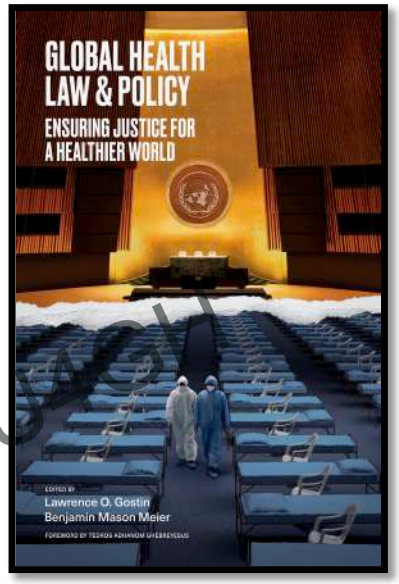
Framing Global Health Law



Benjamin Mason Meier, JD, LLM, PhD
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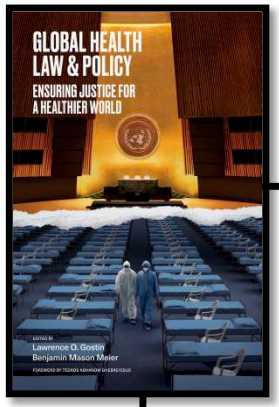
University of Salerno
6 June 2024

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL
O'NEILL INSTITUTE FOR NATIONAL & GLOBAL HEALTH LAW GEORGETOWN LAW
Global Health Law Consortium



Introduction

Foundations of Global Health Law & Policy

Lawrence O. Gostin and Benjamin Mason Meier

Globalization has unleashed new health threats, connecting societies in shared vulnerability to common challenges, including infectious disease, non-communicable disease, environmental pollution, injuries, and inequitable poverty. The COVID-19 pandemic has made clear the cataclysmic health threats of a rapidly globalizing world and the limitations of domestic law and policy in addressing economic, social, and political determinants of health. No country acting on its own can stem major health hazards that go well beyond national borders. Where national laws cannot reach threats beyond national borders, global law is necessary to promote health and justice. If globalization has presented global challenges to disease prevention and health promotion, global health law offers the promise of bridging national boundaries to promote public health and reduce health inequities.

Global health law seeks to establish strong and innovative governance to respond to the major health challenges of the 21st century. Law and policy have become crucial to the advancement of global health. Global health law encompasses the study and practice of international law—both "hard" law treaties that bind states and "soft" law instruments that shape norms, processes, and institutions to realize the highest attainable standard of physical and mental health throughout the world. As an academic field of study, global health law has become a basis to describe new legal and policy frameworks that apply to the new set of public health threats, non-state actors, and regulatory instruments that structure global health. Ensuring justice in global health, the field of global health law is infused with norms of equity, social justice, and human rights, striving for collective action and mutual solidarity throughout the world, with particular concern for the world's most disadvantaged people. This burgeoning field requires a foundational text.

This chapter introduces the central importance of global health law to advance global health with justice, providing a foundation for this book by laying out the role of law and policy in global health. Framing the need for law in global health, Part I examines public health at the global level, raising an imperative for global health law. Part II defines global health law as encompassing binding

Global Health – Promoting Public Health Throughout the World

Global Governance – From WHO to the World

Global Law – Bridging Hard & Soft Law

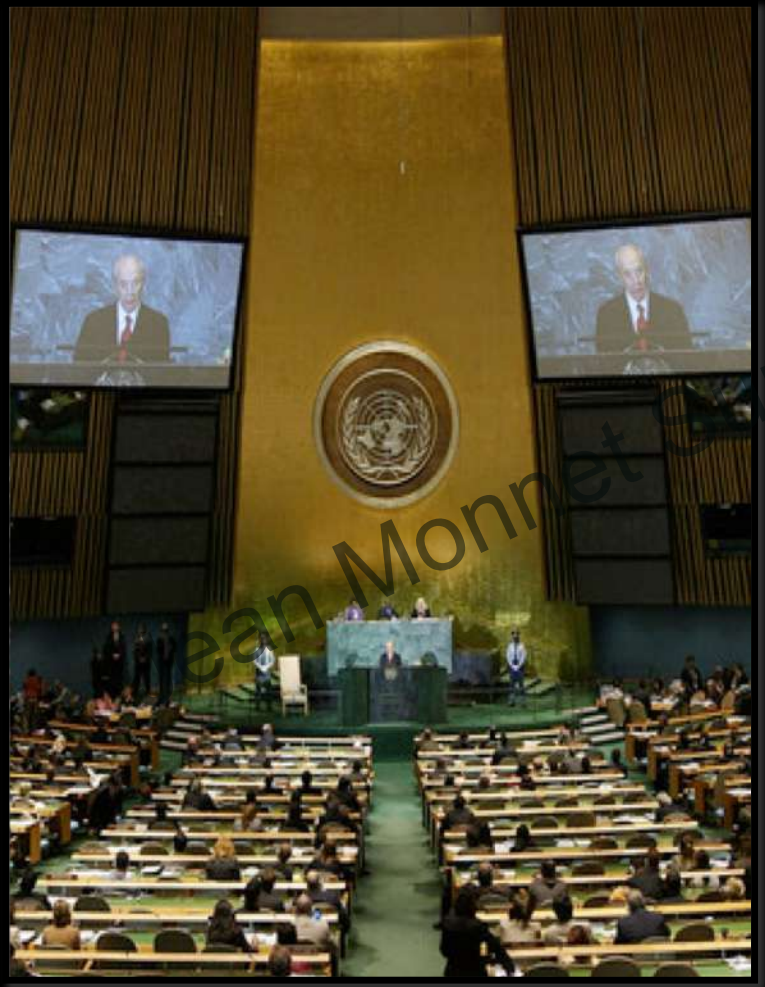
Global Health Is Public Health

- Globalization Impacts Public Health
- Global Health as a Contested Field
  - Medical Interventions vs. Public Health Promotion

- Public Health Vision of Global Health
  - Population-level Policies
  - Underlying Determinants of Health

∴ Need for Multisectoral Approach

Global Health Requires Global Governance



"The promotion of global health necessitates global governance beyond the reach of national governments, requiring international organizations, national governments, and non-governmental actors to come together under law to respond to globalized health threats."

"International Health" is Born

Preventing Disease Requires International Cooperation

- International Agreements for Disease Reporting
- Humanitarian Efforts to prevent, control, and treat "tropical disease"

Why did early international efforts fail to achieve true international cooperation?

Threats across All Nations

"Globalizing forces fueled the spread of infectious diseases and disease vectors, transborder trade of harmful products, environmental degradation, and economic shocks, resulting in sweeping health consequences across the world."

Need for Collective Action to Address Global Determinants of Health

International Health Governance

- Inconsistent Public Health Measures across Nations Led to the International Sanitary Conferences
- Periodic Conferences Become Permanent Institutions

What did early institutions of international health governance provide that was lacking in international sanitary conferences?

International Sanitary Conferences

First International Sanitary Conference (1851)

⬇

International Sanitary Convention (1903)

⬇

International Public Health Institutions

- Pan American Sanitary Bureau (1902)
- OIHP (1907)
- League of Nations Health Office (1920)

Office International d'Hygiène Publique

The World at War

War as the Ultimate Threat to Health & Human Rights

- Origins in Eugenics
- Fascism on the Rise
- Allies Come Together through UNRRA

How did the horrors of World War II shape the development of the UN as a new system of global health governance?

Post-War Governance

World War II

⬇

UN Charter

⬇

WHO Constitution

1945 San Francisco Conference on International Organization

WHO

World War II

⬇

UN Charter

⬇

WHO Constitution

Why was WHO's mandate so much broader than that of previous institutions?

International Health Conference (New York, 1946)

- One Organization of Global Governance
- Member State Governing Structure

- Sweeping Mission & Core Functions

WHO

World War II

⬇

UN Charter

⬇

WHO Constitution

UN Secretary-General Trygve Lie & WHO Director-General Brock Chisholm (Paris, 1948)

CONSTITUTION

OF THE

WORLD HEALTH ORGANIZATION

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being

rights of every human being without distinction of race, religion, political belief,

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.

Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures.

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WHO

World War II

⬇

UN Charter

⬇

WHO Constitution

Why did states delineate multiple types of legal authorities (binding and non-binding) for multiple types of global health challenges?

- WHO Legal Authorities

Varied Instruments Provide Policy Flexibility

- International Unity under International Law

Lawmaking in Global Health

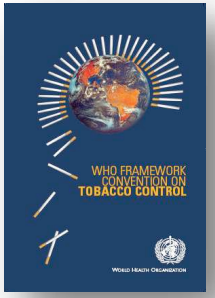
International Law under UN Charter

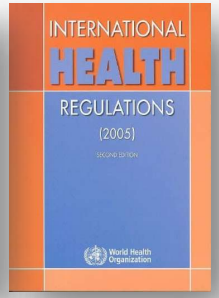
- International Law under UN & Specialized Agencies

WHO Constitution establishes varied legal authorities

- Conventions
- Regulations
- Recommendations

Key Legal Successes





Pandemic Agreement (2025)?

Why has WHO long refrained from the development of "hard" international health law?

Justice under Global Law

- Collective Global Action – addressing common threats and shared burdens across nations and sectors
- Arising out of International Law
  - Binding AND Non-Binding Frameworks
  - State AND Non-State Actors
- Common Norms

PLOS GLOBAL PUBLIC HEALTH

REVIEW

The World Health Organization was born as a normative agency: Seventy-five years of global health law under WHO governance

Lawrence O. Gostin[1]*, Benjamin Mason Meier[2], Safura Abdool Karim[3], Judith Bueno de Mesquita[4], Gian Luca Burci[5], Danwood Chirwa[6], Alexandra Finch[1], Eric A. Friedman[1], Roojin Habibi[7], Sam Halabi[1], Tsung-Ling Lee[8], Brigit Toebes[9], Pedro Villarreal[10]

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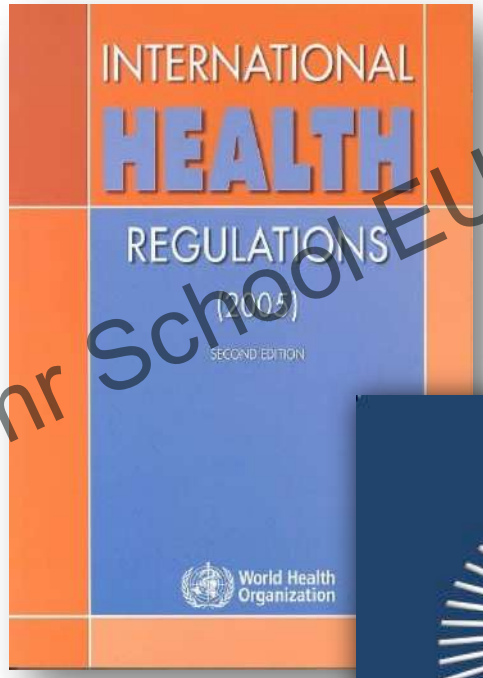
Editor: Srikanth Kondreddy, University of Ottawa, CANADA

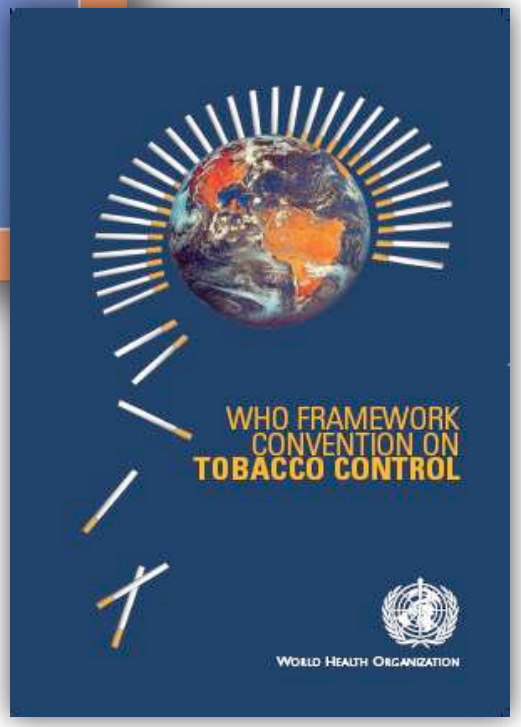
Abstract

The World Health Organization (WHO) was born as a normative agency and has looked to global health law to structure collective action to realize global health with justice. Framed by its constitutional authority to act as the directing and coordinating authority on international health, WHO has long been seen as the central actor in the development and implementation of global health law. However, WHO has faced challenges in advancing law to prevent disease and promote health over the past 75 years, with global health law constrained by new health actors, shifting normative frameworks, and soft law diplomacy. These challenges were exacerbated amid the COVID-19 pandemic, as states neglected international legal commitments in national health responses. Yet, global health law reforms are now underway to strengthen WHO governance, signaling a return to lawmaking for global health. Looking back on WHO's 75th anniversary, this article examines the central importance of global health law under WHO governance, reviewing the past successes,

Hard vs. Soft Law

Limitations of International Law





Disadvantages of Hard Law

- Need for State Consent
- No Guarantee of Implementation
- No Enforcement Mechanisms

Preference for "Softer" Forms of Normative Authority

Global Health Law is (Mostly) Soft Law

Framing Standards of Legal Behavior

- Non-binding, but . . .
  - Agreement
  - Normative Character
  - Consequences for Noncompliance
- Shape Behavior of State and Non-State Actors

How does soft law complement hard law in the development of obligations in global health?

"The reliance on these non-legally binding norms has hastened the transformation of international health law, made primarily between states and international organizations, into global health law, which looks to both state and non-state actors."

Hard Law	Soft Law
Legally Binding	Frame Standards
Legal Accountability	Compliance through Persuasion
Declares State Obligations	Applies to Non-State Actors
Requires International Consensus	Adopted More Quickly

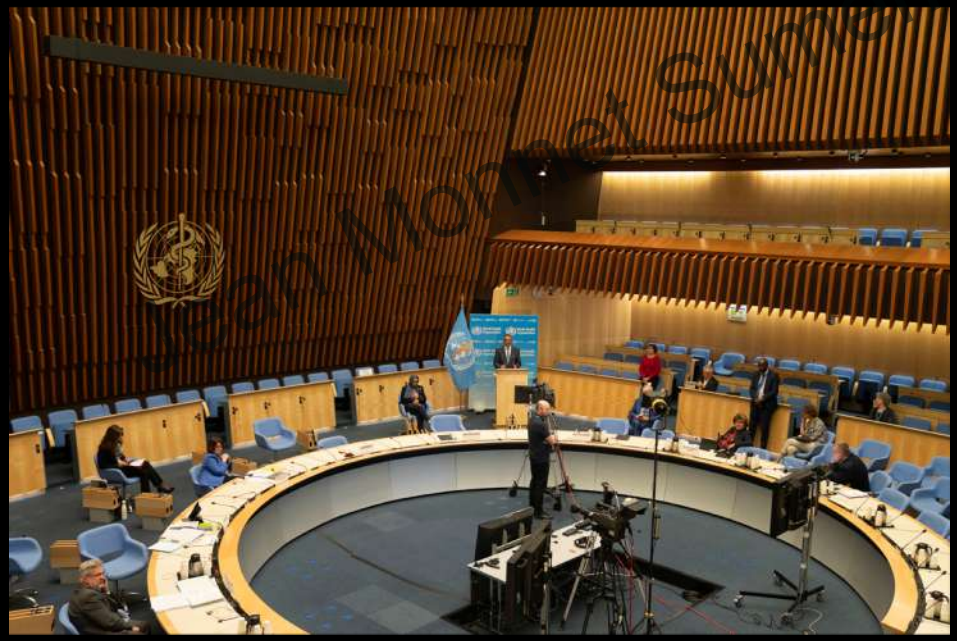
Soft Law is Necessary

- Respond Quickly to Emerging Threats
- Develop Evolving Obligations amid Uncertainty
- Set Complex Standards across Sectors & Non-State Actors
- Raise Awareness as a Foundation for Hard Law

Why does global health law rely heavily on soft law to shape public health throughout the world?

Soft Law in the COVID-19 Response

WHO & UN Resolutions to align national COVID-19 preparedness and response with international obligations



WHO's "most salient normative activity has been to create 'soft' standards underpinned by science, ethics, and human rights"

73rd World Health Assembly (2020)

Hard Law in the COVID-19 Response: IHR Limitations

China Notification

Violative Nationalist Responses

December | January | February | March | April


Has Global Health Law Risen to Meet the COVID-19 Challenge? Revisiting the International Health Regulations to Prepare for Future Threats

Global Health Law

Lawrence O. Gostin, Roojin Habibi, and Benjamin Mason Meier

WHO PHEIC

Global Solidarity?

Hard Law Reforms

A Global Health Law Trilogy: Transformational Reforms to Strengthen Pandemic Prevention, Preparedness, and Response

Global Health Law

Benjamin Mason Meier[1], Roojin Habibi[2], and Lawrence O. Gostin[3]

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Keywords: International Health Regulations, Global Health Security Agenda, Pandemic Treaty, World Health Organization, COVID-19

Abstract: This is a pivotal moment in the global governance response to pandemic threats, with crucial global health law reforms being undertaken simultaneously in the coming years: the revision of the International Health Regulations, the implementation of the GHSA Legal Preparedness Action Package, and the negotiation of a new Pandemic Treaty. Rather than looking at these reforms in isolation, it will be necessary to examine how they fit together, considering: how these reforms can complement each other to support pandemic prevention, preparedness, and response; what financing mechanisms are necessary to ensure sustainable health governance; and why vital norms of equity, social justice, and human rights must underpin this new global health system.

About This Column

Lawrence O. Gostin and Benjamin Mason Meier serve as the section editors for Global Health Law. Professor Gostin is University Professor at Georgetown University and the Founding Linda D. & Timothy J. O'Neill Professor of Global Health Law at Georgetown University Law Center and Director of the World Health Organization Collaborating Center on National and Global Health Law. Professor Meier is a Professor of Global Health Policy at the University of North Carolina at Chapel Hill and a Scholar at the O'Neill Institute for National and Global Health Law. This column will feature timely analyses and perspectives on law, policy, and justice in global health.

The COVID-19 pandemic has been the greatest health crisis of our lifetimes, but the glaring limitations of the public health response offer a unique opportunity to launch necessaryl reforms in global health governance. In reshaping global health governance to prepare for future threats, international initiatives in the coming years will give rise to sweeping revisions of global health law. The international community is simultaneously undertaking three potentially transformative legal reforms: the revision of the International Health Regulations (IHR), the implementation of a Legal Preparedness Action Package under the Global Health Security Agenda (GHSA), and the negotiation of a new Pandemic Treaty. Taken together, these reforms could enable the world to better prevent, prepare for, and respond to future pandemics, but it will be crucial to harmonize these legal initiatives, recognizing interconnections across the global health law landscape.

Limitations of Global Health Law in the COVID-19 Response

The ongoing COVID-19 pandemic has exposed fundamental gaps in global health law and governance. Revealing weaknesses in the foundations of pandemic prevention, preparedness, and response, the IHR have proven ineffective in shaping national responses to public health emergencies, with governments overlooking public health evidence, and undermining international health cooperation. The World Health Organization (WHO), which oversees IHR implementation, became embroiled in political controversy, keeping the Organization from holding governments to account for clear neglect of health recommendations and legal obligations. Despite fundamental IHR reforms in 2005 in the wake

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Hard & Soft Law in COVID-19 Response

- Hard Law
  - IHR
  - Pandemic Agreement?
- Soft Law
  - WHA Resolutions Provide Clarifications

Why must future reforms of global health law include both binding and non-binding components under hard and soft law?

Global Health Law
A New Field Emerges

Introducing Global Health Law

Global Health Law

Lawrence O. Gostin and Benjamin Mason Meier

Global health law describes the legal frameworks that structure global health. Laws and regulations, when based on the best available evidence, can promote healthy behaviors, regulate hazardous activities, and ensure socially responsible corporate marketing and products. These regulatory frameworks operate in virtually every realm of health, including infectious and noncommunicable diseases, mental health, injuries, and the safety and effectiveness of vaccines, pharmaceuticals, and medical products. Law can help structure universally affordable, accessible, and equitable health systems that promote universal health coverage. Beyond discrete attention to health risks, the rule of law and good governance are crucial for ensuring health and well-being.

Where global health has come to frame efforts to advance public health across countries, law has become crucial to addressing the global health threats that have arisen in a rapidly globalizing world. Globalization has unleashed the spread of disease, connected societies in shared commerciality, and highlighted the limitations of domestic law in ensuring global determinants of health. In this interconnected world, no country acting alone can stem health hazards that go beyond national borders. Yet if globalization has presented challenges to disease prevention and health promotion, global health law offers the promise of bridging national boundaries to advance global norms and alleviate health inequities.

Arising out of international health law — which has long structured multilateral cooperation to respond to infectious disease threats — global health law seeks to structure the contemporary governance architecture for global health. In responding to health harms throughout the world, global health law has "evolve[d] beyond its traditional confines of formal sources and subjects of international law" to advance global health with justice.[1] This focus on global health has necessitated action beyond the reach of national governments, requiring both state and non-state actors to come together to respond to globalized health threats. Global health law seeks to frame this new governance to respond to the major health challenges of the twenty-first century.

The field of global health law has thus become a basis to conceptualize the legal institutions that apply to the changing public health threats, non-state actors, and regulatory norms that structure global health. Beyond the traditional purview of international health law, global health law describes evolving legal efforts to address:

- New health threats — including non-communicable disease, injuries, mental health, dangerous products, and other globalized health threats,
- New health actors — including transnational corporations, private philanthropists, civil society, and other non-state actors, and
- New health norms — including "soft law" instruments, global strat-

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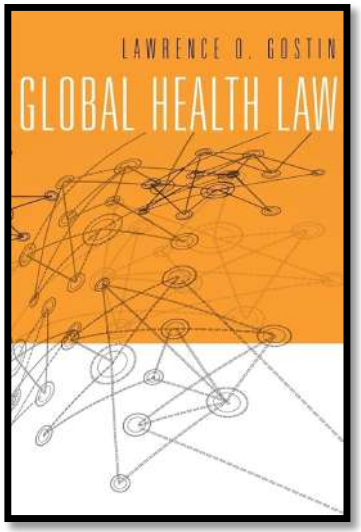
- From International Health Law to Global Health Law
- An Academic Discipline
  - Rising Health Threats
  - Proliferating Health Actors
  - Expanding Policy Instruments (The EU Role in Global Health)
- Ten Years of Global Health Law



Existential Threats

Populist Nationalism

- Rejecting Public Health Science
- Violating Fundamental Rights
- Undermining Global Solidarity

Cataclysmic Pandemic

- Unprecedented Health Threat
- Widespread Inequities
- Limitations of Global Health Law Reforms

Global Health Law – More Necessary Than Ever…

A Rising Imperative for EU Leadership in Global Health Law

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Benjamin Mason Meier
Professor of Global Health Policy
University of North Carolina at Chapel Hill

Lawmaking in Global Health

International Law under UN Charter

- New Era of Multilateral Lawmaking
- International Law under UN Governance
- Establishment of Specialized Agencies – Leap of Faith

Why did the UN Charter seek to centralize lawmaking under the UN and its specialized agencies?

International Court of Justice in The Hague

WHO Constitution establishes varied legal authorities

(1) international conventions
(2) international custom
(3) general principles of law
(4) judicial decisions and "the teachings of the most highly qualified publicists"

Why did the WHO Constitution provide authority to develop different types of legal instruments?

The Complexification of Global Health Diplomacy

Diplomacy Within WHO

- Political Groupings within WHO Governing Bodies
- WHO Director-General
- Non-State Actors and Experts

Diplomacy across an Expanding Global Health Landscape

- Proliferation of global health institutions
- Political networks address health (G7, G20, EU)

Coordination Challenges