

At-Risk Populations & Vaccine Injury Compensation

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I INTRODUCTION

Developing a new vaccine takes, on average, ten years.¹ In the case of COVID-19, however, the pharmaceutical industry developed vaccines in a matter of months, and three quickly received emergency use authorization (EUA).² As discussed in Chapter 15, by Sachs, Ouellette, Price, and Sherkow, and in others in this volume, this record-breaking pace of development raised concerns regarding rare undetected side effects and ones that would manifest only in the long term.

This chapter argues that the potential for vaccine-related harms raises acute concerns for vulnerable populations. These harms have a disparate impact on low-income people, who are disproportionately non-White, and who have limited financial resources to obtain medical care, weather job losses, and pursue injury compensation. When a vaccine is given as a countermeasure during a declared public health emergency (PHE), the problem is acute because of the limited availability of injury compensation.

This chapter reviews and assesses the two existing mechanisms to which injured parties can turn for remedies: (1) the National Vaccine Injury Compensation Program (VICP), which applies to most vaccines given in the United States; and (2) the far less generous and less accessible Countermeasures Injury Compensation Program (CICP), which applies to vaccinations given as

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¹ The Coll. of Physicians of Phila., Vaccine Development, Testing, and Regulation, History of Vaccines. org, www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation (last updated Jan. 17, 2018).

² US Food & Drug Admin., FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020), www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid; Jen Christensen, Johnson & Johnson's COVID-19 Vaccine Gets Emergency Use Authorization From FDA, CNN (Feb. 27, 2021), www.cnn.com/2021/02/27/health/johnson-johnson-covid-19-vaccine-fda-eua/index.html.

countermeasures during PHEs.³ It highlights the health and financial disparities suffered by vulnerable populations during a pandemic and its aftermath, and how the CICP intensifies these disparities. This chapter then develops a proposal for legal reform to the injury-compensation and vaccine-approval processes that aims to protect the disadvantaged and enhance equity.

II VACCINE SIDE EFFECTS

During the COVID-19 pandemic, Pfizer/BioNTech and Moderna enrolled 44,000 and 30,000 subjects, respectively, in the studies upon which they relied to obtain initial EUA from the Food and Drug Administration (FDA).⁴ With tens of thousands of trial participants, common side effects that occur fairly soon after vaccination were identified.⁵ But there was little opportunity to identify adverse events that might appear in the longer term or that are rare enough that they would be discovered only after a significant percentage of the public had been vaccinated. Such side effects could include joint pain, anaphylaxis, and neurological conditions such as encephalitis, transverse myelitis, or Guillain-Barré Syndrome, which are known to occur with other vaccines.⁶ A case in point is the National Swine Flu Immunization Program. In 1976, the federal government decided to protect the public from swine flu and quickly advanced the administration of a vaccine. Forty million vaccines were administered in just a few months. Unfortunately, 450 vaccinated people developed Guillain-Barré Syndrome, a rare and serious neurological disorder that can result in muscle weakness and paralysis.⁷ The program was quickly suspended, but the harm was done. Regrettably, it triggered an enduring public

³ A countermeasure is defined as a “vaccination, medication, device, or other item recommended to diagnose, prevent or treat a declared pandemic, epidemic or security threat.” Health Res. & Servs. Admin., Countermeasures Injury Compensation Program (CICP), www.hrsa.gov/cicp (last visited Nov. 2020).

⁴ Denise Grady & Katie Thomas, Moderna and Pfizer Reveal Secret Blueprints for Coronavirus Vaccine Trials, NY Times (Sept. 17, 2020), www.nytimes.com/2020/09/17/health/covid-moderna-vaccine.html.

⁵ Helen Branswell, Comparing the Covid-19 Vaccines Developed by Pfizer, Moderna, and Johnson & Johnson (February 2, 2021), www.statnews.com/2020/12/19/a-side-by-side-comparison-of-the-pfizer-biontech-and-moderna-vaccines/.

⁶ Health Res. & Servs. Admin., Vaccine Injury Table, www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf (last visited Jan. 5, 2021). For example, the possibility that the AstraZeneca and Johnson & Johnson vaccines could cause extremely rare, life-threatening blood clots was not discovered until millions of people had been vaccinated. Angela Dewan, et. al., Here’s What to Know About the Risk of Blood Clots and the AstraZeneca Vaccine, CNN (Apr. 3, 2021), www.cnn.com/2021/04/02/health/astrazeneca-blood-clots-explainer-intl-cmd-gbr/index.html; Anne Flaherty, Rare Reactions to Johnson & Johnson Vaccine Remain a Mystery, Putting Many Women on Edge, ABC News (Apr. 17, 2021), <https://abcnews.go.com/Politics/rare-reactions-johnson-johnson-vaccine-remain-mystery-putting/story?id=77092178>.

⁷ Rebecca Kreston, The Public Health Legacy of the 1976 Swine Flu Outbreak, Discover Mag. (Sept. 30, 2013), www.discovermagazine.com/health/the-public-health-legacy-of-the-1976-swine-flu-outbreak.

mistrust of flu vaccinations and often appears as part of the anti-vaccination movement's narrative.⁸

III VACCINE INJURY COMPENSATION PROGRAMS

The United States is fortunate to have a robust system to compensate individuals who suffer vaccine injuries. This system, however, is not available to those vaccinated with a countermeasure during a declared PHE.

A The National Vaccine Injury Compensation Program

The VICP is normally available to anyone who is injured by a vaccine after the FDA approves it and the Centers for Disease Control and Prevention (CDC) recommends it for children or pregnant women.⁹ The VICP covers most vaccines administered in the United States. This no-fault program was created in the 1980s to ensure relatively quick and fair compensation for vaccine injuries and to insulate manufacturers from liability as an incentive for them to pursue vaccine development.¹⁰ Claimants who develop recognized symptoms of injuries listed in the Vaccine Injury Table within a certain amount of time after vaccination need not prove that the injuries were caused by the vaccine. Rather, they present evidence only about the extent of their damages.¹¹ When an injury is not listed in the Vaccine Injury Table, petitioners must prove that it was caused or exacerbated by the vaccine.¹² Claim denials can be appealed to the Court of Federal Claims.¹³

The VICP offers up to \$250,000 for pain, suffering, and emotional distress,¹⁴ as well as attorneys' fees and legal expenses to good-faith claimants.¹⁵ At the end of

⁸ *Id.*

⁹ Health Res. & Servs. Admin., Covered Vaccines, www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html (last visited Dec. 2020).

¹⁰ Health Res. & Servs. Admin., About the National Vaccine Injury Compensation Program, www.hrsa.gov/vaccine-compensation/about/index.html (last visited Dec. 2020) (hereinafter, About VICP); Health Res. & Servs. Admin., National Vaccine Injury Compensation Program, www.hrsa.gov/vaccine-compensation/index.html (last visited Nov. 2020).

¹¹ Health Res. & Servs. Admin., Who Can File a Petition?, www.hrsa.gov/vaccine-compensation/eligible/index.html (last visited Dec. 2020); Health Res. & Servs. Admin., Frequently Asked Questions, www.hrsa.gov/vaccine-compensation/faq (last reviewed Apr. 2023).

¹² The Off. of Special Masters, US Ct. of Fed. Claims, Guidelines for Practice Under the National Vaccine Injury Compensation Program 47 (2020), www.uscfc.uscourts.gov/sites/default/files/Guidelines-4.24.2020.pdf.

¹³ *Id.*

¹⁴ Health Res. & Servs. Admin., What You Need to Know About the National Vaccine Injury Compensation Program (VICP), 12 (2019), www.hrsa.gov/sites/default/files/hrsa/vicp/about-vaccine-injury-compensation-program-booklet.pdf.

¹⁵ Health Res. & Servs. Admin., How to File a Petition, www.hrsa.gov/vaccine-compensation/how-to-file/index.html (last visited Dec. 2020). Prior to 2017, the average time to resolve a VICP case was 575 days, or approximately 1.5 years. In 2017, HHS adopted a final rule that added Shoulder Injury Related to Vaccine Administration (SIRVA) injuries to the Vaccine Injury Table. SIRVA injuries are injuries

2022, the Vaccine Injury Compensation Trust Fund (VICTF) was valued at over \$4 billion.¹⁶ The VICTF is funded by a seventy-five-cent excise tax on each vaccine dose, which is paid by the manufacturers.¹⁷ From 2006 through 2018, the VICP approved about 70 percent of claims.¹⁸ Since 2015, the fund has paid out an average of \$216 million per year to an average of 615 claimants per year.¹⁹

B *The Countermeasures Injury Compensation Program*

The benefits offered under the VICP are not available to people injured by vaccines given as countermeasures during declared PHEs.²⁰ When the Department of Health and Human Services (HHS) declares a PHE, it triggers the Public Readiness and Emergency Preparedness (PREP) Act.²¹ This federal law requires that claimants bring claims relating to countermeasures that are used during a PHE exclusively under the CICIP.²² Such countermeasures include not only vaccines, but also drugs, equipment, and more. Awards under the CICIP are paid by the Covered Countermeasures Process Fund (CCPF). Congress funds the CCPF through emergency appropriations to HHS that HHS may transfer to the CCPF.²³ Manufacturers do not contribute to this fund as they do to the VICTF.

related to the intramuscular injection of a vaccine. Adding these SIRVA claims “dramatically” increased the number of claims filed in the VICP. Since 2017, the average amount of time for a VICP case to finally resolve has increased significantly, to 751 days, or approximately two years. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 85 Fed. Reg. 43794 (proposed July 20, 2020) (to be codified at 42 C.F.R. pt. 100), www.federalregister.gov/documents/2020/07/20/2020-15673/national-vaccine-injury-compensation-program-revisions-to-the-vaccine-injury-table.

¹⁶ United States Department of the Treasury, Vaccine Injury Trust Fund, Nov. 2022, www.treasurydirect.gov/ftp/dfi/tfmb/dfvii122.pdf, at 6.

¹⁷ About VICP, *supra* note 10 (“Trivalent influenza vaccine ... is taxed \$.75 because it prevents one disease; measles-mumps-rubella vaccine, which prevents three diseases, is taxed \$2.25.”).

¹⁸ Ken Alltucker, Consumers Filed 106 Injury Claims From COVID-19 Vaccines, Ventilators and Hydroxychloroquine. Here’s Why None Have Been Paid, USA Today (Mar. 28, 2021), www.usatoday.com/story/news/health/2021/03/28/covid-19-vaccines-hydroxychloroquine-generate-dozens-injury-claims/6995509002/.

¹⁹ Tom Hals, COVID-19 Era Highlights U.S. ‘Black Hole’ Compensation Fund for Pandemic Vaccine Injuries, Reuters (Aug. 21, 2020), www.reuters.com/article/us-health-coronavirus-vaccines-liability/covid-19-era-highlights-u-s-black-hole-compensation-fund-for-pandemic-vaccine-injuries-idUSKBN25H1E8.

²⁰ Cong. Rsch. Serv., The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures (Sept. 21, 2020), <https://crsreports.congress.gov/product/pdf/LSB/LSB10443>.

²¹ 42 U.S.C. § 247d-6d.

²² Cong. Rsch. Serv., *supra* note 20.

²³ *Id.* Both the Coronavirus Aid, Relief, and Economic Security (CARES) Act and the Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSA) appropriate funding that HHS may use for the Covered Countermeasure Process Fund. “CPRSA appropriates \$3.1 billion to the Secretary to respond to COVID-19, including the development and purchase of countermeasures and vaccines, while allowing these funds to ‘be transferred to, and merged with’ the Covered Countermeasure Process Fund. Similarly, the CARES Act appropriates \$27 billion to the Secretary for similar purposes, again providing that the Secretary may transfer these funds to the Covered Countermeasure Process Fund.” *Id.*

The CICIP is far less generous than the VICP.²⁴ It compensates people only for serious injuries,²⁵ requires a heightened burden of proof regarding injury causation,²⁶ and has a one-year statute of limitations following the date of vaccination.²⁷ Individuals are bound by the one-year filing deadline regardless of when their symptoms appear or are determined to be associated with the vaccine. Furthermore, the deadline applies to pregnant women, who must file claims on behalf of their babies within one year of being themselves vaccinated, leaving parents with only a few months to discover any injuries after their baby is born.²⁸ The CICIP also limits damages awards.²⁹ For example, under the CICIP, claimants can recover a maximum of only \$50,000 in lost income for each year out of work. The CICIP also denies any compensation for pain, suffering, and emotional distress, as well as for attorneys' fees and costs.³⁰ There is no opportunity to appeal claim denials.³¹

Furthermore, the CICIP process for pursuing compensation is lengthier, more difficult, and more expensive because of the absence of reimbursement for attorneys' fees and costs.³² It is important to note that those receiving countermeasure vaccines

²⁴ Health Res. & Servs. Admin., Comparison of Countermeasures Injury Compensation Program (CICIP) to the National Vaccine Injury Compensation Program (VICP), www.hrsa.gov/cicp/cicp-vicp (last viewed Nov. 2020).

²⁵ Serious injuries are generally those that warrant hospitalization or lead to a significant disability, loss of function, or death. 42 C.F.R. § 110.3(z). Some of the most common injuries caused by *all* vaccines, including COVID-19 vaccines, which are not likely to be viewed as "serious" and will not warrant compensation under the CICIP, are SIRVA injuries. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, *supra* note 15. SIRVA injuries are injuries related to the intramuscular injection of a vaccine. *Id.* The costs associated with these shoulder injuries can be significant as these injuries can prevent those whose jobs involve lifting from being able to work for, potentially, long periods of time. Examples of positions that involve lifting include nurses, nursing aids, grocery workers, meat processors, firefighters, and custodial staff, just to name a few. Many of these front-line positions are filled by people from low-income and minority populations. The CICIP's narrow compensation scheme results in these workers being left to bear the cost of the losses associated with these SIRVA injuries as they will never be compensated for these injuries if they were vaccinated during the PHE.

²⁶ Determinations of causation must be "based on compelling, reliable, valid, medical and scientific evidence." 42 U.S.C. § 247d-6e(b)(4).

²⁷ 42 C.F.R. § 110.42.

²⁸ 42 C.F.R. § 110.3(n)(1)(3); Countermeasures Injury Compensation Program (CICIP): Administrative Implementation, Interim Final Rule, 75 Fed. Reg. 63666 (Oct. 15, 2010) (codified at 42 C.F.R. pt. 110) (corrected by Countermeasures Injury Compensation Program (CICIP): Administrative Implementation, Interim Final Rule, 758 Fed. Reg. 64955 (Oct. 21, 2010)), www.federalregister.gov/documents/2010/10/15/2010-25110/countermeasures-injury-compensation-program-cicp-administrative-implementation-interim-final-rule.

²⁹ Health Res. & Servs. Admin., Countermeasures Injury Compensation Program Request for Benefits Form Instructions 1-2, www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-request-form-instructions.pdf (last updated Mar. 2020).

³⁰ Health Res. & Servs. Admin., About CICIP, www.hrsa.gov/cicp/about (last visited Nov. 2020); Nicholas M. Pace et al., COVID-19 Vaccine Campaign Must Include Fair Compensation for Side Effects, *The Hill* (Dec. 17, 2020), thehill.com/opinion/healthcare/530546-the-compensation-system-for-potential-side-effects-is-an-important-part-of.

³¹ 42 U.S.C. § 247d-6d(b)(5)(C).

³² See *supra* text accompanying notes 30.

during a declared PHE can never pursue injury claims under the VICP, even if their symptoms appear or are linked to the vaccine after the declaration is lifted.³³ If they were vaccinated during a declared PHE, they are forever barred from the VICP with respect to the injection in question.

The CICIP was first implemented in 2010.³⁴ Up until 2020 and the declared COVID-19 PHE, the CICIP received 485 claims (mostly related to the H1N1 vaccine approved in 2009) but awarded compensation to only 39 people, for a total of \$5.7 million.³⁵ While the VICP has a 70 percent payment rate for claims filed from 2006 through 2018, the CICIP has rejected 90 percent of injury claims since it was created.³⁶ As of the end of March 2023, 11,252 COVID-19-related claims were filed with the CICIP.³⁷ As of March 1, 2023, the CICIP rendered decisions on 630 COVID-19 claims. Twenty-one claims were granted, and 630 were denied.³⁸ Over two-thirds of the claims were for vaccines, with the remainder relating to other COVID-19 treatments.³⁹

IV PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT TRADEOFFS

PREP Act immunity for all countermeasures is designed to accomplish two main goals. First, this immunity encourages manufacturers to speed innovative treatments to market during declared PHEs when there are no other viable treatments. Manufacturers are more willing to skip the usual time it takes to invest in safety through testing when they are given immunity from liability.

Second, PREP Act immunity is an attempt to manage the risk that quickly designed and produced countermeasures might cause a large number of injuries. At the same time that manufacturers are being encouraged to forego their usual testing protocols, PHEs drive the FDA to speed the temporary licensure of countermeasures using a lower standard of safety and effectiveness through its fast-track EUA process.⁴⁰ Together, these measures hold the potential to increase the number and seriousness of any unintended countermeasure injuries.

³³ Countermeasures Injury Compensation Program (CICIP): Administrative Implementation, Interim Final Rule, 75 Fed. Reg. at 63,666.

³⁴ Health Res. & Servs. Admin., HHS Sets Regulations to Implement Countermeasures Injury Compensation Program (Oct. 15, 2010), www.hrsa.gov/about/news/press-releases/2010-10-15-cicip.html.

³⁵ Hals, *supra* note 19.

³⁶ Alltucker, *supra* note 18.

³⁷ Health Res. & Serv. Admin, Countermeasures Injury Compensation Program (CICIP) Data, <https://www.hrsa.gov/cicip/cicip-data#table-1> (last visited April 5, 2023).

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ Under § 564(a)(1) of the Federal Food, Drug, and Cosmetic Act, the FDA can issue an EUA when the product may be effective in diagnosing, treating, or preventing the disease or condition; the known and potential benefits outweigh the known and potential risks; and there is no adequate, approved, and available alternative to the product for diagnosing, treating, or preventing such disease or condition. Guidance for Industry, Emergency Use Authorization of Medical Products and Related Authorities, 82 FR 4362 (Jan. 13, 2017), www.federalregister.gov/documents/2017/01/13/2017-00721/emergency-use-authorization-of-medical-products-and-related-authorities-guidance-for-industry-and.

The tradeoffs that are the centerpiece of the PREP Act may make some sense for most countermeasures, but they do not appear to do so for vaccines. First, countermeasures that have the greatest potential to cause injuries are treatments such as drugs and devices (e.g. antiviral medication and ventilators), which will be used to treat those who have fallen ill from pandemic-triggering diseases. The manufacturers of these countermeasures have no immunity absent the PREP Act. Consequently, granting these manufacturers immunity to encourage their speed to market, while providing sick consumers with quick access to possible treatments, provides a positive tradeoff for consumers for the loss of access to compensation for all but the most serious of injuries.

In contrast, vaccines, as preventatives, fall into a different category. First, the target population for vaccines is healthy people. As such, there is no “access to treatment” benefit for this population that provides a tradeoff for withholding compensation for injuries. Second, in the context of vaccines, there already is a system, the VICP, that, in the absence of the PREP Act, offers immunity to manufacturers to encourage speed to market while adequately compensating *all* people who are injured by vaccines. It is simply unethical to severely limit compensation for healthy consumers who are injured after agreeing to be vaccinated with an experimental vaccine. They often do so not only for their own benefit, but also for the good of society in that their vaccination promotes herd immunity.

V VULNERABLE POPULATIONS AND THE VACCINE INJURY COMPENSATION PROBLEM

People are less likely to obtain compensation for injuries arising from vaccines they received as countermeasures during a declared PHE than they are for injuries associated with vaccines included in the VICP. Furthermore, the VICP process for pursuing compensation is more burdensome.⁴¹ Those receiving countermeasure vaccines during a declared PHE can never pursue injury claims under the VICP, even if their symptoms appear or are linked to the vaccine after the declaration is lifted.⁴²

These concerns are particularly acute for low-income people and people of color because these groups typically endure the greatest difficulties during public health disasters and their aftermaths. During the COVID-19 pandemic, racial and ethnic minorities suffered a death rate that was more than double that of White people.⁴³

⁴¹ See *supra* text accompanying notes 30–31.

⁴² Countermeasures Injury Compensation Program (VICP): Administrative Implementation, Interim Final Rule, 75 Fed. Reg. at 63,666.

⁴³ Nat'l Urb. League, State of Black America Unmasked: 2020 Executive Summary 12, <http://sobadev.iamempowered.com/sites/soba.iamempowered.com/files/NUL-SOBA-2020-ES-web.pdf> (last visited Dec. 30, 2020); Dylan Scott & Christina Animashaun, COVID-19's Stuningly Unequal Death Toll in America, in *One Chart*, Vox (Oct. 2, 2020), www.vox.com/coronavirus-covid19/2020/10/2/21496884/us-covid-19-deaths-by-race-black-white-americans.

Likewise, infection rates were significantly higher in economically disadvantaged areas than in wealthier ones.⁴⁴ Similar patterns were evident in past disasters, such as the 1918 Spanish influenza pandemic.⁴⁵ Vaccinating members of minority and low-income populations during pandemics should therefore be a high priority.

A Vaccine Hesitancy and Lack of Access to Compensation

At the same time, however, there are high levels of vaccine skepticism and reluctance to be vaccinated in poor and minority communities.⁴⁶ In some cases, vaccine hesitancy may stem from long-standing inequities in medical treatment and abuses that have resulted in general mistrust of government. A well-known example is the infamous Tuskegee Study.⁴⁷ In this study, which lasted from 1932 until 1972, researchers deprived African American men of penicillin for syphilis, without informing them that a cure was available, because they wanted to study the natural course of the disease.⁴⁸

In a Kaiser Family Foundation poll conducted in August and September 2020, 49 percent of Black respondents stated that they would probably not or definitely not accept a COVID-19 vaccine, compared with 33 percent of White respondents.⁴⁹ Similarly, a Pew Research Center poll conducted in November 2020 revealed that while 71 percent of Black respondents knew someone who had been hospitalized or died because of COVID-19, only 42 percent planned to obtain a COVID-19 vaccine.⁵⁰

During 2021, overall hesitancy dropped as more information was gathered regarding the effectiveness and safety of the COVID-19 vaccines.⁵¹ However, hesitancy continued to be a significant concern among all groups.⁵² If the media had covered stories

⁴⁴ Phillip Reese, High-Poverty Neighborhoods Bear the Brunt of COVID's Scourge, Kaiser Health News (Dec. 15, 2020), <https://khn.org/news/article/high-poverty-neighborhoods-bear-the-brunt-of-covids-scourge/>.

⁴⁵ Clare Bambra et al., The COVID-19 Pandemic and Health Inequalities, 74 *J. Epidemiol. Community Health* 964, 964 (2020).

⁴⁶ Shadim Hussain, We Need 'Horizontal' Trust to Overcome Vaccine Skepticism, Wired (Nov. 21, 2020), www.wired.com/story/we-need-horizontal-trust-to-overcome-vaccine-skepticism/.

⁴⁷ Rueben C. Warren et al., Trustworthiness Before Trust – COVID-19 Vaccine Trials and the Black Community, 383 *New Eng. J. Med.* e121, e121 (2020).

⁴⁸ Ctrs. for Disease Control & Prevention, The Tuskegee Timeline, www.cdc.gov/tuskegee/timeline.htm (last visited Mar. 2, 2020).

⁴⁹ Liz Hamel et al., Race, Health, and COVID-19: The Views and Experiences of Black Americans, Kaiser Fam. Found. 17 (Oct. 2020), <http://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf>.

⁵⁰ Cary Funk & Alec Tyson, Intent to Get a COVID-19 Vaccine Rises to 60% as Confidence in Research and Development Process Increases, *Pew Rsch. Ctr.* 6, 8 (Dec. 2020), www.pewresearch.org/science/wp-content/uploads/sites/16/2020/12/PS_2020.12.03_covid19-vaccine-intent_REPORT.pdf.

⁵¹ Emmarie Huettelman, Covid Vaccine Hesitancy Drops Among All Americans, New Survey Shows, Kaiser Health News (Mar. 30, 2021), <https://khn.org/news/article/covid-vaccine-hesitancy-drops-among-americans-new-kff-survey-shows/>.

⁵² Reuters Staff, COVID-19 Vaccine Hesitancy Among Black Americans Drops – Poll, Reuters (Mar. 30, 2021), www.reuters.com/article/us-health-coronavirus-vaccine-hesitancy-idUSKBN2BMoWY.

of individuals who were injured and not adequately compensated, vaccine hesitancy might have intensified. As the Presidential Commission for the Study of Bioethical Issues pointed out in the context of clinical trials generally, people may be more willing to participate in research if they are assured that they will be compensated if injured.⁵³ Similarly, people may be more willing to participate in mass vaccination programs if they know they will be taken care of in the event that they are harmed. Conversely, knowing that they will not be compensated may discourage participation.

B Compensation Inequities and Structural Racism

After an emergency declaration is lifted, newly vaccinated individuals can be eligible for VICP compensation if the CDC has recommended the vaccine for routine administration to children or pregnant women.⁵⁴ However, delaying vaccination until the end of a declared PHE can be particularly dangerous for minority and lower-income workers, including many essential workers. Many suffer from chronic conditions, such as asthma, heart disease, and diabetes, that make it more likely that they will suffer more severely from infectious diseases.⁵⁵ In addition, those with a lower socioeconomic status often have the highest risk of infection because they come in close contact with others at work, while taking public transportation, or while living in crowded households. In fact, employees working in person may have no choice as to whether to receive a vaccine once it is available. Employers may require workers to obtain vaccines. The US Equal Employment Opportunity Commission has determined that such employer mandates are lawful.⁵⁶

At the same time, low-income people who most need to be vaccinated are the most financially at risk. A serious vaccine injury could thus be catastrophic for them if they are not appropriately compensated. Having access only to the CICP rather than the VICP can thus have a disproportionate adverse impact on poor communities.

By contrast, the people who can afford to wait for vaccinations until an emergency declaration has ended, triggering VICP availability, will tend to be more

⁵³ Presidential Comm'n for the Study of Bioethical Issues, *Moral Science: Protecting Participants in Human Subjects Research* 61 (Dec. 2011; updated edition June 2012), <https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/Moral%20Science%20June%202012.pdf>.

⁵⁴ Health Res. & Servs. Admin., *Frequently Asked Questions*, www.hrsa.gov/cicp/faq (last visited Dec. 2020).

⁵⁵ Ctrs. for Disease Control & Prevention, *People with Certain Medical Conditions*, www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (last updated Dec. 29, 2020); Kenneth E. Thorpe et al., *The United States Can Reduce Socioeconomic Disparities by Focusing on Chronic Diseases*, *Health Affs. Blog* (Aug. 17, 2017), www.healthaffairs.org/doi/10.1377/hlblog20170817.061561/full/.

⁵⁶ US Equal Emp. Opportunity Comm'n, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws* (Dec. 16, 2020), www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws; Vimal Patel, *Employers Can Require Workers to Get COVID-19 Vaccine, U.S. Says*, *NY Times* (Dec. 18, 2020), www.nytimes.com/2020/12/18/us/eeoc-employers-coronavirus-mandate.html.

privileged. This group will probably consist largely of people who can work remotely and socially isolate until they feel confident about the vaccine's safety profile. They tend to be disproportionately well educated, high earners, and White.⁵⁷ If those with socioeconomic advantages choose to wait for vaccines while their working-class counterparts cannot, they may be compensated far more liberally for the same types of vaccine injuries. Differences between the VICP and CICP could therefore reinforce long-established inequities rooted in income, race, and ethnic identity.

VI PROPOSALS FOR LEGAL REFORM

We argue that anyone who receives a vaccine that is a countermeasure to a PHE should have immediate access to the VICP. Disadvantaged people with the greatest need for vaccination, who are also the most at risk of financial harm, should benefit from an efficient and fair system of injury compensation. Moreover, penalizing early recipients of vaccines could undermine the important public health goal of vaccinating as many people as possible as quickly as possible in order to achieve herd immunity.

Experts predict that the world will face future global pandemics, and many have long worried about bioterrorism attacks.⁵⁸ Establishing the correct incentives and relief mechanisms for people who receive vaccinations is therefore of critical importance.

A straightforward modification to address the inequities that the CICP propagates is to amend the PREP Act. Under this approach, lawmakers would establish that all vaccines that the FDA approves and the CDC recommends to ameliorate a PHE will be covered by the VICP, regardless of whether they are to be administered to pregnant women or children.⁵⁹ This would include vaccines receiving an EUA.⁶⁰

The carve-out would not impact any other countermeasures, such as drugs and devices, that have an EUA. Injury claims related to those countermeasures would

⁵⁷ Matt Simon, *Your Income Predicts How Well You Can Socially Distance*, *Wired* (Aug. 5, 2020), www.wired.com/story/your-income-predicts-how-well-you-can-socially-distance/; Vasil Yasenov, *Who Can Work from Home?*, *IZA – Inst. of Lab. Econ.* (May 4, 2020), www.iza.org/publications/dp/13197/who-can-work-from-home.

⁵⁸ *Reduce Risk to Avert 'Era of Pandemics,' Experts Warn in New Report*, *UN News* (Oct. 29, 2020), <https://news.un.org/en/story/2020/10/1076392>; *Greater Risk of Bioterrorism Post-Corona*, *Deutsche Welle* (May 25, 2020), www.dw.com/en/coronavirus-experts-warn-of-bioterrorism-after-pandemic/a-53554902.

⁵⁹ The provision to be amended is 42 U.S.C. § 247d–6d (i)(1). The following language could be added at the end of subparts (A) and (C) of this provision: “except that all vaccines that are recommended by the CDC for children or pregnant women are excluded from this Act and claims for injuries from these vaccines can be pursued under the Vaccine Injury Compensation Program.”

⁶⁰ Federal law empowers the FDA Commissioner to “allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions ... when there are no adequate, approved, and available alternatives.” US Food & Drug Admin., *Emergency Use Authorization*, www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last updated Jan. 25, 2022); 21 U.S.C. § 360bbb–3 (2010).

still be submitted to the CICP. The vaccine carve-out is justified because vaccines are given to healthy people in part for the good of society in that they protect the collective. By contrast, drugs and devices approved under an EUA are provided to unhealthy individuals to treat and cure their individual maladies. As this proposal deals solely with the liability of vaccine manufacturers, it also would not impact state and federal measures that provide immunity from liability to health care providers who administer vaccines.

The second element of this proposal is that Congress should require manufacturers to pay a seventy-five-cent excise tax per dose for all vaccines that the FDA approves and that the CDC recommends as PHE countermeasures. This excise tax will serve to ensure that the VICTF is adequately financed. As noted in Section III, such a tax already applies to vaccines included in the VICP.⁶¹ During a PHE, when the government purchases vaccines and then distributes them to the public without charge, part of this purchase price can be allocated to cover the excise tax. This action will provide immediate funding for the VICP to cover any increase in the number of claims. In addition, Congress should expand the number of special masters who handle VICP cases because this docket is likely to grow significantly.⁶² This measure will ensure that claims will be processed expeditiously.

VII CONCLUSION

Even the most carefully developed and tested vaccine can lead to injuries. Such injuries can disproportionately affect vulnerable populations who are most in need of vaccinations but are also at risk of financial ruin if harmed by a vaccine. Fortunately, injured parties can usually attain appropriate recovery through the generous and accessible VICP. However, during a declared PHE, individuals receiving vaccines that are countermeasures can turn only to the much less robust CICP if they are injured.

This difference is not simply technical. It can have severe ramifications, especially for disadvantaged populations. In some cases, people in high-risk communities may struggle to decide whether they should forego a vaccine and risk becoming infected, or risk a vaccine injury for which they could receive little if any compensation.

This chapter has proposed legal changes to rectify this wrong. It argues that the PREP Act should be amended to ensure that relevant vaccines are covered by the VICP rather than the CICP. Rendering the VICP available to all injured parties, including members of vulnerable communities, would advance multiple goals. It would promote public health by encouraging the public to pursue early vaccination, enhance equity, and increase the likelihood of adequate relief in all injury cases.

⁶¹ See *supra* note 17 and accompanying text.

⁶² US Ct. of Fed. Claims, Vaccine Claims/Office of Special Masters, www.uscfc.uscourts.gov/vaccine-program-readmore (last visited Jan. 17, 2021).

