

Comparative Lack of Accountability: An International Examination of COVID-19 Vaccine Injury Claim Systems

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ABSTRACT

Five years ago, the world was in lockdown, seeking protection from dangers presented by the COVID-19 pandemic. At the time, many people were confused and afraid given the lack of information about the disease and its potential impacts. When scientists quickly created vaccines to help inoculate against infection, a collective sigh of relief could be heard across the globe. Yet, much like the disease itself, COVID-19 vaccines arrived on the scene with little in the way of warnings or details. This lack of information included possible injuries that might result from vaccination protocols or processes for addressing claims relating to such injuries.

Indeed, today many still do not know that courts of law in the United States ban legal claims relating to COVID-19 vaccination injuries. Thus, these claims are handled very differently than any other kind of legal cause of action. The same is true in many other countries.

This Article sheds further light on these differences, their origins, and concerns about the implications of specialized ad hoc systems that render COVID-19 vaccine manufacturers largely immune from possible liability. This Article further suggests that COVID-19 vaccine manufacturers,

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particularly given the massive financial profits they have enjoyed to date, should not receive such expansive legal protections. And, absent other avenues for relief, those who brought about such protections may need to be held to account.

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I. INTRODUCTION

Five years ago, the international community learned about the first COVID-19 diagnosis.¹ At the time of the initial outbreak, physicians and

1. See Mary Kekatos, *COVID-19 Timeline: How the Deadly Virus and World's Response Have Evolved Over 4 Years*, ABC NEWS (Mar. 11, 2024, 4:13 AM), <https://perma.cc/Z8LR-SERQ> (noting that in December 2019 the WHO was informed by Chinese officials about a “mysterious pneumonia-like illness that originated in Wuhan” and was spreading); Xixing Li et al., *Who Was the First Doctor to Report the COVID-19*

the public considered the disease novel and a mystery.² Many professionals worked hard to quickly understand the illness and prevent further infections—including risking their own health and wellbeing to treat patients.³ On the other hand, many people, even high-level government officials, widely shared conflicting guidance and erroneous information.⁴ In short order, the disease transitioned from a local hospital concern to a global pandemic that took millions of lives.⁵

Outbreak in Wuhan, China?, 61 J. NUCLEAR MED. 782, 782 (2020) (documenting the timeline of reports out of Wuhan, China, in December 2019, first by Dr. Zhang Jixian and then Dr. Li Wenliang).

2. See Krishna Mohan Agrawal et al., *Study and Overview of the Novel Corona Virus Disease (COVID-19)*, 1 SENSORS INT'L 1 (Sept. 6, 2020), <https://perma.cc/MRL9-8EFX> (explaining that the “new disease” became known by several names including “novel coronavirus disease,” “COVID-19” and a “SARS CoV-2” virus); Farshad Hemmatia et al., *Mysterious Virus: A Review on Behavior and Treatment Approaches of the Novel Coronavirus, 2019-nCoV*, 51 ARCHIVES MED. RSCH. 375, 382 (2020) (admitting, a year into the pandemic, that the world-wide clinical community still “do not know much about precision mechanism and function of this new virus”).

3. See Stephen M. Hahn, Comm’r of Food & Drugs, FDA, *The Critical Role of Health Care Professionals During the COVID-19 Pandemic* (Aug. 10, 2020), <https://perma.cc/DJ6M-AC7Y> (remarks of FDA Commissioner recognizing the “hard work, thoughtfulness, and commitment” of “health care professionals who have risked their own health to serve their patients” even while there is “much more to learn about this disease, with many unanswered questions”); see also Li et al., *supra* note 1, at 782 (noting that Dr. Li Wenliang, who “blew the whistle” about the novel coronavirus was “reprimanded initially for ‘disrupting public order’ in China”).

4. See Rebecca H. Nagler et al., *Public Perceptions of Conflicting Information Surrounding COVID-19: Results from a Nationally Representative Survey of U.S. Adults*, 15 PLoS ONE 1 (Oct. 21, 2020), <https://perma.cc/QW4G-J238> (reporting on declaration from the WHO that “We’re not just fighting an epidemic; we’re fighting an info-demic.”); see also Deborah Netburn, *A Timeline of the CDC’s Advice on Face Masks*, L.A. TIMES (July 27, 2021, 4:47 PM), <https://perma.cc/GJ22-RGBR> (noting the U.S. federal government at one point informed citizens that masking would not help contain the disease); *In his Own Words: Trump and the Coronavirus*, REUTERS (Oct. 2, 2020, 2:40 AM), <https://perma.cc/H6NS-7BKJ> (quoting President Donald Trump as stating “We have it totally under control. It’s one person coming in from China, and we have it under control. It’s going to be just fine.”).

5. See Daniel M. Weinberger et al., *Estimation of Excess Deaths Associated with the COVID-19 Pandemic in the United States, March to May 2020*, 180 JAMA 1336, 1337 (2020) (explaining that in just a few months the disease “rapidly grew into a global pandemic”); see also *Number of COVID-19 Deaths Reported to WHO*, WORLD HEALTH ORG., <https://perma.cc/7VDE-6ZXM> (last visited Apr. 29, 2024) (documenting more than 3 million reported deaths in the Americas, 2 million reported deaths across Europe, and approximately 1.5 million reported deaths in Africa, Asia and the Western Pacific combined).

The world continues to grapple with the implications of COVID-19.⁶ The disease spared few communities from serious illness or death.⁷ In the United States, COVID-19 hit neighborhoods of color, nursing homes, and prisons especially hard.⁸ Loved ones everywhere continue to grieve the loss of family members.⁹ Many people now have increased anxiety and other mental health disorders, in part because of isolation and desperation experienced during lockdowns.¹⁰ Those lockdowns negatively impacted education systems and outcomes.¹¹ And the global economy is still unstable due to business closures, job losses, and other financial setbacks.¹²

6. See Michaela C. Schippers, *For the Greater Good? The Devastating Ripple Effects of the COVID-19 Crisis*, 11 FRONTIERS PSYCH. 2 (Sept. 28, 2020), <https://perma.cc/2M9C-4LZ8> (cataloging wide range of long-term implications of COVID-19); Modupe Coker et al., *Things Must Not Fall Apart: The Ripple Effects of the COVID-19 Pandemic in Sub-Saharan Africa*, 89 PEDIATRIC RSCH. 1078, 1078 (2021) (warning about the “direct and indirect impacts of COVID-19 among children” in Sub-Saharan Africa); see also *COVID-19 Fueling Anti-Asian Racism and Xenophobia Worldwide*, HUM. RTS. WATCH (May 12, 2020, 3:19 PM), <https://perma.cc/RTL3-BAJA> (warning about “anti-immigrant, white supremacist, ultra-nationalist, antisemitic, and xenophobic conspiracy theories” in connection with COVID-19).

7. See Drew Broach, *A \$2.8 Million Memorial to COVID Victims is Being Built in Jefferson Parish*, NOLA.COM (Feb. 18, 2024), <https://perma.cc/3YKW-EV2X> (reporting that the memorial will pay tribute to the more than 1,400 people lost to COVID in Jefferson Parish, Louisiana); Joseph R. Betancourt, *Communities of Color Devastated by COVID-19: Shifting the Narrative*, HARVARD HEALTH BLOG (Oct. 22, 2020), <https://perma.cc/RK6X-VPSJ> (reporting on deaths in cities such as New Orleans, Chicago and Detroit).

8. See Betancourt, *supra* note 7 (lamenting that, due to long-standing health inequalities, Black and Latino residents were several times more likely to contract COVID-19 than their white counterparts); Emily Paulin, *COVID-19 Nursing Home Deaths Climb Ahead of Expected Winter Surge*, AARP (Dec. 14, 2023), <https://perma.cc/KA43-WJMM> (estimating that 1/6 of all persons who died of COVID in the United States were nursing home residents, a group that represents only 1% of the country’s entire population); Jennifer Valentino DeVries and Allie Pichon, *As the Pandemic Swept Through America, Deaths in Prison Rose Nearly Fifty Percent*, N.Y. TIMES (Feb. 19, 2023), <https://perma.cc/R8JM-EE5P>.

9. See Emily Smith-Greenaway et al., *1 in 8 U.S. Deaths from 2020 to 2021 Came from COVID-19 – Leaving Millions of Relatives Reeling from Distinctly Difficult Grief*, PENN STATE SOC. SCI. RSCH. INST. (July 12, 2022), <https://perma.cc/FJP3-W9F4> (estimating 9 million people in the U.S. “lost a close relative to COVID-19”).

10. See Schippers, *supra* note 6, at 3 (warning that “[a]s half of the world is in some kind of lockdown, this is arguably the largest psychological experiment ever,” with likely “ripple effects on every aspect of human life,” including increased anxiety, depression and substance use or abuse).

11. See Collin Binkley, *Test Scores Show How COVID Set Kids Back Across the U.S.*, PBS (Oct. 24, 2022, 10:16 AM), <https://perma.cc/5B2M-9N2M>.

12. See generally MOMINA AIJAZUDDIN ET AL., WORLD BANK GRP., FINANCE FOR AN EQUITABLE RECOVERY (2022) (cataloging interconnected economic repercussions of the pandemic, impacting everything from job security to national poverty rates); Ian Bezek, *Seven Companies that Went Bankrupt Due to COVID*, U.S. NEWS (May 12, 2023), <https://perma.cc/SVU5-XY46>.

Yet at least one sector of society benefitted from the coronavirus: a group of pharmaceutical companies that created and distributed COVID-19 vaccines. In fact, these entities generated tremendous new income and wealth as a result of the pandemic. As will be further discussed, some companies did offer vaccination injections “at cost” for some period of time.¹³ Those companies still brought in billions of dollars of new revenue during their “not-for-profit” period.¹⁴ And the others, who approached the pandemic like any other kind of business endeavor, generated billions of dollars, not just in revenue, but in raw profit.¹⁵

To be sure, COVID-19 vaccines did a lot of good for our world. And manufacturers have many reasons to feel proud and receive appropriate compensation. On the other hand, COVID-19 vaccines harmed some people.¹⁶ As admitted by health experts and the manufacturers themselves, negative side effects of vaccination range from relatively minor medical episodes to life-threatening complications and death.¹⁷

Yet, unlike injuries that flow from other medicines—including other vaccines—courts of law in the United States have not handled claims

13. See Chris Isidor, *Here’s What COVID Vaccines are Worth to Big Pharma*, CNN, <https://perma.cc/FC2G-U4U8> (Mar. 15, 2021, 7:59 AM) (“Although Johnson & Johnson (JNJ) has said it will provide the vaccine on a not-for-profit basis as long as the world continues suffering from the pandemic, that doesn’t mean the company won’t ever make money from it.”).

14. See Julia Kollewe, *From Pfizer to Moderna: Whose Making Billions from COVID-19 Vaccines?*, GUARDIAN (Mar. 6, 2021, 6:55 AM), <https://perma.cc/A6X5-67SH> (describing vaccination sales of different manufacturers including Johnson & Johnson, Pfizer, Moderna, and AstraZeneca).

15. See *id.* As will be further described, other companies also produced COVID-19 vaccines domestically and globally, including Novovax, which created a “protein subunit vaccine.” See Elaine Chen, *Novovax Will be Able to Provide COVID-19 Vaccines This Fall*, STAT (June 6, 2024), <https://perma.cc/S4KG-VHAC>.

16. See Anne R. Bass et al., NAT’L ACADS. OF SCIS., ENG’G, & MED., *Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration* 195 (2024) (confirming, to a scientific certainty, various medical harms that have been caused by various COVID-19 vaccines, while finding insufficient evidence to determine causation for others).

17. See, e.g., *id.* at 199–202 (finding, among other things, connection between Janssen, Pfizer, and Moderna COVID-19 vaccinations and cases of myocarditis); *COVID-19: Safety of COVID-19 Vaccines*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 3, 2023), <https://perma.cc/TW7T-R5UZ> (noting that most people suffer only minor side-effects following coronavirus vaccine administration, such as soreness at injection site, but that some “people have experienced more significant adverse effects after COVID-19 vaccination”); see also Arpan Rai, *AstraZeneca Withdraws COVID Vaccine World-Wide After Admitting it Can Cause Rare Blood Clots*, THE INDEPENDENT (May 8, 2024, 2:30 PM), <https://perma.cc/799V-L4CM> (reporting that in rare cases blot clots and low blood platelet counts are attributable to the Covishield vaccine and noting company has now withdrawn the drug from global markets).

relating to COVID-19 vaccines.¹⁸ Instead, the government provided manufacturers with a range of legal benefits and litigation protections that shielded them from traditional lawsuits and court judgments.¹⁹ These manufacturer protections were provided not only in this country, but in other nations as well.²⁰ Like the COVID-19 outbreak itself, specialized claim processing systems for COVID-19 vaccine injuries are not just novel but largely a mystery to members of the general public.²¹ And like the pandemic, these developments may result in long-term negative impacts.

This Article sheds light on COVID-19 vaccine injury claim protocols established in the United States and abroad. Further, this Article explains that such structures—including the one created in the United States under the Public Readiness and Emergency Preparedness (PREP) Act of 2006—are currently overwhelmed by backlogs, have provided compensation in very few cases, and are problematic in many other ways too. Moreover, the Article explores a range of other concerns for potentially impacted persons around the world who were not clearly informed when they received their COVID-19 vaccination that they were waiving the right to sue for monetary damages if the drug harmed them.

Finally, this Article explores emerging advocacy initiatives that seek to address COVID-19 injury claim system shortcomings. Joining with those engaged in such efforts, we conclude by urging new thinking around existing COVID-19 claim administration—especially given what we know now, including the financial gain many COVID-19 vaccine manufacturers enjoyed. Like any meaningful legal system, those established to address COVID-19 injury claims must be transparent, accountable, and amenable to reform. We also urge pharmaceutical companies to come forward and do the right thing for those individuals who have legitimate claims of harm as a result of using their products.

18. See *Countermeasure Injury Compensation Program (CICP)*, U.S. HEALTH RES. & SERVS. ADMIN., <https://perma.cc/9ATR-562D> (Jan. 2023) (providing information to public about seeking compensation for claims relating to COVID-19 vaccination injuries).

19. See SARA M. THARAKAN & NINA M. HART, CONG. RSCH. SERV., IF11905, *LIABILITY ISSUES RELATED TO COVID-19 VACCINE MANUFACTURING AND GLOBAL DISTRIBUTION 1* (2021) (describing immunity offered under the United States Public Readiness and Emergency Protocol (PREP) Act to protect and incentivize COVID-19 vaccine manufacturers domestically).

20. See generally *id.* (comparing immunity protections for COVID-19 manufacturers in the United States with systems in other countries); Flavia Beccia, *COVID-19 Vaccination and Medical Liability: An International Perspective in 18 Countries*, 10 *VACCINES* 1 (Aug. 22, 2022), <https://perma.cc/EZ7N-NZTT> (describing the development of new systems for legal liability in connection with COVID-19 vaccine injuries).

21. See Knvul Sheikh, *Four Years On, the Mysteries of COVID are Unraveling*, N.Y. TIMES, <https://perma.cc/DZZ3-QZJE> (Mar. 11, 2024).

II. INTERNATIONAL DEVELOPMENT AND DEPLOYMENT OF COVID-19 VACCINES

Faced with the global health crisis created by COVID-19, world leaders turned to pharmaceutical companies to help stem the tide of serious illness and death caused by the disease.²² For instance, in May 2020, the United States Department of Health and Human Services, along with Department of Defense and international support, launched “Operation Warp Speed.”²³ This initiative represented both a policy initiative and economic incentive program to support a handful of American drug manufacturers to “have as many as 300 million doses of [COVID-19] vaccines available and deployed by mid-2021.”²⁴

Ordinarily, it takes ten or more years for pharmaceutical companies to develop, test, approve, and move a vaccine to market in the United States. But COVID-19 vaccines moved through all these steps in just a matter of months.²⁵ Governments reduced federal testing timeframes to allow manufacturing to begin in tandem with clinical trials taking place domestically and abroad, including in Australia, the United Kingdom (UK), Brazil, and South Africa.²⁶ Under “Operation Warp Speed,” governments provided some drug companies billions of dollars in federal financial support to expedite vaccine development.²⁷

22. See J.H. Kim et al., *Operation Warp Speed: Implications for Global Vaccine Security*, 9 LANCET GLOB. HEALTH e1017, e1017 (2021) (describing various international public-private collaborations that sought to address the COVID-19 pandemic).

23. See generally U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-139, OPERATION WARP SPEED: ACCELERATED COVID-19 VACCINE DEVELOPMENT STATUS AND EFFORTS TO ADDRESS MANUFACTURING CHALLENGES (2021) [hereinafter OPERATION WARP SPEED].

24. See Moncei Slaoui & Matthew Hepburn, *Developing Safe and Effective Vaccines: Operation Warp Speed's Strategy and Approach*, 38 NEW ENG. J. MED. 1701, 1701 (2020); see also Kim et al., *supra* note 22, at e1017 (explaining other countries also financially supported expedited pandemic vaccine development programs, but “OWS is the largest of the global efforts for development of COVID-19 vaccines”).

25. See OPERATION WARP SPEED, *supra* note 23, at 5–9 (comparing the traditional path followed for vaccine development and accelerated COVID-19 approvals); see also *Pfizer and BioNTech to Provide the European Union More than 200 Million Additional Doses*, PFIZER (Dec. 20, 2021, 7:00 AM), <https://perma.cc/N5GW-LGGY> [hereinafter *Pfizer and BioNTech*] (noting that “uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19)”).

26. See *Pfizer and BioNTech*, *supra* note 25; see also Slaoui & Hepburn, *supra* note 24, at 1702 (“OWS is supporting the companies financially and technically to commence process development and scale up manufacturing while their vaccines are in preclinical or very early clinical stages.”).

27. See OPERATION WARP SPEED, *supra* note 23, at 10–14 (outlining federal financial support and contracts provided for development and manufacturing vaccines, worth more than \$10 billion); see also David J. Sencer CDC Museum, *COVID-19 Timeline*, <https://perma.cc/C5C6-NMPW> (noting that as part of Warp Speed, President Trump provided supportive funding to six companies working on promising drugs to protect against COVID-19).

Beyond financial support and streamlined approvals, the United States government promised domestic drug manufacturers immunity from court claims and lawsuits in connection with the vaccines as a pandemic “countermeasure.”²⁸ This drug manufacturer immunity decision occurred in March 2020, when Alex Azar, then Secretary of Health and Human Services, invoked his powers under the PREP Act.²⁹

Congress passed the PREP Act in response to a range of incidents during the early 2000s, including the September 11 attack on the World Trade Center, anthrax scares, and the avian flu outbreak.³⁰ The law allows the Secretary of Health and Human Services not only to declare public health emergencies for the entire country but also provides legal liability protection to those who develop and deploy medical “countermeasures” to address public health crises.³¹ These countermeasures apparently include vaccinations.

The United States was not alone in this approach to incentivizing a race to create and supply COVID-19 vaccines. Indeed, most wealthy nations, like the UK, offered manufacturers financial benefits and legal protections to facilitate quick access to pandemic prophylactic medicines.³² The terms of all these agreements are not entirely public. But backed by international support and assurances, several companies—including Pfizer and Moderna with their mRNA shots, and AstraZeneca and Johnson and Johnson (J & J) with their viral vector drugs—developed vaccines in record time.³³ Ultimately, these companies became some of the largest suppliers of COVID-19 vaccines worldwide.³⁴ The companies

28. See 85 C.F.R. § 15198 (2020).

29. See *id.*; see also 42 U.S.C. § 247d-6d (“The PREP Act”).

30. See Junying Zhao et al., *Reforming the Countermeasures Injury Compensation Program for COVID-19 and Beyond: An Economic Perspective*, 9 J. L. & BIOSCIENCES 1, 5 (2022) (providing historical context for the PREP Act’s passage).

31. See *id.*

32. See, e.g., THARAKAN & HART, *supra* note 19, at 2 (describing how domestic manufacturers obtained protections abroad by way of foreign “immunity laws, no-fault compensation laws, or contractually negotiated provisions” for COVID-19 vaccines); see also *Liability and Protection of Vaccine Manufacturers: International Experience and Georgian Perspective*, MG L. (Jan. 5, 2021), <https://perma.cc/H3X3-T7BH> (explaining how the UK “provided Pfizer and Moderna with a statutory indemnity that shields these manufacturers from the potential civil claims brought by the general public”).

33. See *WHO Issues Additional COVID-19 Vaccine for Emergency Use and Issues Interim Policy Recommendations*, WORLD HEALTH ORG. (May 7, 2021), <https://perma.cc/23YG-RER2> (listing six manufacturers for international emergency approval as of summer 2021, including Moderna, Pfizer, Johnson & Johnson, and AstraZeneca). For more on differences between mRNA and viral vector drugs, see Emma Vines, *COVID-19 Vaccines: A Quick Guide*, PARLIAMENT OF AUSTRALIA (Nov. 11, 2021), <https://perma.cc/YH24-NNKR>.

34. See Alex Berezow, *Comparing COVID Vaccines: Pfizer vs. Moderna vs. AstraZeneca/Oxford*, AM. COUNCIL ON SCI. & HEALTH (Nov. 23, 2020), <https://perma.cc/9GG7-NN62> (contrasting the three main COVID vaccines then available).

also partnered with other entities to move vaccines to market, ramp up production, and distribute their products globally.³⁵

Some nations lacked economic means to participate in incentive programs or to purchase the vaccine doses needed for their citizenry. Therefore, the World Health Organization (WHO) and other partners worked with Gavi, a non-governmental organization, to create a COVID-19 vaccination initiative to assist lower-income countries. Gavi was established in 2000 to provide childhood vaccinations in poorer countries. To accomplish its stated mission of achieving health equity, Gavi established a Vaccine Alliance that included non-profit groups, medical providers, and countries in need of vaccines.³⁶

Gavi brought a similar collaborative approach to COVID-19 vaccine distribution. Specifically, it launched the COVAX Facility (“COVAX”),³⁷ a public-private consortium to obtain and provide COVID-19 vaccines globally, including to nations with struggling economies.³⁸ Through COVAX, Gavi signed early agreements with Astra-Zeneca, Pfizer, Moderna, and J & J, to purchase vaccines even before manufacturers and governments fully developed and approved them.³⁹ Gavi did so hoping to rapidly roll out up to two billion doses of the vaccine, with wealthier national partners helping to subsidize the shots needed for economically

internationally); *see also* Chris Isidore, *Johnson and Johnson Expects its COVID Vaccine Sales to Surge, But Still Lag its Rivals*, CNN BUS. (Jan. 25, 2022), <https://perma.cc/DC6Y-U547> (comparing global sales of COVID-19 vaccines suppliers Johnson & Johnson, AstraZeneca, Moderna and Pfizer).

35. *See* Kim et al., *supra* note 22, at e1018 (describing the licensing and manufacturing agreements between companies in the United States and other countries, including in India and South Korea); *see also* *Pfizer and BioNTech, supra* note 25 (noting that U.S. drug company, Pfizer, partnered with German company, BioNTech, to produce COVID-19 vaccine at a German plant); *AstraZeneca Receives \$1Billion in U.S. Funding for Oxford Coronavirus Vaccine*, CNBC (May 21, 2020), <https://perma.cc/E2ET-A5JD>.

36. According to the Gavi Website: “By improving access to new and under-used vaccines for millions of the most vulnerable children, the Vaccine Alliance is transforming the lives of individuals, helping to boost the economies of lower-income countries and making the world safer for everyone.” *About Our Alliance*, GAVI, <https://perma.cc/3NSW-W3DH> (last visited July 23, 2024).

37. *See* *What Was the COVAX Facility?*, GAVI, <https://perma.cc/R8QC-CHPT> (last visited July 23, 2024) (explaining the “COVAX Facility was responsible for global procurement and delivery at scale for COVAX – managing the end-to-end effort including relationships with the 195 countries and territories that signed on as participants and/or donors”).

38. *See* Gavi Staff, *The Gavi COVAX AMC Explained*, GAVI (Feb. 15, 2021), <https://perma.cc/N5RA-SW4P> (providing a description of global collaborative efforts to support low income countries to receive COVID vaccinations).

39. *See* *Gavi Signs Agreement with Johnson and Johnson for Supply of COVID-19 Vaccine to COVAX*, GAVI, (May 21, 2021), <https://perma.cc/SV8N-V46T> (listing Johnson & Johnson, AstraZeneca, Pfizer, and Moderna as among 8 companies who entered COVID-19 purchase agreements with Gavi).

challenged nations.⁴⁰ However, as Gavi acknowledged, “[n]ever before has a life-saving health intervention against such an immediate global health threat been made available to people in the Global North and South simultaneously at such speed.”⁴¹

The rushed nature of this ambitious initiative, along with other oversights, missteps, and challenges along the way, contributed to multiple failings.⁴² For instance, many countries with struggling economies received doses that had short expiration periods.⁴³ These countries could not transport doses rapidly enough by boat or on foot—particularly to remote locations—before the doses spoiled.⁴⁴ Failure to account for lack of refrigeration also prevented proper storage and distribution of COVAX-supplied vaccines.⁴⁵ Thus, African countries, such as Malawi and South Sudan, either returned or destroyed countless doses because these countries could not timely administer the vaccines.⁴⁶

In the meantime, many in the United States simply visited local vaccination sites run by medical professionals to quickly obtain their shots. By the end of 2021, “only 8.5% of people in low-income countries had received at least one vaccine dose, versus 76–78% in high and upper-middle-income countries.”⁴⁷ It is likely that few in the United States and other wealthy nations are aware of the extreme disparities in vaccine access, despite COVAX efforts. Unfortunately, COVAX did not realize its goal of achieving equitable access to COVID-19 vaccines.⁴⁸

40. See Hannah Balfour, *\$150 Million Made Available for COVID-19 Vaccine Adverse Event Compensation Scheme*, EUR. PHARM. REV., (April 30, 2021), <https://perma.cc/GP7A-STP5>.

41. *Id.*

42. See Olivia Goldhill, “Naively Ambitious:” *How COVAX Failed on its Promise to Vaccinate the World*, STAT NEWS (Oct. 8, 2021), <https://perma.cc/QCJ4-Q5HP> (uncovering that country leaders expressed “confusion and frustration” about COVAX as the system unfolded, including “being left in the dark over when, if ever, deliveries would arrive”).

43. See Peter Mwai, *COVID-19 Vaccines: Why Some African Nations Can’t Use Their Vaccines*, BBC (June 8, 2021), <https://perma.cc/2G9U-JP9F>.

44. *See id.*

45. *See id.*

46. *See id.*; see also Katherine Ginsbach et al., *An Analysis of COVAX’s Equity Mandate with Reference to Liability and Indemnity*, NOTRE DAME J. INT’L & COMPAR. L. ONLINE (Apr. 15, 2024), <https://perma.cc/3YQ3-GZVF> (asserting that the number of rejected or spoiled doses for economically challenged nations ran into the millions).

47. See Antoine de Bengy Puyvallée & Katerini Tagmatarchi Storeng, *COVAX, Vaccine Donations and the Politics of Global Vaccine Inequity*, 18 GLOBALIZATION & HEALTH 2 (Mar. 5, 2022), <https://perma.cc/LXN2-GLGR>; see also Goldhill, *supra* note 42 (“As richer countries roll out booster shots, 98% of the people in low-income countries remain unvaccinated.”)

48. See Goldhill, *supra* note 42; see also Havard Rydland et al., *The Radically Unequal Distribution of Covid-19 Vaccinations: A Predictable Yet Avoidable Symptom of the Fundamental Causes of Inequality*, 9 HUMANS. & SOC. SCIS. COMM’NS 1 (Feb. 23, 2022), <https://perma.cc/2F2Y-H2B5> (accurately forecasting how, regardless of COVAX’s

More than this, COVAX also helped to protect and build the wealth of manufacturers. For instance, to receive access to the drugs, COVAX expected countries to indemnify COVAX partners against losses associated with vaccine-related injury claims—except those based upon willful misconduct.⁴⁹ In lower-income countries, where indemnity agreements or legal reforms might not be possible legally, financially, or otherwise,⁵⁰ COVAX helped protect manufacturers from legal claims in other ways.⁵¹ COVAX did so by establishing a free-standing administrative program to address vaccine injury claims by persons living in poorer COVAX-served nations.⁵²

Despite distribution challenges, inequitable access, and other shortcomings, overall vaccination appears to have been a largely successful intervention for battling COVID-19 globally.⁵³ A collective sigh of relief exuded from economically robust nations as vaccine administration began, particularly for high-risk people.⁵⁴ The launch of the

apparently well-intended efforts, “better resourced individuals and countries will jockey to harness the greatest vaccine benefit for themselves, leaving large populations of disadvantaged people unprotected”).

49. See COVAX, BRIEFING NOTE: ADDITIONAL INFORMATION ON INDEMNIFICATION FOR COVAX AMC PARTICIPANTS 2 (2020), <https://perma.cc/JV54-5CEJ> (warning “each country receiving COVID-19 Vaccines through the COVAX Facility, whether distributed under an emergency use authorization or recently licensed will be required to indemnify manufacturers, donors, distributors, and other stakeholders (the ‘Indemnified Entities’) against any losses they incur from the deployment and use of those Vaccines”).

50. See Sam Halabi et al., *No-Fault Compensation for Vaccine Injury — The Other Side of Equitable Access to Covid-19 Vaccines*, 383 NEW ENG. J. MED. e125(1), e125(3) (Oct. 28, 2020) (acknowledging financial, constitutional, political and other impediments to agreeing to indemnify manufacturers but encouraging establishment of “no-fault” claim systems).

51. See Ginsbach et al., *supra* note 46 (emphasizing that protecting manufacturers from liability and money judgments was a priority that drove COVAX’s no-fault award schemes). A program at Georgetown University Law assisted the COVAX effort by, among other things, providing legal information and resources to help nations establish their own non-litigation based claims systems. See, e.g., O’NEILL INST. FOR NAT’L & GLOB. HEALTH L., GEORGETOWN L. CTR., PRECEDENTIAL LIST OF STATUTES, REGULATIONS, AND DECREES TO IMPLEMENT COVID-19 RELATED INDEMNITY AND COMPENSATION (n.d.), <https://perma.cc/SQ2D-K39N> (listing of model legislation and other legal agreements created by Georgetown Law and provided by Gavi to COVAX participating nations).

52. See COVAX, *supra* note 49, at 3 (describing how claimants from the 92 participating countries should be encouraged to use the COVAX administrative system to seek “full and final settlement of any claims”). The 92 countries generally represented those “economies with a gross national income per capita of less than \$4,000.” See Ginsbach et al., *supra* note 46.

53. See *COVID-19 Vaccine Efficacy Summary*, INST. FOR HEALTH METRICS & EVALUATION (Nov. 18, 2022), <https://perma.cc/4DLA-C5WA> [hereinafter *Vaccine Efficacy*] (offering analysis of multiple studies across numerous countries to document vaccine success rates for preventing death, hospitalization, and disease transmission).

54. See Alice Park et al., *How COVID-19 Vaccinations Rolled Out at Hospitals Across the U.S.*, TIME (Dec. 14, 2020, 11:31 PM), <https://perma.cc/23LG-9WFM> (describing optimism and relief inspired by the vaccination roll out, with one Rhode Island

program gave many people hope and facilitated plans to return to life as usual.⁵⁵ But more importantly, as more people received full vaccinations, COVID-19 death rates and hospitalizations fell internationally.⁵⁶ Ultimately, less people contracted severe cases of COVID-19 than the number that would have without the vaccines.⁵⁷

Vaccine manufacturers benefitted, too—some through massive financial windfalls. Total revenue and profit numbers are not easy to track across the industry. But, as an example, Pfizer went from reporting approximately \$41 billion in revenue in 2020 to over \$81 billion in 2021, based upon its sale of COVID-19 vaccines.⁵⁸ During this same period, the company's profits reached the tens of billions.⁵⁹ Similarly, Moderna went from reporting losses in 2020 to “surging revenues amid vaccine sales” in 2021 for its COVID-19 drug, Spikevax.⁶⁰ In the end, the company saw \$18.5 billion in total revenue for 2021, making \$12 billion in profit.⁶¹

hospital staffer crying when they received an email notice for availability of COVID immunization shots at the facility); see also Hermann Brenner, *Focusing COVID-19 Vaccinations on the Elderly and High-Risk People*, LANCET REG'L HEALTH – EUR., Feb. 2, 2021, at 1, 1 (describing similar reactions and benefits in Europe).

55. See, e.g., Theresa Macherer, *Distribution Begins for First COVID-19 Vaccine Authorized in the United States*, SMITHSONIAN MAG. (Dec. 15, 2020), <https://perma.cc/UM4T-FBFH> (quoting one early U.S. recipient of the vaccine who stated: “I feel hopeful today. Relieved. I feel like healing is coming.”); *U.S. Starts Vaccine Roll Out as High-Risk Medical Workers Go First*, N.Y. TIMES, <https://perma.cc/KU3S-4DB4> (Jan. 4, 2021) (As U.S. COVID deaths reached 300,000, and vaccination finally began, a Louisiana pharmacist noted: “Today is the first day on the long road back to normal.”).

56. See Anderson Ikeokwu et al., *Unveiling the Impact of COVID-19 Vaccines: A Meta-Analysis of Survival Rates Among Patients in the United States Based Upon Vaccination Status*, 15 CUREUS 8 (Aug. 10, 2023), <https://perma.cc/BD9Z-UF6W> (finding “unvaccinated patients with COVID-19 infection are 2.46 times more likely to die from COVID-19 infection compared to those who are vaccinated with COVID-19 infection”). See generally *Vaccine Efficacy*, supra note 53.

57. See Ikeokwu et al., supra note 56, at 9 (“Vaccination has been linked to a considerable decrease in the number of symptomatic COVID-19 infections in adults as well as improved protection against severe disease.”); see also Dan Yu-Lin, *Effectiveness of COVID-19 Vaccines over a 9-Month Period in North Carolina*, 386 NEW ENG. J. MED. 933, 933 (2022) (evaluating the overall impact of COVID-19 vaccines in one state).

58. See Manas Mishra & Michael Erman, *Pfizer Says 2021 COVID-19 Vaccine Sales to Top \$33.5 Bln, Sees Need for Boosters*, REUTERS (July 29, 2021, 12:54 PM), <https://perma.cc/WB8K-ANPW> (indicating that Pfizer “raised its 2021 sales forecast for its COVID-19 vaccine by 39% to \$33.5 billion”).

59. See Chris Isidore, *Pfizer Revenues and Profits Soar on its COVID Vaccine Business*, CNN BUS., <https://perma.cc/9FRZ-CYJT> (Nov. 2, 2021, 12:31 PM) (noting revenues around \$36 billion for the drug in 2021, and billions in company profits).

60. *Moderna Q2 Results to Estimates: Boosts FY21 COVID-19 Vaccine Sales Outlook*, RTT NEWS (Aug. 5, 2021, 7:18 AM), <https://perma.cc/E6E7-KZBV> (describing how “Advance Purchase Agreement” deals helped company forecast tremendous growth and profit).

61. See Erin Brady, *Moderna's \$12 Billion in 2021 Profit Fueled by COVID Vaccine Sales*, NEWSWEEK (Feb. 12, 2022, 12:37 PM), <https://perma.cc/25KS-Y74P>.

And it is not just the companies themselves that benefited. Their executives also made millions—in some cases billions—of dollars in connection with their development and deployment of COVID-19 vaccines during desperate times.⁶² Some executives continue to aggressively grow their companies based on COVID-19 drugs along with their own financial portfolios. Last year, Moderna CEO Stephane Bancel sought to increase COVID-19 vaccine prices by 400% while also drawing a 50% salary increase, exorbitant bonuses, and \$393 million in stock options.⁶³ His extreme profiteering drew criticism, including from some in Congress.⁶⁴ Despite criticism, Bancel continues without legal impediment.

The COVID-19 vaccine story has not been so positive for everyone. Some companies ultimately ended their efforts to bring a drug to market or failed to generate profits for some or all of their time producing COVID-19 vaccines.⁶⁵ More than this, COVID-19 vaccinations actually physically harmed some individuals.

It is true that, to date, confirmed COVID-19 vaccine injuries are relatively rare.⁶⁶ They range from minor side-effects and health impacts to life-threatening conditions and death as a result of the vaccination.⁶⁷ And investigations continue to consider other possible injuries and illnesses that scientists have not yet fully studied or discovered.⁶⁸ While such

62. See Hanna Ziady, *COVID Vaccine Profits Mint 9 New Pharma Billionaires*, CNN BUS., <https://perma.cc/JV35-T3DJ> (May 21, 2021, 4:03 PM) (reporting that “nine new billionaires are worth a combined \$19.3 billion, enough to vaccinate some 780 million people in low-income countries”).

63. See Beth Mole, *Moderna Rakes in Surprise Profits Ahead of 400% Price Hike*, ARS TECHNICA (May 5, 2023, 12:26 PM), <https://perma.cc/HXK9-CCU8>.

64. See *id.*

65. See Hannah Kuchler & Leila Abboud, *Why the Three Biggest Vaccine Makers Failed on COVID-19*, FIN. TIMES, Feb. 16, 2021, ProQuest, Doc. No. 2502136688 (describing how Merck Pharmaceuticals abandoned its efforts to develop a COVID-19 vaccine); Tom Espiner, *AstraZeneca to Take Profits from COVID Vaccine*, BBC (Nov. 12, 2021), <https://perma.cc/6HMK-LBP7> (starting in 2022 the company planned to sell some of its vaccine doses at a modest profit); Press Release, Johnson & Johnson, Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA for Emergency Use (Feb. 27, 2021), <https://perma.cc/9H3D-25KV> (promising non-profit approach to sale of its COVID-19 vaccine, Ensemble, during the pandemic period).

66. See Apoorva Mandavilli, *COVID Vaccine Side Effects: 4 Take Aways for Our Investigation*, N.Y. TIMES (May 3, 2024), <https://perma.cc/R4K5-P8Y7> (reporting on studies of rare instances of injuries including blood-clotting, myocarditis, and shingles).

67. See *id.*; see also *Selected Adverse Events Reported After COVID-19 Vaccination*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/6URF-34WE> (Sept. 12, 2023) (reporting on rare cases of anaphylaxis, myocarditis, pericarditis, thrombosis and death following administration of some COVID-19 vaccines); *COVID-19 Vaccines and Adverse Events of Special Interest: Study of 99 Million Vaccinated Individuals*, 42 VACCINE 2200, 2204–05 (Jan. 30, 2024) (confirming statistically significant connection across multiple continents for neurological, hematological, and cardiovascular conditions following vaccination for COVID-19).

68. See Bruce Y. Lee, *Is “Long Vax Syndrome” a Rare COVID-19 Side Effect? Here’s What’s Known*, FORBES (Jan. 10, 2023, 3:21 PM), <https://perma.cc/RR6X-YZKU>

injuries may be rare—so too were individualized assessments of risk or warnings of possible serious side-effects at the time COVID-19 vaccinations were introduced to market.⁶⁹ What follows are just some accounts from around the world relating to reports of such harms, from mild symptoms to serious injuries to death.

III. SAMPLING OF VACCINE INJURY ALLEGATIONS REPORTED WORLDWIDE

A. *Johnson & Johnson (Ensemble)*

Monica Melkonian, a 52-year-old health care professional, received her single-shot J & J COVID-19 viral vector vaccine on April 7, 2021.⁷⁰ Ten days later, she died of an acute episode of thrombosis with thrombocytopenia syndrome (TTS), an unusual blood clotting disorder, which led to a fatal brain bleed.⁷¹ Remarkably, Monica’s husband, also in the health care industry, remains supportive of COVID-19 vaccines.⁷² But he believes the lack of disclosures provided during the roll-out was problematic.⁷³ Without detailed warnings and other important instructions, he believes patients like his wife could not meaningfully weigh and consider their options prior to vaccination.⁷⁴

At this point, it is undisputed that at least 60 people died from TTS in the United States after receiving J & J’s COVID-19 vaccine.⁷⁵ To be sure, cases are rare given that 18 million people received the drug in this country after its emergency approval in February 2021.⁷⁶ But women approaching middle age have developed a heightened risk for the condition after vaccination at a rate of one case in every 100,000.⁷⁷

(raising concerns about “a potential rare condition in which people’s immune systems may be overreacting to the Covid-19 vaccine” and urging further investigative studies like one currently underway at Yale); *see also* Roya Hosseini & Nayere Askari, *A Review of Neurological Side Effects of COVID-19 Vaccination*, 28 EUR. J. MED. RSCH. 5 (Feb. 25, 2023), <https://perma.cc/D42S-NTQR> (noting range of mild to life-threatening neurological side-effects reported after vaccination, worthy of greater study).

69. *See* World Health Organization, *COVID-19 Vaccine Side Effects*, YOUTUBE (Mar. 31, 2021), <https://perma.cc/FS5Z-9P4P> (warning of possibility of mild or moderate post-vaccination effects like pain at inoculation location, chills, or short-term fever).

70. *See* Markian Hawryluk, *His Wife Died from Johnson & Johnson Covid Vaccine Complications. Why He’s Still Pro-Vaccine*, NBC NEWS (Mar. 2, 2022, 5:00 AM), <https://perma.cc/SY68-LT6Y> (interviewing Stan Thomas, whose wife died of TTS after receiving the J & J vaccine).

71. *See id.*

72. *See id.*

73. *See id.*

74. *See id.*

75. *See id.*

76. *See id.*

77. *See id.*

However, most similarly situated patients—like Monica Melkonian—had no idea of their risk at the time they received their J & J shot.⁷⁸

After cases like Monica Melkonian’s came to light, the United States only briefly paused use of J & J vaccines during 2021. Usage resumed about a week or so later, with confusing amended cautions from the government.⁷⁹ In June 2021, the United States government actually donated three million doses of the J & J vaccine for use in Brazil.⁸⁰

By January 2022, renewed public concerns arose. The CDC then recommended using other vaccines, if available, before turning to J & J vaccines.⁸¹ But in May 2022, WHO issued even stronger warnings. These warnings are somewhat hard to understand because WHO wrote them for experts rather than lay readers. But the notices urged manufacturers and medical professionals to transition from formulas like those used by J & J in its single-shot viral vector dose to multi-shot mRNA vaccines formulations that presented less risk.⁸²

The Food and Drug Administration (FDA) did not formally end J & J COVID-19 vaccine use in the United States until May 2023. And the FDA only ended use after the manufacturer specifically asked the FDA remove the vaccine from the emergency approval list.⁸³ When this occurred, the United States permitted several million doses that it had already purchased to “go bad” by remaining in storage beyond their expiration dates.⁸⁴ This turn of events took place in tandem with a rather muted and seemingly carefully managed messaging campaign about

78. See *id.*; see also *Questions About COVID-19 Vaccination*, AM. HEART ASS’N, <https://perma.cc/QZ9H-3KJV> (last visited Oct. 3, 2023) (vaguely referencing a few rare side effects that may occur following vaccination with the Pfizer, Moderna, and Novovax drugs, indicating that other unnamed possible side effects are still being studied, and noting without referencing any injuries that the J & J Vaccine is no longer available in the U.S.).

79. Press Release, FDA, FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review (Apr. 23, 2021), <https://perma.cc/Z9QU-GYGA>.

80. See *The United States Donates 3 Million Doses of Johnson & Johnson Vaccine to Brazil*, U.S. EMBASSY & CONSULATES IN BRAZ. (June 25, 2021), <https://perma.cc/Y7XQ-GHAL>.

81. See Sara E. Oliver et al., *Use of the Janseen (Johnson & Johnson) COVID-19 Vaccine: Updated Recommendations*, 71 MMWR MORBIDITY MORTALITY WKLY. REP. 90, 94 (2021) (warning that “Pfizer-BioNTech or Moderna mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination” and that the J & J drug might be used in limited “situations, including for persons with a contraindication to receipt of mRNA COVID-19 vaccines”).

82. See Beth Mole, *J & J’s COVID Vaccine is Dead in the U.S.; FDA Revokes Authorization*, ARS TECHNICA (June 3, 2023, 5:24 PM), <https://perma.cc/ER43-NQ2F> (citing to WHO’s May 18, 2023 statements urging change in direction for vaccine development and deployment).

83. See *Janseen COVID-19 Vaccine*, FDA, <https://perma.cc/8YNY-HGXX> (last visited July 23, 2024) (noting that in May 2023, J & J requested that its own emergency use authorization be permitted to expire)

84. See Mole, *supra* note 82.

declining needs for the drug.⁸⁵ At the time, neither J & J nor government regulators offered meaningful public statements about the deaths or details of how survivors would be compensated.⁸⁶ It also appears that other parts of the world, including Great Britain and Northern Ireland, continued to use the vaccine.⁸⁷

B. AstraZeneca (Vaxzevria)

Across the Atlantic, many people report that family members died or suffered serious injuries after receiving the COVID-19 vaccine created by AstraZeneca and Oxford University, another viral vector-based drug rather than one using mRNA. For instance, Australian-born Melle Stewart worked as a successful actor in musical theater prior to receiving her shots in England.⁸⁸ Before the lockdown, she played the lead in Cole Porter's *Kiss Me Kate*, at Belfast's Lyric Theatre in Northern Ireland.⁸⁹ Following her AstraZeneca vaccination, she suffered a stroke that required invasive brain surgery, and now has difficulty talking.⁹⁰

Kurt Weideling lost his wife Nicola, who was a senior marketing manager at Oxford, after she received the AstraZeneca/Oxford-developed drug.⁹¹ Like Monica Melkonian, Nicola Weideling suffered a catastrophic bleed on the brain. Dan Harris's family tells a similar story.⁹² Harris was a healthy 32-year-old when he got his AstraZeneca COVID-19 vaccination in the UK.⁹³ Less than two weeks later, he died from a brain

85. *See id.*

86. *See* Nacha Cattan, *FDA Revokes Authorization of J&J's Covid Vaccine as Demand Wanes*, BLOOMBERG (June 5, 2023, 11:05 AM), <https://perma.cc/PSW9-LNMK>; *see also, e.g.*, SUDHAKAR AGNIHOTHRAM, MEMORANDUM SUPPORTING REVOCATION OF JANSSEN'S EUA 27205, at 2 (2023), <https://perma.cc/Q5RY-CKDX> (describing how J & J's COVID-19 vaccine would no longer be used or sold in the United States).

87. *See* *Regulatory Approval of COVID-19 Vaccine Janssen*, GOV.UK, <https://perma.cc/TP7K-E4QA> (Oct. 19, 2023) (providing "[i]nformation for healthcare professionals and the public about the COVID-19 Vaccine Janssen" through October 2023); *see also* GOV.UK, UPDATED INFORMATION SHEET RELATING TO JANSEEN COVID-19 VACCINE (2023), <https://perma.cc/44XJ-7DWY>.

88. *See* *Australian Actress Melle Stewart Suffers Massive Stroke After AstraZeneca Vaccine*, NEWS.COM.AU (Nov. 11, 2023, 12:17 AM), <https://perma.cc/X7SK-SWXN> [hereinafter *Stewart Suffers Massive Stroke*].

89. *See* Robert Mendick, *'Every Day is Hard': The Families Battling for AstraZeneca Vaccine Compensation*, TELEGRAPH (Nov. 9, 2023, 5:11 PM), <https://perma.cc/ADA5-THAR>.

90. *See id.*

91. *See* Robert Mendick, *'Oxford Developed Jab That Killed My Wife, Then Made £143m'*, TELEGRAPH (Nov. 24, 2023, 2:14 PM), <https://perma.cc/V4B8-PAAJ>.

92. *See* Mendick, *supra* note 89.

93. *See id.*

hemorrhage.⁹⁴ His death certificate noted adverse reaction to the COVID-19 vaccine as the cause of his death.⁹⁵

Ross Wightman, a pilot and real estate agent in Canada, became paralyzed within 30 days of receiving his AstraZeneca vaccine.⁹⁶ The father of two young children was hospitalized for an extended period of time and ultimately diagnosed with Guillain-Barré Syndrome.⁹⁷ Since his release from the hospital, his mobility remains limited, and he uses a wheelchair.⁹⁸

As these accounts mounted, some countries stopped using AstraZeneca's vaccine.⁹⁹ But official stakeholders, including WHO, continued to assert that the drug's benefits outweighed its risks.¹⁰⁰ Thus, many nations continued to use it. Finally, in May 2024, the manufacturers withdrew the medicine from the market, similar to the way J & J did several months before.¹⁰¹ In doing so, they merely focused on reduced demand in light of other medicines available.¹⁰²

But now—after dozens died of blood clots and hundreds more were otherwise negatively impacted by clotting in the UK alone¹⁰³—AstraZeneca does admit its vaccine likely contributed to blood disorders and TTS.¹⁰⁴ Again, people may consider injuries like these rare given the millions who received the vaccination and did not report such effects.¹⁰⁵

94. *See id.*

95. *See id.*

96. *See* Janyse McGregor, *Applications Open for Federal Vaccine Injury Compensation*, CBC (June 4, 2021, 4:00 AM), <https://perma.cc/4Z48-7A6S> (highlighting the case of Ross Wightman in Canada).

97. *See id.*

98. *See id.*

99. *See* Megan Redshaw, *20+ Countries Suspend Use of AstraZeneca Vaccine, But Regulators Insist "Benefits Outweigh Risks,"* CHILD.'S HEALTH DEFENSE (Mar. 16, 2021), <https://perma.cc/X3S8-LVZD>.

100. *See id.* (reporting that WHO and the European Medicines Agency (EMA) defended continued use of the AstraZeneca Vaccine even as several nations, including Italy, France, and Denmark placed restrictions on continued use of at least some batches of the drug).

101. *See* Melissa Davey, *AstraZeneca Withdraws Covid-19 Vaccine Worldwide, Citing Surplus of Newer Vaccines*, GUARDIAN (May 7, 2024, 10:18 PM), <https://perma.cc/XAW4-ET3Y> (quoting company officials as claiming the "surplus of available updated vaccines" drove their decision to take the AstraZeneca vaccine off the market).

102. *See id.*

103. *See* Michael Levenson, *British Man Died of Rare Blood Syndrome Linked to AstraZeneca's Vaccine*, N.Y. TIMES (Apr. 20, 2023), <https://perma.cc/CW28-CH3H> (estimating approximately 40 deaths and 200 cases of clotting as of April 2023); *see also* Mendick, *supra* note 89.

104. *See, e.g.,* Justine Ra, *AstraZeneca Admits Covid-19 Vaccine May Cause Blood Clots in "Very Rare" Cases*, PHARM. TECH. (May 1, 2024), <https://perma.cc/W6C3-3E9K> (reporting on AstraZeneca's admission).

105. *See* Ra, *supra* note 104.

Still some, like Melle Stewart and her family, feel misled about the safety of the medicine and possible vaccine consequences—including limits on compensation for those injured by the drug.¹⁰⁶

C. *Moderna (Spikevax)*

In Canada, the press reported on the experience of Tisir Otahbachi of Quebec, who suffered a severe and painful skin condition after receiving the Moderna COVID-19 vaccine in the summer of 2021.¹⁰⁷ Shortly after his vaccination, Otahbachi developed severe blistering, weeping, and peeling all over his body. The condition caused him significant physical discomfort such that he could not work or even bathe. To him, this condition seemed to be an obvious adverse vaccination effect.¹⁰⁸ Yet according to Otahbachi, most medical professionals did not want to seriously consider this possibility. He believes most doctors “were very worried and scared” to name the vaccine as a cause because they did not want to undermine vaccination efforts.¹⁰⁹

Otahbachi is not alone. According to the Canadian Broadcasting Corporation, approximately 20 people have reported serious skin conditions, called erythema multiforme, after receiving Moderna’s vaccine.¹¹⁰ Some researchers have noted “growing evidence” of skin infections and related reactions following Moderna shots and Moderna acknowledges that in some very rare instances a serious skin rash can result, though claims that it generally resolves in minutes.¹¹¹

More recently, Karolina Stancik’s story has drawn media attention in the United States. At age 24, she received Moderna’s COVID-19 shots as part of military vaccination efforts.¹¹² Shortly thereafter, she suffered several life-threatening medical episodes, including a stroke and heart attack.¹¹³ She accused the military of abandoning her and explained that she is dealing with mounting medical costs without a continuing military salary or medical benefits.¹¹⁴ In response, in June 2024, the United States Department of Defense ultimately labeled Stancik as a soldier injured “in

106. See *Stewart Suffers Massive Stroke*, *supra* note 88; see also Mendick, *supra* note 89.

107. See Alistair Steele, “My Body Was Burning,” *Suffering Since COVID Shots, Gatineau Man Desperate for Relief*, CBC (Jan. 9, 2023, 4:00 AM), <https://perma.cc/WCD7-GQ4W> (reporting on Otahbachi’s experience).

108. See *id.*

109. *Id.*

110. See *id.*

111. *Id.*

112. *COVID Vaccine Caused Heart Attacks, Stroke: Solider*, MSN (June 25, 2024, 8:23 AM), <https://perma.cc/6WMA-W4NG>.

113. See *id.*

114. See *id.*

the line of duty”—and acknowledged the vaccine possibly caused her injuries.¹¹⁵

D. Pfizer (Comirnaty)

In 2021, Stephanie and Patrick de Garay provided heart-wrenching testimony to the FDA relating to their daughter, Maddie.¹¹⁶ Twelve-year-old Maddie took part in Pfizer’s Ohio vaccine study, hoping to help other youth stay healthy.¹¹⁷ However, after her vaccination, she had near-fatal adverse reactions.¹¹⁸ These reactions included severe abdominal and chest pains, persistent nausea and vomiting, blood in her urine, erratic blood pressure and heart rate, and memory loss.¹¹⁹ She spent months in the hospital, now uses a wheelchair, cannot bathe herself, and eats with a feeding tube.¹²⁰

Yet, the de Garays believe doctors running Maddie’s clinical trials failed to report all her post-vaccine conditions to federal regulators.¹²¹ Instead, “functional abdominal pain” appears to be the only noted side effect.¹²² More than this, Pfizer and its collaborators promised the family that they would cover any of Maddie’s medical care costs associated with participation.¹²³ The de Garays say they received a referral to Medicaid instead.¹²⁴

On the African continent, Desmond Milligan alleges that he became paralyzed hours after his Pfizer COVID-19 vaccination.¹²⁵ Just 41 years old at the time, he says the vaccine “irrevocably” changed his life in the course of a single day.¹²⁶ Like others, he believes doctors did not give him enough information to appreciate the possible side effects of the drug.¹²⁷

115. Elizabeth Lawrence, *Army Admits Veteran Suffered COVID Vaccine Injury “In the Line of Duty”*: Report, AM. MIL. NEWS (June 25, 2024), <https://perma.cc/BUQ5-SWKW>.

116. See Stephanie de Garay, Comment Letter on Notice of Meeting of the Vaccines and Related Biological Products Advisory Committee (Nov. 5, 2021), <https://perma.cc/T4S5-JM2T>; see also Notice of Meeting of the Vaccines and Related Biological Products Advisory Committee, 86 Fed. Reg. 56959 (Oct. 13, 2021).

117. See de Garay, *supra* note 116.

118. See *id.*

119. See *id.*

120. See *id.*

121. See *id.*

122. *Id.*

123. See *id.*

124. See *id.*

125. See FREEDOM ALL., *Desmond Milligan*, <https://perma.cc/9CQ6-7SK9> (last visited July 19, 2024).

126. *Man Claims R31m for COVID-19 Jab “Paralysis,”* JUTA MED. BRIEF (Oct. 4, 2023), <https://perma.cc/G3G9-W4PS>.

127. See *id.*

As a result, he feels that Pfizer's and the government's negligence should allow him to receive meaningful monetary compensation and damages.¹²⁸

E. Other Injury Concerns and Ongoing Investigations

Other parts of the world, including India and Pakistan, developed and used other COVID-19 vaccines.¹²⁹ People reported negative impacts in many of those nations arising out of those vaccines too.¹³⁰ Indeed, beyond the stories and illnesses outlined above, vaccine recipients around the world have raised questions about everything from tinnitus and long-term fatigue¹³¹ to neurological problems¹³² and latent autoimmune diseases like rheumatoid and psoriatic arthritis.¹³³ Thus, regardless of manufacturer or drug formulation, many believe more investigation is needed, particularly for delayed-onset and chronic injuries.¹³⁴

128. *See id.*

129. *See* Nicoletta Lanese, *Quick Guide: Most Widely Used COVID-19 Vaccines and How They Work*, LIVE SCI., (Mar. 22, 2022), <https://perma.cc/8E3C-Y3TN> (noting dozens of vaccines were developed and 20 or so ultimately were administered world-wide); *see also* Vines, *supra* note 33 (referencing the Covaxin vaccine from Bharat Biotech in India and the BBIBP-CorV from Sinopharm of China used by Australian international students).

130. *See, e.g.*, Vivek Chauhan, *KGMU Study Shows Psychiatric, Neuro Side Effects of Covishield*, TIMES INDIA (June 26, 2024, 1:08 PM), <https://perma.cc/8HXY-B5WN>; Sana Ali, *70,102 Adverse Events After Vaccination Reported in India: Govt Data*, BUS. TODAY (Feb. 7, 2022, 4:42 PM), <https://perma.cc/V75D-RNNG>.

131. *See* Apoorva Mandavilla, *Thousands Believe COVID Vaccines Harmed Them. Is Anyone Listening?*, N.Y. TIMES, <https://perma.cc/W6GD-HMM6> (May 4, 2024) (reporting ongoing concerns about a range of conditions).

132. *See* Jacqui Wise, *COVID-19: Two Rare Vaccine Side Effects Detected in Large Global Study*, BRIT. MED. J. 1 (Feb. 26, 2024), <https://perma.cc/T9FY-K4MY> (reporting on study showing statistically significant increase in cases of transverse myelitis and acute disseminated encephalomyelitis).

133. Indeed, one of the authors of this paper, Mae Quinn, suffered onset of severe psoriatic arthritis following vaccination, impacting her mobility and other basic functions. Most doctors have disregarded possible connection to the vaccine. *But see* Ming Guo et al., *Insights into New Autoimmune Diseases After COVID-19 Vaccination*, 22 AUTOIMMUNE REV. 10 (Apr. 17, 2023), <https://perma.cc/FQ6C-PXYB> (reporting on multiple cases of autoimmune disease onset following COVID-19 vaccination and noting “[f]urther exploration is necessary to establish a causal relationship”); Karolina Akinosogluo et al., *COVID-19 Vaccine and Autoimmunity: Awakening the Sleeping Dragon*, 226 CLINICAL IMMUNOLOGY 1 (Apr. 3, 2021), <https://perma.cc/SYL9-LDUP> (stating “we hypothesize that, even though, COVID-19 vaccination does not provoke de novo immune mediated adverse events, it is possible that, the immunologic response triggers pre-existing underlying dysregulated pathways”).

134. *See* sources cited *supra* note 68; CARY FUNK ET AL., PEW RSCH. CTR., AMERICANS’ LARGELY POSITIVE VIEWS OF CHILDHOOD VACCINES HOLD STEADY 39 (2023), <https://perma.cc/Z68Q-AR9H> (“[M]ajority of Americans continue to say . . . ‘we don’t really know yet if there are serious health risks from COVID-19 vaccines.’”).

IV. COMPARISON OF SYSTEMS FOR EVALUATING COVID-19 VACCINE INJURY CLAIMS

On the other hand, there may be doubts about some vaccine injury claims. These doubts are understandable, especially because some of the loudest COVID-19 vaccination critiques have come from unreliable sources, such as extremists with a political agenda.¹³⁵ But in the United States and abroad, particularly for persons of color and other minoritized groups, history provides very good reason to be concerned about government-based and other mass medicalization programs.¹³⁶ More recent activities on the part of health and other officials—including inequitable delivery of medicine to poorer countries and affirmative misinformation to undermine China and its international vaccine campaign—have undermined their credibility.¹³⁷

135. See Kunihiko Miyazaki et al., *Aggressive Behavior of Anti-Vaxxers and Their Toxic Replies in English and Japanese*, 9 HUMANS. & SOC. SCIS. COMM'NS 1 (July 5, 2022), <https://perma.cc/JQ8E-HJBR> (noting attack posts on social media by persons and groups opposed to COVID-19 vaccines); Jonathan Jarry, *A Dozen Misguided Influencers Spread Most of the Anti-Vaccination Content on Social Media*, MCGILL: OFF. SCI. & SOC'Y (Mar. 31, 2021), <https://perma.cc/S8KE-K98S> (reporting about misleading social media claims, including that “Pfizer’s COVID-19 vaccine had killed more people than the disease itself”); see also Sophie Mylan & Charlotte Hardman, *COVID-19, Cults, and the Anti-Vax Movement*, 397 LANCET 1181, 1181 (2021) (recommending “contextual understanding . . . for vaccine hesitancy” rather than marginalization of those in the anti-vax movement). But see Matthew Impelli, *Fauci Reveals Vaccine Conversation with Robert F. Kennedy, Jr.*, NEWSWEEK (July 2, 2024, 10:03 AM), <https://perma.cc/BK4P-GKEQ> (interviewing Dr. Anthony Fauci, who asserts Robert F. Kennedy is authentically concerned and cares a great deal about children but alleging Kennedy and his organization, Children’s Health Defense, are spreading information without sufficient scientific basis).

136. See Belinda Archibong & Francis Annan, *What do Pfizer’s 1996 Drug Trials in Nigeria Teach Us About Vaccine Hesitancy?*, BROOKINGS (Dec. 3, 2021), <https://perma.cc/N8G2-PHV7> (recounting how a group of Black Muslim children in Nigeria suffered injuries or death after receiving Pfizer’s test drug, Trovan, with Nigerian parents reporting the company misled them about the study); Tessa Chelouch, *Teaching Hard Truths About Medicine and the Holocaust*, 23 AMA J. ETHICS 59, 61 (2021) (explaining the eugenics and medicalization justifications deployed by Nazi Germany murderers during the Holocaust); Ada McVean, *40 Years of Human Experimentation in America: The Tuskegee Study*, MCGILL: OFF. SCI. & SOC'Y (Jan. 25, 2019), <https://perma.cc/6ABV-2HXE> (Canadian review of “scientific racism” in the United States, including “the heinous nature of the Tuskegee Experiment” which, without consent, visited great harm on Black men in the context of a “study” on syphilis); BRENDA GUNN, U.N. OFF. OF THE HIGH COMM’R FOR HUM. RTS., *IGNORED TO DEATH: SYSTEMIC RACISM IN THE CANADIAN HEALTHCARE SYSTEM 1* (2017), <https://perma.cc/LN8C-VGDU> (lamenting “[w]idespread health disparities . . . for Indigenous peoples in Canada,” in part due to the history of racism in the nation’s healthcare system).

137. See Chris Bing & Joel Shectman, *Pentagon Ran Secret Anti-Vax Campaign to Undermine China During Pandemic*, REUTERS (June 14, 2024, 9:45 AM), <https://perma.cc/WM4V-53JB> (reporting on a “clandestine operation” run by the U.S. military to “sow doubt about the safety and efficacy of vaccines and other life-saving aid that was being supplied by China” to the Philippines); *The Pentagon Ran a Secret Anti-*

Moreover, doctors have long recognized that even under the best of circumstances, real and serious injuries can result from medicines—including vaccines.¹³⁸ Thus, at least in the United States, courts permitted individuals to turn to the justice system to have medical and vaccine injury claims evaluated and considered.¹³⁹ This evaluation and consideration took place in the context of traditional jury trials or, in the case of vaccine claims, by way of special federal court of claims dockets. Courts use such judicial processes to weed out unsubstantiated accusations, redress well-founded allegations, and provide claimants with a largely transparent process where they feel heard and respected—even if they do not prevail.¹⁴⁰

However, as noted, pharmaceutical companies convinced many governments to limit their litigation risks and redirect COVID-19 vaccine claims away from existing judicial processes. As a result, governments and vaccine partners developed a range of “no-fault,” corporate-favoring court alternatives. Much like the pandemic itself, these systems have quickly swept across the globe. Thus, in the United States—unbeknownst to many laypeople and lawyers alike—court processes are unavailable for COVID-19 vaccine injuries claims.

Many other nations, too, have worked to divert COVID-19 vaccine injury matters away from courts and traditional adjudicative methods at the request of COVAX and manufacturers. This global phenomenon occurred with little warning to consumers, little information about how the alternative systems would operate, and little understanding of the potential impacts.¹⁴¹ Here we seek to shed further light on some of these new

Vax Campaign to Undermine China During Pandemic, an Investigation Finds, ABC AUSTRALIA (Jun. 15, 2024), <https://perma.cc/WZP6-6SY2> (doing the same).

138. See René F. Najera, *Historical Vaccine Associated Incidents*, HIST. OF VACCINES (Mar. 21, 2023), <https://perma.cc/QA74-J79F> (describing range of historical incidents and accidents where vaccines caused injuries, even for medicines that had been long-trusted).

139. See Richard Marcus, *Putting American Procedural Exceptionalism into a Globalized Context*, 53 AM. J. COMPAR. L. 709, 709 (2005) (reviewing several books that compare the practices of courts across in different countries); Anne-Marie Slaughter, *A Global Community of Courts*, 44 HARV. INT’L L.J. 191, 196 (2003) (describing shared concepts and values across national courts around the world, including “constitutional cross-fertilization”).

140. See Justin Sevier, *Procedural Justice in COVID-19 Era Civil Trials*, 71 DEPAUL L. REV. 493, 501 (2022) (describing centrality of court processes to contemporary understandings of justice, including the “quality of the process by which courts adjudicate cases—as well as the interpersonal treatment to which parties and witnesses are subjected”); David Barnhizer, *The Virtue of Ordered Conflict: A Defense of the Adversarial System*, 79 NEB. L. REV. 657, 658–59, 675–76 (2000) (asserting “widespread access to the adversary system with its formalized rules of conflict is essential,” allowing citizens to “assert their grievances through law and to defend against others’ grievances against them”).

141. See, e.g., Lisa Munger, *Will U.S. Pharma See Lawsuits Over COVID Vaccine Side Effects?*, BIOSPACE (June 20, 2023), <https://perma.cc/JF3A-8ZLX> (describing how

alternative claim systems, largely a mystery to many—even now, five years after the first case of COVID-19.

A. Alternative Systems – COVAX Partner Countries

Countries that accessed COVID-19 vaccines through the COVAX system were expected to create mechanisms that protected Gavi’s partners and consortium stakeholders.¹⁴² These protections included new protocols for addressing vaccine injury claims against manufacturers.¹⁴³ Gavi expected economically stable countries, like South Africa and Australia, to create their own such mechanisms.¹⁴⁴ As for low- and middle-income countries, they were provided with access to a COVAX-run vaccine injury claim system and urged by Gavi to utilize it as the only mechanism for injury compensation for their citizens.¹⁴⁵

1. Low- and Middle-Income Countries – AMC Economies

COVAX’s non-court-based international claim system for vaccine injury compensation is the first of its kind.¹⁴⁶ WHO, a COVAX partner, established the initiative in February 2021 when it signed an agreement with insurance giant, Chubb Limited (Chubb).¹⁴⁷ Chubb then launched a no-fault, lump-sum compensation initiative for low- and middle-income COVAX participating nations.¹⁴⁸ Chubb and WHO now direct the citizens

U.S. COVID vaccine manufacturers negotiated with the government – not individual patients – to obtain legal releases from liability). Indeed, neither author of this article – one who received shots in North America and the other who was vaccinated in Africa – remember being presented with specific information from medical staff about manufacturer protections from legal liability at the time injections were administered.

142. See *supra* notes 49–52 and accompanying text.

143. See *id.*; see also Rudolph Nkgadima, *Explained: SA’s Vaccine No-Fault Compensation, How It Works and How You Can Claim*, INDEP. ONLINE (Apr. 21, 2021), <https://perma.cc/SR33-NRU9> (quoting South Africa’s Health Minister as explaining this “is a standard condition, also given the nod by the World Health Organization (WHO)” which would “effectively would indemnify vaccine manufacturers, but still allow anyone adversely affected by Covid-19 vaccines to claim recompense”).

144. See *No Fault Compensation Programme for Covid-19 Vaccines is a World First*, WORLD HEALTH ORG. (Feb. 22, 2021), <https://perma.cc/VMM6-H5SR>.

145. See *id.*

146. See *id.*

147. See *id.* (describing Chubb as “the world’s largest publicly traded property and casualty insurance company” including “operations in 54 countries and territories” providing “commercial and personal property and casualty insurance, personal accident and supplemental health insurance, reinsurance and life insurance to a diverse group of clients” in addition to being an “underwriting company” whose work is to “assess, assume and manage risk with insight and discipline”).

148. See *id.*; see also Katelyn J. Yoo et al., *COVAX and Equitable Access to COVID-19 Vaccines*, 100 BULL. WORLD HEALTH ORG. 315, 315 (2022) (noting that in most of these countries citizens have an annual income equivalent to less than \$4000 in the United States).

of 92 low- and middle-income countries, referred to as COVAX Advance Market Commitment (“AMC”) eligible economies, to this non-court-based system.¹⁴⁹

As explained by WHO, the program was “financed initially through Gavi COVAX AMC donor funding, calculated as a levy charged on all doses of COVID-19 vaccines distributed through the COVAX Facility to the AMC eligible economies.”¹⁵⁰ As a result of the levies, Gavi COVAX AMC donor funding initially raised \$105 million in capital to support the claims fund.¹⁵¹ But Chubb also entered into agreements with various other insurance agencies to add to the coverage, raising the amount to \$150 million cumulatively for all claims across all continents submitted through the COVAX system.¹⁵² The program is primarily run through an online portal: www.covaxclaims.com. Thus, the COVAX-run injury claim system expects those living in AMC economies to submit a vaccine injury claim form and other supporting documentation by way of a computer.¹⁵³ However, the program will also accept applications by email or postal mail.¹⁵⁴

Notably, application forms are available in English, Spanish, and French only.¹⁵⁵ If an applicant does not speak those languages, the program expects them to contact the nearest COVAX claim regional center for assistance.¹⁵⁶ However, for 92 countries, only 11 regional

149. COVAX AMC eligible countries include Afghanistan, Burkina Faso, Burundi, Chad, Congo, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Korea, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Togo, Uganda, and Yemen. See COVAX, AMC ELIGIBLE ECONOMIES 6 (2021), <https://perma.cc/V67E-YVN3>; see also *Frequently Asked Questions (FAQs) Relating to the COVAX No-Fault Compensation Program for AMC Eligible Economies*, COVAX CLAIMS, <https://perma.cc/3GMF-A3KY> (last visited July 20, 2024) [hereinafter *Frequently Asked Questions*].

150. *No Fault Compensation Programme for Covid-19 Vaccines is a World First*, *supra* note 144.

151. See Hannah Balfour, *\$150 Million Made Available for COVID-19 Vaccine Adverse Event Compensation Scheme*, EUR. PHARM. REV. (Apr. 30, 2021), <https://perma.cc/TJC7-WT38>.

152. See Press Release, Chubb, Chubb and Marsh Collaborate to Secure Insurance Coverage for the COVAX No-Fault Compensation Program for 92 Low- and Middle-Income Countries (Apr. 29, 2021), <https://perma.cc/4FVC-8E3W> (noting that “[i]nsurance broker Marsh led the global placement of the bespoke solution” while “Chubb is the lead insurer, supported by a further 10 insurers located in the U.S., U.K., Germany, Ireland, Switzerland and Bermuda”).

153. See *No Fault Compensation Programme for Covid-19 Vaccines is a World First*, *supra* note 144; see also *Frequently Asked Questions*, *supra* note 149.

154. See *Frequently Asked Questions*, *supra* note 149.

155. See *id.*

156. See *id.*

centers exist.¹⁵⁷ As a result, the program assigns all 42 AMC countries in southern Africa to a single regional office.¹⁵⁸

Once a person submits an application, staff will investigate the claim to determine whether the claimant has suffered “permanent impairment or death associated with a COVID-19 [v]accine procured or distributed through the COVAX Facility, or the administration of such a [v]accine, within any AMC Eligible Economy.”¹⁵⁹ In addition, beyond proof of permanent impairment or death, the claimant must show they have one of the few identified conditions or injuries set forth in a COVAX claim system-created chart to qualify for compensation.¹⁶⁰ These include specific diagnoses like TTS, Guillain-Barre Syndrome, and Clarkson’s Disease (capillary leak syndrome).¹⁶¹

Different from other COVID-19 injury claims systems, COVAX then renders a financial award using a formula that accounts for annual cost of living for the region. That formula is:

GDP per capita of the relevant AMC eligible economy in which the claimant resides x 12 x a harm factor dependent on the nature of the injury and the level impairment (ranging from 0.1 to 1.5 - expected average 1.0).¹⁶²

According to Gavi and COVAX claim administrators, this formula intends to compensate persons fairly and equitably.¹⁶³ Gavi and claim administrators provide the following example to demonstrate this approach:

Based on an average GDP per capita for AMC countries of \$2,500 adjusted up to \$3,333 to factor in a security margin and to include costs to be reimbursed for hospitalizations associated with valid claims, the average pay-out is $\$3,333 \times 12 \times 1.0 = \$40,000$.¹⁶⁴

Thus, a physical injury in a COVAX nation is valued differently from the same injury in a wealthy nation. A compensation discount is provided

157. *See Contact Us*, COVAX CLAIMS, <https://perma.cc/7X7P-H3QA> (last visited July 21, 2024).

158. *See id.*

159. COVAX CLAIMS, <https://perma.cc/VRM4-W64V> (last visited July 21, 2024).

160. *See generally* COVAX, COVAX NO FAULT COMPENSATION PROGRAM FOR AMC ELIGIBLE ECONOMIES: VACCINATION INJURY TABLE (2023), <https://perma.cc/6JCM-YJEP>.

161. *See id.*

162. COAL. FOR EPIDEMIC PREPAREDNESS INNOVATIONS ET AL., COVAX NO-FAULT COMPENSATION PROGRAM FOR AMC ELIGIBLE ECONOMIES 9 (2021), <https://perma.cc/Z3Q5-3VNV> (PowerPoint presentation)

163. *See id.*

164. *Id.*; *see also Program Protocols*, COVAX CLAIMS, <https://perma.cc/SH79-85ES> (explaining, for instance, that a harm rate of “1” as in the above example is used in cases of death).

because the vaccine victim just so happens to live in an economically struggling nation – a practice that stands in contrast to Gavi concerns for equity.

The COVAX claims system materials offer warnings and somewhat confusing instructions about the possibility of seeking compensation through other means while also seeking relief from the COVAX system.¹⁶⁵ The materials also repeatedly drive home that awards provided by the COVAX compensation system serve as complete and final settlement of all claims for impacted individuals in AMC-eligible economies. This system requires claimants to sign away the right to pursue any other causes of action before receiving funds from COVAX.¹⁶⁶

As of May 31, 2024, the COVAX AMC system received 172 applications for vaccine injury compensation.¹⁶⁷ Most of the requests—59 in all—were from claimants in Africa, while 21 came from the East Asia Pacific region, and the rest came from people in other countries.¹⁶⁸ Apparently, some arrived without sufficient information, like proof of COVAX vaccination.¹⁶⁹ To date, of the 172 applications, the system approved 16 for compensation.¹⁷⁰ Of the 16 successful applications, 13 came from the East Asia Pacific region while only three African claimants had compensation requests approved.¹⁷¹ Some of the 172 applications are currently under consideration and the window to apply is still open for many months.¹⁷² Nevertheless, as will be further discussed below, COVAX applications and award numbers seem quite low—especially for African nations.

2. South Africa

The COVAX vaccine injury claim fund did not include South Africa because compared to other African countries, COVAX considers South Africa more financially stable.¹⁷³ Thus, while considered a member of the COVAX Facility group, manufacturers pressed South Africa to create its own alternative claim compensation system to be able to receive

165. See *Program Protocols*, *supra* note 164.

166. See *id.*

167. See COVAX, COVAX APPLICATION AND CLAIMS DATA (2024), <https://perma.cc/8JVZ-7X2T>.

168. See *id.*

169. See *id.*

170. See *id.*

171. See *id.*

172. See *id.*; see also *Program Protocols*, *supra* note 164.

173. See Aisha Abdool Karim & Joan Van Dyk, *How South Africa's COVID Vaccine Injury Fund Will Work*, BHEKISISA CTR. HEALTH JOURNALISM (Apr. 20, 2021), <https://perma.cc/6L2V-Z87Q> (“South Africa is not one of the 92 countries and territories that qualify to use [the COVAX-run injury claim system] “because the country is too wealthy”).

vaccines.¹⁷⁴ On April 15, 2021, the country posted proposed regulations for the no-fault compensation scheme—but only in very general terms.¹⁷⁵ In addition, South Africa gave concerned citizens only five days, through April 19, to share their thoughts and input, a much shorter period than usual for regulatory comments in South Africa.¹⁷⁶ South Africa used this short commenting period because Pfizer and J & J required country-based legal protections to be in place by April 30, 2021, to allow for vaccinations to begin in May 2021.¹⁷⁷

Given the speed of these efforts, many unanswered questions relating to the claim system remained, even as vaccinations began.¹⁷⁸ The South African Health Minister released little information about the program for much of 2021.¹⁷⁹ South Africa named retired South African Chief Justice Sandile Ngcobo head of the project.¹⁸⁰ Justice Ngcobo informed the public that he would oversee an Adjudication Panel that would decide claims based on whether the use of a COVID-19 vaccine causally related to injuries.¹⁸¹ But South Africa's government did not officially disclose the finer details about how the system would operate until April 2022.¹⁸² As of June 2022, the government was still seeking qualified professionals to serve on and assist the Adjudication Panel, including medical professionals, financial experts, and those with insurance actuarial experience.¹⁸³

Ultimately, claimants were directed to submit applications by way of an official form.¹⁸⁴ As part of their request they had to demonstrate they

174. *See id.* (referencing in general terms the indemnity conditions accepted by the government, protecting manufacturers from the kind of direct litigation that would ordinarily occur in the country).

175. *See id.* (stating that “regulations published on 15 April leave the finer details of the fund’s management up to directives from the health department or committees it appoints”).

176. *See id.* (describing the compressed time frame and concerns raised about the lack of details).

177. *See id.*

178. *See id.* (stating that “specifics of the pay-out system in South Africa will still be determined”).

179. *See* Press Release, Dep’t of Coop. Governance, Republic of S. Afr., Minister Nkosazana Dlamini Zuma on Regulations for Coronavirus COVID-19 Vaccine Injury No-fault Compensation Scheme (Apr. 22, 2021), <https://perma.cc/M5HV-M5WU>.

180. *See* Nkgadima, *supra* note 143.

181. *See id.*

182. *See generally* DEP’T OF HEALTH, REPUBLIC OF S. AFR., GOV’T NOTICE NO. 46196, DIRECTIONS ON THE ESTABLISHMENT OF A COVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME: ISSUED IN TERMS OF THE DISASTER MANAGEMENT ACT, 2002 (2022), <https://perma.cc/YXQ5-WYED>.

183. *See* DEP’T OF HEALTH, REPUBLIC OF S. AFR., ADVERT: ADJUDICATION PANEL COVID-19 VACCINE INJURY NO-FAULT COMPENSATION SCHEME (June 2022), <https://perma.cc/9BBK-2V5F>.

184. *See* DEP’T OF HEALTH, *supra* note 182, at 20.

received either the Pfizer or J & J vaccine in a country with an approved vaccination location sometime after May 21, 2021.¹⁸⁵ Thereafter, the Adjudication Panel was permitted to ask the claimant to undergo examination by government-appointed medical experts. Otherwise, claimants were required respond to inquiries for more information to determine the injury's cause.¹⁸⁶ The Adjudication Panel did not define the quantum of proof needed to prevail—other than a government determination that it was “causally linked.”¹⁸⁷

The no-fault system only covered “serious injuries” resulting in mental or physical impairment or death.¹⁸⁸ The Adjudication Panel set the maximum payout for death at a lump sum of 150,000 South African rands—which equals approximately \$8,200 dollars in the United States.¹⁸⁹ Less serious injuries were entitled to smaller payouts, proportionate to the severity of the injury, based upon a chart.¹⁹⁰

At the outset, the government anticipated between 800 and 2,000 claims based upon over 38 million vaccination doses.¹⁹¹ Consequently, the government set aside 250 million rands for payouts during the first year of the claim system alone.¹⁹² But as of June 2023, the South African government reported that it had received only 49 written claims to the no-fault system and determined 30 unfounded. The South African government made three payouts to families for vaccine-related deaths for a total of 450,000 rands.¹⁹³ All other awards totaled just 121,000 rands—less than \$6,700 dollars in the United States.¹⁹⁴

Finally, some literature indicates that the South African court and “no-fault” systems are not mutually exclusive, suggesting that seeking a remedy through both is possible.¹⁹⁵ However, according to the implementing regulations for South Africa's COVID-19 Vaccine Injury Compensation Scheme, by submitting a claim to the system, an individual “waives and abandons his or her right to institute legal proceedings in a

185. *See id.* at 23–25.

186. *See id.* at 14.

187. *Id.*

188. *See id.* at 11.

189. *See id.* at 28.

190. *See id.*

191. *See* Mayibongwe Maqhina, *Covid-19 Compensation Scheme Pays Out R450 000 for Three Deaths Linked to Covid-19 Vaccinations*, INDEP. ONLINE (June 21, 2023), <https://perma.cc/T3YK-93HU>.

192. *See id.*

193. *See id.*

194. *See id.*

195. *South Africa Covid Vaccine NFCS*, CTR. FOR SOCIO-LEGAL STUDS., UNIV. OF OXFORD, <https://perma.cc/SC3Y-PYFN> (last visited July 20, 2024) (explaining that Court litigation and NFCS are mutually exclusive - see Regulations 376/2021, 96(1)).

[c]ourt against any party for a claim arising from a harm, loss[,] or damage caused by a vaccine injury.”¹⁹⁶

This legal bar language is quite expansive if read literally, as it suggests even unsuccessful claims to the “no-fault” system would preclude litigation, not only against the manufacturer but also government officials and other partners.¹⁹⁷

3. Australia

The Australian government also worked in partnership with COVAX, agreeing to obtain a large percentage of its medicines through the collaborative distribution of vaccines worldwide.¹⁹⁸ As with South Africa, COVAX deemed Australia ineligible to participate in the COVAX no-fault injury claims system given its wealth.¹⁹⁹ Thus, COVAX required Australia to create its own mechanisms to help protect vaccine manufacturers from in-country lawsuits for vaccine harms.

Towards the end of 2021, the Australian government launched its administrative compensation scheme for those who allegedly suffered injuries from COVID-19 vaccines.²⁰⁰ The Australian government presented the compensation scheme as an important innovation that “gives people a way to seek compensation instead of going through legal proceedings.”²⁰¹ The system allows individuals who suffer covered vaccine-related harms to seek a one-time compensation payment for losses or expenses.²⁰² Initially, claimants needed to demonstrate at least \$5,000 of uncovered costs—but the system lowered it to a \$1,000 threshold to allow for more awards.²⁰³ In addition, while the initial cap for claims was

196. DEP’T OF HEALTH, REPUBLIC OF S. AFR., GOV’T NOTICE NO. 44485, DISASTER MANAGEMENT ACT, 2002, AMENDMENTS TO REGULATIONS ISSUED IN TERMS OF SECTION 27(2), at 7 (2021), <https://perma.cc/MNU4-4P46> (describing “[e]ffect of submission of claims on right to claim damages in court proceedings”).

197. *Id.*

198. *See Australia Commits AU\$ 80 Million to Guarantee Access to COVID-19 Vaccines for All*, GAVI (Aug. 28, 2020), <https://perma.cc/BZ69-XZEY> (reporting that “[t]he Australian Government will contribute AU\$ 80 million to Gavi’s COVAX Advance Market Commitment (AMC), a financing instrument aimed at supporting the participation of 92 lower- and middle-income economies”).

199. *See id.*

200. *See generally Covid-19 Vaccine Claims Scheme Policy 2021*, AUST’L DEP’T OF HEALTH & AGED CARE (2023), <https://perma.cc/VKW5-JUJL> (indicating current policy and amendments dating back to the September 2021 program launch).

201. *COVID-19 Vaccine Claims Scheme*, SERVS. AUSTL., <https://perma.cc/97UK-N2AR> (Feb. 6, 2024).

202. *See id.*; *see also* Frank Chung, *Payouts Begin Under Australia’s Vaccine Injury Claims Scheme*, NEWS.COM.AU (Feb. 17, 2022, 11:00 AM), <https://perma.cc/G4EU-WRK2> (noting that pressure from a legislator resulting in the amount being lowered).

203. *See* Chung, *supra* note 202.

\$20,000, Australia appears to have modified this cap to allow for more money in some instances.²⁰⁴

Still, a medical professional needs to sign off on claims, certifying that a person's condition is sufficiently linked to an adverse reaction to a COVID-19 vaccine. Thus, claimants must have a treating doctor who will indicate their reported injury is one that is recognized by the system, meets the required level of severity, and is caused by their vaccination.²⁰⁵ In addition, their injury must have caused an overnight stay in a hospital.²⁰⁶

Many within the country heavily criticized this scheme. Some have argued that program documentation requirements are too onerous and claim response times are too slow.²⁰⁷ Others say the system leaves families destitute while awaiting resolution of their claims and that the awards are far too low.²⁰⁸ There are also concerns that the system lists only a small number of officially recognized side effects as covered under the law.²⁰⁹ Indeed, as of February 2023, people filed over 3,000 claims with the Australian system.²¹⁰ But after many months, the system approved only 3%—about 100 claims—for payments.²¹¹

B. *Alternative Systems in Non-COVAX Connected Countries*

Manufacturers requested legal protection from money judgments from countries outside of the COVAX system, in exchange for expedited access to new vaccines for their citizens.²¹² By and large, jurisdictions outside the COVAX system entered into individual bilateral legal protection agreements with the companies.²¹³ The aforementioned countries then sought to have COVID-19 vaccine claims handled through nationally funded administrative claims systems outside of the courts—

204. *See id.* *See generally* COVID-19 VACCINE CLAIMS SCHEME, AUSTL. GOV'T (Dec. 19, 2023), <https://perma.cc/XQB2-T5JX> (describing various changes to program over time).

205. *See* Chung, *supra* note 202.

206. *See id.*

207. *See* Amy Landsley & Tyrone Clark, 'Severely Damaged' and Abandoned: Australian Victims of COVID-19 Vaccine Injuries Feel They Are 'Not Being Heard' by Australian Government, SKY NEWS, <https://perma.cc/8XGB-ZH3K> (Feb. 9, 2023) (cataloguing complaints by Australian's seeking to be compensated through the government's new system).

208. *See id.*

209. *See id.*; *see also* *Who Can Get It?*, SERVS. AUSTL., <https://perma.cc/KQH8-R63X> (Feb. 6, 2024) (listing covered injuries and expressly excluding others).

210. *See* Landsley & Clark, *supra* note 207.

211. *See id.*

212. *See supra* notes 25–28 and accompanying text.

213. *See* Alexandra L. Phelan et al., *Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access*, 396 LANCET 800, 800 (2020) (describing and critiquing bilateral agreements between wealthy nations and COVID-19 vaccine manufacturers, noting they can be high-risk endeavors that also drive inequity through "vaccine nationalism").

either pre-existing programs or new ones.²¹⁴ The United States, the UK, and Canada provide examples of these kinds of national “no-fault” administrative approaches.

1. United States

As noted, in his March 2020 Federal Register public health emergency declaration, the Secretary for the Department of Health and Human Services Alex Azar made clear his intent to legally protect COVID-19 drug manufacturers who created COVID-19 vaccines.²¹⁵ But the implications for injured parties were far less than clear.²¹⁶ Secretary Azar’s statement suggested that the Department would deal with COVID-19 vaccine injury claims as part of a Countermeasures Injury Compensation Program (“CICP”).²¹⁷ However, Secretary Azar provided no further details for that program, such as how to file claims for compensation. Instead, as part of the written notice, Secretary Azar simply directed interested persons to call a toll-free telephone number for more information.²¹⁸

This lack of information was likely because the United States had not previously utilized, in an expansive way, the special CICP system authorized by the PREP Act of 2006 until it administered COVID-19 vaccines. Although established in 2006, the United States did not fund the CICP system for many years, and the system did not start receiving claims until 2010.²¹⁹ Between 2010 and 2020, the program received fewer than 500 claims in all, almost all related to H1N1 vaccines, and approved only about 40 of those applications, for a total of approximately \$6 million in

214. See Cho Ryok Kang et al., *COVID-19 Vaccine Injury Compensation Program: Lessons Learned From a Review of 10 Implementing Countries*, 39 J. KOR. MED. SCI. 1, 6–7, 9 (2024), <https://perma.cc/7MC3-LHKY> (describing the efforts of several countries that created new administrative systems to handle vaccine injury claims relating to COVID-19, including Canada, Australia, and Singapore); see also Randy G. Mungwira et al., *Global Landscape Analysis of No-fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, 15 PLOS ONE 4 (May 21, 2020), <https://perma.cc/8C26-P8TW> (observing that “[t]he number of countries implementing no-fault compensation programmes for vaccine injuries has increased steadily from 19 in 2010 to 25 in 2018”).

215. See Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15201 (March 17, 2020) (providing the only exception to liability immunity relates to willful misconduct in connection with administration of the countermeasure); see also 42 U.S.C. § 247d-6d(c).

216. See Notice of Declaration, 85 Fed. Reg. at 15201.

217. See *id.* at 15203.

218. See *id.*

219. See Tom Hals, *COVID-19 Era Highlights U.S. ‘Black Hole’ Compensation Fund for Pandemic Vaccine Injuries*, REUTERS (Aug. 21, 2020, 10:22 AM), <https://perma.cc/UBW5-K4S4>.

awards.²²⁰ Therefore, in many ways, the CICIP feels like a brand new system being used for COVID-19 vaccine claims.

Indeed, Secretary Azar's June 2022 announcement about the CICIP system strongly suggested a response still in progress, as it failed to answer many questions.²²¹ For instance, the Federal Register announcement informed potential claimants that they had one year to submit claims from the time of "the covered countermeasure that is alleged to have caused the injury."²²² However, the announcement did not even describe the concept of a countermeasure, failing to use familiar terms like COVID-19, coronavirus, or pandemic in the Federal Register post.²²³

To this day, these terms are also conspicuously missing from the landing page of the online government-run portal that the announcement directed potential claimants to: <https://injurycompensation.hrsa.gov>.²²⁴ There, the website lists two government "injury compensation programs," the National Vaccine Injury Compensation Program ("VICP") and the Countermeasures Injury Compensation Program ("CICIP").²²⁵ Only by scrolling down and clicking on the fifth box in the CICIP column—labeled "What documents should I submit with my Request for Benefits Package?"—would a potential claimant learn that this system relates to COVID-19 vaccine injuries.²²⁶

Relatedly, the June 2022 Federal Register post indicated that "effective immediately," the CICIP program would "provide[] benefits to certain persons who sustain serious physical injuries or death as a result of administration of use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act."²²⁷ It also vaguely and generally referenced benefits for some survivors of those who died from COVID vaccines.²²⁸ But the post did not specify which survivors

220. *See id.*; *see also* Robert Roos, *Pending Injury Claims over 2009 H1N1 Vaccine Increase*, *CTR. FOR INFECTIOUS DISEASE RSCH. & POL'Y* (Sept. 15, 2021), <https://perma.cc/5LVH-NB4X>.

221. *See* Notice of Countermeasures Injury Compensation Program: Electronic Submissions, 87 Fed. Reg. 37877 (June 24, 2022).

222. *Id.*

223. *See id.*

224. *See id.*; *see also* *Countermeasure Injury Compensation Program (CICIP)*, *supra* note 18 (referencing two government run "injury compensation programs," the National Vaccine Injury Compensation Program (VICP) and the Countermeasures Injury Compensation Program (CICIP)). *See generally* *Injury Compensation Programs*, *U.S. HEALTH RES. & SERVS. ADMIN.*, <https://perma.cc/KQ6K-Z8ZD> (last visited Aug. 15, 2024).

225. *Injury Compensation Programs*, *supra* note 224.

226. And this is only because the CDC COVID-19 Vaccination Record Card is listed as an example of one of the items of proof to be submitted. *See id.*

227. Notice of Countermeasures Injury Compensation Program: Electronic Submissions, 87 Fed. Reg. 37877 (June 24, 2022).

228. *See id.*

would be eligible, explain how claims for victims or survivors would be evaluated or, very importantly, indicate that the CICIP would now serve as the single method for seeking COVID-19 vaccine injury compensation, precluding court cases, liability findings, or money judgments against manufacturers and their covered partners—absent willful misconduct.²²⁹

Instead, the June 2022 Federal Register post directed potential claimants to submit a completed Request for Benefits and release of medical records form, along with: (1) “[a]ll medical records documenting medical visits, procedures, consultations, and test results that occurred on or after the administration or use of the covered counter measure”; (2) “[a]ll hospital records, including the admission history and physical examination, the discharge summary,” etc., relating to the alleged injury; and (3) “[a]ll medical records for 1 year prior to administration or use of the covered countermeasure as necessary to indicate an injured countermeasure recipient’s pre-existing medical history.”²³⁰ Beyond this information, the post directed any questions to a single person—the Director of Injury Compensation programs—by postal mail or telephone.²³¹

By invoking his powers under the PREP Act and creating the CICIP, the Secretary of Health also chose to divert COVID-19 vaccine claims away from the existing specialized claim system for vaccine injuries—the VICP.²³² The United States Court of Federal Claims administers the VICP, a system that handles childhood shot injury and related vaccination matters, as an equitable court system without jury determinations.²³³ There claimants are able to present their cases to a federal court of claims adjudicator to seek appropriate compensation and a court judgment in their favor.²³⁴

Beyond judges overseeing proceedings, other significant differences exist between the existing VICP and new CICIP program created for COVID-19 vaccine claims. For instance, the VICP program has handled

229. *See id.*; *see also* 42 U.S.C. § 247d-6d (b)(7) (“No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.”); KEVIN HICKEY, CONG. RSCH. SERV., LSB10443, THE PREP ACT AND COVID-19, PART 1: STATUTORY AUTHORITY TO LIMIT LIABILITY FOR MEDICAL COUNTERMEASURES 2 (2022) (explaining that PREP Act coverage appears to preclude “at a minimum, most state law tort, medical malpractice, and wrongful death claims arising from the administration of covered countermeasures”).

230. Notice of Countermeasures Injury Compensation, 87 Fed. Reg. at 37877.

231. *See id.*

232. *See Injury Compensation Programs, supra* note 224.

233. *See Hals, supra* note 219.

234. *See id.*; *see also* U.S. HEALTH RES. & SERVS. ADMIN., WHAT YOU NEED TO KNOW ABOUT THE VACCINE INJURY COMPENSATION PROGRAM (VICP) 7 (2019), <https://perma.cc/DM3L-M6CZ> [hereinafter WHAT YOU NEED TO KNOW] (providing 15 pages of guidance for persons seeking to file injury claims with the federal Court of Claims’ VICP).

thousands of cases since its inception and awarded an average of over \$200 million annually.²³⁵ The court provides attorneys' fees so that claimants can receive quality representation.²³⁶ As the many critics of the CICIP have pointed out, the CICIP's burden of proof is harder to meet, the time period for bringing claims is shorter, and the compensation amounts are far more limited.²³⁷

Others have argued that the CICIP lacks transparency, historically and currently. Historically, the program has not published decisions in individual cases, provided detailed information about how the CICIP makes its decisions, or shared granular data about compensation awards. Thus, even before the pandemic, the CICIP left observers to largely guess about its internal workings and the rationales of its decisionmakers. These concerns have only increased in the wake of COVID-19 vaccine filings.²³⁸

As of June 2024, people submitted approximately 13,000 COVID-19 countermeasure injury claims to the CICIP, about 10,000 of which were for alleged vaccine injuries (versus injuries from other countermeasures, like ventilators).²³⁹ The system rendered decisions in roughly 2,800, with about 10,000 matters still under consideration.²⁴⁰ Of the 2,800 matters decided, the CICIP found only 50 people eligible for compensation.²⁴¹ Less than 15 people have actually received payments.²⁴² According to vaccine claim experts like Professor Renée Gentry, the CICIP provided little information publicly to explain decision delays or compensation denials.²⁴³ Even

235. See Hals, *supra* note 219.

236. See WHAT YOU NEED TO KNOW, *supra* note 234, at 6 ("If certain minimal requirements are met, the VICP will pay your lawyer's fees and other legal costs related to your claim, whether or not you are paid for a vaccine injury or death.").

237. See Katharine Van Tassel, *Covid-19 Vaccine Injuries — Preventing Inequities in Compensation*, 384 NEW ENG. J. MED. e34(1), e34(2) (2021) (observing that "CICIP is far less generous and less accessible than the VICP"); see also Brooke Conrad, *Those Injured by COVID-19 Vaccine Still Waiting for Government Compensation*, NAT'L DESK (Apr. 3, 2023, 12:05 PM), <https://perma.cc/HEM3-H58V> (quoting elected officials and academics who believe the CICIP system suffers from many shortcomings and is inadequate to serve COVID-19 vaccine injury victims); Maryanne Demasi, *Covid-19: Is the US Compensation Scheme for Vaccine Injuries Fit for Purpose?* 377 BRIT. MED. J. 1 (Apr. 19, 2022), <https://perma.cc/K6MS-HVN6> (reporting on "[s]enators, lawyers, doctors, and others" who see the CICIP as a "more costly, opaque, and less generous system" than the VISIP).

238. See Junying Zhao et al., *Reforming the Countermeasures Injury Compensation Program for COVID-19 and Beyond: An Economic Perspective*, 9 J.L. & BIOSCIENCES 3 (June 30, 2022), <https://perma.cc/7UHU-VELZ>.

239. See *Countermeasures Injury Compensation Program (CICIP) Data*, U.S. HEALTH RES. & SERVS. ADMIN. <https://perma.cc/RZ2F-4APW> (July 2024).

240. See *id.*

241. See *id.*

242. See *id.*

243. See Renée Gentry, Professor, George Washington Univ. L. Sch., *National Vaccine Injury Compensation Program Needs Modernizing* 8 (Mar. 21, 2024), <https://perma.cc/7EQN-98CJ>; see also Renée Gentry & Richard Hughes IV, *Insult To The*

claimants are unclear about the status of their cases.²⁴⁴ Yet this is the system provided to Monica Melkonian, the de Garay family, and others in this country.

2. United Kingdom

Since 1961, the UK has maintained a single pre-existing no-fault vaccine claim system, which the UK expanded to allow for COVID-19 vaccination injury cases.²⁴⁵ Thus, the UK erected its Vaccine Damage Injury system at an earlier time and with less haste than the COVAX or Australian programs. Unlike the United States' CICIP approach, the UK's system serves as an additional forum for impacted individuals and families to seek compensation, which is available to claimants in addition to courts.²⁴⁶

People in England, Scotland, Wales, and Northern Ireland can seek a £120,000 lump-sum, tax-free payment if any vaccination shots disabled them—including those for COVID-19.²⁴⁷ To receive this payment, individuals must demonstrate a severe condition that produces 60% disability, which has included injuries such as loss of vision or even severe narcolepsy due to vaccination.²⁴⁸ For children, people must file claims after children reach two years of age, while adults have up to six years from the time of vaccination to submit their claims.²⁴⁹

As part of the UK Vaccine Damage Injury program: “[M]edical assessors are required to prepare medical assessment reports using standardized forms and processes that provide clear medical reasoning regarding causality and disability in language that is easy for a non-medical person to understand.”²⁵⁰ In addition, the program has greater

Injured: The Case For Modernizing Vaccine Injury Compensation, HEALTH AFFAIRS (July 19, 2023), <https://perma.cc/BRT2-CHFB>.

244. See Demasi, *supra* note 237, at 3 (recounting the experience of Michelle Zimmerman who explains: “Had I not called and written so often, I would not have known that they lost all record of me until it was too late to resubmit.”); Conrad, *supra* note 237 (describing a congressional hearing where a legislator had to directly ask Health and Human Services Secretary Xavier Becerra about the status of Cody Flint’s application – with Becerra erroneously suggesting it had been granted).

245. See Kang et al., *supra* note 214, at 7.

246. Cf. ASTRAZENECA UK LTD. & SEC’Y OF STATE FOR BUS., ENERGY, & INDUS. STRATEGY, SUPPLY AGREEMENT FOR AZD1222 32 (2024), <https://perma.cc/94B9-3ZTZ> (giving an example of a redacted advance purchase agreement reflecting a page full of redacted indemnification clauses).

247. See *Vaccine Damage Payment*, GOV.UK, <https://perma.cc/QDV2-6LKJ> (last visited Aug. 15, 2024).

248. See *id.*

249. See *id.*

250. See Kang et al., *supra* note 214, at 7.

credibility than some others as it is run as a public-private partnership in which a non-governmental medical expert reviews every decision.²⁵¹

In the UK, data from the Vaccine Disability Payment scheme demonstrates 137 payouts, which amounted to £16.4 million in relation to COVID-19 vaccine injuries, including 50 deaths and other injuries like stroke, vision loss, blood clots, and lung inflammation.²⁵² Unlike many other systems, such as those for the United States and COVAX, individuals can still pursue legal actions after receiving the disability payment.²⁵³

Indeed, people filed several cases in the UK court system against Oxford-AstraZeneca relating to its COVID-19 vaccine.²⁵⁴ One of the first claimants, Jamie Scott, a father of two, claimed to have suffered a brain injury resulting from a clot after he received the “jab” in 2021, leaving him unable to work.²⁵⁵ Others joined him in pursuing litigation, including the widower and two young children of Alpa Tailor, who lodged a second claim after their mother died from blood clots following a dose of the AstraZeneca vaccine.²⁵⁶ The claims focus on the manner in which medical professionals calculated and communicated risk to vaccine users, claiming medical professionals “vastly overstated” the vaccine’s efficacy and undermined consumer ability to meaningfully weigh their options.²⁵⁷

However, for the most part, the court claimants just want a level of compensation that appreciates the grievous nature of their families’ losses, which they feel £120,000—a total damages amount established many years ago—does not satisfy.²⁵⁸ As explained by one law firm representing British families in the courts:

None of the families with whom we are working want to bring a legal claim against AstraZeneca. They would prefer to have their injuries and losses acknowledged by AstraZeneca with appropriate

251. *See id.*

252. *See id.*

253. *See id.*

254. *See* Sam Tobin, *AstraZeneca facing two London lawsuits over COVID-19 vaccines*, REUTERS (Aug. 23, 2023, 1:43 PM), <https://perma.cc/YB5L-R8BU> (referencing legal claims to be brought by over 50 people in the UK).

255. *See id.*

256. *See id.*

257. *Id.*; *see also* Christian Yates, *AstraZeneca Sued Over Jab: Could it Be Down to a Misunderstanding of How Risk is Calculated?*, CONVERSATION (Nov. 14, 2023, 12:06 PM), <https://perma.cc/SF3N-W4V2> (explaining risk-based allegations for several claimants who have filed suit in the UK based upon failure to properly warn).

258. *See Claimant Group Brings Legal Claim Against AstraZeneca under Consumer Protection Act 1987*, HAUSFELD (Mar. 24, 2023), <https://perma.cc/6SFN-8ZEB> [hereinafter *Hausfeld Legal Claims Against AstraZeneca*]; *see also* Rachel Schraer, *Vaccine Damage Payment Scheme: The Battle for Compensation*, BBC (June 22, 2022), <https://perma.cc/Z2NG-RLPF> (quoting claimants who complain the government’s vaccine injury compensation award amount has not been reviewed for increase since 2010).

compensation to be paid. Those with whom we are working have been forced to begin legal action because the Vaccine Damage Payment Scheme offers inadequate funds to families devastated not only by the emotional impact of injury and loss – but also by the financial consequences.²⁵⁹

Kurt Weideling has also joined in the lawsuits against AstraZeneca on behalf of his wife who died after vaccination, as has Australian singer Melle Stewart, who received a vaccine in the UK.²⁶⁰

3. Canada

In contrast to both the United States and the UK, at the start of the COVID-19 pandemic, Canada, as a nation, did not have a specialized vaccine injury claim system through the courts or otherwise.²⁶¹ The Canadian province of Quebec, however, did have one.²⁶² Thus, when pharmaceutical companies demanded that the Canadian government ensure indemnity and protections against litigation for COVID-19 vaccines,²⁶³ the Canadian federal government looked to Quebec's administrative claim system as a model for a new national scheme.²⁶⁴ In December 2020, the federal government announced it would be creating a Vaccine Injury Support Program (“VISP”).²⁶⁵

The goal was to establish a non-court-based program for Canadians to seek financial support if they experienced a serious and permanent injury after receiving an authorized vaccine, including those for COVID-19.²⁶⁶ However, the Canadian government wanted a non-governmental

259. *Hausfeld Legal Claims Against AstraZeneca*, *supra* note 258.

260. See Robert Mendick, *AstraZeneca in £80m Covid Jab Compensation Claim Set to Be One of Biggest Battles of Its Kind*, TELEGRAPH (Jan 24, 2024, 5:03 PM), <https://perma.cc/5DD8-UQPP>; see *Stewart Suffers Massive Stroke*, *supra* note 88.

261. See Kang et al., *supra* note 214, at 7. See generally *Vaccine Injury Support Program*, PUB. HEALTH AGENCY OF CAN., <https://perma.cc/P8XB-4VFA> (last visited Aug. 15, 2024).

262. See Kang et al., *supra* note 214, at 7; see also Laura Osman, *Ottawa injects another \$36M into vaccine injury compensation fund*, NAT'L POST (Apr. 24, 2024), <https://perma.cc/97L2-VU3Y> (noting that since 1985 Quebec had its own administrative claims system to compensate vaccine-related injuries).

263. See Janyse McGregor, *Applications Open for Federal Vaccine Injury Compensation*, CBC (June 4, 2021, 4:00 AM), <https://perma.cc/G3BQ-7MNN> (describing how “the federal government’s COVID-19 vaccine purchase contracts required it to set up a national no-fault compensation program, retroactive to early December”).

264. See Terry Murray, *Canada’s Long Road to a Vaccine Injury Compensation Program*, 193 CAN. MED. ASS’N J. E294, E294–95 (2021) (offering insights into Quebec’s provincial program as potential model for Canada’s national system).

265. See *id.* at E294 (referencing Prime Minister Justin Trudeau’s preliminary announcement in December 2020 that a program would be forthcoming); see also McGregor, *supra* note 263 (describing the development and launch of Canada’s VISP in the wake of the COVID-19 pandemic).

266. See *Vaccine Injury Support Program*, *supra* note 261.

third-party to run the system.²⁶⁷ In March 2021, the Canadian government selected Raymond Chabot Grant Thornton (“RCGT”) Consulting as the private administrator and, by June 2021, RCGT formally launched the program.²⁶⁸ The government believed that retaining a consulting group like RCGT would bring credibility to the system, assuring Canadians that their claims were being evaluated independently.²⁶⁹ RCGT later changed its name to Oxaro.²⁷⁰

Like the COVAX system, the Canadian VISP shared information with prospective claimants by way of an online platform.²⁷¹ However, in contrast, VISP presents the steps of the process in a more clear and transparent fashion.²⁷² For instance, people need to submit all compensation applications by mail.²⁷³ Once received, VISP assigns a medical professional to conduct a preliminary screening and determine if the claim needs more medical records.²⁷⁴ Also differentiating the Canadian system from some others, VISP assigns a case manager to each claimant as a point of contact throughout the process.²⁷⁵ Ultimately, three doctors review every claim before VISP makes a final determination.²⁷⁶

Still, especially at the outset, people critiqued the system. Some criticized the program’s failure to make clear how it would determine compensation amounts.²⁷⁷ Others expressed frustration with the high threshold for severity of injury and the length of time it took for the system

267. See *Public Health Agency of Canada Vaccine Confidence Webinar Series: Understanding Canada’s Vaccine Injury Support Program*, GOV’T OF CANADA, <https://perma.cc/GF3M-FVX6> (Dec. 28, 2022).

268. See *id.*

269. See *id.*

270. See OXARO, <https://perma.cc/N45R-FW8V> (last visited Aug. 15, 2024) (explaining that in July 2023 RCGT decided to become Oxaro “to emphasize the start of a new chapter where we offer a wider range of digital and advisory services to our public sector clients”).

271. See *Frequently Asked Questions*, PUB. HEALTH AGENCY OF CAN., <https://perma.cc/F84M-8N2D> (last visited July 21, 2024).

272. See *generally id.*

273. See *id.*

274. See *id.*

275. See *id.*

276. See *id.*

277. See *Frequently Asked Questions*, *supra* note 271 (noting awards are “determined on a case by case basis” but “based on a pre-determined financial support payment framework” based on the one in Quebec); see also McGregor, *supra* note 265 (noting concerns about subjectivity in compensation awards).

to review requests.²⁷⁸ For instance, after running for about 18 months, the system received nearly 1,300 claims but only approved about 50.²⁷⁹

One of the earliest claimants to receive an award announcement was Ross Wightman. He reported that the maximum award possible was 284,000 in Canadian dollars—but he received somewhat less and has been dealing with delays in receiving payments.²⁸⁰ Beyond this lump-sum, tax-free payout, Wightman is also potentially eligible for up to 90,000 Canadian dollars annually in lost wage replacement.²⁸¹ After operating for three years, the VISP has now received 2,628 claims, completed review of 2,392, and approved 183 for compensation.²⁸² To date, VISP has awarded over 14 million in Canadian dollars in total to the 183 successful claimants.²⁸³

As for Tisir Otahbachi, he has not received compensation for his painful skin condition.²⁸⁴ Because he received a vaccine in Quebec, guidelines required him to file his claim with its provincial system.²⁸⁵ The system denied his first effort to obtain funds because the doctor who supported his claim did not practice in that province.²⁸⁶ He has now found a local allergist who believes the evidence “strongly suggests the vaccine played a role in bringing these symptoms on.”²⁸⁷ He is hopeful the system might now approve his claim. In the meantime, Otahbachi is still paying out of pocket for treatment and remains without wages, given his inability to work.²⁸⁸

Guidelines do not legally preclude those who seek financial relief from the Canadian VISP or Quebec’s provincial system from also

278. See McGregor, *supra* note 263 (sharing additional concerns of claimants and explaining that “serious and permanent injury” under the system means “a severe, life-threatening or life-altering injury that may require in-person hospitalization, or a prolongation of existing hospitalization, and results in persistent or significant disability or incapacity, or where the outcome is a congenital malformation or death.”).

279. See Karin Larsen, *\$2.8 Million Paid Out So Far by Vaccine Injury Support Program*, CBC (Jan. 7, 2023), <https://perma.cc/YH7U-UP9J>.

280. See Jon Hernandez, *B.C. Man Among First Canadians Approved for COVID-19 Vaccine Injury Payout*, CBC (June 1, 2022), <https://perma.cc/HP8A-QHWV> (reporting on Ross Wightman’s case and award, including sharing photo of award letter); Michele Brunoro, *‘Completely demoralizing’: B.C. men with COVID-19 vaccine injuries frustrated by compensation delays*, CTV NEWS VANCOUVER (Jan. 5, 2023), <https://perma.cc/Y576-WDBD> (calling out payment delays, including for Wightman).

281. See *id.*

282. See *Program Statistics*, PUB. HEALTH AGENCY OF CAN., <https://perma.cc/JJ47-MRY5> (last visited July 21, 2024).

283. See *id.*

284. See Steele, *supra* note 107.

285. See *id.*

286. See *id.*

287. *Id.*

288. See *id.*

pursuing litigation.²⁸⁹ But if people successfully sue the manufacturers, Canada has apparently agreed to make them whole under indemnity agreements.²⁹⁰ Thus far, Canada's alternative system seems to have successfully deterred direct litigation against manufacturers.

V. ADVOCACY AROUND COVID-19 VACCINE INJURY CLAIM SYSTEMS & CALLS FOR CHANGE

A. *Organizing, Information Sharing, and Legislative Efforts*

As explained, existing responses to COVID-19 vaccine injuries, including government-established alternative compensation claim systems, frustrate many living in the nations described above. Individuals, non-profit groups, and collaboratives have taken action in a range of ways. Such efforts include everything from testifying at public hearings to legislative efforts and crowdsourcing documents that other advocates might use.²⁹¹

The UK and United States held public hearings to consider responses from citizens impacted by COVID-19 vaccine injuries. In February 2024, the House Committee on Oversight and Accountability's Select Subcommittee on the Coronavirus Pandemic heard from a variety of concerned groups and individuals²⁹²—including legal experts and law professors like Renée Gentry.²⁹³ Based on what they heard, the congressional members hosting the meeting took the FDA to task for not having a firm handle on injury numbers and similarly admonished the CICIP for its backlog of thousands of cases.²⁹⁴

In the UK, Parliament is conducting the COVID-19 Inquiry and holding a range of hearings to focus on different issues and concerns—including the vaccine injury claim system.²⁹⁵ Both experts and lay witnesses participated by testifying to raise awareness and share accounts

289. See *Frequently Asked Questions*, *supra* note 271 (indicating claimants are not required to waive their right to litigate but are generally required to pay back VISIP funds if they obtain a damages award from the court system).

290. See Rachel Gilmore, *Coronavirus Vaccine Makers are Shielded from Liability*, GLOB. NEWS (Dec. 14, 2020, 3:54 PM), <https://perma.cc/8SKC-8HWL>.

291. See, e.g., Hong Xiao et al., *Sex, Racial, and Ethnic Representation in COVID-19 Clinical Trials*, 183 JAMA INTERNAL MED. 50, 56–57 (2022) (noting, among other things, that data showed good representation of Black individuals in COVID-19 treatment trials but underrepresentation in prevention trials, in addition to lack of sex, race, and ethnic documentation for some trials).

292. See Press Release, House Oversight Committee, Hearing Wrap Up: Americans Deserve Improved Vaccine Injury and Compensation Systems (Feb. 16, 2024), <https://perma.cc/5UEM-PECB>.

293. See generally Gentry, *supra* note 243.

294. See House Oversight Committee, *supra* note **Error! Bookmark not defined.**

295. See *What is the UK Covid-19 Inquiry?*, UK COVID-19 INQUIRY, <https://perma.cc/H7Z5-CTC8> (last visited July 21, 2024).

from England, Wales, North Ireland, and Scotland.²⁹⁶ Attorney Joseph Bryce offered the experiences of his clients, noting the “horribly unfair” treatment they have received in Scotland after coming forward with COVID-19 vaccine injuries.²⁹⁷

Testimonial accounts in both the UK and United States aid in driving legislative efforts, too. For instance, the UK Parliament introduced the COVID-19 Vaccine Damage Payments Bill to modify the compensation claim system, including by increasing the payment award cap.²⁹⁸ Parliamentary debate somewhat echoed information shared at the Inquiry, though noting that more needed to be done, rather than simply taking testimony and issuing a report.²⁹⁹ However, to date, Parliament has not passed a bill.³⁰⁰

In the United States, the House of Representatives jointly introduced the Vaccine Injury Modernization Compensation Act as a bipartisan measure.³⁰¹ The Act seeks to move COVID-19 vaccine injury claims from the backlogged administrative VICP to the court-based VICP, in addition to adding magistrates to the VICP and increasing award caps for COVID-19 vaccine matters.³⁰² The bill, supported by many, including experts in the field,³⁰³ is still pending.

Concerned citizens are engaging in other COVID-19 vaccine claim system activism too. The non-profit group Public Health and Medical Professionals for Transparency takes no position on the quality or quantity of data provided to date for COVID-19 vaccination impacts in the United States. However, this group believes that the public should be provided with as much information as possible. Thus, Public Health and Medical Professionals for Transparency has launched crowdsourcing, Freedom of Information Act requests, and litigation campaigns to shed further light on COVID-19 vaccine studies and related information. The group is sharing

296. See *Core Decision-making and Political Governance (Module 2)*, UK COVID-19 INQUIRY, <https://perma.cc/666G-T32C> (last visited July 21, 2024) (including reference to specific inquiries for UK territories outside of England like Northern Ireland, Scotland and Wales).

297. See Helen McArdle, *Scottish COVID Inquiry: Vaccine Injury Stigma ‘Horrific’*, HERALD (Oct. 14, 2023), <https://perma.cc/YZL7-8V6U>.

298. See *generally* Covid-19 Vaccine Damage Payments Bill 2022–3, HC Bill [45] (UK).

299. See HC Deb (20 Oct. 2023) (738) col. 500 (UK).

300. See HC Bill [45].

301. See Vaccine Injury Compensation Modernization Act of 2023, H.R. 5142, 118th Cong. (2023).

302. See Press Release, Lloyd Doggett, U.S. Rep., House of Reps., Rep. Doggett Files Legislation to Modernize Vaccine Injury Compensation Program (Aug. 4, 2023), <https://perma.cc/D63U-NRSQ>.

303. See, e.g., Gentry & Hughes, *supra* note 243.

the information it receives, including documents and data from vaccine clinical trials on its website.³⁰⁴

In South Africa, a non-profit group, Health Justice Initiative, made public information requests to access the contracts between country leaders and vaccine manufacturers. After their requests were denied, the group filed a lawsuit and was ultimately provided with access to the documents. Since then, they have released analysis suggesting that manufacturers charged South Africa more per dose than the European Union, which the manufacturers dispute.³⁰⁵ Similar grassroots transparency initiatives have occurred in countries beyond those examined for purposes of this Article.³⁰⁶ Beyond country-specific advocacy and organizing efforts, some groups have focused on international information sharing. These efforts included obtaining and posting online the contracts between COVID-19 manufacturers and various nations.³⁰⁷

B. Legal Challenges

Beyond the South African litigation mentioned above, people also filed lawsuits in Australia and the United States relating to COVID-19 vaccine injuries and the claim systems. These lawsuits are striking given that these three systems—in contrast to those in the UK and Canada—took a harder line on protecting vaccine manufacturers (and governments that signed indemnity agreements) by precluding court claims to advance negligence claims. In some ways, these suits serve as creative litigation workarounds to seek transparency and accountability.

For instance, in April 2023, lawyers filed a class action lawsuit directly against Australian government officials in the country's federal

304. *See id.*

305. *See* Elena Rogozenska, *NGO Wins Access to Secret Johnson & Johnson, Pfizer COVID-19 Contracts in South Africa*, CORPWATCH (Sept. 15, 2023), <https://perma.cc/6PBN-X34G>.

306. For instance, in Israel a grassroots organization called the People's Committee has formed to address alleged underreporting of vaccine injuries by media, government officials, and other sources. Founded by health professionals, attorneys and concerned citizens, it has collected over 4,700 testimonies of people reporting serious and even fatal injuries after being inoculated. *See The Testimonies Project*, VAX TESTIMONIES, <https://perma.cc/FQX2-UYUS> (last visited July 20, 2024). The viral Israeli-made documentary, "The Testimonies Project," drew from this pool and highlighted Israelis who believe the vaccine caused them injuries such as cardiac, blood, neurological, autoimmune, and skin disorders. *See id.* ("The Testimony Project was born to give a platform to all the victims after the Covid-19 vaccine, and to make the voices of those who are ignored by the Israeli media heard."),.

307. *Cf.* ASTRAZENECA UK LTD. & SEC'Y OF STATE FOR BUS., ENERGY, & INDUS. STRATEGY, *supra* note 246, at 32 (giving an example of a redacted advance purchase agreement reflecting a page full of redacted indemnification clauses).

court system for COVID-19 vaccination injuries.³⁰⁸ The suit named as defendants members of the Department of Health and Aged Care and the Deputy Secretary of Health Products Regulation Group. The plaintiffs seek to recover compensation on behalf of more than 500 people allegedly injured as a result of taking one or more COVID-19 vaccines.³⁰⁹ In light of the apparent limits on their ability to sue manufacturers, the plaintiffs allege that the defendants negligently approved and monitored the COVID-19 vaccines, breached statutory duties, and engaged in misfeasance while in public office.³¹⁰ As of April 2024, the lawsuit is pending and the law firm handling the case provides updates online.³¹¹

People in the United States filed similar lawsuits intended to work around negligence claim protections provided to vaccine manufacturers. What follows is just a sampling; people continue to file more lawsuits as this Article goes to press.³¹² For instance, in October 2023, a group of plaintiffs filed a federal lawsuit in Louisiana challenging the constitutionality of the CICIP.³¹³ They allege that despite suffering several degrees of severe injuries shortly after receiving the COVID-19 vaccine— injuries diagnosed by their doctors as vaccine-related—the CICIP unjustly denied their compensation claims.³¹⁴ They also argue that the federally run program is legally flawed in several key aspects.

First, they contend that the CICIP operates with insufficient transparency and a lack of due process, making it nearly impossible for claimants to successfully navigate the system and receive fair compensation.³¹⁵ Moreover, the plaintiffs argue that the evidentiary standards required by the CICIP are excessively stringent.³¹⁶ Even with medical diagnoses linking their injuries to the COVID-19 vaccine, many

308. See NR Barbi Solicitor, *Class Action – COVID-19 Vaccine Related Injuries*, COVID VAX CLASS ACTION, <https://perma.cc/MN36-R7XR> (last visited July 20, 2024) (relating to class action litigation in Australia and providing case documents to allow claimants and others to learn about the proceedings).

309. See *id.*; see also Sonia Hickey, *Class Action Commenced Over Covid-19 Vaccine Injuries*, SYDNEY CRIM. LAWS. (Aug. 5, 2023), <https://perma.cc/WE7P-SCFX>.

310. See Max Aitchison, *Class Action Lawsuit Over Covid Vaccine Injuries Targets the Australian Government: ‘There has Been a Cover-up,’* DAILY MAIL (Apr. 26, 2023, 10:57 PM), <https://perma.cc/TN7K-FXT4>.

311. See NR Barbi Solicitor, *supra* note 308.

312. See Mark Harper, *Florida Woman Says COVID-19 Shots Made her Sick, but Federal Law Protects Vaccine Makers*, DAYTONA BEACH NEWS-J. (July 3, 2024, 8:59 AM), <https://perma.cc/E6HV-CPLH> (explaining that Michelle Utter of Florida along with members of the group Moms for America, a group from Ohio, filed a lawsuit seeking to challenge the immunity agreements provided to COVID-19 vaccine manufacturers).

313. See generally Complaint, *Smith v. U.S. Health Res. & Servs. Admin.*, No. 3:23-cv-01425 (W.D. La. filed Oct. 10, 2023).

314. See Ian Lopez, *Covid Vaccine Injury Suit May Fuel Federal Overhaul*, LITIGATION, BLOOMBERG L. (Nov. 3, 2023, 9:05 AM), <https://perma.cc/A8XL-NDLY>.

315. See *id.*

316. See *id.*

claimants find their applications rejected due to the program's rigid criteria for establishing causation.³¹⁷ This rejection, they assert, violates their constitutional rights, as it denies them a reasonable opportunity to seek redress for their injuries.³¹⁸

People also recently filed two important lawsuits directly against vaccine manufacturers in the United States. First, a Utah mother of two, Brianne Dressen, filed suit in May 2024, against AstraZeneca.³¹⁹ She enrolled in a clinical trial for the company in November 2020, suffered injuries after a single dose, and was diagnosed by the National Institute of Health (NIH) with "post-vaccine neuropathy."³²⁰ Her case alleges the company breached its contract with her and is financially responsible for her injuries from the vaccines.³²¹

Second, the Attorney General for Kansas, Kris Kobach, brought suit on behalf of the state alleging that Pfizer engaged in false and misleading commercial practices when it sold its COVID-19 vaccines to residents of Kansas without sufficiently identifying health risks.³²² Interestingly, Kobach's complaint suggests that Pfizer actually declined financial incentives under Operation Warp Speed in order to avoid transparency and accountability requirements.³²³ This denial allowed Pfizer to hide critical data and information from consumers and harm them.³²⁴ By framing the Attorney General's lawsuit as one about misconduct versus negligence, and having government representatives bringing the case versus individual claimants, the State of Kansas has strong grounds to avoid arguments about legal hurdles based upon promised protections or indemnity.

VI. SOME OBSERVATIONS, POINTS OF COMPARISON, AND RECOMMENDATIONS FOR REFORM

The above discussion obviously does not provide comprehensive coverage of every country impacted by COVID-19 vaccine injuries or the

317. *See id.*

318. *See id.*; *see also* Christian Britschgi, *Lawsuit: COVID Vaccine Injury Claims Diverted to Unconstitutional 'Kangaroo Court,'* YAHOO NEWS (Nov. 21, 2023), <https://perma.cc/CG4Y-5KA8>.

319. *See generally* Complaint, *Dressen v. AstraZeneca AB*, No. 2:24-cv-00337 (D. Utah filed May 13, 2024).

320. Ian Lopez, *AstraZeneca Sued Over Covid-19 Vaccine Clinical Trial Injury (1)*, BLOOMBERG L. (May 13, 2024), <https://perma.cc/WK79-DEDN>.

321. *See id.*

322. *See generally* Complaint, *Kansas v. Pfizer, Inc.*, No. 6:24-cv-01112 (D. Kan. filed June 2024).

323. *See id.* at 6.

324. *See id.* at 9–53; *see also* Miranda Nazarro, *Kansas Sues Pfizer Over 'Misleading Statements' about COVID Vaccine*, THE HILL (June 17, 2024, 9:28 PM), <https://perma.cc/6QRL-3EWU> (reporting on lawsuit claims that "Pfizer misled Kansas residents about the risks of the company's COVID-19 shot when it claimed it was safe and allegedly hid evidence of the shot's link to myocarditis and pregnancy issues").

systems every nation is using to compensate people harmed.³²⁵ However, this Article offers some insights into a few of the largest alternative claim compensation systems, covering a total of 97 countries. Therefore, this Article allows for some general, but important points of comparison, observation, and possible takeaways that are of use today—and in the days ahead.

First, by comparing systems, there are obvious lessons for striking the right balance between ensuring access to protective medical measures like emergency vaccines, while also sufficiently supporting the people that these medical decisions may ultimately harm. Although not perfect, countries like Canada have not added to the burdens of people who have suffered injuries by extremely limiting financial awards. Instead, the no-fault claims system provides for meaningful compensation. The awards obviously will not make things exactly right for persons harmed by COVID-19 vaccines, but does allow for both a substantial lump-sum monetary award and ongoing income replacement.

Relatedly, it is deeply troubling that corporate insurance entities, who are not particularly interested in addressing financial inequality, are responsible for establishing injury compensation amounts. Indeed, if COVAX really wished to focus on addressing inequities in economically challenged nations, it should not acquiesce to payment and other structures that continue to value personhood in some parts of the world less than others. That is, we could have used the COVID-19 crisis as a moment to reset some of the imbalance in our world, rather than merely reinforcing unequal access to material resources in African countries and other financially unstable nations.

Similarly, Canada's system is not so aligned with manufacturers or so protective of governmental interests that it has precluded additional claimant relief by way of court-based advocacy. Canada's system stands in contrast to other nations like the United States, which has barred such lawsuits by way of federal law and regulation, or South Africa, where merely filing a claim with the alternative system works to prohibit a person from litigating in the court system. Such arrangements, we believe, have been correctly characterized as questionable as a matter of public policy and law too.

In part because of these and other systemic flaws in the United States and South Africa, the alternative claim systems have not served their litigation deterrent purposes as well as the Canadian system. Ironically,

325. See generally, e.g., Stefano D'Errico et al., "First Do No Harm". *No-Fault Compensation Program for COVID-19 Vaccines as Feasibility and Wisdom of a Policy Instrument to Mitigate Vaccine Hesitancy*, 9 VACCINES (Sept. 30, 2021), <https://perma.cc/RG4Z-VJGE> (offering insights into vaccine injury claim systems across several additional nations including Belgium, China, and France).

there seems to be sparse litigation in Canada, even though the state's administrative claim system does not preclude it. Thus, the balance its system struck in terms of incentives on both sides—for manufacturers and consumers—was at least close to appropriate to serve its expressed ends as well.

Any administrative vaccine injury claim system should also be as procedurally clear, transparent, and fair as possible to gain and retain legitimacy. Comparing features across systems, it seems like all countries examined could improve with regard to clarity and accessibility of protocols. Simple, non-legal language describing a system's features is essential for all impacted persons, especially those filing claims without legal counsel, to understand them. In our opinion, the vocabulary and messaging in the United States is some of the least helpful to *pro se* injured parties, using obscure terms like “countermeasures” to describe covered actions.

Beyond wording and language, system information and features need to be accessible. Such accessibility should consider language differences, cultural differences, and technological differences. The current COVAX system has received very few claims to date—with only three people in all of Africa (other than South Africa) receiving compensation through the system. It seems unlikely there are so few claims because COVID-19 vaccines did not injure people in Africa at the same rate as other places in the world. Instead, amongst other deterrents, we believe impacted persons do not really know about the system, have access to information presented in their language, or have technological or other resources available to submit their requests for compensation.

Similarly, some might interpret the limited claim numbers and payouts in South Africa as proof of a lack of vaccine-related injuries. However, as in the COVAX system, there may be other explanations. For instance, there was some confusion about how and where people needed to submit claims. Some individuals filed for compensation under South Africa's Compensation for Occupational Injuries and Disease Act—essentially workers' compensation claims—because employers required their vaccination.³²⁶ Guidelines then barred those who took this route from submitting claims to the no-fault system.³²⁷

Others may have believed that simply reporting an adverse event following immunization (“AEFI”) to the government was sufficient for seeking compensation. Indeed, while people submitted only 49 formal

326. See Melissa Cogger & Talita Laubscher, *South Africa: Recourse for Employees Who are Injured as a Result of Vaccinations*, BOWMANS L. (Apr. 22, 2022), <https://perma.cc/7MS6-JKLQ> (clarifying the interaction between the existing employment-based claim system and the new COVID-19 claim system).

327. See *id.*

written claims, over 3,000 clinically significant AEFIs were on file for the same period.³²⁸ And finally, some may not have submitted claims, erroneously believing they were time barred. People believed this because at the outset, the claim system was designed to shut down at the end of the emergency pandemic period. However, the government extended the system's operations to some end date unknown.³²⁹

Across systems it would be best if there was also clear information and streamlined protocols to account for other relevant systems—including other administrative pathways. For instance, in the United States it is unclear how CICP impacts unemployment or Social Security benefits, disability claims, or even veterans' benefits—as in the case of Karoline Stancik.

For these and other reasons, we believe that, at least in the United States, it would be best for the government to shift claims from the CICP to the VICP. To be sure, the VICP is imperfect, and we are hopeful that it will be improved in the days ahead. But this system is a more transparent arm of our federal court system that also provides for the possibility of paid legal assistance to navigate the system.

Further, VICP decisions are public and published, allowing for further insight and understanding of operations. And, beyond mere internal administrative appeal review, the VICP allows claimants to seek review by federal courts of appeals judges. Not only might such transparency and accountability provide assurances to individual claimants, but the public could at least read and learn about the ways in which vaccine companies caused injuries. Currently, the VICP not only shields manufacturers from legal liability but also procedurally shields them from the accountability provided by written and published trial court and appellate decisions.

Relatedly, beyond reform of existing claims systems themselves, we believe more fundamental rethinking is needed to account for global inequity and racial injustice. The idea that governments permitted vaccine manufacturers to approach COVID-19 vaccine production like any other business endeavor lacks the moral mooring essential to human dignity and a civilized world. And that government leaders capitulated to such one-sided demands for corporate protection is deeply disappointing and violative of their primary commitments to the communities they serve. In these ways, we stand with advocates and impacted persons who are

328. *See id.*; *see also* Maqhina, *supra* note 191.

329. *See* Thabo Baloyi, *Vaccine Injury Compensation Scheme Extended, as State of Disaster Ends*, S. AFR. (May 4, 2022, 5:22 AM), <https://perma.cc/2T7W-F45Q> (noting that the South African government said it would continue to accept claims program but that it “remains unclear” exactly how long the program will run).

seeking to challenge legal frameworks that have allowed for such strong protections for manufacturers.³³⁰

Indeed, governments, medical professionals, and vaccine manufacturers denied the public essential information that may have impacted vaccination decisions—including meaningful details regarding the protections provided to the manufacturers that produced the products nurses injected into people’s bodies. It is hard to see how individuals knowingly and voluntarily consented to these arrangements, in the context of a global crisis, given this lack of information. Additionally, the extreme financial benefits reaped by manufacturers and industry leaders seem far from fair, just, or legally unassailable—especially under the circumstances of a pandemic.

In the here and now we also wonder about further creative contract and administrative agency challenges that may be brought to dislodge the one-sided wealth amassed by pharmaceutical giants and their leadership.³³¹ Further, we might also look to taxation laws as a means of balancing the financial unfairness gained through corporate capture of national interests at a time of desperation. In the days ahead, indemnity clauses should better account for such unconscionable wealth accumulation. Indeed, countries and COVAX could have built in limitations on financial gain and profit, allowing for a return of funds to those in need once manufacturer profits reached a supersaturation point.

Beyond legal reforms, vaccine manufacturers should also come forward to do the right thing. These companies and their corporate leaders should actively fund compensation schemes to ensure timely and fair compensation for affected individuals. These compensation schemes would assist efforts to meaningfully cover medical expenses and lost wages, in addition to providing equitable relief that will level the playing field beyond actual lost wages in COVAX countries. Through voluntary contributions, manufacturers and corporate leaders could also help fund further studies and investigations relating to possible long-term and chronic side effects. Finally, all of these recommendations suggest greater

330. See generally Ariel Gorodensky & Jillian Koehler, *State Capture Through Indemnification Demands? Effects on Equity in the Global Distribution of COVID-19 Vaccines*, 15 J. PHARM. POL’Y & PRAC. (2022), <https://perma.cc/39EY-8HM4>.

331. See Coral Davenport et al., *Here’s What the Court’s Chevron Ruling Could Mean in Everyday Terms*, N.Y. TIMES (June 28, 2024), <https://perma.cc/U6CP-DF92> (crediting Professor Rachel Sachs with suggesting that “the complex set of rules devised and governed by the Department of Health and Human Services . . . could be challenged in new ways”). See generally *SEC v. Jarkesy*, 144 S. Ct. 2117 (U.S. 2024); *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244 (U.S. 2024).

empathy now, and in the days ahead, for persons who report conditions that they fear vaccinations may have caused or exacerbated.³³²

VII. CONCLUSION

Allegations of COVID-19 vaccine injuries appear to be on the rise, surfacing a lack of accountability on the part of vaccine manufacturers. The broad protections and legal immunity granted to companies to expedite vaccine development and distribution has unfairly limited recourse for many who suffer adverse effects, ranging from mild to severe. This situation, left unaddressed, will work to further erode public trust in vaccination programs and likely lead to even greater vaccine hesitancy. But it is not too late to change course and demonstrate true commitment to effective international pandemic management and equitable public health protections.

332. See Kizzmekia S. Corbett-Helaire, *Empathy Should Guide Responses to Reported Vaccine Injuries*, STAT NEWS (June 11, 2024), <https://perma.cc/YQ6Z-NW59> (“When someone somewhere feels harmed, it is the duty of scientists and health care providers to heed these people and listen.”).