

Faculty Publications

2022

Vulnerable Populations and Vaccine Injury Compensation: The Need for Legal Reform

Katharine A. Van Tassel

Case Western University School of Law, katharine.vantassel@case.edu

Sharona Hoffman

Case Western Reserve University School of Law, sharona.hoffman@case.edu

Follow this and additional works at: https://scholarlycommons.law.case.edu/faculty_publications

 Part of the [Food and Drug Law Commons](#), and the [Health Law and Policy Commons](#)

Repository Citation

Van Tassel, Katharine A. and Hoffman, Sharona, "Vulnerable Populations and Vaccine Injury Compensation: The Need for Legal Reform" (2022). *Faculty Publications*. 2092.
https://scholarlycommons.law.case.edu/faculty_publications/2092

This Book Chapter is brought to you for free and open access by Case Western Reserve University School of Law Scholarly Commons. It has been accepted for inclusion in Faculty Publications by an authorized administrator of Case Western Reserve University School of Law Scholarly Commons.

Vulnerable Populations and Vaccine Injury Compensation: The Need for Legal Reform[†]

Katharine Van Tassel, JD, MPH* and Sharona Hoffman, JD, LLM, SJD**

1. 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.² As discussed in the chapters by Sachs, Ouellette, Price, and Sherkow, among others in this volume, this record-breaking pace of development raised concerns regarding rare undetected side effects or 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.

The chapter reviews and assesses the two existing mechanisms to which injured parties can turn for a remedy: 1) the National Vaccine Injury Compensation Program (VICP), which applies to most vaccines given in the U.S. and, 2) the far less generous and less accessible Countermeasures Injury Compensation Program (CICP), which applies to vaccinations given as countermeasures³ during PHEs. It highlights the health and financial disparities suffered by

[†] This chapter is based in part on Katharine Van Tassel, Carmel Shachar & Sharona Hoffman, *Covid-19 Vaccine Injuries — Preventing Inequities in Compensation*, 384 NEW ENG. J. MED. ____ (2021).

* Visiting Professor of Law, Case Western Reserve University School of Law, Cleveland, Ohio.

** Edgar A. Hahn Professor of Law and Professor of Bioethics, Co-Director of Law-Medicine Center, Case Western Reserve University School of Law, Cleveland, Ohio.

¹ The College of Physicians of Philadelphia, *The History of Vaccines: Vaccine Development, Testing, and Regulation*, HISTORYOFVACCINES.ORG, <https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation> (last updated Jan. 17, 2018).

² U.S. Food & Drug Administration, *FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine* (Dec. 18, 2020), <https://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 (February 27, 2021), available at <https://www.cnn.com/2021/02/27/health/johnson-johnson-covid-19-vaccine-fda-eua/index.html>.

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 Resources and Services Administration, *Countermeasures Injury Compensation Program (CICP)*, <https://www.hrsa.gov/cicp> (last reviewed Nov. 2020).

vulnerable populations during a pandemic and its aftermath and how these disparities are intensified by the CACP. The 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.

2. 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 Emergency Use Approval (“EUA”) from the Food & 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 is vaccinated. Such side effects could include joint pain, anaphylaxis, and neurological conditions like 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 given 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. Unfortunately, it triggered an enduring public mistrust of flu vaccinations and often appears as part of the narrative of the anti-vaccination movement.⁸

3. 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.

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

⁵ Helen Branswell, *A Side-by-Side Comparison of the Pfizer/BioNTech and Moderna Vaccines*, STAT NEWS (Dec. 19, 2020), <https://www.statnews.com/2020/12/19/a-side-by-side-comparison-of-the-pfizer-biontech-and-moderna-vaccines/>.

⁶ Health Resources and Services Administration, *Vaccine Injury Table*, <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf> (accessed 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 (April 3, 2021), available at <https://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 (April 17, 2021), available at <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), <https://www.discovermagazine.com/health/the-public-health-legacy-of-the-1976-swine-flu-outbreak>.

⁸ *Id.*

3.1 The VICP

The National Vaccine Injury Compensation Program (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 the majority of 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 Federal Court of Claims.¹³

The VICP offers up to \$250,000 for pain, suffering, and emotional distress¹⁴ as well as attorneys' fees and legal expenses to good faith claimants.¹⁵ As of the end of 2020, the Vaccine Injury Compensation Trust Fund ("VICTF") was valued at over \$4 billion.¹⁶ The VICTF is funded by a \$.75 excise tax on each vaccine dose that is paid by the manufacturers.¹⁷ From

⁹ Health Resources and Services Administration, *Covered Vaccines*, <https://www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html> (last reviewed Dec. 2020).

¹⁰ Health Resources and Services Administration, *About the National Vaccine Injury Compensation Program*, <https://www.hrsa.gov/vaccine-compensation/about/index.html> (last reviewed Dec. 2020) [hereinafter *About VICP*]; Health Resources and Services Administration, *National Vaccine Injury Compensation Program*, <https://www.hrsa.gov/vaccine-compensation/index.html> (last reviewed Nov. 2020).

¹¹ Health Resources and Services Administration, *Who Can File a Petition?*, <https://www.hrsa.gov/vaccine-compensation/eligible/index.html> (last reviewed Dec. 2020); HEALTH RESOURCES AND SERVICES ADMINISTRATION, WHAT YOU NEED TO KNOW ABOUT THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP) 8 (April 2019), <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/resources/about-vaccine-injury-compensation-program-booklet.pdf>.

¹² The Office of Special Masters, United States Court of Federal Claims, *Guidelines for Practice Under the National Vaccine Injury Compensation Program*, 47 (2020), <https://www.uscfc.uscourts.gov/sites/default/files/Guidelines-4.24.2020.pdf>.

¹³ *Id.*

¹⁴ HEALTH RESOURCES AND SERVICES ADMINISTRATION, *supra* note 11, at 12.

¹⁵ Health Resources and Services Administration, *How to File a Petition*, <https://www.hrsa.gov/vaccine-compensation/how-to-file/index.html> (last reviewed December 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 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 2 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), available at <https://www.federalregister.gov/documents/2020/07/20/2020-15673/national-vaccine-injury-compensation-program-revisions-to-the-vaccine-injury-table>.

¹⁶ National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, *supra* note 6.

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

2006 through 2018, the VICP has approved about 70% 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

3.2 The CICP

The same benefits are not available to people injured by vaccines given as countermeasures during a declared PHE.²⁰ The Department of Health and Human Services' declaration of a PHE 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 only under the Countermeasures Injury Compensation Program (CICP).²² Such countermeasures include not only vaccines, but also drugs, equipment, and more. CICP awards are paid by the Covered Countermeasure 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.

¹⁸ Ken Alltucker, *Consumers Filed 106 Injury Claims From COVID-19 Vaccines, Ventilators and Hydroxychloroquine. Here's Why None Have Been Paid*, USA TODAY (March 28, 2021), available at <https://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), <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>.

²⁰ CONGRESSIONAL RESEARCH SERVICE, *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.A. § 247d-6d (2010).

²² Congressional Research Service, *supra* note 20.

²³ Congressional Research Service, *supra* note 20. Both the 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, short 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 attorney’s 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 during a declared PHE can never pursue injury claims under the VICP, even if their symptoms appear or are linked to the vaccine

²⁴ Health Resources and Services Administration, *Comparison of Countermeasures Injury Compensation Program (CICIP) to the National Vaccine Injury Compensation Program (VICP)*, <https://www.hrsa.gov/cicp/cicp-vicp> (last reviewed 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). One 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 Shoulder Injury Related to Vaccine Administration (“SIRVA”) injuries. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, supra* note 16. 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, fire fighters, 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, 75 Fed. Reg. 64955 (Oct. 21, 2010), <https://www.federalregister.gov/documents/2010/10/15/2010-25110/countermeasures-injury-compensation-program-cicp-administrative-implementation-interim-final-rule>.

²⁹ HEALTH RESOURCES AND SERVICES ADMINISTRATION, COUNTERMEASURES INJURY COMPENSATION PROGRAM REQUEST FOR BENEFITS FORM INSTRUCTIONS 1-2 (updated Mar. 2020), <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-request-form-instructions.pdf>.

³⁰ Health Resources and Services Administration, *About CICIP*, <https://www.hrsa.gov/cicp/about> (last reviewed Nov. 2020); Nicholas M. Pace et al., *COVID-19 Vaccine Campaign Must Include Fair Compensation for Side Effects*, THE HILL (Dec. 17, 2020), <https://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 associated with notes 29-30.

after the declaration is lifted.³³ If they were vaccinated while a PHE emergency declaration was in place, 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) but awarded compensation to only 39 people, for a total of \$5.7 million.³⁵ While the VICP has a 70% payment rate for claims filed from 2006 through 2018, the CICIP has rejected 90% of injury claims since it was created.³⁶ As of the end of March 2021, 106 COVID-19-related claims were filed with the CICIP.³⁷ One-half of the claims were for vaccines, with the remainder relating to hydroxychloroquine and other COVID-19 treatments.³⁸

4. PREP 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 a declared PHE 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, the PHE is driving the FDA to speed the temporary licensure of countermeasures using a lower standard of safety and effectiveness through its fast-track Emergency Use Approval process.³⁹ Together, these measures hold the potential to increase the number and seriousness of any unintended countermeasure injuries.

The trade-offs 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 hold the greatest potential to cause injuries are treatments such as drugs and devices. Drugs and devices, such as antiviral drugs or ventilators, will be used to treat those who have fallen ill from

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

³⁴ Health Resources and Services Administration, *HHS Sets Regulations to Implement Countermeasures Injury Compensation Program* (Oct. 15, 2010), <https://www.hrsa.gov/about/news/press-releases/2010-10-15-cicp.html>.

³⁵ 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>.

³⁶ Alltucker, *supra* note 18.

³⁷ *Id.*

³⁸ *Id.*

³⁹ Under section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act, the FDA can issue an Emergency Use Approval 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 (January 13, 2017), available at <https://www.federalregister.gov/documents/2017/01/13/2017-00721/emergency-use-authorization-of-medical-products-and-related-authorities-guidance-for-industry-and>.

the pandemic-triggering disease. 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 fall into a different category as preventatives. First, the target population for vaccines are healthy people. As such, there is no ‘access to treatment’ benefit for this population that provides a trade-off 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 a vaccine. 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 to promote herd immunity.

5. 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.⁴⁰ 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.⁴¹

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.⁴² Likewise, infection rates were significantly higher in economically disadvantaged areas than in wealthier ones.⁴³ Similar patterns were evident in past disasters, such as the 1918 Spanish influenza pandemic.⁴⁴ Vaccinating members of minority and low-income populations should therefore be a high priority.

5.1 Vaccine Hesitancy and Lack of Access to Compensation

⁴⁰ See *supra* text associated with notes 29-30.

⁴¹ Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Interim Final Rule, 75 Fed. Reg. at 63,666.

⁴² NATIONAL URBAN 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> (accessed Dec. 30, 2020); Dylan Scott & Christina Animashaun, *COVID-19's Stunningly Unequal Death Toll in America*, in *One Chart*, VOX (Oct. 2, 2020), <https://www.vox.com/coronavirus-covid19/2020/10/2/21496884/us-covid-19-deaths-by-race-black-white-americans>.

⁴³ 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/>.

⁴⁴ Clare Bambra et al., *The COVID-19 Pandemic and Health Inequalities*, 74 J. EPIDEMIOLOGY COMMUNITY HEALTH 964, 964 (2020).

At the same time, however, there are high levels of vaccine skepticism and reluctance in poor and minority communities.⁴⁵ In some cases, vaccine hesitancy may stem from longstanding inequities in medical treatment and abuses that have resulted in general mistrust of government. A well-known example is the infamous Tuskegee Study.⁴⁶ In this study, which spanned 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.⁴⁷

In a Kaiser Family Foundation poll conducted in August and September 2020, 49% of Black respondents stated that they would probably not or definitely not accept a COVID-19 vaccine, compared to 33% of White respondents.⁴⁸ Similarly, a Pew Research Center poll conducted in November 2020 revealed that while 71% of Black respondents knew someone who had been hospitalized or died because of COVID-19, only 42% planned to obtain a COVID-19 vaccine.⁴⁹

During 2021, overall hesitancy dropped as more information was gathered regarding the effectiveness and safety of the COVID-19 vaccines.⁵⁰ However, hesitancy continued to be a significant concern among all groups.⁵¹ If the media begins to cover stories of individuals who were injured but not adequately compensated, such hesitancy may intensify. 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 assured that they will be compensated if injured.⁵² 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. On the other hand, knowing that they will not get compensated may discourage participation.

5.2 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

⁴⁵ Shadim Hussain, *We Need 'Horizontal' Trust to Overcome Vaccine Skepticism*, WIRED (Nov. 21, 2020), <https://www.wired.com/story/we-need-horizontal-trust-to-overcome-vaccine-skepticism/>.

⁴⁶ Rueben C. Warren et al., *Trustworthiness Before Trust — COVID-19 Vaccine Trials and the Black Community*, 383 NEW ENG. J. MED. e121, e121 (2020).

⁴⁷ Centers for Disease Control and Prevention, *The Tuskegee Timeline*, <https://www.cdc.gov/tuskegee/timeline.htm> (last reviewed Mar. 2, 2020).

⁴⁸ Liz Hamel et al. *Race, Health, and COVID-19: The Views and Experiences of Black Americans*, KAISER FAMILY FOUNDATION 17 (Oct. 2020), <http://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf>.

⁴⁹ Cary Funk and Alec Tyson, *Intent to Get a COVID-19 Vaccine Rises to 60% as Confidence in Research and Development Process Increases*, PEW RESEARCH CENTER 6, 8 (Dec. 2020), https://www.pewresearch.org/science/wp-content/uploads/sites/16/2020/12/PS_2020.12.03_covid19-vaccine-intent_REPORT.pdf.

⁵⁰ Kaiser study March 30, 2021.

⁵¹ Reuters Staff, *COVID-19 Vaccine Hesitancy Among Black Americans Drops – Poll* (March 30, 2021), available at <https://www.reuters.com/article/us-health-coronavirus-vaccine-hesitancy-idUSKBN2BM0WY>.

⁵² The Presidential Commission for the Study of Bioethical Issues, *Moral Science: Protecting Participants in Human Subjects Research* (December 2011; undated edition June, 2012), at 61, available at <file:///C:/Users/kav7/Documents/KVT%20publishing/Harvard-Yale%20Workshop%20book%20chapter/Moral%20Science%20June%202012.pdf>.

children or pregnant women.⁵³ 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.⁵⁴ 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, and the U.S. Equal Employment Opportunity Commission has determined that such employer mandates are lawful.⁵⁵

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 CICIP rather than the VICP can thus have a disproportionate adverse impact on poor communities.

By contrast, the people who can afford to wait for vaccination until an emergency declaration has ended, triggering VICP availability, will tend to be more 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.⁵⁶ 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 CICIP could therefore reinforce long-established inequities rooted in income, race, and ethnic identity.

6. 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

⁵³ Health Resources and Services Administration, *Frequently Asked Questions*, <https://www.hrsa.gov/cicp/faq> (last reviewed Dec. 2020).

⁵⁴ Centers for Disease Control and Prevention, *People with Certain Medical Conditions*, <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html> (updated Dec. 29, 2020); Kenneth E. Thorpe et al., *The United States Can Reduce Socioeconomic Disparities by Focusing on Chronic Diseases*, HEALTH AFF. BLOG (Aug. 17, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170817.061561/full/>.

⁵⁵ U.S. Equal Employment Opportunity Commission, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws* (Dec. 16, 2020), <https://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*, N.Y. TIMES (Dec. 18, 2020), <https://www.nytimes.com/2020/12/18/us/eeoc-employers-coronavirus-mandate.html>.

⁵⁶ Matt Simon, *Your Income Predicts How Well You Can Socially Distance*, WIRED (Aug. 5, 2020), <https://www.wired.com/story/your-income-predicts-how-well-you-can-socially-distance/>; Vasil Yassenov, *Who Can Work from Home?*, IZA INST. LABOR & ECON. (May 4, 2020), <https://www.iza.org/publications/dp/13197/who-can-work-from-home>.

undermine the important public health goal of vaccinating as many people as possible as quickly as possible to achieve herd immunity.

Experts predict that the world will face future global pandemics, and many have long worried about bioterrorism attacks.⁵⁷ Establishing the correct incentives and relief mechanisms for people who receive vaccinations is therefore of critical importance.

6.1 Amending the PREP Act

A straight-forward 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.⁵⁸ This would include vaccines receiving an emergency use authorization (EUA).⁵⁹

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 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 to protect the collective. By contrast, drugs and devices approved under an EUA are provided to unhealthy individuals to treat and cure their individual maladies.

The second element of this proposal is that Congress should require manufacturers to pay a 75-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 Vaccine Injury Compensation Trust Fund is adequately financed. As noted above, such a tax already applies to vaccines included in the VICP.⁶⁰ 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 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.⁶¹ This measure will ensure that claims will be processed expeditiously.

⁵⁷ *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>; *Coronavirus: Experts Warn of Bioterrorism After Pandemic*, DEUTSCHE WELLE (May 25, 2020), <https://www.dw.com/en/coronavirus-experts-warn-of-bioterrorism-after-pandemic/a-53554902>.

⁵⁸ 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.”

⁵⁹ 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.” U.S. Food & Drug Administration, *Emergency Use Authorization*, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> (current as of Dec. 30, 2020); 21 U.S. Code § 360bbb–3 (2010).

⁶⁰ See *supra* note 17 and accompanying text.

⁶¹ United States Court of Federal Claims, *Vaccine Claims/Office of Special Masters*, <https://www.uscfc.uscourts.gov/vaccine-program-readmore> (accessed Jan. 17, 2021).

7. 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 CACP if 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.

The 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 CACP. 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.