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No-Fault Vaccine Injury Compensation Systems Adopted Pursuant to the COVID-19 Public Health Emergency Response

Sam Halabi

Katherine Ginsbach

Katie Gottschalk

John Monahan

Judith Murungi

NO-FAULT VACCINE INJURY COMPENSATION SYSTEMS ADOPTED PURSUANT TO THE COVID-19 PUBLIC HEALTH EMERGENCY RESPONSE

Sam Halabi[*]

Katherine Ginsbach[**]

Katie Gottschalk[***]

John Monahan[****]

Judith Murungi[*****]

ABSTRACT

No-fault vaccine injury compensation systems have developed over the course of the twentieth century, mostly in the richest countries in the world. Acknowledging that severe reactions to vaccines are rare, but can result in serious and sometimes complex injury, these systems provide financial and social support for those suffering these rare side effects. During the COVID-19 pandemic, and the rapid development and deployment of vaccines using novel technologies, these systems have proliferated not only among wealthy countries, where in their modern form they originated and spread, but also low- and middle-income ones. Adopting varying approaches to funding, eligibility, administration, process, and components of compensation and rights of appeal, these new systems offer protections to populations in low- and middle-income countries that until 2020 covered only those in relatively wealthy states, especially Europe and North America. The purpose of this Article is twofold.

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[*] Co-Director, Center for Transformational Health Law and Senior Scholar, O'Neill Institute for National and Global Health Law; Adjunct Professor of Law, Georgetown University Law Center. J.D. Harvard, M.Phil. Oxford, B.S. Kansas State University.

[**] Senior Associate with the Center for Transformational Health Law at the O'Neill Institute. J.D., M.S. in global health from University of Notre Dame.

[***] Co-Director, Center for Transformational Health Law and Executive Director, O'Neill Institute for National and Global Health Law; Visiting Professor of Law, Georgetown University Law Center. LL.M. Georgetown University, J.D. New York Law School, B.A.
University of Colorado.

[****] Professor, Senior Lecturer in Law, and Senior Scholar at the O'Neill Institute. J.D., B.A. Georgetown University.

[*****] Advocate, High Court of Kenya. LL.M. University of Nairobi, LLB. Uganda Christian University.

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First, it provides the first comprehensive landscape analysis of no-fault vaccine injury compensation systems since before the COVID-19 pandemic. That analysis identifies twenty-five such systems, almost all of which were established for routine immunizations. Second, it provides an accessible resource for advocates and planners in low- and middle-income countries that may benefit from an analysis of administrative, funding, eligibility, and compensation alternatives that they may consult when considering whether and how to construct their own no-fault vaccine injury compensation systems.

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I. INTRODUCTION

Vaccines are the quintessential public health intervention for preventing the spread of infectious disease and, as a result, the highest public health priority in the world is deploying a safe and effective vaccine against COVID-19.[1] As of August 31, 2022, twelve vaccines have been approved for emergency or conditional use; twenty-one vaccines have been authorized for early or limited use; and one hundred twenty-three vaccines are currently being testing in clinical trials, with forty-two at Phase III.[2] COVID-19 vaccines currently in use have clearly prevented serious illness, and now the evidence is growing that they reduce transmission.[3] A recent analysis suggests a single dose of either Pfizer's or AstraZeneca's COVID-19 vaccine reduces the risk of transmitting SARS-CoV-2 by as much as half.[4] The end of the COVID-19 pandemic will depend on global access to vaccines.[5]

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[1] *More Than 150 Countries Engaged in COVID-19 Vaccine Global Access Facility*, WORLD HEALTH ORG. (July 15, 2020), https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility; *see generally* Sam F. Halabi & Saad B. Omer, *Evidence, Strategies, and Challenges for Assuring Vaccine Availability, Efficacy, and Safety*, *in* GLOBAL MANAGEMENT OF INFECTIOUS DISEASE AFTER EBOLA 223 (Sam F. Halabi et al. eds., 2016) (examining evidence, strategies, and challenges surrounding vaccine safety).

[2] Carl Zimmer et al., *Coronavirus Vaccine Tracker*, N.Y. TIMES, https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html (Aug. 31, 2022).

[3] Trefis Team, *What to Expect as Moderna's COVID-19 Vaccine Moves to Phase 3 Trials*, FORBES (July 29, 2020, 9:30 AM), https://www.forbes.com/sites/greatspeculations/2020/07/29/what-to-expect-as-modernas-covid-19-vaccine-moves-to-phase-3-trials/?sh=527d8ef31e96 ("These trials will determine if the vaccine protects against Covid-19 and whether it will be cleared for use in the general public. Patients who recover from Covid-19 generate antibodies that help to prevent re-infection and per interim data from its phase 1 trials that involved 45 people, Moderna said that the people inoculated with the vaccine generated antibodies that were 4x compared to people who'd recovered from Covid. The phase 3 trial will help to validate this at a larger scale and is expected to enroll 30,000 participants in the U.S."); Carl Zimmer et al., *Coronavirus Vaccine Tracker*, N.Y. TIMES (Jan. 5, 2021), https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html.

[4] Ross J. Harris et al., Impact of Vaccination on Household Transmission of SARS-CoV-2 in England 1 (2021) (unpublished manuscript) (on file with Public Health England), https://go.nature.com/3e3iu1i ("Vaccination against SARS-CoV-2 with either ChAdOx1 nCoV-19, produced by AstraZeneca, or BNT162b2, produced by Pfizer, has been shown to produce a robust antibody response (1,2), and is effective in both preventing cases and reducing the severity of COVID-19 in vaccinated individuals(3,4). While fewer cases will reduce disease burden, it is not yet clear whether these vaccinations will also reduce transmission in the minority who have been vaccinated but develop post-vaccination infection."); Ross J. Harris et al., Correspondence, *Effect of Vaccination on Household Transmission of SARS-CoV-2 in England*, 385 NEW ENG. J. MED. 759, 759 (2021), https://www.nejm.org/doi/full/10.1056/nejmc2107717 ("Overall, the likelihood of household transmission was approximately 40 to 50% lower in households of index patients who had been vaccinated 21 days or more before testing positive than in households of unvaccinated index patients; the findings were similar for the [ChAdOx1 nCoV-19 and BNT162b2] vaccines.").

[5] Mitsuru Mukaigawara, et al., *An Equitable Roadmap for Ending the COVID-19 Pandemic*, 28 NATURE MED. 893, 895–96 (2022), https://doi.org/10.1038/s41591-022-01787-2 ("First, equitable production, supply and distribution of COVID-19 vaccines is critical for expanding full vaccination coverage and building immunity across countries . . . . Vaccine donations are commendable but not sustainable. The low vaccine uptake in LMICs

A. Side Effects of COVID-19 Vaccines

Yet, like nearly all vaccines, COVID-19 vaccines generate rare, serious side effects ranging from soreness at the injection site to fever and muscle pain to, exceptionally, anaphylaxis and other severe reactions.[6] For all vaccines, these events are rare: less than one severe adverse event occurs per ten million doses for tetanus toxoid vaccines and between one to two severe adverse events per one million doses for inactivated influenza vaccine.[7] Yet the injuries resulting from serious adverse events following immunization (SAEFI) can be complex and in some cases require lifelong care.[8]

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is slowing the end of the pandemic . . . . As of 25 February 2022, the projected vaccine coverage (at least one dose) was 61% globally, but this February 2022, the projected vaccine coverage (at least one dose) was 61% globally, but this rate dropped to 15% in the World Health Organization African Region, although vaccine supply provided by the vaccine-access facility COVAX has finally exceeded demand. Lack of vaccine equity suggests that COVID-19 will continue to affect LMICs disproportionately, even if HICs observe an end of regional epidemics.").

[6] Joanna Sugden, *Rollout of Pfizer-BioNTech Covid-19 Vaccine Slows in U.K. Due to Allergic Reaction Monitoring*, WALL ST. J. (Dec. 14, 2020, 12:46 PM), https://www.wsj.com/articles/rollout-of-pfizer-biontech-covid-19-vaccine-slows-in-u-k-due-to-allergic-reaction-monitoring-11607967990; Press Release, U.S. Food and Drug Admin., FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine (Apr. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough; Kari Oakes, *PRAC Investigates Heart Inflammation Reports with Pfizer Vaccine*, REGUL. FOCUS (May 7, 2021), https://www.raps.org/news-and-articles/news-articles/2021/5/prac-investigates-heart-inflammation-reports-with.

[7] Jeanne P. Spencer, et al., *Vaccine Adverse Events: Separating Myth from Reality*, 95 AM. FAM. PHYSICIAN 786, 786–87 (2017) ("Common local reactions to vaccines include pain, swelling, and erythema at the injection site. Systemic reactions, including fever, irritability, drowsiness, and rash, may also occur. Use of a longer needle (25 mm vs. 16 mm) decreases injection site reactions. The fourth dose of the diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine is associated with an increased incidence of fever and injection site reactions compared with the first dose (one in four children). One out of 30 children reports up to seven days of swelling of the entire thigh or upper arm after the fourth or fifth dose. Syncope may occur–especially in adolescents–after administration of the human papillomavirus (HPV) vaccine; quadrivalent meningococcal conjugate vaccine (MCV4); or tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine. Because of this, adolescents should be observed for 15 minutes after receiving these vaccines.").

[8] Clare Looker & Heath Kelly, *No-Fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes*, 89 BULL. WORLD HEALTH ORG. 371, 374 (2011) ("Vaccine injuries can be severe and complex, and are often suffered by children who require a lifetime of care and may not qualify for [social support programs]."); Minji Jeon, et al., *Adverse Events Following Immunization Associated with the First and Second Doses of the ChAdOx1 nCoV-19 Vaccine among Healthcare Workers in Korea*, VACCINES, Sept. 28, 2021, at 10–11 ("In our study, there were no reports of serious adverse events, except for one case of thrombocytopenia, which spontaneously recovered within a few days. By 8 August 2021, 11.56 million doses of the ChAdOx1 nCoV-19 vaccine were administered in Korea, and 78,058 adverse events were reported. The incidence of severe adverse events was 0.03% (3109/11,563,991): encephalopathy, 223 (19.3 per million); Guillain Barre Syndrome, 104 (9.0 per million); thrombocytopenic purpura, 787 (68.1 per million); and anaphylaxis, 78 (6.7 per million). In particular, only two cases of thrombosis with thrombocytopenia syndrome (TTS) were reported (0.2 per million). In particular, only two cases of thrombosis with thrombocytopenia syndrome (TTS) were reported (0.2 per million). As a result, to reflect the risk of this fatal adverse event, the ChAdOx1 nCoV-19 vaccination policy was revised to be recommended for

COVID-19 vaccines are no exception. In March 2021, after more than twenty-five million people received at least one dose of AstraZeneca's ChAdOx1 nCoV-19 vaccine, twenty countries paused vaccinations after reports of patients experiencing clotting disorders and rare types of strokes.[9] The European Medicines Agency (EMA) safety committee undertook a review of sixty-two cases of cerebral venous sinus thrombosis and twenty-four cases of splanchnic vein thrombosis, eighteen of which were fatal.[10] On April 7, 2021, the EMA concluded that unusual blood clots with low blood platelets should be listed as a very rare side effect.[11] As of this writing, the risk of death from thrombosis with thrombocytopenia syndrome (TTS) following immunization with AstraZeneca's Vaxzevria vaccine is approximately 1.6 in one million.[12]

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those aged 50 and over as of July 2021. On the other hand, 803 cases of anaphylaxis and 412 cases of TTS were reported in the United Kingdom (administration: 38.5 million doses as at 4 August 2021) and 55 cases of anaphylaxis and 157 cases of TTS were reported in the Germany (administration: 11.5 million doses until 30 June 2021) []. This is significantly higher than the results of an interim analysis of four clinical trials on the ChAdOx1 nCoV-19 vaccine, which reported that the incidence of thromboembolic events, including coronary artery occlusion, ischemic stroke, pulmonary embolism, and thrombosis, was less than 0.1% []. The difference in the incidence of severe adverse events across countries may be attributed to differences in the total number of vaccinations or racial differences. In terms of vaccine hesitancy, medical education or contents of mass media that reinforce confidence in the safety of novel vaccines may have led to a shift toward vaccine acceptance. Therefore, we considered our findings to be quite important, because they support the fact that the incidence of severe adverse events is not very high.").

[9] Kai Kupferschmidt & Gretchen Vogel, *European Countries Resume Use of AstraZeneca's COVID-19 Vaccine*, SCIENCE (Mar. 18, 2021), https://www.sciencemag.org/news/2021/03/european-countries-resume-use-astrazenecas-covid-19-vaccine-hoping-pause-has-not-dented ("More than 20 countries stopped vaccinations earlier this week following reports of mostly young patients who suffered severe clotting disorders and rare types of strokes shortly after receiving the AstraZeneca vaccine. Today, within hours of EMA's statement, Germany, France, Italy, Spain, the Netherlands, and at least seven other countries said they will restart vaccinations as early as Friday.").

[10] *AstraZeneca's COVID-19 Vaccine: EMA Finds Possible Link to Very Rare Cases of Unusual Blood Clots with Low Platelets*, EUR. MEDS. AGENCY (Apr. 7, 2021), https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood ("EMA is reminding healthcare professionals and people receiving the vaccine to remain aware of the possibility of very rare cases of blood clots combined with low levels of blood platelets occurring within 2 weeks of vaccination. So far, most of the cases reported have occurred in women under 60 years of age within 2 weeks of vaccination. Based on the currently available evidence, specific risk factors have not been confirmed. People who have received the vaccine should seek medical assistance immediately if they develop symptoms of this combination of blood clots and low blood platelets.").

[11] *Id.*; *see also* EUR. CTR. FOR DISEASE PREVENTION & CONTROL, OVERVIEW OF EU/EEA COUNTRY RECOMMENDATIONS ON COVID-19 VACCINATION WITH VAXZEVRIA (May 18, 2021), https://www.ecdc.europa.eu/sites/default/files/documents/Overview%20EU%20EEA%20country%20recommendations%20on%20COVID-19%20vaccination%20Vaxzevria%20and%20scoping%20review%20of%20evidence.pdf.

[12] *Coronavirus Vaccine - Summary of Yellow Card Reporting*, GOV.UK, https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting#introduction (Oct. 7, 2022); *AstraZeneca Vaccine: Risk of Death Is 1 in a Million, but What Does That Mean?*, AUSTL. ACAD. OF SCI. (Aug. 24, 2021),

In the United States, administration of the Janssen (a unit of Johnson & Johnson) COVID-19 vaccine was paused after reports of six cases of a rare and severe type of blood clot in individuals.[13] After analysis of data drawn from 6.8 million administrations, the CDC found the risk of thrombosis with thrombocytopenia syndrome at a rate of seven per one million vaccinated women between eighteen and forty-nine years old.[14] As of March 18, 2022, out of more than eighteen million people who received the Janssen vaccine, sixty cases of TTS were reported and nine people died.[15] On May 5, 2022, the U.S. Food and Drug Administration limited approval of the vaccine in the United States to individuals eighteen and older for whom the other authorized or approved vaccines "are not accessible or clinically appropriate," or who choose to receive it because they would otherwise not receive a vaccine.[16]

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https://www.science.org.au/curious/people-medicine/astrazeneca-vaccine-risk-death-1-million-what-does-mean.

[13] Press Release, U.S. Food and Drug Admin., *supra* note 6; Sara E. Oliver, et al., *Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices*, 71 MORBIDITY & MORTALITY WKLY. REP. 90 (2022) ("On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the adenovirus-vectored COVID-19 vaccine (Janssen Biotech, Inc., a Janssen Pharmaceutical company, Johnson & Johnson), and on February 28, 2021, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for its use as a single-dose primary vaccination in persons aged ≥18 years (*1*,*2*). On April 13, 2021, CDC and FDA recommended a pause in the use of Janssen COVID-19 vaccine after reports of thrombosis with thrombocytopenia syndrome (TTS), a rare condition characterized by low platelets and thrombosis, including at unusual sites such as the cerebral venous sinus (cerebral venous sinus thrombosis [CVST]), after receipt of the vaccine.* ACIP rapidly convened two emergency meetings to review reported cases of TTS, and 10 days after the pause commenced, ACIP reaffirmed its interim recommendation for use of the Janssen COVID-19 vaccine in persons aged ≥18 years, but included a warning regarding rare clotting events after vaccination, primarily among women aged 18–49 years.").

[14] Jessica R. MacNeil, et al., *Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients*, 70 MORBIDITY & MORTALITY WKLY. REP. 651, 652 (2021) ("Thirteen TTS cases occurred among women aged 18−49 years, and two occurred among women aged ≥50 years; no cases postauthorization were reported among men.¶ TTS reporting rates to VAERS were 7.0 cases per million Janssen COVID-19 vaccine doses administered to women aged 18−49 years and 0.9 per million to women aged ≥50 years. Among subgroups by age (18–29, 30−39, 40–49, 50–64, and ≥65 years), the reported rate was highest among women aged 30−39 years, with 11.8 TTS cases per 1 million Janssen COVID-19 doses administered. The median age was 37 years (range = 18−59 years), and the median interval from vaccination to symptom onset was 8 days (range = 6−15 days).").

[15] Laurie McGinley & Carolyn Y. Johnson, *FDA Sharply Limits Use of Johnson & Johnson Shot Due to Rare Blood Clots*, WASH. POST (May 5, 2022, 5:40 PM), https://www.washingtonpost.com/health/2022/05/05/fda-johnson-and-johnson-vaccine/.

[16] Press Release, U.S. Food and Drug Admin., Coronavirus (COVID-19) Update: FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals (May 5, 2022), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-janssen-covid-19-vaccine-certain-individuals ("Today, the U.S. Food and Drug Administration has limited the authorized use of the Janssen COVID-19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines

As of August 2021, more than 1,600 cases of myocarditis or pericarditis had been reported to the U.S. Vaccine Adverse Event Reporting System (VAERS), after hundreds of millions of mRNA (Pfizer and Moderna) vaccine doses were administered.[17] The evidence to date suggests that the risk of myocarditis after receiving mRNA-based COVID-19 vaccines increased across multiple age and sex strata and was highest after the second vaccination dose in adolescent males and young men.[18]

B. The History and Purpose of No-Fault Vaccine Compensation Systems as a Mechanism for Addressing Severe Side Effects

The relationship between immunization's critical role for public health on the one hand, and, on the other, the small number of individuals suffering SAEFI poses an ethical and practical dilemma.[19] Leaving those individuals and their

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are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.").

[17] Matthew E. Oster et al., *Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021*, 327 J. AM. MED. ASS'N 331, 331 (2022), https://jamanetwork.com/journals/jama/fullarticle/2788346 ("Among 192 405 448 persons receiving a total of 354 100 845 mRNA-based COVID-19 vaccines during the study period, there were 1991 reports of myocarditis to VAERS and 1626 of these reports met the case definition of myocarditis. Of those with myocarditis, the median age was 21 years (IQR, 16-31 years) and the median time to symptom onset was 2 days (IQR, 1-3 days). Males comprised 82% of the myocarditis cases for whom sex was reported. The crude reporting rates for cases of myocarditis within 7 days after COVID-19 vaccination exceeded the expected rates of myocarditis across multiple age and sex strata. The rates of myocarditis were highest after the second vaccination dose in adolescent males aged 12 to 15 years (70.7 per million doses of the BNT162b2 vaccine), in adolescent males aged 16 to 17 years (105.9 per million doses of the BNT162b2 vaccine), and in young men aged 18 to 24 years (52.4 and 56.3 per million doses of the BNT162b2 vaccine and the mRNA-1273 vaccine, respectively). There were 826 cases of myocarditis among those younger than 30 years of age who had detailed clinical information available; of these cases, 792 of 809 (98%) had elevated troponin levels, 569 of 794 (72%) had abnormal electrocardiogram results, and 223 of 312 (72%) had abnormal cardiac magnetic resonance imaging results. Approximately 96% of persons (784/813) were hospitalized and 87% (577/661) of these had resolution of presenting symptoms by hospital discharge. The most common treatment was nonsteroidal anti-inflammatory drugs (589/676; 87%).").

[18] Martina Patone, et al., *Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection*, 28 NATURE MED., 410, 410–19 (2022).

[19] Michelle Mello, *Rationalizing Vaccine Injury Compensation*, 22 BIOETHICS 32, 33 (2008) ("The unusual decision not to provide an alternative mechanism for compensation is indicative of a broader problem of inconsistency in the American approach to vaccine-injury compensation policy. Compensation policies have tended to reflect political pressures and economic considerations more than any cognizable set of principles."); Sam Halabi & John Monahan, *Sharing the Burden of Ebola Vaccine Related Adverse Events*, 24 TUL. J. INT'L & COMPAR. L. 131, 136 (2015) ("If supporting governments accept all liabilities for adverse events attributed to Ebola vaccines, they are potentially responsible for substantial claims that might erode their credibility when undertaking future vaccination or access to-medicines programs. On the other hand, effective risk-sharing may set a useful precedent for future public health emergencies. There is a public health preparedness value in agreeing to compensate individuals through predefined legal or regulatory mechanisms. In the vaccination context generally, the traditional argument is that the public health benefits of vaccination so far outweigh the risks that we, as a community, compensate individuals who pay the price in experiencing adverse events. The

families to bear the costs of their injuries would mean that the community would benefit from these individuals' contributions to herd immunity, leaving the uninjured to receive a health benefit at the cost of the injured.[20] Second, without such a system, those suffering SAEFI may, and often must, resort to litigation against vaccine manufacturers based on theories that manufacturers of products, who gain financially from their sale, should also be responsible for the costs they impose.[21] The potential cost of liabilities for injuries or death deters manufacturers from selling to countries where they perceive the risks are too high.[22]

No-fault vaccine injury compensation systems provide one answer to this dilemma.[23] No-fault vaccine injury compensation systems provide a

argument is also true for public health emergencies where rapid response to an evolving threat in the face of imperfect information counsels toward aggressive action.").

[20] Michelle Mello, *Rationalizing Vaccine Injury Compensation*, 22 BIOETHICS 32, 33 (2008); Sam Halabi, *Solving the Pandemic Vaccine Liability Problem*, 12 U.C. IRVINE L. REV. 122, 146–47 (2021) [hereinafter Halabi, *Vaccine Liability*] ("The first approach, requiring individuals with vaccine injury to bear their own costs, is an extreme utilitarian version of the fundamental social contract supporting immunization. From the claimant's perspective, litigation is adversarial, protracted, uncertain, and requires that an attorney agree to take the case, which may pose a considerable obstacle for claimants with low earnings or fairly minor injuries. It effectively pushes the costs of herd immunity to innocent parties. In this utilitarian view, the benefits of vaccination so outweigh the risks that communities accept that some individuals will experience adverse events in return for herd immunity.").

[21] Halabi, *Vaccine Liability*, *supra* note 20 ("'The second approach, requiring manufacturers to pay, is based on the integrity and dignity of the individual person—those whose products cause injury should make whole those individuals who experienced an adverse event.' 'Vaccine manufacturers dislike tort because of the uncertainty involved in allowing juries to determine injury causation and damages awards. Even if catastrophically large awards rarely occur, the threat of them weighs heavily on manufacturers and their insurers.' These two approaches are commonly approached worldwide, yet they 'destabilize the effort to promote immunization by failing fundamental tests for fairness' by (1) requiring people with few resources to pay for serious (if rare) injuries and (2) introducing economic uncertainty.").

[22] *See* Yoko Nishikawa, *Japan to Buy H1N1 Flu Vaccine from Glaxo, Novartis*, REUTERS (Oct. 6, 2009, 8:28AM), https://www.reuters.com/article/us-flu-japan/japan-to-buy-h1n1-flu-vaccine-from-glaxo-novartis-idUSTRE5953AJ20091006 ("Talks on the purchases have been delayed due to liability concerns, with the foreign makers asking to get immunity from responsibility in case of any side effects from vaccination. The government now plans to submit a bill to parliament so that it could pay compensation to patients who suffer from any side effects of imported vaccine or pay lawsuit-related costs on behalf of foreign makers."); Ben Hirschler & Stephanie Nebehay, *Drugmakers May Need Indemnity of Fast-Tracked Ebola Vaccines*, REUTERS (Oct. 23, 2014, 4:51AM), https://www.reuters.com/article/us-health-ebola-vaccine-idUSKCN0IC0TZ20141023.

[23] Randy Mungwira et al., *Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, 15 PLOS ONE, May 21, 2020, at 1, 5 ("These programmes do not require the injured party or their legal representative to prove negligence or fault by the vaccine provider, health care system or the manufacturer prior to compensation. They serve to waive the need for accessing compensation through litigation processes, which are often viewed as an adversarial approach requiring establishment of fault by at least one party prior to compensation. The term 'no-fault' implies a measure put in place by public health authorities, private insurance companies, manufacturers and other stakeholders to compensate individuals inadvertently harmed by vaccines.").

mechanism, funded and administered in various ways, to make those injured by vaccines, or their families, whole.[24] Relatedly, because these systems provide exclusive and predictable channels of recourse, manufacturers can effectively manage the potential cost of liabilities.[25]

1. No-Fault Compensation Systems for Routine Immunizations

Because no-fault vaccine injury compensation systems provide this mutual advantage, they have steadily proliferated since the legal principle justifying them was established in 1953.[26] In that year, "the German Supreme Court ruled that people who were injured by compulsory vaccination (in this case smallpox) were entitled to compensation. Germany enacted a compensation programme in 1961."[27] In the 1970s, concerns over side effects related to the diphtheria-tetanus-pertussis vaccination—a combined childhood immunization against three common and deadly diseases that has saved tens of millions of lives—led to programs being established in Austria, Denmark, Japan, New Zealand, Sweden, Switzerland, and the United Kingdom.[28] In the 1980s, Taiwan, Finland, and Quebec implemented programs; Italy, Norway, and Republic of Korea followed in the 1990s.[29]

The history of the no-fault compensation system in the United States reflects the broader policy and justice concerns at work in other countries. Within the United States, vaccine side effects were (before the adoption of its no-fault compensation system for childhood immunizations in 1986) generally amenable to state law claims made under principles of strict liability as well as negligence claims specific to "unavoidably unsafe" products, which require only that makers of medicines and vaccines properly prepare and market them, as well as

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[24] Halabi & Monahan, *supra* note 19, at 136 ("[I]n some countries, existing pharmacovigilance systems may fail to detect key signals until after the vaccines have already been administered to hundreds or thousands or millions of people. Many of the individuals vaccinated could develop medical conditions, by chance alone and unrelated to the vaccine, at some point following vaccination. It is inevitable that many will expect to be compensated. This is why [IFPMA] call(s) for a waiver of liability for the manufacturing and use of pandemic vaccines.").

[25] Hirschler & Nebehay, *supra* note 22; Thi Bao Anh Nguyen, *No-Fault Versus Strict Liability Compensation Systems in Medical Malpractice Law in Vietnam in Comparision with Belgium, France, and England*, ASIAN J. L. & ECON., Mar. 8, 2019, at 1 ("As an alternative to the tort or fault-based system in medical malpractice, a no-fault compensation system has been viewed as having the potential to overcome problems inherent in the tort system. This is through the provision of fair, speedy and adequate compensation for medically injured victims. A no-fault compensation system allows patients to be compensated without proof of provider's fault or negligence.").

[26] Looker & Kelly, *supra* note 8, at 371–72.

[27] *Id.*

[28] *Id.*

[29] *Id.* at 372.

supply sufficient warnings about their use.[30] The general idea for maintaining the possibility of liability for side effects is that it supplies an incentive for manufacturers to invest continually in the safety of their products and that, as between an uninjured (and presumptively compensated) manufacturer and an injured vaccine recipient, the law should favor making the injured person whole.[31] After the adoption of the National Childhood Vaccine Injury Act of 1986, vaccine side effects are almost entirely routed to a no-fault compensation system administered through the U.S. Court of Federal Claims.[32]

Toward the mid-1990s, when the majority of the world's no-fault compensation systems were established, scholars in law and public health began to undertake landscape analyses in an effort to elaborate how no-fault compensation systems are funded and administered, as well as how compensation is determined and procedural aspects like rights to appeal are decided.[33] In the early 1990s, the World Health Organization's (WHO) efforts

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[30] RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. L. INST. 1965); Bruesewitz v. Wyeth, 562 U.S. 223, 251 (2011) (Sotomayor, J., dissenting) ("Blackletter products liability law generally recognizes three different types of product defects: design defects, manufacturing defects, and labeling defects (*e.g.*, failure to warn).").

[31] *Bruesewitz*, 562 U.S. at 226, 250 (Sotomayor, J., dissenting) ("Vaccine manufacturers have long been subject to a legal duty, rooted in basic principles of products liability law, to improve the designs of their vaccines in light of advances in science and technology.").

[32] *Vaccine Claims/Office of Special Masters*, U.S. CT. OF FED. CLAIMS, https://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters (last visited Jan. 14, 2022); Nora Freeman Engstrom, *A Dose of Reality for Specialized Courts: Lessons from the VICP*, 163 U. PENN. L. REV. 1631, 1659–60 (2015) ("Toward that end, Congress established the Vaccine Injury Compensation Program (VICP), a no-fault scheme run out of the U.S. Court of Federal Claims and jointly administered by the Department of Health and Human Services (HHS) (which serves as the respondent and therefore represents the Fund's interests in all VICP proceedings) and the Department of Justice (DOJ) (which represents HHS). Financed by a seventy-five-cent excise tax on each vaccine dose administered (which creates the Fund upon which injury victims draw), the VICP is intended to provide adequate, though abridged, compensation to all individuals injured by covered vaccines via "less-adversarial, expeditious, and informal proceeding[s].")

[33] Geoffrey Evans, *Vaccine Injury Compensation Programs Worldwide*, 17 VACCINE (Supp. 3) S25, S25 (1999) ("Approximately a dozen countries provide some form of compensation for injuries (or deaths) following vaccination. More than anything else, they were instituted in the belief governments have a special responsibility to those injured by properly manufactured and administered vaccines used in public health programs. Administratively, most are managed through the national government, including decisions on eligibility for and amount of compensation. Eligibility may depend on the recipient's age, citizenship or residency status, category of vaccine (e.g., recommended, compulsory), the location it is administered (public vs private ambulatory setting), or satisfying certain time frames for filing a claim. Since few vaccine-related injuries have a clinical or laboratory marker, proving actual causation is difficult. Causation decisions are usually based on the balance of probabilities standard of more likely than not. All countries require that the effects be long lasting (e.g., greater than 6 months), and nearly all provide coverage for medical costs, disability pensions, and death benefits, while noneconomic damages (pain and suffering) are included much less frequently. Funding is generally from the national treasury, with some programs receiving support from lower governmental entities or vaccine manufacturers. After nearly 4 decades of operation, vaccine injury compensation program appears to be an increasingly accepted component of immunization programs today.").

to promote childhood immunization worldwide had stalled, and public-health planners had sought various ways to close the gap that remained.[34] Studies published in 1999, 2011, and 2020 tracked the steadily expanding number of programs worldwide, although even by 2020, only twenty-five such systems existed, and all but three of those operated in wealthy countries or provinces.[35]

2. No-Fault Compensation Systems for Emergency Immunizations

Special no-fault compensation systems for public health emergencies developed soon after those for routine immunizations. The U.S. experience with the 1976 H1N1 outbreak was an early and perhaps first example.[36] The influenza pandemic of 1918 killed an estimated 50 million people, so governments around the world and the WHO have invested steeply in preparation for influenza epidemics and pandemics.[37] In 1976, soldiers in Ft. Dix, New Jersey were diagnosed with the H1N1 strain of the influenza virus. The U.S. Centers for Disease Control and Prevention (CDC) hosted a press conference and although the virus never spread out of the base, the outbreak garnered significant media attention.[38] President Ford initiated a program to vaccinate "every man, woman,

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[34] Sam Halabi, *The Origins and Future of Global Health Law*, 108 GEO. L.J. 1607, 1616–17 (2020) ("Important exceptions to this assessment were its early effort to eradicate malaria, and a later, more successful effort to eradicate smallpox. The latter commenced in 1961 but failed in the face of inadequate funding and the greater attention paid to malaria. By 1967, the vast resources required to eradicate malaria became clear to the international community, and resources were redirected toward smallpox initiatives. The smallpox program was an important turning point in global health law's trajectory. The campaign's success was the result of legal authorizations for immunization, surveillance, and quarantine first by African then South Asian governments. The campaign also committed to training healthcare workers, building laboratories, and creating regular public health reporting systems. In 1974, the World Health Assembly expanded the smallpox program into the Expanded Programme on Immunization (EPI), with the goal of 'reduc[ing] morbidity and mortality by making immunization services available for all children of the world by 1990.'").

[35] Mungwira et al., *supra* note 23, at 5; *see* Josephine Gittler, *Controlling Resurgent Tuberculosis: Public Health Agencies, Public Policy, and Law*, 19 J. HEALTH POL. POL'Y & L. 107, 139–40 (1994) (analyzing public health measures as part of broader social safety planning).

[36] Rebecca Kreston, *The Public Health Legacy of the 1976 Swine Flu Outbreak*, DISCOVER MAG. (Sept. 30, 2013, 9:30 AM), https://www.discovermagazine.com/health/the-public-health-legacy-of-the-1976-swine-flu-outbreak.

[37] *See* Brooke Killian Kim & Jessica C. Wilson, *COVID-19: Tort Immunity for Vaccines and Antivirals — Lessons from the Swine Flu of 1976*, DLA PIPER (April 8, 2020), http://pdf.dlapiper.com/pdfrenderer.svc/v1/ABCpdf9/GetRenderedPdfByUrl//COVID-19%20%20tort%20immunity%20for%20vaccines%20and%20antivirals.pdf/?url=https://www.dlapiper.com:443%2Fen%2Fus%2Finsights%2Fpublications%2F2020%2F04%2Fcovid-19—tort-immunity-for-vaccines-and-antivirals%2F%3F%26pdf%3D1&attachment=false; *see generally* H.R. DOC. NO. 77-115 (1977) (describing issues developed during the U.S. Comptroller General's review of the National Influenza Immunization (Swine Flu) Program).

[38] President Gerald R. Ford, Remarks Announcing the National Swine Flu Immunization Program in the White House Briefing Room (Mar. 24, 1976) (transcript available at the Gerald R. Ford Presidential Library &

and child in the United States."[39] Vaccine manufacturers began developing a vaccine.[40] The U.S. government and pharmaceutical manufacturers agreed in advance to an indemnification of risk for the manufacturer, which resulted in the U.S. government defending suits arising from the vaccine complications. Ultimately, the United States was named as a defendant in over 1,000 lawsuits and paid approximately $83 million in claims.[41]

In 2003, after the U.S. suffered both physical attacks at the World Trade Center and anthrax attacks through the U.S. Postal Service, the Secretary of the U.S. Department of Health and Human Services (DHHS) "announced that certain individuals should receive smallpox vaccine or other countermeasures to be prepared to serve the civilian population in the event of a smallpox bioterrorism event."[42] In April 2003, Congress passed and the President signed the Smallpox Emergency Personnel Protection Act of 2003.[43] The law established the Smallpox Vaccine Injury Compensation Program to provide medical and lost employment income coverage to persons who sustain a covered medical injury as a direct result of receiving smallpox vaccination.[44]

Museum); H.R. DOC. NO 77-115, *supra* note 37, at 3, 8-9, 11, 14; RICHARD E. NEUSTADT & HARVEY V. FINEBERG, THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE 1 (1978).

39 Kim & Wilson, *supra* note 37.

40 *Id.*

41 *Id.* at 3.

42 Paul Clark & Stan Levin, *The Smallpox Vaccine Injury Compensation Plan*, 46 CLIN. INFECTIOUS DISEASES (SUPP. 3) S179, S179 (2008) ("Congress passed and President George W. Bush signed on 30 April 2003 the Smallpox Emergency Personnel Protection Act of 2003 []. This act created the Smallpox Vaccine Injury Compensation Program (hereafter referred to as "the Program") to provide medical and lost employment income coverage as a payer of last resort to individuals who received a smallpox vaccination voluntarily under a DHHS-approved smallpox emergency response plan and who sustain a covered medical injury as a direct result of the vaccination. In addition, certain individuals who sustained smallpox vaccine injuries through exposure to the vaccine by coming into physical contact with vaccine recipients would also be considered for Program benefits (vaccinia contacts), as would individuals who are exposed to other vaccinia contacts. Individuals who sustained a medical injury through other covered countermeasures, such as administration of vaccinia immune globulin or cidofovir, are also covered by the act. Certain survivors would receive death benefits if the smallpox vaccine proved to be fatal to eligible individuals, whether they had received the smallpox vaccination or were exposed to vaccinia through contact.").

43 *Id.*

44 *HHS Sets Rules for Smallpox Vaccine Injury Compensation*, CIDRAP (Dec. 15, 2003), cidrap.umn.edu/news-perspective/2003/12/hhs-sets-rules-smallpox-vaccine-injury-compensation ("HHS has published an online table that lists and defines the complications covered by the vaccination program. The list includes, among other conditions, significant local skin reactions, inadvertent inoculation, generalized vaccinia, eczema vaccinatum, progressive vaccinia, postvaccinial encephalopathy, and vaccinial myocarditis or pericarditis. The table lists how soon after vaccination (or secondary exposure) the first symptoms or signs of a complication must appear to warrant a presumption that the problem is vaccine-related, HHS said. People who experience a condition described in the table within the specified time need not prove it was caused by the vaccine to qualify for benefits, the announcement states. HHS also said there may be smallpox vaccine

In 2005, after a global threat posed by the H5N1 strain of the influenza virus, and in light of past national security threats, the United States adopted a comprehensive law addressing vaccine injuries suffered after the Secretary of Health and Human Services determined that a public health emergency existed.[45] The Public Readiness and Emergency Preparedness (PREP) Act was enacted on December 30, 2005.[46] The law extended immunity against legal claims related to the manufacturing, testing, development, distribution, and administration of emergency vaccines.[47] The law provides for a publicly funded and administered program of compensation for those suffering severe side effects. The purpose of the act is to encourage companies to release medical countermeasures promptly during public health emergencies.[48] The PREP Act precludes liability for defects in diagnostics, therapeutics, and vaccines under both federal and state law for any loss "caused by, arising out of, or resulting from" the application of a "covered countermeasure."[49] PREP Act declarations have been made for H1N1, Ebola, botulism toxin, anthrax, smallpox, and acute radiation syndrome.[50] For COVID-19, a "covered countermeasure," is:

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complications that are not listed in the table. "'A person who can present sufficient evidence to prove likely causation may still be eligible for program benefits",' the statement says.").

[45] Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, Pub. L. No. 109-148 (2005) (codified as amended at 42 U.S.C. § 247d-6d); Samson S. Y. Wong and Kwok-yung Yuen, *Avian Influenza Virus Infections in Humans*, 129 CHEST 156, 156 (2006) ("Migratory birds and, less likely, bird trafficking are believed to be globalizing the avian influenza A/H5N1 epidemic in poultry. More than 200 human cases of avian influenza virus infection due to A/H5, A/H7, and A/H9 subtypes mainly as a result of poultry-to-human transmission have been reported with a > 50% case fatality rate for A/H5N1 infections. A mutant or reassortant virus capable of efficient human-to-human transmission could trigger another influenza pandemic."); Lawrence O. Gostin, Commentary, *Public Health and Civil Liberties in an Era of Bioterrorism*, 21 CRIM. JUST. ETHICS 2, 2 (2002).

[46] U.S. Department of Health and Human Services, *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*, PUB. HEALTH EMERGENCY, www.phe.gov/Preparedness/legal/prepact/Pages/4-PREP-Act.aspx#:~:text=The%20PREP%20Act%20was%20enacted,247d-6d%20and%2042%20U.S.C. (last visited Jan. 14, 2020) (stating that PREP was first enacted as Pub. L. No. 109-148).

[47] *See generally* Looker & Kelly, *supra* note 8 (describing no-fault vaccine injury compensation in the United States, among other countries).

[48] KEVIN J. HICKEY, CONG. RCHS. SERV., LSB10443, THE PREP ACT AND COVID-19, PART 1: STATUTORY AUTHORITY TO LIMIT LIABILITY FOR MEDICAL COUNTERMEASURES 1, 4 (updated Apr. 13, 2022), https://crsreports.congress.gov/product/pdf/LSB/LSB10443.

[49] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15198 (Mar. 17, 2020).

[50] Notice of Declaration under the Public Readiness and Emergency Preparedness Act, 79 Fed. Reg. 73314 (Dec. 10, 2014); HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Botulism Countermeasures, 73 Fed. Reg. 61864 (Oct. 17, 2008); HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Anthrax Countermeasures, 73 Fed. Reg 58239 (Oct. 6, 2008); HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Smallpox Countermeasures, 73 Fed. Reg. 61869 (Oct. 17, 2008); INST. OF MED. OF THE

> (1) any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used (a) to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or (b) to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause; or
>
> (2) any device used in the administration of any such product, and all components and constituent materials of any such product that has been authorized pursuant to a declaration by the Secretary of Health and Human Services.[51]

U.S. Secretary of Health and Human Services issued the initial PREP Act declaration covering COVID-19 vaccines on March 17, 2020. [52] In order to qualify for PREP Act immunity, a covered countermeasure, including a COVID-19 vaccine, must be approved by the U.S. Food and Drug Administration, either pursuant to conventional licensure or under an emergency use authorization.[53] Manufacturers and distributors are immune from liability regardless of the geographical area where the countermeasure was administered or used.[54]

As part of the same law limiting manufacturer liabilities for covered countermeasures, the United States provides a system of compensation for those suffering severe side effects. The Countermeasures Injury Compensation Program (CICP) was created by the PREP Act.[55] Should an individual experience an injury as a result of the use of a covered countermeasure, he or she is allowed to submit a claim to the Health Resource and Services Administration (an agency within the Department of Health and Human

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NAT'L ACADEMIES, COMM. ON SMALLPOX VACCINATION PROGRAM IMPLEMENTATION, BD. OF HEALTH PROMOTION & DISEASE PREVENTION, REVIEW OF THE CENTERS OF DISEASE CONTROL AND PREVENTION'S SMALLPOX VACCINATION PROGRAM IMPLEMENTATION, LETTER REPORT 1 (2003), https://nap.nationalacademies.org/catalog/10601/review-of-the-centers-for-disease-control-and-preventions-smallpox-vaccination-program-implementation (letter report to Julie Gerberding, Director of the Centers for Disease Control and Prevention); HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Acute Radiation Syndrome, 73 Fed. Reg. 61866 (Oct. 17, 2008); David W. Ogden et al., *COVID-19: Immunity Under the PREP Act: When Does It Apply to Private Sector Efforts to Help Combat COVID-19?*, WILMERHALE (Mar. 30, 2020), https://www.wilmerhale.com/en/insights/client-alerts/20200330-immunity-under-the-prep-act-when-does-it-apply-to-private-sector-efforts-to-help-combat-covid19.

[51] 42 U.S.C. § 247d-6d(i) (2020).

[52] Notice of Declaration under the Public Readiness and Emergency Preparedness Act, *supra* note 50, at 15200–01.

[53] Ogden et al., *supra* note 50.

[54] Notice of Declaration under the Public Readiness and Emergency Preparedness Act, *supra* note 50, at 15198.

[55] 42 U.S.C. § 247d-6e (2020).

Services). A claimant must complete a Request for Benefits form and submit medical evidence within a year of being administered or having used the countermeasure.[56] Once a claim has been submitted, it is reviewed by medical staff within the program to determine a causal link.

If DHHS has published an injury table for the covered countermeasure, the claimant is entitled to a presumption of causation. If not, the claimant must prove causation through "compelling" evidence.[57] Once causation is established, claimants are compensated.[58] There is no adversarial process or presentation of further evidence to a court or special tribunal.[59] The CICP has received 485 claims since it began accepting claims related to H1N1 vaccines in 2010. Of those claims, thirty-nine individuals have received compensation with a total $5.7 million paid.[60] Of the 485 claims filed with the CICP, 373 were related to the H1N1 vaccine.[61]

Other countries have integrated immunizations for public health emergencies into their already existing systems for routine vaccinations. This has been the approach for the United Kingdom, the People's Republic of China, and Thailand.[62] Still, other countries, which are the focus of this Article, adopted entirely new systems specifically for the COVID-19 public health emergency and may retain those systems after the pandemic is formally declared over.

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[56] *Filing for Benefits*, HRSA (April 2022), https://www.hrsa.gov/cicp/filing-benefits.

[57] Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMIN. L. REV. 785, 834 n.252 (2011) ("There is language in the Act indicating that petitioners must satisfy their burden of proof by introducing 'compelling, reliable, valid, medical and scientific evidence.'") (emphasis omitted) (citing 42 U.S.C. §§239a(c)(2), 247d-6e(b)(4)).

[58] Robert Roos, *HHS: 386 Injury Claims Filed Over H1N1 Countermeasures*, CIDRAP (Mar. 16, 2011), https://www.cidrap.umn.edu/news-perspective/2011/03/hhs-386-injury-claims-filed-over-h1n1-countermeasures.

[59] The CICP Claims Process is administrative and does not require adversity or the further presentation of evidence before a court or special tribunal. *Filing for Benefits*, *supra* note 56.

[60] Tom Hals, *COVID-19 Era Highlights U.S. 'Black Hole' Compensation Fund for Pandemic Vaccine Injuries*, REUTERS (Aug. 21, 2020, 7:08 AM), https://www.reuters.com/article/us-health-coronavirus-vaccines-liability/covid-19-era-highlights-u-s-black-hole-compensation-fund-for-pandemic-vaccine-injuries-idUSKBN25H1E8.

[61] Roos, *supra* note 58.

[62] Tommie Crum et al., *Current Situation of Vaccine Injury Compensation Program and a Future Perspective in Light of COVID-19 and Emerging Viral Diseases [version 2; peer review: 2 approved]*, F1000RES., Dec. 7, 2021, at 1, 5; *B1.7bn for Adverse Jab Effects*, BANGKOK POST (Apr. 9, 2022, 8:40 AM), https://www.bangkokpost.com/thailand/general/2292514/b1-7bn-for-adverse-jab-effects; Duncan Fairgrieve et al., *In Favour of a Bespoke COVID-19 Vaccines Compensation Scheme*, 21(4) LANCET INFECTIOUS DISEASES 448 (2021).

3. Global No-Fault Injury Compensation Systems

As early as 2017, legal and medical scholars advocated for a global compensation system as an essential aspect of worldwide preparedness for an infectious disease emergency.[63] During the Ebola public health emergency in Guinea, Liberia, and Sierra Leone, the WHO adopted an insurance scheme for then pre-licensed (now fully licensed) vaccines that were deployed under emergency use authorization.[64]

In March 2021, the WHO announced the establishment of a limited vaccine injury compensation system, administered in partnership with ESIS, Inc., a subsidiary of Chubb, a global insurer.[65] But the reach of the WHO/ESIS, Inc.

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[63] Sam F. Halabi & Saad B. Omer, *A Global Vaccine Injury Compensation System*, 317 *JAMA* 471, 471 (2017) ("A global vaccine-injury compensation system to bring economic certainty would represent a substantial advance to this critical component of the global public health system and build trust necessary for vaccines—especially in emergency contexts. Such a system would address barriers to vaccine manufacturers' participation as well as perceptions that contribute to vaccine hesitancy in low-resource countries. A prominent perception shared by persons in low-resource settings is that diseases with pandemic potential that affect the global poor are neglected by the world's major medical research institutions. When one of those diseases threatens Europe or North America, those institutions and their sponsoring governments invest in relevant medical research but do so using the global poor as relatively unprotected human research subjects. A global vaccine injury compensation system may reduce the hesitancy among those making the decision to receive a candidate vaccine with a limited safety profile.").

[64] WORLD HEALTH ORG., WORKSHOP ON EXPANDED ACCESS TO EXPERIMENTAL EBOLA VACCINES DURING OUTBREAKS 21–22 (2017), https://indico.un.org/event/24764/material/slides/3.pdf ("The ultimate objective of this special insurance product is to facilitate emergency response action and timely deployment of experimental vaccines in the event of infectious disease outbreaks for which no licensed vaccine exists. While manufacturers of experimental vaccines will be required to assume liability arising from failure to manufacture their product in accordance with current Good Manufacturing Practices and agreed specifications, recipient countries will (as was the case during the 2014-2016 Ebola outbreak) as a condition for receiving experimental vaccine be required to assume liability and indemnify WHO, donors and manufacturers for other risks arising out of the use of the product. At the same time, WHO would obtain insurance coverage for the benefit of recipient countries, to provide compensation to individuals who suffer from serious AEFI. The insurance would have two levels: (i) a first level based on an annual premium, to keep the insurance open over time; and (ii) a second level of insurance to be obtained when an outbreak occurs, with a premium based on agreed criteria (vaccine safety profile, Gross Domestic Product of the country where the experimental product would be used and the number of people that would receive the product). The insurance could also include a certain coverage for manufacturers, i.e. in case an individual refuses to accept the compensation offered under the insurance and wishes to pursue a liability claim against the manufacturer in a court of law (or any similar forum).").

[65] COVAX AMC, https://covaxclaims.com (last visited Sept. 13, 2022) (explaining that "[t]he Program provides no-fault lump-sum compensation in full and final settlement of any claims to individuals who have suffered a Serious Adverse Event resulting in permanent impairment or death associated with a COVID-19 vaccine procured or distributed through the COVAX Facility, or the administration of such a vaccine, within any AMC Eligible Economy. The Program is administered by ESIS, Inc. (the 'Administrator')," which is an independent claims administrator with over thirty years of relevant claims handling experience and regional centers around the world able to assist Program applicants in all 92 AMC Eligible Economies).

global mechanism is limited.[66] That system only covers vaccines received through the COVAX Facility (COVAX), an international COVID-19 vaccine procurement partnership. COVAX aims to supply approximately twenty percent of an eligible country's immunization needs.[67] Procurement of vaccines to reach the herd immunity threshold from a twenty percent supply will inevitably reply upon more than one supplier. Thus, a system parallel to the WHO/ESIS, Inc. mechanism is required for countries committed to no-fault vaccine injury compensation. Most governments acknowledge this need but lack guidance on how to establish such a system.[68] Many countries have reached out to COVAX partners – CEPI, GAVI, the WHO, and UNICEF - as well as multilateral development banks for assistance which they have limited capacity to provide.[69] The need for governments to consider the feasibility of a no-fault compensation system and how it may be established are therefore unacknowledged and serious concerns as COVID-19 vaccines are procured and distributed.[70]

Similarly, the African Vaccine Acquisition Trust (AVAT) has established a partnership with ESIS, Inc. but, together with other sources of vaccines, will not cover an entire population.[71] Moreover, those multinational systems will expire

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[66] *Program Protocol*, COVAX AMC, https://covaxclaims.com/program-protocol/ (last visited Sept. 13, 2022) ("For clarity, the Program will not provide compensation for any non-Serious Adverse Events. Any such non-Serious Adverse Events are outside the scope of the Program. In addition, the Program will not provide compensation for any serious or non-serious adverse events arising from any COVID-19 vaccine which has not been received through the COVAX Facility or has been administered in any country, territory or economy which is not an AMC Eligible Economy. Furthermore, in the event a government of any AMC Eligible Economy authorizes, recommends or permits the use of a Vaccine in a manner other than in accordance with that Vaccine's label (as approved by the functional or stringent regulatory authority of reference, as applicable), then Serious Adverse Events arising from such use of the Vaccine shall only be eligible for compensation under the Program (subject to and in accordance with this Protocol), if and to the extent such use of the Vaccine complies with the recommendations of the WHO Strategic Advisory Group of Experts on Immunization (SAGE) and WHO guidance relating to the implementation of such recommendations.").

[67] Seth Berkley, *COVAX explained*, GAVI (Sept. 3, 2020), https://www.gavi.org/vaccineswork/covax-explained; Gavin Yamey, *A Coronavirus Vaccine Should Be for Everyone, Not Just Those Who Can Afford it*, STATNEWS (Mar. 5, 2020), https://www.statnews.com/2020/03/05/coronavirus-vaccine-affordable-for-everyone/ ("Without price controls, poor countries are unlikely to be able to afford or access enough vaccines to protect their populations."); Adam Hancock, *Why Developing countries May Be the Last to Get the Vaccine*, EU OBSERVER (May 28, 2020), https://euobserver.com/health-and-society/148470 ("To put it bluntly, they simply can't afford most of the new vaccines being produced.").

[68] Tom Vandersteegen et al., *The Impact of No-Fault Compensation on Health Care Expenditures: An Empirical Study of OECD Countries*, 119 HEALTH POL'Y 367, 367–68 (2015).

[69] *172 Countries and Multiple Candidate Vaccines Engaged in COVID-19 Vaccine Global Access Facility*, WORLD HEALTH ORG. (Aug. 24, 2020), https://www.who.int/news/item/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility.

[70] Yasuhiro Fujiwara et al., *No-Fault Compensation Schemes for COVID-19 Medical Products*, 397 LANCET 1707, 1707 (2021).

[71] AVAT NFCS, PROTOCOL FOR AVAT NO FAULT COMPENSATION SCHEME (2021), https://avatclaims.com/wp-content/uploads/2021/07/AVAT-Compensation-Program-Protocol.pdf.

with the end of the pandemic. National systems remain necessary for both routine and emergency immunization.[72]

This Article makes two significant contributions. First, it contributes the most comprehensive analysis to date of no-fault compensation systems for vaccine injury established *in the emergency context*. This distinction is essential for the classes of eligibility of those injured; how systems are established, administered, and funded; and the relationship between these systems and access to vaccines. Second, while no-fault compensation systems for routine immunizations have been established largely in high-resource countries, systems developed pursuant to the COVID-19 pandemic have been established mostly in low- or middle-income countries in Africa, Asia, Central and South America.[73] Neighboring countries, many of which have sought guidance or deliberated the feasibility of vaccine injury compensation, may benefit from a publicly available resource explaining how these systems have been established in countries with similar legal systems, history, and structure of social support.

Part II of this Article assesses previous landscape analyses of no-fault vaccine injury compensation systems worldwide, including their methods and approaches. Part III structures the analysis undertaken in this Article into five major categories or features of no-fault vaccine injury compensation systems both as a contribution to the existing literature and as a resource to planners in countries considering adoption of such a system. Part IV provides a brief conclusion.

II. MATERIALS AND METHODS

The methodological approaches researchers have adopted for no-fault vaccine injury compensation system landscape analyses have adapted as the number of systems has proliferated and the regions of the world covered have expanded as well. In 1999, Geoffrey Evans, a researcher at the U.S. Department of Health and Human Services, assembled a survey through "information gathered for each country via telephone interviews and correspondence from June, 1998 to May, 1999," presumptively after a literature review.[74] Clare Looker and Heath Kelly's 2011 landscape analysis broadly established the current approach, characterized by word searches in major medical, public health, law, and social sciences databases:

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[72] Halabi & Omer, *supra* note 63, at 471.

[73] David L. Heymann et al., *Global Health Security: the lessons from the West African Ebola Virus Disease Epidemic*, 385 LANCET 1884 (2015).

[74] Evans, *supra* note 33, at S31.

> We used a meta-search engine (Supersearch MetaLib®) to identify key published resources on vaccine-injury compensation schemes. Databases searched were: Web of Science®, Scopus v.4 (Elsevier), Medline (ISI), CINAHL®Plus (EBSCO), PsycINFO® (CSA), PubMed, Academic Search Premier (EBSCO), Expanded Academic ASAP (Gale), JSTOR, LegalTrac (Gale) and Law Journal Library (Hein). Keywords entered were vaccine AND injury AND compensation; "vaccine injury"; vaccine AND damage AND compensation; vaccine AND compensation; "vaccine policy"; "vaccine injury" AND international; and "vaccine injury" AND [country name]. We scanned reference lists of key full text papers. We used citation tracking in PubMed, Google Scholar, ScienceDirect and EBSCOhost to forward track key papers and identify articles cited in mainstream journals. We performed a grey literature search in Google using the same keywords. We searched web pages of international organizations, bilateral agencies, nongovernmental organizations, consultancy firms and universities involved in funding, delivering or evaluating immunization services. We perused national government web sites to find details of specific country's schemes. Finally we contacted key individuals involved in vaccine compensation programmes throughout the world.[75]

Randy Mungwira and his co-authors undertook an initial scoping review of published and unpublished literature.

> Structured literature search was done using PubMed, Excerpta Medica dataBASE (EMBASE), Cumulative index to Nursing and Allied Health Literature (CINAHL) and Global Online Access to Legal Information (GOALI) using the following predefined keywords: vaccine injury AND compensation programs; AEFI AND compensation; vaccine AND injury AND no-fault compensation; vaccine damage payment; and vaccine liability claims.[76]

Mungwira's team also had access to WHO central and regional offices for purposes of distributing a structured survey.[77] However, it appears that the survey instrument was largely used to understand details of the systems identified, not to identify entirely new ones.[78]

This Article adopts the methodological approach of these previous studies. Duplicating the methodology adopted by Looker, Kelly, and Mungwira et al., a

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[75] Looker & Kelly, *supra* note 8, at 371.
[76] Mungwira et al., *supra* note 23, at 2.
[77] *Id.*
[78] *Id.*

landscape analysis of published literature was conducted to identify countries that have implemented vaccine injury no-fault compensation programs pursuant to the COVID-19 pandemic and to analyze those systems. Published data was supplemented with official documents accessed from government websites. A structured literature search was undertaken using Bloomberg Law, Westlaw, PubMed, Excerpta Medica dataBASE (EMBASE), Cumulative index to Nursing and Allied Health Literature (CINAHL) and Global Online Access to Legal Information (GOALI) using the following predefined keywords: vaccine injury AND compensation programs; AEFI AND compensation; vaccine AND injury AND no-fault compensation; vaccine damage payment; and vaccine liability claims. In addition, the COVID-19 Law Lab, a database constructed through a partnership between WHO, UNDP, UNAIDS, and the O'Neill Institute for National and Global Health Law, was searched to identify those laws adopted during the course of the COVID-19 public health emergency that addressed vaccine injury. Fifteen statutes, regulations, or administrative decrees establishing no-fault vaccine injury compensation systems were identified and reviewed. Secondary references to legislative or regulatory measures were identified in another three countries.

III. ANALYSIS

This Part analyzes the results of the literature review and analysis, categorizing new no-fault compensation systems adopted pursuant to the COVID-19 public health emergency according to their administrative features, funding, eligibility criteria, elements of compensation, and rights to appeal adverse administrative or judicial conclusions. The results show that, unlike in previous periods, no-fault vaccine injury compensation systems are proliferating not only in wealthy countries like Australia and Canada, but in low- and middle-income countries like Guatemala, Malaysia, and Peru.

Establishing no-fault vaccine injury compensation systems was necessary, in part, for COVID-19 vaccines, as vaccine manufactures required the government to exempt them at least partly from liability and potential lawsuits.[79] In South Africa, for example, vaccine manufacturer Janssen (a unit of Johnson & Johnson) required the government to establish a no-fault vaccine injury compensation system as part of the bargain for receiving vaccines.[80] No-fault

[79] S'thembile Cele, *South Africa to Establish Compensation Fund to Allay J&J Concerns*, BLOOMBERG (Apr. 15, 2021, 7:23 AM), https://www.bloomberg.com/news/articles/2021-04-15/s-africa-to-establish-compensation-fund-to-allay-j-j-concerns#xj4y7vzkg.

[80] *Id.*

compensation addresses the limitations of litigation systems that, by their nature, conclude that a party is liable, or not, for injury or death associated with the administration of a vaccine.[81] Legal systems worldwide are diverse, and vaccine manufacturers prefer the predictability of a no-fault system to the uncertainties that accompany both common law and civil law systems. Common law systems are built in significant part on judges' decisions with judgments binding future cases based on the *stare decisis* principle.[82] Civil law systems prioritize written code and the new application of that written code to the facts as applied by judges who are also selected through diverse means.[83] Of the eighteen expansion no-fault compensation systems, twelve of the countries follow a civil law system.

No-fault vaccine injury compensation systems reduce the variations that can result from individuals accessing the court systems and the consideration to whether specific legislation is required to either limit the scope of a certain restriction or in setting out all the terms governing the relationship for vaccine distribution.[84] Legal systems can be costly, cumbersome, prone to delay, and the burden is often on the injured party seeking redress.[85] Compensation programs provide an expedited means of redress for rare injuries and arguably increase in public trust in immunization by providing fair, no-fault, lump sum compensation to eligible individuals who suffer certain serious adverse events after receiving a COVID-19 vaccines.[86]

A. Establishment, Administration, and Funding of No-Fault Vaccine Injury Compensation Systems

The number of countries implementing no-fault compensation programs for vaccine injuries over the course of the COVID-19 pandemic increased from twenty-five in 2018 to forty-three in 2022: Australia, Brazil, Canada, Colombia, the Czech Republic, Estonia, Guatemala, Honduras, Hong Kong, Lebanon,

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[81] Katie Attwell et al., *Mandatory Vaccination and No Fault Vaccine Injury Compensation Schemes: An Identification of Country-Level Policies*, 37 VACCINE 2843, 2844 (2019), https://doi.org/10.1016/j.vaccine.2019.03.065.

[82] Flavia Beccia et al., Review, *COVID-19 Vaccination and Medical Liability: An International Perspective in 18 Countries*, VACCINES, Aug. 7, 2022, at 1, 10, https://doi.org/10.3390/vaccines10081275.

[83] *Id.* at 10.

[84] *Key Features of Common Law or Civil Law Systems*, THE WORLD BANK (Mar. 2, 2022), https://ppp.worldbank.org/public-private-partnership/legislation-regulation/framework-assessment/legal-systems/common-vs-civil-law.

[85] William J. Gaine, *No-fault Compensation Systems*, 326 BRIT. MED. J. 997, 997 (2003).

[86] *COVAX No-Fault Compensation Program*, WORLD HEALTH ORG. (June 30, 2022), https://www.who.int/initiatives/act-accelerator/covax/no-fault-compensation#:~:text=It%20provides%20fair%2C%20no%2Dfault,Facility%20until%2030%20June%20202; Gaine, *supra* note 85, at 997-98.

Malaysia, Peru, the Philippines, Poland, Singapore, South Africa, Tunisia, and Ukraine added programs during this time. The COVID-19 pandemic has accelerated the adoption of no-fault vaccine injury compensation systems, especially in low- and lower-middle-income countries.

No-fault compensation schemes are the most common tool used by governments to protect all those who are damaged by compulsory or recommended vaccinations and as a way to reduce vaccine hesitancy.[87] These schemes can increase adequacy and fairness of compensation as they provide clear legal guidance on how to access compensation for vaccine injuries.[88]

1. Administration

Governments seeking to establish no-fault vaccine injury compensation systems generally must choose between two alternatives: incorporate vaccine injury claims and compensation into existing bureaucratic infrastructure, like national health or social security systems, or create new bureaucracies.[89] Of the eighteen expansion no-fault compensation systems, ten dedicate the administration of their no-fault vaccine injury compensation systems to their national ministries of health. Ministries of health worldwide interact with a wide range of institutions, governments, and aid agencies, potentially offering administrative and technical advantages over using a generalized litigation system for vaccine injuries.[90] Moreover, ministries of health may adopt a range of administrative approaches. Canada has authorized the Public Health Agency of Canada to contract with a private-sector third party administrator (Raymond Chabot Grand Thornton) to process and adjudicate claims.[91] Hong Kong has

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[87] Stefano D'Errico et al., Review, *"First Do No Harm". No-Fault Compensation Program for COVID-19 Vaccines as Feasibility and Wisdom of a Policy Instrument to Mitigate Vaccine Hesitancy*, VACCINES, Sept. 30, 2021, at 1, 8.

[88] Mungwira et al. *supra* note 23.

[89] *See e.g.* REP. OF LEB. MIN. OF PUB. HEALTH; LEBANON NATIONAL DEPLOYMENT AND VACCINATION PLAN FOR COVID-19 VACCINES 1, 12 (2021), https://www.moph.gov.lb/userfiles/files/Prevention/COVID-19%20Vaccine/Lebanon%20NDVP-%20Feb%2016%202021.pdf (establishing a new vaccine injury compensation system for Lebanon); Vaccine Damage Payments Act 1979, c. 17 (UK), https://www.legislation.gov.uk/ukpga/1979/17/contents; The Vaccine Damage Payments Regulations 1979, SI 1979/432, Part II (UK); The Vaccine Damage Payments (Specified Disease) Order 2020, SI 2020/1411, ¶ 2 (UK).

[90] FRANCIS OMASWA & JO I. BOUFFORD, STRONG MINISRIES FOR STRONG HEALTH SYSTEMS 29–30 (2014), https://media.nyam.org/filer_public/50/f7/50f7e4c5-cedd-42c2-a3f4-b573c64c08d0/sm-handbook-070114.pdf.

[91] *Call for applications to administer the Vaccine Injury Support Program*, GOV'T OF CAN. (June 16, 2021), canada.ca/en/public-health/services/funding-opportunities/grant-contribution-funding-opportunities/call-applications-vaccine-injury-support-program.html ("The Public Health Agency of Canada requires that the third-party administrator have experience and expertise in administering similar support

similarly contracted with AXA Hong Kong (the regional entity of the large French insurance firm) to administer claims under its system.[92] Colombia and Tunisia have established evaluation committees and require claims to be heard through existing administrative channels.[93] The Philippines has delegated its compensation system to PhilHealth, a social insurance corporation of the Philippines Department of Health.[94] Australia has similarly employed Services Australia, an executive agency similar to the U.S. Social Services Administration, to administer claims under its system.[95] Malaysia's fund is managed by the National Disaster Management Agency.[96] While Poland's initial administration will occur through its Ministry of Health, it has clarified that the system will eventually be formed into a separate agency.[97] Legislation in Colombia, the Czech Republic, Guatemala, Honduras, Lebanon, Peru, South Africa, and Tunisia specify the use of expert committees to evaluate the merits of claims before payments may issue.[98]

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programs. Funding to administer the program and manage financial support payments will be provided to the third-party administrator through a 5-year Contribution Agreement with the Public Health Agency of Canada.").

92 *Indemnity Fund for Adverse Events Following Immunization with Coronavirus Disease-2019 Vaccines*, THE GOV'T OF THE H.K. SPECIAL ADMIN. REGION (2020), https://www.covidvaccine.gov.hk/en/AEFI_Fund.

93 L. 2064, diciembre 9, 2020, DIARIO OFFICIAL [D.O.] (Colom.) [hereinafter Colombian L. 2064]; Loi n° 2021-10 du 2 mars 2021, fixant des dispositions dérogatoires relatives à la responsabilité civile résultant de l'utilisation des vaccins et des médicaments contre le virus SARS-CoV-2 et la réparation des dommages causés par celui-ci [Law No. 2021-10 of 2 March 2021, Laying Down Exceptions Provisions Relative to Liability Arising Out of the Use of Vaccines and Drugs Against the SARS-CoV-2 Virus and Compensation of the Damage Caused by Them], JOURNAL OFFICIEL DE LA RÉPUBLIQUE TUNISIENNE [OFFICIAL JOURNAL OF THE REPUBLIC OF TUNISIA], Mar. 2, 2021, No. 22, p. 518 [hereinafter Tunisian Law No. 2021-10 of 2 March 2021].

94 Melvin Jabar et al., *Knowledge on and Membership in PhilHealth: The Case of Overseas Filipino Workers*, 36 SOC. WORK IN PUB. HEALTH 677, 678 (2021).

95 *Services Australia*, AUSTL. GOV'T, https://www.servicesaustralia.gov.au.

96 Nicholas Chung, *RM50,000 Compensation for Vaccine Side Effects*, FREE MALAY. TODAY (Mar. 22, 2022, 1:10 PM), https://www.freemalaysiatoday.com/category/nation/2021/03/22/govt-announces-covid-19-vaccine-injury-fund/.

97 *Poland Sets Up Compensation Fund to Cover Adverse Effects of Vaccines*, FIRST NEWS (Jan. 12, 2021), https://www.thefirstnews.com/article/poland-sets-up-compensation-fund-to-cover-adverse-effects-of-vaccines-18997.

98 Colombian L. 2064, *supra* note 93; Zákon o náhradê újmy zpusibené povinnym očkováním [Act on Compensation for Damage Caused by Compulsory Vaccination], Zákon č. 116/2020 Sb. (Czech) [hereinafter Czech Act No. 116/2020]; Acuerdo Ministerial 40-2021, Ministerio de Salud Publica y Asistencia Social [Ministerial Agreement 40-2021, Ministry of Public Health and Social Assistance of Guatemala], Diario de Centro América 17-02-2021 (Guat.) [hereinafter Guatemalan Ministerial Agreement 40-2021], https://legal.dca.gob.gt/GestionDocumento/VisualizarDocumento?verDocumentoPrevia=True&versionImpresa=True&doc=85775; Decreto No. 193-2020 [Decree No. 193-2020], Ley Especial para la Garantía de la Atención por Eventos Adversos Graves Atribuidos a la Aplicación o Uso de la VACUNA Contra el COVID-19 y en su Caso para la Compensación Sin Culpa [Special Law for the Guarantee of the Care for Serious Adverse Events Attributed to the Application or Use of the Vaccine Against COVID-19 and, Where Applicable, for Compensation Without Fault], sec. A, no. 35,505, LA GACETA, 3 Febrero 2021 (Hond.) [hereinafter Honduran Decree No. 193-2020], https://www.tsc.gob.hn/web/leyes/Decreto-193-2020.pdf; REP. OF LEB. MIN. OF PUB. HEALTH, *supra* note 89; Decreto de Urgencia Nº 031-2021, marzo 10, 2021 [Emergency Decree No. 031-2021,

The implementation of a scheme into a well-established, comprehensive national social welfare system is thought to increase the efficiency of compensation programs.[99] Conversely, there is not yet a body of evidence supporting or rejecting the use of ad hoc committees. Creating stand-alone committees or entirely different programming can take time to establish and create confusion in accessing compensation, but in low-resource settings, they may nevertheless work more expeditiously than the general litigation system.

2. Funding

Adequate funding of no-fault vaccine injury compensation systems is essential to their survival and their legitimacy to the public. In systems established for routine immunizations, the funding sources have been diverse: general revenues, contributions from vaccine manufacturers, and special contributions from insurance companies have all been used to cover the cost of administering and paying out claims and other support.[100] In the United States, for example, the government funds its Vaccine Injury Compensation Program (VICP) for routine childhood immunizations through a $0.75 levy on each dose (so the measles, mumps, and rubella vaccine, for example, would be $2.25) of the vaccine sold, then funds the no-fault program with the levy.[101] The VICP trust holds approximately three billion dollars from this levy with about 150 million being deposited every year.[102] By contrast, its system for emergencies, the Countermeasure Injury Compensation Program, is funded through special allocations from Congress when emergencies are declared.[103]

Of the eighteen expansion no-fault compensation systems, sixteen commit to funding compensation through general revenues. Tunisia's law states unequivocally that "l'État est exclusivement responsable de la réparation des dommages résultant de l'utilisation des vaccins [the State is exclusively responsible for compensating the damage resulting from the use of vaccines]" and that such compensation "est imputé sur les ressources générales du budget

March 10, 2021], Diario Oficial del Bicentenariao (Peru) [hereinafter Peruvian Emergency Decree No. 031-2021], https://busquedas.elperuano.pe/normaslegales/decreto-de-urgencia-que-aprueba-medidas-economico-financiera-decreto-de-urgencia-n-031-2021-1933993-1/; Tunisian Law No. 2021-10 of 2 March 2021, *supra* note 93; Disaster Management Act: Regulations: Coronavirus COVID-19 Vaccine Injury No-Fault Compensation Scheme 376 of 2021 (S. Afr.).

99 Mungwira et al., *supra* note 23, at 11.

100 Looker & Kelly, *supra* note 8, at 371–72.

101 Engstrom, *supra* note 32, at 1660.

102 Mungwira et al., *supra* note 23, at 6.

103 42 U.S.C. § 247d-6d (2020).

de l'Etat [is charged to the general resources of the state budget]."[104] An early draft of the Philippines law dedicated one percent of the contract price for vaccine procurement to support the fund, although its law also suggests the use of general budget revenues. South Africa funds the scheme with funds appropriated by an Act of Parliament or from contingencies, and funds donated to the scheme.[105] From 2022, the Polish government has stated that vaccine producers will also contribute, with initial funding by the money that the government has earmarked for fighting the COVID-19 pandemic.[106] Honduras has established a special fund from general revenues.[107] Peru has authorized the use of specialized debt instruments guaranteed by multilateral agencies. The Inter-American Development Bank offers one such specialized guarantee to client countries.[108] Only Estonia has definitively funded its compensation system through a levy on private sector actors—vaccine distributors—based on a combination of the number of doses marketed in Estonia and the payment rate established by the government.[109] The Legislative Council of Hong Kong committed an initial fund size of one billion Hong Kong dollars.[110]

B. Eligibility

Eligibility for payment or support from a no-fault vaccine injury compensation system is a complicated feature—it is ultimately a determination about who may receive compensation and under which conditions. Multiple factors are relevant. The regulatory pathway and category of vaccine may affect eligibility. For example, vaccines authorized through so-called "emergency use" pathways weigh evidence differently than those submitted for licensure during non-emergency circumstances. Risks and benefits may be balanced differently and recommend that no-fault compensation be a policy option under such

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104 Tunisian Law No. 2021-10 of 2 March 2021, *supra* note 93, art. 6–7.

105 Disaster Management Act, *supra* note 98, at 5.

106 *Poland Sets Up Compensation Fund*, *supra* note 97.

107 Honduran Decree No. 193-2020, *supra* note 98.

108 Taos Turner, *IDB to Support Latin America and the Caribbean to Negotiate Faster Access to Vaccines*, INTER-AMERICAN DEV. BANK (Mar. 11, 2021), https://www.iadb.org/en/news/idb-support-latin-america-and-caribbean-negotiate-faster-access-vaccines.

109 Eva Lehtla, *Vaktsiinikindlustuse eelnõu sai valitsuse heakskiidu ja liigub arutamiseks Riigikokku* [*The Vaccine Insurance Bill Was Approved by the Government and Is Moving to the Riigikoku for Discussion*], SOTSIAALMINISTEERIUM (Jan. 13, 2022, 10:52 AM), https://www.sm.ee/et/uudised/vaktsiinikindlustuse-eelnou-sai-valitsuse-heakskiidu-ja-liigub-arutamiseks-riigikokku?utm_source=POLITICO.EU&utm_campaign=5b6a1c6530-EMAIL_CAMPAIGN_2022_01_14_05_59&utm_medium=email&utm_term=0_10959edeb5-5b6a1c6530-190468597.

110 Nick Beckett & Jonathan Chu, *Vaccine Compensation Regimes in Hong Kong*, CMS (Jun. 2, 2021), https://cms.law/en/int/expert-guides/cms-expert-guide-to-vaccine-compensation-regimes/hong-kong.

circumstances. Eligibility may also depend on the severity of the injury, the relationship of the individual seeking compensation to the person who suffered the harm, the means by which the vaccine was obtained and administered, and similar factors regulated the state's determination of why no-fault compensation exists and for whom it is intended to benefit. It must also be decided whether compensation is available to citizens only, or includes authorized permanent or temporary residents, or simply to all within a given territory who suffered the relevant harm.

1. Approved Vaccines

Of the eighteen no-fault compensation systems, all are designed to cover serious adverse reactions caused by coronavirus vaccines. Seven of the systems require the vaccine to be registered or authorized for emergency use. Brazil's law states that compensation is only for vaccines that have been approved through the respective registration or authorization for emergency use by the National Health Surveillance Agency (ANVISA).[111] Singapore's vaccines must be authorized for use under the Health Services Authority's Pandemic Special Access Route and/or registered under the Health Products Act.[112] In South Africa, compensation is available for persons who suffer harm, loss, or damage as a result of vaccine injury caused by the administration of a COVID-19 vaccine registered or otherwise approved by the South African Health Products Regulatory Authority, procured and distributed by the National Government, and administered at an official vaccination facility.[113] Canada covers all current and future Health Canada-authorized vaccines or immunoglobulins that provide protection from preventable infectious disease, administered in Canada on or after December 8, 2020.[114] Tunisia's system covers only vaccines and drugs with a marketing authorization.[115] Peru's system requires only that the vaccine was acquired by its ministry of health.[116]

Colombia's liability regime is applicable only for COVID-19 vaccines and other vaccines that are subject to an emergency approval or a temporary special

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[111] Lei No. 14.125, de 10 de Março de 2021, Diário Oficial da União [D.O.U.] de 10.03.2021 (Braz.) [hereinafter Brazilian Law No. 14.125], https://www.in.gov.br/en/web/dou/-/lei-n-14.125-de-10-de-marco-de-2021-307639844.

[112] *Vaccine Injury Financial Assistance Programme for COVID-19 Vaccination*, MINISTRY OF HEALTH SING. (2021), https://www.moh.gov.sg/covid-19/vaccination/vifap.

[113] Disaster Management Act, *supra* note 98.

[114] Pub. Health Agency of Can., *Frequently Asked Questions*, VACCINE INJ. SUPPORT PROGRAM, https://www.vaccineinjurysupport.ca/en/faq (last visited Sept. 15, 2022).

[115] Tunisian Law No. 2021-10 of 2 March 2021, *supra* note 93.

[116] Peruvian Emergency Decree No. 031-2021, *supra* note 98.

approval.[117] The Czech Republic ties compensation to compulsory vaccination carried out by a health care provider.[118] The Philippines designates immunizations delivered through its COVID-19 Vaccination Program.[119]

Guatemala, Honduras, Lebanon, Malaysia, and Poland designate vaccines against COVID-19, without further specification.[120]

2. Timelines of Injury and Vaccination

One of the most vexing problems in constructing no-fault compensation systems is establishing causation between the vaccination and the resulting injury. Addressing this problem is particularly important in low-resource settings where trained healthcare workers, diagnostic equipment, and laboratories may be scarce. One approach to this problem is to use the temporal association between vaccination and injury as a proxy for other forms of establishing causation with requisite certainty.

Compensation systems may specify timelines for processing claims and rendering decisions that correspond to this way of tailoring eligibility for compensation to timeframes. Honduras' law allows only sixty business days after vaccine administration.[121] Singapore's law provides for three years from the date of occurrence for individuals to submit an application, which must be further validated by a physician.[122] Tunisia's law applies to vaccines and drugs that have been imported and used during a period of two years after the effective date of the adoption of the no-fault compensation system law.[123]

Brazil, Guatemala, Lebanon, Malaysia, Peru, and Poland do not specify timelines for claims related to vaccine administration.[124] The Philippines

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[117] Colombian L. 2064, *supra* note 93.

[118] Czech Act No. 116/2020, *supra* note 98; Vyhláška o očkování proti infekčním nemocem [Decree on Vaccination Against Infectious Diseases], Zákon č. 537/2006 Sb. (Czech) [hereinafter Czech Decree No. 537/2006], https://www.zakonyprolidi.cz/cs/2020-116/.

[119] An Act Establishing the Coronavirus Disease 2019 (COVID-19) Vaccination Program Expediting the Vaccine Procurement and Administration Process, Providing Funds Therefor, and Other Purposes, Rep. Act No. 11525, § 10 (Feb. 26, 2021) (Phil.) [hereinafter Filipino Rep. Act No. 11525], https://www.officialgazette.gov.ph/2021/02/26/republic-act-no-11525/.

[120] Guatemalan Ministerial Agreement 40-2021, *supra* note 98; Honduran Decree No. 193-2020, *supra* note 98; REP. OF LEB. MIN. OF PUB. HEALTH, *supra* note 89; Chung, *supra* note 96; *Poland Sets Up Compensation Fund*, *supra* note 97.

[121] Honduran Decree No. 193-2020, *supra* note 98.

[122] *Vaccine Injury Financial Assistance Programme*, *supra* note 112.

[123] Tunisian Law No. 2021-10 of 2 March 2021, *supra* note 93.

[124] Guatemalan Ministerial Agreement 40-2021, *supra* note 98; Honduran Decree No. 193-2020, *supra* note 98; REP. OF LEB. MIN. OF PUB. HEALTH, *supra* note 89; Chung, *supra* note 96.

similarly omits timelines for claims but notes that the fund shall be available for release and disbursement for five years from the effect of the Act.[125] South Africa, Colombia, and Czech Republic state that additional procedural rules as to timelines will issue.[126]

3. Injured Party

While the individual experiencing SAEFI is universally eligible for compensation, some systems allow others to claim loss. The Czech Republic and South Africa allow for dependents or those close to the injured vaccinated persons to file claims.[127] Canada, Colombia, Guatemala, Honduras, and Peru state that the individual must have received the vaccine in the national territory, although Canada includes certain Canadians serving government abroad.[128] Colombia limits compensation to COVID-19 vaccines administered by the Colombian State.[129] Singapore allows citizens, permanent residents or long-term pass holders who have been recommended to receive the COVID-19 vaccine and who experience a serious side effect assessed by a doctor to be related to the COVID-19 vaccination received in Singapore to apply for VIFAP.[130]

Brazil, Lebanon, Malaysia, the Philippines, Poland, and Tunisia do not address the definition of injured party.[131]

4. Types of Injuries Covered

All eighteen systems cover serious adverse events following immunization. Eight of the countries include hospitalization, with Poland requiring a fourteen-day hospitalized stay to qualify for a single compensation payment.[132] Estonia's plan covers "serious health damage" lasting four months or more or death.[133]

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[125] Filipino Rep. Act No. 11525, *supra* note 119, § 10.

[126] Colombian L. 2064, *supra* note 93; Czech Decree No. 537/2006, *supra* note 118, § 4(2)(c); Disaster Management Act, *supra* note 98, § 101.

[127] Czech Decree No. 537/2006, *supra* note 118, § 2(2); Disaster Management Act, *supra* note 98.

[128] Pub. Health Agency of Can., *supra* note 114; Colombian L. 2064, *supra* note 93; Guatemalan Ministerial Agreement 40-2021, *supra* note 98; Honduran Decree No. 193-2020, *supra* note 98, art. 2; Peruvian Emergency Decree No. 031-2021, *supra* note 98.

[129] Colombian L. 2064, *supra* note 93.

[130] *Vaccine Injury Financial Assistance Programme*, *supra* note 112.

[131] Brazilian Law No. 14.125, *supra* note 111; REP. OF LEB. MIN. OF PUB. HEALTH, *supra* note 89; Chung, *supra* note 96; *Poland Sets Up Compensation Fund*, *supra* note 97; Tunisian Law No. 2021-10 of 2 March 2021, *supra* note 93.

[132] *Poland Sets Up Compensation Fund*, *supra* note 97.

[133] Lise-Lotte Lääne, et al. *Important Legal Developments in the Healthcare & Life Sciences Sector in the Baltics*, SORAINEN (Mar. 29, 2022), https://www.sorainen.com/publications/important-legal-developments-in-the-healthcare-life-sciences-sector-in-the-baltics/.

Australia, Canada, Guatemala, Honduras, Hong Kong, Malaysia, the Philippines, Singapore, and Ukraine define compensable injuries consistently with regulatory classifications of serious adverse events: 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.[134] Additionally, Australia allows hospitalization as an independent ground for eligibility, but individual costs must exceed AUD$1,000. As reports of adverse events for specific vaccines have grown, Australia has similarly incorporated them into its scheme:

> If you had AstraZeneca Vaxzeria, the following clinical conditions are accepted under the scheme: anaphylactic reaction, thrombosis with Thrombocytopenia Syndrome; capillary leak syndrome; demyelinating disorders including Guillain Barre Syndrome (GBS); thrombocytopenia, including immune Thrombocytopenia.
>
> If you've had Pfizer/Biontech Comirnaty or Moderna Spikevax, the following clinical conditions are accepted under the scheme: anaphylactic reaction; myocarditis; pericarditis.
>
> If you had Novavax Nuvaxovid, the clinical condition of anaphylactic reaction is accepted under the scheme.[135]

South Africa's regulations mirror regulatory classifications for SAEFI, but add that other serious damage may be compensable if agreed upon by the cabinet member responsible for health in consultation with the cabinet member responsible for finance.[136]

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[134] *See* WORLD HEALTH ORGANIZATION, ADVERSE EVENTS FOLLOWING IMMUNIZATION: CAUSALITY ASSESSMENT 1 (July 2002), http://apps.who.int/iris/bitstream/handle/10665/191391/a87773_eng.pdf?sequence=1 ("WHO standard definition for drug and vaccine adverse events is 'any untoward medical occurrence that results in death, hospitalization or prolongation of hospitalization, persistent or significant disability/incapacity, or is life threatening'. Additional AEFIs that need systematic causality assessment are: AEFIs that may be caused by a programme error, e.g., a cluster [] of bacterial abscesses; serious unexplained AEFI occurring within 30 days after vaccination and not listed in product label; events causing significant parental or community concern. Signal: Reported information on possible causal relationship between AEFI and vaccine; relationship previously unknown or incompletely documented."); *Who can Get Support Under Covid-19 Vaccine Claims Scheme?*, SERVICES AUSTL., https://www.servicesaustralia.gov.au/who-can-get-support-under-covid-19-vaccine-claims-scheme?context=55953; Pub. Health Agency of Can., *supra* note 114; Guatemalan Ministerial Agreement 40-2021, *supra* note 98; Honduran Decree No. 193-2020, *supra* note 98, art. 8; Edith Lin, *Hong Kong Indemnity Fund for Vaccine-Related Deaths, Injuries Must Speed Up Claims Process, Critics Say*, S. CHINA MORNING POST (May 17, 2022), https://www.scmp.com/news/hong-kong/health-environment/article/3178116/coronavirus-hong-kong-indemnity-fund-vaccine; Chung, *supra* note 96.

[135] *Who can Get Support Under Covid-19 Vaccine Claims Scheme?*, *supra* note 134.

[136] Disaster Management Act, *supra* note 98, § 93.

Tunisia's law defines "serious" as bodily injury that is life-threatening or has resulted in a permanent physical disability equal to or greater than twenty percent, total physical incapacity, or injury requiring a medical or surgical procedure to avoid permanent incapacity.[137] Colombia has established an Evaluation Council comprised of at least five expert members, with technical support from a scientific group to evaluate the adverse effects generated by the COVID-19 vaccine to determine eligibility.[138] Brazil, the Czech Republic, South Africa, Lebanon, Peru, and Ukraine cover "adverse" or "severe adverse" events but do not provide further detail or definition.[139]

C. Process, Decision making and Standard of Proof

Processes for submitting claims to no-fault compensation systems vary and may be as simple as completing forms and as complicated as requiring legal counsel. Similarly, some systems require those suffering SAEFI to demonstrate a causal link between the vaccine and the relevant damages, while others rely on a more lenient standard that requires only a showing of injury proximate in time to vaccination.

Where no-fault systems established prior to COVID-19 adopted judicial and quasi-judicial processes for the presentation of evidence and standards of proof, no-fault systems established after COVID-19 generally rely upon expert committees and ad hoc determination of causation. Of the eighteen systems, fourteen have provided procedures for establishing an independent committee that will review serious adverse reactions and decide compensation.

Canada's Vaccine Injury Support Program (VISP), administered by Raymond Chabot Grant Thorton (RCGT), an accounting firm, adjudicates decisions on individual claims through a committee of independent medical experts.[140] The committee is "comprised of three (3) physicians [who] review claimants' medical records to determine if a probable link exists between the injury and the vaccine."[141] The Czech Republic's law requires the applicant to submit a description of the injury and an indication of the extent of the injury,

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[137] Tunisian Law No. 2021-10 of 2 March 2021, *supra* note 93.

[138] Colombian L. 2064, *supra* note 93.

[139] Brazilian Law No. 14.125, *supra* note 111; Czech Decree No. 537/2006, *supra* note 118; Disaster Management Act, *supra* note 98; REP. OF LEB. MIN. OF PUB. HEALTH, *supra* note 89, at 33; Peruvian Emergency Decree No. 031-2021, *supra* note 98; Borys Danevych, et al., *Vaccine Compensation Regimes in Ukraine*, CMS (Aug. 16, 2021), https://cms.law/en/int/expert-guides/cms-expert-guide-to-vaccine-compensation-regimes/ukraine.

[140] Pub. Health Agency of Can., *supra* note 114.

[141] *Id.*

when and to whom the vaccine was administered, how the injury manifested, how long it lasted, and the identity of the selected vaccine.[142]

Guatemala's law establishes a Committee for the Evaluation of Serious Adverse Reactions to Vaccines comprised of five national experts with extensive experience in vaccination.[143] Lebanon's and Peru's laws authorize specialized scientific/medical committees established by ministries of health.[144]

The laws of Brazil, Colombia, Guatemala, and Malaysia authorize an administrative procedure for claims, but those procedures have not yet been issued.[145] The Philippines' fund is administered by PhilHealth, and within PhilHealth, a committee of medical and vaccine experts promulgate the guidelines on the monitoring, evaluation, investigation, and reporting mechanisms to identify SAEFI.[146]

Honduras' law requires individuals to submit information that includes the health establishment where the vaccine was administered, date of application, number of doses, manufacturer's name, lot number, expiration date, as well as the name of the vaccinator.[147] The law creates a unit within the Ministry of Health charged with investigating the claim.[148]

Singapore reviews applications through an "independent clinical panel for the severity and relatedness of the side effect to the COVID-19 vaccine" as assessed by a medical doctor.[149]

South Africa's scheme convenes a panel consisting of a retired judge appointed by the cabinet member responsible for health who also appoints the assessors of the causality panel; the assessors of the quantum panel; the members of the adjudication panel; and the remaining members of the appeal panel. "The appeal panel, adjudication panel, causality panel and quantum panel must take decisions and make assessments in accordance with" eligibility requirements issued in later regulations.[150] Tunisia's law similarly dedicates adjudication to a

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142 Czech Act No. 116/2020, *supra* note 98; Czech Decree No. 537/2006, *supra* note 118.

143 Guatemalan Ministerial Agreement 40-2021, *supra* note 98.

144 REP. OF LEB. MIN. OF PUB. HEALTH, *supra* note 89, at 12; Peruvian Emergency Decree No. 031-2021, *supra* note 98.

145 Brazilian Law No. 14.125, *supra* note 111; Colombian L. 2064, *supra* note 93; Guatemalan Ministerial Agreement 40-2021, *supra* note 98; Chung, *supra* note 96.

146 Filipino Rep. Act No. 11525, supra note 119, § 9.

147 Honduran Decree No. 193-2020, *supra* note 98.

148 *Id.*

149 *Vaccine Injury Financial Assistance Programme*, *supra* note 112.

150 Disaster Management Act, *supra* note 98.

multidisciplinary committee, whose remit, composition, terms of operation, and referral procedures are to be fixed by governmental decree and determination of the nature of the damage, its causes, and the amount of compensation, if due, within a maximum period of three months from the date of receipt of the compensation claim.[151]

The laws of Brazil, Lebanon, Malaysia, the Philippines, and Poland do not address standards of proof or burdens that claimants must meet for compensation.[152]

D. Elements of Compensation

The level of compensation may be considered relative to the severity of the injury, access to care, and its anticipated costs to the individual and family. Systems may cover a relatively broad class of damages, including death, injury, disability, pain and suffering, and other forms of economic and non-economic loss resulting from the injury. The level of compensation offered by the system may be considered along with other governmental arrangements (e.g., social security programs).

Five of the eighteen systems have specific amounts allocated to individuals who suffer SAEFI. Canadian individuals "may receive income replacement indemnities; injury indemnities; death benefits; coverage for funeral expenses; reimbursement of eligible costs such as otherwise uncovered medical expenses."[153] Malaysia's law allows those who suffer serious side effects that require lengthy treatment in the hospital can receive RM50,000 ($10,573) and those who suffer permanent impairments or death to receive RM500,000 ($105,730).[154] Poland's law allows for a single compensation payment in the range of PLN 10,000 ($2,048) to PLN 100,000 ($20,482).[155] Singapore provides an injury-compensation table: $225,000 for death or permanent severe disability, $10,000 for inpatient ICU hospitalization, and $2,000 for inpatient hospitalization alone.[156] Under Peru's system, compensation is calculated on the basis of the minimum living wage in effect at the time of the determination of

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151 Tunisian Law No. 2021-10 of 2 March 2021, *supra* note 93.

152 Brazilian Law No. 14.125, *supra* note 111; REP. OF LEB. MIN. OF PUB. HEALTH, *supra* note 89, at 12; Chung, *supra* note 96; Filipino Rep. Act No. 11525, supra note 119, § 9; *Poland Sets Up Compensation Fund*, *supra* note 97.

153 Pub. Health Agency of Can., *supra* note 114.

154 Chung, *supra* note 96.

155 *Poland Sets Up Compensation Fund*, *supra* note 97.

156 *Vaccine Injury Financial Assistance Programme*, *supra* note 112.

the SAEFI.[157] Those injured and not otherwise insured are enrolled in Peru's Comprehensive Health Insurance (SIS).[158] Estonia's system allows for a compensation range of €2,000 ($1,957) to €100,000 ($97,828).[159]

While the Czech Republic Ministry of Health does not designate a specific sum or class of damages, it will award compensation for damage in the claimed amount if it concludes that the vaccinated person is entitled to it pursuant to Act No. 116/2020.[160] Damages are determined by proof submitted by the claimant.[161]

Brazil, Malaysia, Colombia, Honduras, Lebanon, Philippines, South Africa, and Tunisia do not address elements of compensation.[162] Guatemala's compensation system relies on its national network of services of health to determine both the appropriate compensation amount and compensation mechanism for affected persons, according to each person's need.[163]

E. Litigation Rights

Compensation systems may allow victims to appeal initial decisions to either administrative tribunals or courts. Of the eighteen systems, six allow for individuals to appeal. Canada's law allows a claimant to appeal a decision through an appeal committee comprised of different panel members than those who made the initial determination.[164] South Africa's appeal mechanism is similar, it allows a dissatisfied clamant to appeal to a higher panel, which may confirm, vary or set aside the decision of the adjudication panel, call for and receive new information or evidence relevant to the claim, and appoint qualified persons to assist in the evaluation of the claim.[165] An appeal panel decision in South Africa is final and binding, save for where a party seeks to review the decision under the Promotion of Administrative Justice Act.[166] In Colombia and

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157 Peruvian Emergency Decree No. 031-2021, *supra* note 98.

158 *Id.*

159 *Covid-19 Vaccine-Related Injury Compensation*, EESTI HAIGEKASSE, https://www.haigekassa.ee/en/people/benefits/covid-19-vaccine-related-injury-compensation (last visited Sept. 15, 2022).

160 Czech Act No. 116/2020, *supra* note 98.

161 *Id.*

162 Brazilian Law No. 14.125, *supra* note 111; Chung, *supra* note 96; Colombian L. 2064, *supra* note 93; Honduran Decree No. 193-2020, *supra* note 98; REP. OF LEB. MIN. OF PUB. HEALTH, *supra* note 89; Filipino Rep. Act No. 11525, supra note 119; Disaster Management Act, *supra* note 98; Tunisian Law No. 2021-10 of 2 March 2021, *supra* note 93.

163 Guatemalan Ministerial Agreement 40-2021, *supra* note 98.

164 Pub. Health Agency of Can., *supra* note 114.

165 Disaster Management Act, *supra* note 98, at 8.

166 *Id.* at 9.

Peru, claimants must exhaust initial expert committee proceedings before filing claims in administrative tribunals.[167] The Czech Republic's law requires the individual to go through the claim processes as a condition for the possible exercise of the right to sue.[168] Tunisian law provides that a claimant may appeal to administrative tribunals if a claim is rejected or not paid within three months.[169]

Only one country, Lebanon, explicitly states that individuals have only one recourse to seek compensation for injuries related to vaccine injury, the specialized scientific/medical committee.[170] The remaining laws do not address whether a claimant may appeal an initial decision.

F. Next Steps

Establishing no-fault vaccine injury compensation systems may expedite procurement of vaccines during future pandemics and provide assurance in rare circumstances where a severe reaction occurs.[171] This is as true for a global response as it is for national responses. In addition to the eighteen expansion no-fault compensation systems, COVAX established the COVAX No-Fault Compensation Program for Advance Market Commitment (AMC) Eligible Economies. This program was established for eligible individuals in the ninety-two AMC Eligible Economies that have received a COVID-19 vaccine distributed through COVAX.[172] This program helps to reduce the financial exposure for AMC Eligible Economies by minimizing the number of instances in which these economies may be required to indemnify manufacturers and ensure that affected eligible individuals have access to fair compensation while reducing the risk of litigation for manufacturers.[173] These compensation programs can provide precedents and potential models for a sustainable solution in compensation schemes for routine vaccinations as well as responding to new outbreaks. Future epidemics could occur in parts of the world where no-fault compensation schemes have not been established, meaning that manufacturers developing vaccines for diseases in those regions or deploying vaccines there

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[167] Colombian L. 2064, *supra* note 93; Peruvian Emergency Decree No. 031-2021, *supra* note 98.

[168] Czech Act No. 116/2020, *supra* note 98.

[169] Tunisian Law No. 2021-10 of 2 March 2021, *supra* note 93.

[170] REP. OF LEB. MIN. OF PUB. HEALTH, *supra* note 89.

[171] 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. (Perspective) e125(1), e125(3) (2020), https://www.nejm.org/doi/full/10.1056/NEJMp2030600.

[172] *COVAX No-Fault Compensation Program: Explained*, WHO, https://www.who.int/initiatives/act-accelerator/covax/no-fault-compensation/covax-no-fault-compensation-program-explained (July 7, 2022).

[173] *Id.*

will continue to face substantial liability risks.[174] Whether individual countries or a global compensation scheme that grows out of the COVID-19 pandemic, a no-fault approach would include a recognition that unintended medical injuries are unavoidable; compensation that is modest and based on needs proportionate to the injury; a consistent approach to reviewing cases of injury; involvement from necessary government agencies; and a set time frame from date of injury during which claims could be filed.[175] To incentivize manufactures to support the development of vaccines against future epidemics and pandemics, global mechanisms that were instituted during COVID-19 to address and restrict liability risk for manufactures should be maintained.[176]

IV. CONCLUSION

No-fault vaccine injury compensation systems have proliferated as a result of balancing community and manufacturer interests in the rollout of COVID-19 vaccines. Most of these new systems have been adopted in low- and middle-income countries in contrast to the systems adopted for routine immunization before the COVID-19 pandemic. This Article has classified and analyzed these new systems, adopted during emergencies, to both expand the understanding of these systems for public health planners and to serve as an important resource for countries seeking to adopt such systems for their response.

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[174] John D. Winter, et al., *Towards a Global Solution on Vaccine Liability and Compensation*, 74 FOOD & DRUG L. J., no. 1, 2019, at 1, 12, 13, 15.

[175] Roger Collier, *No-fault Compensation Program Overdue, Experts Say*, 183 CAN. MED. ASS'N J. E263, E264 (Mar. 22, 2011).

[176] Winter, *supra* note 174, at 12, 13.

APPENDIX

Region	Country	Form of Law	Summary Provisions
Africa	South Africa	Disaster Management Act: Regulations: Coronavirus COVID-19 Vaccine Injury No-Fault Compensation Scheme 376 of 2021 (S. Afr.)	In April 2021, South Africa enacted regulations for the establishment of a COVID-19 Vaccine Injury No-Fault Compensation Scheme. According to the regulations, the National Department of Health is responsible for the administration of the scheme and its funds, although a service provider may be appointed. The funds of the scheme consist of funds appropriated by an Act of Parliament or from contingencies, and funds donated to the scheme. Those funds shall not be utilized for purposes other than the scheme. The scheme includes an appeal panel, an adjudication panel, a causality panel and a quantum panel. The regulations determine the qualifications that the experts of each panel must have. The scheme covers persons who suffered severe injuries resulting in permanent or significant injury, serious harm to a person's health and other serious damage or death. Claims are subject to appeal, but filing a claim to the scheme bars other legal proceedings in a court.
Region	**Country**	**Form of Law**	**Summary Provisions**

Africa	Tunisia	Loi n° 2021-10 du 2 mars 2021, fixant des dispositions dérogatoires relatives à la responsabilité civile résultant de l'utilisation des vaccins et des médicaments contre le virus SARS-CoV-2 et la réparation des dommages causés par celui-ci [Law No. 2021-10 of 2 March 2021, Laying Down Exceptions Provisions Relative to Liability Arising Out of the Use of Vaccines and Drugs Against the SARS-CoV-2 Virus and Compensation of the Damage Caused by Them], JOURNAL OFFICIEL DE LA RÉPUBLIQUE TUNISIENNE [OFFICIAL JOURNAL OF THE REPUBLIC OF TUNISIA], Mar. 2, 2021, No. 22, p. 518	The law grants immunity from civil liability for all parties involved in the development, manufacture, distribution, deployment of COVID-19 vaccines (except for intentional violation of law), and establishes a multidisciplinary committee to adjudicate claims for damage resulting from vaccine administration to be paid from the State Budget.

Region	Country	Form of Law	Summary Provisions
Americas	Brazil	Lei No. 14.125, de 10 de Março de 2021, Diário Oficial da União [D.O.U.] de 10.03.2021 (Braz.)	Law No. 14,125, published in official gazette on March 10, 2021, provides for indemnity consistent with the terms included in the underlying vaccine acquisition or supply agreement. According to Article 3: "The Federal Executive Branch may institute its own administrative procedure for evaluating demands related to post-vaccination adverse events."
	Canada-federal	Allocation to Public Health Agency of Canada Action to Enter into Administrative Agreement	The Public Health Agency of Canada (PHAC) announced on December 10, 2020 that it is implementing a pan-Canadian no-fault vaccine injury support program for all Health Canada approved vaccines in collaboration with provinces and territories, building on the model in place in Québec. PHAC contracted with RCGT, Inc. to administer the program.

Region	Country	Form of Law	Summary Provisions
Americas	Colombia	L. 2064, diciembre 9, 2020, DIARIO OFFICIAL [D.O.] (Colom.)	Under the law, a COVID-19 Evaluation Council will be created to determine causality (precondition to claimant's pursuing litigation). If causality is found, a case may be brought against the government. The legislation provides liability protections for manufacturers, with exceptions for willful misconduct/gross negligence or a failure to comply with GMP/regulatory requirements.

Region	Country	Form of Law	Summary Provisions
Americas	Guatemala	Acuerdo Ministerial 40-2021, Ministerio de Salud Publica y Asistencia Social [Ministerial Agreement 40-2021, Ministry of Public Health and Social Assistance of Guatemala], Diario de Centro América 17-02-2021 (Guat.)	Guatemala published a norm on exemption from liability and compensation for serious adverse reactions attributable to COVID-19 vaccines on February 18, 2021 (Acuerdo Ministerial 40-2021, Norma de Excepción de Responsabilidad y Compensación por Reacciones Adversas Serias Atribuibles a las Vacunas Contra el COVID-19). The norm establishes a committee for the evaluation of serious adverse events, formed by five national experts with extensive experience in vaccination. The committee will determine whether the adverse events have been caused by a COVID-19 vaccine, the seriousness of the event, and whether the injury is eligible for compensation. The norm also foresees the establishment of a regime to compensate serious adverse events through the national health services, except in those cases where the event is the result of the recipient's fraudulent and intentional conduct.

Region	Country	Form of Law	Summary Provisions
Americas	Honduras	Decreto No. 193-2020 [Decree No. 193-2020], Ley Especial para la Garantía de la Atención por Eventos Adversos Graves Atribuidos a la Aplicación o Uso de la VACUNA Contra el COVID-19 y en su Caso para la Compensación Sin Culpa [Special Law for the Guarantee of the Care for Serious Adverse Events Attributed to the Application or Use of the Vaccine Against COVID-19 and, Where Applicable, for Compensation Without Fault], sec. A, no. 35,505, LA GACETA, 3 Febrero 2021 (Hond.)	Decree No. 193-2020, published on February 3, 2021 (Ley Especial para la Garantía de la Atención por Eventos Adversos Graves Atribuidos a la Aplicación o Uso de la Vacuna contra el COVID-19 y en su Caso para la Compensación sin Culpa) establishes an NFCS in relation to serious adverse events resulting in impairment or death associated with the administration of a COVID-19 vaccine. The injured party must file a claim before a care unit established under the Decree within 60 business days after the administration of the vaccine. A decision on the compensation must be issued within 300 business days. The Decree also establishes a dedicated fund that will cover no-fault compensations and any indemnification obligations of the government vis-à-vis vaccine manufacturers.

Region	Country	Form of Law	Summary Provisions
Americas	Peru	Decreto de Urgencia Nº 031-2021, marzo 10, 2021 [Emergency Decree No. 031-2021, March 10, 2021], Diario Oficial del Bicentenariao (Peru)	Emergency Decree issued in March 2021 to finance COVID-19 immunization process and create a compensation mechanism for serious adverse events caused by vaccines. Creates a technical committee (ESAVI) to conduct preliminary assessment of causal relationship between reported adverse events and vaccines. Final Report by ESAVI finding a causal relationship is a pre-requisite for a claimant to initiate an administrative claim for compensation through the judicial process.
Asia	Hong Kong	Action 1 of the Legislative Council Finance Committee	The Government of Hong Kong Special Administrative Region has issued summary provisions at https://www.covidvaccine.gov.hk/en/AEFI_Fund.

Region	Country	Form of Law	Summary Provisions
Asia	Lebanon	Law No. 211 (2021) Regulating the Emerging Use of Medical Products to Combat the COVID-19 Pandemic	Law provides immunity to manufacturers/others involved in administering vaccines and providing medical treatment for COVID-19 except for "intentional misconduct." Law also requires the establishment of a specialized scientific committee to evaluate claims for "serious injuries" and that compensation will be paid from a fund established by the Government of Lebanon.
	Malaysia	MOH Announcement (2021)	On March 22, 2021, the government announced a COVID-19 vaccine injury fund. The fund will provide RM50,000 for vaccine recipients who suffer serious side effects that require hospitalization and RM500,000 for those who suffer permanent injuries or death.

Region	Country	Form of Law	Summary Provisions
Asia	Philippines	An Act Establishing the Coronavirus Disease 2019 (COVID-19) Vaccination Program Expediting the Vaccine Procurement and Administration Process, Providing Funds Therefor, and Other Purposes, Rep. Act No. 11525, § 10 (Feb. 26, 2021) (Phil.)	SB 2057 was approved by the Senate and signed by the President in February 2021: http://legacy.senate.gov.ph/lisdata/3453131370!.pdf. While limited to COVID-19 vaccines, this legislation provides immunity from liability except for willful misconduct (Sec. 8) and establishes a compensation fund (500M pesos) (Sec. 9) to be administered by PhilHealth.
	Singapore	Administrative Action (2021)	On January 28, 2021, Singapore announced the Vaccine Injury Financial Assistance Programme (VIFAP) for COVID-19 vaccines: https://www.moh.gov.sg/news-highlights/details/update-on-covid-19-vaccination-programme.

Region	Country	Form of Law	Summary Provisions
Europe	Czech Republic	Zákon o náhradê újmy zpusibené povinnym očkováním [Act on Compensation for Damage Caused by Compulsory Vaccination], Zákon č. 116/2020 Sb. (Czech)	Statutory scheme under Act No. 116/2020 on Compensation for Damage Caused by Compulsory Vaccination (effective starting April 8, 2020): https://www.zakonyprolidi.cz/cs/2020-116/. Administered by the Ministry of Health.
	Estonia	Amendment to Medicinal Products Act	Summary provisions available at https://vaktsineeri.ee/en/news/government-approved-the-principles-of-the-vaccine-insurance/.
	Poland*	MOH Announcement	On January 12, 2021, Ministry of Health announced establishment of fund and thresholds for eligibility as well as future administrative features.
	Ukraine	MOH Announcement	Decree of the Cabinet of Ministers 31 March 2021
Oceana	Australia	*Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) Declaration 2020* (Austl.); *COVID-19 Vaccine Claims Scheme Policy 2021* (Austl.)	Services Australia has issued summary provisions at: https://www.servicesaustralia.gov.au/what-costs-you-can-claim-under-covid-19-vaccine-claims-scheme?context=55953.