

Reforming the International Law and Organization of New Vaccines for the World's Most Vulnerable People

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The global system for developing new vaccines against diseases that disproportionately kill and disable the world's poorest people has become a victim of its own success. As the pace with which safe and effective vaccines against neglected tropical diseases are developed accelerates, the world is increasingly finding itself moving from a situation typified by low supply to one of dysfunctional demand. Safe and effective vaccines against chikungunya virus disease were approved in the last two years but remain largely undeployed despite a global epidemic. The governments where CHIKV levels its most significant toll have bigger and more expensive problems. At three hundred fifty dollars a dose, the vaccines are many times more than most victims of CHIKV make in a year and in some cases a decade. Thus, these vaccines that could save hundreds of lives, millions of dollars, and spare infants a fate of permanent blindness remains largely undistributed. Without changes, this appears to be the fate of emerging candidates against Lassa, Rift Valley Fever, and to some extent even characterizes the response to the mpox public health emergency. This Article analyzes this critical and growing problem in the global legal framework for vaccine access, including the inability of current global organizations

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to address it, and recommends measures to either fix the global vaccine infrastructure or establish an entirely new global procurement agency for vaccines against neglected tropical diseases.

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Introduction

On November 9, 2023, the U.S. Food and Drug Administration (FDA) granted marketing approval for the first and only vaccine against chikungunya virus disease (CHIKV), an affliction that takes its heaviest toll on infants, children, and the immunocompromised in some of the poorest countries in the world.¹ On the one hand, the approval of IXCHIQ®, the marketing name for

1. Susan Scutti, *FDA Approves First Chikungunya Vaccine*, FOGARTY INT'L CTR. (Jan. 2024), <https://www.fic.nih.gov/News/GlobalHealthMatters/january-february-2024/Pages/FDA-approves-first-chikungunya-vaccine.aspx> [<https://perma.cc/24F7-D6Y3>]; Gabriel Ribeiro dos Santos et al., *Global Burden of Chikungunya Virus Infections and the Potential Benefit of Vaccination Campaigns*, 31 NAT. MED. 2342–2349 (2025), <https://doi.org/10.1038/s41591-025-03703-w>. On January 19, 2026, Valneva withdrew its biologics license application (BLA) – its

the vaccine developed by a French life sciences firm Valneva, was pathbreaking success.² Under conventional assumptions of supply and demand, however, there should be no meaningful market for a CHIKV vaccine: the governments and people where the disease is endemic cannot afford it; there are not enough tourists from wealthy countries traveling to endemic regions to sustain a market; and defense or national security interests arguably do not provide sufficient incentives for wealthy governments to support research at the scale seen for diseases like HIV.³ Rather, supported by international vaccine charity the Coalition for Epidemic Preparedness Innovations (CEPI) and drawn by the incentive offered by FDA's priority voucher program, Valneva brought to market a candidate developed over decades at the U.S. National Institutes of Health and supported by a range of US government funders. IXCHIQ is the world's first licensed vaccine against chikungunya virus disease.⁴

However, the vaccine lists in the United Kingdom for £160.00⁵ and approximately €200 per dose in France.⁶ Governments that might purchase IXCHIQ in larger quantities face more urgent and expensive public health problems, and Gavi, the most important source of support for vaccine procurement in low- and middle-income countries, will not fund its purchase because

legal authorization to sell the vaccine in the United States – after FDA suspended its marketing license in August 2025 after reports of adverse events in elderly recipients. Press Release, *Valneva Provides Update On Chikungunya Vaccine IXCHIQ*, VALNEVA (Jan. 19, 2026), https://valneva.com/wp-content/uploads/2026/01/2026_01_19_IXCHIQ_US_Licence_Withdrawal_PR_EN_Final.pdf [<https://perma.cc/PH2Q-P2QA>]; *FDA and CDC Recommend Pause in Use of IXCHIQ® (Chikungunya Vaccine, Live) in Individuals 60 Years of Age and Older While Postmarketing Safety Reports are Investigated*, U.S. FOOD & DRUG ADMIN. (May 9, 2025), <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-and-cdc-recommend-pause-use-ixchiq-chikungunya-vaccine-live-individuals-60-years-age-and-older> [<https://perma.cc/B8KZ-PZJK>]; IXCHIQ remains licensed in Europe, Canada, Brazil, and the United Kingdom. Valneva, *Valneva Provides Chikungunya Vaccine IXCHIQ® Update*, YAHOO! FINANCE (Jan. 19, 2026), <https://uk.finance.yahoo.com/news/valneva-provides-chikungunya-vaccine-ixchiq-170000238.html> [<https://perma.cc/F77V-PW7Q>].

2. Press Release, *Valneva Receives First Marketing Authorization for IXCHIQ® in a Chikungunya Endemic Country*, VALNEVA (Apr. 14, 2024) <https://valneva.com/press-release/valneva-receives-first-marketing-authorization-for-ixchiq-in-a-chikungunya-endemic-country/> [<https://perma.cc/J6DS-BLCF>].

3. Maria Elena Bottazzi & Peter J. Hotez, “Running the Gauntlet”: Formidable Challenges in Advancing Neglected Tropical Diseases Vaccines from Development Through Licensure, and a “Call to Action,” 15 *HUM. VACCINES & IMMUNOTHERAPEUTICS* 2235–2242 (2019), <https://doi.org/10.1080/21645515.2019.1629254>; Compare the scale of U.S. government HIV/AIDS investment under PEPFAR, (authorizing \$15 billion over five years for HIV/AIDS response), with the absence of comparable national security appropriations for CHIKV; DARPA did in fact support data modeling for CHIKV spread, but it was primarily aimed at understanding data integration, rather than addressing the disease itself.

4. Susan Scutti, *FDA Approves First Chikungunya Vaccine*, FOGARTY INT’L CTR. (Jan. 2024), <https://www.fic.nih.gov/News/GlobalHealthMatters/january-february-2024/Pages/FDA-approves-first-chikungunya-vaccine.aspx> [<https://perma.cc/24F7-D6Y3>].

5. IXCHIQ®: The UK’s First Chikungunya Vaccine, WOODSTOCK ROAD CHEMIST (July 6, 2025), <https://woodstockroadchemist.com/introducing-ixchiq-at-woodstock-road-chemist-the-new-chikungunya-vaccine/> [<https://perma.cc/R3NY-KRXM>].

6. Vaishnavi Chandrashekhhar, *Serious Side Effects Dim Hopes for the First Chikungunya Vaccine*, 391 *SCIENCE* 536 (Feb. 5, 2026), <https://www.science.org/content/article/serious-side-effects-dim-hopes-first-chikungunya-vaccine> [<https://perma.cc/8D7A-7YSC>].

the disease does not impose a sufficiently high burden in one or more of its priority countries, most of which are sub-Saharan Africa.⁷

Thus, one of the great successes of modern vaccine research and development is adrift at sea: safe, effective, and purchased by almost no one.⁸ This is true despite widespread chikungunya outbreaks in Argentina, Bolivia, Brazil, Pakistan, and Peru, many of which are ongoing.⁹ What is more, currently promising vaccine candidates against other neglected diseases like Lassa, Chagas, and Rift Valley Fever may suffer the same fate. Indeed, the current epidemic of mpox, for which there are two safe and effective vaccines and a third that may be used second line, demonstrate the same problem.¹⁰

This Article assesses the contours and extent of this gap in what is otherwise the tremendous success of developments in the law and finance of vaccines against neglected diseases over the last three decades. What used to be characterized as a devastating lack of supply has become a problem of dysfunctional demand – the world increasingly has the vaccines, but the current structure of demand and financial resources means there is no one to pay for them. This Article also proposes immediate and actionable solutions based on the reform of Gavi's mandate to explicitly include the London Declaration on Neglected Tropical Diseases, bid scoring enhancements to promote technology transfer with manufacturers in endemic regions, the commitment of the G7 governments to elevate neglected diseases as part of their human security agenda, and ultimately the establishment of a special procurement fund for use by PAHO and UNICEF, the world's most important distributors of vaccines.

Part I of this Article assesses the history and current status of neglected diseases under international law. Part II analyzes the development of new legal institutions to facilitate vaccine access decades of efforts by the World Health Organization and UNICEF plateaued: Gavi and CEPI. Part II evaluates the international legal institutions developed to support the WHO -led effort toward

7. At the time of its U.S. licensure, IXCHIQ was reported to cost approximately \$350 per dose. John Loepky, *FDA Approves First Chikungunya Vaccine as Mosquito-Borne Diseases Spread*, HEALTHLINE (Nov. 15, 2023), <https://www.healthline.com/health-news/fda-approves-first-chikungunya-vaccine-as-mosquito-borne-diseases-spread> [https://perma.cc/XB7V-GJ2N]; Press Release, VALNEVA, *Valneva Responds to French Government's Call for Vaccine Supply of IXCHIQ Against Chikungunya Outbreak in La Réunion* (Mar. 24 2025), [https://valneva.com/press-release/valneva-responds-to-french-governments-call-for-vaccine-supply-of-ixchiq-against-chikungunya-outbreak-in-la-reunion/#:~:text=Saint%20Herblain%20\(France\)%2C%20March,agreements%20with%20the%20Islands%20wholesalers](https://valneva.com/press-release/valneva-responds-to-french-governments-call-for-vaccine-supply-of-ixchiq-against-chikungunya-outbreak-in-la-reunion/#:~:text=Saint%20Herblain%20(France)%2C%20March,agreements%20with%20the%20Islands%20wholesalers) [https://perma.cc/55VT-P9D2].

8. See, e.g., Rob Gatter, *The New Global Framework for Pandemic Influenza Virus and Vaccine Sharing in The GLOBALIZATION OF HEALTHCARE: LEGAL AND ETHICAL ISSUES* 272-85 (I. Glenn Cohen ed., 2013).

9. Mariam Amjad, *Chikungunya Surge in Pakistan: A Call for Rapid Public Health Measures*, 6 *INFECTIOUS DISEASES CLINICAL MICROBIOLOGY* 349-350 (2024); for an updated picture of chikungunya updates, see European Ctr. for Disease Prevention & Control, *Chikungunya Monthly Surveillance Report*, <https://www.ecdc.europa.eu/en/chikungunya-monthly> [https://perma.cc/R5UK-DE4L] (last visited Mar. 31, 2026).

10. Carmen Paun, *US Has Wasted Hundreds of Thousands of Vaccines Meant For Africa, Health Officials There Say*, POLITICO PRO (Jul. 17, 2025), <https://subscriber.politicopro.com/article/2025/07/mpox-africa-vaccines-wasted-foreign-aid-00460290> [https://perma.cc/GJ4J-ZCR5]; V. S. Mithi, *Mpox in Africa: Funding Cuts and Delayed Global Actions Fuelling New Epicentres*, 13 *LANCET GLOB. HEALTH* e1512, e1512–13 (2025), [https://doi.org/10.1016/S2214-109X\(25\)00241-4](https://doi.org/10.1016/S2214-109X(25)00241-4).

global vaccine access that originated in the 1960s. Part IV analyzes how this effort has retained critical gaps in access by those suffering from neglected diseases. Part V offers solutions to address this gap. Part VI provides a brief conclusion.

I. Neglected Diseases

Neglected tropical diseases (NTDs) represent a heterogeneous category of diseases caused by a variety of pathogens such as viruses, bacteria, parasites, fungi, and toxins, and are associated with significant adverse effects on health, social structures, and economic stability.¹¹ NTDs are more prevalent in the tropical regions, primarily affecting some of the most vulnerable people in the world, especially children.¹²

Together, malaria and NTDs cause an estimated 720,100 deaths and 62 million disability-adjusted life years (DALYs), ranking these conditions among our leading global health threats. But the . . . 2017 numbers also highlight the fact that approximately one-half of those deaths and DALYs affect children under the age of 5 years, whereas approximately two-thirds of deaths and DALYs affect children and adolescents under the age of 20 years.¹³

NTDs affect more than 1.5 billion people worldwide, southeast Asia and Africa by far the most impacted.¹⁴

11. *Neglected Tropical Diseases*, WORLD HEALTH ORG., <https://www.who.int/health-topics/neglected-tropical-diseases> [<https://perma.cc/Y8ZM-MAMB>] (last visited Aug. 29, 2024) (“In addition to significant mortality and morbidity - approximately 120,000 deaths and 14.1 million disability adjusted life years (DALYs) lost annually, NTDs cost developing communities the equivalent of billions of United States dollars each year in direct health costs, loss of productivity and reduced socioeconomic and educational attainment. They are also responsible for other consequences such as disability, stigmatization, social exclusion and discrimination and place considerable financial strain on patients and their families. In spite of this, NTDs have historically ranked very low and almost absent from the global health policy agenda – only to gain recognition in 2015 with the Sustainable Development Goals (SDG target 3.3). SDG3 can therefore be achieved only if the NTD goals are met but, because interventions to tackle NTDs are widely cross-sectoral, increasing their global prioritization can in fact catalyze progress to achieve all SDGs.”). Among other pathogens and conditions, they include Buruli ulcer; Chagas disease; dengue and chikungunya; dracunculiasis; echinococcosis; foodborne trematodiasis; human African trypanosomiasis; Lassa fever; leishmaniasis; leprosy; lymphatic filariasis; mycetoma, chromoblastomycosis and other deep mycoses; noma; onchocerciasis; rabies; Rift Valley Fever, scabies and other ectoparasitoses; schistosomiasis; soil-transmitted helminthiasis; snakebite envenoming; taeniasis/cysticercosis; trachoma; and yaws.

12. WORLD HEALTH ORG., *ENDING THE NEGLECT TO ATTAIN THE SUSTAINABLE DEVELOPMENT GOALS: A ROAD MAP FOR NEGLECTED TROPICAL DISEASES 2021–2030* (2021).

13. Peter J. Hotez, Audrey R. Odom John & A. Désirée LaBeaud, *Pediatric Tropical Medicine: The Neglected Diseases of Children*, 13PLOS NEGLECTED TROPICAL DISEASES (2019), <https://doi.org/10.1371/journal.pntd.0007008>.

14. *Global Report on Neglected Tropical Diseases 2024*, WORLD HEALTH ORG., <https://www.who.int/teams/control-of-neglected-tropical-diseases/global-report-on-neglected-tropical-diseases-2024> [<https://perma.cc/UV89-L2GM>] (last visited Mar. 31, 2026) (“In 2022, 1.62 billion people required interventions against NTDs. . . The highest proportion was in the South-East Asia Region (51.4%), followed by the African (35.8%), Eastern Mediterranean (4.6%), Western Pacific (4.6%), Americas (3.2%) and European (0.4%) regions.”).

A. Typology, Morbidity, and Mortality of NTDs

NTDs are Type III diseases, a designation that drives law, investment, and policy. The classification of diseases into three types was first introduced by the Commission on Macroeconomics and Health and elaborated in the report of the Commission on Intellectual Property Rights, Innovation and Public Health.^{15,16} The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) of the World Health Assembly was thereafter tasked with developing its analysis around the disease types.¹⁷

The categorization of diseases into different types is based on several factors, such as a country's wealth, its level of development, and disease burden indicated by the incidence rates within the population.¹⁸ Type I diseases are prevalent in both high-income and low- or middle-income countries, with a relatively similar disease burden affecting a substantial number of vulnerable populations in each.¹⁹ Type II diseases are prevalent in both high-income and low- or middle-income countries, with a significant proportion of cases in low-income countries. Type III diseases, on the other hand, predominantly or exclusively affect developing nations.²⁰ Type II diseases are typically classified as neglected diseases, highlighting their relative limited attention and resources. In comparison, Type III diseases are considered as extremely neglected diseases, indicating an even more profound lack of focus and support.²¹ Some prominent examples of type I, II, and III diseases include cancer, HIV/AIDS, and infectious tropical diseases such as malaria, respectively.^{22,23}

15. WORLD HEALTH ORG., MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT; REPORT OF THE COMMISSION ON MACROECONOMICS AND HEALTH (Jeffrey D. Sachs ed., 2001).

16. WORLD HEALTH ORG., COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 228 (2006).

17. World Health Assembly, *Consultative Expert Working Group on Research and Development: Financing and Coordination*, 1, 119, Res. A65/24 (Apr. 20, 2012), https://apps.who.int/gb/ebwha/pdf_files/wha65/a65_24-en.pdf [<https://perma.cc/UBM9-XPRW>].

18. World Health Org. Secretariat, *Defining Disease Types I, II, and III*, 1, 1-2 (Nov 14, 2012), https://keionline.org/sites/default/files/WHO_definitions_Types1-3_14Nov2012.pdf [<https://perma.cc/Q5RU-APNN>]. (“Type I: 0.0 - < 3.0 i.e. the disease burden is approximately the same and no more than 3 times higher in low/middle income countries than high income countries. Type II: > 3.0 < 35.0 the disease burden is at a rate that is between 3.0–35.0 times higher in low/middle income countries than in a high income country. Type III: > 35.0 the disease burden is at a rate that is at least 35.0 times and up to more than a 1000 times higher than is recorded in high income countries.”).

19. *Id.*; see also Matthew M. Coates, et. al, *Burden of Disease Among the World's Poorest Billion People: An Expert-Informed Secondary Analysis of Global Burden of Disease Estimates*, 16 PLOS ONE (2021), <https://doi.org/10.1371/journal.pone.0253073> [<https://perma.cc/4F6K-FNRE>].

20. *Consultative Expert Working Group on Research and Development: Financing and Coordination*, WORLD HEALTH ASSEMBLY 23, Res. A65/24 (Apr 20, 2012), https://apps.who.int/gb/ebwha/pdf_files/wha65/a65_24-en.pdf.

21. WORLD HEALTH ORG., MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT; REPORT OF THE COMMISSION ON MACROECONOMICS AND HEALTH (Jeffrey D. Sachs ed., 2001).

22. James Love, *Balancing Options for Health Research and Development*, 90 BULLETIN OF THE WORLD HEALTH ORG. 796 (2012).

23. WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS : REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, 1, 13, (2006).

In 2012, WHO developed a working list of disease classifications based on the 2004 Global Burden of Diseases report and the respective Disability Adjusted Life Years (DALYs).²⁴ The total DALYs per 100,000 population for low- and middle-income countries were aggregated and compared with the DALY figures of high-income countries. Based on this comparison, ratios were calculated and ranked from high to low, subsequently leading to subjective categorization into groups corresponding with the intended representation of disease types. Per this classification, Type I diseases correspond to disease burden that is roughly the same across low- and middle-income and high-income countries, with the burden being no more than three times higher in low- and middle-income countries. Type II diseases exhibit a burden that is between 3 and 35 times greater in low- and middle-income countries compared to high-income countries. Type III diseases, on the other hand, have a burden that is at least 35 times higher and can exceed 1000 times higher in low- and middle-income countries than in high-income countries.²⁵

NTDs are not a new phenomenon and have been present for millennia, with national and international organizations defining them differently.²⁶ The conceptual framework for NTDs was developed in the years following the adoption of the Millennium Development Goals (MDGs).²⁷ The phrase “neglected tropical diseases” was introduced to generate political support, advance research and development, and secure funding to address the challenges posed by these diseases.^{28,29} Recognizing the growing burden of NTDs, the World Health Organization (WHO) established a new Department of Control of NTDs in 2005 to support global efforts in the control, elimination, and eradication of NTDs.³⁰ WHO initially classified 13 diseases as NTDs in 2010, comprising seven helminthic parasites, three bacterial infections, and three protozoal infections.³¹

24. World Health Org. Secretariat, *supra* note 18; For the GBD, see also IHME, *GLOBAL BURDEN OF DISEASE (GBD)*, <https://www.healthdata.org/research-analysis/gbd> [https://perma.cc/6CJE-7SQ8] (last visited Aug. 30, 2024).

25. World Health Org. Secretariat, *supra* note 18.

26. Institute of Medicine (US) Forum on Microbial Threats, *Workshop Overview, in The Causes and Impacts of Neglected Tropical and Zoonotic Diseases: Opportunities for Integrated Intervention Strategies*, NAT'L LIBR. OF MED., <https://www.ncbi.nlm.nih.gov/books/NBK62526/> [https://perma.cc/9AQA-58GV] (last visited Aug 29, 2024).

27. Peter J. Hotez, *The Neglected Tropical Diseases and the Neglected Infections of Poverty: Overview of Their Common Features, Global Disease Burden and Distribution, New Control Tools, and Prospects for Disease Elimination*, NAT'L LIBR. OF MED. (2011), <https://www.ncbi.nlm.nih.gov/books/NBK62521/> (last visited Aug 29, 2024).

28. Peter J. Hotez et al., *Incorporating a Rapid-Impact Package for Neglected Tropical Diseases with Programs for HIV/AIDS, Tuberculosis, and Malaria*, 3 PLOS MED. 576, 576, 577 (2006).

29. David H. Molyneux et al., “Rapid-Impact Interventions”: How a Policy of Integrated Control for Africa's Neglected Tropical Diseases Could Benefit the Poor, 2 PLOS MED. e336, 1064, (2005).

30. *Global Report on Neglected Tropical Diseases 2025*, WORLD HEALTH ORG. (2025), <https://www.who.int/teams/control-of-neglected-tropical-diseases/global-report-on-neglected-tropical-diseases-2025> [https://perma.cc/C8EF-ZHPN]; *Control of Neglected Tropical Diseases, About Us*, WORLD HEALTH ORG., <https://www.who.int/teams/control-of-neglected-tropical-diseases/about> [https://perma.cc/342R-Y6ZF] (last visited Aug. 9, 2025).

31. *Working to Overcome the Global Impact of Neglected Tropical Diseases: First WHO Report on Neglected Tropical Diseases*, WORLD HEALTH ORG. (2010), <https://www.who.int/publications/i/item/9789241564090> [https://perma.cc/UB4Z-7GUZ].

Thereafter, international organizations like WHO, financial institutions such as the World Bank and the Inter-American Development Bank (IDB), government stakeholders such as the U.S. Centers for Disease Control and Prevention (CDC), private foundation or development organizations such as the Bill and Melinda Gates Foundation, bilateral development organizations such as the (now shuttered) US Agency for International Development (USAID), pharmaceutical companies and generic manufacturers, endemic countries, donors, professional and trade associations, global and local non-governmental organizations (NGOs), and academia and research institutes, united on January 30, 2012 to adopt the London Declaration on Neglected Tropical Diseases.³² They pledged to control, eliminate, or eradicate NTDs by 2020.³³ The London Declaration focused on 5 core commitments: sustained expansion of drug supplies and interventions; enhanced research and development through partnerships and funding for novel treatments; improved national and international collaborations through public and private organizations; adequate funding for endemic countries to implement NTD interventions, supported by robust health systems; and provision of technical resources and support.³⁴

The London Declaration, as its name suggests, is not binding international law.³⁵ It is not an agreement made between sovereign states, nor does it represent an approach sustained by a large number of states honored out of a sense of legal obligation.³⁶ However, it does represent a significant political commitment not only from the usual agents of international law (sovereign states) but international organizations, international charities, and the private sector. Like many such declarations, it can ultimately have impact upon the law, especially where it is integrated into agreements or, as proposed here, used to revise the charter of an organization with significant attributes of sovereign states.

WHO developed its first guidance document for the prevention and control of NTDs in 2012,³⁷ followed by a comprehensive NTDs resolution in 2013³⁸ Subsequently, 17 diseases were categorized as NTDs in 2013.³⁹ This list continued

32. *The London Declaration on NTDs*, GLOBAL HEALTH PROGRESS, <https://globalhealthprogress.org/collaboration/the-london-declaration-on-ntds/> [<https://perma.cc/MR2Q-N8CG>] (last visited Aug 9, 2025).

33. *Id.*

34. *Id.*

35. Rebecca Y. Du et al., *Could Violent Conflict Derail the London Declaration on NTDs?* 12 PLOS NEGLECTED TROPICAL DISEASES e0006136 (2018).

36. Curtis A. Bradley & Jack L. Goldsmith, *Presidential Control Over International Law*, 131 HARV. L. REV. 1201, 1207–09 (2018); RESTATEMENT (FOURTH) OF THE FOREIGN RELATIONS L. OF THE U.S. § 301 cmt. a (Am. L. Inst. 2018) [hereinafter Fourth Restatement].

37. World Health Org., *Accelerating Work to Overcome The Global Impact of Neglected Tropical Diseases – A Roadmap For Implementation* (Feb. 11, 2012), <https://www.who.int/publications/item/WHO-HTM-NTD-2012.1> [<https://perma.cc/R56U-NWC3>] (last visited Aug 29, 2024).

38. World Health Assembly, *Neglected Tropical Diseases* (May 27, 2013) https://iris.who.int/bitstream/handle/10665/150163/A66_R12-en.pdf [<https://perma.cc/3AKN-PP9C>].

39. David Molyneux, *Neglected Tropical Diseases*, 26 CMTY. EYE HEALTH J. 21, 22 (2013).

to expand, with inclusion of new diseases in 2016⁴⁰, 2017⁴¹, and 2023⁴². The WHO's latest roadmap for NTDs eradication titled "*Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030*" outlines global and cross-cutting targets for prevention, control, and elimination of NTDs. This roadmap aligns NTDs with the United Nations Sustainable Development Goals (SDGs) and was endorsed by the 73rd World Health Assembly in November 2020.⁴³ This roadmap provides disease specific targets and underscores three key pillars to enhance control, elimination, and eradication of NTDs, including accelerating programmatic action to enhance the efficiency and scope of current interventions; intensifying cross-cutting approaches to address multiple facets of NTD control simultaneously, such as improving sanitation and healthcare infrastructure; and transforming operating models and organizational culture to promote greater country and local leadership.⁴⁴

As of December 2023, WHO has classified 21 diseases as NTDSs.⁴⁵ Notable progress towards the eradication of NTDs has been recorded in the past two decades, marked by achievements such as the successful eradication or substantial reduction of certain diseases.⁴⁶ For instance, diseases like guinea worm are now on the brink of eradication,⁴⁷ and several others, such as lymphatic filariasis,⁴⁸ onchocerciasis,⁴⁹ trachoma,⁵⁰ and schistosomiasis,⁵¹ have seen

40. Ahmed Fahal et al., *Towards Enhanced Control of Mycetoma: A Roadmap to Achieve the UN's Sustainable Development Goals by 2030*, 118 *TRANSACTIONS OF THE ROYAL SOCIETY OF TROPICAL MED. & HYG.* 646, 647 (2024).

41. Amal K. Mitra & Anthony R. Mawson, *Neglected Tropical Diseases: Epidemiology and Global Burden*, 2 *TROPICAL MED. INFECT. DIS.* 36, 37 (2017).

42. World Health Org., *WHO Officially Recognizes Noma as a Neglected Tropical Disease* (Dec. 15, 2023), <https://www.who.int/news/item/15-12-2023-who-officially-recognizes-noma-as-a-neglected-tropical-disease> [<https://perma.cc/9FC7-KCNV>].

43. Timothy Jesudason, *Global Progress Report on Neglected Tropical Diseases*, 24 *THE LANCET INFECT. DIS.* e420 (2024).

44. World Health Org., *Ending the Neglect to Attain the Sustainable Development Goals: A Road Map for Neglected Tropical Diseases 2021–2030* (Jan. 28, 2021), <https://www.who.int/publications/i/item/9789240010352> (last visited Aug. 29, 2024).

45. World Health Org., *supra* note 37; World Health Org., *supra* note 42. These include Buruli ulcer; Chagas disease; dengue and chikungunya; dracunculiasis; echinococcosis; foodborne trematodiasis; human African trypanosomiasis; leishmaniasis; leprosy; lymphatic filariasis; mycetoma, chromoblastomycosis and other deep mycoses; onchocerciasis; rabies; scabies and other ectoparasitoses; schistosomiasis; soil-transmitted helminthiasis; snakebite envenoming; taeniasis and cysticercosis; trachoma; yaws; and noma.

46. Peter J. Hotez & Serap Aksoy, *PLOS Neglected Tropical Diseases: Ten Years of Progress in Neglected Tropical Disease Control and Elimination – More or Less*, 11 *PLoS NEGLECTED TROPICAL DISEASES* e0005355 (2017).

47. The Carter Center, *Guinea Worm Eradication Program*, <https://www.cartercenter.org/programs/guinea-worm/> [<https://perma.cc/B6QW-2MTD>] (last visited Mar. 26, 2026).

48. World Health Org., *Lymphatic Filariasis*, <https://www.who.int/news-room/fact-sheets/detail/lymphatic-filariasis> [<https://perma.cc/E2JJ-2WA8>] (last visited Aug. 29, 2024).

49. World Health Org., *Elimination of Human Onchocerciasis: Progress Report, 2020*, <https://www.who.int/publications/i/item/who-wer9646-557-567> [<https://perma.cc/RH7K-UU3K>] (last visited Aug. 29, 2024).

50. World Health Org., *Eliminating Trachoma: WHO Announces Sustained Progress with Hundreds of Millions of People No Longer at Risk of Infection*, <https://www.who.int/news/item/27-06-2019-eliminating-trachoma-who-announces-sustained-progress-with-hundreds-of-millions-of-people-no-longer-at-risk-of-infection> [<https://perma.cc/BS4T-HCGM>] (last visited Aug. 29, 2024).

51. World Health Org., *Schistosomiasis*, <https://www.who.int/news-room/fact-sheets/detail/schistosomiasis> [<https://perma.cc/2RBF-9PMK>] (last visited Aug. 29, 2024).

dramatic decreases in their prevalence due to extensive mass drug administration campaigns and improved public health strategies.⁵² However, despite these advancements, several unmet targets remain.⁵³ Significant challenges persist in the complete eradication or control of certain diseases. These include persistent geographical and logistical barriers, such as remote or conflict-affected regions where health interventions are difficult to implement.⁵⁴ In some cases, inadequate infrastructure and limited healthcare resources hinder the delivery of essential services.⁵⁵ Additionally, emerging resistance to treatments and a lack of effective vaccines for some NTDs continue to pose significant roadblocks.⁵⁶ Even for diseases where licensed vaccines exist, there are gaps in coverage and disparities in access to treatment, particularly in the most marginalized and underserved populations.⁵⁷

B. The March of Global Immunization

Immunization is one of the most effective strategies for the prevention and control of infectious diseases.^{58,59} The history of global immunization predates 200 BCE with early inoculation efforts to prevent smallpox.⁶⁰ However, it wasn't until the early 18th century that the world's first successful vaccine against smallpox was commercialized.⁶¹ Dr. Edward Jenner, popularly recognized as the father of immunology,⁶² was the first person to confer scientific status on the deliberate use of immunization for controlling infectious diseases.⁶³ Thereafter, the 1800s witnessed the development of many vaccines, including

52. Shuaibu Abdullahi Hudu et al., *An Insight into the Success, Challenges, and Future Perspectives of Eliminating Neglected Tropical Disease*, 24 SCI. AFR. e02165 (2024).

53. David H Molyneux et al., *The History of the Neglected Tropical Disease Movement*, 115 TRANSACTIONS ROYAL SOC'Y TROPICAL MED. & HYG. 169 (2021).

54. Julie Jacobson J & Sophie Bush, *Neglected Tropical Diseases, Neglected Communities, and Conflict: How Do We Leave No One Behind?*, NAT'L LIBR. OF MED., Trends Parasitol. 2018 Mar;34(3):175-177. doi: 10.1016/j.pt.2017.10.013. Epub 2017 Nov 20. PMID: 29162404; PMCID: PMC5840506; *To End the Neglect of Neglected Tropical Diseases*, 18 LANCET REG'L HEALTH W. PAC. (2022), [https://www.thelancet.com/journals/lanwpc/article/PIIS2666-6065\(22\)00007-4/fulltext](https://www.thelancet.com/journals/lanwpc/article/PIIS2666-6065(22)00007-4/fulltext) [https://perma.cc/JC65-VAEH].

55. Bruno Marchal et al., *Neglected Tropical Disease (NTD) Control in Health Systems: The Interface Between Programmes and General Health Services*, 120 ACTA TROPICA S177 (2011).

56. Shuaibu Abdullahi Hudu et al., *An Insight into the Success, Challenges, and Future Perspectives of Eliminating Neglected Tropical Disease*, 24 SCI. AFR. e02165 (2024).

57. Jessica Clark et al., *How Correlations Between Treatment Access and Surveillance Inclusion Impact Neglected Tropical Disease Monitoring and Evaluation—A Simulated Study*, 17 PLoS NEGLECTED TROPICAL DISEASES e0011582 (2023).

58. F. E. Andre et al., *Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide*, 86 BULL. WORLD HEALTH ORG. 140 (2008).

59. Vanessa Rémy, York Zöllner & Ulrike Heckmann, *Vaccination: The Cornerstone of an Efficient Healthcare System*, 3 J MKT. ACCESS HEALTH POL'Y (2015).

60. Cary P. Gross & Kent A. Sepkowitz, *The Myth of the Medical Breakthrough: Smallpox, Vaccination, and Jenner Reconsidered*, 3 INT'L J. INFECTIOUS DISEASES 54, 54-60 (1998).

61. Stefan Riedel, *Edward Jenner and the History of Smallpox and Vaccination*, 18 PROC. (BAYLOR UNIV. MED. CTR.) 21 (2005). See also WILLIAM H. McNEILL, PLAGUES AND PEOPLES (1976).

62. FAQ: *Adult Vaccines: A Grown-Up Thing to Do*, NAT'L LIBR. OF MED. (2012), <http://www.ncbi.nlm.nih.gov/books/NBK562896/> [https://perma.cc/8SGC-TF7J] (last visited Aug 30, 2024).

63. Stefan Riedel, *Edward Jenner and the History of Smallpox and Vaccination*, 18 PROC. (BAYLOR UNIV. MED. CTR.) 21 (2005).

the first laboratory-produced vaccine, and the first vaccines for rabies, cholera, and anthrax.⁶⁴ The 1900s further witnessed the development of many modern-day vaccines for diseases such as influenza, yellow fever, pertussis, polio, hepatitis B, measles, mumps, rubella, and pneumococcal pneumonia.⁶⁵

The 1900s is recognized as the era of mass immunization efforts, with malaria and smallpox the top aim of those efforts.⁶⁶ Within a decade of its formation in 1948, the World Health Assembly adopted a resolution in 1958 for the global eradication of smallpox.⁶⁷ However, more than 20% of WHO resources at the time were being expended on malaria eradication, which significantly constrained funding for other initiatives.⁶⁸ As a result, smallpox efforts were faltering due to limited investment, insufficient vaccine supply, and a lack of coordinated infrastructure.⁶⁹ The vast resources required to eradicate malaria became clear to the international community, and resources were redirected into smallpox initiatives.⁷⁰ In 1966, the World Health Assembly approved a \$2.4 million budget to support a 10-year smallpox eradication plan.⁷¹ This plan was comprised of two components, i.e., systematic vaccination and surveillance and containment.⁷² As a part of surveillance measures, all health facilities were required to establish special containment teams and report cases weekly.⁷³ In 1967, WHO launched an intensified smallpox eradication programme with the goal of smallpox eradication through enhanced surveillance and immunization efforts.⁷⁴ This was a significant step toward global immunization and an important turning point in global health law's trajectory. Several other primary health care programs also benefited from the global smallpox efforts.⁷⁵ The success was the result of legal authorizations by first African then South Asian governments for immunization, surveillance, and quarantine followed by their

64. Nat'l Research Council (U.S.) Div. of Health Promotion and Disease Prevention, *Vaccines: Past, Present, and Future*, VACCINE SUPPLY AND INNOVATION (1985), <https://www.ncbi.nlm.nih.gov/books/NBK216821/> [<https://perma.cc/5JYL-ZPMQ>] (last visited Aug. 30, 2024); Kendall A. Smith, *Louis Pasteur, the Father of Immunology?*, 3 FRONTIERS IMMUNOL. 68 (2012).

65. David A. Montero et al., *Two Centuries of Vaccination: Historical and Conceptual Approach and Future Perspectives*, 11 FRONT. PUB. HEALTH 1326154 (2024).

66. Joel G. Breman, *Smallpox*, 224 J. INFECTIOUS DISEASES S379 (2021).

67. Edward A. Belongia & Allison L. Naleway, *Smallpox Vaccine: The Good, the Bad, and the Ugly*, 1 CLINICAL MED. RES. 87 (2003).

68. D. A. Henderson & Petra Klepac, *Lessons from the Eradication of Smallpox: An Interview with D. A. Henderson*, 368 PHIL. TRANS. ROYAL SOC'Y B: BIOLOGICAL SCI. 20130113 (2013).

69. Edward A. Belongia & Allison L. Naleway, *Smallpox Vaccine: The Good, the Bad, and the Ugly*, 1 CLINICAL MED. RES. 87 (2003).

70. Henderson & Klepac, *supra* note 68; Marcel Tanner & Don de Savigny, *Malaria Eradication Back on the Table*, 86 BULL. WORLD HEALTH ORG. 82 (2008).

71. Frank Fenner et al., *Development of The Global Smallpox Eradication Programme, 1958-1966*, SMALLPOX AND ITS ERADICATION 365-420 (1988) https://biotech.law.lsu.edu/blaw/bt/smallpox/who/red-book/9241561106_chp9.pdf [<https://perma.cc/LQ6P-72VY>] (last visited Aug. 30, 2024).

72. Emma Kerrod et al., *Surveillance and Control Measures During Smallpox Outbreaks*, 11 EMERGING INFECTIOUS DISEASES 291 (2005).

73. Donald A. Henderson, *Principles and Lessons from the Smallpox Eradication Programme*, 65 BULL. WORLD HEALTH ORG. 535, 536 (1987).

74. John F. Wickett, *The Final Inch: The Eradication of Smallpox and Beyond*, 30 SOCIAL SCIENTIST 62, 67 (2002).

75. Sam Halabi, *The Origins and Future of Global Health Law: Regulation, Security, and Pluralism*, 108(6) GEO. L.J. 1607, 1616 (2020).

commitment to train healthcare workers, build laboratories, and create regular public health reporting systems.⁷⁶ The smallpox endemic countries dropped from 31 to 5 within a six-year period from 1967 to 1973.⁷⁷ In 1980, WHO declared smallpox eradicated acting on the recommendations of the WHO Global Commission for the Certification of Smallpox Eradication.⁷⁸

In 1974, WHO expanded the smallpox program into the Expanded Programme on Immunization, now the Essential Programme on Immunization (EPI), with the goal of reducing morbidity and mortality by making immunization services available for all children of the world by 1990.⁷⁹ EPI initially targeted diseases such as diphtheria, measles, polio, tetanus, tuberculosis, and pertussis.^{80,81} EPI also underscored the importance of disease surveillance for understanding disease epidemiology, monitoring programme progress, and identifying shortcomings.⁸² The combination of EPI and UNICEF's Universal Childhood Immunization campaign successfully increased global immunization rates for the six EPI vaccines from 5% to 80% by 1990.⁸³ Currently, EPI recommends vaccines for 13 diseases universally and country-specific guidance for another 17 diseases, expanding its initial coverage to include adolescents and adults, alongside children as well.⁸⁴ Two vaccines against malaria have been approved – RTS,S and R21/Matrix-M.⁸⁵

Following the eradication of smallpox, WHO launched the Global Polio Eradication Initiative in 1988 targeted at eradication of polio by 2000.⁸⁶ Polio had been eradicated in the Americas by 1994, followed by Europe in 2002.⁸⁷

76. Henderson & Klepac, *supra* note 68, at 3, 7.

77. *Id.* at 3.

78. Donald A. Henderson, *The Eradication of Smallpox – An Overview of the Past, Present, and Future*, 29 *VACCINE* D7, D9 (2011).

79. R. H. Henderson, *The Expanded Programme on Immunization of the World Health Organization*, 6 *Suppl 2 REV. INFECTIOUS DIS.* S475 (1984).

80. 27 *WORLD HEALTH ASSEMBLY, WHO Expanded Programme on Immunization*, (1974), <https://iris.who.int/handle/10665/92778> [<https://perma.cc/NJY4-NSEF>] (last visited Aug. 30, 2024).

81. Andrew J. Shattock et al., *Contribution of Vaccination to Improved Survival and Health: Modelling 50 Years of the Expanded Programme on Immunization*, 403 *LANCET* 2307 (2024).

82. Henderson & Klepac, *supra* note 68, at 4.

83. World Health Org., *50th Anniversary of the Expanded Programme on Immunization (EPI)*, [https://www.who.int/news-room/events/detail/2024/01/01/default-calendar/50th-anniversary-of-the-expanded-programme-on-immunization-\(epi\)](https://www.who.int/news-room/events/detail/2024/01/01/default-calendar/50th-anniversary-of-the-expanded-programme-on-immunization-(epi)) [<https://perma.cc/69FL-WMQ3>] (last visited Aug 30, 2024).

84. *Global Immunization Efforts Have Saved At Least 154 Million Lives Over the Past 50 Years*, UNICEF (Apr. 24, 2024), <https://www.unicef.org/press-releases/global-immunization-efforts-have-saved-least-154-million-lives-over-past-50-years> [<https://perma.cc/JUJ5-C7ZS>].

85. Dinah V. Parums, *Current Status of Two Adjuvanted Malaria Vaccines and the World Health Organization (WHO) Strategy to Eradicate Malaria by 2030*, 29 *MED. SCI. MONIT.* e939357, at 1 (2023).

86. Bruce Aylward & Rudolf Tangermann, *The Global Polio Eradication Initiative: Lessons Learned and Prospects for Success*, 29 *VACCINE* D80 (2011).

87. *25 Years of Being Polio-Free in the Americas*, PAN AM. HEALTH ORG. (2019), <https://www.paho.org/en/news/21-10-2019-25-years-being-polio-free-americas> [<https://perma.cc/UT8Y-UTHH>] (last visited Aug 30, 2024); World Health Org., *Statement – European Region 20 Years Polio-Free: A Celebratory Moment but a Fragile Legacy* (Oct. 24, 2022), <https://www.who.int/europe/news/item/24-10-2022-statement—european-region-20-years-polio-free—a-celebratory-moment-but-a-fragile-legacy> [<https://perma.cc/JCZ6-FDPK>].

By 2003, the diseases remained endemic in only six countries.⁸⁸ As of 2024, polio remains endemic in two countries i.e., Afghanistan and Pakistan and has recently reemerged in Gaza, Palestine.⁸⁹

WHO has also partnered with the private sector for global immunization efforts, such as the Meningitis Vaccine Project launched in 2001 in partnership with PATH with support from the Bill & Melinda Gates Foundation for the development of conjugate vaccines.⁹⁰

In 2015, WHO launched the WHO Global Malaria Programme (GMP) for coordinating global malaria elimination efforts.⁹¹ GMP's work is guided by the "Global technical strategy for malaria 2016–2030" adopted by the World Health Assembly in May 2015 and updated in 2021, with the most recent operational strategy published in April 2024.⁹² As a part of GMP, WHO initiated the malaria vaccine pilot implementation in Ghana, Malawi and Kenya in 2019.⁹³

In 2016, WHO also launched the R&D Blueprint, a global strategy for rapid initiation of research and development initiatives during epidemics.⁹⁴ The primary objective of the preparedness plan is to accelerate the availability of effective tests, vaccines, and medicines crucial for averting widespread crises.⁹⁵

In 2019, WHO prequalified the Ebola vaccine, making it the fastest vaccine prequalification effort in its history.⁹⁶ In 2021, a global Ebola vaccine stockpile

88. Robert D. Lamb et al., *Eradicating Polio in Afghanistan and Pakistan*, CTR. FOR STRATEGIC & INT'L STUD., (Aug. 13, 2012), <https://www.csis.org/analysis/eradicating-polio-afghanistan-and-pakistan> [https://perma.cc/DSS6-6JHH].

89. *Endemic Countries*, GLOBAL POLIO ERADICATION INITIATIVE, <https://www.archive.polioeradication.org/where-we-work/polio-endemic-countries/> (last visited Mar. 27, 2026); Peter Doherty Inst. for Infection and Immunity, *World Polio Day 2024: A Challenging Year for Global Eradication* (Oct. 24, 2024), <https://www.doherty.edu.au/articles/world-polio-day-2024-a-challenging-year-for-global-eradication/> [https://perma.cc/D445-TU4M].

90. PATH, *The Meningitis Vaccine Project: A Groundbreaking Partnership*, <https://www.path.org/our-impact/articles/about-meningitis-vaccine-project/> [https://perma.cc/QTY2-TF8P] (last visited Aug. 30, 2024).

91. See generally World Health Org., *Global Malaria Programme*, <https://www.who.int/teams/global-malaria-programme> [https://perma.cc/F6X2-CVXT] (last visited Aug. 30, 2024).

92. World Health Org., *Global Technical Strategy for Malaria 2016–2030: 2021 Update* (2021), <https://www.who.int/publications/i/item/9789240031357> <https://perma.cc/Z8GM-V4U>; World Health Org., *Global Malaria Programme Operational Strategy 2024–2030* (2024), <https://www.who.int/publications/i/item/9789240090149> [https://perma.cc/C2VP-6WNV].

93. World Health Org. Regional Office for Africa, *Malaria Vaccine Pilot Launched in Ghana* (Apr. 30, 2019), <https://www.afro.who.int/news/malaria-vaccine-pilot-launched-ghana> [https://perma.cc/2TSS-FCSS]; World Health Org., *RTS,S Malaria Vaccine Reaches More Than 650,000 Children in Ghana, Kenya and Malawi Through Groundbreaking Pilot Programme* (Apr. 20, 2021), <https://www.who.int/news/item/20-04-2021-rt-s-s-malaria-vaccine-reaches-more-than-650-000-children-in-ghana-kenya-and-malawi-through-groundbreaking-pilot-programme> [https://perma.cc/M8GW-GBTW].

94. Massinissa Mehand et. al., *The WHO R&D Blueprint: 2018 Review of Emerging Infectious Diseases Requiring Urgent Research and Development Efforts*, 159 *ANTIVIRAL RESEARCH* 63 (2018).

95. World Health Org., *R&D Blueprint*, <https://www.who.int/teams/blueprint> [https://perma.cc/C8FS-X7BB] (last visited Aug. 30, 2024).

96. World Health Org., *WHO Prequalifies Ebola Vaccine, Paving the Way for Its Use in High-Risk Countries* (Nov. 12, 2019), <https://www.who.int/news/item/12-11-2019-who-prequalifies-ebola-vaccine-paving-the-way-for-its-use-in-high-risk-countries> [https://perma.cc/JEA5-LHUY].

was established by the International Coordinating Group (ICG) on Vaccine Provision, which includes the WHO, UNICEF, the International Federation of Red Cross and Red Crescent Societies (IFRC), and Médecins Sans Frontières (MSF), with financial support from Gavi, the Vaccine Alliance.⁹⁷

Most recently, WHO spearheaded the global immunization efforts during the Covid-19 pandemic.⁹⁸ Nonetheless, WHO has generally remained committed to the study of diseases and public health problems and evidence based recommendations and resolutions, and not law-making per se, although recent amendments to the International Health Regulations and the draft Pandemic Agreement show that WHO is increasingly exercising its legal authorities.

II. The New Institutions of Vaccine Access: Gavi and CEPI

Until 2000, global efforts at increasing vaccine access, at least as a legal matter, were largely treated as activities of United Nations specialized agencies: the World Health Organization and UNICEF.⁹⁹ Correspondingly, the actions taken by those agencies relied upon the consent and action of national governments, sometimes formally incorporating immunization into national law, and at other times essentially allowing those agencies to operate within their borders respecting their diplomatic status.¹⁰⁰ At the turn of the century, Gavi and CEPI, new international organizations, emerged with more diverse governance structures, novel financing mechanisms, and a focus on vaccines at different points in their development and access. Gavi was established to address the procurement and sustainable supply of vaccines against EPI diseases, although its mandate eventually expanded.¹⁰¹ CEPI was established to support the development of vaccines for diseases for which there were no treatments and for which the market would unlikely produce, in other words, vaccines for NTDs. They operated as much or more through private contract as through public national and international law.

97. World Health Org., *Ebola Vaccine Stockpiles*, <https://www.who.int/groups/icg/ebola-virus-disease/ebola-stockpiles> [<https://perma.cc/GU3F-MREF>] (last visited Aug. 30, 2024).

98. See generally Pan American Health Org., *Timeline of WHO's Response to COVID-19* (July 2, 2020), <https://www.paho.org/en/news/2-7-2020-timeline-whos-response-covid-19> [<https://perma.cc/9MS9-KACN>].

99. Ann Listrand et. al, *The World of Immunization: Achievements, Challenges, and Strategic Vision for the Next Decade*, 224 J. INFECTIOUS DISEASES S452 (Supp. 2 2021). (“In response, in 1984, the Universal Childhood Immunization initiative led by the United Nations Children’s Fund (UNICEF) in collaboration with the World Health Organization (WHO) was established, with the ambitious aim of increasing DTP3 coverage to 80% globally by 1990.”).

100. Anthony Costello et al., *Where’s the Leadership? Future Commitments of UNICEF and WHO for Global Child Health*, 362 BMJ k3219 (2018).

101. Sam Halabi & Lawrence O. Gostin, *Global Health Funding Agencies: Developing New Institutions to Finance Health Needs*, in GLOBAL HEALTH LAW & POLICY: ENSURING JUSTICE FOR A HEALTHIER WORLD 365, 370-373 (Lawrence O. Gostin & Benjamin Mason Meier eds., 2023).

A. Gavi

1. *Gavi's History and Role in Global Vaccination*

In a renewed effort to complete the work begun with the WHO's EPI, the Bill and Melinda Gates Foundation together with WHO, UNICEF, the World Bank, and several large pharmaceutical firms established the Global Alliance for Vaccines and Immunizations (Gavi) in 2000.¹⁰² Gavi was conceived before its legal structure and governance arrangements were fully developed. In its early years, it operated through two separate boards: the Board of the Global Alliance for Vaccine and Immunization and the Gavi Fund Board, which served as the Alliance's fiduciary arm.¹⁰³ In 2008, these boards were merged to form the Gavi Alliance Board, now comprising of twenty-eight members representing donor and recipient governments, the Bill and Melinda Gates Foundation, international organizations, vaccine manufacturers, civil society, and academic institutions.¹⁰⁴ While Gavi receives donor support through a number of mechanisms, including direct support from donors, it is largely financed through the sales of securities, detailed below, which is one of the means by which it has achieved sustainability and significant impact. On June 25, 2025, the United States government, a significant source of support, announced that it would no longer support Gavi.¹⁰⁵

Under the Gavi model, low- and middle-income states identify immunization needs, apply for funding, and implement approved vaccination programs.¹⁰⁶ Under Gavi's program, donors guarantee the price of eligible vaccines. Pharmaceutical firms, in turn, guarantee the vaccines at an affordable price to participating countries.¹⁰⁷ The relationships in Gavi are governed by contract, with significant influence on the firms that participate.¹⁰⁸

Gavi's support addresses more than just vaccine procurement and its mandate has slowly widened over time. Primarily, it ensures the reliable supply and distribution of vaccines to low-income countries, targeting regions with limited access to immunization.¹⁰⁹ Additionally, it fortifies health systems to

102. *About Us, Gavi*, <https://www.gavi.org/about-us> [https://perma.cc/28L9-M85G] (last visited Mar. 31, 2026); Andrew J. Shattock et al., *Contribution of Vaccination to Improved Survival and Health: Modelling 50 Years of the Expanded Programme on Immunization*, 403 *THE LANCET* 2307 (2024).

103. Fatma Tanis, *RFK Jr. Says U.S. Will Stop Funding Global Vaccine Group Over 'Vaccine Safety' Issues*, NPR WSKG: GOATS AND SODA (June 25, 2025, 7:39 PM), <https://www.npr.org/sections/goats-and-soda/2025/06/25/g-s1-74554/rfk-jr-vaccine-safety-gavi> [https://perma.cc/5F46-MTTZ]; ALLAN SAUL, *VACCINES FOR NEGLECTED DISEASES, VACCINE DESIGN: INNOVATIVE APPROACHES AND NOVEL STRATEGIES* 243 (Rino Rappuoli & Fabio Bagnoli eds., 2011).

104. *Id.*

105. Fatma Tanis, *RFK Jr. Says U.S. Will Stop Funding Global Vaccine Group Over 'Vaccine Safety' Issues*, NPR WSKG (June 25, 2025, 7:39 PM), <https://www.npr.org/sections/goats-and-soda/2025/06/25/g-s1-74554/rfk-jr-vaccine-safety-gavi> [https://perma.cc/5F46-MTTZ].

106. Julian Lob-Levyt, *Contribution of the GAVI Alliance to Improving Health and Reducing Poverty*, 366 *PHIL. TRANSACTIONS ROYAL SOC'Y B* 2743, (2011); UNDP Health Implementation Manual, *About Gavi*, <https://healthimplementation.undp.org/the-partnership/the-undp-gavi-partnership/about-gavi/> [https://perma.cc/EA5P-7C5V] (last visited Apr. 17, 2026).

107. Halabi & Gostin, *supra* note 101, at 370-373.

108. *Id.*

109. *Mission & Vision, Gavi*, <https://www.gavi.org/about-us/mission-vision> [https://perma.cc/28L9-M85G] (last visited Mar. 31, 2026).

enhance immunization efforts by providing critical resources such as training for healthcare workers, transportation support, and cold chain equipment necessary for maintaining vaccine quality and transparency.¹¹⁰ Gavi also facilitates access to specialized technical assistance through a network of partners, which supports the implementation and scaling of vaccination programs.¹¹¹ This comprehensive strategy not only improves immediate vaccination efforts but also strengthens the overall health infrastructure, promoting long-term sustainability and resilience in global health systems.¹¹²

Eligibility for Gavi support is largely based on the national income profile of the government.¹¹³ In 2024, countries become eligible for Gavi support if their most recent gross national income (GNI) per capita was less than or equal to US\$ 1,810 (according to the latest World Bank data published in July each year).¹¹⁴ As a result of this eligibility standard, the countries eligible for the most Gavi support are in sub-Saharan Africa, and none are in South America or the Asian sub-continent.¹¹⁵

Gavi works through five-year strategy periods.¹¹⁶ The Vaccine Investment Strategy (VIS) broadly covers the decisions of the board regarding specific vaccines and related support for infrastructure and preparedness.¹¹⁷ For example, the 2024 VIS includes future vaccination programs for tuberculosis (adolescent

110. *We Strengthen Health Systems*, GAVI, <https://www.gavi.org/our-work/health-systems-immunisation-strengthening> [https://perma.cc/A9KP-SYDR] (last visited Mar. 27, 2026); Sam Halabi, Michelle Rourke & Rebecca Katz, *The Law and Ethics of Data Sharing during Infectious Disease Emergencies*, J. HEALTH CARE L. & POL'Y (forthcoming) (<https://papers.ssrn.com/abstract=3375089>).

111. Greg Kuzmak, & The Rockefeller Foundation, *How New Training Approaches Are Transforming Health Workers' Ability to Deliver Vaccine*, GAVI (Feb. 21, 2022), <https://www.gavi.org/vaccineswork/how-new-training-approaches-are-transforming-health-workers-ability-deliver> [https://perma.cc/J9HF-HFFC].

112. *Phase V (2021–2025)*, GAVI, <https://www.gavi.org/our-alliance/strategy/phase-5-2021-2025> [https://perma.cc/PZ2S-U5TB] (last visited Aug. 30, 2024).

113. Adam Soble et al., *Gavi Support for Typhoid Conjugate Vaccines: Moving from Global Investments to Country Introduction*, 71 CLINICAL INFECTIOUS DISEASES (Suppl. 2) S160, S160 (2020) (“Countries are eligible to receive Gavi support based on gross national income (GNI) per capita. As GNI per capita increases, countries increasingly finance immunization program costs before transitioning from Gavi support.”).

114. Alex Olateju Adjagba et al., “*Are We Ready to Transition from the Global Alliance for Vaccines and Immunization Support?*” *Perceptions From 15 Kenyan Counties*, 49 PAN AFR. MED. J. 29, at 2 (2024) (explaining that for eligibility for Gavi support, a country's most recent gross national product needed to be less than or equal to \$1,810 USD according to the latest World Bank data published in July each year, this eligibility threshold is adjusted for inflation annually, and once their three-year average GNI per capita surpasses the threshold the countries transition to the accelerated phase after which Gavi reduces funding support).

115. Chukwudi E. Okafor & Obinna I. Ekwunife, *Introducing Rotavirus Vaccine in Eight Sub-Saharan African Countries: A Cost-Benefit Analysis*, LANCET GLOB. HEALTH (2021).

116. Gunjan Gandhi, *Charting The Evolution of Approaches Employed by the Global Alliance for Vaccines and Immunizations (GAVI) to Address Inequities in Access to Immunization: A Systematic Qualitative Review of GAVI Policies, Strategies and Resource Allocation Mechanisms Through an Equity Lens (1999-2014)*, BMC PUB. HEALTH 1198 (2015).

117. *Vaccine Investment Strategy 2024*, GAVI <https://www.gavi.org/our-alliance/strategy/vaccine-investment-strategy-2024> [https://perma.cc/J5XF-8TX4] (last visited Mar. 31, 2026).

vaccines), group B streptococcus, and dengue fever, as well as global stockpiles for mpox.¹¹⁸

Specific diseases may be approved for Gavi's "learning agenda" which means that Gavi will support research to better understand factors that may affect its support, like surveillance gaps or burden of disease.¹¹⁹ The decision to place a disease on the learning agenda can be a significant "pull" for investment, as it suggests that Gavi support may be forthcoming in a future VIS. Against this backdrop, in 2023, Gavi shortlisted CHIKV for its learning agenda and an article in the *Lancet* mistakenly designated it as having been included.¹²⁰

2. IFFIm

Gavi partially funds its programs through sales of international bonds, which are backed by commitments from donor governments.¹²¹ Long-term financial commitments are made through pledges to the International Finance Facility for Immunization (IFFIm) by the governments of Australia, France, Italy, the Netherlands, Norway, South Africa, Spain, Sweden, and the United Kingdom.¹²² Similar to IFFIm pledges, long-term pledges are also directed towards the Advance Market Commitment (AMC), which is designed to incentivize the development and availability of vaccines for underserved populations. So far, Gavi has launched AMC for pneumococcal vaccines and COVID-19 AMC for COVAX.¹²³ Lastly, the loan buy-down facility enables Gavi to secure low-interest loans by providing a mechanism to reduce the cost of borrowing.¹²⁴

In sum, is the most important non-government actor "pulling" vaccines—including new vaccines, infrastructure to provide them, and healthcare workers to deliver them—to the populations that need them. For the 2021-25 period,

118. *Vaccine Investment Strategy 2024*, GAVI, <https://www.gavi.org/our-work/strategy> [<https://perma.cc/K4P3-XDUE>] (last visited Mar. 27, 2026); Richard G. White et. al, *The Full Value of Vaccine Assessments Concept-Current Opportunities and Recommendations*, 12 *VACCINES* 435 (Basel 2024).

119. *Vaccine Investment Strategy 2024*, GAVI, <https://www.gavi.org/our-alliance/strategy/vaccine-investment-strategy-2024> [<https://perma.cc/7GX7-VSDV>] (last visited Mar. 31, 2026) ("In-principle approvals via the VIS allow Gavi to begin market signaling and preparedness activities in advance, which is a critical part of Gavi's model to accelerate access to lower-income countries so new vaccines can be deployed as soon as they become available. Learning agendas are research implementation questions that Gavi can support to provide evidence for the launch, implementation and effective scale-up of a vaccine programme or stockpile. The Gavi Board also approved a learning agenda on vaccination against Shigella and, given the levels of coverage achieved, current epidemiology and country demand, recommended sunseting the routine COVID-19 vaccine programme at the end of 2025.")

120. Henrik Salje & Oscar Cortés Azuero, *The Deadly Potential of Chikungunya Virus*, 24 *LANCET INFECTIOUS DISEASES* 442-444 (2024).

121. Sarah Hughes-McLure & Emma Mawdsley, *Innovative Finance for Development? Vaccine Bonds and the Hidden Costs of Financialization*, 98 *ECONOMIC GEOGRAPHY* 145 (2022).

122. Int'l Fin. Facility for Immunisation (IFFIm), *About IFFIm*, <https://iffim.org/> [<https://perma.cc/BY2U-DLDH>] (last visited Aug. 30, 2024).

123. *Pneumococcal AMC*, GAVI (2017), <https://www.gavi.org/investing-gavi/innovative-financing/pneumococcal-amc> [<https://perma.cc/T8QL-SGFL>] (last visited Aug. 30, 2024); *Gavi COVAX AMC*, GAVI (2020), <https://www.gavi.org/gavi-covax-amc> [<https://perma.cc/M8Z3-5NRG>] (last visited Aug. 30, 2024).

124. Halabi & Gostin, *supra* note 101.

Gavi's forecasted budget to do so was approximately \$13.6 billion, so its weight in global vaccine markets is significant and even decisive.¹²⁵

B. CEPI

If represents the “pull” side of vaccine access, then CEPI represents the younger and, so far, smaller “push” side of vaccine access for NTDs. The Coalition for Epidemic Preparedness Innovations was established to promote the development of next-generation vaccines for diseases with either unlikely or unattainable commercial market incentives.¹²⁶ The Ebola public health emergency in West Africa jolted the world into awareness that neglected diseases like Ebola could rapidly become universal threats.¹²⁷ Like Gavi, it originated as a domestic (Norwegian) charity, operating with offices in London, Oslo, and Washington, DC. CEPI's board is comprised of twelve voting members, four investors, and eight independent members representing competencies including industry, global health, science, resource mobilization, finance, and five non-voting observers.¹²⁸

CEPI was conceived at the World Economic Forum meeting in Davos as a new partnership for a coordinated, international, and intergovernmental plan for development and deployment of new vaccines.¹²⁹ The primary objective was to address significant gaps in vaccine funding and implementation, with a focus on optimizing resource allocation for vaccine development.¹³⁰ CEPI supports the early-stage development of vaccines against known threats, ensuring that the investigational vaccines are stockpiled and ready for deployment if necessary.¹³¹ It also plays a crucial role in funding and accelerating the

125. *Financial Update, Including Forecast, GAVI* (July 24, 2025), <https://www.gavi.org/sites/default/files%20/board/minutes/2025/24-25-july05%20-%20Finacial%20Update%20including%20forecast%20-%20PPT.pdf> [<https://perma.cc/H9G8-X5K3>].

126. Stanley A. Plotkin, *Vaccines for Epidemic Infections and the Role of CEPI*, *HUM. VACCINE & IMMUNOTHERAPEUTICS*, 2755, 2756 (2017) (“The organization now called the Coalition for Epidemic Preparedness and Innovations (CEPI) came into being because in the light of Ebola and Zika there were multiple proposals to establish an international fund to develop vaccines against emerging epidemic infections.”).

127. Halabi & Gostin, *supra* note 101.

128. *CEPI Board*, CEPI, <https://cepi.net/cepi-board> [<https://perma.cc/U4R7-VTCX>] (last visited Apr. 6, 2026).

129. Valentina Bernasconi et al., *Developing Vaccines against Epidemic-Prone Emerging Infectious Diseases*, 63 *BUNDESGESUNDHEITSBLETT GESUNDHEITSFORSCHUNG GESUNDHEITSSCHUTZ* 66 (2020).

130. *Equitable Access*, CEPI, <https://cepi.net/equitable-access> [<https://perma.cc/UK45-5S7R>] (last visited Apr. 17, 2026).

131. Dimitrios Gouglas et al. *CEPI: Driving Progress Toward Epidemic Preparedness and Response*. 41 *EPIDEMIOLOGICAL REV.* 28 (2019) (“CEPI's initial strategic objectives, established in 2016 [], were aimed at advancing vaccine candidates against each of its first priority pathogens (Lassa virus, MERS-CoV, a Nipah virus) through to evidence of safety and immunogenicity in humans (phase 2a) by 2022 and to establish a diverse portfolio of platform technologies that can accelerate development, manufacture, and clinical evaluation of vaccines in response to outbreaks of new EIDs, designated ‘Disease X’ by WHO. In January 2019, CEPI expanded its list of priority pathogens to include chikungunya and Rift Valley fever. According to initial estimates, a minimum of \$1 billion would be required to bring at least 4 EID vaccines through to the end of phase 2a trials and to fund investigational stockpiles of these in case of an international health emergency.”); Katherine E. Bliss, *Strengthening Global Health Security through Critical Immunization Programs*, *CSIS* (2023), <https://www.csis.org/analysis/strengthening-global-health-security-through-critical-immunization-programs> [<https://perma.cc/9YMB-2ABA>].

development and production of vaccines for unknown or novel pathogens.¹³² CEPI furthermore supports and funds global infrastructure for vaccine development and distribution.¹³³ Although CEPI initially channeled nearly all of its investments into vaccine research and development, its mission has broadened over time to support clinical trial and regulatory readiness, vaccine manufacturing capacity in middle-income countries, and non-vaccine biological medical interventions.¹³⁴ From its inception, it adopted equitable access as one of its core principles.

Over time, CEPI expanded its mandate to lead development of vaccines for a range of pathogens with potential to cause epidemics and pandemics.¹³⁵ To some extent, this expansion of mission was driven by the COVID-19 pandemic.¹³⁶ CEPI launched a collaborative initiative with Gavi and WHO targeted at the development of COVID-19 vaccines popularly recognized as the Access to COVID-19 Tools (ACT) Accelerator.¹³⁷ The ACT Accelerator promoted coordination of resources and responsibilities between governments, scientists, businesses, civil society, philanthropists, and global health funding organizations.¹³⁸ The ACT-Accelerator was organized into four key pillars, each supported by various organizations to address different aspects of the global health response: diagnostic, therapeutics, health systems and vaccines.¹³⁹

CEPI stood up the vaccine pillar with Gavi and WHO.¹⁴⁰ Popularly known as COVAX, the platform played a crucial role in coordinating efforts to finance, select, procure, and distribute COVID-19 vaccines globally.¹⁴¹ CEPI possessed rights to direct use of vaccines it supported including Moderna's, Novavax's, and the University of Oxford/AstraZeneca's vaccines.¹⁴² CEPI used its rights under its agreements to direct partners to match with countries supported by Gavi, which ultimately served as the contracting agent.¹⁴³ WHO evaluated countries' readiness to receive doses as a matter of cold chain, personnel, and infrastructure. While not as central to COVAX, major development banks like the World Bank and the Asian Development Bank played key financing roles.¹⁴⁴

132. *Preliminary Business Plan 2017–2021*, COAL. FOR EPIDEMIC PREPAREDNESS INNOVATIONS, (2016), https://cepi.net/wp-content/uploads/2019/02/CEPI-Preliminary-Business-Plan-061216_0.pdf [<https://perma.cc/ALD2-KCPL>].

133. Sam Halabi et al., *CEPI and the Partnerships of Equitable Global Vaccine Access*, 51 J. L. MED. & ETHICS 234, 237 (2023).

134. Dimitrios Gouglas et al., *CEPI: Driving Progress Toward Epidemic Preparedness and Response*, 41 EPIDEMIOLOG. REV. 28 (2019).

135. Halabi & Gostin, *supra* note 101, at 373.

136. *Id.* at 366 (analyzing the expanding missions of both CEPI and Gavi).

137. Suerie Moon et al., *Governing the Access to COVID-19 Tools Accelerator: Towards Greater Participation, Transparency, and Accountability*. 399 LANCET 488 (2022).

138. World Health Org., *The Access to COVID-19 Tools (ACT) Accelerator*, <https://www.who.int/initiatives/act-accelerator> [<https://perma.cc/HLR7-CREL>] (last visited Aug. 30, 2024).

139. Moon et al., *supra* note 137.

140. World Health Org., *What is the Access to COVID-19 Tools (ACT) Accelerator, How is it Structured and How Does It Work?* (2021).

141. World Health Org., *COVAX*, <https://www.who.int/initiatives/act-accelerator/covax> [<https://perma.cc/58D3-PSWU>] (last visited Aug. 30, 2024).

142. Halabi et al., *supra* note 133, at 234.

143. *Gavi COVAX AMC*, GAVI (2020), <https://www.gavi.org/gavi-covax-amc> [<https://perma.cc/4FD2-VTDC>] (last visited Aug. 30, 2024).

144. Halabi & Gostin, *supra* note 101, at 367.

Vaccines for 92 low-income “donor-supported” countries were funded through COVAX.¹⁴⁵

CEPI possessed the world’s largest portfolio of Covid-19 vaccine use rights by funding developers through these new partnerships. CEPI was also able to invest in vaccine technology platforms across various universities and private entities, assuming greater responsibilities for regulatory approvals and negotiations with manufacturers.¹⁴⁶

While Gavi is dedicated to increasing access for established vaccines such as those for measles, mumps, and rubella, CEPI was created with the focus of advancing the development of next-generation vaccines designed to tackle emerging diseases that pose a threat of epidemics or pandemics. Gavi works to enhance the accessibility of proven immunizations and ensure their availability in underserved communities, thereby enhancing global health through existing solutions. In contrast, CEPI addresses the need for innovative vaccines by investing in research and development for new vaccines that can prevent or mitigate the impact of novel pathogens. The aim of this approach is to stay ahead of the potential health crisis by preparing for future threats with cutting-edge technologies and scientific advancements.¹⁴⁷

C. Global Health Philanthropies

The rapid expansion and notable growth of investments in vaccine development and distribution are not only facilitated by Gavi and CEPI, but substantial financial support provided by prominent philanthropic foundations has supported not only those organizations but independent efforts to develop vaccines, expand their availability, and reduce their price.¹⁴⁸ Among these, the Gates Foundation, Rockefeller Foundation, and the Wellcome Trust have been pivotal in driving this growth.¹⁴⁹ Their contributions have not only increased the overall funding available but have also significantly influenced the scope and impact of various global health initiatives. The Gates Foundation, in particular, has played a leading role in facilitating global access to immunization.¹⁵⁰ From 1998 to 2007, it was one of the top grant providers, with five of the top eleven recipients of its grants being major health partnerships like CEPI and

145. *Id.* at 383.

146. *Id.* at 377.

147. *Id.* at 387.

148. Antoine de Bengy Puyvalée, Katerini T. Storeng & Simon Rushton, *The Gates Foundation’s Network Diplomacy in European Donor Countries*, 21 *GLOBAL HEALTH* 22 (2025).

149. Caroline Hadley, *The Power of Giving*, 5 *EMBO REP.* 751 (2004) (“The HHMI funds scientists in the Baltics, Central and Eastern Europe, Russia and the Ukraine—areas that rarely receive any money for research. The Open Society Institute, founded by Hungarian billionaire George Soros, has foundations in these areas to support public health programmes and initiatives to combat infectious diseases such as AIDS and tuberculosis. The HHMI, the Wellcome Trust, the Rockefeller Foundation, the Volkswagen Foundation, the Gates Foundation and other private charities have begun to support research projects and public health programmes in sub-Saharan Africa.”).

150. Giulia Carbonaro, *Why Does WHO Rely So Much on Bill Gates’ Money?*, *EURONEWS* (Mar. 2, 2023), <https://www.euronews.com/health/2023/02/03/how-is-the-world-health-organization-funded-and-why-does-it-rely-so-much-on-bill-gates> [https://perma.cc/XEF4-LF3V].

Gavi.¹⁵¹ These also include the Global Fund, which addresses AIDS, tuberculosis, and malaria, the Medicines for Malaria Venture, the International AIDS Vaccine Initiative, and the Global Alliance for TB Drug Development.¹⁵² Its financial backing has enabled the development of new vaccines, the creation of innovative treatments, and the strengthening of health systems in low-resource settings.¹⁵³

III. The Gaps in Vaccine Push-Pull Legal Architecture: Chikungunya, Nipah, and Rift Valley Fever

Despite the significant advances made in developing new vaccines and expanding access, critical gaps remain even when the system drives development and licensure of safe and effective vaccines against NTDs. Chikungunya is one such example, but others, especially those on WHO's and CEPI's priority pathogens list, appear likely to follow.

A. Disease Burden and Market for Chikungunya, Nipah, and Rift Valley Fever

1. *Chikungunya*

Chikungunya or Chikungunya virus infection (hereinafter CHIKV) is an arboviral disease that primarily affects tropical and subtropical countries, leading to its identification as a priority pathogen by CEPI and WHO.¹⁵⁴ Infected individuals typically experience fever and joint pain, which may last for years and adversely affects quality of life.¹⁵⁵ Other symptoms include headache, joint swelling, muscle pain and rash.¹⁵⁶ The mortality rate for CHIKV is roughly 1 in 1,000, and pediatric populations and those over 65 who contract CHIKV are at heightened risk of long-term complications and mortality.¹⁵⁷ Roughly up to 85% of the population infected with CHIKV can experience symptoms which start with a fever that breaks 102°F or 39°C, signaling what is termed as the “acute phase”.¹⁵⁸ Immunodeficient populations, in particular, are susceptible

151. David McCoy et al., *The Bill & Melinda Gates Foundation's Grant-Making Programme for Global Health*, 373 *LANCET* 1645 (2009).

152. Johanna Hanefeld, *The Global Fund to Fight AIDS, Tuberculosis and Malaria: 10 Years On*, 14 *CLIN MED (LONDON)* 54 (2014).

153. Halabi et al., *supra* note 133.

154. Neil Cherian et al., *Strategic Considerations on Developing a CHIKV Vaccine and Ensuring Equitable Access for Countries in Need*, 8 *NPJ VACCINES* 1 (2023).

155. World Health Org., *Chikungunya Fact Sheet*, (Apr. 14, 2025), <https://www.who.int/news-room/fact-sheets/detail/chikungunya> [<https://perma.cc/V32F-VGVW>].

156. *Id.*

157. Natasja Vennik et al., *Clinical Outcomes of Chikungunya Across Age Groups: A Systematic Review*, *PLOS NEGLECTED TROPICAL DISEASES* (Oct. 2025), <https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0013580> [<https://perma.cc/E9BT-PL6G>]; Claudia Caglioti et al., *Chikungunya Virus Infection: An Overview*, 36 *NAT'L LIBR. OF MED.* 211 (2013).

158. Raja Jagannathan et al., *Epidemiology, Clinical Manifestations, and Diagnosis of Chikungunya Fever: Lessons Learned from the Re-Emerging Epidemic*, *INDIAN J. DERMATOL.* (2010), <https://pmc.ncbi.nlm.nih.gov/articles/PMC2856377/> [<https://perma.cc/Y7V3-SFKR>]; Felicity J. Burt et al., *Chikungunya Virus: An Update on the Biology and Pathogenesis of This Emerging Pathogen*, 17 *LANCET INFECTIOUS DISEASES* 107 (2017).

to liver failure, brain swelling, and seizures; infants, in particular, are at risk of developing sight issues, retinal lesions, acute disseminated encephalomyelitis and Guillain-Barré syndrome.¹⁵⁹

CHIKV is mainly transmitted to humans via mosquito but can also be transmitted vertically from mother to child in utero.¹⁶⁰ CHIKV is most prominent in tropical and sub-tropical climates, specifically in environments near still or human-stored water.¹⁶¹ There are three known genotypes of the virus: the West African, East African and Asian genotypes; more recently, the Asian genotype has evolved into two distinct lineages.¹⁶² There are two principal species of mosquito that are known to carry CHIKV: one is the Asian tiger mosquito or *A. albopictus*, and the second is *A. aegypti* or the yellow fever mosquito, which is the commonly accepted principal vector for viral spread.¹⁶³ As indicated by the names of the genotypes the disease was thought to have originated in Africa and spread to the Indo-Pacific region and further into the Asian continent.¹⁶⁴ Global infection rates are variable, but starting in the mid-2000s, CHIKV was identified in the Western hemisphere for the first time, in Brazil, then in the Caribbean and reached Florida in 2013.¹⁶⁵ The geographic spread of infection has been attributed to the invasive nature of *A. Albopictus* to Europe and the Americas, despite *A. Aegypti* still being considered the main vector; in addition, the detection of the Zika virus in Brazil in 2015 has led to a theory that CHIKV may be co-infectious and not just having coterminous symptoms.¹⁶⁶

Historical records indicate that CHIKV began spreading across the Pacific around the 18th Century but was formally identified in the 1950s in Tanzania.¹⁶⁷ In 2004, reports of large-scale outbreaks spread from Africa and Asia to the Americas and Caribbean.¹⁶⁸ After the “re-emergence” of the virus in 2004, WHO designated CHIKV as a major public health risk, and since that time, the number of recorded cases has been estimated at over 3 million in 43 countries.¹⁶⁹ Several challenges make the study of CHIKV and the development of treatment difficult; most notably, infection rates are variable. Many of the countries in which outbreaks are most common do not have continuous monitoring

159. *Id.*; see also Rohit Mehta et al., *The Neurological Complications of Chikungunya Virus: A Systematic Review*, 28 REV. IN MED. VIROLOGY e1978 (2018).

160. Timothée Laurent et al., *Architecture of the Chikungunya Virus Replication Organelle*, 11 ELIFE e83042 (2022).

161. Centers for Disease Control & Prevention, *Chikungunya*, (2024), <https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/chikungunya> [<https://perma.cc/9SMC-F32A>] (last visited Aug. 30, 2024).

162. I-Ching Sam et al., *Genotypic and Phenotypic Characterization of Chikungunya Virus of Different Genotypes from Malaysia*, 7 PLOS ONE e50476, 1 (2012).

163. Felicity J. Burt et al., *Chikungunya: A Re-Emerging Virus*, 379 LANCET 662 (2012).

164. *Id.*

165. *Id.*

166. *Id.*

167. Coal. for Epidemic Preparedness Innov., *CEPI Awards up to US \$23.4 Million to Valneva for Late-Stage Development of a Single-Dose Chikungunya Vaccine*, <https://cepi.net/cepi-awards-us234-million-valneva-late-stage-development-single-dose-chikungunya-vaccine> [<https://perma.cc/3KP6-V3W4>] (last visited June 20, 2024).

168. *Id.*

169. Int'l Vaccine Inst., *Chikungunya*, <https://www.ivi.int/what-we-do/disease-areas/chikungunya/> [<https://perma.cc/CZ8F-HR6Y>] (last visited Aug. 30, 2024).

capabilities to identify an outbreak contemporaneous with growth.¹⁷⁰ When the virus was introduced to Europe and the United States in 2013, the genetic code of CHIKV was elevated as a public health priority, but laboratory confirmation of the outbreaks in endemic regions remains low.¹⁷¹ Currently, diagnosis for both treatment and research is also challenging as RT-PCR blood tests are required, the test often takes longer than the symptomatic period, and false positives are common because of CHIKV's co-endemicity with other arboviruses (e.g., dengue, Zika).¹⁷²

2. *Rift Valley Fever*

Rift Valley Fever (RVF) is an acute viral infection that largely affects cattle, sheep, and goats but also, people and wildlife.¹⁷³ RVF is, like dengue, chikungunya, and Zika, transmitted by the *Aedes* mosquito and breaks out after heavy rainfall. According to the World Health Organization (WHO), "RVF is one of the emerging infectious diseases that mainly affects the poor and marginalized populations that lack access to health services and are readily ignored."¹⁷⁴ As with chikungunya, these populations are subjected to a cycle of ill health and poverty that exacerbates the burden of disability. Around 1% of infections lead to fatal hemorrhagic disease.¹⁷⁵

The virus that causes RVF was first discovered in 1930 during an outbreak of the virus in sheep in Kenya's Rift Valley.¹⁷⁶ Humans usually contract RVF through infected mosquitoes. Infection may also spread if people are exposed to the blood, body fluids, or tissues of infected animals. Direct exposure to fluids of infected animals takes place during slaughter and through veterinary procedures.¹⁷⁷ As a result, slaughter of animals and seeking treatment for their illnesses are the major reasons that RVF has its heaviest impact on populations that rely upon livestock rearing. RVF antibodies have been discovered in African buffalo, black rhino, lesser kudu, impala, African elephant, kongoni, and waterbuck, thus meaning that wildlife represents an additional reservoir of the virus.¹⁷⁸

170. Felicity J. Burt et al., *Chikungunya: A Re-Emerging Virus*, 379 LANCET 662 (2012).

171. *Id.*

172. David M. Morens & Anthony S. Fauci, *Chikungunya at the Door—Déjà Vu All over Again?*, 371 NEW ENG. J. MED. 885 (2014).

173. Christine Jost et al., *Epidemiological Assessment of the Rift Valley Fever Outbreak in Kenya and Tanzania in 2006–2008*, 83 AM. J. TROP. MED. HYG. 65 (Supp. 2 2010).

174. G. O. Muga et al., *Sociocultural and Economic Dimensions of Rift Valley Fever*, 92 AM. J. TROP. MED. HYG. 730 (2015), <https://doi.org/10.4269/ajtmh.14-0363>; World Health Org., *Hemorrhagic Fever Task Force, Rift Valley Fever Outbreaks in East Africa*, Proceedings of the International Conference on Emerging Infectious Diseases (Mar. 8–12, 1998).

175. Brian Bird et al., *Complete Genome Analysis of 33 Ecologically and Biologically Diverse Rift Valley Fever Virus Strains Reveals Widespread Movement and Low Genetic Diversity Due to Recent Common Ancestry*, 81 J. VIROLOGY 2805 (2007).

176. R. Daubney & J.R. Hudson, *Enzootic Hepatitis or Rift Valley Fever: An Undescribed Virus Disease of Sheep, Cattle and Man from East Africa, with an Account of an Experimental Inoculation of Man by P.C. Garnham*, 34 J. PATHOL. & BACTERIOL. 545 (1931).

177. World Health Org., *Rift Valley Fever, Fact Sheet* (2024), <https://www.who.int/news-room/fact-sheets/detail/rift-valley-fever> [<https://perma.cc/5X8M-GBW3>].

178. A.G. Evans et al., *Prevalence of Antibodies Against Rift Valley Fever Virus in Kenyan Wildlife*, 136 EPIDEMIOLOGY & INFECTION 1261 (2008).

3. *Lassa Fever*

Lassa fever, caused by *Lassa mammarenavirus*, is a zoonotic infectious disease primarily transmitted by the common African rat, with outbreaks of human infection regularly reported Sierra Leone, Liberia, Guinea, and Nigeria.¹⁷⁹ Transmission of the disease is generally through indirect or direct exposure to the rodent, rather than from human-to-human transmission.¹⁸⁰ Approximately 80% of infections result in relatively minor symptoms but in the remaining cases, symptomatic disease can lead to severe symptoms requiring hospitalization and causing death.¹⁸¹

Climate change is causing the spread of the rodent and the potential number of infections to explode.¹⁸² Moreover, the most impacted regions are also those without significant resources for diagnostics, surveillance and reporting, so the extent of its spread and threat are largely unknown. “The case fatality rate (CFR) of Lassa fever is estimated at 15%, with wide variability. Two recent studies of populations in Nigeria recorded CFRs of 14% and 31%, with a study in Sierra Leone estimating a CFR of 69%.”¹⁸³

B. Vaccine Developers

1. *CHIKV*

Pushed by the possibility of earning one of FDA’s priority review vouchers – awarded to sponsors that develop drugs or vaccines for tropical diseases or rare pediatric diseases or to use as medical countermeasures – as well as funding from CEPI, a race to develop the first safe and efficacious CHIKV vaccine emerged over the course of the last 10 years. Valneva, a French life sciences firm, won that race and the FDA priority review voucher, and did so with CEPI support. Other candidates supported by CEPI are nearing or completing Phase III clinical trials, and Bavarian Nordic recently obtained licensure of a second vaccine. Valneva recently earned marketing approval in the EU as well as Brazil including a pediatric indication there.¹⁸⁴

Valneva, Emergent BioSolutions (in 2023, Bavarian Nordic acquired Emergent’s traveler vaccine portfolio which included Vivotif and Vaxchora, both marketed vaccines for the prevention of typhoid fever and cholera respectively, and a Phase III vaccine candidate for the prevention of Chikungunya virus),

179. O.O. Balogun et al., *Lassa Fever: An Evolving Emergency in West Africa*, 104 AM. J. TROP. MED. HYG. 466 (2021).

180. D.W. Redding et al., *Geographical Drivers and Climate-Linked Dynamics of Lassa Fever in Nigeria*, 12 NAT. COMM’NS 5759 (2021).

181. David Simons, *Lassa Fever Cases Suffer from Severe Underreporting Based on Reported Fatalities*, 15 INT’L HEALTH 608 (2023).

182. *Id.*

183. *Id.*

184. See *Commission Authorises Chikungunya Vaccine*, EUROPEAN COMM’N, (July 24, 2024), https://ec.europa.eu/commission/presscorner/detail/en/ip_24_3502 [<https://perma.cc/WE99-628U>]; Press Release, *Valneva Receives First Marketing Authorization for IXCHIQ® in a Chikungunya Endemic Country*, VALNEVA (Apr. 14, 2025), <https://valneva.com/press-release/valneva-receives-first-marketing-authorization-for-ixchiq-in-a-chikungunya-endemic-country/> [<https://perma.cc/J6DS-BLCF>].

Bharat Biotech International Limited, and Themis (acquired by Merck which then discontinued its CHIKV vaccine line) all vied in the CHIKV vaccine race.¹⁸⁵ In 2018, Valneva was awarded FDA Fast Track Designation for the CHIKV candidate vaccine, and to meet the need, Valneva utilized a surrogate endpoint of protection established in a non-human primate infection model to study potential virality development better.¹⁸⁶ In 2022, Valneva completed a Biological License Application (BLA) submission to the U.S. FDA.¹⁸⁷ The development was supported by a CEPI investment of USD 23.4 million for the end product of a single-dose vaccine.¹⁸⁸

The Bavarian Nordic CHIKV vaccine is a virus-like-particle (VLP) vaccine that includes hydrogel as an adjuvant.¹⁸⁹ The vaccine uses CHIKV strain 37997, which belongs to the West African lineage and is designed as a single-dose vaccine.¹⁹⁰ Bavarian Nordic began its rolling Biologics License Application (BLA) to the FDA in April 2024, completed the same in June 2024, and has recently received FDA approval on February 14, 2025.¹⁹¹ The Priority Review designation reduced the FDA's review period to six-months instead of the standard ten-month timeframe.¹⁹²

Bharat Biotech is developing a whole virion CHIKV vaccine using the "CHIK 03/06 Indian strain," a development of the East African lineage.¹⁹³ The Bharat Biotech vaccine is a two-day regime that has to be developed 28 days apart and is currently in Phase 2b/3 clinical trials in India, with several smaller 2/3 trials ongoing in Thailand, Panama, Colombia, Guatemala and Costa Rica.¹⁹⁴ Bharat Biotech aspires to achieve licensure through the Drug Controller General of India (DCGI). The licensure likely depends on Phase 3 safety and immunogenicity data supported by active and passive immunization studies in non-human primate studies (NHPs).¹⁹⁵ It is unclear where Bharat Biotech will seek marketing approval. The multinational nature of the trials suggests that

185. See Cherian et al., *supra* note 154.

186. *Id.*

187. See Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, *IXCHIQ*, VALNEVA (Nov. 10, 2023), https://valneva.com/wp-content/uploads/2023/11/2023_11_10_BLA_Approval_PR_En_Final_.pdf [https://perma.cc/8JTR-C5SJ]

188. See CoL for Epidemic Preparedness Innov., *supra* note 176.

189. See Cherian et al., *supra* note 154, at 2.

190. *Id.*

191. Press Release, *Bavarian Nordic A/S, Bavarian Nordic Completes BLA Submission to U.S. FDA for its Chikungunya Vaccine Candidate*, GLOBENEWSWIRE (June 17, 2024), <https://www.globenewswire.com/news-release/2024/06/17/2899781/0/en/Bavarian-Nordic-Completes-BLA-Submission-to-U-S-FDA-for-its-Chikungunya-Vaccine-Candidate.html>; Press Release, *Bavarian Nordic A/S, Bavarian Nordic Receives U.S. FDA Approval of Chikungunya Vaccine for Persons Aged 12 and Older*, GLOBENEWSWIRE (Feb. 14, 2025), <https://www.globenewswire.com/news-release/2025/02/14/3026914/0/en/Bavarian-Nordic-Receives-U-S-FDA-Approval-of-Chikungunya-Vaccine-for-Persons-Aged-12-and-Older.html> [https://perma.cc/FZG5-2PTC]; see *Bavarian Nordic Announces FDA Acceptance and Priority Review of the BLA for its Chikungunya Vaccine*, BAVARIAN NORDIC (Aug. 13, 2024), <https://www.bavarian-nordic.com/investor/news/news.aspx?news=6967#:~:text=COPENHAGEN%2C%20Denmark%2C%20August%2013%2C,to%20prevent%20disease%20caused%20by> [https://perma.cc/XEK7-VS6U].

192. See U.S. Food & Drug Admin., *February 14, 2025 Approval Letter — VIMKUNYA* (Feb. 14, 2025), <https://www.fda.gov/media/185478/download> [https://perma.cc/4YNN-X6N3].

193. See Cherian et al., *supra* note 154, at 2.

194. *Id.* at 4.

195. *Id.* at 2.

Bharat Biotech may eventually seek approval in other CHIKV-affected countries in Latin America and Southeast Asia.¹⁹⁶

The Themis CHIKV vaccine is a measles-vectored vaccine that uses CHIKV structural proteins.¹⁹⁷ The Themis vaccine is designed on a two-doses system administered 28 days apart. It completed Phase 2 trials in 2022 in Germany and Austria, and a Phase 2a trial in Puerto Rico and the contiguous US.¹⁹⁸ The Themis vaccine received an FDA Breakthrough Therapy designation, a Fast-Track designation, and an EMA Priority Medicine designation.¹⁹⁹ In February 2023, however, Merck discontinued the Themis studies.²⁰⁰

2. RVF

As with chikungunya, several organizations are developing Rift Valley Fever (RVF) vaccines with CEPI support, although other organizations are also participating. Afrigen Biologics, a South African startup supported by the World Health Organization, the Medicines Patent Pool, as well as private capital, is working on an mRNA-based vaccine with funding from CEPI. The University of Oxford and the Kenya Medical Research Institute (KEMRI)-Wellcome Trust Research Programme are developing a vaccine using the ChAdOx1 platform that was used to develop the Vaxzevria COVID vaccine that saved the most lives worldwide. CEPI is supporting a total of four different RVF vaccine candidates, and is also supporting clinical trial planning for sites in East Africa.

3. Lassa Fever

Researchers from Thomas Jefferson University and the University of Maryland Baltimore, in collaboration with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Geneva Foundation, have developed a promising new vaccine candidate that protects against Lassa fever.²⁰¹ That vaccine candidate effectively prevents severe cases of Lassa fever and death in preclinical animal models and paves the way for research in people.²⁰² IAVI and members of the global Viral Hemorrhagic Fever Consortium have been collaborating since 2018 to accelerate clinical development of IAVI's single-dose LASV vaccine candidate in studies supported

196. *Id.*; Int'l Vaccine Inst., *IVI and Costa Rica*, <https://www.ivi.int/who-we-are/ivi-and-costa-rica/> [<https://perma.cc/Z7HK-XZ2R>] (last visited Mar. 27, 2026)

197. *Id.* at 1.

198. *Id.* at 2.

199. Cherian et al., *supra* note 154, at 1.

200. See James Waldron, *Merck Admits Defeat in Chikungunya Vaccine Race with Valneva*, FIERCE BIOTECH (2023), <https://www.fiercebiotech.com/deals/merck-admits-defeat-race-valneva-get-first-chikungunya-vaccine-market> [<https://perma.cc/QB5C-9269>] (last visited Mar. 31, 2026).

201. Gabrielle Scher, et al., *Inactivated Rabies-Based Lassa Fever Virus Vaccine Candidate LASSARAB Protects Nonhuman Primates from Lethal Disease*, 9 NPJ VACCINES 143 (2024), <https://doi.org/10.1038/s41541-024-00930-z>.

202. *Id.* at 1, 2.

and funded by CEPI and the European & Developing Countries Clinical Trials Partnership (EDCTP).”²⁰³

However, without specific plans to make these vaccines affordable or accessible, they will face the same challenges in distribution that CHIKV vaccines have faced.

C. Valneva, CEPI, and Their Partners

Discovery Valneva SE (“Valneva”) is a French biotech company headquartered in Saint-Herblain, France.²⁰⁴ Valneva was created by the merger of the companies Intercell and Vivalis SA in 2013 and is traded publicly on Euronext Paris (formerly the Paris Bourse) securities market but used to be listed on the Vienna Stock Exchange.²⁰⁵ The company specializes in vaccine development and has manufacturing sites in Livingston, Scotland, Solna, Sweden, Vienna, Austria and other offices in Canada and the United States²⁰⁶ Valneva has developed vaccines for Japanese encephalitis (approved in Europe, America and Austria)) and a vaccine for cholera (approved in Europe and Austria)).²⁰⁷ Valneva also has a notable failed vaccine development: specifically a therapeutic vaccine for *Pseudomonas aeruginosa*,²⁰⁸ *Staphylococcus aureus* (developed in collaboration with Merck)²⁰⁹ and a therapeutic vaccine against hepatitis C.²¹⁰ Valneva collaborated with Dynavax Technologies to develop a candidate for an inactivated whole virus vaccine against COVID-19 derived from Valneva’s approved Japanese encephalitis vaccine.²¹¹ The Phase 1/2 trial was completed and fully reported by August 2021. Valneva agreed with the UK government to provide up to 100 million doses manufactured in Valneva’s Livingston Scotland

203. IAVI, *Participants in Nigeria Vaccinated in First-Ever Phase 2 Lassa Fever Vaccine Clinical Trial*, Sponsored by IAVI, <https://www.iavi.org/press-release/iavi-c105-lassa-fever-vaccine-clinical-trial/> [https://perma.cc/T5GZ-R4Z] (Mar. 31, 2026).

204. *CEPI Awards Up to U \$23.4 million to Valneva for Late-Stage Development of a Single-Dose Chikungunya Vaccine*, VALNEVA, <https://valneva.com/press-release/cepi-awards-up-to-us23-4-million-to-valneva-for-late-stage-development-of-a-single-dose-chikungunya-vaccine/> [https://perma.cc/X2SB-FPT8] (last visited June 15, 2024).

205. *Press Release, Valneva SE, Completion of Merger Between Vivalis and Intercell to Form Valneva*, GLOBENEWSWIRE (May 28, 2013), <https://www.globenewswire.com/news-release/2013/05/28/1783914/0/en/Completion-of-Merger-between-Vivalis-and-Intercell-to-form-Valneva.html>

206. *Manufacturing and Services*, VALNEVA, <https://valneva.com/products/manufacturing-services/> [https://perma.cc/CXJ8-D9AZ] (last visited Aug 30, 2024).

207. *Japanese Encephalitis Vaccine - IXIARO®*, VALNEVA, <https://valneva.com/products/ixiaro/> [perma.cc/94FL-G44U] (last visited Aug. 30, 2024); *Cholera Vaccine - DUKORAL®*, VALNEVA, <https://valneva.com/products/dukoral/> [perma.cc/CXJ8-D9AZ] (last visited June 21, 2024).

208. *Valneva Writes Off Hospital-Acquired Infection Vaccine Following Phii/III Miss*, FIERCE BIOTECH, <https://www.fiercebiotech.com/biotech/valneva-writes-off-hospital-acquired-infection-vaccine-following-phii-iii-miss> [https://perma.cc/9MU5-BHLE] (last visited June 19, 2024).

209. *Katie Reid, Merck Ends Trial of Intercell’s MRSA Vaccine*, REUTERS (June 8, 2011), <https://www.reuters.com/article/us-intercell-merck-idUSTRE75711P20110608/> [https://perma.cc/EZU3-ZCW8] (last visited June 19, 2024).

210. *Intercell Hepatitis C Vaccine Meets Primary Endpoints*, FDA NEWS, https://www.natap.org/2007/HCV/082107_01.htm [https://perma.cc/36VB-SP44] (last visited June 19, 2024).

211. *Dose Finding Study to Evaluate the Safety, Tolerability and Immunogenicity of an Inactivated, Adjuvanted SARS-CoV-2 Virus Vaccine Candidate Against COVID-19 in Healthy Subjects*, CLINICALTRIALS.GOV, <https://clinicaltrials.gov/study/NCT04671017> [https://perma.cc/U7PD-UXHA] (last visited June 25, 2024).

facility, and the UK government pre-ordered 60 million.²¹² Valneva's vaccine order was canceled by the UK government not due to the quality of the vaccine but due to financial complications related to Brexit.²¹³ On top of the CHIKV vaccine, Valneva is planning the release of a Lyme disease vaccine in 2024 with the help of Pfizer, who bought an 8.1% stake in Valneva for \$95.24 million in 2022 to develop the vaccine.²¹⁴

D. The Gaps in Vaccine Access after Approval

1. *Chikungunya*

Despite the successful efforts of CEPI and developers to bring IXCHIQ to market, the vaccine remains largely unused. During the period October 1, 2022–March 11, 2023, a total of 81,037 suspected, probable, or confirmed Chikungunya cases were recorded by the Ministry of Health of Paraguay. Cumulative national incidence was 1,073 cases per 100,000 population (3,088 per 100,000 population in Asunción). The outbreak spread to border regions with Argentina and Brazil. Of 47,116 probable or confirmed cases 4,604 (10%) resulted in hospitalizations and 52 people died. Among 208 (0.4%) cases in infants aged ≤29 days (neonates), 140 hospitalizations and eight deaths were reported, accounting for the highest case fatality rate (3.8%) among all age groups.²¹⁵

Paraguay illustrates the structural gaps that existing push- and pull-based vaccine financing mechanisms fail to address. While CEPI successfully supported Phase III trials including one now under way in Brazil, there simply is insufficient financing or market incentive in making the vaccine available to populations in Paraguay. The most common source for vaccine procurement is Gavi, the vaccine alliance. But in 2024, countries become eligible for Gavi support if their most recent gross national income (GNI) per capita was less than or equal to US\$ 1,810. Paraguay's GNI per capita is approximately three times this threshold, even though the burden of Chikungunya disease falls disproportionately on the poorest Paraguayans.

212. Allie Nawrat, *Q&A with Valneva: UK Government Scales Up COVID-19 Manufacturing*, PHARMA. TECH. (Aug. 6, 2020), <https://www.pharmaceutical-technology.com/features/valneva-manufacturing-uk-government-covid19/> [<https://perma.cc/K2XZ-RCQ5>] (last visited June 25, 2024).

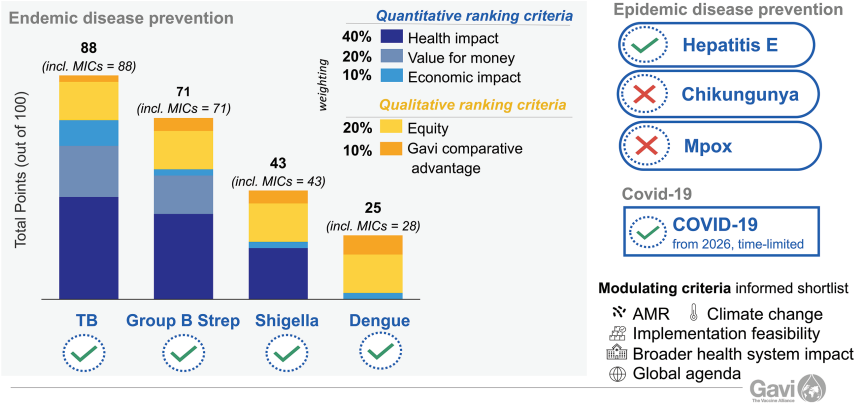
213. Suzi Ring, *U.K. Threw COVID Vaccine Maker Under Bus Over Contract, Valneva CEO Says*, BLOOMBERG (Nov. 24, 2021), <https://www.bloomberg.com/news/articles/2021-11-24/u-k-threw-covid-vaccine-maker-under-bus-over-contract-ceo-says> [<https://perma.cc/H85G-EUN4>].

214. Reuters, *Pfizer to Buy 8.1% Stake in French Vaccines Company Valneva*, ECONOMIC TIMES (June 20, 2022), <https://economictimes.indiatimes.com/news/international/business/pfizer-to-buy-8-1-stake-in-french-vaccines-company-valneva/articleshow/92330582.cms> [<https://perma.cc/WW9A-CABM>].

215. Martha Torales et al., *Notes from the Field: Chikungunya Outbreak — Paraguay, 2022–2023*, 72 MMWR MORB. MORTAL. WKLY. REP. 636 (2023), <http://dx.doi.org/10.15585/mmwr.mm7223a5>.

Figure 1

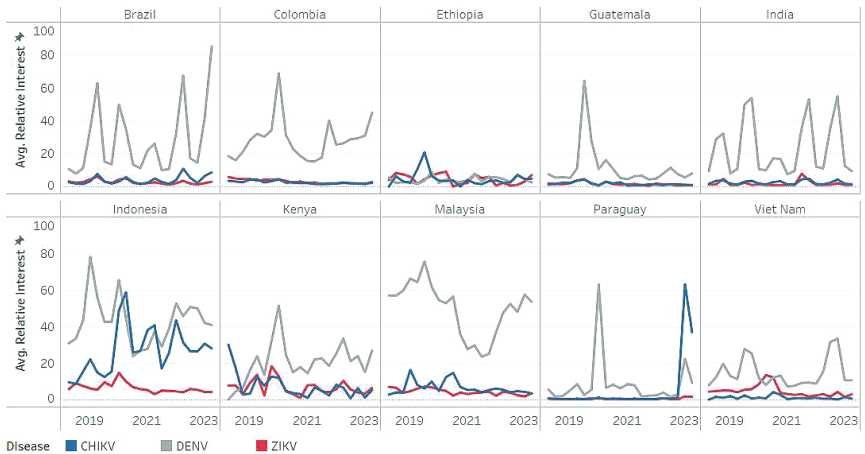
Proposed vaccine shortlist



The government of Paraguay’s principal priority for vaccine procurement with its own funds is a vaccine against the dengue virus, which imposes a greater economic, morbidity and mortality burden on Paraguay’s population.

This is similarly true for the governments of Argentina, Bolivia, Brazil, China, Pakistan, and Peru as well as a number of island countries in the Indian Ocean that are battling a CHIKV outbreak. As the Google Trends analysis below demonstrates, governments affected by mosquito-borne illnesses are far more likely to invest limited resources to battle dengue and Zika, rather than chikungunya.

Figure 2



The profile of CHIKV and demand for IXCHIQ are similar for Rift Valley Fever and Lassa as well as Nipah and Chagas disease.

2. RVF and Lassa Fever

While RVF and Lassa Fever vaccine candidates have yet to reach licensure, a Phase II study is under way in Kenya for RVF and a Phase III trial is under way for Lassa. If these candidates are shown to be safe and effective, they will nevertheless face the same supply-demand problem as those countries battling chikungunya. RVF and Lassa level their most significant toll on countries ineligible for Gavi support, and they have more significant public health threats they must use limited dollars for over even proven vaccines.

IV. Solutions

With new approved vaccines for CHIKV available in parts of the world in 2025 and several others in the late stages of development, the barriers to access and affordability that remain for countries with endemic regions persist. The previous sections of this Article have reviewed the structural causes of the persistent access and affordability gap for CHIKV vaccines and highlighted similar challenges likely to arise for vaccines targeting other neglected tropical diseases.

This section will propose structural solutions to close this gap. Specifically, it will examine the following four ideas: adapting the Gavi mission to expand eligibility using WHO's standards for evaluating NTDs; relying on World Bank Interest Free Loans; creating a special, top-down global fund for neglected diseases (including CHIKV); and shifting the manufacturing or production of neglected disease vaccines to endemic countries, in order to improve affordability and accessibility.

A. Adapting Gavi's Mission

Gavi (the Global Vaccine Alliance) currently and historically has determined its priority countries (e.g., the countries eligible to receive Gavi financing) using a World Bank determined GNI threshold for low-income countries.²¹⁶ In 2024, for example, Gavi's threshold for eligibility was US \$ 1810 GNI (updated annually using inflation adjustments by the World Bank), making lower-middle and upper-middle countries ineligible for Gavi assistance, as has been true since Gavi's inception.²¹⁷

As previously mentioned, the countries in which CHIKV is endemic are largely lower-middle or upper-middle countries, rather than low-income, and therefore most often do not fall within Gavi eligibility for support. Countries including Brazil, Argentina, Thailand, the Maldives, and India, suffer high rates of CHIKV, but classify as lower-middle, or upper-middle countries by World Bank standards, meaning that they do not receive Gavi support for access.

At the same time, many of these countries tend to have relatively limited financial resources for vaccine purchasing themselves, often due in part to having to prioritize other diseases, sometimes with higher rates of mortality (such

216. *Co-Financing Policy*, GAVI, <https://www.gavi.org/programmes-impact/programmatic-policies/co-financing-policy> [<https://perma.cc/47RJ-DP5P>] (last visited Mar. 31, 2026).

217. *Id.*

as malaria or dengue), or having to dedicate health budgets to other competing priorities like non-communicable diseases, road safety, or other health threats. The effect of this is that with limited healthcare budgets, endemic CHIKV countries most often do not have the resources to include public funding for a low-mortality (but still serious) disease like CHIKV in their funding prioritization, resulting in a dangerous and ongoing gap in access to solutions.

An actionable solution for closing this gap would be for Gavi to expand its mission to allow financing for vaccine procurement and distribution for a CHIKV vaccine for currently ineligible middle-income countries, in special circumstances like those that meet NTD thresholds: where the burden of disease is 500 to 1000 times higher than in high income countries. Specifically, Gavi could modify its eligibility criteria to include lower-middle or upper-middle countries where a disease burden threshold is crossed rather than the less precise use of GNI per capita.

Gavi's current charter reads that

The purpose of the Gavi Alliance is to promote health by: (i) providing vaccines and the means to deliver such vaccines to people *in the poorest countries* (ii) facilitating the research and development of vaccines of primary interest to the developing world; and (iii) to provide support in connection with achieving the foregoing purposes by helping to strengthen health care systems and civil societies supporting such purposes in the developing world.

We propose that Gavi's charter be amended:

The purpose of the Gavi Alliance is to promote health by: (i) providing vaccines and the means to deliver such vaccines to people [**suffering from the greatest burden of preventable Type III diseases**]; (ii) facilitating the research and development of vaccines of primary interest to the developing world; and (iii) to provide support in connection with achieving the foregoing purposes by helping to strengthen health care systems and civil societies supporting such purposes in the developing world.

This relatively simple change would allow Gavi to incorporate the international consensus reached through the London Declaration on Neglected Tropical Diseases and would bridge the gap between poor people who happen to be in a poor enough *country* and help all vulnerable people in countries worldwide, even if the economy of the country in which they live happens to be a bit too well off.

B. Bid Score Enhancements for LMIC Manufacturers

The reality is that neglected tropical diseases disproportionately devastate people living in tropical conditions, many where mosquitoes thrive. A second recommendation would therefore address how to increase the capacity for new vaccines to be manufactured in or near those populations. Currently, breakthrough vaccines are manufactured largely in wealthy countries.

As the global procurement system now operates, tenders for fulfilling vaccine RFPs from international organizations like UNICEF and PAHO require a standard bidding process where all manufacturers participate on an equal

playing field. But manufacturers in places like Brazil and India are closer to where CHIKV is endemic and levels its greatest toll. If bids from LMIC manufacturers would receive score enhancements for their proximity to endemic areas, it could provide an incentive for IP rights holding company like Valneva to enter into technology transfer agreements with partners like Serum Institute of India making the vaccine more appealing as a supply and demand matter. This complementary solution could channel global efforts for technology transfer to endemic countries – specifically, toward shifting the manufacturing and production of the CHIKV vaccine to endemic countries, in order to create local access and affordability. If technically feasible, a shift toward local manufacturing and production could create more accessible supply directly in endemic regions.²¹⁸

At present, IXCHIQ and VIMKUNYA are the only FDA approved CHIKV vaccines.²¹⁹ Critically, in 2021, Valneva, the vaccine manufacturer of IXCHIQ together with Instituto Butantan in Brazil signed an agreement for the local development, manufacturing, and marketing of IXCHIQ as part of the framework of an agreement signed between CEPI, and Valneva in 2019, which provides funding of up to 24.6 million for vaccine access.²²⁰ This model and agreement provides a strong example of the feasibility of supporting technology transfer and local development of vaccines in an endemic country.²²¹ While CEPI facilitated technology transfer is a positive step, being more competitive on the international bidding playing field may be more so.²²²

C. Global or Regional Funds for NTD Vaccines

Outside of expanding Gavi's mandate and facilitating technology transfer, a third compelling solution would be to develop a novel global fund focused on supporting vaccine access for neglected diseases in lower-middle and upper-middle countries. Just as the explosion of HIV/AIDS cases worldwide, particularly in Africa, prompted an acknowledgment that a coordinated global commitment to funding in low- and middle-income countries was needed, leading to the establishment of the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the G7 could similarly commit itself to a Global Fund for NTD Vaccines.

The idea of a global fund dedicated to funding interventions to address the disproportionate burden of these three diseases was first discussed at the G8 Summit in Kyushu-Okinawa in 2000, with Japan's leadership fundamental to putting this discussion on the agenda. Through this G8 diplomacy, states reached a consensus that HIV/AIDS, tuberculosis, and malaria were threatening

218. Ganesh Kumraj et al., *Capacity Building for Vaccine Manufacturing Across Developing Countries: The Way Forward*, 18 HUMAN VACCINES IMMUNOTHER. 529 (2020).

219. *Chikungunya – VLA1553*, VALNEVA, <https://valneva.com/research-development/chikungunya/> [https://perma.cc/68EZ-LMAH] (last visited Mar. 31, 2026).

220. *Id.*

221. Tabata Viapiana, *Institute Submits Brazil's First Chikungunya Vaccine for Approval amid Rising Cases*, BRAZIL REPORTS (Dec. 18, 2023), <https://brazilreports.com/institute-submits-brazils-first-chikungunya-vaccine-for-approval-amid-rising-cases/5642/> [https://perma.cc/L79V-MW54] (last visited Aug. 30, 2024).

222. Cherian et al., *supra* note 154, at 1.

to “reverse decades of development and to rob an entire generation of hope for a better future.”

In 2001, during a special summit of the Organization of African Unity, African leaders voiced support for the creation of a global fund separate from WHO, with this support for a global health “war chest” finding strong support across the United Nations (UN). Championed by UN Secretary General Kofi Annan, the 2001 UN General Assembly Special Session on AIDS called for the formal creation of the Global Fund.

While the list of endemic countries may be narrow for any given disease, a new global fund could focus on providing a top-down approach to providing support for diseases that are neglected or under-financed due to a combination of factors such as Gavi ineligibility (or recent transition from Gavi eligibility), or high and competing disease burden priorities. Such a fund could provide specific funding for neglected tropical diseases, and in so doing, work to close significant immunization gaps in non-Gavi-eligible middle-income countries for neglected tropical diseases.²²³

These funds could also be supported at the regional level. The PAHO Revolving Fund, for example, provides bulk procurement and low prices for 41 routine immunizations. An annex to the fund for NTDs endemic to South America could serve as a smaller scale model. AVAT, the trust established for the African Union to procure the Johnson & Johnson vaccine for COVID-19 could serve as another kind of model and implementing partner.²²⁴

Conclusion

This Article has identified critical gaps that remain even after public private partnerships stepped in to not only continue the success of EPI as undertaken by WHO and UNICEF, but to fuel development of novel vaccines against NTDs and make them accessible and affordable to the populations that need them. Because these gaps lie between the “push” activities of CEPI and global philanthropies and the “pull” incentives of Gavi and national treasuries and ministries of health, new solutions are needed. This Article has proposed the adaptation of Gavi’s mandate, offering bid scoring enhancements to manufacturers located in endemic regions, and prioritization on the agenda of the G7 including global or regional funds modeled on the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Taking these steps could save hundreds of thousands of lives and spare just as many the prospect of lifelong disability.

223. World Bank Group, *IBRD Flexible Loan*, <https://treasury.worldbank.org/en/about/unit/treasury/ibrd-financial-products/ibrd-flexible-loan> [https://perma.cc/SYQ2-4T6Y] (last visited Aug. 30, 2024).

224. World Bank Group, *How the World Bank Group Is Helping Countries Address COVID-19 (Coronavirus)*, <https://www.worldbank.org/en/news/factsheet/2020/02/11/how-the-world-bank-group-is-helping-countries-with-covid-19-coronavirus> [https://perma.cc/CB6F-K384] (last visited Aug. 30, 2024).