Comparing No-Fault Compensation Systems for Vaccine Injury

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I. INTRODUCTION

The rapid development and deployment of vaccines has been, and remains, key to overcoming the pandemic caused by the SARS-CoV-2 virus. The speed with which scientists developed and pharmaceutical companies produced COVID-19 vaccines has been a much-lauded success, however, the distribution and administration of the vaccines has raised political, logistical, and ideological challenges that proved more difficult to overcome.[1] A particularly intractable problem for the global community was the equitable distribution of the vaccine between rich and poor.[2] However, even in countries where vaccines were available in sufficient quantity, the success of immunization programs depended on the population's willingness to be vaccinated.

Yet, like nearly all vaccines, COVID-19 vaccines have the potential to generate rare, serious side effects ranging from soreness at the injection site to fever and muscle pain to, exceptionally, anaphylaxis and other

1. We thank Anne Mazur, Rafael La Rotta, Stefanie Benitez, and Alya Dabbagh of the World Health Organization, as well as Stéphanie Chuffart-Finsterwald and Zarmine Hussain of Sigma Legal Ltd., for their input with respect to international no-fault compensation schemes.

2. *See* Lawrence O. Gostin, Sam F. Halabi & Kevin A. Klock, *An International Agreement on Pandemic Prevention and Response*, 326 J. AM. MED. ASS'N. 1257, 1257 (2021), https://jamanetwork.com/journals/jama/fullarticle/2784418 (citing Press Release, World Health Organization, Global Leaders Unite in Urgent Call for International Pandemic Treaty, (Mar. 20, 2021), https://www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-international-pandemic-treaty).

severe reactions.[3] For all common vaccines, these events are rare.[4] Yet the injuries resulting from serious adverse events following immunization (SAEFI) can be complex and, in some cases, require lifelong care.[5] COVID-19 vaccines are no exception.[6]

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3. Joanna Sugden, *Rollout of Pfizer-BioNTech Covid-19 Vaccine Slows in U.K. Due to Allergic Reaction Monitoring*, WALL ST. J. (Dec. 14, 2020), https://www.wsj.com/articles/rollout-of-pfizer-biontech-covid-19-vaccine-slows-in-u-k-due-to-allergic-reaction-monitoring-11607967990; Press Release, United States Food and Drug Administration, FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Through Safety Review (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 [hereinafter FDA April 23, 2022 Press Release]; Kari Oakes, *PRAC Investigates Heart Inflammation Reports with Pfizer Vaccine*, REGUL. AFFS. PROS. SOC'Y: REGUL. NEWS (May 7, 2021), https://www.raps.org/news-and-articles/news-articles/2021/5/prac-investigates-heart-inflammation-reports-with.

4. For example, less than one severe adverse event occurs per ten million doses for tetanus toxoid vaccines and one to two severe adverse events per one million doses for inactivated influenza vaccines. *See* Jeanne P. Spencer, Ruth H. Trondsen Pawloski, & Stephanie Thomas, *Vaccine Adverse Events: Separating Myth from Reality*, 95 AM. FAM. PHYSICIAN 786, 786 (2017), https://www.aafp.org/pubs/afp/issues/2017/0615/p786.html.

5. *See* Michelle M. Mello, *Rationalizing Vaccine Injury Compensation*, 22 BIOETHICS 32, 39 (2008) ("In [some countries], vaccine injuries were viewed as special due to their severity, complexity, and propensity to befall children and others who would not qualify for extensive benefits under existing accident insurance 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*, 9 VACCINES 1, 10-11 (2021) ("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). As a result, to reflect the risk of this fatal adverse event, the ChAdOx1 nCoV-19 vaccination policy was revised to be recommended for 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) [20,21]. 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.").

6. In March 2021, after more than 25 million people received at least one dose of AstraZeneca's ChAdOx1 nCoV-19 vaccine, 20 countries paused vaccinations after reports of

Although the COVID-19 vaccines have proven to be remarkably safe, one mechanism to shore up support for immunization in light of these rare side effects has consisted of providing financial support to people who suffered rare adverse reactions to the vaccine. This has led to the introduction of new schemes, or the expansion of existing schemes, that provide no-fault compensation to those who have suffered vaccination injuries.[7] The number of vaccine injury compensation schemes has nearly doubled since COVID-19 arrived, making it timely to engage in a comparative assessment of the current global landscape of vaccine injury compensation schemes.[8]

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patients experiencing clotting disorders and rare types of strokes. The European Medicines Agency (EMA) safety committee undertook a review of 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis, 18 of which were fatal. *See* Kai Kupferschmidt & Gretchen Vogel, *European Countries Resume Use of AstraZeneca's COVID-19 Vaccine, Hoping Pause Has Not Dented Confidence*, 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."). On April 7, 2021, the EMA concluded that unusual blood clots with low blood platelets should be listed as a very rare side effect. *See AstraZeneca's COVID-19 Vaccine: EMA Finds Possible Link to Very Rare Cases of Unusual Blood Clots With Low Blood Platelets*, EUR. MEDS. AGENCY (April 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. As of this writing, the risk of death from thrombocytopenia syndrome (TTS) following immunization with AstraZeneca's Vaxzevria vaccine was approximately 1 one in 1 one million. *See AstraZeneca Vaccine: Risk of Death is 1 in a Million, But What Does That Mean?*, AUSTL. ACAD. OF SCI. (Aug. 24, 2021), https://www.science.org.au/curious/people-medicine/astrazeneca-vaccine-risk-death-1-million-what-does-mean. In the U.S., administration of Janssen's, 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. *See* FDA April 23, 2022 Press Release, *supra* note 3. On May 5, 2022, the U.S. Food and Drug Administration limited approval of the vaccine in the U.S. to individuals eighteen and older for whom the other authorized or approved vaccines were not accessible or clinically appropriate or to those who chose to receive it because they would otherwise not receive a vaccine. *See* Press Release, United States Food and Drug Administration, 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 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.").

7. *See* Sam F. Halabi & Saad B. Omer, *A Global Vaccine Injury Compensation System*, 317 J. AM. MED. ASS'N. 471, 471 (2017).

8. *See id.*

The policy responses to redressing serious adverse reactions caused by vaccines are many and varied. Scholars have identified three broad options for responding to the need for support of those who have been subject to vaccine injury.[9] The first is a minimalist approach that entails injured persons bearing the costs associated with their injuries with assistance provided solely by means of standard social welfare and health benefits provided by the state.[10] Second, compensation may be sought through legal proceedings brought against those responsible for producing, or in certain cases distributing, the vaccines in question.[11] The legal entitlements vary considerably between jurisdictions, as claims may be subject either to the ordinary civil liability rules, or alternatively to more specific rules relating either to products in general, or in certain cases to medicinal products specifically. It is fair to say, however, that such claims in the midst of a pandemic would have to surmount substantial legal obstacles. Third, compensation may be sought from a dedicated compensation scheme outside the normal litigation system, generally premised upon no-fault liability. The discussion in this Article focuses on the latter schemes, which are generally government-created and specifically respond to vaccine injuries. The advantages of such a mechanism over the other options, which entail either patients bearing the costs themselves or seeking compensation though litigation against private sector, have been widely discussed, and we will also examine the broader rationales below.[12]

First, this Article gives an overview of the historical evolution leading to the current approach to vaccine damage compensation schemes. Next, the Article explores the different underlying rationales and justifications for taking the issue of vaccine side effects outside the traditional court system and establishing dedicated schemes. Then, the Article identifies and discusses a series of transversal themes, including the eligibility criteria for benefitting from such programs, the issues of causation and quantum, funding of the schemes, process and administration issues, as well as the relationship with litigation before the courts. Finally, from a normative perspective, the Article sets out a series of transversal principles applicable to such schemes, drawing upon the comparative and historical research undertaken in the earlier sections.

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9. *Id.* ("There are 3 types of approaches to addressing vaccine injury . . . ").

10. *Id.*

11. *Id.*

12. *See also id. See* Duncan Fairgrieve et al., *Products in a Pandemic: Liability for Medical Products and the Fight Against COVID-19*, 11 EUR. J. RISK REGUL. 565, 598 (2020).

II. OVERVIEW OF VACCINE INJURY COMPENSATION SCHEMES

Vaccine injury compensation schemes are becoming a more common part of the remedial landscape in many countries. The development of the COVID-19 vaccines has accelerated that process with a number of new schemes accompanying the rollout of COVID-19 vaccination programs, such as the recently created Canadian and Australian schemes.[13] The number of such schemes has increased over time. In 2011, only nineteen vaccine injury compensation schemes existed;[14] in 2018 that had increased to twenty-five,[15] and more recently in 2021, scholars identified eighteen additional programs having been created by 2021,[16] amounting to an increase of more than fifty percent since the appearance of COVID-19.

A brief historical background on no-fault vaccine injury compensation schemes may provide useful context before examining these schemes in detail.[17] The initial schemes, which developed from the 1960s onwards, have their intellectual roots in the interwar period. In the German Weimar Republic, fierce debates about compulsory smallpox vaccination resulted in an influential official committee recommending compensation for adverse effects (*Entschädigungspflicht*).[18] However, in view of ongoing uncertainty about how to define and diagnose a "true" adverse effect, no legally binding scheme was implemented. Subsequently, administrative bodies in Nazi Germany sought to boost acceptance for vaccination by calling on authorities to facilitate equitable compensation payments (*Billigkeitszuwendungen*) for victims while

13. For the pan-Canadian scheme, *see Vaccine Injury Support Program (VISP)*, PUB. HEALTH AGENCY CAN., vaccineinjurysupport.ca/en (last visited July 5, 2022); for the Australian scheme, *see COVID-19 Vaccine Claims Scheme*, SERVS. AUSTL., www.servicesaustralia.gov.au/covid-19-vaccine-claims-scheme (last visited July 5, 2022).

14. Clare Looker & Heath Kelly, *No-Fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes*, 15 BULL. WORLD HEALTH ORG. 371, 371 (2011).

15. Randy Mungwira et al., *Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, 15 PUB. LIBR. SCI.: PLOS ONE 1, 4 (2020).

16. Sam Halabi et al., *No-Fault Vaccine Injury Compensation Systems Adopted Pursuant to COVID-19 Public Health Emergency Response*, 37 EMORY INT'L L. REV. 55 ("The number of countries implementing no-fault compensation programmes for vaccine injuries over the course of the COVID-19 pandemic increased from 25 in 2018 to 43 in 2021.").

17. *See* Looker & Kelly, *supra* note 14, at 371-72.

18. For a discussion of the Resolution of the Prussian State Health Council in 1925, s*ee* Malte Thießen, *Security, Society, and the State: Vaccination Campaigns in 19th and 20th Century Germany*, 46 HIST. SOC'Y RSCH. 211, 233 (2021).

courts continued to deny claims.[19] After the Second World War, communist East Germany facilitated its initially voluntary, and later compulsory, mass vaccination campaigns by accepting, and then formally regulating, compensation claims of victims of adverse effects from 1949 onwards.[20]

In West Germany, the Federal Supreme Court confirmed in 1952 that the compulsory smallpox vaccination, introduced in 1874, was compatible with the fundamental rights protections in the post-war Basic Law of 1949.[21] In 1953, the Court held that persons injured by compulsory vaccination were entitled to compensation.[22] In this decision, the Court drew on customary law that recognized compensation claims for sacrifices made in support of the common good (*Aufopferungsanspruch*), which can be traced back to the Prussian General State Law Code of 1794.[23] The ruling caused a flood of litigation aimed at obtaining compensation for adverse effects. By 1954, this led to calls for strict control of compensation payments by Germany's federal health office (*Bundesgesundheitsamt)*, which feared a resulting loss of public trust in vaccines and renewed attempts to define criteria for legitimate claims.[24] After some states such as North Rhine Westphalia began to recognize claims on the basis of a likelihood of a vaccine injury from 1953 onwards, West Germany's 1962 Federal Law on Infectious Diseases (*Bundesseuchengesetz*) introduced a statutory compensation scheme for injuries arising from compulsory or officially recommended vaccinations.[25] In 1971, this Act was amended to include more detailed

19. MALTE THIEßEN, IMMUNISIERTE GESELLSCHAFT: IMPFEN IN DEUTSCHLAND IM 19. UND 20. JAHRHUNDERT [IMMUNIZED SOCIETY: VACCINATION IN GERMANY IN THE 19TH AND 20TH CENTURIES] 81, 148, 157 (2017).

20. *See* Christiane Meyer et al., *Anerkannte Impfschäden in der Bundesrepublik Deutschland 1990-1999*, [*Recognized Vaccine Damage in the Federal Republic of Germany 1990-1999*] 45 BUNDESGESUNDHEITSBLATT 364, 365 (2002) [hereinafter Meyer et al.]; Malte Thießen, *Vorsorge als Ordnung des Sozialen: Impfen in der Bundesrepublik und der DDR*, [*Prevention as a Social Order: Vaccination in the Federal Republic and the GDR*] 10 STUD. CONTEMP. HIST. 409, 416 (2013).

21. Bundesgerichtshof [BGH] [Federal Court of Justice] Jan. 5, 1952, 4 Entscheidungen Des Bundesgerichtshofes in Strafsachen [BGHST] 375, 375 (Ger.).

22. Bundesgerichtshof [BGH] [Federal Court of Justice] Feb. 19, 1953, 9 Entscheidungen Des Bundesgerichtshofes in Strafsachen [BGHZ] 83, 83 (Ger.); Thießen, *supra* note 18, at 230-31.

23. Comment, *Sovereign Responsibility and the Doctrine of Sacrifice (Aufopferungsanspruch*), 24 UNIV. CHI. L. REV. 513, 516 (1957).

24. Thießen, *supra* note 18, at 230-32.

25. *See* Gesetz zur Verhütung und Bekämpfung übertragbarer Krankheiten beim Menschen (Bundes-Seuchengesetz), [Law on the Prevention and Control of Communicable Diseases in Humans (Federal Disease Law)], July 18, 1961, BGBL I at 1012-1029 (Ger.).

provisions on the assessment of compensation and to allow claims based on likelihood of causality (including medical uncertainty about likelihood) rather than strict proof.[26]

Other European countries were also developing schemes of their own. In 1964, France legislated in favor of a compensation scheme that complemented compulsory childhood vaccinations.[27] This was inspired by the aforementioned German legislation,[28] and also influenced by the developing theories of no-fault liability in French administrative law developed by the *Conseil d'Etat.*[29] This jurisprudence echoed the German *Aufopferungsanspruch*¸ as discussed below.[30] The original French scheme has now been subsumed within a broader no-fault medical accident scheme administered by the *Office National d'Indemnisation des Accidents Médicaux, des Affections Iatrogènes et des Infections Nosocomiales* (ONIAM).[31]

During the 1970s, vaccine compensation schemes developed in other countries due to growing concerns of side effects arising from the Diphtheria-Tetanus-Pertussis (DTP) vaccination. Programs were created in Scandinavia as well as Japan, New Zealand, and the United Kingdom (UK). In the UK, the Vaccine Damage Payments Scheme was introduced in response to campaigns by victim advocacy groups including the

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26. Zweites Gesetz zur Änderung des Bundes-Seuchengestzes [Second Act to Amend the Federal Disease Act], 25 BUNDESGESETZBLATT 1401, 1401 (1971); Entwurf eines Zweiten Gesetzes zur Änderung des Bundes-Seuchengesetzes [Draft of a Second Law to Amend the Federal Disease Law], VI/2176 BUNDESTAGS-DRUCKSACHE 2, 15 (1971). *See* Thießen, *supra* note 18, at 232-33 (noting that compulsory vaccinations were effectively abandoned in the mid-1960s). Between 1976 and 1990, West German pension offices (*Versorgungsämter*), which administer the claims process, recognized 1,139 (24.93%) of 4,569 claims with the vast majority of claims made in relation to smallpox vaccinations, which ended in 1982. In reunified Germany, the success rate of claims fell to 389 (15%) of 2,543 claims between 1991 and 199). *See* Meyer et al., *supra* note 20, at 365.

27. *See* Loi 64-643 du 1 juillet 1964 relative à la vaccination anti-poliomyélitique obligatoire [Law 64-643 of July 1, 1964 on mandatory polio vaccination], JOURNAL OFFICIEL DE LA REPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], July 2, 1964, p. 5762.

28. *See* Travaux Préparatoires de l'Assemblée Nationale, Rapport de M. Mainguy au nom de la commission des affaires culturelles [Preparatory Works of the National Assembly, Report by M. Mainguy on behalf of the Committee on Cultural Affairs] at 322-23.

29. *See generally* DUNCAN FAIRGRIEVE, STATE LIABILITY IN TORT: A COMPARATIVE LAW STUDY 136-64 (2003) (discussing no-fault liability in French and English law).

30. *See infra* Part III.

31. *See* SIMON TAYLOR, MEDICAL ACCIDENT LIABILITY AND REDRESS IN ENGLISH AND FRENCH LAW 54 (2015).

Association of Parents of Vaccine Damaged Children,[32] originally created as an interim scheme until the Pearson Committee's recommendations were implemented.[33] The temporary became permanent, and the scheme is still in force today.[34] Public opinion also played a major part in the creation of the Japanese no-fault compensation program in 1970, when severe adverse reactions occurring after smallpox vaccinations led the government to enact a temporary compensation system.[35] In 1976, the scheme became permanent and was incorporated into the Japanese Immunization Act, with this scheme first aimed at providing a no-fault compensation for routine vaccinations, such as those for diphtheria, pertussis, polio, and measles, but later extended to adverse events resulting from "temporary" vaccinations, like those for H1N1 during its epidemic outbreak.[36] Due to the severe age eligibility conditions of the Immunization Act,[37] the scheme coexists with a more general health

32. *See* THE PEARSON COMMISSION, ROYAL COMMISSION ON CIVIL LIABILITY AND COMPENSATION FOR PERSONAL INJURY, REPORT, 1978, Cm. 7054-I, at 292-99 (UK) [hereinafter THE PEARSON COMMISSION].

33. *See* CAROL HARLOW, COMPENSATION AND GOVERNMENT TORTS, 149-51 (1982); Gareth Millward, *A Disability Act? The Vaccine Damage Payments Act 1979 and the British Government's Response to the Pertussis Vaccine Scare*, 30 SOC. HIST. MED. 429, 429-47 (2016). *See also Secretary of State for Work and Pensions v. FG on behalf of John (A Minor)* [2017] EWCA (Civ) 61 [20] (discussing the Vaccine Damage Payments Act of 1979 and upholding the First-tier Tribunal's ruling that John was entitled to compensation under the Act).

34. *See generally* Vaccine Damage Payments Act 1979, c. 17 (UK) (establishing the United Kingdom's vaccine injury compensation scheme); Richard Goldberg, *Vaccine Damage Schemes in the US and UK Reappraised: Making Them Fit For Purpose in the Light of COVID-19*, 42 LEGAL STUDIES 576, 588-96 (2022) (discussing the Vaccine Damage Payments Act's application to COVID-19 vaccine injuries).

35. *See* Mikio Kimura & Harumi Kuno-Sakai, *Immunization System in Japan: Its History and Present Situation*, 30 ACTA PAEDIATRICA JAPONICA 109, 109 (1988).

36. *See* Tetsuo Nakayama, *Vaccine Chronicle in Japan*, 19 JOURNAL OF INFECTION AND CHEMOTHERAPY 787, 787-89 (2013).

37. *See id.* at 789 (noting that as the Japanese vaccination scheme developed, "the vaccination schedule became much tighter than that in the 1990s"). This age gap was highly criticized after HPV vaccination adverse reactions. *See* Koichiro Yuji & Haruka Nakada, *Compensation Programs After Withdrawal of the Recommendation for HPV Vaccine in Japan*, 12 HUMAN VACCINES & IMMUNOTHERAPEUTICS 1321, 1321 (2016) (noting that "in April 2013, the HPV vaccination was added by the Japanese Ministry of Health, Labour, and Welfare (MHLW) to the National Immunization Program (NIP) schedule for Japanese girls aged 12-16" and "[a]pproximately 3.38 million girls between 6th grade and the first year of high school have been vaccinated. Of these, 2,584 (0.08%) have complained of health problems, and according to the MHLW, 186 (0.005%) have not recovered.").

compensation system administered by the Japanese Pharmaceutical and Medical Device agency.[38]

Whilst the initial vaccine compensation schemes were concentrated in high-income countries, it is to be noted that the number of schemes in lower income countries has increased markedly in recent times, including Vietnam and Nepal among them.[39] Although vaccine injury schemes all have the provision of compensation to those affected by adverse effects consequent upon vaccination in common, they are, on closer review, quite varied, with diverse institutional designs.

The architecture and approach of such schemes differ in many ways. First, some of these schemes are solely designed as "top up" schemes in the sense that they are simply adjuncts to other benefits or awards granted by the state. This is often the case in countries with highly developed social welfare and health systems, such as the Nordic countries, where there has traditionally been generous social security, unemployment, and medical provision. In such circumstances, the vaccine injury payments scheme functions as a supplementary measure to an already very well-resourced benefits system. This evidently impacts on levels of quantum and ultimately the costs of running the system.[40]

Second, an alternative approach integrates the vaccine programs into broader no-fault schemes. Other areas in which statutory no-fault compensation schemes are present include the products-related spheres of asbestos and contaminated blood, as well as the broader areas of criminal victims' injury, motor accidents, and medical accidents. One marked tendency is for no-fault schemes established in the medical or pharmaceutical sphere to include vaccine injury compensation. In France, the vaccine injury scheme has, as previously discussed, been integrated into the broader fund run by the ONIAM, which also covers medical

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38. *See* Tomohiro Katura et al., *Comparison of Immunization Systems in Japan and the United States—What Can Be Learned?*, 38 VACCINE 7401, 7405 (2020) (noting that the Japanese Pharmaceuticals and Medical Device agency compensates claimants with claims arising from vaccines that are not included in the National Immunization Program).

39. *See* Mungwira et al., *supra* note 15, at 4-5 ("The number of countries implementing no-fault compensation programmes for vaccine injuries has increased steadily from 19 in 2010 to 25 in 2018. As compared to previous decades there is, however, no acceleration in the number of countries. In recent years and for the first time, a low and a lower-middle-income country, Nepal and Viet Nam respectively, have instituted such programmes.").

40. As one report has noted, with respect to Nordic schemes, this "wider contextual assistance helps to keep the costs of compensation from the scheme at modest levels." Martin Keane et al., *Vaccine Injury Redress Programmes: An Evidence Review*, HEALTH RESEARCH BOARD 8 (2019), https://www.hrb.ie/fileadmin/2._Plugin_related_files/Publications/2019_Publication_files/2019_HIE/Evidence_Centre/Vaccine_injury_redress_programmes._Final_report.pdf [hereinafter HEALTH RESEARCH BOARD].

accidents.[41] A similar development has occurred in Japan,[42] and likewise the Nordic schemes are part of a broader set of no-fault medical schemes.[43] This is also the case of New Zealand, where the Accident Compensation Corporation operates a universal no-fault personal injury compensation scheme.[44]

A third approach is to create dedicated compensation schemes for vaccine injury as stand-alone regimes. Examples of vaccine-specific schemes are the National Swine Flu Vaccination scheme in the United States or, relating to COVID-19, the COVAX No-Fault Compensation Program that covers ninety-two low and middle income countries and economies, the so-called "AMC Eligible Economies."[45] However, they are more often general schemes covering a number of different vaccines for a number of different pathologies, as is the case with the UK's scheme,[46] or the French scheme before it was integrated into a broader no-fault medical accidents scheme.[47]

Fourth, and set against the previous examples, is a very different compensation model that responds to the pre-existing litigation landscape. The prime example of this is the U.S. National Vaccine Injury Compensation Program scheme,[48] which is highly complex. It may seem counterintuitive to design a non-litigious scheme in a way that requires that claimants have a "high level of legal representation . . . in order to navigate the scheme."[49] However, the importance of the litigation model

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41. *See* SIMON TAYLOR, MEDICAL ACCIDENT LIABILITY AND REDRESS IN ENGLISH AND FRENCH LAW 54 (2015).

42. *See* Sonia Macleod & Christopher Hodges, *The Japanese Pharmaceutical Injury Scheme*, *in* REDRESS SCHEMES FOR PERSONAL INJURIES 405-17 (2017).

43. *See* Matti Urho, *Compensation for Drug-Related Injuries*, 26 EUR. REV. PRIV. L. 467, 486 (2018).

44. For details of the New Zealand scheme, *see What We Cover*, ACCIDENT COMPENSATION CORPORATION, https://www.acc.co.nz/im-injured/what-we-cover/ (last visited Nov. 22, 2022); Kim Watts & Martina Poppa, *Injecting Fairness into COVID-19 Vaccine Injury Compensation: No-Fault Solutions*, 12 J. EUR. TORT L. 1, 20-21 (2021); Kim Watts, *New Zealand*, *in* COMPENSATION FUNDS IN COMPARATIVE PERSPECTIVE 89 (Thierry Vansweevelt & Britt Weyts eds., 1st ed. 2020).

45. *See generally* COVAX AMC, https://covaxclaims.com/fr/ (last visited Nov. 22, 2022). AMC stands for advance market commitment. The AMC Eligible Economies are those eligible to have their participation in the COVAX Facility supported by the COVAX AMC.

46. *See* Vaccine Damage Payments Act 1979, *supra* note 34; *see also Vaccine Damage Payment*, www.gov.uk/vaccine-damage-payment (last visited Nov. 22, 2022).

47. *See* TAYLOR, *supra* note 41, at 58-59.

48. For details of the U.S. scheme, *see National Vaccine Injury Compensation Program*, HEALTH RESOURCES & SERVICES ADMINISTRATION, www.hrsa.gov/vaccine-compen sation (last visited Nov. 22, 2022).

49. HEALTH RESEARCH BOARD, *supra* note 40, at 118.

in the United States as well as the U.S. tradition of adversarial administrative justice help explain this specific approach to vaccine compensation.

Fifth, there are a series of miscellaneous schemes that in some sense have been created by historical accident. The classic example of this is the UK Vaccine Damage Payment Scheme, which, as has been discussed, was set up only as a temporary scheme. Indeed, payments under the scheme, officially known as a Vaccine Damage Payment, are not regarded officially as compensation, and are therefore not a bar to any civil proceedings for compensation.[50] However, where civil proceedings are successful, a prior Vaccine Damage Payment is considered as a payment on account and will thus reduce the damages received by the claimant.[51] An award can also affect other social security benefits such as universal credit and income support.[52]

A final model is an international scheme that applies to several countries. This was mooted by Halabi and Omer in 2017,[53] pointing to administrative and other advantages that such an international system would present. Precedents of mass compensation funds at an international level unrelated to vaccine injuries include the United Nations Compensation Commission to provide reparations for losses and damage suffered as a direct result of Iraq's unlawful invasion and occupation of Kuwait in 1990-1991 and the Trust Fund for Victims accompanying the establishment of the International Criminal Court.[54] The most prominent

50. *See* Vaccine Damage Payments Act 1979, *supra* note 34, § 6(4).

51. *See id.*

52. *See Vaccine Damage Payment*, *supra* note 46.

53. *See* Halabi & Omer, *supra* note 7, at 471 ("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.").

54. *See* Sam Halabi, Andrew Heinrich & Saad Omer, *No-Fault Compensation for Vaccine Injury–The Other Side of Equitable Access to Covid-19 Vaccines*, 383 NEW ENG. J. MED. e125(1), e125(2)-e125(3) (2020) ("Compensation funds have served large groups of people, including in low- and middle-income countries. After the Iraqi invasion of Kuwait, the United Nations created the United Nations Compensation Commission in 1991. The commission evaluated nearly 2.7 million claims and issued 1.5 million awards with an aggregate value of more

international vaccine compensation scheme is now the COVAX No-Fault Compensation Program, launched in 2021, which provides no-fault compensation to eligible individuals in the AMC Eligible Economies.[55] COVAX is a worldwide initiative aimed at equitable access to COVID-19 vaccines, co-led by the Vaccine Alliance Gavi, the Coalition for Epidemic Preparedness Innovations and the World Health Organization.[56] The scheme is temporary[57] and provides lump sum benefits in full and final settlements to those who suffer a permanent impairment or death associated with a COVID-19 vaccine, or the administration of a COVID-19 vaccine, which is procured or distributed through COVAX.[58]

III. THE RATIONALES OF THE VACCINE COMPENSATION SCHEMES

Like other medicines, vaccines are subject to detailed and complex regulation designed to ensure the highest standards of product safety. Vaccines are, however, in some ways, quite specific types of medicinal products given that they are not taken to address an underlying current pathology or pre-existing condition but generally as a purely preventive measure. In other words, vaccines are generally taken to address a risk of

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than US $50 billion and was an early and lauded model for accurate and efficient mass-claims processing. The Trust Fund for Victims is another applicable model. This fund was created to provide support to victims of crimes perpetrated by people convicted in the International Criminal Court. It has routinely made payments to more than 100,000 people per year, including those in rural regions of the Democratic Republic of Congo, Uganda, and the Central African Republic. According to external evaluations, the fund makes such payments "in an effective and efficient way." These compensation systems demonstrate that it would be possible to create a global, centralized compensation commission for injuries related to COVID-19 vaccines.").

55. *See* GLOBAL ALLIANCE FOR VACCINES AND IMMUNIZATION, THE LIST OF AMC-ELIGIBLE ECONOMIES 4 (2021), https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_12-05-21.pdf.

56. *See* Seth Berkley, *COVAX Explained*, GLOBAL ALLIANCE FOR VACCINES AND IMMUNIZATION (Sept. 3, 2020), https://www.gavi.org/vaccineswork/covax-explained ("Coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, COVAX . . . will support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, and negotiate their pricing. All participating countries, regardless of income levels, will have equal access to these vaccines once they are developed.").

57. The scheme was initially limited to vaccines earmarked for distribution until June 30, 2022, but this has been extended to June 30, 2023.

58. *See COVAX No-Fault Compensation Program*, WORLD HEALTH ORG., https://www.who.int/initiatives/act-accelerator/covax/no-fault-compensation (last visited Nov. 22, 2022) (noting that the COVAX program "provides fair, no-fault, lump sum compensation to eligible individuals who suffer certain serious adverse events after receiving a COVID-19 vaccine distributed through the COVAX Facility . . . .").

exposure to an infectious disease in the future,[59] as well as to contribute to protecting society more broadly. This impacts upon the legal framework applicable to such products and most notably the regime applicable in case of vaccine injury. In this Part, the public policy and ethical reasoning underpinning such schemes are examined.

One of the primary rationales in favor of compensation for vaccine injury is relatively simple and has deep historic roots. As governments and public health authorities encourage, and in some circumstances even require, citizens to be vaccinated, if persons are injured by such vaccines, compensation should be provided or facilitated by the state. This is especially so as immunity protection against infectious diseases benefits in many cases not only the person vaccinated, but also serves the community's objective of achieving herd immunity. Indeed, the idea that a person who suffers disproportionate detriment if they agree to make a sacrifice for the wellbeing of the community should receive support from that community underlies the early vaccinations schemes in Germany and France, as described above.[60] The same position was also adopted by the Pearson Commission on personal injury reform established in the UK in the 1970s, which examined the arguments in favor of compensation for damage caused by vaccination and concluded that "there is a special case for paying compensation for vaccine damage where vaccination is recommended by a public authority and is undertaken to protect the community."[61]

A vaccine provides a dual benefit: both a direct benefit to the person receiving it in terms of personal immunization and an indirect benefit to other members of the community through each individual's contribution to wider immunity. Depending on the pathogen and vaccine efficacy,[62] the degree of immune protection at a societal level can translate into reduced social costs, such as fewer admissions to publicly supported medical facilities and unimpeded ability to work. An additional indirect benefit can also arise from reducing transmissions if a vaccinated individual is less infectious. Some vaccine programs can also contribute to herd immunity by reducing the risk of transmission to vulnerable

59. It is, however, noted that there are therapeutic vaccines and immunization outside infectious diseases, as in the case of the vaccine against tetanus.

60. For discussion of the French scheme, *see generally* TAYLOR, *supra* note 41; for discussion of the German scheme, *see generally* Thießen, *supra* note 18.

61. THE PEARSON COMMISSION, *supra* note 32, ¶ 1398; *see also* Kumanan Wilson & Jennifer Keelan, *The Case for a Vaccine Injury Compensation Program for Canada*, 103 CAN. J. PUB. HEALTH 122, 122 (2012), https://pubmed.ncbi.nlm.nih.gov/22530534/.

62. As well as, of course, availability and uptake.

members of society such as children, the elderly, those who are immuno-compromised, or people who cannot be vaccinated for medical reasons. It is thus possible to identify both individual as well as altruistic reasons for being vaccinated.[63] This latter altruistic dimension of vaccination sets it apart from many other products, particularly other healthcare products, in respect of which the administration is, as we have already seen, principally an individual response to an underlying pathology.[64] Particular considerations arise with respect to rare persons who suffer vaccine damage and help to justify a preferential treatment of those persons. The societal benefit generated by vaccination militates in favor of compensating those who suffer severe adverse effects. The injured individual has paid a high price for benefits that have often accrued not only to themselves but also to the rest of the population, especially if this individual was at low risk of severe disease or long-term effects resulting from a specific pathogen.[65] It would therefore be inequitable in such circumstances to leave the individual burden where it lies and not to provide redress.[66]

This rationale also links to the notion of acceptability of risk. Whilst societal attitudes to risk are contextual and have differed greatly over time, it is possible to argue that tolerance for product risk has reduced considerably in recent years.[67] As heightened standards of product safety have been achieved over time, an increasing degree of safety has naturally generated increased expectations on the part of consumers. This is particularly the case with respect to healthcare products where much of the increased regulatory protection has been achieved as a response to product crises. In the case of vaccines, reduced tolerance for product hazards is also coupled with the wider effects of the so-called epidemiological transition of the post-war period, which saw lifestyle and

63. *See* JAMES COLGROVE, STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN 20TH CENTURY AMERICA 435 (2006).

64. Though some medicines have been used on a mass basis to curb community transmission of pathogens, for example, antimalarials and anti-TB drugs.

65. *See* Looker & Kelly, *supra* note 14, at 371 ("At a population level, it is considered that these small risks are balanced by the benefits of widespread population immunization. However this means that an individual occasionally bears a significant burden for the benefit provided to the rest of the population. Although these vaccine-related adverse events occur occasionally due to negligence, more often there is no clearly attributable fault.").

66. *See generally* Britta Lundgren, *Solidarity at the Needle Point—The Intersection of Compassion and Containment During the A(H1N1) Pandemic in Sweden 2009*, 4 SOCIOLOGY AND ANTHROPOLOGY 1108 (2016) (discussing the role that solidarity and collectivism played in the Swedish response to the A(H1N1) pandemic).

67. *See generally* ULRICH BECK, RISK SOCIETY: TOWARDS A NEW MODERNITY (1992) (discussing changing social attitudes towards risk).

chronic diseases replace infectious disease as primary health risks in wealthier societies.[68] Fading memories of, and reduced risk from, infectious diseases naturally resulted in reduced tolerance for risks resulting from products designed to prevent these diseases.[69] In light of reduced overall tolerance for product failure and reduced infectious disease risks in many nations, the general public might as a consequence be thought less prepared to accept vaccine-related risks given that the biomedical intervention is not being administered therapeutically but rather preventatively.

Compensation for vaccine damage has thus been justified by reference to solidarity principles, according to which it would be inequitable to leave loss where it falls. Instead, all members of a community should share in offsetting the consequences of that risk when activities are undertaken for the benefit of society generally.[70] Evidence of such considerations may be found during the establishment of vaccine schemes. In the UK, during the parliamentary process leading to the enactment of the Vaccine Damage Act 1979, a Minister explained the basis of that scheme in terms reminiscent of solidarity principles as "the community as a whole has sought to share a responsibility for the hardship that has fallen upon [the victims]."[71] This is also reminiscent of the French *égalité devant les charges publiques*, which is said to underpin no-fault State liability in French law and which entails that compensation should be provided for those that have shouldered a disproportionately large burden or loss caused by activities pursued in the common good.[72] German law also encapsulates similar notions within the doctrine of *Aufopferungsanspruch*, according to which compensation is granted for sacrifices made by individuals in support of the common good.[73] This notion, deriving from Prussian-era rules ensuring compensation for

68. *See* Abdel R. Omran, *The Epidemiologic Transition: A Theory of the Epidemiology of Population Change*, 83 MILBANK Q. 731, 736-41 (2005).

69. This is evidenced by the OPV switch in respect of polio vaccines whereby certain types of oral polio vaccines (OPV) were phased out in favor of an inactivated polio vaccine (IPV). *See* WORLD HEALTH ORG. EUR., *Withdrawl of Trivalent Oral Polio Vaccine in the European Region (OPV Switch)*, (Apr. 5, 2019), https://www.who.int/europe/news-room/fact-sheets/item/withdrawal-of-trivalent-oral-polio-vaccine-in-the-european-region-(opv-switch) (last visited July 5, 2022).

70. *See* COLGROVE, *supra* note 63, at 444.

71. HARLOW, *supra* note 33, at 149.

72. *See generally* PIERRE DELVOLVÉ, LE PRINCIPE D'EGALITÉ DEVANT LES CHARGES PUBLIQUES 2-5 (1969); FAIRGRIEVE, *supra* note 29.

73. *See* Comment, *Sovereign Responsibility and the Doctrine of Sacrifice (Aufopferungsanspruch*), 24 UNIV. CHI. L. REV. 513, 516 (1957).

expropriation (due to the personal sacrifice of property interest in favor of community benefit),[74] was applied by the *Bundesgerichtshof* in 1953 as a basis for providing compensation for persons injured by compulsory smallpox vaccination.[75] This decision gave impetus to the creation of the vaccine compensation scheme in Germany, which, as previously mentioned, was the first such program worldwide.

Placing principles of solidarity and equality before principles of public burdens is also seen sometimes as reflecting broader notions of fairness.[76] Mello has argued that solidarity and fairness combine as underlying rationales: 'Fairness and solidarity both militate in favor of a safety net for those whose sacrifice is especially large.'[77] Mello also notes that whilst an appeal to solidarity might run counter to some traditional values of U.S. society, it might be specifically applicable to the situation of health emergencies. The excerpt is worth quoting in full:

> The notion of solidarity is out of step with strongly held American values such as self-reliance, voluntary assumption of risk, and individual decision-making about whether and how much insurance to buy. The principle seems to find greater traction during emergencies, however, and in other circumstances in which the risk in question is neither voluntarily encountered nor easily insured against. Solidarity could perhaps be used to justify compensation of severe effects of vaccines during public health emergencies, but it is a fragile buttress for a more general policy of compensation of vaccine injuries in the US.[78]

The solidarity principle can also be seen as underpinning the reaction to the COVID-19 public health crisis more broadly, with states having attempted to mitigate the economic effects of the pandemic by providing support to businesses and the general public or increasing the portions of their budgets allocated to health and social care provision. Within such a context of exceptional public sector support, it is arguably equally important to ensure that those individuals directly affected by the publicly organized public health initiative of mass emergency vaccination receive financial redress in respect of rare harms thereby sustained.

It is possible also to identify utilitarian justifications for the provision of vaccine injury compensation. Amongst these is the need to promote the

74. *See id.*
75. *See* BGHZ 9, *supra* note 22, ¶ 9.
76. *See also* Halabi & Omer, *supra* note 7, at 471.
77. Mello, *supra* note 5, at 40.
78. *Id.*

acceptability of vaccines, particularly at a time of international emergency due to the pandemic. It has been argued that the provision of compensation if an adverse event occurs is a necessary part of ensuring vaccine acceptability and encouraging vaccine take-up. From a historical perspective, Mello has noted that the offering of compensation for smallpox-vaccine-related injuries in the United States was "to encourage first responders to submit to voluntary vaccination."[79] Similar arguments have also been made in modern times in the context of the COVID-19 crisis.[80] Empirical evidence to support such an approach is, however, still lacking, and some commentators have thus opined that there is insufficient evidence that vaccine compensation programs either improve or decrease vaccine confidence.[81] Despite this uncertain empirical position, the availability of vaccine compensation signals that the state itself trusts the safety of the products that it is encouraging the public to take. As Millward has shown in an analysis of the history of the Vaccine Damage Compensation Act scheme in the UK, this was a key factor in the creation of that scheme. The UK Government at the time believed that the creation of such a scheme "would allay the fears of parents by showing that if something went wrong the state would protect them. It was also seen as a sign of strength and confidence."[82]

Another utilitarian justification is linked to the need to encourage or protect vaccine development. After earlier debates during the 1960s and 1970s had stalled, the 1986 National Childhood Vaccine Injury Act in the United States was passed both in response to public pressure from vaccine safety activists concerned about the DTP vaccine and growing government immunization mandates and industry concerns about allegedly spiraling claims as well as the fear that large damages awards were driving vaccine manufacturers out of the market. Litigation risks are seen to be particularly problematic in pandemics. Although one has to be careful about reifying arguments made by interested actors, authors such as Mello note that "[c]ompanies may be especially reluctant to produce new vaccines against a threatening pandemic because time pressure may mean less opportunity to test the vaccine fully and, therefore, greater risk

79. *Id.* at 35.

80. Fairgrieve et al., *In Favour of a Bespoke COVID-19 Vaccines Compensation Scheme*, 21(4) LANCET INFECTIOUS DISEASES 448, 449 (2021) ("Guaranteeing that recipients of COVID-19 vaccines are automatically eligible to compensation, that covers not only healthcare costs but also loss of livelihoods, will help maintain public vaccine acceptance.").

81. Wilson & Keelan, *supra* note 61, at 124.

82. Millward, *supra* note 33, at 441.

of injury."[83] Vaccine manufacturers have made use of concerns about such risks to good effect in their procurement contract negotiations, obtaining extensive indemnities, in effect transferring litigation risks primarily back to the public sector. Extensive indemnities were provided during the H1N1 pandemic in 2009, which attracted criticism from many quarters and gave rise to a highly critical Council of Europe report.[84] This was accompanied by a strongly-worded Resolution of the Parliamentary Assembly of the Council of Europe that called on Member States to "ensure that the private sector does not gain undue profit from public health scares and that it is not allowed to absolve itself of liabilities with a view to privatizing profits whilst sharing the risks."[85] Similar such indemnities were obtained from UK and European authorities in the context of COVID-19 vaccines.[86]

IV. CROSS-CUTTING THEMES

Vaccine compensation schemes share the underpinning concept of facilitating the provision of compensation for vaccine injury by means of a dedicated administrative scheme. Despite this common premise, the actual specificities of the schemes across the world vary a good deal. In this Part, we identify and discuss a series of transversal themes, comparing and contrasting the differing features and operation of the schemes.

A. Eligibility

Eligibility is a complex aspect of no-fault vaccine injury compensation that determines who can receive compensation. A host of factors may be relevant. The regulatory pathway and category of vaccine similarly may affect eligibility, and relevant issues include: Is the vaccine

83. Mello, *supra* note 5, at 36.

84. *See* Eur. Parl. Ass., *La Gestion de la Pandémie H1N1: Nécessité de plus de Transparence* [*The Management of the H1N1 Pandemic: Need for More Transparency*], 26th Sess., Doc. No. 12283, (2010); *see generally* Eur. Parl. Ass., *Rapport sur l'Évaluation de la Gestion en 2009-2010 de la Grippe H1N1 en Europe* [*Report on the Evaluation of the Management in 2009-2010 of Influenza H1N1 in Europe*], Doc. No. 2153 (2011).

85. Eur. Parl. Ass., *Gestion de la Pandémie H1N1: Nécessité de Plus de Transparence* [*The Management of the H1N1 Pandemic: Need for More Transparency*], Resolution 1749 ¶ 8.6 (Jun. 24, 2010).

86. *See* Jean-Sébastien Borghetti et al., *Procurement of COVID-19 Vaccines: Why Were Legal Liabilities Transferred to the Public Sector?*, 2 INDRET 364, 365 (2021) ("At a time when public trust is in short supply, it is appropriate to question why such across-the-board legal safeguards have been accorded to healthcare producers, particularly given that substantial public funds have been expended to subsidise the research and clinical trial phase.").

authorized in an emergency with a limited body of evidence supporting its regulatory approval? Is the vaccine mandated by the state generally and required for access to schools, work, and other aspects of social inclusion? 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 regulating the state's determination of why no-fault compensation exists and for whom it is intended to benefit.[87] 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.

Eligibility for compensation is most appropriate for vaccines administered pursuant to emergency use, when regulators may take a more nuanced risk-benefit view in light of the commercial risks to manufacturers and the risk of a given pathogen's morbidity and mortality burden relative to the risk of an adverse reaction by an individual.[88] This is illustrated by the COVID-19 pandemic, where the emergency vaccine program resulted in the creation of schemes in countries that hitherto had not had one, such as Australia and Canada.[89]

Separately, when governments mandate that individuals receive vaccinations, or impose conditions such that employers and other societal actors impose vaccination requirements, the case for eligibility is quite strong.[90] Thus, compulsory vaccination, whether in routine or emergency circumstances, sufficiently deprives the individual of agency in the vaccination decision and has done so for a societal benefit, so that the individual who subjects herself to vaccination has a strong claim for eligibility.[91] Unsurprisingly, therefore, many of the first schemes, such as those in Germany and France described above, concerned compensation solely for compulsory vaccination, and this is still the case in France,

87. *See* Looker & Kelly, *supra* note 14.

88. *See* Mello, *supra* note 5, at 40.

89. For the pan-Canadian scheme, *see Vaccine Injury Support Program*, *supra* note 13; for the Australian scheme, see *COVID-19 Vaccine Claims Scheme*, *supra* note 13.

90. *See* Mello, *supra* note 5, at 36 ("It is a well-accepted principle of public health law and ethics that the government may exercise its coercive powers to restrict individual liberty in ways that are reasonably calculated to achieve public health goals. Accompanying the exercise of coercive power, however, should be measures to promote fairness to individuals who are burdened by it.").

91. THE PEARSON COMMISSION, *supra* note 32, ¶ 1398 ("We concluded that there is a special case for paying compensation for vaccine damage where vaccination is recommended by a public authority and is undertaken to protect the community."). *See also* Wilson & Keelan, *supra* note 61, at 122.

though the scheme was extended to cover (non-mandatory) H1N1 and COVID-19 emergency vaccines.[92] The Italian scheme has been extended beyond mandatory vaccination to cover now "strongly-recommended" vaccines.[93] The UK Vaccine Damage Payments scheme covers only those vaccines that are specifically added to the scheme by means of delegated legislation.[94]

For similar reasons, eligibility may be restricted to those whose access to vaccines is controlled by the government. Eligibility may be limited to those vaccines properly registered with a national regulatory authority, distributed through authorized channels, and/or administered by licensed healthcare professionals. The Canadian scheme covers all Health Canada authorized vaccines providing protection from preventable infectious disease administered in Canada after December 2020.[95] Peru's scheme requires only that the vaccine administered was procured by the country's ministry of health.[96] The case for eligibility is weaker for those who obtain vaccines through illicit channels, who receive an immunization with a vaccine that has not been properly registered, or which is administered by an unauthorized or unlicensed party.

While the case for eligibility for emergency use authorized vaccines and compulsory vaccination is persuasive, the case for eligibility when vaccines are fully approved, but not compulsory, is weaker, though still persuasive. Consider the example of an individual who wants to travel, for purely recreational reasons, to an area where yellow fever or Japanese encephalitis are endemic. The individual wishes to obtain the individual benefit of immunization, but the corresponding public health benefit is correspondingly weaker or non-existent. In these circumstances, and under the law of many countries, the individual is not eligible for vaccine injury compensation.

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92. For discussion of the French scheme, *see generally* TAYLOR, *supra* note 41 and accompanying text. For discussion on the German scheme, *see generally* Thießen, *supra* note 18.

93. *See* D'Errico et. al., *"First Do No Harm." No-Fault Compensation Program for COVID-19 Vaccines as Feasibility and Wisdom of a Policy Instrument to Mitigate Vaccine Hesitancy*, VACCINES 1, 7-11 (2021) (discussing the Italian scheme).

94. *See id.* COVID-19 was added to the diseases to which the Act applies by virtue of the Vaccine Damage Payments (Specified Disease) Order 2020. *See* Vaccine Damage Payments (Specified Disease) Order 2020, §§ 2, 3 (Eng.), https://www.legislation.gov.uk/uksi/2020/1411/article/1/made.

95. *See Vaccine Injury Support Program*, *supra* note 13, for further details.

96. Emergency Decree No. 031-2021 ("DU 031"), published in the Extraordinary Edition (Mar. 10, 2021). *See* Halabi et al., *supra* note 16.

Eligibility may be limited on the basis of the illness, disability or death of the vaccinated person. In some systems, hospitalization serves as an effective proxy for eligibility, either the need for hospitalization at all, or the need for a threshold stay, for example, fourteen days. Poland, for example, requires a fourteen-day hospital stay to qualify for a single compensation payment.[97]

International definitions, especially those issued by the World Health Organization have been influential. Generally, a serious adverse event following immunization is defined as an adverse event following immunization (AEFI) that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, or results in persistent or significant disability or incapacity or a congenital anomaly or birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious.[98] An AEFI is defined as any untoward medical occurrence following immunization that does not necessarily have a causal relationship with the usage of the vaccine.

Eligibility criteria under vaccine injury compensation schemes may exceed these or place limitations upon them. For example, a law may provide that "serious" bodily injury is an 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.[99] In the UK, applicants must show at least sixty percent disablement as a pre-condition of gaining compensation,[100] a criterion that has been subject to criticism and compares unfavorably with the Norwegian scheme, where those seeking support must show fifteen percent disability or injuries worth more than approximately (the equivalent of) US $1,000. In China, the requirement is to show death or serious injury caused by inoculation.[101] Similarly,

97. Halabi et al., *supra* note 16.

98. *Cumulative Pharmacovigilance Glossary (Version 1.1)*, THE COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES, https://cioms.ch/publications/product/cioms-cumulative-pharmacovigilance-glossary/ (last visited July 5, 2022).

99. 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, Government of Tunisia, Law No. 2021-10 (Mar. 2, 2021) (Tunis.).

100. *See Vaccine Damage Payments Act 1979*, *supra* note 34, § 1(4). This derives from the Industrial Injuries and War Pensions Schemes dating from before the Second World War. *See* Millward, *supra* note 33, at 442; FG (A Minor) v. Secretary of State for Work and Pensions [2017] EWCA (Civ) 61, ¶¶ 34-42 (discussing the threshold).

101. Regulation on the Administration of Circulation and Vaccination of Vaccines (promulgated by the State Council, effective Apr. 25, 2016), CLI.2.269113(EN) (Lawinfochina)

eligibility may depend not on pre-established criteria, but rather on experts determining eligibility without such constraints. An individual or panel of health professionals may make eligibility determinations ad hoc. Guatemala's regulations, for example, establish a Committee for the Evaluation of Serious Adverse Reactions to Vaccines made up of five national experts with extensive experience in vaccination.[102]

Just as severity of injury may delineate eligibility from non-eligibility, so may the proximity of the injury, illness, disability, or death in time or place to the vaccination. Given the difficulties with causation, explored in more detail below, evidence-based proxies, even if imperfect, may be used for eligibility. Compensation systems may specify timelines for (1) an injury to manifest; (2) a claim to be properly filed; and (3) the verification or evidence used to support the relationship between a vaccine and an injury.

Given that no-fault vaccine injury compensation represents a bargain between a state with broad interest in widespread immunization and an individual, with both individual and collective interests, the question of citizenship and eligibility goes to the heart of the role of the state. If the state is under the obligation to protect all those under its control, then citizenship should not be the touchstone inquiry for eligibility but rather the reach and control of the state. If, however, the bargain is fundamentally about the relationship between the taxpaying public with full rights and a share of those benefits when the state undertakes a particular exercise, then eligibility may rely upon a citizenship inquiry. In any case, eligibility may be divided for analytical purposes on those who are citizens, those who are not citizens but enjoy some authorized rights relative to the state administering the no-fault compensation system, and those who do not enjoy such rights but may nevertheless be included (or excluded) based on the state's rationales.

Related to citizenship and state control, geographical scope of eligibility is a relevant factor. For example, the system may limit eligibility to vaccines administered in the state territory. This is the case in Canada.[103] Such a limitation would need to be cognizant of citizens and

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at art. 46. *See* Langfang Fei & Zhou Peng, *No-Fault Compensation for Adverse Events Following Immunization: A Review of Chinese Law and Practice*, 25 MED. L. REV. 99, 104 (2017). ("Only if an inoculated person dies or becomes severely disabled, or if any of his organs or tissues is injured due to an unusual response to vaccination, shall he be paid a lump sum of compensation.").

102. Guatemalan Ministry of Public Health and Social Assistance, Ministerial Agreement 40-2021 (2021). *See* Halabi et al., *supra* note 16.

103. The Canadian Vaccine Injury Support Program covers vaccines providing protection from preventable infectious disease administered in Canada after December 2020. *See Vaccine Injury Support Program*, *supra* note 13.

non-citizens who may nevertheless have rights even though they are outside the territory at the time of immunization, such as those serving in an overseas military capacity.

Eligibility intuitively applies to the individual suffering the vaccine injury or death. But harm to that individual's health may, and often will, also affect others. If the person is a mother to young children or a primary earner for a family or village, then the circle of eligibility may expand, as may the benefits or compensation analyzed below. For example, South Africa allows for dependents or those close to the injured vaccinated persons to file claims, and such eligibility criteria are commonly found in all such schemes.[104] Related to the compulsory factor of eligibility, the status of the recipient as a child or an adult may also serve as an eligibility boundary.

B. Causation and Quantum

The issue of causation has always been a thorny one in pharmaceutical and healthcare litigation, and this is amplified within the context of vaccine injury compensation schemes given that the no-fault nature of these schemes inevitably shifts the emphasis to causation as a control factor.

Many vaccine compensation schemes adopt a preponderance of evidence/balance of probabilities approach,[105] which entails in essence that the fact-finder must consider that it is more likely than not that the ultimate injury was caused by the vaccine.[106] There have also been attempts to adopt standards of proof that are deliberately more liberal than the standard adopted by courts so as to divert claimants from civil litigation.[107] Indeed, in Sweden, this was the explicit reason for the

104. Regulations Establishing COVID-19 Vaccine Injury No-Fault Compensation Scheme, art. 93(2), established under Disaster Management Act of 2002 § 27 (S. Afr.). *See* Halabi et al., *supra* note 16.

105. This approach is sometimes phrased differently, such as "preponderant probability" under the Swedish scheme. Urho, *supra* note 43, at 483.

106. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 16 ("Most schemes adopt a 'balance of probabilities' as the standard of proof. This standard is called 'preponderance of evidence' or 'preponderance of probabilities' in other jurisdictions."). And see analysis in Mungwira et al., *supra* note 15.

107. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 8 ("In the four Nordic countries—Denmark, Finland, Norway, and Sweden—compensation for vaccine injuries is handled as part of a wider drug injury compensation scheme; the wider drug injury scheme is part of or a sister to a medical treatment scheme . . . All four schemes employ a more relaxed standard of proof based on the principle of preponderance of probability (or the principle that the medicine more likely

"preponderant probability" approach that was purposefully designed to be a lower standard of proof than in product liability cases before the courts, and which has been interpreted as meaning "slightly more than fifty percent."[108]

Evidential difficulties still remain, however, because the particular nature of vaccines often entails a degree of scientific uncertainty about potential side effects, a fortiori in the case of emergency vaccines.[109] Presumptions have therefore been applied in some jurisdictions. In the United States, a claim by a person who has suffered a vaccine-related injury following the administration of a vaccine listed in a vaccine injury table and suffered an injury covered by the Act, occurring within a specific time listed in the table,[110] is known as a "Table claim," in respect of which causation is presumed. For other injuries, known as "off-table claims," causation is no longer presumed and claimants must show by a preponderance of evidence that their injuries were "caused-in-fact" by the vaccination in question.[111] In France, a controversial line of cases involving the Hepatitis B vaccination that was alleged to have given rise to demyelinating diseases saw the Cour de Cassation accept "serious, specific and consistent circumstantial evidence point[ing] to the vaccine as the cause of the disease."[112] This method of proof of causation by way of presumptions, even if based on correlations unsupported by scientific evidence, was accepted by the CJEU as compatible with the causal requirement of the European Product Liability Directive in the *Sanofi*

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than not caused the injury) is more favorable for claimants than the rigorous causation requirements that would pertain in the courts.").

108. Christopher Hodges, *Nordic Compensation Schemes for Drug Injuries*, 29 J. CONSUMER POL'Y 143, 150 (2006).

109. *See* Lee M. Hampton et al., *General Determination of Causation Between COVID-19 Vaccines and Possible Adverse Events*, 39 VACCINE 1478, 1478 (2021) (addressing the context of the new COVID-19 vaccines).

110. Goldberg, *supra* note 34, at 5-8.

111. This can be an uphill struggle. *See id.* at 7 ("by comparison with the relaxation of the burden of proving causation for injuries which are Table claims, the burden of proof on the petitioner in an off-Table claim is a heavy one.").

112. Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., May 22, 2008, Bull. civ I, No. 05–20317 (Fr.); Cour de cassation [Cass.] [supreme court for judicial matters] 1e civ., June 25, 2009, Bull. civ I, No. 08–12781 (Fr.). *See also* RICHARD GOLDBERG, MEDICINAL PRODUCT LIABILITY AND REGULATION 128-29 (2013); Jean-Sebastien Borghetti, *Causation in Hepatitis B Vaccination Litigation in France: Breaking through Scientific Uncertainty?*, 91 CHIC. KENT L. REV. 543 (2016).

Pasteur decision,[113] though there has been much doctrinal criticism of the French case law.[114]

More radically, arguments have been made in favor of relaxing the causation requirements by means of a "benefit-of-the-doubt standard" or alternatively by means of a shift in the burden of proof.[115] The latter approach seems indeed to have been adopted in Hong Kong, where there is a notably liberal approach to causation in the vaccine compensation program, with eligibility arising where "the evaluation outcome of the Expert Committee cannot rule out that the event is not associated with the administration of a vaccine under the Government's COVID-19 Vaccination Program."[116] At the end of September 2022, 1,158 applications had been made to the Hong Kong fund, with 803 cases in which determination of causation has been completed.[117] Of these, 468 cases were concluded as "consistent with casual association with immunization" and 335 cases were concluded as "inconsistent with causal

113. Case C-621/15, N.W, L.W & C.W v. Sanofi Pasteur MSD SNC, Caisse primaire d'assurance maladie des Hauts-de-Seine & Carpimko, ECLI:EU:C:2017:484, ¶¶ 11-17 (June 21, 2017).

114. *See* critical analysis in Marco Rizzi, *A Dangerous Method: Correlations and Proof of Causation in Vaccine Related Injuries*, 9 J. EUR. TORT L. 289 (2018) ("In Sanofi, the CJEU is therefore endorsing a method of proof of causation that is far from uncontroversial in the very legal system from which it originates. The fact is that, as commentators have stressed, the broad provisions of the French Code Civil do not of themselves provide French tort law with sophisticated 'conceptual tools needed to address' the complex distinction between scientific and legal causation in litigation involving technically advanced products."). In particular, it has been argued that the CJEU in *Sanofi Pasteur* unhelpfully conflated the separate concepts of defectiveness and causation in its judgment. *See* Richard Goldberg, *Vaccine Liability in the Light of COVID-19: A Defence of Risk-Benefit*, 30 MED. L. REV. 243, 253-54 (2022); DUNCAN FAIRGRIEVE & RICHARD GOLDBERG, PRODUCT LIABILITY 740-44, ¶¶ 17.114-17.118 (3d ed., 2020).

115. *See* discussion of the debate in the U.S. in Goldberg, *supra* note 34, at 5-8 ("Others have argued that in view of the difficulties in proving causation-in fact cases, the preponderance of evidence standard should be modified to a more generous 'benefit-of-the doubt standard,' resolving close cases in favour of the petitioner. A radical approach to causation has been suggested, which is to shift the burden of proof to the government in vaccine injury proceedings to prove by a preponderance of evidence that the petitioner's injury was not caused by a vaccine.").

116. *Terms and Conditions for the Indemnity Fund for Adverse Events Following Immunization with Coronavirus Disease-2019 (COVID-19) Vaccines (AEFI Fund)*, THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION, § 1.3 (2022), https://hk-axa-web-2020.cdn.axa-contento-118412.eu/hk-axa-web-2020/1d15cea6-f0a8-49e8-ade8-8056f8f30368_20220628+AEFI+Fund+terms+and+conditions+_Eng_Final.pdf [hereinafter "AEFI Fund"].

117. *See AEFI Fund Application Overview*, THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION (2022), https://www.covidvaccine.gov.hk/pdf/AEFI_Fund_overview_ENG.pdf (conveying the results contained in the report of the Hong Kong Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation).

association with immunization" or "unclassifiable."[118] This does seem to result in a form of reversal of the burden of proof, as long as sufficient evidence has been brought forward by the claimant to overcome the "unclassifiable" hurdle.

Goldberg, however, has cautioned that adopting an overly-generous approach to causation might result in a doubting of the relevant science and thus paradoxically undermine the acceptability of vaccines.[119] Rizzi and Vicente also have raised concerns about the CJEU's decision in *Sanofi*, commenting that the reasoning of the Court engages in "tautological reasoning" that "is not only unhelpful but potentially dangerous in the context of vaccines, where individual and public health concerns are intimately intertwined."[120]

The diversity of approaches is also apparent in relation to the benefits available if an eligible injury is established, as well as the methods for determining quantum of loss sustained. Some systems award compensation as a fixed or variable lump sum,[121] while others provide periodic benefits such as pensions, particularly for injuries or disabilities with lasting or permanent consequences, or combine elements of both.[122] Compensation for medical costs and care expenses has particular significance in countries that do not offer free and universal access to medical care.[123] Where medical and other social benefits are available from government sources, the schemes are more likely to operate as a "top up" and provide compensation only for expenses not covered otherwise.[124] While compensation for loss of earnings, or loss of earning

118. *Id.*

119. Goldberg, *supra* note 34, at 8 ("Yet these more generous approaches to petitioners may result in undermining the need to be on the side of science in the resolution of cases and in so doing set an unhelpful precedent in increasing vaccine hesitancy.").

120. Marco Rizzi & Lécia Vicente, *Defectiveness and Causation in Vaccine Liability Cases: The Jurisprudence of the Supreme Court of the United States and the Court of Justice of the European Union*, *in* THE TRANSFORMATION OF ECONOMIC LAW: ESSAYS IN HONOUR OF HANS-W. MICKLITZ 384 (Lucila de Almeida et al. eds., 2019).

121. Such as Norway, Switzerland and the UK. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 17. In the UK, this is a capped amount of £120,000, applicable in all cases regardless of actual harm suffered.

122. For example, Austria, Germany, New Zealand and the USA. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 17.

123. In Japan, an annuity is also available for persons caring for a disabled individual. *See National Pension Service*, JAPAN PENSION SERVICE, https://www.nenkin.go.jp/international/japanese-system/nationalpension/nationalpension.html (discussing the Japanese national pension system).

124. *See generally* Urho, *supra* note 43 (discussing the Scandinavian schemes). *See also* HEALTH RESEARCH BOARD, *supra* note 40, at 14 ("much of the costs are absorbed by social security, welfare, and national health schemes, and many schemes acknowledge this by framing

capacity, is a major component of personal injury awards under general law, it tends to be more restricted, both in availability and amount, under vaccine compensation schemes, thereby reflecting the distinctive underlying bases of the schemes.[125] Compensation for non-pecuniary losses, such as physical pain and suffering or loss of amenities, is a further component available under some of the systems, such as those of France, Germany, Switzerland, and most Nordic countries.[126] If the vaccine has caused a person's death, death benefits to dependents are available, usually in the form of a lump sum benefit.

A number of systems provide standardized amounts of compensation based on the extent of the injury.[127] Standardized amounts are more common in systems that have a capped amount of compensation. While this approach provides ease of administration, it tends to leave claimants with severe or longer-lasting injuries more exposed than a case-by-case assessment, of which the United Kingdom Vaccine Damage Payments Act is a prime example.[128]

In a number of jurisdictions, vaccine injuries are compensated as part of schemes of wider application, such as in the New Zealand Accident Compensation Act 2001; in the Nordic countries, general no-fault schemes for medical injuries provide coverage.[129] In Quebec, the amounts available mirror those awarded in case of car accidents, as calculated under the rules and regulations in the Automobile Insurance Act.[130] In France, the scheme is part of the ONIAM no-fault compensation scheme, which inter alia aims to provide "full compensation" to victims of serious medical accidents, as well as those with vaccine injury.[131]

There are also significant differences in actual and maximum pay-outs.[132] However, comparisons of quantum or average claims between countries and world regions can be misleading due to differences in

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compensation payments as a 'top-up' payment or by raising eligibility requirements to exclude all but 'severe' injuries").

125. However, the insurance-administered programs in Finland and Sweden compensation decisions follow general liability law. *See* Sonia MacLeod et al., *Nordic Injury Compensation Schemes*, *in* REDRESS SCHEMES FOR PERSONAL INJURIES 165 (2017).

126. *See* Urho, *supra* note 43.

127. *See*, *e.g.*, AEFI Fund, *supra* note 117, § 8. *See also* analysis in Mungwira et al., *supra* note 15.

128. *See generally* Vaccine Damage Payments Act 1979, *supra* note 34.

129. *See* MacLeod et al., *supra* note 125, at 161-65.

130. *See* Mungwira et al., *supra* note 15.

131. *See Compensation Schemes*, OFFICE NATIONAL D'INDEMNISATION DES ACCIDENTS MÉDICAUX, www.oniam.fr/procedure-indemnisation (last visited July 5, 2022). For a comparative Franco-British analysis, *see generally* TAYLOR, *supra* note 41.

132. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 112-14.

purchasing power. The COVAX No-Fault Compensation Program takes these differences into account in the assessment of benefits. Its compensation formula that reflects the cost of living across the eligible economies is as follows:

> Gross Domestic Product (GDP) per capita of the AMC-Eligible Economy in which the claimant resides x 12 x a harm factor ranging from 0.1 to 1.5 dependent on the nature of the injury and level of impairment resulting from the COVAX-distributed COVID-19 vaccine or its administration, as evaluated based upon the most recently published edition of the American Medical Association's (AMA) Guides to the Evaluation of Permanent Impairment.[133]

The impairment percentages or ratings contained in the AMA's Guides are developed by medical specialists and are consensus-derived estimates which reflect the severity of the medical condition and the degree to which the impairment decreases an individual's ability to perform common daily activities. The impairment rating represents the extent of a whole person impairment of an individual, based on the organ or body function affected by an injury.

In addition, the COVAX No-Fault Compensation Program provides eligible claimants who have been hospitalized, or whose existing hospitalization has been prolonged for more than twenty-four hours, with a flat hospital benefit of US $100 for each day of their hospitalization or prolongation of hospitalization, capped at sixty days.

C. Process and Administration of the Schemes

One of the principal raisons d'être of a compensation scheme is that it provides swifter and easier access to a remedy than resort to the courts. To what extent do the schemes meet this goal?

In general, vaccine compensation schemes are designed to operate as an administrative process and are thus very different from legal proceedings, eschewing an adversarial process, and thereby reducing costs and complexity.[134] Most programs do not require legal

133. *COVAX No-Fault Compensation Program: Explained*, WORLD HEALTH ORG., https://www.who.int/initiatives/act-accelerator/covax/no-fault-compensation/covax-no-fault-compensation-program-explained (last visited July 5, 2022).

134. *See* Looker & Kelly, *supra* note 14, at 374-75 ("Many countries use an administrative process for deciding compensation eligibility and payment amounts . . . Proponents of these schemes believe this administrative approach is less adversarial, has lower costs, lessens the need to apportion blame and maximizes the opportunity for those with genuine vaccine injuries to receive just compensation.").

representation and there is generally no administrative fee associated with the submission of a claim.[135] One exception is the U.S. scheme, which is a hybrid administrative-judicial scheme, requiring claimants to file a petition with the U.S. Court of Federal Claims against the Secretary of the Department of Health and Human Services (HHS).[136] This specific feature of the U.S. scheme, however, sets it apart from most other vaccine compensation schemes.

The fact that the schemes adopt administrative processes does not necessarily mean that they are simple. While most programs around the globe do not require legal representation, the processes are not always straightforward for non-lawyers. Some schemes are somewhat cumbersome in claims handling and adjudication, which can delay timely access to compensation for claimants.[137] The new Canadian scheme requires proof of vaccination, first medical assessment by a doctor, expert medical opinion, receipts and bills resulting from vaccine injury, and self-reported personal information.[138] As we have seen above, the causal requirement can often present a significant obstacle to surmount for claimants. The U.S. system has to some extent side-stepped the issue by allowing for a process for pre-determining causation if a vaccine injury is included on the vaccine injury table, though Goldberg has remarked that the burden of proof in respect of those claiming for an off-table claim is a heavy one given the particular context of vaccine injuries.[139]

Indeed, research has suggested that schemes have not always ensured timely access to compensation for claimants.[140] The best outcomes seem to have been achieved in countries where the vaccine program is part of a broader compensation scheme, such as the New

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135. The U.S. scheme incurs a high level of overhead running costs, mainly due to the high level of legal representation that claimants require in order to navigate the scheme. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 9.

136. For further details of the scheme, see *How to File a Petition*, HEALTH RESOURCES & SERVICES ADMINISTRATION, www.hrsa.gov/vaccine-compensation/how-to-file (last visited July 5, 2022).

137. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 110. ("Our analysis of the data we collected suggests that only some of the schemes we reviewed have made progress on improving timely access to compensation for claimants.").

138. *See Submit a Claim*, VACCINE INJURY SUPPORT PROGRAM, https://vaccine injurysupport.ca/en/submit-a-claim (last visited July 5, 2022).

139. *See* discussion in Goldberg, *supra* note 34, at 7 ("By comparison with the relaxation of the burden of proving causation for injuries which are Table claims, the burden of proof on the petitioner in an off-Table claim is a heavy one.").

140. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 110 ("Our analysis of the data we collected suggests that only some of the schemes we reviewed have made progress on improving timely access to compensation for claimants.").

Zealand injury scheme and the Nordic schemes. Urho has singled out the New Zealand and the Finnish schemes as performing particularly well.[141] It has been argued that the key features of success for the Nordic schemes are the non-adversarial approach, the decision-making process of an expert panel as well as a lowered standard of proof.[142]

In light of the inherent complexities, it is evident that applicants would benefit from legal support in navigating the process. However, legal aid is generally not available for claims under vaccine schemes, other than certain university clinical programs[143] and regional hotlines.[144] The exception is again the U.S. program which, due to its quasi-judicial nature, requires a relatively high level of legal representation.[145] It is reported that reasonable legal fees are reimbursed as long as there is a "good faith, reasonable basis" for the claim.[146]

How could access be facilitated to the schemes? Given the reduction in availability of legal aid, any significant improvement of access to justice is more likely to come from strategies to improve legal functioning and capability rather than public sources.[147] Accessibility of these schemes might thus be enhanced by deploying digital solutions such as Online Dispute Resolution (ODR) accompanied by intelligent self-help tools. In the context of vaccine injury, access to such schemes might

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141. Urho, *supra* note 43, at 499-501 (New Zealand), 477-79 (Finland).

142. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 110.

143. We note the existence of two programs in North America: *George Washington Vaccine Injury Litigation Clinic*, THE GEORGE WASHINGTON UNIVERSITY, https://www.law.gwu.edu/vaccine-injury-litigation-clinic (last visited July 5, 2022); and a legal help technology aimed to assist applicants to determine their eligibility to compensation and submit a claim, *Vaccine Mediator*, CONFLICT ANALYTICS LAB, https://tool.myopencourt.org/vaccine-mediator (last visited Jul. 5, 2022).

144. We note that both the COVAX No-Fault Compensation Program and the Canadian VISP have a contact page. The Canadian program's language suggests that a Team Member may be able to assist users in their application. *See Vaccine Injury Support Program*, *supra* note 13.

145. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 9 ("the scheme incurs a high level of overhead running costs, mainly due to the high level of legal representation that claimants require in order to navigate the scheme.").

146. Jennifer Keelan & Kumanan Wilson, *Designing a No-Fault Vaccine-Injury Compensation Programme for Canada: Lessons Learned from an International Analysis of Programmes*, MUNK SCHOOL BRIEFINGS 1, 15 (2011).

147. Hugh McDonald, *Assessing Access to Justice: How Much" Legal" Do People Need and How Can We Know?*, 11 U.C. IRVINE L. REV. 693, 699 (2020) ("Widespread commentary suggests there will never be enough public resources to simply provide public lawyers to everyone who might benefit from access to one. Consequently, the route to enhancing access to justice more than likely lies with strategies and innovations that help people to do more to access and use law themselves. These are the bottom-up strategies to build legal capability and improve legal functioning.").

benefit from a process including advisory tools and assisting users in determining their eligibility for compensation, though real-time human assistance and technical support would inevitably be required. One such university pilot initiative, the Vaccine Mediator,[148] has been launched in respect of adverse effects caused by COVID-19 vaccines. The pilot provides reliable health information, along with guidance on vaccine injury compensation in respect of the U.S. and Canadian schemes.

The development of such ODR tools, combined with AI-powered self-help systems, might improve access to justice.[149] There has been an increase in the use of AI-based technology investment and adoption by U.S. administrative agencies in the medicines sphere, with the FDA-piloted automated tools for post-market surveillance of drug and medical devices based on adverse event reports.[150] AI tools have been successfully used to improve the accuracy and efficiency of formal adjudication in the adjacent sphere of social welfare provision.[151] There are potential

148. The pilot has been undertaken by a team of researchers at Queen's Law, Université de Paris Dauphine PSL and Oxford University in consultation with the Canadian Vaccine Injury Support Program (VISP). *See* MY OPEN COURT, https://myopencourt.org/ (last visited July 5, 2022).

149. James E. Cabral et al., *Using Technology to Enhance Access to Justice*, 26 HARV. J. L. & TECH. 241, 246 (2012) ("Since 2000, access to legal resources and information specifically targeted to low-income people has grown tremendously. Every state now offers a statewide legal aid website, where legal services providers collaborate with other access to justice organizations to provide a portal for self-help resources and a public entry point for intake and referrals to specific organizations that offer assistance. Statewide legal aid websites are also used to coordinate pro bono attorneys and volunteers, provide training materials, and enable advocates to privately collaborate and share resources.").

150. David Freeman Engstrom et al., *Government by Algorithm: Artificial Intelligence in Federal Administrative Agencies*, N.Y.U. SCH. OF L. 1, 53 (2020), https://dx.doi.org/10.2139/ssrn.3551505 ("Because preapproval studies cannot identify all possible side effects or problems with a drug or therapeutic biological product, the FDA maintains a system of postmarket surveillance and risk assessment centered on analysis of a growing pool of data about adverse events and medication error reports. The agency uses the results of these analyses to update rulemaking and guidance, and, on rare occasions, to reevaluate an approval decision. The FDA has publicly discussed the FAERS pilot projects since at least 2017.").

151. One novel experiment in the use of AI at the Social Security Administration (SSA) involved clustering for micro-specialization. *See id.* at 39-40 ("The Appeals Council has explored the use of clustering algorithms to improve case processing. The existing approach randomly assigned cases to adjudicators. SSA hypothesized that case clustering could help adjudicators accumulate times at the Appeals Council level. Since October 2018, the tool has been used approximately 70,000 times at the hearing level."). A second experiment involved accelerating appeals with predicted likelihood of success. *See id.* ("To improve case processing at the initial application level, SSA promulgated new rules that included provision for automatically identifying claimants most likely to qualify for benefits for Quick Disability Determination (QDD) . . . Officials at SSA reported that the model identified 10% of cases as likely to receive fully favorable as compared with the average fully favorable rate of 2.5-3% for all claims at the hearings level.").

opportunities to reduce costs, improve the quality of decisions and facilitate access to legal information for self-represented litigants.

D. Systemic Issues

Alongside the intrinsic issues examined in the previous subparts, a further factor to consider is how the compensation scheme, once set up, sits within the broader legal system. We identify three principal themes: (1) how the compensation scheme interacts and overlaps with litigation; (2) how it interacts with other social security schemes; and (3) how it is funded.

1. Interaction with Litigation

The first issue to consider is the relationship between a compensation scheme and broader liability regimes. Compensation schemes originated at a time when liability was anchored to the criterion of fault. Since proving fault can be extremely difficult, particularly with scientifically complex products such as vaccines, most victims were left without compensation. While the issue of access to justice in cases involving complex proof of fault was addressed by Western legal systems through the adoption,[152] or reinforcement,[153] of strict liability rules for damage caused by defective products, vaccine injury posed its own set of solidaristic and utilitarian issues transcending defectiveness. We identify three modes of interaction between no-fault schemes and liability systems:[154]

A third experiment involved natural language processing for quality assurance. *See id.* ("Known as the Insight program, these tools were principally developed by Kurt Glaze, an SSA attorney-turned-programmer, primarily to improve the quality of decision writing. At the hearing level, Insight is used to identify weaknesses in draft opinions, ensuring that adjudicators have properly gone through the analysis required by regulations . . . Since August 2017, the tool has been used 200,000 times at the Appeals Council level. Since October 2018, the tool has been used approximately 70,000 times at the hearing level.").

152. *See* 1 THE DEVELOPMENT OF PRODUCT LIABILITY 21-50 (Whittaker ed., 2010).

153. For example, the Italian Civil Code establishes a strict liability rule for dangerous activity. *See* Codice civile [C.c] [Civil Code], art. 2050 (It.). The production, distribution and administration of vaccines is considered a dangerous activity. *See* Cass. sez. tre, 27 aprile 2011, n. 9406, Giust. civ. 4, 19 (It.).

154. Note that, for COVID-19 vaccines, governments have included explicit protections from liability in procurement contracts with manufacturers via extensive indemnities whereby the procuring governments will indemnify manufacturers in case of claims. *See, e.g., Advance Purchase Agreement ("APA") For the Production, Purchase, and Supply of a COVID-19 Vaccine in the European Union*, art. 14 (2020), https://ec.europa.eu/info/sites/default/files/apa_astrazeneca.pdf. *See* Borghetti et al., *supra* note 86, at 364. ("The European Commission accepted in Article 14 of the agreement an extremely broad indemnity of the manufacturer covering almost any and

a) The compensation scheme precludes the application of liability rules. This is the case for example in the U.S., where the legal regime in place for vaccine compensation explicitly excludes recourse to litigation by creating an entirely alternative adjudicatory mechanism.[155]

b) The compensation scheme allows the application of liability rules. In France, for example, product liability litigation against alleged vaccine injuries has been common since the 1990s despite the existence of a compensation scheme.[156]

c) The compensation scheme allows the application of liability rules, but de facto liability rules are not applied. This is the case, for example, in Italy.[157] Interestingly, the amount of indemnity awarded, the procedure regulating access to the scheme and the broader health and welfare system are relatively similar in Italy and in France. Reasons for the different impact of compensation schemes on litigation likely include the fact that Italian victims have less incentive to file product liability claims because of the costs and the lengthiness of the judicial proceedings. Furthermore, in Italy (and in France) the indemnity award is considered deductible from compensation.[158]

In general, the fast, easy, and affordable procedures of compensation schemes tend to be effective in addressing the issue of access to justice for vaccine injury victims. Providing a less adversarial and accessible avenue to predetermined sums is indeed an attractive alternative to

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every defect imaginable whether that be the vaccine's inherent characteristics, manufacturing / distribution, and storage issues, labelling errors or even problems due to administration of the vaccine. This is a potentially significant burden to place on the state, and ultimately taxpayers.").

155. National Childhood Vaccine Injury Compensation Act, 42 U.S.C. §§ 300aa-1-300aa-34 (1986); Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d (2005). *See* Goldberg, *supra* note 34.

156. *See* Borghetti, *supra* note 112; Rizzi, *supra* note 114. Even though it often happens in practice that claimants will seek compensation in court after having been compensated through a scheme, whether and to what extent such combination is possible has been a matter of debate. *See* JONAS KNETSCH, LE DROIT DE LA RESPONSABILITE ET LES FONDS D'INDEMNISATION 409-53, ¶¶ 560-617 (2013).

157. The no-fault compensation scheme is established under Law 210/1992 and covers mandatory and recommended vaccinations. *See* Legge 25 febbraio 1992, n.210 (It.).

158. *See* Cass., sez. un., 11 gennaio 2008, n.584, Foro it. 2008, II (It.). Note that this is also the case in France and the UK, where, however, deductibility has not prevented litigation.

cumbersome litigation.[159] However, from a systematic standpoint, exclusion of liability rules, whether by law or in practice, is not without consequences. Liability rules perform an important deterrence function, and where litigation is either precluded or regularly avoided, there is a risk of under-deterrence. The risk is obvious where applicable liability rules are based on fault, but it can extend to systems adopting strict liability rules and risk-utility reasoning.[160]

2. Interactions with Other Social Security Mechanisms

Compensation schemes are arguably a sui generis hybrid between social security mechanisms, with which they share fundamental goals, and ADR mechanisms, with which they share certain structural aspects. Compensation schemes can serve two functions. They can either be top-up schemes where other welfare provisions already cover aspects of vaccine injury, as is the case with the Scandinavian schemes discussed above, or they can fill a gap where vaccine injuries fall outside the scope of such other provisions. However, the relationship between compensation schemes and other forms of social security can be difficult. Two examples will be of use.

Until the introduction of COVID-19 vaccine claims scheme, Australia has not had any form of compensation scheme for vaccine injuries. The country's reliance on litigation alone stands as a stark reminder of the difficulties that injured plaintiffs can face in proving defectiveness and causation. Indeed, not a single case has been successful to date. The absence of a comprehensive scheme makes Australia an outlier within OECD countries,[161] for reasons that remain under-researched. One contributing factor has been the mistaken belief that the National Disability Insurance Scheme (NDIS)[162] already performs that function. The NDIS provides Australians who have a permanent and

159. Mungwira et al., *supra* note 15, at 9.

160. Under a strict liability regime inspired by risk-utility reasoning, a producer who takes the risk to pursue a certain activity is encouraged to invest in scientific and technological research aimed at preventing risk of harm. *See* William M. Landes & Richard A. Posner, *A Positive Economic Analysis of Product Liability*, 14 JOURNAL OF LEGAL STUDIES 535, 555 (1985); Michael Faure, *Economic Analysis of Product Liability*, *in* EUROPEAN PRODUCT LIABILITY 650-51 (Piotr Machnikowski ed., 2016).

161. Randy Mungwira et al., *Economic and Immunization Safety Surveillance Characteristics of Countries Implementing No-Fault Compensation Programmes for Vaccine Injuries*, 37 VACCINE 4370, 4372 (2019).

162. *National Disability Insurance Scheme Act 2013* (Cth) (Austl.); *see What is the NDIS?*, NATIONAL DISABILITY INSURANCE AGENCY, https://www.ndis.gov.au/understanding/what-ndis (last visited July 5, 2022).

significant disability with funding for supports and services. Whilst NDIS has a critical role in assisting individuals with disabilities, it is not suited for many sufferers of vaccine adverse events, because they are ineligible.[163] Thus, at one end of the spectrum, there are legal systems where the very existence of other forms of social security can prevent compensation schemes from coming into existence.

At the other end of the spectrum sits a system like Italy, where social security mechanisms exist alongside the compensation scheme. This coexistence, which is not at all problematic per se, can produce distorting effects where the administration of the compensation scheme is exceedingly permissive. Indeed, adjudicators of the Italian scheme have for some time indulged in what has been described as a welfarist attitude. The relatively small sums involved in the compensation scheme have often been awarded regardless of the merits of the claim, to provide benefits to a struggling individual or their family.[164] In this sense, the scheme departs from its legislative mandate, and performs a role that is closer to that of a social safety net from which the claimant may already benefit.

3. Funding of Compensation Schemes

Most vaccine compensation schemes are government-initiated and created by legislation.[165] The pattern of funding of these schemes is quite

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163. *See* Marco Rizzi et al., *No-Fault Compensation for COVID-19 Vaccine Injuries in Australia*, MJA INSIGHT+ (Sept. 27, 2021), https://insightplus.mja.com.au/2021/36/no-fault-compensation-for-covid-19-vaccine-injuries-in-australia/ (last visited July 5, 2022). Given the specific circumstances of the pandemic, the Australian government introduced a targeted COVID-19 vaccine injury compensation plan on 28 August 2021. *See No-Fault Covid-19 Indemnity Scheme*, MINISTERS: DEPARTMENT OF HEALTH AND AGED CARE, https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/no-fault-covid-19-indemnity-scheme (last visited July 5, 2022).

164. Marco Rizzi et al., *Legitimising a "Zombie Idea": Childhood Vaccines and Autism–the Complex Tale of Two Judgments on Vaccine Injury in Italy*, 17 INT'L J. L. CONTEXT 548, 558 (2021).

165. Note, however, that in most Scandinavian countries the schemes are administered by the private sector. In Finland, since 1984, there is a voluntary system covering medicine (including vaccines) related injuries, whereby pharmaceutical injuries insurance is taken out, and the claims handling processed by the Finnish Co-operative for Pharmaceutical Injury Indemnities. In respect of COVID-19 vaccines, the Finnish government has granted an insurance guarantee to the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities. In Sweden, the Swedish Pharmaceutical Insurance Association runs a scheme providing compensation in the event of medicine-related injury. It was set up by companies and organizations that work with pharmaceuticals in Sweden and covers 99% of all pharmaceutical products in Sweden. The Norwegian scheme is Government-run, though it is also funded by contributions from the pharmaceutical industry. *See* detailed analysis in Urho, *supra* note 43.

varied,[166] but a majority are financed by public funds—whether by central government and/or decentralized entities such as regional or local authorities. For example, in Japan, the scheme is funded by municipalities (twenty-five percent), the prefectural government (twenty-five percent) and national treasury (fifty percent),[167] although exceptionally the compensation for COVID-19 vaccines is funded entirely by the central government. The Chinese scheme is also run on a decentralized model, with local authorities running and financing the initiative,[168] but this has resulted in different amounts being awarded depending upon the geographical location.[169]

Other examples of central government funding in different parts of the world include the Canadian scheme, the scheme run by the Korea Disease Control and Prevention Agency, and the state-run scheme in Peru.[170] In Southeast Asia, the programs in Malaysia, Singapore, and Thailand are also all funded by central government sources.[171]

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166. Halabi et al., *supra* note 16.

167. Yobō Sesshu-hō [Immunization Act], Law No. 68 of 1948, arts. 25-27, *translated in* (Japanese Law Translation), https://www.japaneselawtranslation.go.jp/en/laws/view/2964/en (Japan) [hereinafter "Immunization Act"].

168. *See* Fei & Peng, *supra* note 101, at 103-04 ("The Regulation further requires the people's government of each province, autonomous region, or municipality directly under the central government to formulate specific local regulations for compensation.").

169. *Id.* at 113 ("There is also a large difference across one-time compensation amounts.").

170. Decreto de Urgencia [Urgency Decree] No. 031-2021 (Mar. 10, 2021) (Peru) (approving a compensation regime to be paid by the Peruvian state, which is said to have been funded by specialized debt instruments guaranteed by multilateral agencies); Halabi et al., *supra* note 16.

171. For Malaysia, *see Garis Panduan Permohonan Bantuan Khas Kewangan Kesan Mudarat Vaksin COVID-19 Kementerian Kesihatan Malaysia* [Guidelines for Special Financial Assistance Applications for Harmful Effects of the COVID-19 Vaccine Ministry of Health Malaysia], NAT'L DISASTER MGMT. AGENCY, https://covid-19.moh.gov.my/garis-panduan/gp-umum-covid19/PERMOHONAN_BANTUAN_KHAS_KEWANGAN_KESAN_MUDARAT_VAKSIN_COVID-19_kk12072021.pdf (last visited July 10, 2022). For Singapore, *see Vaccine Injury Financial Assistance Programme for COVID-19 Vaccination*, MINISTRY OF HEALTH SING., https://www.moh.gov.sg/covid-19/vaccination/vifap#:~:text=The%20Vaccine%20Injury%20Financial%20Assistance,Vaccination%2C%20and%20who%20experienced%20serious (last visited July 10, 2022). For Thailand, *see* Jadej Thammathach-Aree, *Fairness and People's Safety: Our Priority in the COVID-19 Vaccination Program*, NAT'L HEALTH SEC. OFF., https://eng.nhso.go.th/view/1/DescriptionNews/Fairness-and-peoples-safety-our-priority-in-the-COVID-19-vaccination-program/341/EN-US (last visited Dec. 4, 2022). Thailand's no-fault compensation program is supported by section 41 of the National Health Security Act. *See* National Health Security Act, B.E. 2545 (A.D. 2002), NAT'L HEALTH SEC. OFF., https://eng.nhso.go.th/assets/portals/1/files/NHS%20ACT_book_revised%20Apr5.pdf. *See* N. Masirah Mustaffa et al., *Special Financial Assistance for Damage Caused by COVID-19 Vaccines in Malaysia: A Review Analysis*, (forthcoming).

Some other schemes are not funded solely from the public revenue. The Scandinavian schemes are all funded by contributions from industry, generally by means of a percentage levy calculated by reference to the sales turnover of pharmaceutical companies in the country.[172] In the United States, the Vaccine Injury Compensation Program is also funded by a levy per dose, which is currently fixed at a seventy-five cent excise tax per dose of a vaccine.[173] In Poland, the vaccine producers are reported as having contributed to the scheme.[174] The COVAX No-Fault Compensation Program is funded by COVAX via a donor funded levy on each dose delivered through COVAX to the AMC Eligible Economies.[175]

Normatively, this is a complex topic. On the one hand, arguments based upon accountability and deterrence may suggest that industry, which is responsible for developing, producing, and ultimately selling these products, should participate financially in the schemes. On the other hand, it may be countered that the overwhelming public health interest in increasing vaccination uptake entails that it is right for the public sector to assume the costs of compensation for adverse events, particularly where the government mandates or highly recommends vaccination. Indeed, the circumstances of the COVID-19 pandemic and the accompanying increased call on resources have also resulted in specific provision being made for funding of the schemes. In certain countries, central authorities have exceptionally intervened to fund compensation for serious adverse reactions caused by COVID-19 vaccines (such as in Japan).[176] Set against this are concerns about the socialization of risk and privatization of profit,[177] an issue that was raised by the Parliamentary Assembly of the Council of Europe in respect of the H1N1 pandemic.[178]

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172. *See* Urho, *supra* note 43.

173. *See About the National Vaccine Injury Compensation Program*, HEALTH RES. SERVS. ADMIN., www.hrsa.gov/vaccine-compensation/about (last visited July 5, 2022).

174. Halabi et al., *supra* note 16.

175. Namely, US $ 0.10 levy per dose for 2 dose vaccines and US$ 0.20 per dose for single dose vaccines. *See generally COVAX No-Fault Compensation Program: Explained*, *supra* note 133.

176. In Japan, the National Vaccine Injury Compensation Program extends to routine vaccinations that have been required by the government. The Program is provided for under the Immunization Act. *See* Immunization Act, *supra* note 167.

177. *See generally* Eleonora Rajneri, *Il Vaccino Anti COVID-19. La Normativa Speciale e il Meccanismo di Distribuzione dei Rischi e dei Benefici* [The COVID-19 Vaccine. The Special Regulations and the Mechanism for the Distribution of Risks and Benefits], 2 CONTRATTO E IMPRESA 510, 510-522 (2021) (discussing specifically the distribution of risks and profits for COVID-19 vaccines).

178. Eur. Parl. Ass., *supra* note 84, ¶ 8.6 ("The Assembly also calls on member states to: . . . ensure that the private sector does not gain undue profit from public health scares and that it is

V. PRINCIPLES APPLICABLE TO VACCINE INJURY COMPENSATION SCHEMES

In this Part, we undertake the more normative exercise of identifying the principles underpinning successful vaccine compensation funds. Drawing upon the comparative law work set out above, a series of transversal principles applying to vaccine schemes is proposed, with an accompanying commentary analyzing the scope and content of the relevant principles. These principles are not intended to be set in stone and are designed to provide benchmarks as to how vaccine schemes can be structured. It is recognized that resource and other related constraints might in certain jurisdictions result in a limitation of the extent to which the principles are achieved, though these might nonetheless be considered as longer-term objectives to achieve in terms of more developed schemes.

A. Eligibility

- Special care should be taken in determining the criteria for eligibility, depending upon factors such as the severity of the injury, proximity in time between the administration of the vaccine and the occurrence 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 so on.

The issue of eligibility is a key aspect of vaccine injury schemes as it determines the contours of those able to make claims for compensation. The criteria need to be determined by relevant authorities and policymakers so as to ensure that the underlying rationales of the schemes are achieved.

- Eligibility may be limited to those vaccines properly registered with the national regulatory authority or otherwise authorized for use in the country, distributed through authorized channels, and/or administered by licensed healthcare professionals.

Restrictions may be placed on eligibility depending upon the avenues through which vaccines have been distributed. There may be a requirement that the vaccine in question was properly registered with, or otherwise authorized by, a national regulatory authority, distributed through authorized channels, and/or administered by licensed healthcare

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not allowed to absolve itself of liabilities with a view to privatizing profits whilst sharing the risks. In order to avoid this, member states should be ready to develop and implement clear national guidelines for dealing with the private sector and to co-operate with one another in negotiations with international corporations whenever necessary."). *Cf.* discussion *supra* Part III.

professionals. In contrast, the underlying rationale in favor of eligibility is weaker for those who have obtained vaccines through illicit channels, or who receive an immunization with a vaccine that has not been properly registered, or otherwise authorized, or which is administered by an unauthorized or unlicensed party.

- The criteria should be clear and consistently applied, and applicants should have a chance to challenge any unfavorable decision concerning eligibility.

Whilst discretion may be exercised by policymakers in establishing the terms of eligibility, the applicable criteria should be set out in clear and understandable terms and applied in a consistent manner by the relevant authorities. Public confidence in the vaccination system is a crucial factor in its success, and therefore consistent and transparent procedures for dealing with vaccine injury harm are imperative. As with any administrative decision, there should be a procedure available for challenging a denial of eligibility before an independent and easily accessible tribunal or independent appeals panel.

B. Causation and Quantum

- An injured person should be required to prove causation by demonstrating a sufficient likelihood of causation. Difficulties in proving causation should not disadvantage applicants unfairly.

Although there are very different approaches to assessing causation in each jurisdiction, many schemes adopt a "balance of probabilities" approach whereby it must be shown that it was more likely than not that the vaccine caused the injury in question. Some systems make use of presumptions or other evidential techniques in order to facilitate the burden of proof in such cases.

- The amount of compensation awarded by a scheme should be sensitive to the circumstances and individual losses of the applicant. If a vaccination has caused death, the dependents should be able to seek compensation.

Existing programs differ as to the range of benefits available for successful applicants and the exact methodology adopted for determining quantum of loss sustained. As we have seen above, the manner in which benefits are paid vary greatly (by means of lump sums, periodic benefits

or a hybrid approach).[179] Despite these differences in approach and taking into account the level of resources available and other related constraints, it is important not to lose sight of the basic underlying principles that should apply to such schemes. The amount of compensation awarded by a scheme should be sensitive to the circumstances of the applicant, thereby taking into account the exact injury and impairment caused by the vaccination, as well as, where possible, the impact on the person's livelihood. If the person in question is deceased, then relatives and/or dependents should be authorized to make a claim on behalf of the deceased or for the dependency. In case of injury or death of a minor, then a legal guardian should be able to seek relevant compensation.

- The methods of calculation and the form of payments may vary legitimately, but compensation levels should be sufficient to provide a realistic alternative to the bringing of legal proceedings.

It is recognized that the level and exact form of payments will depend upon the resources available to the scheme in question, which ultimately is a decision for the authorities responsible for providing the relevant funding. Given the role of such schemes in facilitating the bringing of claims in lieu of litigation, it is important that the scheme is sufficiently attractive to divert claimants away from seeking compensation before the courts. Whilst this may not mean that the levels of compensation from schemes will equate to judicial awards for personal injury, it is important for the amounts to be perceived as fair and equitable so as to ensure take up of, and reinforce confidence in, the schemes. Note that while the amounts awarded may not be at the same level as court awards, compensation schemes are usually more accessible and the procedure is easier, swifter, and generally has a greater chance of success since the level of proof required is typically lower.

- The procedure for establishing loss and for assessing the quantum should be transparent and fair, and applicants should be allowed to make submissions and provide evidence. A formal review or appeal of decisions should be available.

As mentioned above, public trust in the vaccination system is an important factor in ensuring its success, and therefore consistent and transparent procedures are similarly crucial. As with any administrative decision, there should be a procedure available for review of the decisions

179. *See generally* Urho, *supra* note 43 (comparing and contrasting schemes across jurisdictions).

of the scheme administrator before an independent tribunal or independent appeals panel.

C. Systemic Issues

- In general, at a national level, neither a claim to nor a payment from a vaccine compensation scheme should ipso facto exclude the bringing of judicial proceedings in respect of the same factual circumstances, though account can be taken of compensation already granted in terms of any damages awarded, and different principles may apply to international schemes.

At a national level, most jurisdictions do not exclude claims from being brought before the courts to supplement funds received from vaccine schemes, even though one of the raisons d'être of schemes is admittedly to discourage litigation. Indeed, the level of compensation should be such as to discourage the bringing of claims, given the fact that any compensation received will be taken into account by the courts. The exercise of one remedial route should not ipso facto exclude the pursuit of another route to compensation. At an international level, however, different principles have applied. For instance, payments under the COVAX No-Fault Compensation Program, the AVAT No-Fault Compensation Scheme, and the UNICEF COVID-19 Vaccine Facility No-Fault Compensation Scheme are in full and final settlement of any claims, precluding court proceedings and seeking and obtaining compensation in respect of the same injury from or through any other compensation program or other means.

- The availability of income support payments and public healthcare may be taken into account in assessing the quantum of compensation.

There may be overlap between social security payments and compensation from vaccine injury schemes. In order to avoid double payment, social security and related payments can be factored into the process of calculating compensation via offsetting or deductions. Indeed, as noted above, some vaccine compensation schemes are explicitly framed as "top-up" schemes designed to supplement pre-existing welfare entitlement, so that the latter payments need to be taken into account in setting quantum.[180]

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180. *See* HEALTH RESEARCH BOARD, *supra* note 40, at 14 ("[M]uch of the costs are absorbed by social security, welfare, and national health schemes, and many schemes

> • Compensation schemes must be adequately funded so that they function effectively and can meet their objectives of paying compensation.

Adequate resources need to be made available by the relevant authorities so as to ensure the effective functioning of schemes over the long term and in line with the scope of the scheme and eligibility for payments.

> • In terms of the funding of compensation schemes, an appropriate balance should be found as to the source of funding. In case of vaccination mandated by the government, public sector funding of compensation is logical. However, it is equally important to ensure that a deterrence function of liability is maintained, and that states avoid a systematic and unjustifiable socialization of risk and privatization of profits.

The pattern of funding of schemes across the globe is varied, though a majority of schemes are financed by public funds. Funding from public sources is particularly apposite in respect of schemes established concerning emergency vaccines. Set against this, accountability and deterrence-based arguments might suggest that there should also be a participation from industry, which is responsible for developing, producing, and ultimately selling vaccines. Otherwise, there may be an unjustifiable transfer of risk to the public sector. In such a case, the operation of schemes must evidently remain free from undue influence by industry.

D. Process and Administration of the Schemes

> • Schemes should not charge a fee to any affected eligible person to apply for compensation and should be as accessible and user-friendly as possible. An online filing facility would be an advantage, potentially making use of modern Online Dispute Resolution and machine learning techniques.

Easy access to these schemes is paramount, processes should therefore be simple, swift and accessible without fee. Where resources allow it, use should be made of technology in order to facilitate access. In particular, it may be that access to schemes would be enhanced by digital solutions such as Online Dispute Resolution (ODR) and other intelligent self-help tools.

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acknowledge this by framing compensation payments as a 'top-up' payment or by raising eligibility requirements to exclude all but 'severe' injuries.").

- Support and assistance should be made available to affected patients to assist them in making applications.

In light of the inherent complexities in these cases, applicants would benefit from administrative support in navigating the vaccine compensation process.

- The scheme should be well-publicized, with proper public outreach and dissemination of information regarding the scheme to the general public.

VI. CONCLUSION

In this Article, we have examined the topical theme of compensation funds for adverse effects caused by COVID-19 vaccines. The presence of such funds and the availability of compensation is an important aspect in ensuring the overall acceptability of vaccines, as has been shown during the recent COVID-19 pandemic with the increase in number of schemes worldwide as well as the development of the pioneering COVAX No-Fault Compensation Program, launched in 2021, and covering over ninety different countries. Having analyzed the operation of these schemes from a comparative perspective, we have gone on to identify and set out a series of abstract principles applicable to vaccine compensation schemes in the form of benchmarks that should be considered when establishing such a scheme. As a way of summarizing these principles, we would conclude with the following hallmarks of a successful fund:[181] (1) These funds should be accessible, with low legal and financial barriers, good sign-posting, and facilitate the evaluation of harm; (2) transparent, with a transparent decision-making process and compensation framework, as well as clear funding responsibilities; (3) timely, with clear and short time-frames for compensation decision-making; and (4) deliver an amount of compensation that has a reasonable relationship with the harm and provides a realistic alternative to a legal claim.

181. *See also* Urho, *supra* note 43, at 503 (identifying three "qualifications" applying to such funds: transparency, fairness, and functionality).