compensation have been filed, of which 24,602 have been adjudicated, with 11,659 determined to merit compensation.[61] The Program has paid out more than $5.3 billion in compensation since its inception, and as of September 30, 2024, the Trust fund has a current balance of more than $4.6 billion.[62]

Covered Vaccines and Injuries

To receive compensation through VICP, the injured person must have received a vaccine that is (1) recommended by the CDC for routine administration to children or pregnant women,

Vaccine Injury Compensation Program, HRSA, https://www.hrsa.gov/vaccine-compensation/index.html (last updated Apr. 2025).

[54] 42 U.S.C. §§ 300aaa-11–300aa-15; 26 U.S.C. §§ 4131, 4132, 9510; 42 C.F.R. § 100.3; *Vaccine Injury Table*, HRSA, https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf.

[55] Pub. L. No. 99-660, § 311, 100 Stat. 3758 (1986); *see, e.g.*, S. REP. NO. 99-483, at 2–6 (1986); H. REP. NO. 99-908, at 4–7 (1986).

[56] RESTATEMENT (SECOND) OF TORTS § 281; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 1, 10. *See also* CRS In Focus IF11291, *Introduction to Tort Law*, by Kevin M. Lewis.

[57] RESTATEMENT (SECOND) OF TORTS §§ 901–917.

[58] Alyeska Pipeline Serv. Co. v. Wilderness Soc'y, 421 U.S. 240, 247 (1975).

[59] 42 U.S.C. §§ 300aa-13–300aa-15.

[60] *Id.* §§ 300aa-13–300aa-15, 300aa-21–300aa-22; 26 U.S.C. §§ 4131, 4132, 9510.

[61] *Data & Statistics*, HRSA, https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/vicp-stats-02-01-25.pdf (last updated Feb. 1, 2025).

[62] *Id.*; *see also Vaccine Injury Trust Fund Investment Summary*, Bureau of the Fiscal Service, https://web.archive.org/web/20250204195109/https://treasurydirect.gov/ftp/dfi/tfmb/dfivi0924.pdf (Sept. 30, 2024), at 2.

(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.[63] The types of vaccines subject to the excise tax are specified in statute and therefore can be amended only by an act of Congress.[64]

To be entitled to VICP compensation, an injured party must first show receipt of a "covered vaccine."[65] Not every FDA-approved vaccine is covered by VICP. The NCVIA included an initial Vaccine Injury Table listing vaccines covered by the Program.[66] Under the Act, the Secretary may promulgate regulations to amend the Vaccine Injury Table to include additional vaccines recommended by the CDC for routine administration to children or pregnant women within two years of such a recommendation.[67]

In addition to having received a covered vaccine, the injured party must show either that (1) they 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 more likely than not caused the injury.[68] The Vaccine Injury Table 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 temporally associated with receipt of a covered vaccine.[69] Individuals who allege vaccine-related injuries not included in the Table, or who allege a Table injury but experience symptom onset outside of the specified timetable, may still file a petition. To be entitled to VICP compensation, such individuals are required to prove, by a preponderance of the evidence, that the vaccine received was the "but-for" cause of the injury.[70]

Procedure for Obtaining Compensation

To receive VICP compensation, 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).[71] 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 or experienced a significant aggravation of an illness, disability, injury, or condition either
    - set forth in the Vaccine Injury Table for the particular vaccine, and the first symptom or manifestation occurred within the required time period, or
    - caused by the vaccine;

[63] 42 U.S.C. § 300aa-14; 26 U.S.C. §§ 4132, 9510.

[64] 26 U.S.C. § 4132.

[65] 42 U.S.C. §§ 300aa-11(c), 300aa-33(5).

[66] *Id.* § 300aa-14(a).

[67] *Id.* § 300aa-14(e).

[68] *Id.* § 300aa-11(c). For more information about OSM proceedings, the adjudication of vaccine petitions, and proving causation, see CRS In Focus IF12213, *The National Vaccine Injury Compensation Program and the Office of Special Masters*, by Hannah-Alise Rogers (last updated Sept. 14, 2022).

[69] 42 U.S.C. §§ 300a-11, 300aa-14.

[70] *Id.* § 300a-11(c)(1)(C)(ii).

[71] *Id.* § 300aa-11.

- 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.[72]

Petitions for vaccine-related *injuries* must generally be filed within three years of the first symptom of the injury or significant aggravation.[73] 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.[74] 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.[75]

When a person files a petition with the Claims Court, the clerk of the court forwards the petition to the Office of Special Masters (OSM), and the chief special master assigns the petition to one of the eight special masters.[76] The court's guidelines for attorneys practicing in VICP, referred to as the Vaccine Rules, require the Secretary to review the petition within 30 days of its filing to determine whether the record is complete and to determine the government's position on the appropriateness of compensation.[77] Instead of filing a formal answer to the petition, as would be required in traditional court proceedings, the Secretary is required to file a report within 90 days of the petition's filing outlining any legal and/or factual issues with petitioner's claim and any medical conclusions reached by the Secretary's experts.[78] The 90-day period is often extended for a variety of reasons, for example, because more time is needed to file additional medical records, the special master ordered the petitioner to file an expert report, or the parties wish to discuss settlement.[79]

HRSA reports that as of February 1, 2025, approximately 60% of compensated petitions are the result of a settlement agreement.[80] If the parties cannot resolve the case via settlement, the special master may hold an evidentiary hearing on the petition or issue a ruling based on the administrative record.[81] In either case, the assigned special master issues a decision regarding whether the petitioner is entitled to compensation under VICP and, if so, how much.[82] Vaccine hearings resemble civil trials in that they allow for the presentation of evidence, including testimony from expert witnesses, but VICP proceedings offer more flexible, informal procedures

[72] *Id.* § 300aa-11(c).

[73] *Id.* § 300aa-16(a).

[74] *Id.*

[75] *Id.* § 300aa-16(b).

[76] *Id.* §§ 300aa-12(c)(1), 300aa-12(d); *see also Vaccine Claims/Office of Special Masters*, U.S. COURT OF FEDERAL CLAIMS, https://www.uscfc.uscourts.gov/vaccine-claims-office-special-masters (last visited Apr. 10, 2025).

[77] *Vaccine Rules, Appendix B, Rules of the United States Court of Federal Claims*, U.S. COURT OF FEDERAL CLAIMS, https://www.uscfc.uscourts.gov/sites/cfc/files/rcfc_vaccine.pdf (revised July 29, 2024).

[78] *Id.*

[79] *Id.*

[80] *Data & Statistics*, HRSA, https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/vicp-stats-02-01-25.pdf (last visited Feb. 1, 2025). In a settlement agreement, the Secretary agrees to compensate the petitioner without conceding that the vaccine was responsible for the petitioner's injuries. Settlements are particularly common for Table injuries. *Id.*

[81] *Guidelines for Practice Under the National Vaccine Injury Compensation Program*, U.S. COURT OF FEDERAL CLAIMS, https://www.uscfc.uscourts.gov/sites/cfc/files/vaccine_guidelines.pdf (revised Mar. 11, 2024).

[82] 42 U.S.C. § 300aa-12.

to allow for expeditious resolution.[83] The special master has 240 days from the date a petition is filed to issue an entitlement decision that includes factual findings and legal conclusions, though the parties may suspend the proceedings by motion for up to 150 days if necessary.[84]

The petitioner has 30 days after the special master issues an entitlement decision to appeal the decision to the Claims Court.[85] The court then has 120 days to uphold the decision, issue its own decision, or remand to the special master for further proceedings.[86] If the parties do not appeal the special master's decision within 30 days, or when the Claims Court issues a decision after review, judgment is entered and the petitioner has 60 days to appeal the judgment to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit).[87] If the parties choose not to appeal the decision, the judgment becomes final.[88]

After a final judgment, the petitioner has 90 days to accept or reject the judgment.[89] If the judgment awards compensation and the petitioner chooses to accept the judgment, the petitioner is entitled to an award of compensation but may not file a civil action for damages related to the injury or death. If the judgment awards compensation but the petitioner rejects the judgment, the petitioner is not entitled to any compensation from VICP but may file a civil action for damages against the manufacturer.[90] Petitioners who do not act to accept or reject the judgment within 90 days are deemed to have accepted the judgment and are also barred from filing civil claims.[91] A petitioner may also withdraw the 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.[92] (Petitioners may opt not to withdraw their petitions if they do not want to risk proceeding in civil court.[93])

In addition to limiting the availability of civil actions against manufacturers to parties who have gone through VICP's process, the NCVIA imposes certain limitations on vaccine manufacturers' liability in civil proceedings.[94] For example, vaccine manufacturers cannot be held liable for injuries or deaths due to unavoidable side effects from properly prepared vaccines accompanied by proper directions and warnings.[95] Any action that proceeds against a vaccine manufacturer is tried in three stages: (1) liability, (2) general damages, and (3) punitive damages.[96] Trifurcating the trial in this manner limits the evidence presented to the judge or jury in the first and second stages to the evidence relevant to each stage of the trial.

[83] *Id.* § 300aa-12(d)(3)(B); *Vaccine Rules, Appendix B, Rules of the United States Court of Federal Claims*, U.S. COURT OF FEDERAL CLAIMS, https://www.uscfc.uscourts.gov/sites/cfc/files/rcfc_vaccine.pdf (last updated July 29, 2024).

[84] 42 U.S.C. § 300aa-12(d)(3). In practice, it takes approximately two to three years for the OSM to adjudicate petitions, according to HRSA data. *See HRSA Data & Statistics*, *supra* note 80, at 7.

[85] 42 U.S.C. § 300aa-12(e)(1).

[86] *Id.* § 300aa-12(e)(2).

[87] *Id.* § 300aa-12(e)–(f).

[88] *Id.* § 300aa-12(e)(3).

[89] *Id.* § 300aa-21(a)(1).

[90] *Id.* § 300aa-21(a).

[91] *Id.* § 300aa-11(a)(2)(A).

[92] *Id.* § 300aa-21(b).

[93] *Id.*

[94] *Id.* § 300aa-22.

[95] *Id.* § 300aa-22(b).

[96] *Id.* § 300aa-23.

Available Compensation

An award for compensation includes

- actual and reasonably projected unreimbursable expenses resulting from the vaccine-related injury, including the cost of diagnosis, medical care, rehabilitation, counseling, vocational training, and custodial care, among others;
- actual and anticipated loss of earnings;
- actual and projected pain and suffering and emotional distress, capped at $250,000;
- the amount of $250,000, in the case of a vaccine-related death; and
- reasonable attorneys' fees and other costs associated with proceeding on the petition.[97]

The NCVIA authorized appropriations to compensate individuals injured by vaccines administered before October 1, 1988.[98] Compensation for injuries related to vaccines administered after October 1, 1988, is paid out of the Vaccine Injury Compensation Trust Fund (Trust Fund).[99] Vaccine manufacturers pay into the Trust Fund through a 75-cent excise tax imposed on covered vaccines.[100] The Trust Fund may be used only 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.[101] Consequently, only vaccines subject to the excise tax are included in VICP.

Possible Transition of COVID-19 Vaccines from Coverage Under CICP to VICP

While COVID-19 vaccines remain covered by a PREP Act Declaration, CICP is the exclusive remedy for injuries associated with the administration of COVID-19 vaccines.[102] As explained in detail in a separate CRS product,[103] the applicable time period for liability immunity under the PREP Act may depend on the type of countermeasure, the means of distribution, the covered person who administers the countermeasure, and other factors.[104] As a result, the point in time when coverage for a countermeasure expires under the PREP Act Declaration may depend on the particular context.

Under the Eleventh Amendment to the COVID-19 PREP Act Declaration, coverage for COVID-19 vaccines was to expire on December 31, 2024.[105] A few weeks before that date, HHS

[97] *Id.* § 300aa-15(a)–(e).

[98] *Id.* § 300aa-15(j).

[99] *Id.* § 300aa-15(i)(2); 26 U.S.C. § 9510.

[100] 26 U.S.C. §§ 4131–4132.

[101] *Id.* § 9510(c).

[102] *See* 42 U.S.C. § 247d-6e(d)(4); *Frequently Asked Questions*, HRSA, https://www.hrsa.gov/cicp/faq (last visited Apr. 10, 2025).

[103] *See* CRS Legal Sidebar LSB10730, *The PREP Act and COVID-19, Part 2: The PREP Act Declaration for COVID-19 Countermeasures*, by Kevin J. Hickey (2025).

[104] *See id.*

[105] *See* Eleventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 88 Fed. Reg. 30769, 30775 (May 12, 2023).

issued the Twelfth Amendment to the PREP Act Declaration,[106] extending PREP immunity time periods for COVID-19 vaccines and certain other COVID-19 countermeasures for an additional five years, until December 31, 2029.[107] Thus, under the current PREP Act Declaration, CICP remains the exclusive remedy for COVID-19 vaccine injury claims through the end of 2029.

That said, the HHS Secretary has wide discretion to set forth the scope of liability immunity under the PREP Act, including whether to grant immunity to certain countermeasures or certain activities.[108] Once a PREP Act declaration for a particular public health threat is issued, it may be amended by the HHS Secretary through the publication of an amendment in the *Federal Register*.[109] Although such amendments may not retroactively limit liability immunity,[110] a future amendment to the COVID-19 PREP Act Declaration could shorten (or extend) the effective time period of coverage for COVID-19 vaccines.[111] When COVID-19 vaccines are no longer covered by the PREP Act, CICP will no longer be an available remedy for injuries caused by COVID-19 vaccines. At that point, unless the vaccines are included in VICP, persons injured by COVID-19 vaccine side effects could pursue remedies under state tort law.

Congress could decide to add COVID-19 vaccines to VICP so that they are covered by that program when PREP Act coverage expires. In order for a vaccine to be added to VICP under existing law, (1) the CDC must recommend the vaccine for routine administration to children and/or pregnant women (which, as explained below, the CDC did in 2023); (2) Congress must enact legislation to apply the excise tax to the vaccine; and (3) the Secretary of HHS must add the vaccine to the Vaccine Injury Table by publishing a notice of coverage.[112] Should the remaining two changes occur, the COVID-19 vaccine would be added to VICP with coverage effective as of the date of the enacted tax.[113]

On October 20, 2022, the CDC's Advisory Committee on Immunization Practices recommended adding COVID-19 vaccines (specifically, the Pfizer, Moderna, and Novavax vaccines) to its regular childhood and adult immunization schedules.[114] Vaccines added to the regular CDC

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[106] *See* 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99875 (Dec. 11, 2024).

[107] *Id.* at 99882.

[108] *See* 42 U.S.C. § 247d-6d(b)(2)–(3).

[109] *Id.* § 247d-6d(b)(4).

[110] *Id.*

[111] 42 U.S.C. § 247d-6d(b)(2)(B). *Compare* Eleventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 88 Fed. Reg. 30769, 30775 (May 12, 2023) *with* 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 Fed. Reg. 99875, 99882 (Dec. 11, 2024).

[112] 42 U.S.C. § 300aa-14(e)(2); 42 C.F.R. § 100.3(a)(XVII).

[113] 42 U.S.C. § 300aa-14(e)(2). Under 42 U.S.C. § 300aa-14(e)(2), when the CDC recommends a new vaccine for routine administration to children or pregnant women, the Secretary is required to amend the Vaccine Injury Table within two years. 42 U.S.C. § 300aa-14(c) describes the process the Secretary must ordinarily take to revise the Table. Under 42 C.F.R. § 100.3(a)(XVII), however, the Table will immediately include any new vaccine recommended by the CDC for routine administration to children and/or pregnant women after the Secretary publishes a "notice of coverage" in the *Federal Register*. When the Secretary revises the Table under this process, the change takes effect as soon as Congress enacts the tax. 42 U.S.C. § 300aa-14 note. Although the COVID-19 vaccine was recommended for routine administration in October 2022, the Secretary has still not amended the Table to include COVID-19. For more information, *see infra* note 117.

[114] Press Release, *ACIP Immunization Schedule Vote*, CDC, https://archive.cdc.gov/#/details?url=https://www.cdc.gov/media/releases/2022/s1020-immunization-vote.html (Oct. 20, 2022); *see also COVID-19 Vaccine: Interim COVID-19 Vaccine Immunization Schedule for Persons 6 Months of Age or Older*, CDC, https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-
(continued...)

immunization schedules are considered recommended for routine use for the purposes of VICP.[115] The CDC formally adopted the recommendation on February 10, 2023, when the recommendation was published in the *Morbidity and Mortality Weekly Report*.[116] This recommendation triggers a statutory obligation for the Secretary to amend the Table to include the COVID-19 vaccine; the injuries, conditions, or deaths that are associated with the vaccines; and the time period in which onset of symptoms or significant aggravation of symptoms must occur.[117] Under the HHS vaccine regulations, the Secretary adds a vaccine to the Table by issuing a notice of coverage, which generally states that the vaccine is covered by VICP as of the date the excise tax applies to the vaccine.[118] Any changes made to the Vaccine Injury Table to add COVID-19 vaccines do not become effective until and unless Congress enacts legislation to extend the excise tax to the COVID-19 vaccines.[119]

Considerations for Congress

The inclusion of COVID-19 vaccines in CICP and their possible transition to VICP present several issues that Congress may consider.

Because of the widespread use of COVID-19 vaccines, HRSA is receiving a volume of CICP claims many times larger than it has received during past public health emergencies. To date, HRSA reports that it has reached a decision in about 30% of the COVID-19 countermeasure claims it has received and that it has compensated less than 2% of claims.[120] Congress may consider whether HRSA needs additional authorities or resources to process these CICP claims expeditiously.

CICP is a more limited program than VICP in several ways. The available compensation is generally lower, and the standard of proof for non-Table injuries is higher. There are fewer

6months-older.pdf (Dec. 8, 2022). For more information about ACIP, *see* CRS In Focus IF12317, *The Advisory Committee on Immunization Practices (ACIP)*, by Kavya Sekar (updated Dec. 2024).

[115] *See, e.g.*, 62 Fed. Reg. 7685 (Feb. 20, 1997) (final rule adding hepatitis B vaccine to the Table); 62 Fed. Reg. 52724 (Oct. 9, 1997) (the notice of compensation for hepatitis B); 63 Fed. Reg. 25777 (May 11, 1998) (final rule adding a date certain for coverage for hepatitis B vaccine). *See also* 69 Fed. Reg. 69945 (Dec. 1, 2004) (notice of coverage adding hepatitis A vaccine to the Table, where the CDC explains, "The two prerequisites for adding Hepatitis A vaccines to the VICP as covered vaccines as well as to the Table have been satisfied. First, the CDC published its recommendation that Hepatitis A vaccines be routinely administered to certain children in the October 1, 1999, issue of the Morbidity and Mortality Weekly Report (MMWR) . . . .").

For more information on the ACIP and its recommendations, see CRS In Focus IF12317, *The Advisory Committee on Immunization Practices (ACIP)*, by Kavya Sekar (updated Dec. 2024).

[116] CDC, *Morbidity and Mortality Weekly Report, Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger – United States, 2023*, Feb. 10, 2023, *available at* https://www.cdc.gov/mmwr/volumes/72/wr/mm7206a1.htm?s_cid=mm7206a1_w#contribAff (last accessed Apr. 9, 2025).

[117] 42 U.S.C. § 300aa-14(e)(2)–(3). Although it has been more than two years since the CDC recommended the COVID-19 vaccine for routine administration to children and pregnant women, HRSA has not updated the Vaccine Injury Table to reflect this change. *See* Complaint, Brundage v. Becerra, No. 25-119 (D.D.C. Jan. 16, 2025) (lawsuit seeking to compel HHS to add the COVID-19 vaccine to the Vaccine Injury Table). It is possible that HRSA has not yet updated the Table to avoid confusion about VICP coverage, as the changes to the Table would not be effective until Congress enacted a tax on the COVID-19 vaccine. *See* 42 U.S.C. § 300aa-14 note ("A revision by the Secretary [to add a new vaccine to the Vaccine Injury Table] shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table . . . .").

[118] *See id.*; 42 C.F.R. § 100.3(a).

[119] *See* 42 U.S.C. § 300aa-14 note.

[120] *See* HRSA, *Countermeasures Injury Compensation Program (CICP) Data*, https://www.hrsa.gov/cicp/cicp-data (last updated Apr. 1, 2025).

opportunities for appeal and reconsideration in CICP as judicial review is not available. CICP claimants have significantly lower rates of success on average as compared to VICP petitioners. Congress may consider whether barriers to CICP compensation could be lowered, or—as some observers argue—the law could be changed so that COVID-19 vaccine injury claims could be brought under VICP.[121]

CICP has also been criticized for lacking transparency and accountability, and having high administrative costs relative to the amounts it awards in compensation.[122] To some degree, the high costs may be attributable to the relatively high standard of proof and lower success rates for CICP claims. Regardless, Congress may consider whether CICP is an efficient way to compensate these claims and whether judicial review or greater transparency in HRSA's decisionmaking process would improve the Program.

Congress could also choose to implement an entirely new program specifically addressing compensation for COVID-19 vaccine-related injuries or deaths. Alternatively, Congress could opt to leave COVID-19 vaccines out of CICP or VICP and allow the traditional tort system to address any vaccine-related injuries after PREP Act coverage ends and CICP no longer applies.

The potential of covering COVID-19 vaccines under VICP presents issues Congress may consider as well. As discussed above, VICP awards are funded by an excise tax and the Program may only compensate injuries resulting from vaccines subject to the excise tax.[123] The term "taxable vaccines" is defined in the tax code to include vaccines against particular diseases—this list of diseases does not currently include COVID-19.[124] Should Congress seek to include COVID-19 vaccines in VICP following the expiration of coverage under the PREP Act and CICP, it would need to amend the tax code to subject COVID-19 vaccines to this excise tax. Alternatively, to facilitate the process of adding new vaccines to the Program, Congress could consider subjecting to the tax any vaccine recommended for routine administration by the CDC, although this would have the effect of removing the current necessity of congressional approval prior to the addition of a new vaccine to VICP.[125] Congress could also decide to change the process outlined above for adding new vaccines to VICP, to create a new program for compensation for COVID-19 vaccine injuries and deaths,[126] or to create a new program applicable only to pandemic vaccines.

Should Congress add COVID-19 to the excise tax and COVID-19 vaccines become covered by VICP, processing COVID-19 vaccine claims under VICP may present other issues, absent further congressional action. For example, the NCVIA caps the number of special masters who may adjudicate petitions at eight.[127] Petitioners being able to file VICP petitions for injuries related to

[121] *See, e.g.*, Maryanne Demasi, *COVID-19: Is the US Compensation Scheme for Vaccine Injuries Fit for Purpose?*, 377 BMJ 1, 2 (Apr. 19, 2022) (citing stakeholders urging changes in law to compensate all COVID-19 vaccine injury claims through VICP).

[122] *See* Junying Zhao et al., *Reforming the Countermeasures Injury Compensation Program for COVID-19 and Beyond: An Economic Perspective*, 9 J.L. & BIOSCI. 1 (2022).

[123] *See* 26 U.S.C. §§ 4131, 9510(c).

[124] *Id.* § 4132(a).

[125] H.R. 3656, the Vaccine Access Improvement Act of 2021 (117th Cong.), introduced on June 1, 2021, proposed amendments to the Internal Revenue Code (26 U.S.C. § 4132(a)(1)) to automatically subject to the excise tax any vaccine the Secretary adds to the Vaccine Injury Table.

[126] H.R. 5687, the Backing the Independent Decisions of Employees Against Nefarious Mandates Act of 2021 (117th Cong.), introduced on October 21, 2021, proposed to authorize a private right of action in federal district court for employees who suffer a vaccine-related injury or death as a result of receiving a COVID-19 vaccine that is mandated by their employer.

[127] 42 U.S.C. § 300aa-12(c)(1).

COVID-19 vaccines would likely result in a substantial increase to the OSM caseload, which has already grown in recent years. For example, more than 1,000 petitions have been filed in the Program each year beginning in fiscal year (FY) 2015, and in FY2021, over 2,000 petitions were filed, a 72.6% increase over FY2020.[128] As of September 30, 2024, more than 3,400 vaccine petitions were pending.[129] Congress may amend the NCVIA to increase both the number of special masters who may adjudicate petitions as well as the OSM budget, so as to accommodate additional court staff.[130]

In light of the potential increased caseload if COVID-19 vaccines are added to VICP, Congress could also consider increasing the staffing and resources of both the Department of Justice, which litigates VICP petitions on behalf of the government, and HRSA, which provides medical experts and administrative support to review the petitions and medical records filed to determine the government's position on petitioner's entitlement to compensation.[131] According to HRSA, a backlog of cases awaiting review began in FY2017 but was significantly reduced at the end of FY2023 due to increased funds.[132] In its FY2025 budget justification, the agency stated that continued funds were needed to ensure that medical claims could be promptly reviewed, to prevent another backlog.[133]

[128] *Data & Statistics*, HRSA, https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/vicp-stats-02-01-25.pdf (last visited Apr. 10, 2025).

[129] *Statistical Case Report for the Fiscal Year October 1, 2023 – September 30, 2024*, COURT OF FEDERAL CLAIMS, https://www.uscfc.uscourts.gov/sites/cfc/files/statistical_report_2024.pdf (last visited Apr. 10, 2025).

[130] H.R. 3655, the Vaccine Injury Compensation Modernization Act of 2021 (117th Cong.), introduced on June 1, 2021, proposed to amend the Public Health Service Act to establish a minimum of 10 special masters. The bill also proposed to increase compensation for pain, suffering, and death, and would have lengthened the statute of limitations for filing vaccine petitions from 36 months to five years.

[131] *Fiscal Year 2024 Justification of Estimates for Appropriations Committees*, HEALTH RES. & SERVS. ADMIN., https://web.archive.org/web/20250309114854/https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2024.pdf, at 449 (last visited Apr. 10, 2025). *Advisory Commission on Childhood Vaccines*, U.S. Dept. Health & Human Servs., https://web.archive.org/web/20241120215301/https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/accv-recommendation-funding-support-vicp-09-12-2022-sge-signature-508.pdf, at 1 (last visited Apr. 10, 2025).

[132] *Fiscal Year 2024 Justification of Estimates for Appropriations Committees*, HEALTH RES. & SERVS. ADMIN., https://web.archive.org/web/20250309114854/https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2024.pdf, at 449 (last visited Apr. 10, 2025).

[133] *Id.*

Appendix. Comparison of Vaccine-Injury Programs: CICP vs. VICP

	Countermeasures Injury Compensation Program (CICP)	Vaccine Injury Compensation Program (VICP)
Scope of Coverage	"Covered countermeasures" under the Public Readiness and Emergency Preparedness Act (PREP Act), such as pandemic and epidemic products used to treat, mitigate, prevent, or cure COVID-19 (e.g., vaccines, personal protective equipment [PPE], tests, treatments)	"Covered Vaccines" are those recommended by the CDC for routine administration to children or pregnant women, subject to a federal excise tax, and added to the Vaccine Injury Table
Covered Injuries	Death, or serious physical injury that (1) warrants hospitalization or (2) leads 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	Nonreimbursed 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; attorneys' fees
Unavailable Benefits	Attorneys' fees, pain-and-suffering damages, punitive damages	Punitive or exemplary damages
Benefit Caps	$50,000/year for lost employment income with lifetime cap of $448,575 for fiscal year (FY) 2025 (except for permanent disability); standard death benefit of $448,575 for FY2025	$250,000 for death; $250,000 for pain and suffering and emotional distress
Filing Deadlines	Within one year of administration of covered countermeasure (or within one year of the issuance of an amended Countermeasure Injury Table)	For injury, within three years of the onset of the first symptom; for death, within two years of the death and four years of the onset of the first symptom

	Countermeasures Injury Compensation Program (CICP)	Vaccine Injury Compensation Program (VICP)
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 based on "compelling, reliable, [and] valid" medical and scientific evidence	Must show (1) the injured person received a vaccine on the Vaccine Injury Table; (2) the injured person 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) the injured person suffered the effects for more than six months or required inpatient hospitalization and surgery or died; and (5) the injured person has not previously collected an award for the injury or death
Initial Decisionmaker	CICP (as delegate of the Secretary of Health and Human Services [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	Parties may seek review of special master eligibility decision by U.S. Court of Federal Claims within 30 days of decision; parties 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, in which case the petitioner could file a tort claim against the manufacturer with certain limitations
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 (2010–2025): 573 claims, 30 compensated (5%) COVID-19 countermeasure claims (as of Apr. 2025): 13,764 claims, of which 10,651 (77.4%) allege injuries from COVID-19 vaccines; of the 4,111 claims where HRSA has reached a decision (29.9% of pending claims), 67 were found eligible for compensation (1.6%)	28,292 petitions as of 2/1/2025, of which 24,602 have been adjudicated: 12,931 were determined ineligible and 11,659 compensated (47%)
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: CRS analysis of 42 U.S.C. §§ 300aa-10–300aa-34; 42 U.S.C. § 247d-6d to -6e; 42 C.F.R. pt. 110; HRSA data.

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