

# Immunizing the Immunizers: How COVID-19 Vaccine Injury Claims and the CICP Will Increase Anti-Vaccine Sentiment in the United States and How HRSA Can Prevent It

KIMBERLY K. HENRICKSON\*

## ABSTRACT

In the United States, COVID-19 vaccine manufacturers and distributors are shielded from liability by the Public Readiness and Emergency Preparedness (PREP) Act, which dictates that claims of injury tied to the COVID-19 vaccines must go through the Countermeasures Injury Compensation Program (CICP). Little is known about the CICP, and it has a poor track record of compensating claimants. Vaccine injuries are extremely rare but occur in certain circumstances. In order to prevent an increase in anti-vaccine sentiment in the United States, the CICP should adopt certain aspects of the National Vaccine Injury Compensation Program (VICP).

## I. INTRODUCTION

The COVID-19 pandemic has heightened public awareness of vaccine development and distribution. Vaccines are a necessary public health measure to counteract the spread of disease; however, rising vaccine hesitancy (i.e., the fear of vaccines) was recently named one of the top threats to global health by the World Health Organization.<sup>1</sup> As with all vaccines, there will be rare instances in which an individual suffers injury after receiving a COVID-19 vaccine.<sup>2</sup> Misinformation about vaccine injuries spreads widely and quickly over the Internet.<sup>3</sup> As the pandemic has raged on, publicly reported willingness towards getting COVID-19 vaccines has fluctuated.<sup>4</sup> Yet, the majority of U.S. citizens must be vaccinated to achieve herd immunity within

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\* J.D. 2022, The George Washington University Law School; B.A. 2017, Washington University in St. Louis. Thank you to those who assisted me through the research and writing process for this Article, with special thanks to Renée Gentry, Peter Meyers, James Hughes, Matt Robinson, my peers at GW Law, and my family.

<sup>1</sup> See Andrew M. Guess, Brendan Nyhan, Zachary O’Keefe & Jason Reifler, *The Sources and Correlates of Exposure to Vaccine-Related (Mis)information Online*, 38 VACCINE 7799, 7799 (2020).

<sup>2</sup> See Peter H. Meyers, *The Trump Administration’s Flawed Decision on Coronavirus Vaccine Injury Compensation: Recommendations for Changes*, 7 J.L. & BIOSCIENCES 1, 2–3 (2020).

<sup>3</sup> See Guess et al., *supra* note 1, at 7799.

<sup>4</sup> See Sarah Kreps, Sandip Prasad, John S. Brownstein, Yulin Hswen, Brian T. Garibaldi, Baobao Zhang & Douglas Kriner, *Factors Associated with US Adults’ Likelihood of Accepting COVID-19 Vaccination*, 3 JAMA NETWORK OPEN 1, 2 (2020).

the country.<sup>5</sup> One variable impacting an individual's willingness to get vaccinated is the available opportunities for compensation in the event of injury. As the world becomes vaccinated against COVID-19, it is important to consider how tort liability shields, while enabling the creation and distribution of COVID-19 vaccines, may fail to adequately compensate those harmed by the COVID-19 vaccine.

Typically, claims of vaccine-related injuries are adjudicated through the National Vaccine Injury Compensation Program (VICP). The VICP began in the 1980s and has since paid billions of dollars to individuals with vaccine-related injuries.<sup>6</sup> However, injuries connected to the COVID-19 vaccine will be adjudicated through a different program. Due to the terms of the Public Readiness and Emergency Preparedness (PREP) Act, COVID-19 vaccine claims will be evaluated by the Countermeasures Injury Compensation Program (CICP) rather than the VICP. The CICP is only used in emergency situations and was used in the past for Ebola, Zika, and Pandemic Influenza countermeasures.<sup>7</sup> The CICP is far less transparent than the VICP and historically pays out fewer claims. Due to the way anti-vaccine information has spread on the Internet during recent years, the failures of the CICP to compensate claimants may lead to increased anti-vaccine sentiment in the United States.

This Article discusses past usages of the CICP, how it operates in practice, and its failure to compensate petitioners in comparison to the VICP. This Article also recommends improvements for the CICP. In Part II, this Article traces the lifecycle of a COVID-19 vaccine injury claim through the lens of a hypothetical Injured Claimant (I.C.), showing how an unsuccessful claim can engender increased anti-vaccine sentiment. Part III contrasts the CICP with the VICP, demonstrating that the VICP is more petitioner-friendly and has historically compensated more petitioners. Part IV outlines how the Health Resources and Services Administration (HRSA) and Congress can make the CICP more similar to the VICP to prevent additional fear and hesitancy towards the COVID-19 vaccine.

## II. THE LIFECYCLE OF A COVID-19 VACCINE CLAIM

### A. *Are Vaccine Injuries Real?*

*Injured Claimant (I.C.) receives a dose of an authorized COVID-19 vaccine. A few hours after receiving his shot, he feels pain near the injection site on his upper arm. Later, this pain morphs into a heavy feeling in his shoulder. The pain lasts for several months, causing*

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<sup>5</sup> See Debbie Kaminer, *Vaccines in the Time of Covid-19: How Government and Businesses Can Help Us Reach Herd Immunity*, 2020 WIS. L. REV. FORWARD 101, 102 (2020).

<sup>6</sup> The Program is funded by the Vaccine Injury Compensation Trust Fund, which collects a \$0.75 excise tax from the manufacturer for each dose administered of a vaccine recommended for routine administration to children by the Centers for Disease Control and Prevention. See *About the National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN. (last reviewed Dec. 2020), <https://www.hrsa.gov/vaccine-compensation/about/index.html> [<https://perma.cc/WF3R-R8EM>]; see Leah Durant, *Proposed Vaccine Injury Rule Raises COVID-19 Concerns*, LAW360 (Aug. 13, 2020, 5:44 PM), <https://www.law360.com/articles/1292170/proposed-vaccine-injury-rule-raises-covid-19-concerns> [<https://perma.cc/CVK6-VM5Y>].

<sup>7</sup> See *Countermeasures Injury Compensation Program (CICP)*, HEALTH RES. & SERVS. ADMIN. (last reviewed Nov. 2020), <https://www.hrsa.gov/cicp> [<https://perma.cc/PP4X-JLJW>].

*difficulties for I.C. while working construction, caring for his children, and golfing.*

Vaccines have tremendous public health benefits: the prevention and eradication of disease.<sup>8</sup> They are helpful and completely safe for most recipients.<sup>9</sup> Serious side effects from vaccines are extremely rare and pale in comparison to the risks posed by the diseases they protect against.<sup>10</sup> As the Centers for Disease Control and Prevention (CDC) has said, “the benefits of vaccines far outweigh the risks.”<sup>11</sup>

However, vaccines can and do cause serious adverse reactions for an extremely small percentage of people.<sup>12</sup> Exact figures are unknown due to the difficulty of determining causation in vaccine claims. Out of millions of vaccines administered per year in the United States,<sup>13</sup> about 30,000 adverse events related to vaccine administration are reported every year to the Vaccine Adverse Event Reporting System (VAERS).<sup>14</sup> Reported reactions include severe allergic reactions, autoimmune diseases, and neurological injuries.<sup>15</sup> However, this number reflects all adverse events claimants believed were related to vaccination, not the number of events *proven* related to vaccination. Of the number of adverse events reported, there is no guarantee *any* of the adverse events were caused by vaccination or would satisfy legal standards for causation under typical routes of recovery for vaccine claims.<sup>16</sup>

Vaccine injuries can be categorized into two main methods of causation. First, the components of a vaccine may cause an adverse physical reaction.<sup>17</sup> Second, human error in the administration of the vaccine, such as injecting the shot in the wrong part

<sup>8</sup> See *Vaccine Safety: Overview, History, and How It Works*, CTRS. FOR DISEASE CONTROL & PREVENTION (last reviewed Sept. 9, 2020), <https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html> [<https://perma.cc/7AMD-28QX>]; *Vaccines and Immunization: Myths and Misconceptions*, WORLD HEALTH ORG., <https://www.who.int/news-room/questions-and-answers/item/vaccines-and-immunization-myths-and-misconceptions> [<https://perma.cc/SQ43-SQEB>].

<sup>9</sup> See *Vaccine Safety: Overview, History, and How It Works*, *supra* note 8; *Vaccines and Immunization: Myths and Misconceptions*, *supra* note 8.

<sup>10</sup> See *Vaccines and Immunizations: Myths and Misconceptions*, *supra* note 8.

<sup>11</sup> *Vaccine Safety: Overview, History, and How It Works*, *supra* note 8.

<sup>12</sup> See Meyers, *supra* note 2, at 13; HEALTH RES. & SERVS. ADMIN., WHAT YOU NEED TO KNOW ABOUT THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP) (Apr. 2019), <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/resources/about-vaccine-injury-compensation-program-booklet.pdf> [<https://perma.cc/M6B2-9YTQ>] [hereinafter HRSA, WHAT YOU NEED TO KNOW].

<sup>13</sup> See Durant, *supra* note 6.

<sup>14</sup> The Vaccine Adverse Event Reporting System (VAERS) is an aggregating reporting system to which individuals send in reports of adverse reactions following vaccinations. It exists to detect potential safety risks in vaccines licensed for distribution in the United States. It is run by the Department of Health and Human Services. See *About VAERS*, DEP’T OF HEALTH & HUMAN SERVS., <https://vaers.hhs.gov/about.html> [<https://perma.cc/ZMC4-KQNH>].

<sup>15</sup> See HRSA, WHAT YOU NEED TO KNOW, *supra* note 12.

<sup>16</sup> Injury claims based on routine vaccine administration are typically adjudicated through the National Vaccine Compensation Program (VICP), explained in greater detail below. See OFF. OF SPECIAL MASTERS, U.S. CT. OF FED. CLAIMS, GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (revised Apr. 24, 2020).

<sup>17</sup> See *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1319, 1320 (2010).

of the arm or failing to safely store the vaccine, can lead to injury.<sup>18</sup> If an individual has certain pre-existing conditions or has suffered an adverse vaccine reaction in the past, that individual may be contraindicated from future vaccines, either generally or only of the type that caused the earlier injury.<sup>19</sup>

One common vaccine injury is Shoulder Injury Related to Vaccine Administration (SIRVA).<sup>20</sup> SIRVA is caused by incorrect technique in vaccine administration and an exuberant inflammatory response.<sup>21</sup> Thus, SIRVA may occur if a vaccine administrator lacks sufficient training, is rushed, or administers the vaccine in a cramped location. SIRVA can include intense shoulder pain and impact one's ability to work, sleep, or enjoy leisure activities.<sup>22</sup> Similar symptoms have been reported by individuals after receiving a COVID-19 vaccine. In a study of persons aged 18–55 who received the Pfizer vaccine, 84.7% reported at least one local injection site reaction during the seven days following vaccination, although only 1% reported severe pain.<sup>23</sup> Pain at the injection site was the most frequent and severe reaction reported.<sup>24</sup>

Because of the rarity of vaccine injuries, it is impossible to predict who will have an abnormal reaction to a vaccine.<sup>25</sup> For those who suffer injury related to any of the COVID-19 vaccines, their only recourse will be through the CICP.<sup>26</sup>

### B. *The PREP Act and the CICP*

*I.C. is not a particularly litigious person, but after months of shoulder pain and disruption to his everyday life, he considers suing. He starts with Internet research, Googling: “injury after COVID vaccine,” “shoulder pain after vaccine administration,” and similar searches. Articles from the CDC<sup>27</sup> and New England Journal of Medicine<sup>28</sup> are longwinded and*

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<sup>18</sup> See *Adverse Events Following Immunization (AEFI)*, WORLD HEALTH ORG., <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/health-professionals-info/aeft> [<https://perma.cc/88W4-QL89>].

<sup>19</sup> “Contraindicated” means the individual is recommended to abstain from further vaccinations generally or of the type that caused their injury. See *Contraindications and Precautions*, CTRS. FOR DISEASE CONTROL & PREVENTION (last reviewed Feb. 4, 2021), <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html> [<https://perma.cc/5F5B-YYPN>].

<sup>20</sup> See Ashley Bancsi, Sherilyn K.D. Houle & Kelly A. Grindrod, *Shoulder Injury Related to Vaccine Administration and Other Injection Site Events*, 56 CANADIAN FAM. PHYSICIAN 40, 40 (2019).

<sup>21</sup> See *id.*

<sup>22</sup> See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 86 Fed. Reg. 6,249 (Jan. 21, 2021).

<sup>23</sup> See *Local Reactions*, CTRS. FOR DISEASE CONTROL & PREVENTION (last reviewed Dec. 13, 2020), <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html> [<https://perma.cc/4LPZ-F28G>].

<sup>24</sup> See *id.*

<sup>25</sup> See *Adverse Events Following Immunization (AEFI)*, *supra* note 18.

<sup>26</sup> See KEVIN J. HICKEY, WEN W. SHEN & ERIN H. WARD, CONG. RSCH. SERV., R46399, LEGAL ISSUES IN COVID-19 VACCINE DEVELOPMENT AND DEPLOYMENT 37 (2020).

<sup>27</sup> See *Local Reactions*, *supra* note 23.

<sup>28</sup> See Katharine Van Tassel, Carmel Shachar & Sharona Hoffman, *Perspective: Covid-19 Vaccine Injuries—Preventing Inequities in Compensation*, 384 NEW ENG. J. MED. e34 (2020).

*abstruse, containing words like “reactogenicity.”<sup>29</sup> I.C. finally stumbles on a USA Today article that introduces him to the PREP Act and the CICIP.<sup>30</sup> He conducts additional research to learn more about both.*

The PREP Act is a tort liability shield enacted in 2005<sup>31</sup> that immunizes all entities involved in the manufacturing and distribution of covered countermeasures, including vaccines, from liability during public health emergencies.<sup>32</sup> PREP protects the economic interests of such entities so they can produce a reliable stream of products without fear of lawsuit.<sup>33</sup> According to Congress, PREP’s purpose is to “ensure that potentially life-saving countermeasures will be efficiently developed, deployed and administered.”<sup>34</sup> PREP Act immunity has been described as “sweeping” by a state appellate court.<sup>35</sup> It can only be invoked when the Secretary of Health and Human Services (HHS) determines the existence or credible risk of a public health emergency.<sup>36</sup> PREP has been previously invoked in connection with Ebola, Zika and Influenza.<sup>37</sup> On February 4, 2020, the U.S. government declared COVID-19 a public health emergency and HHS issued the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19,<sup>38</sup> which triggered the protections of the PREP Act.<sup>39</sup>

PREP outlines specific standards for what its liability shield covers.<sup>40</sup> “Covered persons” under PREP are manufacturers, distributors, and prescribers of covered countermeasures, as well as the federal, state, and local governments that supervise programs dispensing countermeasures or establish policies related to the countermeasures.<sup>41</sup> Such persons are immunized from any legal claims of loss, as long as a “covered countermeasure” caused the loss.<sup>42</sup> “Covered countermeasures” are drugs, biologic products, and devices developed to “diagnose, mitigate, prevent, treat or cure a pandemic or epidemic,” including those used to treat the side effects of a

<sup>29</sup> *Local Reactions*, *supra* note 23.

<sup>30</sup> See Ken Alltucker, *Government Program Tapped to Pay for COVID-19 Vaccine Injuries Rarely sides with consumers*, USA TODAY (Dec. 24, 2020), <https://www.usatoday.com/story/news/health/2020/12/24/covid-vaccine-injuries-sent-program-rejects-most-claims/4006753001> [<https://perma.cc/ZP79-CMCV>].

<sup>31</sup> See Kenya S. Woodruff, *COVID-19 and PREP Act Immunity*, 12 NAT’L L. REV. ONLINE (Aug. 5, 2020), <https://www.natlawreview.com/article/covid-19-and-prep-act-immunity> [<https://perma.cc/G5MW-6MKM>].

<sup>32</sup> *See id.*

<sup>33</sup> See KEVIN M. LEWIS, JOSHUA T. LOBERT, WEN W. SHEN & JON O. SHIMABUKURO, CONG. RSCH. SERV., R46540, COVID-19 LIABILITY: TORT, WORKPLACE SAFETY, AND SECURITIES LAW 7 (2020).

<sup>34</sup> HICKEY ET AL., *supra* note 26, at 35.

<sup>35</sup> *Parker v. Saint Lawrence Cnty. Pub. Health Dep’t*, 102 A.D.3d 140, 143 (N.Y. App. Div. 2012).

<sup>36</sup> HICKEY ET AL., *supra* note 26, at 33.

<sup>37</sup> See *Public Readiness and Emergency Preparedness Act*, U.S. DEP’T OF HEALTH & HUM. SERVS. (last reviewed Mar. 16, 2021), <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx> [<https://perma.cc/WY7M-W8ZB>].

<sup>38</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>39</sup> Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d (2020).

<sup>40</sup> *See id.*

<sup>41</sup> *See id.*; HICKEY ET AL., *supra* note 26, at 33–34.

<sup>42</sup> *See* HICKEY ET AL., *supra* note 26, at 34–35.

product or enhance their effects.<sup>43</sup> Because the purpose of mass inoculation is to curb and ultimately halt disease spread, vaccines are covered countermeasures.<sup>44</sup> Other countermeasures include drug trials and medical devices such as ventilators.

Those who believe a covered countermeasure has caused them injury can file a claim in the CICIP, which exists through a narrow exception to PREP Act immunity.<sup>45</sup> It is administered by the Health Resources and Services Administration (HRSA), an agency of HHS.<sup>46</sup> The CICIP has been used in the past during other public health emergencies.<sup>47</sup> It was first used in 2010 and since then has only paid out on twenty-nine claims, with a total payout of \$6 million.<sup>48</sup> It can only be used by claimants who have suffered serious physical injury or death,<sup>49</sup> or by those pursuing compensation on behalf of someone who died as the result of a countermeasure.<sup>50</sup> In order to pursue a suit under the CICIP, the “serious physical injury . . . must be life-threatening, permanently impair a body function, permanently impair a body structure, or require medical intervention to avoid such permanent impairment or damage.”<sup>51</sup> Claimants in the CICIP do not need to prove willful misconduct, but willful misconduct must be proved if the claimant rejects the compensation awarded and pursues a civil suit.<sup>52</sup> To prove willful misconduct, the claimant must demonstrate the countermeasure was administered: “i) intentionally to achieve a wrongful purpose, ii) knowingly without legal or factual justification, and iii) in disregard of a known or obvious risk that is so great as to make it highly probably that the harm would outweigh the benefit.”<sup>53</sup>

In addition to the high standard of proof, there are built-in statutory defenses to willful misconduct claims.<sup>54</sup> First, covered persons acting “consistent with applicable directions, guidelines or recommendations by the Secretary regarding the administration or use of a covered countermeasure” do not commit willful misconduct as long as they notify an authority within seven days of the injury or death.<sup>55</sup> Regulatory compliance is also a complete defense.<sup>56</sup>

To summarize, to prevail on a civil claim, I.C. must show:

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<sup>43</sup> See *id.*

<sup>44</sup> See Jennifer Schlesinger & Karina Hernandez, *Compensation for Victims of Covid Vaccine Injuries is Limited*, CNBC (last updated Mar. 25, 2021, 9:44 AM), <https://www.cnbc.com/2021/03/25/compensation-for-victims-of-covid-vaccine-injuries-is-limited.html> [<https://perma.cc/5XTF-N5QA>].

<sup>45</sup> See *Frequently Asked Questions*, HEALTH RES. & SERVS. ADMIN. (last reviewed Jan. 2021), <https://www.hrsa.gov/cicp/faq> [<https://perma.cc/9CKG-CZV8>].

<sup>46</sup> See HICKEY ET AL., *supra* note 26, at 37.

<sup>47</sup> See *Countermeasures Injury Compensation Program (CICP)*, *supra* note 7.

<sup>48</sup> See *Countermeasures Injury Compensation Program (CICP) Data*, HEALTH RES. & SERVS. ADMIN. (last reviewed Apr. 2021), <https://www.hrsa.gov/cicp/cicp-data> [<https://perma.cc/QH3Q-B5UN>].

<sup>49</sup> Countermeasures Injury Compensation Program (CICP): Administrative Implementation, 42 C.F.R. § 110.20 (2010).

<sup>50</sup> See HICKEY ET AL., *supra* note 26, at 37.

<sup>51</sup> Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.

<sup>52</sup> See HICKEY ET AL., *supra* note 26, at 37.

<sup>53</sup> *Id.* at 36.

<sup>54</sup> See *id.*

<sup>55</sup> *Id.* at 33.

<sup>56</sup> See *id.* at 36.

- He suffered serious injury after receiving the COVID vaccine, and
- The vaccine was administered or created improperly, intentionally, knowingly, and in disregard of a gross or obvious risk.

Any COVID-19 vaccine licensed or authorized by U.S. Food and Drug Administration (FDA) will fall under PREP's protections.<sup>57</sup> Other countermeasures covered by PREP during the COVID-19 pandemic include ventilators and certain therapeutic drugs.<sup>58</sup>

### *C. Filing for Benefits Under the CICP*

*After reading about PREP and the CICP, I.C. believes he has a valid claim. He has consulted a doctor who believes his shoulder injury will require rehab and surgery. The same doctor opines that his shoulder pain may have been caused by the administration of his COVID-19 shot in an inappropriate location on his upper arm. He received the shot in a small supply closet that was hastily converted to a vaccination site due to the large quantity of people receiving shots that day. I.C. believes he can assert willful misconduct based on these facts. I.C. begins the process of applying for compensation through the CICP.*

The CICP has been called “a black hole”<sup>59</sup> and “the right to file and lose.”<sup>60</sup> Little is known about the program. Most known information about the CICP and instructions for using the program can be found in the Federal Register and on the HRSA website.<sup>61</sup>

#### *1. Causation*

Filing in the CICP consists of completing a “Requests for Benefits” form, which asks claimants about the countermeasure received, the geographic location where the countermeasure was administered, and the alleged injury.<sup>62</sup> The form only allocates a few inches of blank space where the claimant can describe the injury.<sup>63</sup> Claimants are also required to submit all medical records from healthcare providers who provided

<sup>57</sup> *See id.* at 35.

<sup>58</sup> *See id.*

<sup>59</sup> Tom Hals, *COVID-19 Era Highlights U.S. ‘Black Hole’ Compensation Fund for Pandemic Vaccine Injuries*, REUTERS (Aug. 21, 2020), <https://www.reuters.com/article/us-health-coronavirus-vaccines-liability/covid-19-era-highlights-u-s-black-hole-compensation-fund-for-pandemic-vaccine-injuries-idUSKBN25H1E8> [<https://perma.cc/BQ7L-Q3JW>].

<sup>60</sup> Peter Loftus, *People Harmed by Coronavirus Will Have Little Recourse*, WALL ST. J. (Oct. 11, 2020, 12:00 PM), <https://www.wsj.com/articles/people-harmed-by-coronavirus-vaccines-will-have-little-recourse-11602432000> [<https://perma.cc/96TZ-MSBU>].

<sup>61</sup> *See Countermeasures Injury Compensation Program (CICP)*, *supra* note 7; Countermeasures Injury Compensation Program (CICP): Administrative Implementation, 42 C.F.R. § 110.20 (2010).

<sup>62</sup> *See* HEALTH RES. & SERVS. ADMIN., OMB CONTROL NO. 0915-0334, COUNTERMEASURES INJURY COMPENSATION PROGRAM: REQUEST FOR BENEFITS FROM INSTRUCTIONS (2020), <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-request-form-instructions.pdf> [<https://perma.cc/T43Q-JPUB>] [hereinafter HRSA, COUNTERMEASURES INJURY COMPENSATION PROGRAM].

<sup>63</sup> *See id.*

treatment for the injury.<sup>64</sup> While the CICIP claims submissions are evaluated by staff members, there is no available information providing the identities of the evaluators.<sup>65</sup>

Once a claimant submits a “Request for Benefit” form, there is no guarantee of what will happen next or if they should expect further communication with HRSA. Historically, information about the number of claims filed with the CICIP has not been disclosed. HHS has revealed the CICIP has received far more petitions than it has fulfilled.<sup>66</sup> As of March 1, 2022, it has only granted compensation for about 0.4% of claims filed since 2010.<sup>67</sup> During that time, it received 7,547 claims and determined forty-one were eligible for compensation.<sup>68</sup> Of the forty-one claims deemed eligible for compensation, the CICIP only compensated thirty; ten were determined not to have any “eligible reported expenses” and one was pending as of March 1, 2022.<sup>69</sup>

Claimants have already filed in the CICIP alleging injuries related to COVID-19 countermeasures. Of the 7,547 claims filed prior to March 1, 2022, 7,056 of those claims were related to COVID-19 countermeasures.<sup>70</sup> Four thousand ninety-seven of those claims were related to COVID-19 vaccines.<sup>71</sup> As of March 1, 2022, the CICIP had not compensated any claims related to COVID-19 countermeasures.<sup>72</sup> Six claims related to COVID-19 countermeasures were denied compensation.<sup>73</sup> One claim was determined eligible for compensation but was pending review of expenses as of March 1, 2022.<sup>74</sup> The claim regarded an anaphylactic reaction from a COVID-19 vaccine.<sup>75</sup>

There are a few outright features of the CICIP filing process that make it unfriendly for petitioners. Obtaining medical records from providers can be a convoluted and expensive administrative process. It is unclear if or how the CICIP assesses willful misconduct. HRSA does not provide a timeline for when it will inform claimants of their outcome.<sup>76</sup> After an eligibility determination is made, claimants are not given feedback or information about why their claim did or did not prevail.<sup>77</sup>

## 2. Damages

If HRSA finds a claimant eligible for benefits, the claimant will be asked to provide additional information about the types and amount of damages they believe they are owed.<sup>78</sup> The CICIP offers benefits for lost employment income, medical expenses, and

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<sup>64</sup> See *Filing for Benefits*, HEALTH RES. & SERVS. ADMIN. (last reviewed Jan. 2021), <https://www.hrsa.gov/cicp/filing-benefits> [<https://perma.cc/3QR9-Q4TS>].

<sup>65</sup> See *id.*

<sup>66</sup> See *Countermeasures Injury Compensation Program (CICP) Data*, *supra* note 48.

<sup>67</sup> See *id.*

<sup>68</sup> See *id.*

<sup>69</sup> See *id.*

<sup>70</sup> See *id.*

<sup>71</sup> See *id.*

<sup>72</sup> See *id.*

<sup>73</sup> See *id.*

<sup>74</sup> See *id.*

<sup>75</sup> See *id.*

<sup>76</sup> See *id.*

<sup>77</sup> See Meyers, *supra* note 2, at 4.

<sup>78</sup> See *Filing for Benefits*, *supra* note 64.

survivor death benefits.<sup>79</sup> However, all three categories are limited. Regarding lost employment income, the CICIP is a “payer of last resort,” meaning it will not compensate for lost income that can be reimbursed by another third-party payer such as Worker’s Compensation.<sup>80</sup> Claimants are not eligible for lost income if they were out of work for five or fewer days.<sup>81</sup> For medical costs, the CICIP does not cover medical services or items paid for by insurance,<sup>82</sup> and it will only cover items and services it deems “reasonable and necessary.”<sup>83</sup> There are different rules and restrictions on damages for claimants pursuing claims on behalf of individuals who died as a direct result of a countermeasure.<sup>84</sup> There is no information on the website about how the values of such benefits are calculated or even whether such decisions are made on a case-to-case basis or by a flat amount.

#### *D. Filing a Civil Suit After Filing in the CICIP*

*HRSA informs I.C. that he is not eligible for benefits. He is not told why. He attempts to contact HRSA to learn more but is not able to reach anyone with information. He turns to the PREP Act to see what his next options are.*

If a claimant is awarded compensation through the CICIP and elects to receive it, they are precluded from bringing a civil suit against any manufacturer or administrator.<sup>85</sup> If they are not awarded compensation, or reject the compensation offered, they may choose to sue, subject to additional procedural restrictions.<sup>86</sup> First, no matter where the client lives, suit must be brought in the U.S. District Court for the District of Columbia.<sup>87</sup> The suit goes to a three-judge panel.<sup>88</sup> The claimant is there required to meet heightened pleading and discovery standards and is subject to procedural provisions that the Congressional Research Service calls “generally favorable to defendants.”<sup>89</sup> Finally, claimants are subject to a “clear and convincing

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<sup>79</sup> See HEALTH RES. & SERVS. ADMIN., COUNTERMEASURES INJURY COMPENSATION PROGRAM REQUEST FOR BENEFITS FORM INSTRUCTIONS (Mar. 2020), <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-request-form-instructions.pdf> [<https://perma.cc/R2CK-AFB6>].

<sup>80</sup> See *Types of Benefits*, HEALTH RES. & SERVS. ADMIN. (Nov. 2020), <https://www.hrsa.gov/cicp/types-of-benefits> [<https://perma.cc/GG72-E3JZ>].

<sup>81</sup> See *id.*

<sup>82</sup> See *id.*

<sup>83</sup> See *id.*

<sup>84</sup> See *Types of Eligible Requesters*, HEALTH RES. & SERVS. ADMIN. (last reviewed Nov. 2020), <https://www.hrsa.gov/cicp/eligible-requesters> [<https://perma.cc/RBE2-ZHCF>]. (For a survivor to obtain death benefits, the vaccine recipient must have died as a direct result of their injuries caused by the vaccine. Eligible survivors include spouses, children, minor dependents, named beneficiaries, and parents. Survivors are not eligible to recover other benefits such as lost employment income.)

<sup>85</sup> See HICKEY ET AL., *supra* note 26, at 36.

<sup>86</sup> See *id.*

<sup>87</sup> See *id.*

<sup>88</sup> See *id.*

<sup>89</sup> See *id.*

evidence” standard, which is higher than the preponderance of the evidence standard that is typical of civil cases and applied in the VICP.<sup>90</sup>

Because I.C. filed in the CICIP and was not awarded compensation, he can now file a civil lawsuit alleging willful misconduct.<sup>91</sup> But . . . does he want to?

### *E. Anti-Vaccine Sentiment in the United States*

*Now, I.C. is angry. It seems like the “next steps” available are even more restrictive than the CICIP. At the very least, he will have to hire an out-of-state lawyer since he does not live in D.C. He turns to the Internet to see if anyone else has run into this problem. There, he stumbles into a web of conspiratorial conversations about the COVID-19 vaccine and vaccines generally. After perusing this information, he adds his story to the mix.*

The fear of vaccines, often called “vaccine hesitancy” or “vaccine skepticism,” often derives from misinformation spread over the Internet.<sup>92</sup> Anti-vaccine information is spread on the Internet through YouTube videos and social media, as well as by visits to vaccine-skeptical webpages.<sup>93</sup> Potential causes of vaccine hesitancy include distrust of government, large vaccine manufacturers, government–industry partnerships, science, and the medical community; fear of Big Pharma; growing interest in “natural” forms of treatment; and, for those who object to childhood vaccines, resistance to being told how to parent.<sup>94</sup> The COVID-19 vaccine development and distribution process, “Operation Warp Speed,” implicates many of these concepts and will need to overcome additional skepticism based on the accelerated development process.<sup>95</sup>

The spread of misinformation on the Internet often follows developments in the vaccine and public health world. The CDC updated its quarantine protocol in 2016, which included modernization of existing quarantine rules and allowed the CDC to screen travelers.<sup>96</sup> Soon after, “calls to action went up on several anti-vaccine sites and Facebook pages.”<sup>97</sup> Anti-vaccine activists had misunderstood the rule as allowing the CDC to force vaccinations.<sup>98</sup> Thousands of inaccurate comments were submitted in response to the CDC’s Notice of Proposed Rulemaking.<sup>99</sup> Any reports of injury from

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<sup>90</sup> See *id.*

<sup>91</sup> See *id.*

<sup>92</sup> Lenny Grant, Bernice L. Hausman, Margaret Cashion, Nicholas Lucchesi, Kelsey Patel & Jonathan Roberts, *Vaccine Persuasion Online: A Qualitative Study of Two Provacine and Two Vaccine-Skeptical Websites*, 17 J. MED. INTERNET RES. 3 (2015) [<https://perma.cc/G6XZ-PG3P>].

<sup>93</sup> See Guess et al., *supra* note 1, at 7799.

<sup>94</sup> Mariam Siddiqui, Daniel A. Salmon & Saad B. Omer, *Epidemiology of Vaccine Hesitancy in the United States*, 9 HUM. VACCINE & IMMUNOTHERAPEUTICS 2643, 2643 (2013) [<https://perma.cc/C22U-58CJ>].

<sup>95</sup> See Jeffrey Lazarus, Scott C. Ratzan, Adam Palayew, Lawrence O. Gostin, Heidi J. Larson, Kenneth Rabin, Spencer Kimball & Ayman El-Mohandes, *A Global Survey of Potential Acceptance of a COVID-19 Vaccine*, NATURE MED. (2020); see Kaminer, *supra* note 5, at 101.

<sup>96</sup> Dorit Reiss, *Regulating in the Era of Fake News: Anti-Vaccine Activists Respond to the CDC Quarantine Rule*, 79 UNIV. PITT. L. REV. 675, 675 (Summer 2018).

<sup>97</sup> See *id.*

<sup>98</sup> See *id.* at 675, 677, 695–97, 703–06, 708.

<sup>99</sup> See *id.* at 677.

the COVID-19 vaccine will be swept up by the web of Internet sites disseminating inflammatory anti-vaccine information. Additionally, the lack of transparency and counterintuitive rules of the CACP will likely lead to similar misunderstandings regarding COVID-19 vaccine injury compensation. Social media companies may need to proactively restrict vaccine misinformation from being spread on their platforms.<sup>100</sup>

Since vaccines were invented, there have been doubters and non-believers.<sup>101</sup> However, since 2010, there has been a small increase in the number of unvaccinated people in the United States.<sup>102</sup> Correlated with the increasing number of unvaccinated people has been the reoccurrence of previously eradicated diseases.<sup>103</sup> When a previously eradicated disease recurs, it “loses elimination status.”<sup>104</sup> For example, measles lost its elimination status in Great Britain in 2018.<sup>105</sup>

Individual attitudes toward receiving COVID-19 vaccines are currently mixed. In a survey of over 1,000 U.S. adults conducted during Spring 2020, 49% said they would get a vaccine once it became available, 31% said they were unsure, and 20% said they would not.<sup>106</sup> Polling results vary; in another survey taken at roughly the same time, 71% of U.S. adults said they would get the vaccine.<sup>107</sup> The percentage of the population that needs to be vaccinated for the United States to achieve herd immunity has been estimated between 70–90%.<sup>108</sup> The COVID-19 vaccines were administered to the U.S. population in a staggered format, prioritizing older citizens and members of other high-risk groups.<sup>109</sup> Eventually, the vaccines became widely available to all U.S. adults, barring those with certain health conditions. Individuals who are in low-risk groups may fear the risks of the COVID-19 vaccine more than they fear the disease itself and exercise discretion in determining whether to get the vaccine. Thus, those who have observed the growth of anti-vaccine sentiment during the first phases of the distribution process or viewed anti-vaccine information on the Internet during that period may opt out.

Anti-vaccine activists launched smear campaigns before any of the COVID-19 vaccines were authorized by FDA.<sup>110</sup> COVID-19 itself has been the subject of

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<sup>100</sup> See Elizabeth Angeley, *Anti-Vaccination: A Growing Epidemic?*, 32 J. AM. ACAD. MATRIM. L. 271, 302 (2020).

<sup>101</sup> See *id.*

<sup>102</sup> See *id.* at 273.

<sup>103</sup> See *id.*

<sup>104</sup> See *id.*

<sup>105</sup> See *id.*

<sup>106</sup> See Kreps et al., *supra* note 4, at 2.

<sup>107</sup> See *id.*

<sup>108</sup> See Donald McNeil, *How Much Herd Immunity Is Enough?*, N.Y. TIMES (Dec. 24, 2020), <https://www.nytimes.com/2020/12/24/health/herd-immunity-covid-coronavirus.html> [<https://perma.cc/4525-6994>]; Kreps et al., *supra* note 4; Kaminer, *supra* note 5, at 101.

<sup>109</sup> See *How the Vaccine Rollout Is Going in Your State*, N.Y. TIMES, <https://www.nytimes.com/interactive/2020/us/covid-19-vaccine-doses.html> (last updated Apr. 1, 2022) [<https://perma.cc/S9WS-T2TY>].

<sup>110</sup> See Lazarus et al., *supra* note 95.

conspiracies expounded in online films such as “Plandemic.”<sup>111</sup> The fast-tracked development of COVID-19 vaccines has caused vaccine hesitancy in some who typically trust vaccines.<sup>112</sup> Similarly, the inability of the federal government to provide adequate compensation to those injured by COVID-19 vaccines may spur vaccine hesitancy.

There are a few unique aspects of the COVID-19 vaccine development and distribution process that differentiate it from others. First, the vaccines were developed under a program called “Operation Warp Speed,” which was designed to rapidly develop, manufacture, and deliver vaccine doses.<sup>113</sup> Second, some vaccinations have occurred in non-traditional locations such as parking lots.<sup>114</sup> Third, in rare cases, untrained individuals have been found to be administering COVID-19 vaccines.<sup>115</sup> Because of these differentiating factors, individuals who are typically pro-vaccine may exhibit hesitancy towards the COVID-19 vaccine.

It is possible the COVID-19 pandemic itself will increase public awareness of the necessity of vaccines, as “recent history would seem to imply one way to combat the stream of misinformation and unsupported science propagated by those who advocate against vaccination is the outbreak of vaccine-preventable disease.”<sup>116</sup> Beyond this, however, federal and state governments and public health organizations must demonstrate confidence about the safety of the vaccines to ensure the vast majority of the population is incentivized to get vaccinated.<sup>117</sup> An early example of this was when then-President-Elect Biden and former Vice President Pence received a COVID-19 vaccine early on in the vaccine rollout.

Misinformation and conspiracies have already caused bad actors to interfere with the vaccine administration process. On Christmas Eve and Christmas Day 2020, a Wisconsin pharmacist deliberately removed dozens of vials of the Moderna vaccine from the refrigerators they were kept in to maintain the temperature required for successful administration.<sup>118</sup> In his guilty plea, the pharmacist admitted to being

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<sup>111</sup> See Scott Neuman, *Seen ‘Plandemic’? We Take a Close Look at the Viral Conspiracy Video’s Claims*, NAT’L PUB. RADIO (May 8, 2020, 4:52 PM), <https://www.npr.org/2020/05/08/852451652/seen-plantemic-we-take-a-close-look-at-the-viral-conspiracy-video-s-claims> [<https://perma.cc/UHY8-X8CR>].

<sup>112</sup> See Kaminer, *supra* note 5, at 103.

<sup>113</sup> See U.S. DEP’T OF HEALTH & HUMAN SERVS., EXPLAINING OPERATION WARP SPEED (2020), <https://www.nihb.org/covid-19/wp-content/uploads/2020/08/Fact-sheet-operation-warp-speed.pdf> [<https://perma.cc/UZS3-MSEA>].

<sup>114</sup> See *id.*

<sup>115</sup> See Nina Feldman, Max Marin & Alan Yu, *In Philadelphia, A Scandal Erupts Over Vaccination Startup Led by 22-Year-Old*, NAT’L PUB. RADIO (Jan. 29, 2021), <https://www.npr.org/sections/health-shots/2021/01/29/962143659/in-philadelphia-a-scandal-erupts-over-vaccination-start-up-led-by-22-year-old> [<https://perma.cc/WFG8-LHXD>].

<sup>116</sup> See Angeley, *supra* note 100, at 301.

<sup>117</sup> See Kaminer, *supra* note 5, at 101.

<sup>118</sup> See *Pharmacist Who Sabotaged COVID-19 Vaccine to Plead Guilty to Federal Charges*, WISN (Jan. 26, 2021, 10:40 PM), <https://www.wisn.com/article/pharmacist-accused-of-sabotaging-covid-19-vaccine-to-plead-guilty-to-federal-charges/35326222#> [<https://perma.cc/8NB4-YKR6>].

motivated by personal vaccine skepticism and conspiracy theories.<sup>119</sup> Fifty-seven people received doses from the tampered vials, which were called “all but useless.”<sup>120</sup>

To return society to normal operations, state governments, businesses, and schools may implement COVID-19 vaccination mandates that condition the receipt of government benefits, such as public schooling, on getting the vaccine.<sup>121</sup> This may spur additional anti-vaccine sentiment.<sup>122</sup> Individuals will still be able to opt out of vaccination, but will have to obtain exemptions, medical or otherwise, to access such services.<sup>123</sup>

### III. COMPARING THE CICIP WITH THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP)

The purposes of the CICIP and VICP are the same—protecting the economic interests of the corporations involved in vaccine manufacturing and distribution to ensure the U.S. population has a clear path to vaccination.<sup>124</sup> The VICP was created in 1986 to shield vaccine administrators and manufacturers from liability.<sup>125</sup> In 1986, the public became aware of rare but severe side effects of the Diphtheria-Tetanus-Pertussis (DTP) vaccine.<sup>126</sup> Information about these side effects was widely circulated through news reports at the time.<sup>127</sup> An influx of “lawsuits against vaccine companies and health care providers threatened to cause vaccine shortages and reduce U.S. vaccination rates, which could have caused a resurgence of vaccine preventable diseases.”<sup>128</sup> Some vaccine companies halted production, and the industry feared total decimation.<sup>129</sup> As a result, the VICP was created to protect manufacturers from lawsuit and ensure the continued existence of the national vaccine supply.

While the CICIP and VICP have similar goals, the two programs function extremely differently. Like the CICIP, administration of the VICP falls under HRSA’s jurisdiction.<sup>130</sup> The VICP is a no-fault compensation program, which means it does not need to be proven that anyone did anything wrong for a petitioner to receive

<sup>119</sup> *See id.*

<sup>120</sup> *See id.*; *Pharmacist Accused of Spoiling COVID-19 Vaccine Appears in Court*, WISN (Jan. 4, 2021), <https://www.wisn.com/article/pharmacist-accused-of-spoiling-covid-19-vaccine-appears-in-court/35120963> [<https://perma.cc/58MN-5GN4>].

<sup>121</sup> *See* Kaminer, *supra* note 5, at 105–09.

<sup>122</sup> *See id.*

<sup>123</sup> *See id.*

<sup>124</sup> *See* Van Tassel et al., *supra* note 28, at e(34)1.

<sup>125</sup> *See* Durant, *supra* note 6, at 3.

<sup>126</sup> *See Vaccine Injury Compensation Programs*, THE COLL. OF PHYSICIANS OF PHILA.: HIST. OF VACCINES, <https://www.historyofvaccines.org/content/articles/vaccine-injury-compensation-programs> (last updated Jan. 17, 2018) [<https://perma.cc/5L96-3RV5>].

<sup>127</sup> *See* Stephen Sugarman, *Perspective: Cases in Vaccine Court – Legal Battles over Vaccines and Autism*, 357 N. ENG. J. MED. 1275, 1276 (2007).

<sup>128</sup> HRSA, WHAT YOU NEED TO KNOW, *supra* note 12, at 5; *National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/vaccine-compensation/index.html> (last updated Mar. 2022) [<https://perma.cc/ZR2T-44Q5>].

<sup>129</sup> *See id.*

<sup>130</sup> *See* 42 U.S.C. § 300aa-10.

compensation.<sup>131</sup> While the CICIP is only used during public health emergencies, the VICP is available to claimants anytime.<sup>132</sup> The vaccine tied to the claim must be listed on the *Vaccine Table* published by HRSA.<sup>133</sup> The VICP has paid out \$4.3 billion in claims since 1986.<sup>134</sup> Compensation can be obtained for both children and adults and on behalf of the deceased.<sup>135</sup> In comparison with the 10% of claims the CICIP has fulfilled, about 75% of the cases adjudicated through the VICP over the past five years resulted in the petitioner obtaining some kind of compensation.<sup>136</sup> The following section will compare different aspects of the VICP and CICIP, including claims, damages, adjudication processes, and applicable timelines.

### A. Available Claims

The VICP and CICIP have differing rules for bringing claims. Under the VICP, petitioners can bring either Table or Off-Table claims. Table claims are easy to prove: the VICP Table outlines criteria, and if those criteria are met, there is an automatic presumption of causation.<sup>137</sup> The vaccines on the Table are subject to an excise tax, which funds the compensation payments.<sup>138</sup> If the facts of the claim do not meet the delineated criteria, petitioners can also succeed with “Off-Table” claims if they prove causation by a preponderance of the evidence.<sup>139</sup> By contrast, the CICIP only allows claims for “serious physical injury or death” arising via “willful misconduct” in the administration of a countermeasure during a public health emergency, such as the COVID-19 vaccine.<sup>140</sup>

Like in the VICP, the Secretary is authorized by the PREP Act to issue a Table for countermeasures for use in the CICIP.<sup>141</sup> Tables have been created in the past for certain public health issues.<sup>142</sup> However, no Table has been created for any of the COVID-19 vaccines. The CICIP’s website says: “even though a countermeasure injury table for COVID-19 countermeasures has not been established yet, requesters who demonstrate that their injury occurred as the direct result of the administration or use of a covered

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<sup>131</sup> See 42 U.S.C. § 300aa-13.

<sup>132</sup> See *id.*

<sup>133</sup> The Vaccine Table is produced by HHS and lists the vaccines which the VICP covers. It also outlines criteria for claims in which causation is presumed and does not need to be proven by the petitioner. 42 U.S.C. § 300aa-14.

<sup>134</sup> Durant, *supra* note 6.

<sup>135</sup> See 42 U.S.C. §300aa-11(a).

<sup>136</sup> See Meyers, *supra* note 2, at 5–6.

<sup>137</sup> 42 U.S.C. § 300aa-14.

<sup>138</sup> See *Covered Vaccines*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html> (last updated Mar. 2022) [<https://perma.cc/6595-U9VA>].

<sup>139</sup> See 42 U.S.C. § 300aa-11(c).

<sup>140</sup> *Comparison of Countermeasures Injury Compensation Program (CICIP) to the National Vaccine Injury Compensation Program (VICP)*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/cicp/cicp-vicp> (last updated Apr. 2021) [<https://perma.cc/Z9UJ-N92P>].

<sup>141</sup> See 42 U.S.C. § 247d-6e.

<sup>142</sup> For example, tables have been created for smallpox and pandemic influenza. See *Countermeasures Injury Compensation Program (CICIP)*, *supra* note 7.

countermeasure based on compelling, reliable, valid, medical and scientific evidence, may be eligible for compensation.”<sup>143</sup>

As discussed earlier, one of the most common injuries claimed under the VICP is shoulder injury related to vaccine administration (SIRVA).<sup>144</sup> The theory behind SIRVA is that it occurs when a shot is administered into the wrong area of the arm.<sup>145</sup> The pain accompanying SIRVA can severely limit one’s ability to use their arm.<sup>146</sup> In a recent public comment period regarding the potential removal of SIRVA from the VICP Table, SIRVA survivors spoke of lost careers, lessened ability to participate in hobbies, and lower quality of life from the injury.<sup>147</sup> The SIRVA theory is backed up by medical studies and journal articles.<sup>148</sup> Because SIRVA occurs due to incorrect administration of a shot, SIRVA claims could meet the “willful misconduct” standard of the CICP if it was determined the administrator gave the shot with disregard of an obvious risk. However, claims of SIRVA caused by the COVID-19 vaccine are unlikely to fulfill the CICP’s serious injury or death requirement.<sup>149</sup>

### B. Available Damages

The CICP allows claimants to recover medical expenses, lost wages, and survivor death benefits, subject to limitations. The VICP allows petitioners to recover for all of the same categories, as well as for pain and suffering and attorney’s fees.<sup>150</sup> Although filing a claim in the VICP does not require an attorney, most petitioners use one.<sup>151</sup> Even losing petitioners can have their attorney’s fees paid by the court, as long as the case is brought in “good faith and with reasonable basis.”<sup>152</sup> The VICP annually makes hundreds of payments to petitioners for attorney’s fees even when their claims were ultimately unsuccessful.<sup>153</sup> Both compensation for injury and attorney’s fees come out of the Vaccine Injury Compensation Trust Fund.<sup>154</sup> In 2012, over 1,000 payments were made to attorneys for cases that were eventually dismissed because special masters

<sup>143</sup> *About CICP*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/cicp/about> (last updated Nov. 2020) [<https://perma.cc/DW4F-7UL2>].

<sup>144</sup> *See* Durant, *supra* note 6.

<sup>145</sup> *See* Bancsi et al., *supra* note 20 (“[SIRVA] is a preventable occurrence caused by the injection of a vaccine into the shoulder capsule rather than the deltoid muscle.”).

<sup>146</sup> *See National Vaccine Injury Compensation Program (VICP) Revisions to the Vaccine Injury Table*, Notice of Proposed Rulemaking Mandatory Public Administrative Hearing (Nov. 9, 2020) (statement of Mr. Laurie Guerrie).

<sup>147</sup> *See National Vaccine Injury Compensation Program (VICP) Revisions to the Vaccine Injury Table*, Notice of Proposed Rulemaking Mandatory Public Administrative Hearing (Nov. 9, 2020) (statement of Mr. Douglas Miller).

<sup>148</sup> Durant, *supra* note 6.

<sup>149</sup> *Id.*

<sup>150</sup> *See* 42 U.S.C. § 300aa-15; HRSA, WHAT YOU NEED TO KNOW, *supra* note 12, at 12.

<sup>151</sup> *See* HRSA, WHAT YOU NEED TO KNOW, *supra* note 12, at 6.

<sup>152</sup> 42 U.S.C. § 300aa-15(e).

<sup>153</sup> *See* HEALTH RES. & SERVS. ADMIN., VACCINE COMPENSATION DATA AND STATISTICS REPORT (Apr. 2020), <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf> [<https://perma.cc/FBG8-YCVC>] [hereinafter HRSA, VACCINE COMPENSATION DATA].

<sup>154</sup> *See About the National Vaccine Injury Compensation Program*, *supra* note 6.

found the cases had been brought in good faith.<sup>155</sup> Since 2009, the VICP has also provided interim payments to attorneys.<sup>156</sup> Interim payments allow petitioners to continue pursuing their cases through lengthy adjudication processes even when there is no guarantee they will win.<sup>157</sup>

The VICP's payment of attorney's fees, even in losing cases, means that injured petitioners may pursue a claim even if they would not otherwise be able to afford a lawyer. "Promised" payments may make attorneys more likely to take on such clients. The Vaccine Act, which created the VICP, also obliges attorneys consulted by individuals on vaccine-related injuries or deaths to advise those individuals of the program and the possibility for compensation.<sup>158</sup>

The CICIP does not allow claimants to recover for pain and suffering or attorney's fees. Although the process for obtaining compensation from the CICIP is filling out a form,<sup>159</sup> not filing a legal brief, attorneys can help claimants understand their recovery rights and evaluate their likelihood of success. Attorneys can also advise claimants on how to explain their injuries and obtain medical records, which can be an arduous and confusing process for laypeople. Without the CICIP covering attorney's fees, participating in the program will be inaccessible for many.

### C. Adjudication Processes

The adjudication processes of the VICP and CICIP are also very different, as the VICP is an alternative dispute resolution process and the CICIP is entirely administrative. In the VICP, petitioners bring their claim against HHS, which is defended by attorneys from the Department of Justice, Civil Division's Torts Branch.<sup>160</sup> Claims brought under the VICP go to a special "vaccine court" for adjudication.<sup>161</sup> Rather than judges, vaccine court proceedings are presided over by "special masters" who only work on vaccine claims. The Office of Special Masters operates within the U.S. Court of Federal Claims (CFC). Special masters' decisions do not create binding precedent, but they can be appealed first to the CFC, then to the Federal Circuit, and finally to the Supreme Court.<sup>162</sup> During the process of bringing a claim, there are ample opportunities for back-and-forth discourse between the parties and the adjudicator.<sup>163</sup> The special master may even personally question the petitioner during a hearing.<sup>164</sup>

In the CICIP, there are no hearings or adverse parties, just claims for benefits submitted to administrators for review.<sup>165</sup> The CICIP is a regulatory process facilitated by administrators, which uses procedures and standards determined by HHS

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<sup>155</sup> See HRSA, VACCINE COMPENSATION DATA, *supra* note 153.

<sup>156</sup> *See id.*

<sup>157</sup> *See id.*

<sup>158</sup> 42 U.S.C. § 300aa-10(b).

<sup>159</sup> *See Filing for Benefits, supra* note 64.

<sup>160</sup> *See* OFF. OF SPECIAL MASTERS, *supra* note 16, at 5.

<sup>161</sup> *See* 42 U.S.C. § 300aa-11.

<sup>162</sup> *See* VACCINE RULES, R. U.S. CT. FED. CL. APP. B 3, 129.

<sup>163</sup> *See id.*

<sup>164</sup> *See id.*

<sup>165</sup> *See About CICIP, supra* note 143.

regulations.<sup>166</sup> The names of those who evaluate CICIP claims, or even whether they are subject to review by an individual or a group, are not published; the website only says the determination is made by “CICIP medical staff.”<sup>167</sup> One article claims HRSA employed only four people on the program prior to COVID-19 but are planning to hire more.<sup>168</sup> After a claim is submitted to the CICIP, there is no communication between the claimant and HRSA until the claimant receives a letter notifying them of the decision.<sup>169</sup> If the claim is determined worthy of compensation, the claimant is contacted again to submit information regarding the amount and type of compensation they are seeking.<sup>170</sup> HRSA does not publish written decisions or offer any explanations for their decisions.<sup>171</sup> This means there is no publicly available precedent, which prevents claimants from evaluating their chances of success before filing a claim.

There are also no opportunities for CICIP claimants to seek judicial review.<sup>172</sup> A disappointed claimant may request review by “the Associate Administrator of the Healthcare Systems Bureau of HRSA,” in which case an independent, “qualified” panel reviews the decision.<sup>173</sup> It is not clear whether this panel is assembled from the same staff who make the original decision or whether an entirely new panel is put together.<sup>174</sup>

#### *D. Statutes of Limitations and Other Timelines*

Unsurprisingly, petitioners in the VICP have a longer window of time to make their claims than is available to claimants in the CICIP. In the VICP, injured petitioners have until three years after the first symptom of the vaccine injury manifests to file a claim.<sup>175</sup> Similarly, death claims must be filed within two years of the death and four years of when the first symptom of the vaccine injury that led to the death appeared.<sup>176</sup> Under the CICIP, however, claimants must file for benefits within one year after the administration of the countermeasure that led to the injury.<sup>177</sup> Not only does the CICIP impose a shorter timeframe, it uses a different metric to start the clock—the countermeasure’s administration, not the manifestation of injury symptoms. Even with the VICP’s longer timeframe for filing claims, many claims are filed close to the deadline.<sup>178</sup> Occasionally, the petitioner is challenged on when their symptoms first

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<sup>166</sup> See HICKEY ET AL., *supra* note 26, at 37.

<sup>167</sup> See *Filing for Benefits*, *supra* note 64.

<sup>168</sup> See Alltucker, *supra* note 30.

<sup>169</sup> See *Filing for Benefits*, *supra* note 64.

<sup>170</sup> See *id.*

<sup>171</sup> See *id.*

<sup>172</sup> See *id.*

<sup>173</sup> See *Filing for Benefits*, *supra* note 64.

<sup>174</sup> See *id.*

<sup>175</sup> See HRSA, WHAT YOU NEED TO KNOW, *supra* note 12, at 7.

<sup>176</sup> See *id.*

<sup>177</sup> See 42 C.F.R. § 100.2; HRSA, COUNTERMEASURES INJURY COMPENSATION PROGRAM, *supra* note 62, at 1.

<sup>178</sup> See, e.g., *Clubb v. Sec’y of Health & Hum. Servs.*, No. 15-891V, 2017 WL 7310150, at \*2 (Fed. Cl. Aug. 15, 2017).

manifested and must prove it occurred within the proscribed timeline.<sup>179</sup> Given public knowledge about the CICIP is limited, the program's short timeline will impact claimants' abilities to file in the program. It is likely that many potential claimants will not hear about the program until after their statute of limitations has run out.

Additionally, the VICP sets forth a timeline by which it must issue a decision, while the CICIP does not.<sup>180</sup> The VICP is nominally bound to issue a decision within 240 days.<sup>181</sup> Despite this, it takes on average 5.5 years for a case to resolve.<sup>182</sup> By contrast, HHS provides no estimates by which a claimant in the CICIP can expect to receive a decision and does not publish information about how long it has taken in the past. As of March 1, 2022, the CICIP had not compensated any claims related to COVID-19 countermeasures.<sup>183</sup>

#### IV. NECESSARY CHANGES TO THE COUNTERMEASURES INJURY COMPENSATION PROGRAM TO COMBAT ANTI- VACCINE SENTIMENT

To confront the problem of increasing anti-vaccine sentiment, HRSA should integrate certain aspects of the VICP into the CICIP to make the program more petitioner-friendly. A program like the VICP, with its clear requirements for compensation, awards for attorney's fees, and hearings and published decisions, would pose a lesser risk of increasing anti-vaccine sentiment. Given the identical goals of the VICP and CICIP, it is illogical for them to be adjudicated in such different ways. In the interest of transparency, the CICIP should be made into a more adjudicative process. There are multiple ways the CICIP can be changed. It can be changed internally, through HRSA amending its rules through a notice-and-comment period.<sup>184</sup> It can also be changed through amendments to the PREP Act Declaration or by Congress passing a new law altogether.

##### A. *Option I: HRSA Amends the Practices of the CICIP Through Notice-and-Comment Rulemaking*

If the CICIP is to continue, HRSA must amend the program's practices to make it more petitioner-friendly and transparent. Many of the following ideas would be amendments made to the CICIP through HRSA passing new administrative regulations through the notice-and-comment rulemaking process.<sup>185</sup> Others may only require a strategic shift in how the agency explains the nuances of the program on its website. First, HRSA must open the line of communication between claimants and adjudicators. The agency can do this by allowing for written advocacy. The "Request for Benefits" form only asks claimant to describe their injury—it does not ask or

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<sup>179</sup> See *id.* at \*3.

<sup>180</sup> See *Filing for Benefits*, *supra* note 64.

<sup>181</sup> See 42 U.S.C. § 300aa-12(d)(3)(A)(ii).

<sup>182</sup> See Meyers, *supra* note 2, at 6.

<sup>183</sup> See *Countermeasures Injury Compensation Program (CICIP) Data*, *supra* note 48.

<sup>184</sup> See OFF. OF THE FED. REG., A GUIDE TO THE RULEMAKING PROCESS (2011), [https://www.federalregister.gov/uploads/2011/01/the\\_rulemaking\\_process.pdf](https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf) [<https://perma.cc/CM2N-ESSS>].

<sup>185</sup> See *id.*

encourage the claimant to provide context to the medical records they are sending in or even clarify which parts of the records relate to the injury in question.<sup>186</sup> It is difficult to imagine CICIP staff (which is rumored to be only four people<sup>187</sup>) sorting through hundreds of pages of unrelated medical records to get to the few sections related to the vaccine injury. The “Request for Benefits” form should be edited to allow for more in-depth information to be given about the “willful misconduct” alleged, the injury, and the injury’s consequences. It should ask specific questions formulated to seek information about each necessary aspect of the claim.

To achieve greater transparency, the CICIP must publish information about the decisionmakers of the CICIP. In addition to the adjudicators’ qualifications, HRSA should reveal how decisions are made. Are claims judged via a panel discussion, a unanimous or majority vote by a team, or just by one person? The answer is currently unclear. HRSA might argue this violates the decisionmakers’ right to privacy and subjects them to harassment, and potentially violence,<sup>188</sup> from disappointed claimants. However, decisionmakers are often required to give up their privacy when they step into a powerful role. Even despite safety concerns, Article III and state judges are not allowed to hide behind a veil in the interest of safety.<sup>189</sup> The same is true for the special masters of the VICP and Kenneth Feinberg, the former adjudicator of the September 11th Victim Compensation Fund.<sup>190</sup>

Finally, the CICIP must publish, and adhere to, deadlines for when they will update claimants on the status of their cases. Rather than ignoring claimants until final decisions are made, CICIP decisionmakers must contact claimants with an interim decision and/or any outstanding questions they have for the claimant to give the claimant an opportunity to explain any grey areas or provide additional needed information. This gives claimants the opportunity to advocate for themselves.

The CICIP must also extend the deadline by which claimants can file in the program. The deadline currently is one year after the administration of the countermeasure.<sup>191</sup> Specifically for the COVID-19 vaccine, due to the staggered rollout, this deadline for some vaccine recipients may pass before the entire population has been vaccinated and before some injuries are identified. Two changes are needed. First, the starting date for the timeline of filing a claim should be changed from the date of the administration of the vaccine to the date symptoms first manifest. Second, the deadline for filing a claim should be extended to two years from the manifestation of the first symptom to allow more individuals to file claims. This extends the applicable filing period substantially while not rising to the full amount of time allowed in the VICP.

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<sup>186</sup> See HRSA, COUNTERMEASURES INJURY COMPENSATION PROGRAM, *supra* note 62, at 4–5.

<sup>187</sup> See Alltucker, *supra* note 30.

<sup>188</sup> See, e.g., Nicole Hong, William K. Rashbaum & Mihir Zaveri, ‘Anti-Feminist’ Lawyer is Suspect in Killing of Son of Federal Judge in N.J., N.Y. TIMES (July 22, 2020), <https://www.nytimes.com/2020/07/20/nyregion/esther-salas.html> [<https://perma.cc/UZV6-7VGG>].

<sup>189</sup> See Madison Alder, *Online Privacy Shield for Judges Advanced by Senate Judiciary*, BLOOMBERG LAW (Dec. 2, 2021), <https://news.bloomberglaw.com/us-law-week/online-privacy-shield-for-judges-advanced-by-senate-judiciary> [<https://perma.cc/PMG9-48HG>] (last accessed May 29, 2022).

<sup>190</sup> The September 11th Victim Compensation Fund was created to protect the airline industry, World Trade Center, and others from litigation after the 9/11 attacks, while providing assistance to those who were injured or lost a family member. See Meyers, *supra* note 2, at 7.

<sup>191</sup> See *Filing for Benefits*, *supra* note 64.

To further increase transparency, the CICIP must highlight the existing limitations on damages. Being clearer on this point may decrease the number of claims filed because claimants will realize prior to filing a claim that it will not lead to a “payout” of pain and suffering benefits. During use of the CICIP for prior public health emergencies, ten claims were found eligible for compensation but without any compensable economic damages.<sup>192</sup> Adjudicating claims like these are a waste of the CICIP’s resources. These occurrences make the program look stingy and as if there are meritorious injury claims that are simply being ignored, further risking increased anti-vaccine sentiment. HRSA should increase awareness of the CICIP’s damages limitations by amending the “Request for Benefits” form to include an explanation at the top of the form of what damages are available, including an explicit declaration that neither pain and suffering awards nor any kind of “punitive damages” are available through the program. Currently, the form says the CICIP “provides certain medical and lost employment income” but does not specifically disclaim what is *not* compensable by the program.<sup>193</sup>

An important, but potentially risky, change would be a rule requiring the CICIP to publicly publish its decisions. Publicly publishing decisions would make the program more transparent, help potential claimants decide whether to pursue claims within the program, and show the public that serious injuries and deaths from the vaccine are relatively rare. At the same time, publishing decisions may have the negative effect of increasing anti-vaccine sentiment. The number of uncompensated claims, particularly due to the CICIP’s strict standards, could be easily incorporated into misinformation spread in anti-vaccine communities and lead to even more negative opinions regarding the COVID-19 vaccines. While numbers relative to the number of people receiving the vaccine are low, they still may be misinterpreted as posing a real threat due to compression bias.<sup>194</sup> While the transparency of published decisions is appealing, ultimately, the potential risks outweigh the benefits because the numbers are likely to be misinterpreted.

In addition to increasing transparency, HRSA must ground the CICIP in a strong reputation of scientific credibility. The CICIP should borrow the knowledge of an experienced special master to adjudicate claims. Special masters have extensive experience reviewing medical records and evaluating causation theories.<sup>195</sup> To enable a special master to move to the CICIP program, VICP clerks must rearrange their dockets to free up one special master’s schedule for the foreseeable future. This special master will temporarily cease their VICP duties to work with CICIP staff instead. Because this solution has the negative externality of fewer special masters in the VICP, the VICP will need to appoint additional special masters. Advocates have been lobbying the VICP to appoint additional special masters for several years due to overwhelmed dockets.<sup>196</sup>

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<sup>192</sup> See *Countermeasures Injury Compensation Program (CICP) Data*, *supra* note 48.

<sup>193</sup> See HEALTH RES. & SERVS. ADMIN., COUNTERMEASURES INJURY COMPENSATION PROGRAM REQUEST FOR BENEFITS FORM (last updated Mar. 10, 2020), <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-request-form.pdf>.

<sup>194</sup> Compression bias “causes people to over-estimate the frequency of rare risks such as those associated with vaccination.” Siddiqui et al., *supra* note 94, at 2643.

<sup>195</sup> See *Vaccine Claims/Office of Special Masters*, U.S. CT. OF FED. CLAIMS, <https://www.uscfc.uscourts.gov/vaccine-program-readmore> [<https://perma.cc/JLC6-YVMU>].

<sup>196</sup> See H.R. 3003, 116th Cong. (2019); S. 1638, 116th Cong. (2019).

HRSA must allow compensation for attorney's fees in order to give all CICIP claimants the right to an attorney. Obviously, the types of damages that can be awarded depends on how much funding is available and how the program is funded. Payments from the CICIP will come out of the \$30 billion Congress designated for HHS to fight COVID, which included funding vaccine development.<sup>197</sup> The CICIP's current funding model is a finite amount that can only be augmented through a grant from Congress, whereas VICP funding continually grows through the collection of excise taxes on vaccine doses.<sup>198</sup> The CICIP should adopt a rolling funding model of collecting taxes on doses of COVID-19 vaccines to ensure funds continue to be available as more of the population gets vaccinated.

After adopting a rolling funding model, the CICIP should apply the "good faith and under reasonable basis" standard for attorney's fees reimbursement used in the VICP. This standard will enable the CICIP to avoid paying attorney's fees for meritless claims, including those clearly based on anti-vaccine conspiracies. Allowing for the payment of attorney's fees will incentivize attorneys to promote the program and take on clients. While attorneys are not necessary to file a claim in the CICIP, attorneys can help claimants understand whether they are likely to succeed, how best to present their facts, and counsel them on their recovery rights. An experienced attorney can help a claimant understand the strict restrictions such suits are subject to and what it will take to prove "willful misconduct." Most importantly, counsel by an attorney will be crucial for claimants who are awarded damages by the CICIP and tasked with deciding whether to accept the award or pursue civil litigation.

If HRSA does not amend the CICIP, others may take the situation into their own hands and change the program from the outside. The following outlines three practical solutions for eliminating some of the problems with the CICIP and establishing a better process for adjudicating COVID-19 claims by action by parties outside of HHS.

*B. Option II: Congress Amends the PREP Act Declaration to Discontinue the Usage of the CICIP for COVID-19 Vaccines and Incorporates the COVID-19 Vaccines into the VICP Instead*

Another potential change would be for Congress to amend the PREP Act declaration to eliminate the CICIP's usage for COVID-19 vaccines entirely and instead direct COVID-19 vaccine injury claims into the VICP. This would be done by adding the COVID-19 vaccine to the Vaccine Table. The Table is modified by regulation through a notice-and-comment period.<sup>199</sup> Putting the COVID-19 vaccines on the Table will allow claimants to access the same resources available to VICP petitioners, including the right to a hearing and right to be awarded attorney's fees. Because the VICP adjudicates through hearings and publishes its decisions,<sup>200</sup> it is a much more transparent program than the CICIP. It also allows petitioners the right to judicial

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<sup>197</sup> See Tom Hals, *Lawyers Urge Use of 'Vaccine Court' Over U.S. Injury Compensation Fund for Coronavirus*, INSURANCE J. (Aug. 24, 2020), <https://www.insurancejournal.com/news/national/2020/08/24/580098.htm> [<https://perma.cc/G3SK-VGT5>].

<sup>198</sup> See *About the National Vaccine Injury Compensation Program*, *supra* note 6.

<sup>199</sup> See *Frequently Asked Questions*, *supra* note 45.

<sup>200</sup> See VACCINE RULES, R. U.S. CT. FED. CL. APP. B 3, 36.

review through appeal to the Court of Federal Claims, Federal Circuit, and Supreme Court.

With this model, however, there are also a few hurdles. First, it would have to be determined whether there would be a causation-presumed avenue for adjudicating COVID-19 claims<sup>201</sup> or if all claims would be causation-in-fact.<sup>202</sup> In order for there to be causation-presumed claims for the COVID-19 vaccines, enough time would need to pass for there to be an adequate understanding of the illnesses and injuries, if any, caused by the COVID-19 vaccine and the timeline in which the first symptoms of the injury manifests. Thus, any COVID-19 claims on the Table would be more likely causation-in-fact, in which the petitioner sets forth a theory of causation and proves it by the preponderance of the evidence.<sup>203</sup> A second problem with this plan is that the VICP's special masters' dockets are already overwhelmed.<sup>204</sup> Interested parties have been calling for the hiring of additional special masters for years.<sup>205</sup> The attorneys of the Department of Justice, Civil Division's Torts Branch, who advocate on behalf of HHS at VICP hearings, are similarly overwhelmed. The Department of Justice recently issued a job posting for these roles, which indicated an interest in hiring up to thirteen new attorneys to defend the fund.<sup>206</sup>

### *C. Option III: Congress Amends the PREP Act to Require Greater Transparency in the CICP*

If HRSA is reticent to amend CICP on its own, Congress could amend the PREP Act to require the CICP adopt certain practices that will make it more transparent. For example, Congress could amend PREP to require the CICP announce who the adjudicators of the fund are and hire a special master to help adjudicate claims. Congress could also amend PREP to add oversight or reporting requirements to Congress.

### *D. Option IV: Congress Creates New Program for Adjudicating COVID-19 Vaccine Claims*

As a fourth option, Congress could create a new program for adjudicating COVID-19 vaccine claims by passing a law like the National Childhood Vaccine Injury Act of 1986, which created the VICP. Like the VICP, the program would be placed within the review jurisdiction of the Court of Federal Claims and be adjudicated in part by the Office of Special Masters. However, unlike the VICP, the program could also draw on elements of the September 11th Compensation Fund, administered by Kenneth

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<sup>201</sup> If causation-presumed claims were available to petitioners, the criteria would need to be outlined on the Table. The Table would outline the injury, first symptom, and time by which the first manifestation of the symptom would occur. If a claim fulfilled this criteria, causation would be presumed. This is how the VICP Table works. Vaccine Injury Table, 42 U.S.C. § 300aa-14.

<sup>202</sup> *See id.*

<sup>203</sup> *See* OFF. OF SPECIAL MASTERS, *supra* note 16.

<sup>204</sup> *See* H.R. 3003, 116th Cong. (2019); S. 1638, 116th Cong. (2019).

<sup>205</sup> *See id.*

<sup>206</sup> *See Trial Attorney-Torts Branch/Constitutional & Specialized Torts Litigation-Vaccine*, U.S. DEPT OF JUST. (updated Feb. 25, 2021), <https://www.justice.gov/legal-careers/job/trial-attorney-torts-branch-constitutional-specialized-torts-litigation-vaccine-0> [<https://perma.cc/QRQ6-U69E>].

Feinberg.<sup>207</sup> The September 11th Compensation Fund is considered to have “largely succeeded in providing compensation that was generous, prompt, and fair to the petitioners.”<sup>208</sup> One key aspect of the September 11th Compensation Fund was that all claimants in the program had the opportunity to meet in person with the adjudicators and advocate their case, in a manner more informal than the hearings utilized in the VICP.<sup>209</sup> In order to utilize the best available expertise, one or more of the special masters’ dockets could be cleared in order to take on Feinberg’s role. Alternatively, a newly hired special master, or multiple, with experience with vaccine claims could take on this role.

## V. CONCLUSION

Throughout the COVID-19 pandemic, there has been a global spotlight on the development and distribution of COVID-19 vaccines. With anti-vaccine sentiment already rising for several years,<sup>210</sup> the COVID-19 vaccines need to overcome additional skepticism based on their accelerated development processes. Vaccine injuries are extremely rare, but they do occur. As of spring 2021, there were already at least forty-eight claims of injury related to the COVID-19 vaccines.<sup>211</sup> The program set up to adjudicate these claims, the CICP, is extremely opaque and has a poor history of compensating claimants.<sup>212</sup> The VICP has the same goals as the CICP of immunizing vaccine manufacturers and distributors from liability. However, it has been much more successful at compensating petitioners. As the world emerges from the devastating COVID-19 pandemic, the U.S. government needs to ensure there is a transparent and petitioner-friendly compensation program accessible to anyone who believes they have been injured by a vaccine. The best way to accomplish this is by HRSA internally changing the procedures of the CICP to incorporate elements of the VICP or by Congress requiring HRSA to do so by law.

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<sup>207</sup> See Meyers, *supra* note 2, at 7.

<sup>208</sup> See *id.* at 7–8.

<sup>209</sup> See *id.* at 7.

<sup>210</sup> See Angeley, *supra* note 100, at 271.

<sup>211</sup> See *Countermeasures Injury Compensation Program (CICP) Data*, *supra* note 48.

<sup>212</sup> See Meyers, *supra* note 2, at 4–5.