VACCINE INDEMNIFICATION AND ACCESS TO MEDICINES: AN OVERVIEW OF EXISTING APPROACHES

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Accelerating Vaccine Production for Africa

ACCELERATING VACCINE PRODUCTION FOR AFRICA

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About this Initiative

The initiative on Accelerating Vaccine Production in Africa (AVPA) focuses on identifying the key challenges and opportunities for building domestic capabilities for vaccine manufacturing in the region. It is centred around creating a centres of excellence network in the Africa for to build a community of scholars as part of an agenda of strengthening R&D and collaborative learning ecosystems on the topic across several African countries. The initiative combines this with a series of evidence based, policy advisory activities focused on bringing together the private, public and academic sectors in Africa with external counterparts to train talent and increase innovation investments in Africa.

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I. Introduction

Vaccines for the prevention of infectious diseases are critical for saving lives. As noted by the World Health Organization (WHO), immunization "is one of the most successful and cost- effective public health interventions," with around 3 to 5 million deaths prevented annually[1] and the potential to prevent over 1 million additional deaths per year if global vaccination coverage were enhanced.[2] Vaccines are also at the frontlines of the battle against antimicrobial resistance (AMR). Vaccines help prevent diseases and so reduce the use of both first-line and second-line antibiotics, potentially decreasing the emergence of AMR.[3] Moreover, achieving sufficient vaccine coverage in a population promotes herd immunity and is thus an important factor in preventing the spread of resistant strains.[4] In short, vaccines and vaccine development are essential for advancing human wellbeing and reducing sharply the significant economic and social costs of debilitating disease and preventable death.

Despite the incontrovertible impact of vaccines on global health and the relatively rare instances of adverse reactions to immunization, two significant obstacles hinder vaccine development and uptake. First, pharmaceutical firms have historically been biased in favor of developing drug treatments for contracted diseases rather than development of preventative vaccines that would limit the spread of diseases and thus reduce the firms' revenue.[5]

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[1] Immunization, WORLD HEALTH ORGANIZATION (WHO) (Dec. 5, 2019), https://www.who.int/news-room/facts-in-pictures/detail/immunization

[2] Ten threats to global health in 2019, WORLD HEALTH ORGANIZATION (2019), https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019 ; K. P. Klugman & S. Black, Impact of Existing Vaccines in Reducing Antibiotic Resistance: Primary and Secondary Effects, 115 PROC. NATL ACAD. SCI. USA 12896 (2018); F. Micoli et al., The role of vaccines in combatting antimicrobial resistance, 19 NAT REV MICROBIOL 287, 291 (2021), https://doi.org/10.1038/s41579-020-00506-3 ("Vaccines are used prophylactically and are thus effective before bacteria start to multiply following the initial infection (low pathogen burden) and before different tissues and organs are affected, which substantially reduces the likelihood that resistance-conferring mutations will emerge and spread. In addition, whereas antibiotics have a single target (such as the bacterial cell wall or the translation machinery), vaccines usually contain multiple immunogenic epitopes. Thus, more mutations are necessary to confer resistance against a vaccine.").

[3] Id

[4] Id. See also K.U. Jansen & A.S. Anderson, The Role of Vaccines in Fighting Antimicrobial Resistance (AMR), 14(9) HUM VACCIN IMMUNOTHER 2142 (2018).

[5] Burton Weisbrod, The Health Care Quadrilemma: An Essay on Technological Change, Insurance, Quality of Care, and Cost Containment, 29(2) J. ECON. LIT. (1991). See also WILLIAM W. FISHER III & TALHA SYED, INFECTION: THE HEALTH CRISIS IN THE DEVELOPING WORLD AND WHAT WE SHOULD DO ABOUT IT, ch. 2,https://cyber.harvard.edu/people/tfisher/Infection.htm ("We currently rely too heavily on medicines, which cure (or relieve the symptoms of) diseases after they have been contracted, and too little on vaccines, which prevent diseases in the first instance.")

Second, rare but highly publicized vaccine-associated adverse reactions fuel public skepticism about vaccine safety, impeding vaccine uptake.[6] When adverse vaccine reactions do occur, damages ensuing from product liability litigation can be exorbitant, thus potentially deterring vaccine manufacturers from making the costly investments needed for research and development (R&D).[7] To address this latter problem of tort liability, a number of approaches have emerged since the 1970s, of which vaccine indemnification is at the forefront.

This essay seeks to provide an overview of the principal vaccine indemnification schemes currently in existence at both the national and global levels. The paper is structured as follows: Part II outlines the principal justifications and policy framework for vaccine indemnification schemes and Part III provides a brief history of indemnity schemes in leading jurisdictions. Part IV sets forth an overview of existing COVID-19 indemnity mechanisms available in the U.S. and other developed countries. This Part also discusses the currently sole international vaccine injury compensation mechanism established by the COVID-19 Vaccines Global Access (COVAX) initiative. Finally, Part V outlines the impact of vaccine indemnity schemes on access to medicines in low-and-middle-income countries (LMICs).

II. The Policy Framework for Vaccine Indemnification

There are two principal justifications for indemnification schemes designed to address the adverse effects of vaccines. First, indemnification schemes reassure citizens that they will be compensated in the event an adverse post-vaccination event occurs, thus arguably increasing the public's willingness to be vaccinated.[8] As scholars have noted, indemnification potentially helps avoid the collective-action problem raised by new vaccines—there are enormous public benefits to be gained through herd immunity when new vaccines are introduced, but individuals may be unwilling to take on the entire risk themselves.[9]

Second, by reducing vaccine manufacturers' exposure to liability for adverse events, indemnification schemes increase their willingness to provide a steady supply of new

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[6] In 2019, hesitancy and misinformation were viewed by the WHO as the largest threats to achieving vaccine success. WORLD HEALTH ORGANIZATION, supra note 2; Jop de Vriieze, Suspicions grow that nanoparticles in Pfizer's COVID-19 vaccine trigger rare allergic reactions, SCIENCE (Dec. 21, 2020), https://www.science.org/content/article/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

[7] John D. Winter, Camille L. Fletcher & Greg Margolis, Vaccine-Related Liability: Past Approaches, Current Challenges, and Proposals for Encouraging Future Innovation and More Widespread Vaccine Use, 76 FOOD AND DRUG L.J. 2 (2021).

[8] See Christopher Hodges, Covid-19 Vaccines: Injury Compensation Issues, Oxford Legal Research Paper Series, July 2020, at 4, available at https://www.law.ox.ac.uk/sites/files/oxlaw/vaccine_compensation_arrangements_.pdf

[9] See Michelle M. Mello, Rationalizing Vaccine Injury Compensation, 22 BIOETHICS 32, 34-35 (2008) ("The operating assumption here is that some individuals will be willing to undergo vaccination if they know that compensation for resulting injuries is easily obtainable through an administrative program, but not if the only remedy is to file a lawsuit, or if there is no remedy at all.").

vaccines.[10] This is especially critical in emergency situations, such as the COVID-19 pandemic, which demand that large volumes of vaccines be delivered within a short period of time. Relatedly, indemnity schemes can also helpfully minimize the perception of risk because a willingness to pay damages for vaccine-related adverse reactions reinforces a measure of confidence broadly in the institutions responsible for overseeing the safety and efficacy of the vaccine. At the very least indemnity schemes signal that the social benefits of the vaccines far outweigh the risks of adverse reactions for a substantial portion of the public.

The two leading concerns—vaccine hesitancy and the spectre of significant liability for vaccine manufacturers—have historically driven the adoption of vaccine indemnity programs. For example, following an influenza pandemic warning in 1976, vaccine manufacturers with whom the U.S. federal government had contracted to produce vaccines for a national immunization campaign refused to release the vaccines unless the government granted indemnification for potential vaccine adverse effects.[11] Congress capitulated and passed the National Swine Flu Immunization Program of 1976 to do just that.[12] A decade later in 1986, the United States' National Vaccine Injury Compensation Program (VICP) was established with the recognition that lawsuits against vaccine manufacturers would deter vaccine production, leading to shortages and a reduction in U.S. vaccination rates.[13] The VICP had a number of objectives reflecting the importance of aligning the risks and concerns of a diverse set of actors with legislative design features necessary for the effective deployment and administration of a national immunization policy.[14]

The non-indemnity related legislative features include coordinated record-keeping, reporting by health care professionals of vaccine adverse reactions to a centralized

[10] See Hodges, supra note 8, at 4.
[11] D.J. Sencer & J.D. Millar, Reflections on the 1976 Swine Flu Vaccination Program, 12(1) EMERG INFECT DIS. 29 (2006).
[12] Pub. L. No. 94-380, 90 Stat. 1113 (codified at 42 U.S.C. §247b), http://www.gpo.gov/fdsys/pkg/STATUTE- 90/pdf/STATUTE-90-Pg1113.pdf Specifically, §247b(k)(2)(A) of the Act that codified the Program provided that "[t]he United States shall be liable with respect to claims submitted after September 30, 1976 for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program . . .".
[13] National Vaccine Injury Compensation Program, HEALTH RESOURCES & SERVICES ADMINISTRATION (Aug. 2022), https://www.hrsa.gov/vaccine-compensation
[14] H. Cody Meissner, Narayan Nair & Stanley A. Plotkin, The National Vaccine Compensation Program: Striking a Balance Between Individual Rights and Community Benefit, 321 JAMA 343 (Jan. 29, 2019) (describing the VICP's goals to include: "compensate vaccine recipients and families alleged to have experienced a vaccine-related injury, stabilize the vaccine supply by reducing the number of claims brought against vaccine manufacturers, minimize the number of inappropriate claims, coordinate immunization record keeping, require health care professionals to report certain adverse events after immunization through the Vaccine Adverse Event Reporting System, standardize vaccine-specific warnings by creating Vaccine Information Statements, and decrease civil litigation by providing liability protection for vaccine manufacturers and administrators.")

system, and standardizing vaccine-specific warnings to better convey information to the public.[15]

Professor Michelle Mello has identified several secondary ex post non-consequentialist justifications which do not appear explicitly to motivate the establishment of indemnity schemes but nonetheless add meaningful rationales for their use: (1) minimizing the randomized harms of the coercive intervention; (2) providing a reciprocal safety net to frontline workers who have the professional obligation to serve the public during public health emergencies; (3) providing a safety net to those most at risk in getting vaccinated who act against self-interest in receiving vaccination to either benefit society or comply with vaccine mandates; (4) expressing solidarity by "reflecting a broader social judgment that medical risks should be shared"; and (5) compensating for failures in informed consent during public health emergencies.[16] In combination, the justifications for indemnification schemes attempt to inform government design of policies that effectively balance individual risk, societal benefits and incentives to vaccines manufacturers.[17] These schemes also seem the ethically appropriate policy choice in view of the necessary risks involved for vaccine developers, the population at large, and especially for those few who will suffer the occasional adverse event and for whom the cost of treatment for (or other loss related to) the adverse reaction could be significant.

Given the substantial public health benefits of vaccines, many national governments and intergovernmental bodies have created systems through which vaccine manufacturers are indemnified for most vaccine-related liability. There are various mechanisms through which liability can be limited, while those injured by vaccines are simultaneously compensated, including: (1) legislation that gives claimants an alternative (either exclusive or supplemental) to a judicial tort remedy; (2) a dedicated institution (specialized board or court) to review all vaccine injury claims; (3) an insurance program that protects (either fully or partially) vaccine manufacturers; or (4) a change in the underlying tort law relating to vaccine injury (e.g., removing a cause of action for "failure to warn" or limiting the amount of recoverable damages).[18]

In the United States, several legislative schemes are in place through which vaccine manufacturers are indemnified and compensation awarded to those injured by vaccines.[19] These will be discussed in greater detail below in Parts III and IV. In the

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[15] Id.
[16] See Michelle M. Mello, Rationalizing Vaccine Injury Compensation, 22 BIOETHICS 32, 36-40 (2008)
[17] Thus, for example, "[i]n the PREP Act, Congress made the judgment that, in the context of a public health emergency, immunizing certain persons and entities from liability was necessary to ensure that potentially life- saving countermeasures will be efficiently developed, deployed, and administered." See The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures, https://crsreports.congress.gov/product/pdf/LSB/LSB10443 (updated April 13, 2022)
[18] National Research Council, Vaccine Injury Compensation and Liability Remedies, in VACCINE SUPPLY AND INNOVATION (1985).
[19] The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures, CONGRESSIONAL RESEARCH SERVICE (Apr. 13, 2022).

international context, academics have suggested a global vaccine injury compensation system that would balance the competing principles of promoting immunization, while preserving individual dignity.[20] For example, Professors Halabi and Omer suggest that the WHO and existing national systems should work together to create a fund to compensate vaccine-related injuries, which could be supported by an excise tax charged by an independent organization (e.g., Gavi) when distributing vaccines. While some commentators have criticized the proposal for relying on examples of the experimental Zika and Ebola vaccines,[21] the idea of a centralized mechanism to indemnify manufacturers has become especially important in light of the COVID-19 pandemic.[22] Ultimately, however, a variety of approaches exist to limit vaccine manufacturers' liability, including: (1) full immunity that prevents individuals from receiving compensation and shifts costs to patients; (2) an indemnification system wherein governments compensate injuries through contracts with vaccine manufacturers (e.g., the EU and AstraZeneca, the Dominican Republic and Pfizer); and (3) a no- fault compensation system in which individuals apply to a central fund for compensation and no liability ultimately attaches to manufacturers.[23]

[20] The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures, CONGRESSIONAL RESEARCH SERVICE (Apr. 13, 2022).
[21] Anna Mastroianni & Leslie M. Henry, Legal Complexities of Global Vaccine Compensation Systems, 317 JAMA 1911 (2017).
[22] 22 Professor Halabi has also proposed a global strategy for countering the disincentive of vaccine product liability during pandemics that involves combining no-fault compensation systems in countries with an international insurance system and a compensation mega-fund for centralized mass claims administration by the WHO. See Sam F. Halabi, Solving the Pandemic Vaccine Product Liability Problem, 12 U.C. IRVINE L. REV. 111 (2021). There are at between 19 and 25 countries or provinces with no fault compensation schemes. See Clare Lookera & Heath Kelly, No-fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes, 89 Bull World Health Organ., 371–378 (2011) (identifying 19 countries) and Sam Halabi, Andrew Heinrich, Saad B. Omer, No-fault Compensation for Vaccine Injury – The Other Side of Equitable Access to COVID-19 Vaccines, N ENGL J MED. 2020; 383:e125 (identifying 25 countries).
[23] Liability Issues Related to COVID-19 Vaccine Manufacturing and Global Distribution, CONGRESSIONAL RESEARCH SERVICE (Aug. 19, 2021).

III. A Brief History of Vaccine Indemnity Schemes

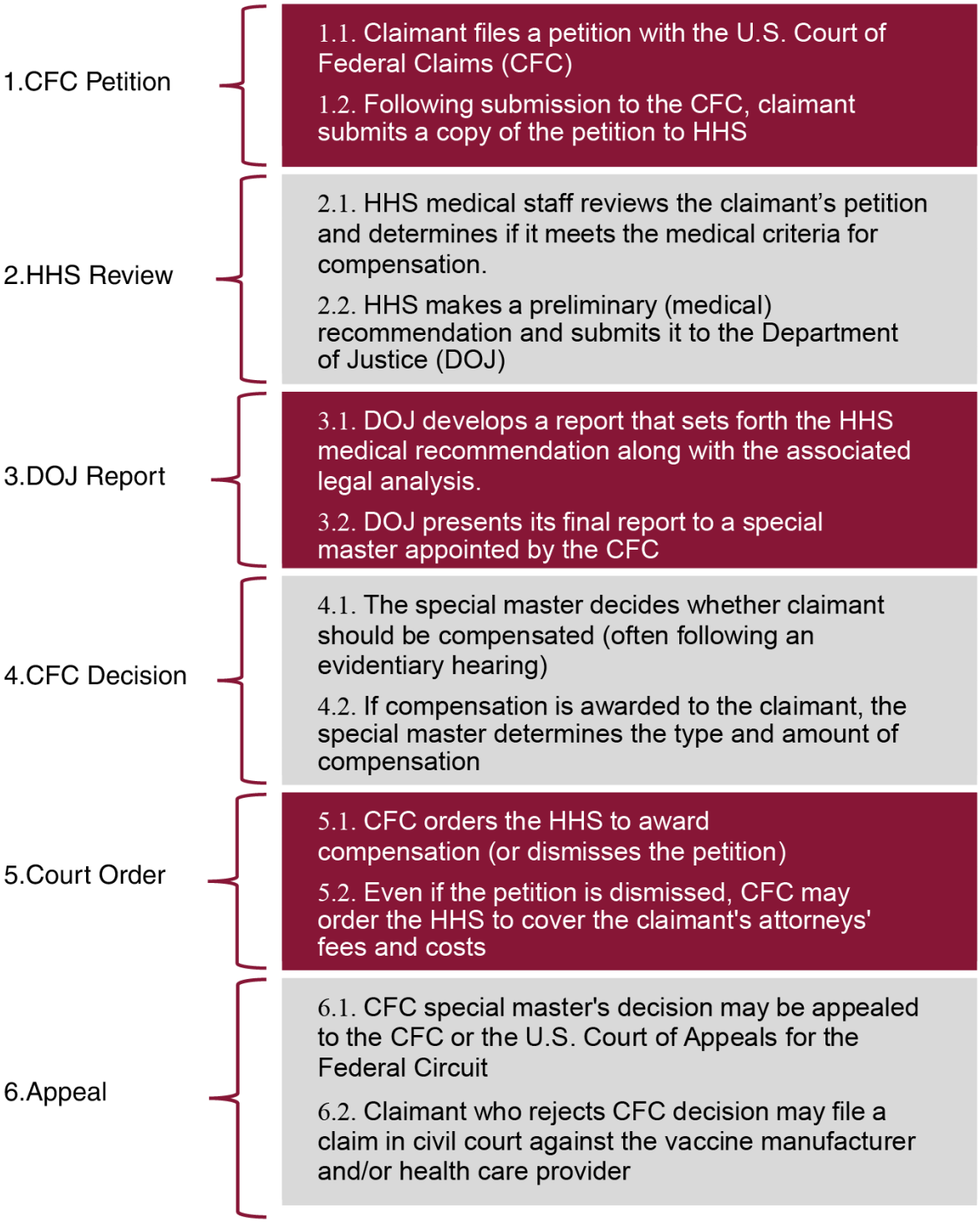
1.United States

In the United States, the National Childhood Vaccine Injury Act (NCVIA) was signed into law by President Reagan in 1986 to eliminate the liability of vaccine manufacturers and encourage a steady supply of vaccines in the country.[24] NCVIA established the National Vaccine Injury Compensation Program (VICP), which created an adversarial, no-fault alternative to the traditional tort system.[25] Administered by the U.S. Department of Health and Human Services (HHS) and funded through a $0.75 (per dose) excise tax on vaccines licensed by the Food and Drug Administration (FDA),[26] VICP allows individuals injured by vaccines to file a petition with the Court of Federal Claims to obtain compensation.[27] The petition is reviewed by HHS medical staff who forward a recommendation to the U.S. Department of Justice, which then drafts a report containing legal analysis based on the HHS medical recommendation and submits it to a court- appointed special master. The special master decides whether the petitioner should be compensated and, if so, determines the amount and type of compensation. On average, the VICP process takes 2-3 years to complete.[28] Petitioners who reject the special master's decision may subsequently file a claim in civil court against the vaccine manufacturer and/or the health care provider who administered the vaccine.[29] The VICP process is summarized in Figure 1 below:

[24] 42 U.S.C. §§ 300aa-1 to 300aa-34.
[25] Unlike in the tort system, a no-fault compensation scheme does not require the claimant to prove negligence or other fault of the vaccine manufacturer or health care provider in order to obtain compensation for injuries. See Randy G. Mungwira et al., Global landscape analysis of no-fault compensation programmes for vaccine injuries: A review and survey of implementing countries, 15 PLOS 1 (2020).
[26] About the National Vaccine Injury Compensation Program, HEALTH RESOURCES & SERVICES ADMINISTRATION (Jul. 2022), https://www.hrsa.gov/vaccine-compensation/about
[27] HEALTH RESOURCES & SERVICES ADMINISTRATION, supra note 13.
[28] Hodges, supra note 8, at 5.
[29] HEALTH RESOURCES & SERVICES ADMINISTRATION, supra note 13.

Figure 1

Overview Of the VICP Process[30]



[30] Id; see also Compensation Programs for Potential COVID-19 Vaccine Injuries, CONGRESSIONAL RESEARCH SERVICE (Oct. 20, 2021), https://crsreports.congress.gov/product/pdf/R/R46982

According to HHS, during the period from October 1, 1988, to August 1, 2022, 25,187 VICP petitions were filed, of which 23,808 related to injuries and 1,379 to deaths.[31] Further, as of August 1, 2022, 21,313 VICP petitions have been adjudicated.[32] Of these, 9,137 were determined to be compensable, while 12,176 were dismissed.[33] The HHS estimates that between 2006 and 2019, for every 1 million doses of VICP-eligible vaccines that were distributed, approximately 1 individual was compensated.[34] To date, the total compensation paid out over the life of the VICP is roughly $4.7 billion.[35]

As previously noted, the establishment of VICP was in large part motivated and shaped by the lessons learned during the failed swine flu vaccination program in 1976.[36] Specifically, many vaccine manufacturers were hesitant to produce swine flu vaccines due to concerns about potential liability for post-immunization adverse effects, such as the Guillain-Barré syndrome.[37] Since its introduction, the VICP has been largely successful in boosting immunization rates in the United States by removing disincentives for vaccine manufacturers, although there remains a need for initiatives directed at overcoming persistent vaccine skepticism—a need made quite acute by the controversy surrounding COVID-19 vaccination efforts. Awareness raising efforts focused on the efficacy of vaccines in promoting and securing public health, despite the rare negative occurrences that require compensation,[38] remains essential for all countries.

2.Other Countries

A number of developed countries established no-fault indemnification programs for rare vaccine-related injuries and deaths starting in the 1970s, including Switzerland (1970), France, (1975), Japan (1976), Denmark (1978), Germany (1979) and the United Kingdom (1979).[39] Most of these compensation programs are managed by national governments with funding from national treasuries, and require claimants to have significant, long-lasting adverse health effects.[40] In contrast to the adversarial system exemplified by VICP, which is court-like and involves lawyers and judges,

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[31] National Vaccine Injury Compensation Program Data Report, HEALTH RESOURCES & SERVICES ADMINISTRATION (Aug. 1, 2022), at 5, https://www.hrsa.gov/sites/default/files/hrsa/vicp/vicp-stats-08-01-22.pdf
[32] Id. at 7.
[33] Id. at 5.
[34] Id. at 1.
[35] Id.
[36] 36 National Research Council, Liability for the Production of and Sale of Vaccines, in VACCINE SUPPLY AND INNOVATION (1985).
[37] H. Cody Meissner, Narayan Nair & Stanley A. Plotkin, The National Vaccine Compensation Program: Striking a Balance Between Individual Rights and Community Benefit, 321 JAMA 343 (Jan. 29, 2019).
[38] James Hamblin, Why the Government Pays Billions to People Who Claim Injury by Vaccines, THE ATLANTIC (May 14, 2019), available at https://www.theatlantic.com/health/archive/2019/05/vaccine-safety-program/589354/
[39] Mungwira et al., supra note 255; National Research Council, Appendix E: Vaccine-Injury Compensation in Other Countries, in VACCINE SUPPLY AND INNOVATION (1985), https://www.ncbi.nlm.nih.gov/books/NBK216811/
[40] Geoffrey Evans, Vaccine injury compensation programs worldwide, 17 VACCINE 25 (1999).

many countries have opted for a non-adversarial administrative model. An example is the United Kingdom's Vaccine Damage Payment Scheme (VDPS), which was introduced in 1979 and provides a single lump-sum payment (currently GBP 120,000) to claimants who were "severely disabled" (at least 60%) following the administration of a listed vaccine.[41] While VDPS claims processing is relatively efficient and takes 6 months on average, the historical success rate of claimants under the scheme is, however, less than 10%.[42] In addition to the compensation scheme, claimants may pursue a civil remedy in court.[43]

An administrative model that has been recognized as highly successful is that used by Scandinavian countries. The Scandinavian approach incorporates vaccine indemnification within a broader compensatory system for injuries caused by medicinal products, which is in turn integrated into an even larger scheme for the compensation of patient injuries.[44] The system is investigative (i.e., non-adversarial) in nature and is based on eligibility criteria (no-fault). It is funded in large part by insurance payments of pharmaceutical companies. The comprehensive, integrated nature of the Scandinavian approach has been noted as being very effective in providing the confidence and support necessary for mass vaccination programs, while affording fair compensation where needed and also ensuring continuous improvement in practice due to efficient data collection and cross-agency sharing.[45]

A salient example of the Scandinavian approach is Sweden, which has established a specialized insurance scheme called the Swedish Pharmaceutical Insurance (SPI)[46] specifically for compensating injuries caused by any pharmaceutical product purchased from a legitimate dealer in Sweden or received in a Swedish medical facility.[47] The scheme also covers adverse side effects due to participation in clinical trials and is coordinated with the country's two other specialized insurance schemes providing compensation for injuries not covered by ordinary healthcare insurance the Patient Insurance and the Road Traffic Insurance.[48] SPI is financed by the shareholders of LFF Service AB (the Swedish Pharmaceutical Insurance Service) comprising, most notably, pharmaceutical companies, R&D companies and medical

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[41] Hodges, supra note 8, at 5.
[42] Id. (indicating that claimant success rate under the VDPS is "typically less than 10%"); Jacqui Wise, Covid-19: UK makes first payments to compensate injury or death from vaccines, BMJ (Jun. 24, 2022), https://doi.org/10.1136/bmj.o1565 (indicating that the historical success rate under the VDPS is 1.7%). See also NHS Business Services Authority, Vaccine Damage Payment Scheme, https://www.nhsbsa.nhs.uk/what-we-do/vaccine-damage-payment-scheme-vdps ("The average non-COVID-19 related claim takes around 6 months to investigate and process from the date we receive a claimant's application form and request their medical records.")
[43] National Research Council, supra note 3939. Payment received from the compensation scheme, if any, is deducted from the court award. Id.
[44] Hodges, supra note 8, at 5.
[45] Id.

[46] In Swedish language, the insurance scheme is called "Svenska Läkemedelsförsäkringen."
[47] A unique type of insurance, Läkemedelsförsäkringen, https://www.lff.se/a-unique-type-of-insurance
[48] Id., at What is covered by the insurance?

universities.[49] LFF handles not only the financing, but also the investigation and administrative processes related to SPI.

The Swedish indemnification scheme is “no-fault” and covers any personal injury (physical and mental) “that with preponderant probability has been caused by a pharmaceutical product and which could not reasonably have been predicted by the doctor.”[50] The time limit for the submission of a claim is 10 years after receiving the relevant medication.[51] Claims are evaluated by LFF claims adjusters in coordination with medical science experts and take on average 4 months to process.[52] The available data indicates that the success rate is around 30%.[53] The amount of compensation is computed based on annually-adjusted tables promulgated under the Tort Liability Act and may also include compensation for additional expenses, pain and suffering, loss of income and the payment of permanent additional expenses.[54] The decision of an SPI claim adjuster may be appealed to the Pharmaceutical Injury Panel (PIP), an independent panel comprised of medical and legal experts as well as laymen appointed by the Swedish government.[55] Claimants unsatisfied with the final PIP decision may initiate suit against SPI in a civil court.[56]

IV. An Overview of Principal Covid-19 Vaccine Indemnity Schemes

1.United States

In the United States, those injured by COVID-19 vaccines can receive compensation through what is known as the Countermeasures Injury Compensation Program (CICP).[57] CICP was established by the Public Readiness and Emergency Preparedness Act (PREPA), which was signed into law by President Bush in 2005.[58] The purpose of PREPA was to protect vaccine manufacturers, as well as device and drug manufacturers, from liability during declared public health emergencies, including pandemics and security threats. Notably, CICP differs from VICP in that it does not cover vaccines for endemic diseases, such as seasonal influenza, and

[49] Id., at Who provides this insurance? LFF shareholders are charged an annual service fee and premium directly related to the size of their operations. Id., at What are the fees and premium?
[50] Id., at Which injuries will the insurance indemnify?
[51] Id.
[52] Id., at How long does the process take?
[53] Om du skadats av ett läkemedel, Läkemedelsförsäkringen, https://www.lff.se/om-du-skadas-av-ett-lakemedel/ ; Einar Perman, Reimbursing Side Effects of Pharmaceutical Drugs - a Scandinavian Specialty, 29(1) J. INSURANCE MED. 36 (1997), https://www.aaimedicine.org/journal-of-insurance-medicine/jim/1997/029-01-0036 pdf (“About 450 claims are handled every year, and 25-30 percent of these are reimbursed. About 10 percent of refused claims are appealed to the review board, which reverses about 10-20 percent of appealed decisions”).
[54] Läkemedelsförsäkringen, supra note 47, at What is covered by the insurance?
[55] Läkemedelsförsäkringen, supra note 47, at Is it possible to appeal? The opinion of the Panel is advisory, but SPI usually follows its recommendation. Id.
[56] Id.
[57] Countermeasures Injury Compensation Program, HEALTH RESOURCES & SERVICES ADMINISTRATION (Nov. 2020), https://www.hrsa.gov/cicp VICP does not extend to vaccines against COVID-19. See Covered Vaccines, HEALTH RESOURCES & SERVICES ADMINISTRATION (Aug. 2022), https://www.hrsa.gov/vaccine - compensation/covered vaccines
[58] 42 U.S.C. § 274d-6d.

claims are resolved administratively through HHS rather than through the judicial process in the Court of Federal Claims.[59] Further, CICP is paid for through appropriations rather than through taxes, and compensation is limited to medical expenses, loss of employment income and a fixed death benefit (i.e., no pain-and-suffering damages or attorneys' fees, in contrast to VICP).[60] Despite the availability of CICP for COVID-19 injury compensation, many have criticized the program for lacking transparency, certainty and efficiency.[61] Notably, some have argued that the program has overly stringent requirements, since claims are required to be filed within a year, compensation is capped and the program is complex and difficult to use.[62]

[59] Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP), HEALTH RESOURCES & SERVICES ADMINISTRATION (Apr. 2021), https://www.hrsa.gov/cicp/cicp-vicp

[60] CONGRESSIONAL RESEARCH SERVICE, supra note 30.

[61] Lloyd Dixon, Kenneth R. Feinberg, Nicholas M. Price & Paul Rheingold, COVID-19 Vaccine Liability and Compensation in the United States, RAND CORP. (2021); see also Tom Hals, COVID-19 Era Highlights U.S. 'Black Hole' Compensation Fund for Pandemic Vaccine Injuries, REUTERS (Aug. 21, 2020); Lauren Gardner, Vaccine injury compensation programs overwhelmed as congressional reform languishes, POLITICO (Jun. 1, 2022

[62] MacKenzie Sigalos, you can't sue Pfizer or Moderna if you have severe Covid vaccine side effects. The government likely won't compensate you for damages either, CNBC (Dec. 17, 2020).

Figure 2 below compares the essential parameters of CICP with those of VICP:

Figure 2 : CICP VS. VICP: A Comparison[63]

Parameter	CICP	VICP
Products covered	Medical countermeasures[64] against the following: – COVID-19 – Marburg – Ebola – Nerve Agents and Certain Insecticides (Organophosphorus and/or Carbamate) – Zika – Pandemic Influenza – Anthrax – Acute Radiation Syndrome – Botulinum Toxin – Smallpox	Vaccines against the following: – Diphtheria – Haemophiles influenza type b polysaccharide conjugate vaccines – Hepatitis A and B – Human papillomavirus – Seasonal influenza – Measles – Mumps – Meningococcal – Pertussis – Pneumococcal conjugate – Polio – Rotavirus – Rubella – Tetanus – Varicella
Injuries covered	– Serious physical injuries – Deaths	– Injuries with effects lasting for more than 6 months after the vaccine was administered *or* which resulted in inpatient hospitalization *and* surgery. – Deaths
Available benefits	– Medical expenses – Lost employment income – Death benefit	– Medical expenses – Legal expenses – Loss of future earning capacity – Pain and suffering (up to $250,000) – Death benefit (up to $250,000)
Legal fees and costs	Not recoverable	Recoverable if petition filed in good faith and on a reasonable basis

[63] HEALTH RESOURCES & SERVICES ADMINISTRATION, supra note 59.
[64] A countermeasure is defined by HHS as a "a vaccination, medication, device, or other item recommended to diagnose, prevent or treat a declared pandemic, epidemic or security threat." HEALTH RESOURCES & SERVICES ADMINISTRATION (Nov. 2020), supra note 57.

Eligible claimants	Injured countermeasure recipient or his/her legal or personal representative	Injured vaccine recipient or his/her legal or personal representative
Filing process	File Request Form and supporting documentation with the Secretary of HHS	File petition and documentation with the U.S. Court of Federal Claims and the Secretary of HHS
Filing deadline	1 year from administration/usage of countermeasure alleged to have caused the injury	– Injury: within three years after the first symptom or manifestation of onset or of the significant aggravation of the injury – Death: within 2 years of the death and within 4 years of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted
Resolution process	Administrative	Judicial
Appeals	– One step administrative reconsideration possible – No judicial appeal permitted	Judicial appeal by either party to higher courts possible
Program funding	Budget appropriations	Vaccine Injury Compensation Trust Fund (funded through an excise tax on each dose of covered vaccines)

2.Other National Schemes

The vast majority of countries have pursued indemnity schemes with vaccine manufacturers in the context of the COVID-19 pandemic, either individually or as part of a regional grouping. In Europe, where liability exemptions are less common than in the U.S., vaccine manufacturers sought waivers during their negotiations with European Union (EU) institutions shielding them from liability except in cases of "wilful misconduct."[65] While the provisions of the ultimate contracts between the EU which negotiated on behalf of its 27 Member States and various pharmaceutical companies have been kept secret to a significant extent, available sources indicate that the degree to which vaccine makers were afforded protections from future

[65] Matt Apuzzo & Selam Gebrekidan, Governments Sign Secret Vaccine Deals. Here's What They Hide, N.Y. TIMES (Jan. 28, 2021), https://www.nytimes.com/2021/01/28/world/europe/vaccine-secret-contracts-prices.html; Donato Paolo Mancini & micheal Peel, Covid-19 vaccine makers lobby EU for legal protection, FINANCIAL TIMES (Aug. 26, 2020), https://www.ft.com/content/12f7da5b-92c8-4050-bcea-e726b75eef4d ; Gabriela Galindo, Coronavirus: Belgian experts 'shocked' as AstraZeneca seeks liability waiver for vaccine, BRUSSELS TIMES (Aug. 21, 2022), https://www.brusselstimes.com/127905/coronavirus-belgian-experts-shocked-as-astrazeneca-seeks-liability-waiver-for-%20vaccine

liability was tied to the pricing of their respective vaccines. For example, the EU contract with AstraZeneca stipulated that in exchange for a lower vaccine price (EUR 2.50 per dose), the company would only be liable for legal costs up to a certain amount and that beyond this threshold, indemnification for vaccine-related injuries would become the responsibility of EU Member States.[66] While technically vaccine liability remained with the company, there is indication that the EU's contract with AstraZeneca included a narrow definition of "side-effects," constraining the ability of vaccine users to claim compensation.[67] Conversely, the consortium of Sanofi and GlaxoSmithKline did not obtain any liability waiver from the EU in exchange for a higher vaccine price (EUR 10 per dose).[68]

In Japan, the national no-fault indemnity scheme pre-dates COVID-19 (1976) and compensates for "abnormal side effects result[ing] from preventive vaccination."[69] The Japanese scheme also covers technologies beyond vaccines to incentivize medical product development.[70] Prior to the commencement of the country's COVID-19 immunization program in February 2021, Japan undertook amendments of its Immunization Act and related regulations. The amendments authorized the government of Japan to, among other things, include in its supply contracts with vaccine manufacturers provisions allowing the government to compensate manufacturers for the "unavoidable side effects" of their vaccines.[71] Provisions imposing the financial responsibility for vaccine-related injuries on the government of Japan were indeed included in the country's contracts with Pfizer and AstraZeneca for the supply of 120 million doses each of their respective vaccines.[72]

In South Korea, the national vaccine indemnity scheme provides compensation for "injur[ies] caused by the relevant vaccination," irrespective of the nature of the vaccine or the fault, or lack thereof, of the vaccine producer or administrator.[73]

Similarly, to Japan and other developed countries, South Korea agreed to compensate vaccine-related injuries in its supply contracts with COVID-19 vaccine manufacturers.[74] Following the onset of the country's vaccination program, the South

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[66] Francesco Guarascio, COVID-19: AstraZeneca gets partial immunity in low-cost EU vaccine deal, WORLD ECONOMIC FORUM (Oct. 2, 2020), https://www.weforum.org/agenda/2020/10/astrazeneca-partial-immunity-eu- vaccine/
[67] Id.
[68] Id.
[69] National Research Council, supra note 36.
[70] Yasuhiro Fujiwara, Yukata Onda & Shuichiro Hayashi, No-fault Compensation Schemes for COVID-19 Medical Products, 397 THE LANCET 1707 (2021).
[71] 71 Norihisa Yamamoto, Yuichi Takahashi & Shuichiro Hayashi, Legal and regulatory processes for Japan's COVID-19 immunization program, 39(43) VACCINE 6449 (Oct. 15, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8413481
[72] Kosuke Takeuchi, Japan to shoulder COVID vaccine liability risks, NIKKEI ASIA (Aug. 20, 2022), https://asia.nikkei.com/Business/Pharmaceuticals/Japan-to-shoulder-COVID-vaccine-liability-risks
[73] Dasol Ro, Daeun Ro & So Yoon Kim, COVID-19 Vaccine Injury Compensation Programs, 3 J. GLOBAL HEALTH SCIENCE 1 (2021), https://e-jghs.org/DOIx.php?id=10.35500/jghs.2021.3.e21
[74] Sangmi Cha, South Korea to compensate nurse paralysed after COVID-19 shot, REUTERS (Aug. 6, 2021), https://www.reuters.com/world/asia-pacific/skorea-nurse-eligible-govt-benefit-after-covid-19-vaccine-reaction-2021-08-06/

Korean Disease Control and Prevention Agency (KDCA) was forced to modify the rules of the country's compensation scheme, specifically the requirement that claimants clearly demonstrate causality between the side effects and the vaccine. Facing criticism and seeking to address vaccine hesitancy, KDCA acknowledged lack of credible data relating to COVID-19 vaccine effects and decided to loosen the causality requirement.[75] The current scheme provides up to up to KRW 10 million (~ USD 7,700) for severe side effects, incapacitation or death due to an administered vaccine.[76] By 6 August 2021, the KDCA had reviewed a total of 1,562 cases, including 14 deaths, for possible compensation for injuries stemming from COVID-19 vaccination, of which 983 had been compensated.[77]

Like the South Korean experience, the existing vaccine indemnity system in Italy was found lacking following the onset of the national COVID-19 vaccination program, albeit for different reasons. The Italian scheme, which was established by Law 210 of 1992, extended only to "vaccination required by the law or by order of an Italian health authority."[78]

Given that COVID- 19 vaccination was not made compulsory in Italy but was merely recommended, injuries stemming from COVID-19 vaccination fell outside the scope of the existing system. In July 2021, local health authorities formally requested the Italian Health Ministry to provide guidance as regards the management of requests for the compensation of injuries caused by COVID-19 vaccination.[79] By October 2021, the Italian Medicines Agency (AIFA) reported 101,110 complaints of side-effects related to COVID-19 vaccination, of which 14.4% were considered serious.[80] In response to significant public pressure, in January 2022, the Italian government introduced a proposal for the extension of the country's vaccine indemnity scheme to non-compulsory vaccinations.[81] In addition, the government proposed the allocation of EUR 50 million in 2022 and EUR 100 million in 2023 to a fund that will

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[75] Stefano D'Errico et al., "First Do No Harm:" No-Fault Compensation Program for COVID-19 Vaccines as Feasibility and Wisdom of a Policy Instrument to Mitigate Vaccine Hesitancy, 9 VACCINES 1116 (2021); Ro et al., supra note 73. A similar problem with the causality requirement has been experienced by institutions in other countries. In the United Kingdom, for example, the NHS Business Services Authority, the body that administers the country's Vaccine Damage Payment Scheme (VDPS), reported receiving 1681 claims in relation to COVID-19 vaccines as of 20 May 2022. Wise, supra note 42. The processing of these claims has been reported to be slow due to, among other things, difficulties with "[e]stablishing a causal relationship between the vaccines and their potential adverse effects." Id.

[76] Ro et al., supra note 73; Asia Watch, South Korea Expands Compensation for Vaccine Side Effects, ASIA PACIFIC FOUNDATION OF CANADA (May 13, 2021), https://www.asiapacific.ca/asia-watch/south-korea-expands-%20compensation-vaccine-side-effects

[77] Cha, supra note 74.

[78] D'Errico et al., supra note 75; see also Paola Frati et al., No-Fault Compensation and Anti-COVID-19 Compulsory Vaccination: The Italian Context in a Broad View, 10 VACCINES 635 (2022).

[79] D'Errico et al., supra note 75;

[80] Giuseppe Fonte & Emilio Parodi, Italy to set aside 150 mln euros for COVID vaccination compensation – draft, REUTERS (Jan. 21, 2022), https://www.reuters.com/world/europe/italy-set-aside-150-mln-euros-covid-vaccination- compensation-draft-2022-01-21/

[81] Id.

compensate persons who suffered permanent disabilities due to COVID- 19 vaccination.[82]

Finally, the government of Australia put in place a custom “vaccine claims scheme” designed to deal specifically with injuries stemming from COVID-19 vaccination. The scheme, which was formally introduced by the Australian Department of Health and Aged Care in September 2021,[83] is open to all persons “who suffer a moderate to severe impact following an adverse reaction” to an approved COVID-19 vaccine.[84] It covers only losses or expenses of AUD 1,000 and above.[85] The Australian compensation scheme has been recognized for its efficiency and robustness in facilitating the twin aims of sufficient vaccine production and fair compensation.[86] Within the first three months of its introduction on 6 September 2021, more than 10 thousand people registered their interest in making a claim under the scheme.[87]

3.Global Level

At the global level, the COVID-19 Vaccines Global Access (COVAX) initiative—co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the WHO—has set up the first (and thus far only) international vaccine injury compensation mechanism covering 92 low- and-middle-income countries (LMICs).[88] Funded by donor contributions, the COVAX No-Fault Compensation Program seeks to attain the dual objective of providing a life-saving supply of COVID-19 vaccines to citizens of resource-constrained economies, while also fairly compensating those injured by vaccine-related adverse events.[89] It is backed by a USD 150 million fund

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[82] Id.
[83] The scheme was formulated in a document entitled “COVID-19 Vaccine Claims Scheme Policy 2021,” made under the Financial Framework (Supplementary Powers) Regulations 1997. See Bill Madden & Tina Cockburn, Australia: The COVID–19 vaccine claims scheme: policy document published, MONDAQ (May 2, 2022), https://www.mondaq.com/australia/healthcare/ 1188946/the-covid19-vaccine-claims-scheme-policy-document- published; Paul Hayes, Finalised no-fault indemnity scheme gives GPs ‘peace of mind’, NEWSGP (Aug. 28, 2021), https://www1.racgp.org.au/newsgp/clinical/finalised-no-fault-indemnity-scheme-gives-gps-peac
[84] COVID-19 Vaccine Claims Scheme, DEPARTMENT OF HEALTH AND AGED CARE, AUSTRALIAN GOVERNMENT, https://www.health.gov.au/initiatives-and-programs/covid-19-vaccine-claims-scheme
[85] Id.
[86] Hau Dinh, What’s the new COVID vaccine indemnity scheme? Two legal experts explain, THE CONVERSATION (July 1, 2021).
[87] Jolyon Attwooll, Processing for COVID-19 vaccine compensation scheme to begin next month, NEWSGP (NOV. 17, 2021), https://www1.racgp.org.au/newsgp/professional/processing-for-covid-19-vaccine-compensation-schem
[88] Anne Mazur et al., COVAX no fault compensation program for COVID-19 vaccine injuries in 92 low and middle income countries, 39 VACCINE 7128 (2021). These nations are also known as Gavi COVAX Advance Market Commitment countries. See also No-fault Compensation Programme for COVID-19 Vaccines is a World First, WORLD HEALTH ORGANIZATION (Feb. 22, 2021).
[89] COVAX No-Fault Compensation Program: Explained, WORLD HEALTH ORGANIZATION (Jul. 7, 2022), https://www.who.int/initiatives/act-accelerator/covax/no-fault-compensation/covax-no-fault-compensation-program-explained

and administered by eleven COVAX regional centers spanning the globe.[90] The Program provides no- fault, lump-sum compensation to citizens and residents of the member countries "who have suffered a serious adverse event resulting in permanent impairment or death following the administration of a COVID-19 [v]accine received through the COVAX Facility until 30 June 2023."[91] To receive compensation, complainants must submit applications to the Program (through an online form, by email or regular mail) with evidence from a healthcare provider.[92]

The COVAX No-Fault Compensation Program offers the benefits of a standardized no- fault process to citizens and residents of poor countries, most of whom would otherwise be unable to obtain any recourse for vaccine-related injuries from institutions at the national level. The Program has streamlined, efficient procedures and is administered by a private entity (ESIS Inc.). Nonetheless, its impact has thus far been constrained by the slow progress of the COVAX initiative as a whole. Despite very ambitious goals, COVAX has thus far missed its targets and delivered only a very small portion (less than 5% as of the end of 2021) of the COVID-19 vaccines administered globally.[93]

As of early 2022, less than 10% of citizens of low-income economies were vaccinated against COVID-19, leading some commentators to label COVAX as a failure.[94] The slow implementation of COVAX had understandably induced the governments of many LMICs to seek individual supply contracts with the manufacturers of COVID-19 vaccines. As was the case with developed economies, LMIC governments were confronted with manufacturers' demands for vaccine injury indemnification. The responses of LMIC governments for such indemnification demands varied across countries. A notable example of a country that has thus far resisted manufacturers' requests for indemnification is India, which has contributed to the unavailability of some leading vaccines most notably those of Pfizer and Moderna in India.[95] Instead, the national immunization program in India has largely

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[90] Contact Us, COVAX AMC, https://covaxclaims.com/contact-us/; Abdul Ghafur, The Slippery Slope of Indemnity for COVID-19 Vaccine Manufacturers, THE WIRE, https://thewire.in/rights/vaccine-indemnity-covid-19-slippery-slope

[91] WORLD HEALTH ORGANIZATION, supra note 89.

[92] How to apply to the Program?, COVAX AMC, https://covaxclaims.com/how-to-apply/

[93] Olivia Goldhill, Rosa Furneaux & Madlen Davies, 'Naively ambitious': How COVAX failed on its promise to vaccinate the world, STAT (Oct. 8, 2021), https://www.statnews.com/2021/10/08/ how-covax-failed-on-its-promise- to-vaccinate-the-world/; Jamie Ducharme, COVAX Was a Great Idea, But Is Now 500 Million Doses Short of Its Vaccine Distribution Goals. What Exactly Went Wrong?, TIME (Sep. 9, 2021), https://time.com/6096172/covax- vaccines-what-went-wrong/

[94] Kate Elder, COVAX: A broken promise for vaccine equity, DOCTORS WITHOUT BORDERS (Feb. 21, 2022), Chelsea Clinton & Katelyn J. Yoo, Is COVAX To Blame For Failing To Close Global Vaccination Disparities?, HEALTH AFFAIRS (Jun. 14, 2022), https://www.healthaffairs.org/do/10.1377/forefront.20220609.695589/full/

[95] Protiti Roy, COVID-19: The Importance of Conditional Indemnity for Vaccine Makers, SCIENCE: THE WIRE (Apr. 8, 2021), https://science.thewire.in/health/covid-19-the-importance-of-conditional-indemnity-for-vaccine-makers/

been driven by domestically produced vaccines, on option that is at present certainly not available to the vast majority of LMICs.[96]

V. Impact of Indemnity Schemes on Access to Medicines In LMICS

There appears to be broad consensus that no-fault compensation programs are necessary to encourage continued vaccine development during pandemics while providing relief for those injured.[97] In particular, combining national compensation programs for routine vaccinations with the aforementioned WHO mechanism for emergency use authorizations is required to increase vaccine access and promote justice.[98] Importantly, during the Ebola outbreak, numerous West African governments refused to offer immunity to pharmaceutical companies, which resulted in a critical shortage of medicinal products.[99] Many countries have learned from this experience for COVID-19. For example, LMICs have proactively engaged with AstraZeneca in bilateral contracts to grant indemnity in return for the provision of COVID-19 vaccines. To complement the existing COVAX compensation scheme, policy experts have suggested the creation of a fund wherein higher-income countries contribute more, or instead manufacturers are charged a standard small tax amount.

Further, as described above, a variety of compensation schemes are possible, including both broad-based programs as well as epidemic-specific programs.[100] In light of the Ebola, Zika, and now COVID-19 pandemics, however, the establishment of a centralized (regional) indemnity framework such as an international immunity treaty across UN Member States, combined with a global compensation fund building upon existing approaches, may be a critical feature for consideration.

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[96] Why were Pfizer and Moderna vaccines not available in India? Health minister responds, WION (Feb. 23, 2022), https://www.wionews.com/india-news/why-were-pfizer-and-moderna-vaccines-not-available-in-india-health- minister-responds-454466

[97] Tommie Crum, Current situation of vaccine injury compensation program and a future perspective in light of COVID-19 and emerging viral diseases, F1000 RESEARCH (Dec. 7, 2021) (analyzing the COVID-19 vaccine injury compensation schemes in 27 countries across four continents).

[98] Sam Halabi, Andrew Heinrich & Saad B. Omer, No-Fault Compensation for Vaccine Injury — The Other Side of Equitable Access to Covid-19 Vaccines, 383 NEW ENG. J. MED. 125 (2020).

[99] Id

[100] John D. Winter, Cassye Cole & Jonah Wacholder, Toward a Global Solution on Vaccine Liability and Compensation, 74 FOOD AND DRUG L.J. 1 (2019).

Conclusion

The indemnification puzzle is an essential part of COVID-19 vaccine equity in the developing world. Higher-income countries who have a surplus of vaccines often cannot donate to lower-income nations because those countries do not have indemnity contracts or national legislation to limit manufacturer liability.[101] Achieving global COVID-19 equity (or equitable access to medicines in other future pandemic contexts) will involve not only reducing intellectual property barriers and increasing capacity for domestic production, but also creating the right incentives for manufacturers to produce vaccines for LMICs without facing the risk of immense liability. Transparent indemnity programs and compensation funds that simultaneously encourage much-needed innovation while reasonably and quickly compensating those individuals adversely affected by rare health events should be a global public health priority—especially for developing and least-developed countries.[102]

[101] Jon Cohen, Countries now scrambling for COVID-19 vaccines may soon have surpluses to donate, SCIENCE (Mar. 9, 2021).
[102] Gavin Yamey et al., It is not too late to achieve global Covid-19 equity, 376 BMJ 1 (2022) (noting that even when LMICs have resources to afford vaccines, "[t]he lack of transparency around vaccine prices and terms of contracts, including indemnity, has been a barrier to countries being able to negotiate and buy vaccines").

Appendix

Overview of Indemnity Schemes in Selected Countries

Country	Pre-COVID Scheme	COVID-Specific Scheme	Process	Funding	Products covered	Injuries covered	Benefits available
USA	VICP (1986) ✓	x	Judicial	Excise tax	Vaccines recommended for routine administration to children and/or pregnant women by CDC	Injuries with effects lasting for more than 6 months or which resulted in inpatient hospitalization and surgery; death	Medical expenses; legal expenses; loss of future earning capacity; pain and suffering (up to $250,00); death benefit (up to $250,000) (individual assessment)
	CICP (2005) ✓	x	Admin.	Budget	Vaccines, medication, devices, and other items identified by HHS	Serious physical injuries; death	Medical expenses; lost employment income; death benefit (individual assessment)

UK	✓ (1979)	x	Admin.	Budget	Vaccines for enumerated diseases and diseases specified by the Secretary of State	Injuries from vaccination resulting in severe disability (at least 60%)	One-off lump sum payment of GBP 120,000 (considered as a benefit, not compensation for damages incurred)
Sweden	✓ (1978)	x	Admin.	Insurance premiums paid by pharma. companies	Any pharmaceutical product purchased from a legitimate dealer in Sweden or received in a Swedish medical facility	Personal injury (physical and mental) “that with preponderant probability has been caused by a pharmaceutical product and which could not reasonably have been predicted by a doctor”	Compensation based on annually adjusted tables promulgated under the Tort Liability Act; additional expenses; pain and suffering; loss of income. compensation of permanent additional expenses

Japan	✓ (1976)	x	Admin.	Budget	Vaccines for diseases specified by law	Injuries; death	Medical expenses; funeral expenses; disability pension; annuity for person caring for disabled individual; death benefit (individual assessment)
South Korea	✓ (2015)	x	Admin.	Budget	Vaccines recommended by the government	Serious side effects; incapacitation; death	Lump-sum payment of up to KRW 10 million (individual assessment)
Italy	✓ (1992)	x	Admin.	Budget	Mandatory and recommended vaccines, transfusions, and haemo-derivatives	Injury or illness, from which a permanent physical–psychological impairment results; death	Any material and non-material damage resulting from vaccination (individual assessment)

Australia	x	✓ (2021)	Admin.	Budget	Enumerated COVID vaccines (AstraZeneca, Pfizer, Moderna, Novavax)	Anaphylactic reaction; thrombosis with thrombocytopenia syndrome; myocarditis; pericarditis; capillary leak Syndrome. demyelinating disorders, including Guillain Barre Syndrome (GBS); thrombocytopenia, including immune thrombocytopenia, identified as a final diagnosis	Lost earnings; out of pocket expenses; paid attendant care services; gratuitous attendant care; loss of capacity to provide domestic services; pain and suffering costs. deceased covid-19 vaccine recipient payments and funeral costs (individual assessment)
India	x	x	N/A	N/A	N/A	N/A	N/A

COVAX (global)	x	✓ (2020)	Admin.	Donor fund (USD 150 million)	Any COVID-19 vaccine received through the COVAX Facility	Serious adverse event resulting in permanent impairment or death	Lump sum derived by a formula (GDP per capita of country in which the claimant resides x 12 x a harm factor ranging from 1.5 to 0.1 dependent on the nature of the injury and level of impairment)

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25. Dasol Ro, Daeun Ro & So Yoon Kim, COVID-19 Vaccine Injury Compensation Programs, 3 J. Global Health Science 1 (2021)

26. Stefano D'Errico et al., "First Do No Harm:" No-Fault Compensation Program for COVID- 19 Vaccines as Feasibility and Wisdom of a Policy Instrument to Mitigate Vaccine Hesitancy, 9 VACCINES 1116 (2021)

27. Paola Frati et al., No-Fault Compensation and Anti-COVID-19 Compulsory Vaccination: The Italian Context in a Broad View, 10 VACCINES 635 (2022)

28. Sam Halabi, Andrew Heinrich & Saad B. Omer, No-Fault Compensation for Vaccine Injury — The Other Side of Equitable Access to Covid-19 Vaccines, 383 NEW ENG. J. MED. 125 (2020)

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