ARTICLES

THE INTERNATIONAL HEALTH REGULATIONS (FOURTH EDITION): ADVANCING SECURITY, SOLIDARITY, AND EQUITY FOR A SAFER AND FAIRER WORLD

ALEXANDRA L. PHELAN*AND LAWRENCE O. GOSTIN†

ABSTRACT

On June 1, 2024, the World Health Assembly adopted a suite of amendments to the World Health Organization's (WHO) International Health Regulations (2005) (IHR). The amendments are the most significant reform of the Regulations since their adoption following the severe acute respiratory syndrome (SARS) outbreak two decades ago. Reflecting the global health injustices seen during successive public health emergencies, including the COVID-19 pandemic, the Regulations now expressly include equity and solidarity as principles for the interpretation and implementation of the treaty. This is reinforced by new provisions to ensure equitable access to health products, a financing mechanism, and additional requirements for international collaboration and cooperation. The amendments further add a new power to declare pandemic emergencies, establish a non-punitive states parties-led implementation committee, and a range of clarifying and modernizing updates to existing provisions. While the amendments are one step towards more equitable international law for global health emergencies, there are a range of areas for improvement to greater realize global health security, solidarity, and equity. While limited by the current geopolitical climate,

* Associate Professor, Johns Hopkins Bloomberg School of Public Health; Senior Scholar, Johns Hopkins Center for Health Security; Faculty Director (Policy) at Johns Hopkins Institute for Planetary Health, Baltimore, United States; S.J.D. Georgetown University Law Center, Washington, D.C., United States; LL.M. Australian National University, Canberra, Australia; LL.B. Monash University, Melbourne, Australia; Representative of Johns Hopkins Center for Health Security, an Annex E Relevant Stakeholder in the negotiations for the amendments to the International Health Regulations and Pandemic Agreement and has advised WHO Member States on the negotiations and the IPPPR on international law. The authors thank Anna Bezruki for research assistance support coding WHO Member State positions upon the adoption of the amendments. Correspondence: aphelan4@jhu.edu.

† Distinguished University Professor; Founding Linda D. & Timothy J. O'Neill Professor of Global Health Law; Co-Faculty Director, O'Neill Institute for National & Global Health Law; Director, World Health Organization Collaborating Center on Global Health Law, Georgetown University Law Center, Washington, D.C., United States; LL.D.(Hon.) University of Sydney, Sydney, Australia; J.D. Duke University, Durham, United States; Member of the WHO Review Committee Regarding Amendments to the International Health Regulations.

the amendments demonstrate shifting global power dynamics and negotiation blocks in global health. They also provide compelling evidence of a broad interpretation of the World Health Assembly's (WHA) unique opt-out power to make regulations with respect to preventing, preparing for, and responding to the international spread of disease. This Article discusses the breadth and content of the amendments to the IHR adopted in 2024 while examining the implications of textual and subject-matter choices on WHO Member State participation, the legal nature of the new obligations, and the scope of the WHA's law-making authority. This Article then identifies areas for normative development and future reform to advance security, solidarity, and equity. Finally, we examine the early impacts of the second Trump presidency on the United States' membership in the WHO and status as an IHR States Party, and the subsequent normative implications for the IHR amendments globally.

I. Introduction

At the height of the COVID-19 pandemic in 2022, amid the suffering and deaths as well as the inequitable distribution of lifesaving resources,

Member States of the World Health Organization (WHO) agreed to negotiate major revisions to the International Health Regulations (2005) (IHR or Regulations). The IHR is the international instrument that governs preparedness for and response to public health emergencies of international concern, including pandemics, and establishes the rights and responsibilities of WHO and national governments. The IHR is among the most widely adopted international treaties with 196 states parties, including the United States. IHR negotiations in Geneva proved contentious, with major tensions emerging on seminal issues such as financing, equity, and compliance. With negotiations on the verge of collapse, WHO Member States adopted the amendments on June 1, 2024, the final day of the Seventy-seventh World Health Assembly (WHA or Assembly).[1] The 2024 amendments to the IHR were made available as a WHA conference paper,[2] and following WHO's formal publication, the amended instrument will be the IHR (Fourth Edition).[3]

The amendments will mark the most substantial changes to the governing framework for the international spread of infectious diseases since the Regulations were significantly revised two decades ago in 2005 in the aftermath of the severe acute respiratory syndrome (SARS) epidemic. They are the first international law reforms made directly in response to the COVID-19 pandemic and explicitly embed equity and solidarity into the governance of global health security. The amendments do this by incorporating both equity and solidarity as principles to guide the interpretation and implementation of the IHR, while also adding new provisions to facilitate and remove barriers to equitable access to health products, a financing mechanism, and expanding obligations for international cooperation and collaboration. The amended IHR will now include a new power for the WHO Director-General to declare pandemic emergencies, bringing WHO alerts in line with Member State expectations, a facilitative and non-punitive IHR states parties-led implementation committee, and updates to existing provisions to clarify and modernize the IHR.[4] The amended Regulations, therefore, have deep historical and real-world meaning. Furthermore,

1. World Health Organization [WHO], WHA77.17, *Strengthening Preparedness for and Response to Public Health Emergencies through Targeted Amendments to the International Health Regulations (2005)* (June 1, 2024), https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_R17-en.pdf.

2. World Health Organization [WHO], A77/A/CONF./14, *International Health Regulations (2005)* (June 1, 2024), https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_ACONF14-en.pdf.

3. The IHR (Fourth Edition) will contain both the 2024 amendments as well as modest amendments adopted in 2022, discussed in further detail in Section III.H below.

4. World Health Organization [WHO], *supra* note 2.

the process towards the amendments and the amendments themselves provide broader insights into WHO's significant law-making powers under its Constitution.[5]

While representing a major advance in global health diplomacy, the IHR still fail to address vital preparedness, response, and equity concerns. Missing entirely from the amendments are equitable access to health products in non-emergency periods, an integrated One Health approach that recognizes the interconnection of human, animal, and environmental health,[6] access to pathogen samples and sequence data and the equitable sharing of their benefits from their use, and updated clarity on the application of travel restrictions that could delay rapid outbreak reporting and the movement of health products.

When the Seventy-seventh WHA adopted the IHR amendments on June 1, 2024,[7] it also extended the negotiations mandate for a new WHO convention, agreement, or other international instrument on pandemic prevention, preparedness, and response (Pandemic Agreement) for a further year.[8] The new treaty proposes to include several core issues glaringly absent from the IHR—a robust Pathogen Access and Benefits Sharing (PABS) system, diversified manufacturing and technology transfer, and a One Health approach.[9] If those efforts collapse, these and other critical gaps will persist in the governance of global health security.

This Article argues that the 2024 amendments to the IHR are a crucial but incomplete step towards greater security, solidarity, and equity within international law for global health emergencies. This Article starts by discussing in Part II how these amendments fit within the larger arc of international law for health emergencies. Section II.A starts by addressing the historical origins of the IHR and how their focus has shifted over time. Section II.B outlines the role of the COVID-19 pandemic as the impetus

5. *See generally* World Health Organization [WHO], *Constitution of the World Health Organization* (1948), July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185.

6. *One Health*, WORLD ORGANISATION FOR ANIMAL HEALTH, https://www.woah.org/en/what-we-do/global-initiatives/one-health (last visited Nov. 5, 2024); *One Health*, WORLD HEALTH ORGANIZATION [WHO], https://www.who.int/health-topics/one-health (last visited Nov. 5, 2024).

7. World Health Organization [WHO], *supra* note 1.

8. World Health Organization [WHO], WHA77(20), *Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response* (June 1, 2024), https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_(20)-en.pdf.

9. World Health Organization [WHO], A77/10, *Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response* (May 27, 2024), https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_10-en.pdf.

for reform on specific issues, while Section II.C details the procedural history leading to the amendments. In Part III, this Article discusses the breadth and content of the adopted amendments. These are examined across eight major themes: a normative shift to equity and solidarity, notifications and associated information sharing, determinations including matters to be considered in making recommendations and a new pandemic emergency power, equitable access to health products during emergencies, border crossing measures like digital vaccine certificates, a new financing mechanism, core capabilities, and an implementation committee.

Part IV contends that the amendments are part of a larger global health law-making project. In Section IV.A, this Article proposes that through the adoption of the amendments, WHO Member States have affirmed a broad interpretation of the scope of the WHA's regulations power under Article 21 of the WHO Constitution, which may facilitate more responsive international law-making in the future. Section IV.B examines potential and substantive weaknesses in the amendments. This section first connects amendments that appear to limit new obligations to terms familiar to international human rights law, before secondly identifying shortcomings that states parties must address, taking advantage of the momentum and potential agility granted by the regulations power under Article 21 of the WHO Constitution. However, even once amendments are adopted, the progressive development of global health law is not immune from shifts in national ideologies. In Part V, this Article examines the immediate implications of United States' President Donald J. Trump's second term, in particular his order to withdraw the United States from membership of the WHO and halting participation in WHO-related negotiations. This part identifies the requirements for withdrawal from WHO membership, differentiating it from IHR states party status and the procedural requirements for rejecting IHR amendments, as well as the potential ramifications for our collective global health security.

This Article then concludes that while crises have recurrently driven IHR reform, states parties should not wait for the next health emergency to address known weaknesses, stronger norms, and obligations for global health security, solidarity, and equity. While there remain significant gaps in substance and governance, the IHR amendments represent a major achievement for international health diplomacy—embedding equity as a core value for the first time and underscoring the importance of multilateralism and mutual obligations in global health security. The increasingly challenging geopolitical environment, particularly the United States' disengagement, should not spook states parties from recognizing this gain, but rather position the amendments

as a timely and prescient reassertion and commitment to global health law and institutional norms.

II. One Step in the Long Arc of History

This part explores how the 2024 amendments to the IHR should be contextualized within an especially long history of international law for health emergencies. Section II.A starts by describing how the IHR's colonial origins shaped their focus on the containment of infectious diseases, which was broadened towards international public health emergencies regardless of their cause following the SARS epidemic. Section II.B examines how the COVID-19 pandemic underscored the need for IHR reforms identified following previous health emergencies, while elevating the urgency for the IHR to address health inequities between states. Finally, Section II.C details how these issues were translated into a reform process that ultimately led to the adoption of the 2024 IHR amendments.

A. *IHR Origins: From Colonialization Towards Equal Partnerships*

The origins of the IHR can be traced to international laws developed largely by European states during the mid-nineteenth century.[10] During an era of proactive colonialism, the International Sanitary Conventions prioritized preventing the spread of diseases perceived as arriving from the Global South to the North, such as cholera and later plague and yellow fever—infectious diseases considered non-endemic to Europe.[11] This approach propelled racism and prejudice while also ignoring diseases such as smallpox and tuberculosis,[12] with smallpox included in later twentieth-century revisions when the disease increased in priority to the Global North, driven by colonization.[13]

Building upon the International Sanitary Conventions, WHO adopted the International Sanitary Regulations (ISR) in 1951 at the Fourth WHA in Geneva.[14] The ISR established obligations for notifications and

10. *See* David Fidler, *From International Sanitary Conventions to Global Health Security: The New International Health Regulations*, 4 Chinese J. of Int'l L. 325, 329 (2005); Lawrence O. Gostin & Rebecca Katz, *The International Health Regulations: The Governing Framework for Global Health Security*, 94 Milbank Q. 264, 266 (2016); Alexandre White, Epidemic Orientalism: Race, Capital, and the Governance of Infectious Disease 90 (2023).

11. Ginevra Le Moli, *The Containment Bias of the WHO International Health Regulations*, 00 British Yearbook of Int'l L. 1, 14 (2023); Matiangai Sirleaf, *White Health as Global Health*, 117 Am. J. Int'l L. Unbound 88, 90 (2023).

12. *See* White, *supra* note 10.

13. Sirleaf, *supra* note 11.

14. World Health Organization [WHO], WHA4.75, *Adoption of the International Sanitary Regulations (WHO Regulations No. 2)* (May 25, 1951), https://iris.who.int/handle/10665/85614.

control measures for plague, cholera, yellow fever, smallpox, typhus, and relapsing fever.[15] The ISR were revised multiple times,[16] including in 1969 when typhus and relapsing fever were removed from the scope of the Regulations and they were renamed the IHR,[17] and in 1981 when smallpox was removed upon its eradication.[18] In 1995, WHO Member States called for the IHR to be revised to reflect the considerable increase in global air traffic and the continuous evolution of public health threats beyond the three diseases now subject to the IHR: plague, cholera, and yellow fever.[19] Despite this, the IHR were not revised until 2005 in the aftermath of the 2002–2003 SARS epidemic, which had revealed the marked inadequacies of the Regulations for health threats in the new millennium.[20]

The IHR, as revised in 2005, shifted focus to all health hazards rather than a set list of infectious diseases; however, the Regulations still perpetuated a "containment bias" aimed at preventing the international spread of disease. The Regulations failed to address the upstream prevention of health threats, such as those emerging through zoonotic spillovers (i.e., the transmission of pathogens from animals to humans),[21] or equitable access to health products, like vaccines and therapeutics, and health care. Further, the IHR, up to its Third Edition, focused nearly exclusively on preparedness, detection, and notification, with limited public health response beyond those related to preventing international spread.[22]

Over the last two decades, the IHR has had several modest amendments (see Table One). Following its complete revision and adoption in 2005, the Second Edition included the lists of states parties and related reservations,

15. World Health Organization [WHO], WHA4/60, *International Sanitary Regulations (WHO Regulations No 2)*, arts. 1, 3 (May 21, 1951), https://iris.who.int/handle/10665/101391.

16. World Health Organization [WHO], WHA22.46, *International Health Regulations* (July 25, 1969) [hereinafter *International Health Regulations 1969*], https://iris.who.int/handle/10665/85816; World Health Organization [WHO], WHA26.55, *Additional Regulations of 23 May 1973 Amending the International Health Regulations (1969), in Particular with Respect to Articles 1, 21, 63 to 71, and 92* (May 23, 1981), http://apps.who.int/iris/handle/10665/92148; World Health Organization [WHO], WHA34.13, *Amendment of the International Health Regulations (1969)* (May 18, 1981) [hereinafter *Amendment of the International Health Regulations 1969*], https://iris.who.int/bitstream/handle/10665/156549/WHA34_R13_eng.pdf.

17. *International Health Regulations 1969, supra* note 16.

18. *Amendment of the International Health Regulations 1969, supra* note 16, at 1.

19. World Health Organization [WHO], WHA48.7, *Revision and Updating of the International Health Regulations* (May 12, 1995), https://iris.who.int/handle/10665/178403.

20. *See* World Health Organization [WHO], WHA56.28, *Revision of the International Health Regulations* (May 28, 2003), https://iris.who.int/handle/10665/78336.

21. Le Moli, *supra* note 11, at 28.

22. *See generally* Gian Luca Burci, *The Legal Response to Pandemics: The Strengths and Weaknesses of the Int'l Health Regulations*, 11 J. OF INT'L HUMANITARIAN LEGAL STUD. 204 (2020).

objections, and declarations upon its entry into force on June 15, 2007.[23] In 2014, the requirements for yellow fever vaccine certificates contained in Annex 7 were amended,[24] entering into force in July 2016, with the Third

TABLE ONE: EDITIONS OF THE IHR (2005) FOLLOWING AMENDMENTS

IHR Edition	Year of Addition/ Amendment (Publication Year)	Amendment Details
First	2005	Complete revision and initiation of the designation IHR (2005).
Second	2007 (2008)	Updated to include lists of states parties, reservations, and other communications, as well as the health part of the aircraft general declaration.
Third	2014 (2016)	Revision of Annex 7 concerning yellow fever vaccination.
Fourth	2022 (forthcoming)	Amendments changing the time periods for entry into force of amendments (twenty-four to twelve months) and for lodging rejections or reservations (eighteen to ten months).
Fourth	2024 (forthcoming)	Significant revisions across entire IHR (2005), including to principles, notifications, declarations, access to health products, financing, collaboration, core capacities, governance, and implementation.

23. WORLD HEALTH ORGANIZATION [WHO], INTERNATIONAL HEALTH REGULATIONS (2005) 59–68 (2d ed. 2005), https://www.who.int/publications/i/item/9789241580410. This edition also included a new Annex 9 that contained the health part of the Aviation General Declaration, completed for international flights regarding any illnesses that occurred on board during flight, and as revised by the International Civil Aviation Organization and entering into force on July 15, 2007.

24. *See generally* World Health Organization [WHO], WHA67.13, *Implementation of the International Health Regulations (2005)* (May 24, 2014), https://apps.who.int/gb/ebwha/pdf_files/wha67/a67_r13-en.pdf. The amendments to Annex 7 changed the period of protection for yellow fever conferred by vaccination and the period of certification validity from ten years to life.

Edition published that same year.[25] Given that the last formal publication of the IHR was the Third Edition in 2016, the next formal publication—incorporating both the amendments adopted in 2022 and 2024[26]—will be designated the IHR (Fourth Edition).

The incorporation of equity and solidarity into the principles with the most recent amendments to the IHR represents a historical sea change. The amendments have the potential to profoundly shift the focus of pandemic prevention, preparedness, and response. Perhaps more importantly, the inclusion of equitable access to health products throughout the text rectifies a glaring oversight in the IHR's dynamics, which prioritized notification and entrenched a containment bias, favoring high-income states. Also vital are the express provisions for sustainable and equitable financing with the establishment of the Coordinating Financial Mechanism, as well as expanded obligations around international collaboration. Through this change in the framing and balance of obligations, the amended IHR represent a significant step towards the realization of equal partnerships in international law for global public health threats.

B. *The COVID-19 Pandemic: Crisis Compelling Reform of Global Health Law*

The 2024 amendments aim to close major gaps illuminated during COVID-19 and recent health emergencies, notably the influenza A(H1N1) pandemic (2009–2010), Ebola outbreaks in West Africa (2014–2016) and the Democratic Republic of Congo (2018–2020), and mpox outbreaks globally (2022) and now ongoing in the DRC and neighboring states.[27] In

25. World Health Organization [WHO], International Health Regulations (2005) (3d ed. 2016), https://iris.who.int/bitstream/handle/10665/246107/9789241580496-eng.pdf?sequence=1.

26. The 2022 amendments entered into force on May 31, 2024, and are described in greater detail in Section III.H below.

27. *See World Health Assembly Agreement Reached on Wide-Ranging, Decisive Package of Amendments to Improve the International Health Regulations*, World Health Organization [WHO] (June 1, 2024), https://www.who.int/news/item/01-06-2024-world-health-assembly-agreement-reached-on-wide-ranging–decisive-package-of-amendments-to-improve-the-international-health-regulations–and-sets-date-for-finalizing-negotiations-on-a-proposed-pandemic-agreement; World Health Organization [WHO], *Report of the Review Committee on the Functioning of the International Health Regulations (2005) in Relation to Pandemic (H1N1) 2009* (May 5, 2011) [hereinafter *IHR Review Committee*], https://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf; *see generally* Lawrence O. Gostin et al., *Toward a Common Secure Future: Four Global Commissions in the Wake of Ebola*, 13(5) PLOS Med e1002042 (2016) [hereinafter Gostin et al., *Toward a Common Secure Future*]; Lawrence Gostin et al., *Ebola in the Democratic Republic of the Congo: Time to Sound a Global Alert?*, 393 The Lancet 617 (2019) [hereinafter Gostin et al., *Ebola in the Democratic Republic of the Congo*], https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30243-0; Caitlin Rivers et al., *The Resurgence of Mpox in Africa*, 332 JAMA 1045 (2024).

particular, these health emergencies have highlighted the impact of rapid outbreak notifications and comprehensive information sharing, mounting immediate public health responses to international alerts, gross global inequities in access to diagnostics, personal protective equipment, vaccines, therapeutics and other health products, the scale of international travel and technological advances, and the need for international solidarity in moments of crisis.

Driven by failures of early and accurate notification of the SARS-CoV-2 outbreak in Wuhan, China,[28] the amendments reinforce the importance of rapid and transparent sharing of scientific information among IHR states parties and WHO. Scientific exchange includes rapid detection and reporting of outbreaks, as well as the sharing of novel pathogens and their genomic sequences.

Following the WHO Director-General's declaration of a Public Health Emergency of International Concern (PHEIC) on January 30, 2020, WHO Member States failed to appropriately heed this global alert and sufficiently prepare for the international spread of SARS-CoV-2.[29] Over the first two months of the worldwide spread of SARS-CoV-2, WHO's failure to characterize the spread of SARS-CoV-2 as a pandemic became a factor in governments delaying national surge response.[30] On March 11, 2020, the WHO Director-General used the term "pandemic" to describe the spread of COVID-19,[31] which was then incorrectly reported and interpreted as a type of formal declaration.[32] And yet, the IHR at that time did not grant WHO authority to declare a pandemic.[33] Proposals to give

28. *China Delayed Releasing Coronavirus Info, Frustrating WHO*, Associated Press (June 2, 2020, 2:52 PM), https://apnews.com/article/fed0f89a3b46cfa401e62ce7386f0cfb.

29. Independent Panel for Pandemic Preparedness and Response, COVID-19: Make It the Last Pandemic 28–33 (2021), https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf.

30. *Id.* at 24.

31. *WHO Director-General's Opening Remarks at the Media Briefing on COVID-19*, World Health Organization [WHO] (Mar. 11, 2020), https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020.

32. *See, e.g.*, William Wan, *WHO Declares a Pandemic of Coronavirus Disease Covid-19*, Washington Post (Mar. 11, 2020), https://www.washingtonpost.com/health/2020/03/11/who-declares-pandemic-coronavirus-disease-covid-19; Dawn Kopecki et al., *World Health Organization Declares the Coronavirus Outbreak a Global Pandemic*, CNBC (Mar. 11, 2020), https://www.cnbc.com/2020/03/11/who-declares-the-coronavirus-outbreak-a-global-pandemic.html.

33. Amy Maxmen, *Why Did the World's Pandemic Warning System Fail When COVID Hit?*, 589 Nature 499, 500 (2021); Clare Wenham et al., Reforming the Declaration Power for Global Health Emergencies, IHR Reform White Paper Series (1) (2020), https://georgetown.app.box.com/s/w0u7k6dwb7404nfcp87bxh34q90dpemn; David Adam, *When Will COVID Stop Being a Global Emergency?*, 614 Nature 201, 202 (2023).

WHO the power to declare an intermediate level of alert had previously been criticized as risking further fragmentation of global health,[34] subsequently echoed by the IHR Review Committee Regarding Amendments to the International Health Regulations.[35] Over the course of negotiations, it became evident that empowering WHO to declare a pandemic was vital for mobilizing global attention and resources. Consequently, the IHR now triggers a new, escalated international alert, empowering the Director-General to declare a "pandemic emergency."

Delayed responses to these alerts exacerbate health emergencies, slowing the distribution of life-saving health products to the states and populations most at risk, thereby increasing spread and the risk that states hoard resources for their own populations. Successive global health emergencies have demonstrated the dire consequences of this with gross inequities within and among states in affordable access to lifesaving health products. In response the amended IHR seek to promote timely and equitable access to the benefits of scientific research, including diagnostics, vaccines, therapeutics, and personal protective equipment. For the first time in the history of the IHR, the Regulations embed equity as one of its core principles.

Additionally, during the pandemic, governments often required proof of vaccination as a condition of international travel—so-called "vaccine passports."[36] Consequently, the IHR now provides greater clarity and detail regarding the types of health documents that states parties can require from travelers, including proof of vaccination.

Finally, the COVID-19 pandemic demonstrated a failure of international cooperation and solidarity, along with widespread non-compliance with IHR obligations. In light of these failures, many low- and middle-income countries (LMICs) demanded a financing system that supported IHR implementation.[37] The new amendments establish for the first time a Coordinating Financial Mechanism (CFM) designed to promote timely, predictable, and sustainable financing for IHR implementation. This includes greater clarity and expanded requirements to

34. Clare Wenham et al., *Problems with Traffic Light Approaches to Public Health Emergencies of International Concern*, 397 THE LANCET 1856, 1857 (2021), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00474-8/abstract.

35. World Health Organization [WHO], A/WGIHR/2/5, *Report of the Review Committee Regarding Amendments to the International Health Regulations (2005)* (Feb. 6, 2023), at 45–47, https://apps.who.int/gb/wgihr/pdf_files/wgihr2/A_WGIHR2_5-en.pdf.

36. Alexandra L Phelan, *COVID-19 Immunity Passports and Vaccination Certificates: Scientific, Equitable, and Legal Challenges*, 395 THE LANCET 1595 (2020), https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)31034-5.pdf; Salima S. Mithani et al., *A Scoping Review of Global Vaccine Certificate Solutions for COVID-19*, 18 HUMAN VACCINES & IMMUNOTHERAPEUTICS 1, 7 (2022).

37. TIAJI SALAAM-BLYTHER & MATTHEW C. WEED, CONG. RSCH. SERV., IF12139, INTERNATIONAL HEALTH REGULATIONS AMENDMENTS (2024).

ensure public health prevention, preparedness, and response capacities that states parties must develop, strengthen, and maintain. To better align state behavior with legal requirements, the amendments also establish a new States Parties Committee for the Implementation of the International Health Regulations (2005) (SPC) composed of states parties to provide non-punitive guidance to facilitate IHR implementation. While advocates urged more robust governance of states parties' obligations, the new SPC is the first time the IHR has adopted any mechanism for government compliance with legal norms.

C. *The Path to IHR Reform: Shifting Power and Strengthened Norms*

Prior to COVID-19, successive independent, scholarly, and expert reviews highlighted states parties' failure to comply with the IHR.[38] Expert review committees tasked specifically with examining IHR functioning during the 2009 H1N1 influenza pandemic and the 2013–2015 Ebola epidemic in West Africa both reiterated the importance of compliance rather than changes in content.[39] Yet, the COVID-19 pandemic drove states to express concerns with compliance, governance, and content. Overall, COVID-19 exacerbated major weaknesses in the IHR's content and scope.[40]

At the Seventy-third WHA in May 2020, WHO Member States directed the WHO Director-General to initiate an independent review of the international health response to COVID-19.[41] Over the following year, the Independent Panel on Pandemic Preparedness and Response (IPPPR) concluded that the IHR "are a conservative instrument as currently constructed and serve to constrain rather than facilitate rapid

38. Rep. of the High-level Panel on the Global Response to Health Crises, *Protecting Humanity from Future Health Crises*, U.N. Doc. A/70/723 (2016); COMMISSION ON A GLOBAL HEALTH RISK FRAMEWORK FOR THE FUTURE & NATIONAL ACADEMY OF MEDICINE, SECRETARIAT, THE NEGLECTED DIMENSION OF GLOBAL SECURITY: A FRAMEWORK TO COUNTER INFECTIOUS DISEASE CRISES (2016), http://www.nap.edu/catalog/21891; Suerie Moon et al., *Will Ebola Change the Game? Ten Essential Reforms before the next Pandemic. The Report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola*, 386 THE LANCET 2204 (2015), https://www.thelancet.com/action/showPdf?pii=S0140-6736%2815%2900946-0; Gostin et al., *Toward a Common Secure Future*, *supra* note 27, at 2–4.

39. *IHR Review Committee*, *supra* note 27, at 13, 129; World Health Organization [WHO], *Implementation of the International Health Regulations (2005): Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response* (May 13, 2016).

40. Sudhvir Singh et al., *How an Outbreak Became a Pandemic: A Chronological Analysis of Crucial Junctures and International Obligations in the Early Months of the COVID-19 Pandemic*, 398 THE LANCET 2109, 2114–2119 (2021), https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2901897-3.

41. World Health Assembly, WHA73.1, *COVID-19 Response* (May 19, 2020), https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf.

action," thereby calling for a redesign of the global surveillance and alert systems, including the adoption of the precautionary principle when responding to novel pathogens, and underscoring vast global inequities in access to diagnostics, vaccines, and therapeutics.[42] The panel also called for a new "Pandemic Framework Convention."[43]

The Director-General subsequently appointed a Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response. This IHR Review Committee recommended increased resources for WHO, an implementation monitoring mechanism, a risk-based approach to new pathogens, protection of human rights, proportionate and evidence-based travel measures, standards for electronic health documents, and the importance of sharing pathogen samples and sequences.[44] That same year, the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme (IOAC) issued its tenth annual report, recommending that WHO Member States agree to targeted revision of the IHR, including amendments relating to risk assessment, a graded PHEIC declaration, and WHO's travel advisory function.[45]

WHO Member States considered these reports from the IPPPR, the Review Committee on the Functioning of the International Health Regulations (2005), and the IOAC, as well as from a Working Group on Strengthening WHO Preparedness and Response to Health Emergencies. This working group was renamed to the Working Group on Amendments to the International Health Regulations (WGIHR) via a WHA decision and the working group subsequently negotiated targeted IHR reforms.[46] The WHA's same decision also established a new body, the IHR Review Committee Regarding Amendments to the International Health Regulations (IHR Review Committee Regarding Amendments) to advise the WGIHR on technical recommendations regarding the

42. INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 29, at 26.

43. *Id.* at 47.

44. World Health Organization [WHO], WHA Doc A74/9 Add.1, *WHO's Work in Health Emergencies. Strengthening Preparedness for Health Emergencies: Implementation of the International Health Regulations (2005)* (May 5, 2021), https://cdn.who.int/media/docs/default-source/documents/emergencies/a74_9add1-en.pdf?sfvrsn=d5d22fdf_1&download=true.

45. *See* World Health Organization [WHO], WHA Doc. A75/16, *Public Health Emergencies: Preparedness and Response, The Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme* (May 11, 2022), https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_16-en.pdf.

46. World Health Organization [WHO], WHA75(9), *Strengthening WHO Preparedness for and Response to Health Emergencies* (May 27, 2022), https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75(9)-en.pdf.

proposed amendments.[47] Lawrence Gostin, one of this Article's authors, was a member of this review committee.[48] In the space of only four months, the review committee reviewed more than 300 proposed amendments across thirty-three existing articles and six new articles.[49] Amendments were proposed by sixteen states parties, including four regional submissions from the WHO Africa Region, the European Union, the Eurasian Economic Union, and the Southern Common Market (MERCOSUR).[50]

The IHR Review Committee Regarding Amendments underscored the need to strengthen core capacities and expand to wider health systems capacities, including One Health, which expressly embody the values of equity, solidarity, and international cooperation.[51] The IHR Review Committee Regarding Amendments further recommended adjusting the incentive structure between rapid reporting and the imposition of travel restrictions, ensuring early notification, full sharing of scientific information and the "equally fulsome" exchange of benefits derived from such data, and improving implementation and compliance.[52]

Considering this report throughout the IHR amendment negotiations, the WGIHR met from early November 2022 on, ending during the Seventy-seventh WHA. The Assembly adopted the full package of proposed amendments in the final hours on June 1, 2024.[53] Despite their wide-ranging substantial nature, the proposed amendments were adopted in a legal manner similar to past amendments, resulting in the IHR (2005, Fourth Edition) rather than a new IHR (2024). As the WGIHR co-chairs noted, "we are not rewriting the IHR to develop an IHR 2024. We are amending the IHR 2005, and they will continue to be reviewed and updated in the future, just as they have been previously amended in 2014 and 2022."[54] This may signal that the IHR will

47. *Id.*

48. *Review Committee Regarding Amendments to the International Health Regulations* (2005), WORLD HEALTH ORGANIZATION [WHO], https://www.who.int/teams/ihr/ihr-review-committees/review-committee-regarding-amendments-to-the-international-health-regulations-(2005) (last visited Nov. 6, 2024).

49. World Health Organization [WHO], *supra* note 35, at 10.

50. *Id.* at 93.

51. *Id.* at 6, 20.

52. *Id.* at 6–8.

53. World Health Organization [WHO], *supra* note 1.

54. Priti Patnaik, *"Equity" Stands A Chance In the International Health Regulations. Without Financing, Compliance at Stake [WGIHR8]*, GENEVA HEALTH FILES (Apr. 23, 2024), https://genevahealthfiles.substack.com/p/ihr-equity-financing-geneva-2024-pandemic-inb.

undergo ongoing improvement, which should advance health security and equity.

Throughout all these processes, common threads emerged, but not all were woven into the amended IHR. The most significant shift was to reframe the Regulations from a Global North perspective of rapid notification and response to one that included vital perspectives from the Global South on equity and solidarity. The success of this new framing will depend on robust implementation, international collaboration, and financing.

Yet, fundamental gaps remain, including the necessity and appropriateness of travel restrictions and their impact on timely outbreak notifications. Future IHR amendments will need to enhance equity still further while safeguarding against discriminatory travel and trade restrictions, which are often targeted at the Global South. Meanwhile, ongoing negotiations for a Pandemic Agreement will remain vital to create mechanisms for global equity, including a robust PABS system and diversified manufacturing of lifesaving medical countermeasures. A One Health approach is also missing from the new IHR amendments and must be addressed in the Pandemic Agreement if Member States wish global health law to embody this principle.

III. The Breadth and Content of the 2024 Amendments to the IHR

The changes in the IHR can be divided across eight major thematic categories: normative shifts, notifications, determinations, health products, border crossings, financing, core capacities, and implementation. In addition to these thematic areas, international collaboration features as a cross-cutting theme throughout the 2024 IHR amendments, recognizing the unequal distribution of resources and burdens of obligations despite global interdependence.

A. *Reflecting Normative Shifts*

Historically, the core purpose and scope under Article 2 of the IHR were limited to the control of the international spread of infectious diseases, the protection of international travel and trade, and ensuring that public health responses are commensurate with risk.[55] The IHR now have an expanded scope to explicitly include *preparing for* the international spread of disease, in addition to their original goal of preventing, protecting against, controlling, and responding to the international spread of

55. World Health Organization [WHO], *supra* note 25, art. 2.

disease.[56] This recognizes the probability of future health threats and the need to actively prepare for them while underscoring the importance—and thus legitimizing the inclusion—of preparedness activities under the IHR. As before, these goals are to be conducted in ways commensurate with and restricted to public health risks while avoiding unnecessary interference with international traffic and trade.[57]

Under Article 3, IHR principles now expressly require that states parties must implement the IHR to "promote equity and solidarity" in addition to full respect for the dignity, human rights, and fundamental freedoms of persons.[58] The express inclusion of equity is historic. It reflects a desire to mitigate the global injustices experienced during the COVID-19 pandemic between countries, in particular inequities between resource-rich, high-income countries gained at the expense of the health, economies, and security of low and middle-income countries (LMICs), and within countries, including the disproportionate burden of the pandemic on historically marginalized populations, including inequities based on race, gender, and national origin.

Similarly, the explicit inclusion of solidarity as a principle reflects a broader movement in international law recognizing the importance of international cooperation that goes beyond the prevailing model of charity, aid, and humanitarian assistance. The IHR now instills a more modern model of equal partnerships and the equitable sharing of both benefits and burdens among states parties. Global conceptions of equity must evolve from a model of discretionary philanthropy to one based on rights, entitlements, and mutual obligations.

B. *Notifications*

The amended IHR do not alter states parties' obligations to notify WHO of events that may constitute a Public Health Emergency of International Concern (PHEIC). However, Article 6 was amended to empower WHO to share notifications with other international organizations (IOs) where the event falls within their competency.[59] In addition to the existing reference to the International Atomic Energy Agency, this new power facilitates the sharing of scientific information between WHO and IOs within the One Health Quadripartite—including the Food and Agriculture Organization, the World Organization for Animal Health, and the United Nations Environmental Program. The

56. World Health Organization [WHO], *supra* note 2, art. 2.

57. *Id.*

58. *Id.* art. 3.

59. *See id.* art. 6.1.

One Health Quadripartite was established through a Memorandum of Understanding in 2022 to facilitate coordination and collaboration between its four constitutive IOs on issues arising at the interfaces of human, animal, and environmental interfaces in the context of the One Health approach.[60] However, the IHR empower only one-way sharing from WHO to other relevant IOs, despite the need for seamless sharing of data among relevant organizations.[61]

To assist states parties in assessing their Article 6 notification responsibilities, the IHR provide a decision instrument in Annex 2.[62] For events that are immediately reportable, the amended Annex 2 removes express reference to "wild type" poliovirus, resulting in all poliomyelitis cases being immediately notifiable when caused by either circulating vaccine-derived poliovirus or wild-type poliovirus.[63]

States parties are now also expressly required to use the decision instrument to assess whether to notify WHO of events that are "clusters of cases of severe acute respiratory disease of unknown or novel cause"[64]—reflecting recent experience with COVID-19. It makes clear that states parties should rapidly report outbreaks of novel respiratory diseases to WHO. The Annex 2 amendment does not, however, substantively alter states parties' obligations; it does not immediately classify such events as potential PHEICs requiring unconditional reporting, and such events would likely already trigger assessment using the decision instrument. Yet, this express inclusion underscores the importance of rapidly assessing and notifying respiratory events given their clear pandemic potential.

Several related provisions underwent language changes that shifted state party obligations, but the language changes are mostly hortatory rather than binding. All this reflects international diplomatic tension: governments were well aware of the importance of early and accurate

60. *See* Memorandum of Understanding between the Food and Agriculture Organization of the United Nations and the World Organisation for Animal Health and the World Health Organization and the United Nations Environment Programme Regarding Cooperation to Combat Health Risks at the Animal-Human-Ecosystems Interface in the Context of the "One Health" Approach and Including Antimicrobial Resistance (2022), https://openknowledge.fao.org/server/api/core/bitstreams/0b6a5a41-4383-4840-acf0-ef374e07a4b3/content (last visited Nov 6, 2024).

61. *See* Colin J. Carlson & Alexandra L. Phelan, *International Law Reform for One Health Notifications*, 400 THE LANCET 462 (2022), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00942-4/abstract.

62. World Health Organization [WHO], *supra* note 2, Annex 2.

63. *Id.*

64. *Id.*

notification and scientific exchange, yet they still zealously defended their national sovereignty and hesitated to accede to new legally binding requirements.

Under Article 8, where an event does not meet the definition of a potential PHEIC requiring notification, particularly due to a lack of information, states parties now "should," rather than "may," keep WHO informed.[65] Such consultation is now required "in a timely manner," however there is no clear temporal requirement to notify.[66] States parties also "should" now consult with WHO on appropriate health measures.[67] In amending this language, WHO Member States deliberately chose to change the nature of the obligation, encouraging states parties to undertake a course of conduct rather than simply express permission. Importantly, the use of "should" instead of "shall" is also a deliberate choice. In English, the more permissive language of "should" does not necessarily rise to the imperative direction of "shall," used elsewhere in the IHR.[68] This imposes normative clarity of how states parties are expected to conduct themselves, even for events that do not expressly require notification. It also avoids inadvertently restricting consultations to circumstances of insufficient information.[69]

The IHR permit WHO to receive reports from unofficial (i.e., nonstate) sources under Article 9.[70] This is an important power that could include sources from independent scientists, health workers, journalists, or civil society. WHO must assess unofficial reports and seek verification from the government in whose territory the event is allegedly occurring, following procedures set out in Article 10.[71] The amendments clarify the timing of verification—WHO must now offer to collaborate with a state party about a received report "upon receiving" information that an event may constitute a PHEIC.[72] If a state party refuses WHO's offer of collaboration and the public health risk justifies doing so, WHO is now actively encouraged—"should" replaces "may"—to share with other states parties information about the event.[73]

---

65. *Id.* art. 8; World Health Organization [WHO], *supra* note 25, art. 8.

66. World Health Organization [WHO], *supra* note 2, art. 8.

67. *Id.*

68. *See, e.g., Id.* art. 6.1.

69. World Health Organization [WHO], *supra* note 35, at 40.

70. World Health Organization [WHO], *supra* note 25, art. 9; World Health Organization [WHO], *supra* note 2, art. 9.

71. World Health Organization [WHO], *supra* note 25, art. 10; World Health Organization [WHO], *supra* note 2, art. 10.

72. World Health Organization [WHO], *supra* note 2, art. 10.3.

73. *Id.* art. 10.4.

For early reporting to be maximally useful, it needs to be openly shared with all WHO Member States.

The amended IHR do not change the requirement that any public health information WHO receives—whether through surveillance, notification, consultation, other sources, or verification—must be shared with all states parties and relevant intergovernmental organizations in confidence and only to the extent necessary to enable a public health response.[74] However, for public health information received through notifications, consultations, and other reports from states parties, WHO can only make this generally available under specific conditions, such as where an event is determined to constitute a PHEIC or—a new type of determination—a "pandemic emergency."[75]

IHR amendments regarding notifications and sharing information with WHO and with other states parties likely arose from failures of rapid and transparent notifications during the initial Wuhan outbreak. WHO became aware of the outbreak and subsequent information from "unofficial" sources, such as media, scientists, and health professionals on the ground, rather than from an official report from China. At the same time, when China did verify the outbreak, its initial description of a "SARS-like" virus misleadingly suggested it had limited human-to-human transmissibility. These delays and inaccuracies likely slowed the international response as the virus rapidly spread across the world.[76]

C. *Determinations*

The amended IHR retain the WHO Director-General's powers to determine that an event constitutes a PHEIC, but now also empower the Director-General to determine whether an event constitutes a pandemic emergency.[77] Both the definition and surrounding language situate pandemic emergencies as a type of PHEIC: not all PHEICs are pandemic emergencies, but all pandemic emergencies are PHEICs. The amended IHR further define pandemic emergencies as restricted to communicable diseases (thus excluding non-infectious hazards) that also meet four criteria, namely that the event is or is at risk of: "(i) having a wide geographical spread to and within multiple States, (ii) exceeding the capacity of health systems to respond, (iii) causing

74. World Health Organization [WHO], *supra* note 25, art. 11.1; World Health Organization [WHO], *supra* note 2, art. 11.1.

75. World Health Organization [WHO], *supra* note 2, art. 11.2.

76. *See generally* LAWRENCE O. GOSTIN, GLOBAL HEALTH SECURITY: A BLUEPRINT FOR THE FUTURE (2021).

77. World Health Organization [WHO], *supra* note 2, art. 12.

substantial social and/or economic disruption (including international traffic and trade), and (iv) requiring rapid, equitable, and enhanced coordinated international action and whole-of-government and whole-of-society approaches."[78]

The amended IHR provide guidance on the sequence of determinations. Under new Article 12, paragraph 4 bis, if the Director-General has determined that an event constitutes a PHEIC, they shall further assess whether the PHEIC also constitutes a pandemic emergency.[79] The Director-General is to use the same sources of information for assessing both PHEICs and pandemic emergencies: information from states parties, the decision instrument in Annex 2, advice of the Emergency Committee, scientific principles, available scientific evidence, and other relevant information, as well as an assessment of the risk to human health, international spread, or interference with international traffic.[80] Throughout the amended IHR, references to PHEICs are supplemented by corresponding references to pandemic emergencies rather than the latter resulting in separate powers or outcomes. The amended IHR clarify the requirements for the termination of PHEICs and pandemic emergencies—when the event no longer meets the relevant Article 1 definition.[81]

As with the determination and termination of a PHEIC, the Emergency Committee also now provides its views to the Director-General on whether an event constitutes a pandemic emergency.[82] The amended IHR clarify the governance of Emergency Committees, which were critiqued as lacking transparency.[83] Firstly, they are now expressly described as expert committees subject to WHO Advisory Panel regulations,[84] which is already defined in Article 47 as the WHO Regulations for Expert Advisory Panels and Committees.[85] The WHO Advisory Panel regulations determine membership and procedures for expert panels and committees.[86] While this does not substantively change the existing Emergency Committee governance arrangements—i.e., that appointments be in line with other WHO expert

78. *Id.* art. 1.

79. *Id.* art. 12.4bis.

80. *Id.* art. 12.4.

81. *Id.* art. 12.5.

82. *Id.* arts. 12.4(c), 48.1.

83. *See, e.g.*, INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 29, at 53, 67.

84. World Health Organization [WHO], *supra* note 2, art. 48.1bis.

85. *Id.* art. 47; World Health Organization [WHO], *supra* note 25, art. 47.

86. World Health Organization [WHO], WHA35.10 (as amended) *Regulations for Expert Advisory Panels and Committees* (1982), https://apps.who.int/gb/bd/PDF/bd47/EN/regu-for-expert-en.pdf.

bodies—it does provide consistency with the text of other IHR articles governing expert bodies, which expressly refer to the WHO Advisory Panel regulation.[87] The composition of the Emergency Committee still contains reference to membership from affected states parties, but instead of being at least one member from where the event arises, it is now from where an event is occurring.[88] While this may present temporal and logistical challenges as an event progresses, underscoring the importance of early Emergency Committee convenings, it also provides considerable flexibility if an event has progressed beyond a single jurisdiction. To improve transparency, the Director-General is now required to provide all states parties with the Emergency Committee composition (a change that had already practically occurred due to criticism following the influenza H1N1 PHEIC) as well as the supporting evidence for any temporary recommendations issued under Article 15.[89]

Temporary recommendations issued during a PHEIC, including a pandemic emergency,[90] as well as standing recommendations for routine or periodic application issued under Article 16,[91] are now expanded to consider factors that have proven controversial during past PHEIC determinations.[92] Recommendations are now required to factor in the need to ensure international travel is not disrupted, particularly as it relates to ensuring the movement of health workers and people escaping humanitarian or life-threatening circumstances, as well as the continuous operation of global supply chains, particularly as it relates to ensuring access to food and health products.[93]

This amendment was likely influenced by widespread travel restrictions imposed during the COVID-19 pandemic, which was widely thought to impede international cooperation. For example, when South Africa rapidly identified and reported the Omicron variant of SARS-CoV-2 on November 24, 2021,[94] it was hit with widespread travel

87. *See, e.g.*, World Health Organization [WHO], *supra* note 2, art. 50.2; World Health Organization [WHO], *supra* note 35, at 75.

88. World Health Organization [WHO], *supra* note 2, art. 48.2.

89. *Id.* art. 49.6.

90. *Id.* art. 15.

91. *Id.* art. 16.

92. *See generally* Gostin et al., *Ebola in the Democratic Republic of the Congo, supra* note 27.

93. World Health Organization [WHO], *supra* note 2, art. 18.3.

94. *See, Classification of Omicron (B.1.1.529): SARS-CoV-2 Variant of Concern*, WORLD HEALTH ORGANIZATION [WHO] (Nov. 26, 2021), https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern.

restrictions.[95] The imposition of travel restrictions not only impedes the public health and humanitarian response, but also acts as an incentive to delay the reporting of novel outbreaks.

D. *Health Products*

The amended IHR, for the first time, contain a suite of norms to embed equitable access to "relevant health products" as an integral part of the global public health response to PHEICs and pandemic emergencies. Obligations related to "relevant health products" are narrowly defined as health products required to respond to a PHEIC or a pandemic emergency rather than health emergencies that do not meet those thresholds.[96] However, what amounts to a relevant health product is then broadly defined to include not only vaccines, diagnostics, and medicines, but also medical devices, vector control products, personal protective equipment, antidotes, cell- and gene-based therapies, and other health technologies.[97] This is an inclusive definition, allowing new technologies not specifically stated in this list to be included.[98]

In one of the most transformative amendments, Article 13 now requires WHO to not only facilitate timely and equitable access to health products based on public health risks and needs, but also to remove barriers to states parties' timely and equitable access.[99] This new legal obligation is temporally limited to after the determination of, and during, a PHEIC or pandemic emergency.[100] To achieve these aims, the Director-General is required to undertake a series of activities: (a) conduct, review, and publish assessments of public health needs and the availability and accessibility of relevant health products; (b) use or facilitate the establishment of WHO-coordinated mechanisms and coordinate with non-WHO mechanisms or networks for timely and equitable access to relevant health products; (c) upon request, support states parties in scaling up and geographically diversifying the production of relevant health products; (d) upon request, and within thirty days, share with states parties product dossiers related to relevant health products manufacturers provide to WHO for approval to enable

95. Marc Mendelson et al., *The Political Theatre of the UK's Travel Ban on South Africa*, 398 THE LANCET 2211, 2211 (2021), https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2902752-5.

96. World Health Organization [WHO], *supra* note 2, art. 1, 13.8.

97. *Id.* art. 1.

98. *Id.*

99. *Id.* art. 13.8.

100. *Id.*

regulatory evaluation; and (e) upon request, support states parties to promote research and development, and strengthen local production of relevant health products.[101]

Both temporary and standing recommendations may now expressly include information about relevant health products.[102] When issuing, modifying, or extending both types of recommendations, the Director-General must consider assessments of the availability and accessibility of relevant health products, as well as share available information about WHO-coordinated mechanisms for access and allocation of relevant health products or any other allocation and distribution mechanisms or networks.[103]

States parties must collaborate and assist each other and WHO with the implementation of these provisions.[104] States parties must also engage relevant stakeholders (e.g., manufacturers and civil society) to facilitate equitable access to relevant health products and make available the relevant terms of states parties' research and development agreements.[105] However, these collaboration obligations are subject to applicable law and available resources,[106] and the latter two are limited to PHEICs and pandemic emergencies.[107] These conditions provide states parties with significant flexibility in meeting a powerful obligation to collaborate. WHO is also tasked with collaborating and assisting states parties, upon request, to facilitate access to relevant health products under Article 44's collaboration and assistance provisions, further entrenching equitable access.[108]

E. *Border Crossings*

The IHR are especially clear that states parties can only require health documents for international traffic if specified in the Regulations.[109] Certificates of vaccination or prophylaxis issued in accordance with the Regulations or in a recommendation (e.g., polio) must comply with requirements set out in Annex 6 or for a disease specified in Annex 7

101. *Id.*
102. World Health Organization [WHO], *supra* note 2, arts. 15.2, 15.2bis, 16, 17d.
103. *Id.* arts. 15.2bis, 16.2.
104. *Id.* arts. 13.9, 13.9(a).
105. *Id.* arts. 13.9(b), 13.9(c).
106. *Id.* art. 13.9.
107. World Health Organization [WHO], *supra* note 2, arts. 13.9(b), 13.9(c).
108. *Id.* art. 44.2(d).
109. *Id.* art. 35; World Health Organization [WHO], *supra* note 25, art. 35.

(currently only yellow fever).[110] There are exceptions for travelers seeking permanent or temporary residence or for the international trade in goods where public health documents are required under other international agreements.[111] Reflecting the technological advancements and practical challenges during the COVID-19 pandemic, health documents may now be issued in either non-digital or digital format.[112] This includes certificates of vaccination or other prophylaxis.[113]

At the borders edge, states parties have obligations to ensure conveyance operators—aircrafts, ships, trains, road vehicles or other forms of transport on international voyages—comply with and inform travelers of health measures adopted for onboard, as well as during embarkation and disembarkation.[114] Health measures at borders now expressly include quarantine.[115] Despite near ubiquitous travel restrictions during COVID-19, the amendments do not explicitly address their necessity or appropriateness, or their potential impact on disincentivizing rapid outbreak notification and health worker and humanitarian responses.

F. *Financing*

Importantly, the amended IHR establish for the first time a Coordinating Financing Mechanism (CFM) under new Article 44 bis.[116] The CFM goal is to promote timely, predictable, and sustainable financing for IHR implementation, maximize the availability of financing, particularly for developing countries, and mobilize new financial resources.[117] The CFM is tasked with a range of activities, including conducting reviews of financial needs and potential funding sources and informing and supporting states parties in accessing funding.[118]

As part of their cross-cutting collaboration obligations, states parties agree to collaborate to mobilize financial resources, including through the CFM, with a particular focus on addressing the needs of developing

110. World Health Organization [WHO], *supra* note 2, art. 36.1; World Health Organization [WHO], *supra* note 25, art. 36.1.

111. World Health Organization [WHO], *supra* note 2, art. 35.1; World Health Organization [WHO], *supra* note 25, art. 35.

112. World Health Organization [WHO], *supra* note 2, art. 35.2.

113. *Id.* art. 36.

114. *Id.* art. 24.

115. *Id.* art. 27.

116. *Id.* art. 44bis.

117. World Health Organization [WHO], *supra* note 2, art. 44bis.1.

118. *Id.* art. 44bis.2.

countries.[119] Critically, states parties also agree to maintain or increase national funding and collaborate to strengthen sustainable financing for IHR implementation.[120] This obligation is nuanced by applicable domestic law and the availability of resources.[121] WHO is also tasked with mobilizing financial resources to develop core public health system capacities.[122] To address perceived weaknesses with the World Bank's Pandemic Fund,[123] states parties agree to encourage existing financing entities to be regionally representative and responsive to the needs and priorities of developing countries.[124] When adopting the proposed package of amendments, WHO Member States resolved that the CFM would also be available for use by future instruments, such as the proposed Pandemic Agreement.[125]

G. *Core Capacities*

Consistently across the amended IHR, public health capacities are now expressly referred to as "core capacities," bringing the IHR terminology in line with global health parlance. In addition, the amended IHR core capacities are now more accurately reflected in the IHR text itself (within Annex 1) rather than subsidiary technical documentation.[126] Core capacities now expressly include obligations to undertake prevention and preparedness activities, as well as collaborate with states parties in developing and strengthening core capacities.[127]

At the local level, core capacities not only include detecting event signals and reporting events, but now also expressly include ensuring access to health services as well as engaging communities and other interested parties in responding to public health risks and events.[128] This scope of activity is broader than PHEICs or pandemic emergencies. At the intermediate level (where a state party has an intermediate level of governance, such as provinces or states), core capacities seek to not only confirm and assess reported events, but also expressly support local activities, including through surveillance, investigations, diagnostics, control measures, access to health services and health products,

119. *Id.* art. 44.2ter.
120. *Id.* art. 44.2bis.
121. *Id.*
122. World Health Organization [WHO], *supra* note 2, art. 44.2(c).
123. World Health Organization [WHO], *supra* note 35, at 71.
124. World Health Organization [WHO], *supra* note 2, art. 44.2ter(a).
125. World Health Organization [WHO], *supra* note 1.
126. World Health Organization [WHO], *supra* note 2, annex 1.
127. *Id.* annex 1, para. 1(a), 4.
128. *Id.* annex 1, para. A.1.

risk communication (including combating misinformation and disinformation), and logistical assistance.[129]

National-level core capacities are not limited to response but now include prevention and preparedness.[130] As a result, national core capacities now also expressly include surveillance, guidance for clinical care and infection control, access to health services and health products, risk communication, and coordination across all levels of government.[131] This is in addition to existing obligations, subject to amendments for clarity, including rapidly determining control measures to prevent transmission, deploying specialized staff, ensuring laboratory analysis of samples (including through linkages with collaborating centers), and establishing a national public health emergency response plan.[132] At airports, ports, and ground crossings, states parties must now additionally ensure access to medical and veterinary laboratories for analysis of samples taken from affected travelers or animals.[133] Finally, the amended IHR now expressly include fragile and humanitarian settings as falling within the scope of public health core capacities.[134]

H. *Governance and Implementation*

The amended IHR addresses several governance challenges to improve implementation and accountability. The Regulations now require states parties to establish a National IHR Authority to supplement the existing obligation to establish a National IHR Focal Point,[135] tasked specifically with coordinating IHR implementation domestically.[136] Both roles can be fulfilled by one or two entities, at the states parties' discretion.[137] While some advocates have critiqued this as redundant or duplicative,[138] tasking

129. *Id.* annex 1, para. A.2.

130. *Id.* annex 1, para. A.3.

131. *Id.*

132. *Id.*

133. *Id.* annex 1, para. B.2.

134. *Id.* art. 13.1.

135. *Id.* art. 4.1.

136. *Id.* art. 4.1bis.

137. *Id.* art. 4.1.

138. *See* David Fidler, *The Amendments to the International Health Regulations Are Not a Breakthrough*, THINK GLOBAL HEALTH (June 7, 2024), https://www.thinkglobalhealth.org/article/amendments-international-health-regulations-are-not-breakthrough; Amrei Müller & Silvia Behrendt, *The 2024 Amendments to the International Health Regulations: A Commentary (Part II: Selected Substantive Amendments)*, OPINIO JURIS (Sept. 20, 2024), http://opiniojuris.org/2024/09/20/the-2024-amendments-to-the-international-health-regulations-a-commentary-part-ii-selected-substantive-amendments/; K M Gopakumar & Nithin Ramakrishnan, *WGIHR Bureau's Push for 2 New National Institutions for IHR Implementation Raises Concerns*, THIRD WORLD NETWORK (Feb. 6, 2024), https://www.twn.my/title2/health.info/2024/hi240202.htm.

express responsibility provides accountability for core capacity implementation as a distinct set of activities from notification obligations. States parties must also take steps, where necessary and appropriate, to adjust their domestic legislative and administrative arrangements to give effect to these entities.[139]

Several reviews examining the functioning of the IHR have highlighted inconsistent implementation, accountability, and compliance with IHR obligations as areas requiring critical attention.[140] Significantly, the amended IHR establish a new States Parties Committee for the Implementation of the International Health Regulations (2005) (SPC) under Article 54 bis.[141] The SPC is non-punitive and facilitative in nature.[142] It is tasked with advancing the effective implementation of the Regulations, with particular regard to the implementation of collaboration and financing obligations under Articles 44 and 44 bis, respectively.[143] While the SPC is comprised of states parties, it is required to establish a Subcommittee to provide technical advice, supporting its broader goal of promoting the exchange of best practices for effective implementation.[144] At its first meeting, the SPC must adopt the terms of reference for the SPC, its Subcommittee, and the CFM, defining arrangements for governance, operationalization, and engagement with other international bodies.[145] Despite the further guidance such terms provide, as well as existing self-assessed reporting obligations under Article 54,[146] the text of Article 54 bis is focused on assisting implementation rather than evaluating states parties' compliance with obligations, even if limited to non-punitive responses.[147] Member States' reluctance to establish compliance and accountability measures was driven by sovereignty concerns, the broader geopolitical environment, and parallel negotiations for the Pandemic Agreement.[148] As a result, the text of Article 54 bis contained the final changes agreed to in the negotiation process.[149]

---

139. World Health Organization [WHO], *supra* note 2, art. 4.2bis.

140. *See, e.g.*, World Health Organization [WHO], *supra* note 44, at 52–54; *IHR Review Committee*, *supra* note 27, at 35–37; INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 29.

141. World Health Organization [WHO], *supra* note 2, art. 54bis.

142. *Id.* art. 54bis.1.

143. *Id.*

144. *Id.* art. 54bis.1(b).

145. *Id.* arts. 54bis.2, 54bis.4.

146. *Id.* art. 54.

147. *Id.* art. 54bis.1.

148. Ashley Bloomfield & Abdullah Assiri, *The Updated International Health Regulations: Good News for Global Health Equity*, 403 THE LANCET 2761, 2761 (2024), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)01248-0/abstract.

149. *Id.*

The states parties participating in the SPC, as well as obligations to implement the amended IHR more broadly, will be dependent on whether existing IHR states parties opt out of, or issue reservations under, the adopted amendments. While the IHR have had universal support to date—with all 194 WHO Member States choosing not to opt out—the amended IHR cannot be divorced from the political context of its adoption at the Seventy-seventh WHA. During the ninth plenary meeting at the Seventy-seventh WHA on June 1, 2024, WHO Member States and Observer States had the opportunity to make oral statements regarding the amended IHR. While most Member States did not make oral statements, three regional groups representing WHO regions made oral statements: the Africa Region and Egypt, the Americas Region, and the European Region (see Table Two). Thirty-five WHO Member States gave oral statements in support of the amended IHR, while one, Slovakia, expressly opposed the amendments. Five WHO Member States reserved their position, referring to pending national elections or leaving open the option to make potential formal treaty reservations.

TABLE TWO: ADOPTION POSITION ON THE AMENDMENTS TO THE IHR DURING THE SEVENTY-SEVENTH WORLD HEALTH ASSEMBLY (2024) PLENARY SESSION[150]

Position	Support		Reserved	Opposed
Member State	• Australia • Bangladesh • Belgium • Brazil • Canada • Central African Republic • China • Colombia • Egypt • Ethiopia • Fiji • France • Germany • Haiti • India • Indonesia • Iraq • Ireland	• Japan • Kenya • Mexico • Monaco • New Zealand • Nigeria • Norway • Pakistan • Qatar • Republic of Korea • Senegal • Singapore • Spain • Switzerland • Tanzania • USA • Uruguay	• Argentina • Iran • The Netherlands • Russian Federation • United Kingdom	• Slovakia
Group	• Africa Region and Egypt • Americas Region • European Region			

150. These positions were derived from statements made by WHO Member States and Observer States during the final plenary session of the Seventy-seventh WHA following the adoption of the amendments on June 1, 2024. Primary coding was completed by AP observing the online live stream of the session while verification and supplemental secondary coding was completed by research assistant, Anna Bezruki, observing an online recording of the session available afterwards at: https://www.who.int/about/governance/world-health-assembly/seventy-seventh. Each statement was coded for its position in relation to the amendments: support, oppose, and reserved (where a clear position was deferred, either due to impending national elections or keeping open possible future reservations or rejections during the opt-out period). One Member State (Costa Rica) made a statement during this session that expressed no position in relation to the amendments, and so it was excluded from analysis.

CONTINUED

Position	Support	Reserved	Opposed
Observer States	• Holy See Palestine[151]		
Total	• Thirty-Five Member States, Three Member State Groups, and Two Observer States	Five	One

Following adoption by the WHA, the IHR establish set time periods and requirements for states parties to reject or make reservations to the amendments. Under the IHR Third Edition, amendments to the IHR entered into force twenty-four months after adoption by the WHA,[152] while the period for lodging a rejection of, or reservation to, an amendment to the IHR was eighteen months after the WHO Director-General officially notified Member States of the WHA's adoption of an amendment.[153] In January 2022, the United States proposed a suite of amendments to the IHR, including modifications to the time periods for entry into force of amendments adopted by the WHA, as well as the time periods for WHO Member States to reject or lodge reservations to amendments.[154] These amendments were adopted at the Seventy-fifth WHA, changing the period for entry into force for IHR amendments from

151. During the same WHA, Palestine's participation in WHO was aligned with its status in the United Nations more broadly, granting it quasi-WHO Member State status. While Palestine remains an Observer State, the resolution granted Palestine expanded rights and privileges in the WHA and other WHO meetings, including being seated with WHO Member States, excluding voting rights and proposing candidates for WHO organs.

152. World Health Organization [WHO], *supra* note 25, art. 59.2.

153. *Id.* art. 59.1.

154. Article 55.2 of the IHR provides that "[t]he text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration." The Seventy-fifth WHA was held between May 22–28, 2022. The United States submitted its proposal for amendments to the WHO on January 18, 2022, and the WHO Director-General officially communicated the proposed amendments to IHR states parties under Article 55.2 of the IHR on January 20, 2022. *See Letter from the Permanent Mission of the U.S. to the U.N. and Other International Organizations in Geneva (No. 4-22)* (Jan. 18, 2022) and *Letter from the WHO Director-General to IHR States Parties (Ref: C.L.2.2022)* (Jan. 20, 2022), both contained in World Health Organization [WHO], WHA A75/18, *Strengthening WHO Preparedness for and Response to Health Emergencies, Proposal for Amendments to the International Health Regulations* (2005), Provisional Agenda Item 16.2 (Apr. 12, 2022), https://apps.who.int/gb/ebwha/pdf_files/wha75/a75_18-en.pdf.

twenty-four months to twelve months and changing the period for lodging a rejection of, or reservation to, an IHR amendment from eighteen months to ten months.[155] These periods begin only after the Director-General officially notifies states parties of the WHA's adoption of the amendment.[156] The changes to the time periods for amendments entered into force on May 31, 2024.[157] Four states parties—the Islamic Republic of Iran, the Kingdom of the Netherlands, New Zealand, and Slovakia—rejected the 2022 amendments, and so the prior time periods remain applicable for those respective states parties.[158] While these amendments were not reflected in Resolution WHA77.17's annexed text of the 2024 amendments (which was prepared prior to May 31, 2024), the 2022 amendments were in force when the WHA adopted the 2024 amendments on June 1, 2024.[159] On September 19, 2024, the WHO Director-General officially notified states parties of the WHA's adoption of the 2024 IHR amendments.[160] Consequentially, the 2024 amendments will enter into force on September 19, 2025 (i.e., twelve months following notification) for all but the four states parties that rejected the 2022 amendments.[161] Similarly, states parties will need to lodge any rejections or reservations to the 2024 amendments by July 19, 2025 (i.e., ten months following notification).[162]

---

155. World Health Organization [WHO], WHA75.12, *Amendments to the International Health Regulations* (2005) (May 22–28, 2022), https://apps.who.int/gb/ebwha/pdf_files/WHA75-REC1/A75_REC1_Interactive_en.pdf#page=1.

156. World Health Organization [WHO], *supra* note 2, art. 59.1; World Health Organization [WHO], *supra* note 25, art. 59.1.

157. These amendments entered into force for most IHR states parties twenty-four months after the amendments were adopted on May 28, 2022 during the eighth plenary meeting of the WHA's Committee A in accordance with the text in force at that time and following the WHO Director-General's official notification, a comparatively rapid three days later on May 31, 2022.

158. World Health Organization [WHO], A77/8, *Implementation of the International Health Regulations*, para. 27 (Apr. 8, 2024), https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_8-en.pdf.

159. World Health Organization [WHO], *supra* note 1.

160. World Health Organization [WHO], *Notification to States Parties of amendments to the International Health Regulations*, C.L.40.2024 (Sept. 19, 2024), https://www.bag.admin.ch/dam/bag/en/dokumente/int/C.L.40.2024%20IHR%20amendments%20English.pdf.download.pdf/C.L.40.2024%20IHR%20amendments%20English.pdf; *International Health Regulations: Amendments*, World Health Organization [WHO], https://www.who.int/news-room/questions-and-answers/item/international-health-regulations-amendments (last visited Nov. 7, 2024).

161. The 2024 amendments will enter into force for these four states parties twenty-four months after notification (i.e. September 19, 2026), unless a rejection or reservation is made to the 2024 amendments within eighteen months (i.e. by March 19, 2026).

162. World Health Organization [WHO], *supra* note 158, at 2.

The breadth of the 2024 amendments to the IHR reflect inadequacies demonstrated over successive health emergencies, and particularly, the inequities and nationalistic approaches taken by states during the COVID-19 pandemic. The amendments shift the framing of the IHR through the incorporation of the principles of equity and solidarity, adjustments to notifications and the empowerment of WHO to share information, the addition of a new pandemic emergency declaration power, the translation of equity into operative provisions around health products and solidarity into obligations around collaboration, financing, and governance and implementation. While the IHR have been amended several times over the two decades since they entered into force, the 2024 amendments are the most significant revision of this pivotal instrument that reorients the governing framework for global health security towards solidarity and equity.

IV. Progress not Paradigm Shift: Outlining a Path for Improvement

While the reorientation of the IHR towards solidarity and equity is an urgent and important shift, it also reflects the iterative nature of IHR reforms in the twenty-first century so far. This iterative change to a single instrument is unlikely to create the profound paradigm shift in international law needed to address the long arm of its colonial underpinning and the injustices demonstrated—in some cases, facilitated by international law—throughout the COVID-19 pandemic.[163] This is evident in the successive health emergencies that have resulted in—and not resulted in—reform to the IHR. International law has been notably described as a discipline of crisis,[164] whereby crises drive reform and the scale of that reform, reflecting "international law's obsession with crises . . . [leading] us to concentrate on a single event or series of events and often to miss the larger picture."[165]

The amendments to the IHR adopted in 2024 represent major progress but not the necessary paradigm shift needed to address larger geopolitical concerns and structural changes necessary to realize global health security, solidarity, and equity. With that context and caveat in mind, this part argues that the IHR amendments adopted in 2024 lay the foundation and outline a path for future, albeit pressing, reforms.

---

163. B.S. Chimni, *Crisis and International Law: A Third World Approaches to International Law Perspective*, *in* Crisis Narratives in International Law 40, 47 (Makane Moïse Mbengue & Jean d'Aspremont eds., 2022).

164. *See* Hilary Charlesworth, *International Law: A Discipline of Crisis*, 65 Mod. L. Rev. 377, 377 (2002).

165. *Id.* at 384.

Section IV.A examines the implications of the 2024 amendments on interpreting the scope of the WHA's power to adopt regulations under the WHO Constitution, particularly in relation to equitable access to health services and goods. Section IV.B then identifies weaknesses that have arisen from Member State choices in relation to both the semantics and content of the amendments, identifying parallels with international human rights law as well as priorities for future IHR reform.

A. *Implications for WHO Law-Making Powers*

The parallel law reform processes in light of the COVID-19 pandemic—namely, the negotiations for the amendments to the IHR and for the Pandemic Agreement—prompted renewed discussion around the scope of WHO's law-making powers under its Constitution.[166] The Pandemic Agreement negotiations kept open the possibility of adopting the new treaty under Article 19, WHA's classic broad treaty power that requires WHO Member States to opt in by signing and ratifying or acceding to the treaty,[167] or under Article 21, WHA's unusual power to adopt regulations within a specific set of categories.[168] Pursuant to Article 22, regulations adopted under Article 21 automatically legally bind WHO Member States following due notice unless they expressly opt out by notifying the WHO Director-General within an agreed period of time.[169] When the IHR were incorporated into the scope of WHO's mandate (at that time, named the International Sanitary Regulations), they were adopted under the WHO Constitution's Article 21 regulations power.[170] Specifically, the regulations were adopted under subsection (a), which permits the WHA to adopt regulations pertaining to "sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease."[171]

During the early drafting of the WHO Constitution, significant attention was given to the law-making power to adopt regulations. The technical committee preparing the draft specifically discussed whether the list of subjects under the draft law-making powers of the Constitution

166. *See, e.g.*, Alexandra Phelan & Nina Schwalbe, *Getting in Formation: WHO Constitutional Heads of Power and the Pandemic Agreement*, OPINIO JURIS (Mar. 13, 2024), https://opiniojuris.org/2024/03/13/getting-in-formation-who-constitutional-heads-of-power-and-the-pandemic-agreement/.

167. World Health Organization [WHO], *supra* note 5, at 19.

168. *Id.* at 21.

169. *Id.* at 22.

170. Dr K.C.K.E. Raja, Report on the Work of the Special Committee on Draft International Sanitary Regulations, at 3, World Health Organization [WHO] (May 25, 1951), https://iris.who.int/handle/10665/101631.

171. World Health Organization [WHO], *supra* note 5, art. 21(a).

was restrictive and to be narrowly construed.[172] The technical committee concluded that the regulations power "should be inclusive of all the subjects upon which the [WHA] might act."[173] When the Constitution was subsequently adopted, this broad reading became even more express through the addition of the word "sanitary," which had an inclusive historical meaning of health and freedom from disease.[174]

When drafting the International Sanitary Regulations in 1951, drafters noted that the intention of Articles 21 and 22 was to provide the WHA with an agile power "to give the new regulations the flexibility made necessary by the rapidity of present advances in medical knowledge and means of transport, but which could not be attained under the older system with its cumbrous procedure of special international conferences and ratifications."[175] As a result, regulations adopted under the regulations power could "promptly and continually [be] adapted to changing circumstances and needs."[176]

In adopting the revised IHR in 2005, WHO Member States set a precedent for interpreting the scope of Article 21(a) broadly, demonstrating that regulations that "prevent, protect against, control and provide a public health response to the international spread of disease" fell under the scope of the power to make regulations pertaining to "sanitary and quarantine requirements and other procedures."[177] Subsequent WHO processes have further demonstrated broad institutional understandings of the scope of this subsection.[178]

During the meetings of the IHR Review Committee Regarding Amendments, the committee noted that proposals to add equitable

172. World Health Organization [WHO] Interim Commission, *Minutes of the Technical Preparatory Committee for the International Health Conference*, at 21 (Mar. 18 – Apr. 5. 1947), https://iris.who.int/bitstream/handle/10665/85572/Official_record1_eng.pdf?sequence=1&isAllowed=y.

173. *Id.* at 22.

174. In later discussions during the 1969 amendment of the name of the International Sanitary Regulations to the International Health Regulations, exchanging "sanitary" for "health" in line with standard words in use and increasing use of the term "health" for measures historically referred to as falling within the scope of the word "sanitary." *See* World Health Organization [WHO], *Fourteenth Report of the Committee on International Quarantine and Special Review of the International Sanitary Regulations*, at 14 (Mar. 27, 1968), https://iris.who.int/bitstream/handle/10665/143488/WHA21_PB-2_eng.pdf?sequence=1&isAllowed=y.

175. World Health Organization [WHO], *International Sanitary Regulations*, at 36 (Apr. 1952), https://apps.who.int/iris/handle/10665/85636.

176. *Id.* at 2.

177. World Health Organization [WHO], *supra* note 5, art. 21(a).

178. Alexandra Phelan & Nithin Ramakrishnan, *Safeguarding Article 21 of the WHO Constitution for Future Global Health Governance [Guest Essay]*, GENEVA HEALTH FILES (Nov. 30, 2022), https://genevahealthfiles.substack.com/p/safeguarding-article-21-of-the-who.

access to medical countermeasures raised the issue of whether it would fall within the scope of the Regulations.[179] With the adopted 2024 amendments to the IHR including a suite of provisions for equitable access to health products, WHO Member States have resolved this question and made this interpretation of Article 21(a) explicit. In a similar fashion to the 2005 revision, the 2024 amendments have emphasized that interpretations of WHA law-making powers are to be broadly read, not only supporting the intentions of these powers at the founding of WHO but also operationalizing the principle of equity now expressly incorporated into the IHR. This opens up the potential scope of the regulations power for future reforms or instruments, including the proposed Pandemic Agreement, in which the choice of law-making power has been a relevant debate.[180]

B. *Future Reforms for Security, Solidarity, and Equity*

This section identifies weaknesses in the IHR amendments that may be addressed in future IHR reforms. This includes semantic choices that temper the nature of obligations, as well as content choices that leave governance gaps for critical issues. Some of these gaps may be addressed by the proposed Pandemic Agreement if adopted, especially if One Health and a PABS system are included. However, other issues—in particular, travel restrictions—are central to the IHR's objective and scope, requiring urgent attention. These weaknesses may be addressed in future IHR reforms that espouse the agility and responsiveness of the WHA's law-making power under Article 21 of the WHO Constitution.

In negotiating the amendments, Member States made several word choices that have implications for the strength of new obligations. Several of the new obligations use hortatory language such as "should," which encourages good faith attempts to fulfill, rather than mandate, obligations.[181] This reflects national pressures to defend sovereignty and domestic control over health policies. Other weaknesses include limiting obligations to being subject to applicable laws and available resources.[182] These limits also reflect national preferences to temper global obligations with resource limitations. In both instances, the IHR amendments protect national sovereignty over equally important requirements of international cooperation and solidarity.

179. World Health Organization [WHO], *supra* note 35, at 70.

180. *See, e.g.*, Phelan & Schwalbe, *supra* note 166.

181. *See* World Health Organization [WHO], *supra* note 2, art. 8.

182. *Id.* arts. 13.9, 44.2bis.

The second limit of "available resources" is not uncommon in international human rights law. The International Covenant on Economic, Cultural and Social Rights, for example, specifies that the realization of the right to health and other social, cultural, and economic rights are to be "to the maximum of [states'] available resources."[183] Still, the Covenant states that such rights are to be achieved "progressively," which requires states to make progress in attaining the right and proscribes retrogressive measures and discrimination.[184] Where IHR obligations contain similar language, such as "shall maintain or increase" in an obligation to increase funding and collaborate, similar interpretations should apply.[185] Notably, the mandatory obligation that states parties "shall undertake" to collaborate and assist with ensuring equitable access to health products is tempered using both limits, without non-retrogressive language.[186] Gaps such as these urgently need to be filled in future amendments.

The IHR amendments are also weakened by several choices around the content of the amendments. Firstly, "relevant health products" are limited to those needed to respond to PHEICs and pandemic emergencies.[187] This is reiterated in the equitable access provisions.[188] As a result, the IHR does not explicitly establish a system for equitable access prior to, or after, a relevant health emergency. The IHR also does not include an integrated One Health approach, despite the inclusion of "prevention" in surveillance as well as the disclosing information to other IOs.[189]

While WHO can use reports from other sources, including other IOs, it still must first verify the report with an affected state party.[190] A truly One Health approach would involve real-time information sharing and responses between all Quadripartite organizations.[191] As a deeply contested issue, a sufficiently robust One Health strategy may not emerge from Pandemic Agreement negotiations.

The amendment of Annex 2 to expressly capture severe acute respiratory diseases of unknown or novel causes moves the decision algorithm closer to the risk-informed and precautionary approaches recommended by the IOAC and IPPPR. Despite requiring states parties to share "public

183. G.A. Res. 2200A (XXI), at 2 (Dec. 16, 1966).
184. Comm. on Econ., Soc. and Cultural Rights, U.N. Doc. E/1991/23 (1990).
185. World Health Organization [WHO], *supra* note 2, art. 44.2bis.
186. *Id.* art. 13.9.
187. *Id.* art. 1.
188. *Id.* art. 13.8.
189. *Id.* arts. 5, 6, annex 1.
190. *Id.* art. 9.
191. Carlson & Phelan, *supra* note 61.

health information" for potential PHEICs,[192] there is no obligation to share pathogen samples or their genetic sequence data. Yet, equity and international legal norms demand scientific exchange coupled with equally fulsome benefits sharing. Pandemic Agreement negotiations focused intensely on creating a PABS system, including negotiation of a dedicated Annex. If new legal instruments are created to address these issues, WHO Member States should amend the IHR to expressly cross-reference and embrace them.

What would prove unacceptable is if the Pandemic Agreement is not adopted or enters into force, or if its norms and governance are weak. Failure of the IHR and/or Pandemic Agreement to ensure robust benefits sharing and a One Health approach will open cavernous cracks in global health security and justice.

Finally, the failure of the amended IHR to prevent discriminatory travel restrictions undermines the core normative bargain at the heart of the Regulations. When revised in 2005, the IHR incentivized states parties to rapidly report notifications on the legal promise against imposing unnecessary travel and trade restrictions. State responses in successive PHEICs chipped away at this norm, but it was almost entirely obliterated during COVID-19. While non-binding recommendations issued by WHO during a PHEIC or pandemic emergency must facilitate international travel and maintain supply chains,[193] there are no amendments that rebuild states parties' trust, such as establishing a binding, transparent, and evidence-informed process for determining the necessity of travel and trade-restrictive measures.

V. The Impact of A Second Trump Presidency

The normative and diplomatic project of global health law and institutional reform built on robust scientific cooperation and equity is facing political headwinds, even beyond the traditional regional divisions we have witnessed throughout the successful negotiations of the IHR and for a Pandemic Agreement. On the first day in office in his second term on January 20, 2025, President Donald J. Trump has profoundly upended the United States' role in global health and international diplomacy and law-making.

In his first administration, President Trump gave one year's notice of the intention of the United States to withdraw from membership in the

192. World Health Organization [WHO], *supra* note 2, art. 6.

193. *Id.* art. 18.3.

World Health Organization.[194] While the WHO Constitution does not contain withdrawal procedures, the United States reserved a right to withdraw from the WHO with one year's notice at the time of ratification.[195] This position derives from a joint resolution of the United States Congress that further conditions this right to withdraw upon fulfilling any financial obligations to WHO in full for that fiscal year.[196] Upon taking office, President Biden retracted the withdrawal notice, maintaining the United States' membership.[197]

Hours after his inauguration, President Trump issued an Executive Order that *inter alia* directed the Secretary of State to immediately notify the United Nations Secretary-General and WHO leadership of the United States' renewed intention to withdraw from membership of the WHO.[198] The United Nations confirmed receipt of a letter of official notification of intent to withdraw dated January 22, 2025.[199] If this is not withdrawn before the one year period expires, withdrawal will take effect on January 22, 2026, provided financial obligations for that fiscal year are paid in full. This latter condition may pose a challenge to timely withdrawal given the Executive Order also directed the pause of all future transfer of "funds, support, or resources" to WHO.[200] Furthermore, implications of this withdrawal of funding for global health, along with a wider foreign aid freeze, is consequential. This will impact not only capacity building and implementation of the IHR globally, but also the likelihood of events that will again put the IHR to the test.

The Executive Order also directed the Secretary of State to immediately "cease negotiations" on both the Pandemic Agreement and the amendments to the IHR. This is despite negotiations for the latter already having concluded the previous year. The order further notes that "actions taken to effectuate such agreement and amendments will have no binding force on the United States". The Executive Order however

194. Lawrence O. Gostin et al., *US Withdrawal from WHO is Unlawful and Threatens Global and US Health and Security*, 396 THE LANCET 293, 293 (2020), https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931527-0.

195. World Health Organization [WHO], *supra* note 5, art. 21.

196. Joint Resolution of the Congress of the United States of America (June 14, 1948) Public Law 643, 80th Cong. 2d sess., S. J. Res.98.

197. Joseph R. Biden JR, *Letter to His Excellency António Guterres* (2021), https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2021/01/20/letter-his-excellency-antonio-guterres/.

198. Exec. Order No. 14,155, 90 Fed. Reg. 8361, 8362 (Jan. 29, 2025).

199. Michelle Nichols, *US to Leave World Health Organization on Jan. 22, 2026, Says UN*, Reuters, Jan. 23, 2025, https://www.reuters.com/business/healthcare-pharmaceuticals/us-leave-world-health-organization-jan-22-2026-says-un-2025-01-23/ (last visited Mar 4, 2025).

200. 90 Fed. Reg. at 8361.

does not expressly direct the executive to notify the WHO Director-General that the United States rejects the amendments. In accordance with the IHR in force at the time of the Executive Order (and which incorporate the 2022 amendments), the 2024 amendments will automatically enter into force for the United States on September 19, 2025 if it does not notify the Director-General of this rejection prior to July 19, 2025 (i.e. ten months following official notification of the amendments).

As was the case with the United States in 1948, WHO Member State status derives from being a States Party to the WHO Constitution.[201] While the United States' withdrawal from WHO means no longer being a States Party to the WHO Constitution, the United States' status as an IHR States Party is based on it being a WHO Member State at the time of the IHR's entry into force and the operation of the WHO Constitution's opt-out requirements. There are no express provisions in the IHR addressing the impact of withdrawal of membership on IHR States Party status. There are however provisions for new WHO Member States to automatically become party to the IHR (subject to any reservation or rejection in the first 12 months of membership), as well as expressly permitting non-Member States Parties, which currently include the Holy See and Liechtenstein.[202] This is the most analogous scenario to the United States: withdrawal from WHO membership but remaining an IHR States Party, and the applicability of the 2024 amendments subject to any rejection or reservation before July 19, 2025. The IHR only establishes withdrawal procedures for such non-Members, who must give the WHO Director-General six months' notice of withdrawal from the IHR, after which the relevant state is to resume application of previous sanitary regulations, the most recent prior being the IHR 1969.[203] As a result, the IHR presume a level of willing engagement in the multilateral system that is not currently reflected in the United States' foreign and global health policy. If other WHO Member States follow a similar trajectory, as is the case with Argentina,[204] not only will these provisions be tested, but so too will the integrity of our common global health security.

201. World Health Organization [WHO], *supra* note 5, art. 4.

202. World Health Organization [WHO], *supra* note 2, art. 64.

203. *Id.* art. 64.2.

204. *Argentina to Withdraw from WHO After Trump Exit, Citing "Deep Differences,"* REUTERS (Feb. 5, 2025), https://www.reuters.com/world/americas/argentina-withdraw-world-health-organization-after-trump-exit-2025-02-05/.

VI. Conclusion

Despite significant weaknesses, the 2024 amendments to the IHR embed historically important obligations for security, solidarity, and equity. The amendments span new principles for interpretation and implementation, outbreak notifications and information sharing, declarations, including a new pandemic emergency power, equitable access to health products, expanded obligations for collaboration and assistance, financing including the CFM, and implementation compliance with the SPC. The WGIHR co-chairs described the IHR amendments as reflecting what was diplomatically possible given broader geopolitical divisions and ongoing Pandemic Agreement negotiations.[205]

The 2024 IHR amendments were a diplomatic success, proving that, even in a period of heightened nationalistic populism, international cooperation is possible. The negotiations could serve as a model for future reforms and demonstrate that the demand for equity from the Global South has resonance. In the end, the Global North avidly sought to buttress global norms of rapid and transparent sharing of scientific information, while the Global South avidly sought to ensure the fair and just distribution of the lifesaving products that emerge from that scientific sharing. In truth, we need global solidarity to achieve *both* dreams. The world needs to share vital scientific data in real-time. But it also needs to equitably share the benefits of that scientific exchange. That is a project the 2024 IHR amendments started, but it is far from complete. The normative impact of reframing the IHR towards equity and solidarity is profound but should not be overstated: future amendments and the Pandemic Agreement must contain stronger norms, compliance, and good governance.

In light of political headwinds in Washington, D.C. and other state capitals, WHO Member States should view the 2024 amendments as a timely and prescient reassertion and commitment to fundamental global health law and institutional norms. While pathogens do not follow a political timetable nor respect borders or populist rhetoric, political decisions drive their emergence and spread. More than ever, it is crucial to reiterate common terms agreed, contest deviations, and assert the applicability of the rule of law. The next catastrophic health emergency or pandemic may be on the horizon. What is at stake—in terms of lives lost, social disintegration, and economic collapse—simply cannot be overstated.

205. Bloomfield & Assiri, *supra* note 148, at 2762.