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# Compensation for COVID-19 Vaccine Injuries

Updated March 31, 2023

**Congressional Research Service**

<https://crsreports.congress.gov>

R46982



## Compensation for COVID-19 Vaccine Injuries

More than 260 million Americans, and billions of people worldwide, have received one or more doses of a vaccine to protect against Coronavirus Disease 2019 (COVID-19). 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 are injured by COVID-19 vaccines 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 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 -approved 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. Due to COVID-19, the number of CICP claims has increased dramatically. As of February 1, 2023, CICP has received 11,252 claims alleging injury or death relating to COVID-19 countermeasures. Of those, 8,067 claims (71.7%) relate to COVID-19 vaccines. HRSA has not yet compensated any CICP claims relating to COVID-19 countermeasures.

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. To be included in the VICP, (1) the vaccine must be recommended by the CDC for routine administration to children or pregnant women; (2) the vaccine must be made subject by 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. Should all of these 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 show either 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.

R46982

March 31, 2023

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## Contents

The Countermeasures Injury Compensation Program (CICP) .....	3
Covered Vaccines and Injuries .....	4
Procedure for Obtaining Compensation .....	4
Available Compensation .....	5
Status of Pending CICP Claims for COVID-19 Countermeasures .....	6
The National Vaccine Injury Compensation Program (VICP) .....	7
Covered Vaccines and Injuries .....	8
Procedure for Obtaining Compensation .....	8
Available Compensation .....	11
Possible Transition of COVID-19 Vaccines from Coverage Under CICP to VICP .....	11
Considerations for Congress.....	13

## Appendixes

Appendix. Comparison of Vaccine-Injury Programs: CICP vs. VICP .....	16
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## Contacts

Author Information.....	17
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More than 260 million Americans have received one or more doses of a Coronavirus Disease 2019 (COVID-19) vaccine,<sup>1</sup> along with billions of people worldwide.<sup>2</sup> The Food and Drug Administration’s (FDA’s) emergency use authorizations for the Pfizer-BioNTech, Moderna, Johnson & Johnson, and Novavax COVID-19 vaccines were based on months-long clinical trials (including safety monitoring) of each vaccine, involving tens of thousands of participants.<sup>3</sup> These trials did not identify any safety concerns that would preclude emergency use authorization.<sup>4</sup> Subsequently, the Pfizer-BioNTech COVID-19 vaccine (later known as Comirnaty) received full FDA approval as a two-dose primary series for individuals 12 years of age and older,<sup>5</sup> and the Moderna COVID-19 vaccine (later known as Spikevax) received full FDA approval as two-dose primary series for individuals 18 years of age and older.<sup>6</sup>

Following authorization, the COVID-19 vaccines have been subject to safety monitoring requirements by 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 health events.<sup>7</sup> 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.<sup>8</sup> As with most vaccines, however, a small percentage of inoculated individuals experience serious adverse reactions to a COVID-19 vaccine.<sup>9</sup> For example, approximately five people per million receiving mRNA COVID-19 vaccines experience anaphylaxis, a severe allergic reaction, following vaccination.<sup>10</sup> (In part 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

<sup>1</sup> *COVID-19 Vaccinations in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (CDC), [https://covid.cdc.gov/covid-data-tracker/#vaccinations\\_vacc-total-admin-rate-total](https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total) (last visited Jan. 24, 2023).

<sup>2</sup> *More Than 12.7 Billion Shots Given: Covid-19 Tracker*, BLOOMBERG, <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/> (last updated Oct. 5, 2022).

<sup>3</sup> Letter from FDA to Pfizer Inc., at 1-2 (May 10, 2021), <https://www.fda.gov/media/144412/download> [hereinafter Pfizer EUA]; Letter from FDA to ModernaTX, Inc., at 1-2 (Aug. 12, 2021), <https://www.fda.gov/media/144636/download> [hereinafter Moderna EUA]; Letter from FDA to Janssen Biotech, Inc., at 1-2 (June 10, 2021), <https://www.fda.gov/media/146303/download> [hereinafter J&J EUA]; *Novavax COVID-19 Vaccine, Adjuvanted*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted> (last visited Jan. 24, 2023).

<sup>4</sup> Pfizer EUA, *supra* note 3, at 2; Moderna EUA, *supra* note 3, at 2; J&J EUA, *supra* note 3, at 2.

<sup>5</sup> See *Pfizer-BioNTech COVID-19 Vaccines*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines> (last visited Jan. 24, 2023); see generally CRS Report R46913, *FDA Approval of the Pfizer-BioNTech COVID-19 Vaccine: Frequently Asked Questions*, by Kevin J. Hickey, Erin H. Ward, and Agata Bodie.

<sup>6</sup> See *Moderna COVID-19 Vaccines*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines> (last visited Jan. 24, 2023).

<sup>7</sup> *Ensuring COVID-19 Vaccine Safety in the US*, CDC, <https://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.

<sup>8</sup> *Possible Side Effects After Getting a COVID-19 Vaccine*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html> (last updated Sept. 14, 2022).

<sup>9</sup> *Selected Adverse Events Reported After COVID-19 Vaccination*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html> (last updated Jan. 23, 2023).

<sup>10</sup> *Id.* (“Anaphylaxis after COVID-19 vaccination is rare and has occurred 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 administered).

treatment of anaphylaxis.<sup>11</sup>) 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.<sup>12</sup> For example, because of the rare risk of thrombosis with thrombocytopenia syndrome and GBS associated with Johnson & Johnson COVID-19 vaccine, CDC recommends use of mRNA COVID-19 vaccines in preference to the Johnson & Johnson vaccines for most patients.<sup>13</sup>

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).<sup>14</sup> 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).<sup>15</sup>

Under the Secretary of Health and Human Services’ (HHS’s) PREP Act Declaration for COVID-19 (and its amendments), COVID-19 vaccines are considered covered countermeasures within the PREP Act’s scope.<sup>16</sup> As a result, CICP—and not VICP—currently applies to injuries resulting from COVID-19 vaccinations while the public health emergency persists and the Declaration

<sup>11</sup> *Interim Considerations: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination*, CDC, <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html> (last updated Sept. 2, 2022).

<sup>12</sup> See *Selected Adverse Events Reported After COVID-19 Vaccination*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html> (last updated Jan. 23, 2023); *Myocarditis and Pericarditis After mRNA COVID-19 Vaccination*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html> (last updated Sept. 27, 2022); 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).

<sup>13</sup> See Sara E. Oliver et al., *Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices — United States, December 2021*, 71 *MMWR* 90, 94 (Jan. 21, 2022), <https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a4.htm>.

<sup>14</sup> *National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN. (HRSA), <https://www.hrsa.gov/vaccine-compensation/index.html> (last updated Jan. 2023); *Covered Vaccines*, HRSA, <https://www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html> (last updated Jan. 2023) (“The National Vaccine Injury Compensation Program (VICP) covers most vaccines routinely given in the U.S.”).

<sup>15</sup> See *Countermeasures Injury Compensation Program (CICP)*, HRSA, <https://www.hrsa.gov/cicp/> (last updated Jan. 2023); Public Readiness and Emergency Preparedness Act, P.L. 109-148, div. C, 119 Stat. 2818 (2005).

<sup>16</sup> Fourth Amendment to the Declaration under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79,190, 79,196 (Dec. 9, 2020) (“Covered countermeasures [include] any vaccine [used to] prevent, treat, or cure COVID-19.”); *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://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx> (last visited Jan. 25, 2023) (links to the COVID-19 PREP Act Declaration and its ten amendments).

remains in force.<sup>17</sup> Compensation through CICIP is generally somewhat more limited than through VICP.<sup>18</sup>

This report reviews and compares the compensation regimes available for vaccine-related injuries under CICIP 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 (CICIP)

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.<sup>19</sup> 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).<sup>20</sup> Pursuant to the PREP Act Declaration and its subsequent amendments,<sup>21</sup> 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.<sup>22</sup>

In addition to providing immunity from liability, the PREP Act established CICIP, a compensation program for individuals seriously injured or killed as a direct result of the administration or use of a covered countermeasure.<sup>23</sup> CICIP is a regulatory process administered by the Health Resources and Services Administration (HRSA).<sup>24</sup> HRSA regulations govern CICIP's procedures and eligibility determinations.<sup>25</sup>

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<sup>17</sup> *Frequently Asked Questions*, HRSA, <https://www.hrsa.gov/cicp/faq> (last visited Jan. 25, 2023) (“COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICIP), not the National Vaccine Injury Compensation Program (VICP).”).

<sup>18</sup> *See Comparison of Countermeasures Injury Compensation Program (CICIP) to the National Vaccine Injury Compensation Program (VICP)*, HRSA, <https://www.hrsa.gov/cicp/cicp-vicp> (last updated Apr. 2021); *see also infra* “Appendix. Comparison of Vaccine-Injury Programs: CICIP vs. VICP.”

<sup>19</sup> 42 U.S.C. § 247-6d(a)–(b).

<sup>20</sup> Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020).

<sup>21</sup> *See Public Readiness and Emergency Preparedness Act*, HHS ASPR, <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx> (last visited Jan. 25, 2023) (linking to the COVID-19 PREP Act Declaration amendments).

<sup>22</sup> *See* 42 U.S.C. § 247d-6d(a); *see generally* *PREP Act Q&As*, HHS ASPR, <https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>. 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* and CRS Legal Sidebar LSB10730, *The PREP Act and COVID-19, Part 2: The PREP Act Declaration for COVID-19 Countermeasures*.

<sup>23</sup> 42 U.S.C. § 247d-6e; *Countermeasures Injury Compensation Program (CICIP)*, HRSA, <https://www.hrsa.gov/cicp/> (last updated Jan. 2023).

<sup>24</sup> *See CICIP Frequently Asked Questions*, HRSA, <https://www.hrsa.gov/cicp/faq/index.html> (last visited Jan. 25, 2023).

<sup>25</sup> *See* 42 C.F.R. pt. 110.

## Covered Vaccines and Injuries

Under the PREP Act and the amended PREP Act 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.”<sup>26</sup> For example, personal protective equipment (PPE) (e.g., respirators), ventilators, therapeutic drugs (e.g., Paxlovid), and monoclonal antibody treatments approved or authorized by FDA to treat or prevent COVID-19 are covered countermeasures under the PREP Act.<sup>27</sup> Notably, FDA-authorized or -approved COVID-19 vaccines—such as those produced by Pfizer, Moderna, Johnson & Johnson, and Novavax—are covered countermeasures under the PREP Act Declaration.

Under the PREP Act, CICIP remedies “shall be exclusive of any other civil action or proceeding” for injuries directly caused by administering covered countermeasures, with limited exceptions.<sup>28</sup> Thus, while the current PREP Act Declaration and public health emergency remain in effect, CICIP is the exclusive remedy for claims within the PREP Act’s scope, including injuries resulting from COVID-19 vaccinations.<sup>29</sup> As discussed below in “Possible Transition of COVID-19 Vaccines from Coverage Under CICIP to VICP,” COVID-19-vaccine-related injuries may eventually be compensable through the VICP after the PREP Act Declaration no longer applies, contingent on certain statutory and regulatory changes.

CICIP compensation is limited to eligible individuals, such as persons injured by countermeasures or their survivors.<sup>30</sup> CICIP 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.<sup>31</sup> 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 CICIP compensation.<sup>32</sup>

## Procedure for Obtaining Compensation

To apply for CICIP compensation, a claimant generally must file a request for benefits within one year of the date the countermeasure was administered.<sup>33</sup> (If the Secretary publishes a new Countermeasure Injury Table, a newly eligible claimant may file within one year after the new

<sup>26</sup> Fourth Amendment to the Declaration under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79,190, 79,196 (Dec. 9, 2020); 42 U.S.C. § 2476d-6d(i)(7).

<sup>27</sup> *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 Jan. 20, 2023) (listing FDA emergency use authorizations for vaccines, drugs, biologics, and medical devices for use against COVID-19).

<sup>28</sup> 42 U.S.C. § 247d-6e(d)(4).

<sup>29</sup> *See id.*; *see also CICIP Frequently Asked Questions*, HRSA, <https://www.hrsa.gov/cicp/faq/index.html> (last visited Jan. 25, 2023) (“COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICIP), not the National Vaccine Injury Compensation Program (VICP).”). The “sole exception” is a claim for willful misconduct. 42 U.S.C. §§ 247d-6d(d)(1), 247d-6e(d)(4).

<sup>30</sup> *See* 42 C.F.R. § 110.10.

<sup>31</sup> *See id.* § 110.3(z); 42 U.S.C. § 247d-6e(e)(3).

<sup>32</sup> *Possible Side Effects After Getting a COVID-19 Vaccine*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html> (last updated Sept. 14, 2022) (describing temporary arm pain, tiredness, muscle pain, fever, and other “common side effects” of COVID-19 vaccines).

<sup>33</sup> 42 C.F.R. § 110.42(a).

Table is established.<sup>34</sup>) In addition to the request form, claimants may need to submit medical records and other evidence to establish eligibility.<sup>35</sup> If determined to be eligible, claimants may submit additional documentation to demonstrate the compensation amount.<sup>36</sup> Eligibility and compensation determinations are made by HRSA (exercising power delegated by the Secretary).<sup>37</sup> Claimants may seek reconsideration of an adverse eligibility decision by HRSA, but the ultimate decisionmaking authority lies with the Secretary.<sup>38</sup> The PREP Act precludes judicial review of the Secretary’s eligibility and compensation decisions.<sup>39</sup>

CICP claimants can prove eligibility for compensation in one of two ways.<sup>40</sup> 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.<sup>41</sup> (The Table established for the H1N1 pandemic influenza vaccine is one example;<sup>42</sup> no such table has yet been promulgated for any COVID-19 countermeasure, including 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.<sup>43</sup> 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.<sup>44</sup>

## 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.<sup>45</sup> Attorneys’ fees and pain-and-suffering damages are not available under CICP.<sup>46</sup> CICP awards are also subject to various annual and

<sup>34</sup> *Id.* § 110.42(f).

<sup>35</sup> *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 Dec. 2022).

<sup>36</sup> *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 Dec. 2022).

<sup>37</sup> *See* 42 C.F.R. § 110.72–110.74.

<sup>38</sup> *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.”).

<sup>39</sup> *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.”).

<sup>40</sup> *See* 42 C.F.R. § 110.20(b)–(c).

<sup>41</sup> 42 U.S.C. § 247d-6e(5)(A).

<sup>42</sup> 42 C.F.R. § 110.100.

<sup>43</sup> *See id.* § 110.20(b).

<sup>44</sup> *See id.* § 110.20(c).

<sup>45</sup> *Id.* § 110.2(a).

<sup>46</sup> *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 Apr. 2021) (“Attorneys’ fees and costs are not paid by [CICP].”); Nicholas M. Pace, Lloyd Dixon & Bethany Saunders-Medina, *The*



lifetime limits. For example, annual lost employment income awards are capped at \$50,000 per year;<sup>47</sup> the standard maximum death benefit is the same as that under the Public Safety Officers' Benefits program (currently \$422,035).<sup>48</sup>

Given the limited number and scope of past PREP Act declarations, CICIP has been used relatively infrequently since the PREP Act's 2005 enactment prior to the COVID-19 pandemic.<sup>49</sup> The majority of the non-COVID-19 CICIP claims have been related to alleged injuries from the H1N1 pandemic influenza vaccine.<sup>50</sup> According to HRSA, for FY2010 through FY2023, CICIP received 513 claims unrelated to COVID-19.<sup>51</sup> Of these, 40 claims (7.8%) were determined to be eligible for compensation and 30 claims (5.8%) have been paid out by CICIP, amounting to over \$6 million in awards.<sup>52</sup> (Ten of the claims determined to be eligible for compensation had no eligible reported medical expenses or lost employment income.) All but one of the 30 claims compensated by CICIP to date relate to injuries from the H1N1 influenza vaccine.<sup>53</sup>

## Status of Pending CICIP Claims for COVID-19 Countermeasures

Due to the COVID-19 pandemic, the number of CICIP claims HRSA has received has increased dramatically. As of February 1, 2023, CICIP has received 11,252 claims alleging injury or death relating to COVID-19 countermeasures, of which 8,067 claims (71.7%) relate to COVID-19 vaccines.<sup>54</sup> HRSA has not yet compensated any CICIP claims relating to COVID-19 countermeasures. Of the 630 COVID-19 claims in which HRSA has reached a decision on eligibility, it has denied 609 claims (96.7%) on various grounds, while determining that 21 claims (3.3%) are eligible for compensation, pending a review of the eligible expenses.<sup>55</sup> The remaining COVID-19 countermeasure claims (approximately 94.4%) are in review or pending review.<sup>56</sup>

Several COVID-19 emergency appropriations allow the Secretary to transfer funds to the Covered Countermeasure Process Fund.<sup>57</sup> HRSA can use such funds, in addition to prior-year fund balances, for CICIP compensation awards.

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*Compensation System for Potential Side Effects Is an Important Part of a COVID-19 Vaccine Campaign*, THE RAND BLOG (Dec. 18, 2020), <https://www.rand.org/blog/2020/12/the-compensation-system-for-potential-side-effects.html> ("The CICIP does not provide any compensation for pain, suffering, emotional distress, or similar damages . . .").

<sup>47</sup> 42 C.F.R. § 110.81(c)(2).

<sup>48</sup> *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 Mar. 23, 2023).

<sup>49</sup> See Pace et al., *supra* note 46 ("The NVICP has handled more than 20,000 vaccine injury claims since its inception, while the CICIP, 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].").

<sup>50</sup> See Bernard Condon & Matt Sedensky, *How U.S. Government Will Handle COVID-19 Vaccine Injury Claims Is Largely a Secret*, INS. J., <https://www.insurancejournal.com/news/national/2020/12/29/595414.htm> (Dec. 29, 2020) ("[Prior to COVID-19], the vast majority of the claims under [CICIP] have stemmed from the H1N1 swine flu vaccine a decade ago.").

<sup>51</sup> See *Countermeasures Injury Compensation Program (CICIP) Data*, HRSA, <https://www.hrsa.gov/cicp/cicp-data> (last updated Mar. 1, 2023) (listing 11,765 total claims, of which 11,252 relate to COVID-19 countermeasures).

<sup>52</sup> See *id.* at tbls. 4 & 5.

<sup>53</sup> See *id.* at tbl. 4. The other claim was for an injury associated with the smallpox vaccine.

<sup>54</sup> See *id.* at tbl. 1.

<sup>55</sup> See *id.* (listing CICIP data for COVID-19 claims as of Mar. 1, 2023).

<sup>56</sup> See *id.*

<sup>57</sup> See, e.g., Coronavirus Aid, Relief, and Economic Security (CARES) Act, P.L. 116-136, div. B, tit. VIII, 134 Stat.

## The National Vaccine Injury Compensation Program (VICP)

After the Secretary terminates the PREP Act Declaration for the COVID-19 pandemic, any injuries or death related to COVID-19 vaccine administration would be addressed in court under tort law, unless the COVID-19 vaccines are added to VICP.<sup>58</sup> VICP provides compensation for injuries and deaths associated with vaccines that are listed on the Vaccine Injury Table and subject to an excise tax.<sup>59</sup>

Congress created the 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.<sup>60</sup> 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., negligent, failed to warn adequately) or, under products liability doctrines, that the vaccine was defective.<sup>61</sup> 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.<sup>62</sup> Regardless of the outcome, both sides generally would be responsible for their own litigation costs.<sup>63</sup>

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.<sup>64</sup> The Program shields 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.<sup>65</sup> 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, 2023, more than 25,860 petitions for compensation have been filed, of which 21,907 have been adjudicated, with 9,565 determined to merit compensation.<sup>66</sup> The Program has paid out more than

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281, 560–61 (Mar. 27, 2020).

<sup>58</sup> 42 U.S.C. §§ 300aa-10–300aa-44; 26 U.S.C. §§ 4131, 4132, 9510. *See also National Vaccine Injury Compensation Program*, HRSA, <https://www.hrsa.gov/vaccine-compensation/index.html> (last updated Nov. 2021).

<sup>59</sup> 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>.

<sup>60</sup> P.L. 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).

<sup>61</sup> 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.

<sup>62</sup> RESTATEMENT (SECOND) OF TORTS §§ 901–917.

<sup>63</sup> *Alyeska Pipeline Serv. Co. v. Wilderness Soc’y*, 421 U.S. 240, 247 (1975).

<sup>64</sup> 42 U.S.C. §§ 300aa-13–300aa-15.

<sup>65</sup> *Id.* §§ 300aa-13–300aa-15, 300aa-21–300aa-22; 26 U.S.C. §§ 4131, 4132, 9510.

<sup>66</sup> *Data & Statistics*, HRSA, <https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-02-01-23.pdf> (last updated Feb. 1, 2023).

\$4.9 billion in compensation since its inception, and the Trust fund has a current balance of more than \$4.3 billion.<sup>67</sup>

## 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, (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.<sup>68</sup> The types of vaccines subject to the excise tax are specified in statute and therefore can be amended only by an act of Congress.<sup>69</sup>

To be entitled to VICP compensation, an injured party must first show receipt of a “covered vaccine.”<sup>70</sup> Not every FDA-approved vaccine is covered by VICP. The NCVIA included an initial Vaccine Injury Table listing vaccines covered by the Program.<sup>71</sup> 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.<sup>72</sup>

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 timeframe specified in the Table, or (2) the vaccine more likely than not caused the injury.<sup>73</sup> 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.<sup>74</sup> 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.<sup>75</sup>

## 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).<sup>76</sup> The petition must generally contain an affidavit and supporting documentation, including relevant medical records, showing the person:

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<sup>67</sup> *Id.* See also *Vaccine Injury Trust Fund*, Bureau of the Fiscal Service, <https://treasurydirect.gov/ftp/dfi/tfmb/dfivi0223.pdf> (Feb. 28, 2023).

<sup>68</sup> 42 U.S.C. § 300aa-14; 26 U.S.C. §§ 4132, 9510.

<sup>69</sup> 26 U.S.C. § 4132.

<sup>70</sup> 42 U.S.C. §§ 300aa-11(c), 300aa-33(5).

<sup>71</sup> *Id.* § 300aa-14(a).

<sup>72</sup> *Id.* § 300aa-14(e).

<sup>73</sup> *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).

<sup>74</sup> 42 U.S.C. §§ 300a-11, 300aa-14.

<sup>75</sup> *Id.* § 300a-11(c)(1)(C)(ii).

<sup>76</sup> *Id.* § 300aa-11.

- 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;
- 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.<sup>77</sup>

Petitions for vaccine-related *injuries* must generally be filed within three years of the first symptom of the injury or significant aggravation.<sup>78</sup> 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.<sup>79</sup> 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.<sup>80</sup>

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.<sup>81</sup> The court’s guidelines for attorneys practicing in the 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.<sup>82</sup> 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.<sup>83</sup> 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 wished to discuss settlement.<sup>84</sup>

Approximately 60% of compensated petitions are the result of a settlement agreement.<sup>85</sup> If the parties cannot resolve the case via settlement, the special master may hold an evidentiary hearing

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<sup>77</sup> *Id.* § 300aa-11(c).

<sup>78</sup> *Id.* § 300aa-16(a).

<sup>79</sup> *Id.*

<sup>80</sup> *Id.* § 300aa-16(b).

<sup>81</sup> *Id.* §§ 300aa-12(c)(1), 300aa-12(d); *see also Vaccine Claims/Office of Special Masters*, U.S. COURT OF FEDERAL CLAIMS, <https://www.usfc.uscourts.gov/vaccine-programoffice-special-masters> (last visited Nov. 24, 2021).

<sup>82</sup> *Guidelines for Practice Under the National Vaccine Injury Compensation Program*, U.S. COURT OF FEDERAL CLAIMS, <https://www.usfc.uscourts.gov/sites/default/files/Guidelines-4.24.2020.pdf> (revised April 24, 2020).

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Data & Statistics*, HRSA, <https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-02-01-23.pdf> (last visited Feb. 14, 2023). 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. *Data & Statistics*, HRSA, <https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-02-01-23.pdf> (last visited Feb. 14, 2023).

on the petition or issue a ruling based on the administrative record.<sup>86</sup> 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.<sup>87</sup> 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 to allow for expeditious resolution.<sup>88</sup> 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.<sup>89</sup>

The petitioner has 30 days after the special master issues an entitlement decision to appeal the decision to the Claims Court.<sup>90</sup> The court then has 120 days to uphold the decision, issue its own decision, or remand to the special master for further proceedings.<sup>91</sup> 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).<sup>92</sup> If the parties choose not to appeal the decision, the judgment becomes final.<sup>93</sup>

After a final judgment, the petitioner has 90 days to accept or reject the judgment.<sup>94</sup> 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 the VICP but may file a civil action for damages against the manufacturer.<sup>95</sup> 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.<sup>96</sup> 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.<sup>97</sup> (Petitioners may opt not to withdraw their petitions if they do not want to risk proceeding in civil court.<sup>98</sup>)

In addition to limiting the availability of civil actions against manufacturers to parties who have gone through the VICP's process, the NCVIA imposes certain limitations on vaccine

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<sup>86</sup> *Guidelines for Practice Under the National Vaccine Injury Compensation Program*, U.S. COURT OF FEDERAL CLAIMS, <https://www.usfc.uscourts.gov/sites/default/files/Guidelines-4.24.2020.pdf> (revised Apr. 24, 2020).

<sup>87</sup> 42 U.S.C. § 300aa-12.

<sup>88</sup> *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.usfc.uscourts.gov/sites/default/files/20.08.03%20FINAL%20Vaccine%20Rules.pdf> (last updated Aug. 3, 2020).

<sup>89</sup> 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 infra* note 87, at 7.

<sup>90</sup> 42 U.S.C. § 300aa-12(e)(1).

<sup>91</sup> *Id.* § 300aa-12(e)(2).

<sup>92</sup> *Id.* § 300aa-12(e)–(f).

<sup>93</sup> *Id.* § 300aa-12(e)(3).

<sup>94</sup> *Id.* § 300aa-21(a)(1).

<sup>95</sup> *Id.* § 300aa-21(a).

<sup>96</sup> *Id.* § 300aa-11(a)(2)(A).

<sup>97</sup> *Id.* § 300aa-21(b).

<sup>98</sup> *Id.*

manufacturers' liability in civil proceedings.<sup>99</sup> 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.<sup>100</sup> Any action that proceeds against a vaccine manufacturer is tried in three stages: (1) liability, (2) general damages, and (3) punitive damages.<sup>101</sup> 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.

## 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.<sup>102</sup>

The NCVIA authorized appropriations to compensate individuals injured by vaccines administered before October 1, 1988.<sup>103</sup> Compensation for injuries related to vaccines administered after October 1, 1988, is paid out of the Vaccine Injury Compensation Trust Fund (Trust Fund).<sup>104</sup> Vaccine manufacturers pay into the Trust Fund through excise taxes imposed on covered vaccines.<sup>105</sup> 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.<sup>106</sup> Consequently, only vaccines subject to the excise tax are included in VICP.

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

While they remain covered by the PREP Act Declaration, CICIP—not VICP—is the exclusive remedy for injuries associated with the administration of COVID-19 vaccines.<sup>107</sup> As explained in

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<sup>99</sup> *Id.* § 300aa-22.

<sup>100</sup> *Id.* § 300aa-22(b).

<sup>101</sup> *Id.* § 300aa-23.

<sup>102</sup> *Id.* § 300aa-15(a)–(e).

<sup>103</sup> *Id.* § 300aa-15(j).

<sup>104</sup> *Id.* § 300aa-15(i)(2); 26 U.S.C. § 9510.

<sup>105</sup> 26 U.S.C. §§ 4131–4132.

<sup>106</sup> *Id.* § 9510(c).

<sup>107</sup> See 42 U.S.C. § 247d-6e(d)(4); *CICP Frequently Asked Questions*, HRSA, <https://www.hrsa.gov/cicp/faq/index.html> (last visited Jan. 25, 2023).

detail in a separate CRS product,<sup>108</sup> 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.<sup>109</sup> As a result, when coverage under the PREP Act Declaration expires depends on the particular context.

For COVID-19 vaccines purchased or distributed by the federal government—which at present includes all COVID-19 vaccines administered in the United States<sup>110</sup>—PREP Act coverage currently extends through October 1, 2024.<sup>111</sup> CICIP would therefore continue to apply to COVID-19 vaccine injuries during that period for federally-purchased vaccines.<sup>112</sup> However, if COVID-19 vaccines eventually transition to distribution through the private market, PREP Act coverage may end sooner than October 1, 2024, for those vaccines. Under the current PREP Act Declaration, PREP Act coverage for COVID-19 countermeasures *not* related to a federal contract generally extends through (a) the final day an applicable Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.<sup>113</sup> The Biden Administration has stated its intention to terminate the federal public health emergency declared under Section 319 of the Public Health Service Act on May 11, 2023.<sup>114</sup> In light of that decision—unless a state or local emergency declaration applies or HHS amends the Declaration—PREP Act coverage for some COVID-19 countermeasures may end prior to October 1, 2024.<sup>115</sup>

When COVID-19 vaccines are no longer covered by the PREP Act, CICIP 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.

After the expiration of PREP Act coverage, Congress could decide to add COVID-19 vaccines to the VICP. To accomplish this under existing law, (1) the CDC must recommend the vaccine for routine administration to children and/or pregnant women; (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.<sup>116</sup> Should all three of these changes occur, the COVID-19 vaccine would be added to the VICP with coverage effective as of the date of the enacted tax.<sup>117</sup>

<sup>108</sup> 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.

<sup>109</sup> See *id.*; Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 87 Fed. Reg. 982, 988 (Jan. 7, 2022) [hereinafter Tenth PREP Act Declaration Amendment].

<sup>110</sup> See *CDC COVID-19 Vaccination Program Provider Requirements and Support*, CDC, <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html> (last updated Oct. 26, 2022).

<sup>111</sup> See Hickey, *supra* note 108; Tenth PREP Act Declaration Amendment, *supra* note 108, at 988. If COVID-19 vaccines are eventually purchased and distributed through private channels, PREP coverage could potentially terminate earlier, depending on whether the public health emergency declarations for COVID-19 remain in effect.

<sup>112</sup> See HHS, *Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap*, <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html> (Feb. 9, 2023).

<sup>113</sup> See *id.*; Hickey, *supra* note 108.

<sup>114</sup> See Executive Office of the President, Statement of Administration Policy (Jan. 30, 2023), <https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf>.

<sup>115</sup> See *HHS Fact Sheet*, *supra* note 112.

<sup>116</sup> 42 U.S.C. § 300aa-14(e)(2); 42 C.F.R. § 100.3(a)(XVII).

<sup>117</sup> 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

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 the regular childhood and adult immunization schedules.<sup>118</sup> Vaccines added to the regular CDC immunization schedules are considered recommended for routine use for the purposes of VICP.<sup>119</sup> The CDC formally adopted the recommendation on February 10, 2023, when the recommendation was published in the *Morbidity and Mortality Weekly Report*.<sup>120</sup> 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.<sup>121</sup> 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 the VICP as of the date the excise tax applies to the vaccine.<sup>122</sup> 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.<sup>123</sup>

## Considerations for Congress

The inclusion of COVID-19 vaccines in CICIP 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 claims under the CICIP many times larger than it has received during past public health emergencies. To date, HRSA has reached decisions on less than 5% of the COVID-19-related claims it has

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within two years. 42 U.S.C. § 300aa-14(c) describes the process the Secretary must ordinarily take to revise the Table. However, under 42 C.F.R. § 100.3(a)(XVII), 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.

<sup>118</sup> Press Release, *ACIP Immunization Schedule Vote*, CDC, <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-6months-older.pdf> (Dec. 8, 2022).

<sup>119</sup> See, e.g. 62 FR 7685 (Feb. 20, 1997) (Final rule adding hepatitis B vaccine to the Table); 62 FR 52724 (Oct. 9, 1997) (the notice of compensation for hepatitis B); 63 FR 25777 (May 11, 1998) (The final rule adding a date certain for coverage for hepatitis B vaccine). See also 69 FR 69945 (Dec. 1, 2004), which is the 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.

<sup>120</sup> 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](https://www.cdc.gov/mmwr/volumes/72/wr/mm7206a1.htm?s_cid=mm7206a1_w#contribAff) (last accessed Mar. 8, 2023).

<sup>121</sup> 42 U.S.C. § 300aa-14(e)(2)–(3).

<sup>122</sup> See *id.*; 42 CFR § 100.3(a).

<sup>123</sup> See 42 U.S.C. § 300aa-14 note.



received.<sup>124</sup> Congress may wish to consider whether HRSA needs additional authorities or resources to process these CICIP claims expeditiously.

CICIP 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 opportunities for appeal and reconsideration in CICIP as judicial review is not available. CICIP claimants have lower rates of success on average as compared to VICP petitioners. Congress may wish to consider whether barriers to CICIP 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.<sup>125</sup>

CICIP has also been criticized for lacking transparency and accountability, and having high administrative costs relative to the amounts it awards in compensation.<sup>126</sup> To some degree, the high costs may be attributable to the relatively high standard of proof and lower success rates for CICIP claims. Regardless, Congress may consider whether CICIP 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 VICP and allow the traditional tort system to address any vaccine-related injuries after CICIP no longer applies.

Covering COVID-19 vaccines under VICP presents issues Congress may wish to consider as well. As discussed above, VICP awards are funded by an excise tax and the Program may only compensate injuries resulting from “taxable vaccines” subject to the excise tax.<sup>127</sup> “Taxable vaccines” are defined in the tax code to include vaccines against particular diseases, which does not include COVID-19.<sup>128</sup> Should Congress wish to include COVID-19 vaccines in VICP following the expiration of coverage under the PREP Act and CICIP, it would need to amend the statute 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.<sup>129</sup> Congress could also decide to change altogether the process outlined above for adding new vaccines to VICP, outline a new program for compensation for COVID-19 vaccine injuries and deaths,<sup>130</sup> or create a new program applicable only to pandemic vaccines.

<sup>124</sup> See *Countermeasures Injury Compensation Program (CICIP) Data*, HRSA, <https://www.hrsa.gov/cicp/cicp-data> (last updated Feb. 1, 2023).

<sup>125</sup> 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).

<sup>126</sup> 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).

<sup>127</sup> See 26 U.S.C. §§ 4131, 9510(c).

<sup>128</sup> *Id.* § 4132(a).

<sup>129</sup> H.R. 3656, the Vaccine Access Improvement Act of 2021 (117<sup>th</sup> 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.

<sup>130</sup> H.R. 5687, the Backing the Independent Decisions of Employees Against Nefarious Mandates Act of 2021, (117<sup>th</sup> 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.

Should Congress add COVID-19 to the excise tax and COVID-19 vaccines become covered by VICP, processing COVID-19 vaccine claims under the 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.<sup>131</sup> Petitioners being able to file VICP petitions for injuries related to COVID-19 vaccines would likely result in a substantial increase to the OSM caseload, which has already grown in recent years. For example, in Fiscal Year (FY) 2021, vaccine petition filings increased by 72.6% over FY2020, and there have been more than 1,000 petitions filed in the Program every year since FY2015.<sup>132</sup> As of September 30, 2022, there are currently more than 3,800 pending vaccine petitions.<sup>133</sup> Congress may wish to 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.<sup>134</sup>

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.<sup>135</sup> According to HRSA, a backlog of cases awaiting review began in FY2017, and it currently takes the agency approximately 12 months to conduct its initial review of each petition,<sup>136</sup> delaying the processing of petitions and the OSM's adjudications.

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<sup>131</sup> 42 U.S.C. § 300aa-12(c)(1).

<sup>132</sup> *Data & Statistics*, HRSA, <https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-02-01-23.pdf> (last visited Feb. 14, 2023).

<sup>133</sup> *Statistical Case Report for the Fiscal Year October 1, 2021 – September 30, 2022*, COURT OF FEDERAL CLAIMS, <https://www.usfc.uscourts.gov/sites/default/files/AOstats-2022.pdf> (last visited Feb. 14, 2023).

<sup>134</sup> H.R. 3655, the Vaccine Injury Compensation Modernization Act, (117<sup>th</sup> 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.

<sup>135</sup> *Fiscal Year 2024 Justification of Estimates for Appropriations Committees*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2024.pdf>, at 462 (last visited Mar. 29, 2023). *Advisory Commission on Childhood Vaccines*, U.S. Dept. Health & Human Servs., <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 Mar. 29, 2023).

<sup>136</sup> *Id.* at 445.

## Appendix. Comparison of Vaccine-Injury Programs: CICIP vs. VICP

	<b>Countermeasures Injury Compensation Program (CICIP)</b>	<b>Vaccine Injury Compensation Program (VICP)</b>
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 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 CICIP 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 for lost income (except for permanent disability); and standard death benefit of \$389,825.45 for FY2022	\$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 injuries, within three years of the onset of the first symptom; for deaths, within two years of the death and four years of the onset 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 injured 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

	<b>Countermeasures Injury Compensation Program (CICP)</b>	<b>Vaccine Injury Compensation Program (VICP)</b>
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	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 they 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	<p>Non-COVID-19 claims (2010–2023): 513 claims, of which 40 were determined eligible and 30 compensated (6%)</p> <p>COVID-19 countermeasure claims (as of March 1, 2023): 11,252 claims, of which 8,067 (72%) allege injuries from COVID-19 vaccines; of the 630 claims reviewed for CICP eligibility, 21 (3.3%) have been held eligible for compensation; most claims (94%) remain in or pending review</p>	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:** 42 U.S.C. §§ 300aa-10–300aa-34; 42 U.S.C. § 247d-6d to -6e; 42 C.F.R. pt. 110; HRSA; CRS.

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