GLOBAL HEALTH LAW & POLICY Ensuring Justice For A Healthier World

EDITED BY

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FOREWORD BY TEDROS ADHANOM GHEBREYESUS

Global Health Law & Policy

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Ensuring Justice for a Healthier World

Edited by LAWRENCE O. GOSTIN and BENJAMIN MASON MEIER





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For those we lost in the COVID-19 pandemic

May their memories inspire the next generation to build a healthier world \ldots

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Foreword: The Law as a Fundamental Determinant of Global Health

Dr. Tedros Adhanom Ghebreyesus

In 1948, as nations sought to build a new world order in the aftermath of World War II, they adopted a foundational instrument of global health law: the Constitution of the World Health Organization. In its unprecedented preambular declaration, the Constitution affirmed that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." In the decades since, global health law and policy have become crucial to addressing major health threats in a rapidly globalizing world, including infectious diseases, non-communicable diseases, injuries, and mental health.

Having long championed the importance of law in global health, I congratulate Professors Lawrence Gostin and Benjamin Meier for this groundbreaking book on *Global Health Law & Policy*, bringing together leading scholars in the Global Health Law Consortium to provide an academic foundation for the next generation of global health leaders.

Global health law, based on the best available evidence, can promote healthy behaviors, regulate hazardous activities, and assure the safety and effectiveness of vaccines, pharmaceuticals, and other medical products. These legal instruments can also shape the underlying social, behavioral, and economic determinants of health. Appropriate law reforms can structure affordable, accessible, and equitable health systems that promote universal health coverage (UHC), providing access to high-quality, affordable health services while ensuring financial protection against potentially impoverishing out-of-pocket expenses.

During my time as Minister of Health in Ethiopia, we made significant changes to laws that increased access to health services and underlying determinants of health for millions of people. These domestic reforms gave me a deep understanding of the importance of global health governance in supporting national health policy—and have informed my work in the World Health Organization (WHO) to advance global health law and policy with WHO's Member States in the World Health Assembly.

Global health law and policy have always been central to WHO's mission and mandate. The WHO Constitution provides the organization with expansive authority to negotiate and codify international treaties, regulations, and recommendations, which WHO has used to develop international instruments to encourage, and at times to bind, states to take action to reduce threats common to all.

WHO's first legal instrument was the International Health Regulations (IHR), which provide the legal foundation for international efforts to prevent, detect, and respond to potential public health emergencies of international concern. Under the IHR, WHO has maintained its principal role in coordinating international cooperation in infectious disease control. Last revised in 2005, the IHR have established a global surveillance and reporting system for infectious disease control and set national minimum standards to prepare for, and respond to, infectious disease outbreaks—balancing health with international travel, trade, and human rights.

Beyond the IHR, WHO Member States have long been reluctant to use WHO's legal authority to adopt conventions or agreements. The most notable exception is the adoption in 2003 of the Framework Convention on Tobacco Control (FCTC), with WHO Member States developing a coordinated response to tobacco under international law. The FCTC sets out specific legal obligations in reducing the supply of and demand for tobacco, providing a crucial model for employing global health law to respond to new health threats.

The COVID-19 pandemic has revealed limitations in the global health architecture. Despite an imperative to come together in facing a common threat, including under the IHR, compliance with a range of global health obligations remains a challenge. International assistance and genuine collaboration to build resilient public health capacities and ensure equity continue to be lacking. The pandemic has served as a stark reminder of the importance of global law for global solidarity.

The international community must learn crucial lessons from the COVID-19 response to reform and rebuild key global norms and institutions. In providing a new legal foundation for global health governance, the World Health Assembly has initiated a process for global health law reforms—through both amendments of the IHR and a new, legally binding WHO convention or agreement on pandemic preparedness and response. The outcome of these international negotiations will have significant implications for the future of global health.

Global health challenges have changed drastically since WHO's founding, from rapid travel and mass migrations to zoonotic spillovers and climate change. Yet, if globalization has presented challenges to disease prevention and health promotion, global law and good governance offer the promise of bridging national boundaries to advance global norms and alleviate health inequities. Safeguarding public health requires cooperation and shared responsibilities among state and non-state actors, which can only be fostered through global health law.

Still, there remain formidable challenges facing global health law. Financial constraints and unsustainable debt threaten gains in health, with funding cuts affecting domestic health systems, international organizations, and key populations. Skepticism toward science and loss of public trust are undermining crucial public health interventions such as vaccinations. Restrictions on civil society and political freedoms are subverting social participation and universal rights. Global threats such as environmental degradation, antimicrobial resistance, and armed conflict are exacerbating divisions within and across nations.

In preparing the next generation to respond to these challenges, *Global Health Law & Policy* draws from the history of the field to examine how the law can be an effective tool to advance global health. Looking beyond the health sector, this foundational text explains how we must meet new health challenges through governance across a range of sectors. Such a comprehensive view of global governance for health will be necessary to prepare today's students for tomorrow's challenges.

I am confident this text will serve as an essential foundation for these students—our future leaders—to make the right to health a reality and advance global health with justice.

Dr. Tedros Adhanom Ghebreyesus Director-General, World Health Organization

Preface: A Field Born of Trying Times

Global health faces an existential crisis. The COVID-19 pandemic has shaken the foundations of public health and revealed the importance of global governance. Where no country acting alone can respond effectively to the health threats of a globalizing world, global governance has become necessary to coordinate the global health response. Yet, amid unprecedented global health challenges, national governments have rejected public health science, violated human rights, and undermined global solidarity. It will be crucial to reform global health governance to prepare for future global health threats, but the world remains divided in confronting common threats through global action. These uncertain times for global health call for the advancement of global health law.

Global health law encompasses the law and policy frameworks that apply to the new public health threats, non-state actors, and regulatory instruments that structure global health. These legal frameworks, placing public health obligations on the global community of state and non-state actors, facilitate social justice in global health through global institutions. Looking beyond the scope of international legal instruments between national governments, global health law extends to an encompassing set of global health determinants through the obligations of state and non-state actors, structuring new forms of global governance responsive to the major health threats of a globalizing world and establishing the normative frameworks necessary to realize global health with justice.

The modern foundations of global health arose from the ashes of crisis. The United Nations (UN) was formed out of the ruins of World War II, bringing nations together to address collective threats through international action. Giving rise to a new system of international governance, the UN Charter called for the establishment of an international health organization, the World Health Organization (WHO), which has evolved alongside other UN institutions to shape global health law and policy over the past 75 years. The COVID-19 pandemic has challenged this international system, threatening the global solidarity necessary to establish global governance for health. The world now approaches a pivotal crossroads in the global governance response, with crucial global health law reforms being undertaken simultaneously amid this ongoing crisis.

Following from these sweeping reforms, there is a need to prepare a new generation to ensure justice for a healthier world, raising an imperative for a foundational text to support students and scholars to address the global health challenges of the future through global health law and policy.

Global health law offers the promise of bridging national boundaries to alleviate global inequities. Arising out of international health law—which narrowly focuses on obligations among states—the academic field of global health law seeks to address a new landscape for global health in a rapidly globalizing world, including the rise of new actors in the global health landscape and new threats beyond the reach of the state. Global health law and policy thus encompass the changing global landscape, norms, and governance necessary to respond to the health challenges of the 21st century. The rapidly expanding literature in the field has fostered a generation of thought leaders in global health law, and the collaborative efforts of these scholars come together in this volume.

Recognizing limitations in legal authority for global health, twenty faculty came together in April 2019 to form the Global Health Law Consortium, bringing together their collective expertise to advance the academic field of global health law; provide authoritative interpretations of legal instruments in global health; and facilitate collaborative global health law research projects. The work of the Consortium would become crucial as the world sought to come together in an unprecedented pandemic response. Through these challenging years, policymakers have looked to the Consortium's academic research to structure the response to COVID-19—and to consider future legal standards in global health governance. We now look to the future of our field. To support the next generation of the field, scholars in the Consortium saw the need to develop this foundational text.

Given the expansive growth of the field, it was necessary to bring together a wide range of the field's leading scholars to develop its seminal text, working across the Global Health Law Consortium and complemented by a larger set of global health scholars throughout the world. The authors who contributed to this edited volume represent the academic leaders in their respective sub-fields, with this volume drawing on their combined expertise to provide a holistic survey of the field. As scholarship on global health law and policy has expanded, over the past decade and especially through the COVID-19 response, these contributors provide a comprehensive introduction to global health law working together to advance law and policy to realize the highest attainable standard of health.

Global Health Law & Policy seeks to define the academic field of global health law, explore its major doctrinal boundaries, establish its relationship with global health governance, and look into some of its enduring controversies. This volume is organized in four main sections, devoted to:

- I. Explaining the conceptual frameworks and governance institutions that define the field—introducing the reader to: the evolving nature of global health and global governance, the encompassing scope of global health law, the expanding actors in the global health landscape, the norms that structure global health efforts, and the diplomatic processes by which global health law and policy are developed.
- II. Applying global health governance to disease prevention and health promotion—providing an understanding of the divergent law and policy approaches taken in global health governance to respond to threats from: the spread of infectious disease, the commercial products that underlie non-communicable disease, the human rights violations undermining mental health policy, and the environmental health challenges that have structured a "One Health" approach.
- III. Examining economic institutions that influence global health—exploring poverty as a fundamental underlying determinant of health and looking to development as a means to improve public health through: the adoption of the Sustainable Development Goals, the evolution of economic development policy, the responses to international trade law, the advancement of corporate social responsibility, and the establishment of global health funding agencies.
- IV. Analyzing international legal efforts to address the rising health threats of a rapidly globalizing world—recognizing efforts in global governance to: frame collective action to address antimicrobial resistance, ensure pathogen sharing in exchange for access to medicines, safeguard sexual and reproductive health and rights, implement international humanitarian law in conflicts and emergencies, mitigate and adapt to the health threats of climate change, and promote universal health coverage.

These sections are intended to be read sequentially, with each chapter building from the one before it while adding new understanding of the field. This volume is thus intended to be read as a single text, rather than a series of independent chapters, providing a complete foundational education across the field of global health law. As an educational text, the contributing authors have followed a consistent structure for their respective chapters to ensure coherence across the volume. With each chapter reviewing the historical evolution, current state, and the forward-looking areas of a distinct sub-field, every chapter includes three case studies—to complement the theoretical analysis of the chapters by highlighting the practical application of global health law. This volume can thus provide a basis for teaching, and to facilitate this pedagogical use, each chapter is followed by questions for consideration, prompting areas for further study or classroom discussion. Upon completion of this theoretical and practical examination of global health law and policy, it is our hope that readers will have acquired a thorough understanding of the social, economic, cultural, legal, and political processes by which global health law and policy frame efforts to realize global health objectives.

We remain immensely thankful for those who supported the development of this foundational text for the field. As editors, we greatly appreciate the groundbreaking contributors to this volume, who recognized the need for a foundational text and employed their interdisciplinary expertise to explain the areas of the field they know best. Developing this volume has required not only the substantive expertise of scholars in the field but also the administrative assistance of students at our respective universities. We remain inspired by the dedicated efforts of Mercy Adekola, Chris Burch, Taylor Corpening, Ryan Doerzbacher, Eric Friedman, Quintin Gay, Hanna Huffstetler, Erin Jones, Ashley Lim, Kerstan Nealy, Neha Saggi, Sonam Shah, Rishabh Sud, and Sarah Wetter, whose work was crucial to developing our own research, reviewing the contributing chapters, and compiling the complete volume. It is our hope that these early experiences in the field will provide a foundation for their promising careers. Finally, we are grateful to Oxford University Press, who have now worked with us on three separate volumes to frame three distinct fields at the intersection of international law and global health. Our publishers have long seen the value of this interdisciplinary scholarship, and we continue to appreciate their faith in our vision for new fields of study to advance health in a globalizing world.

Drawing from the steadfast efforts of our contributing authors throughout the world, research assistants at Georgetown University and the University of North Carolina at Chapel Hill, and editors at Oxford University Press, *Global Health Law & Policy* reflects the dramatic development of the field—highlighting the successes of legal advancements, the challenges of the 21st century, and the resilience of global governance. We look to this book in providing a foundation for students of global health law and policy. *Global Health Law & Policy* will be widely used in policy contexts, health advocacy, and classroom teaching across schools of law, public health, global studies, and public policy, laying an academic foundation for the future of the field. In supporting the continuing struggle to uphold law in global health in these trying times, we hope that this academic text for the field will prove essential for this next generation—who hold the power to build a healthier world.

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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, noncommunicable 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 international law, "soft" law, and global health policy. These law and policy efforts have evolved rapidly in the 21st century, with Part III examining how contemporary challenges in a globalizing world have given rise to the academic field of global health law. Part IV describes the academic basis for the field and outlines the structure of this foundational text, delineating the chapters that describe the institutions of global health law, the role of global health governance, the influence of global economic governance, and the challenges amid rising health threats. This introduction concludes that despite the dramatic development of the field of global health law, the world faces new challenges that threaten to divide the world when solidarity is needed most, with ongoing reforms that will shape global health for generations to come.

I. Law as a Foundation of Global Health

Globalization has tightened connections between nations and peoples, giving rise to shared health threats across the world. These common challenges call for collective action from the global community (Frenk and Moon 2013). In responding to these threats, the modern public health order embraces a more holistic approach to health, now considering socioeconomic conditions, social justice, and preventative measures for health promotion. This framing requires an examination of "the way society organizes itself, produces and distributes wealth, and interacts with the natural environment"-implicating "collective responsibility for unhealthy behavior" (Gostin, Burris, and Lazzarini 1999, 64). Such an expansive focus on the public health threats of a globalizing world allows for consideration of an encompassing set of global health challenges, including ecosystem threats, food availability, democratic governance, and realization of human rights. Shifting away from "international health," a colonial practice that historically focused on controlling infectious disease across national borders, global health looks across health threats to focus on achieving equity in health worldwide (Koplan et al. 2009).

The field of global health has come to encompass the study, research, and practice of public health across the globe. Elevating the central importance of public health, global health examines global determinants of health, recognizing the interconnections between global contexts and local conditions. In the practice of global health, however, a debate has endured on the importance and relative priority of vertical and horizontal interventions:

• Vertical health interventions often look to narrow, disease specific, and specialized approaches to individual health threats (Frenk and Gómez-Dantes 2017).

• Horizontal approaches look across health threats to implement health system interventions that address a wide range of determinants of health (Kickbusch and Buckett 2010).

Vertical health approaches have long faced critiques in public health for seeking to address health threats in isolation, neglecting to address the underlying determinants that lead to the spread of disease and the impediments to wellbeing across populations (Frenk, Gómez-Dantés, and Moon 2014). Looking to horizontal approaches to address public health, global health has come to span a broad approach to determinants of health across sectors—from education, employment, and income to behaviors related to infectious and non-communicable diseases. As an interdisciplinary field, global health now examines the systemic determinants that underlie global health (Lomazzi, Jenkins, and Borisch 2016). To address these determinants of public health at a global level, global health brings together actors to improve underlying determinants of health throughout the world, looking to global governance in structuring these global determinants (Fried et al. 2010). In seeking to achieve this global health governance, state and non-state actors have joined together in a collective effort under global law.

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. Global health thus looks beyond the individual state to encompass a diverse array of non-state actors—including organizations, foundations, and corporations—in understanding and developing collaborative solutions to today's public health challenges. To bring together the work of these state and non-state actors, global health actors engage in varying functions, all with the goal of improving health across borders and throughout the world. Global health looks to address interconnected determinants of health through global collaboration, with local, national, and international actors partnering and integrating their actions to form a global governance structure that seeks to mitigate global threats that undermine public health.

Where global health has come to frame efforts to advance public health across actors, law has become crucial to address the global health governance challenges that have arisen in a rapidly globalizing world. Law directly and indirectly impacts health determinants and outcomes across local, national, and global contexts (Gostin et al. 2019). Structuring health outcomes through law, legal instruments shape underlying determinants of health. These "legal determinants of health" thus influence societal interactions that structure, perpetuate, and mediate underlying determinants of health, establishing standards and norms that guide conduct (e.g., tobacco taxes), resolve disputes (e.g., via courts of law), and

govern institutions (e.g., public and private health systems) (Gostin and Wiley 2016). While laws are developed and operationalized across different levels of governance (locally, nationally, globally), each have "downstream" influence on the lives of individuals and shape the conditions for people to live healthy lives (Gostin, Cohen, and Phelan *forthcoming*). If well designed, law can be a powerful tool for advancing justice in health—from protecting standards for health promotion, to strengthening health systems, to holding institutions accountable for health harms (Magnusson 2017). Operating at the global level to address global determinants of public health through global action, global health law presents a legal framework to structure new efforts by the global community to advance global health.

II. Defining Global Health Law

Global health law encompasses the legal and policy frameworks-both binding and non-binding-that structure public health in a globalizing world. With globalization giving rise to global health threats, global health law has become necessary to address these common threats and shared burdens across nations and sectors. Connecting societies in shared vulnerability, these globalizing forces have exposed the limitations of domestic law in addressing global determinants of health. Laws at the national level are not sufficient to address these global threats because such domestic laws cannot reach beyond national borders, and therefore, global health law is necessary to bridge the gap between global norms and national laws to promote global health (Gostin and Meier 2019). Arising out of international law, which focuses on multilateral cooperation among states, the focus of global health has necessitated action beyond national governments. In bringing together state and non-state actors, global health law seeks to respond to major health challenges in a rapidly globalizing world while improving the health and well-being of the world's people through the establishment of global governance for health.

Global governance has become crucial in developing legal norms and implementing those norms through global institutions. Global health law recognizes that all nations face interconnected public health threats, requiring collective global action to realize global health equity (Gostin 2014). Operationalized through common norms, global health law is guided by values of social justice, mutual solidarity, and human rights (Meier and Gostin 2018). Governance institutions can set norms for global action, form partnerships with key stakeholders, and develop consensus on shared goals for global health (Toebes 2018) under global health law. In uniting states under binding legal obligations and bringing together state and non-state actors under "soft law" commitments, global health law could not exist without global health governance (Gostin, Cohen, and Phelan *forthcoming*).

Through an extensive body of governance institutions, actors have come together to respond to global challenges, working to create coordinated responses to rising threats. International organizations serve as the primary governance institutions for the creation of this legal framework across states-including both binding and non-binding agreements-which, in turn, shapes national responses as states implement international legal obligations. Through the development of international law, these global governance institutions can develop global health law to frame the legal obligations of states, with international organizations providing a basis for member states to negotiate international legal agreements, facilitate international accountability, and shape global health norms (Meier et al. 2020). Yet numerous international organizations and legal regimes now impact health through state and non-state actors, and global health governance requires global health law to encompass multiple sectors and multiple actors-to coordinate actions between these actors and sectors to enhance global health (Gostin and Sridhar 2014). With globalization exacerbating the risks of disease and increasing the need for global cooperation, global health governance grows increasingly crucial in developing international law and global policy to unite state and non-state actors against global threats.

Global health law can thus shape this expanding law and policy landscape for global health, coordinating the global community through institutions of global governance. Law has become a central aspect of governance, with global health governance often taking the form of laws through constitutions, regulations, and bylaws (Gostin 2014). Global health law presents a legal framework to structure coordinated efforts by the global community to advance global health (Toebes 2018). Providing an international legal foundation for global health governance, global health law supports global institutions to negotiate a shared vision of global health, coordinate with organizations across sectors, and align national laws to advance public health in a globalizing world (Gostin and Meier 2019). Global health law thereby sets the global goals necessary to structure global health governance. Facilitating accountability for these shared global health goals, global health law can provide an institutional basis for developing benchmarks, monitoring progress, and enhancing compliance for achieving global health with justice (Gostin 2014).

III. An Evolving Field

The expansion of health law scholarship to encompass global health law has laid out a law and policy framework to structure efforts by the global community to advance global health. The need for law in global health has been in motion for centuries, as populations came to recognize the importance of cooperation across nations to protect public health. A variety of sanitary conventions in the mid-to-late 19th century began to shape the field (Gross 2021). Arising out of efforts to control infectious threats along international trade routes, these legal efforts soon moved beyond infectious diseases to include aspects of environmental health, non-communicable threats of alcohol and tobacco, and occupational health across the globe (Fidler 2001). Some of the first international health organizations, developed in the years leading up to World War II, laid a path for international governance to establish international law to protect public health.

Following World War II, the birth of the United Nations (UN) and World Health Organization (WHO) would provide a permanent foundation for global health governance. These governing institutions, which remain the core of law and policy in the international community, have solidified the focus on law to advance global health (Meier et al. 2020). Amid rising tensions in a globalizing world-through the Cold War, pandemic threats, and inequitable development-global health law would rise in importance (Bélanger 1989). Beyond WHO, global institutions formed rapidly to address global determinants of health, establishing a complex landscape that serves to frame health policies, programs, and practices in the global sphere (Moon et al. 2010). In facing new health challenges, global health law now encompasses binding and non-binding instruments of health law, human rights law, environmental law, trade law, and other law and policy instruments developed across sectors. The interconnections between these areas of global health law have been revealed amid the challenges of the COVID-19 response (Gostin 2021). As the importance of law and policy in global health became more evident, the field of global health law emerged.

The field of global health law has expanded rapidly in the 21st century. Arising out of international health law—which focuses narrowly on international legal relationships among states—global health law has a vast scope, including cooperative partnerships among state and non-state actors and soft law approaches to global health policy. Looking beyond the regulation of states through international treaty law, global health law can apply new global policies to facilitate cooperation across state and non-state actors, frame institutions of global governance, and realize global health with justice. Where once international health law was the only option for states to address issues of international health, contemporary soft law policy instruments (including non-binding international resolutions, global strategies, and codes of practice) have proven far easier to negotiate and adopt—without the need for formal ratification by states (Sekalala 2017). While lacking the formal legal enforceability of international law, these global health policies nevertheless codify consensus across the global

community, providing a foundation under global health law to set priorities, mobilize constituencies, create incentives, coordinate actors, and facilitate accountability in global health. Through hard and soft law norm-setting, global health law seeks to create new policy institutions to alter behaviors, sustain funding, and coordinate partnerships (Gostin 2014). Without the practical need to develop international law, global health law and policy seeks to bind all the actors that influence public health in a globalizing world. Shifting from international health law (with treaties applicable to states) to global health law (with law and policy applied to both state and non-state actors), a proliferation of international, national, non-governmental, and corporate actors has organized to address a multisectoral array of determinants of health (Szlezák et al. 2010). Global health law thus encompasses the changing global landscape and governance necessary to respond to the health challenges of the 21st century.

As an academic discipline, global health law describes the legal and policy frameworks that apply to the expanding set of public health threats, non-state actors, and regulatory instruments that structure global health. Evolving beyond the traditional confines of formal sources and subjects of international law, global health law seeks to describe legal institutions that speak to:

- Rising health threats—including communicable and non-communicable diseases, injuries, mental health, dangerous products, and other globalized health threats;
- Proliferating health actors—including transnational corporations, private philanthropists, civil society, and other non-state actors; and
- Expanding health regulations—including "soft law" instruments, strategy documents, and other norms of global health policy (Gostin 2014).

As the limitations of international law led to the establishment of global health law, stakeholders have engaged a diverse array of actors through the rise of new policy institutions—institutions developed through their normative foundations in justice (Ruger 2018). These law and policy frameworks, placing public health obligations on the global community of state and non-state actors, facilitate justice in global health through global institutions that are governed well, embracing values of transparency, monitoring, multisectoral engagement, and accountability (Gostin, Cohen, and Phelan *forthcoming*).

IV. Structure of the Volume

Where law and policy are complementary approaches to global health law, this foundational text looks to global standards by which to frame government

responsibilities and establish global governance. This volume is organized in four main sections: (1) explaining the conceptual frameworks and governance institutions that define the field, (2) applying global health governance to disease prevention and health promotion, (3) examining economic institutions that influence global health, and (4) analyzing international legal efforts to address the rising health threats of a rapidly globalizing world. These sections are intended to be read sequentially, with each chapter building from the one before it while adding new information to the reader's understanding of the field. To complement the theoretical foundations of the text, each chapter includes brief case studies to highlight the practical application of law and policy in global health.

Section I introduces the reader to the conceptual frameworks and institutional foundations necessary to understand the role of law and policy in protecting and promoting public health in a globalizing world. The first chapter provides an understanding of the evolving meaning of global health, examining the modern birth of global governance under the UN and establishment of international legal authorities under WHO. Given the limitations of international health law in a globalizing world, Chapter 2 introduces the legal foundations for the book by defining global health law, conceptualizing the hard and soft law authorities necessary to bind together the state and non-state actors that make up the expanding global health landscape. This landscape is the focus of Chapter 3, which explores the proliferating actors and partnerships in the global health architecture, analyzing the role of global health law as a foundation of global health governance. Binding these actors together, Chapter 4 considers the normative frameworks that structure global health efforts, considering equity and social justice in global health and human rights under international law. Chapter 5 concludes Section I by looking to the diplomatic process by which global health law and policy are developed, considering the politics of negotiating global health law through global health governance.

This conceptual framework for global health law and policy in Section I establishes a foundation for a closer examination of some of the most pressing legal issues in global health in Sections II through IV.

Shifting to the application of global health law and policy in global health governance, Section II provides the reader with an understanding of the divergent approaches taken in global health governance to respond to leading global health threats. Chapter 6 chronicles how global health law has evolved to combat the spread of infectious diseases, tracing the evolution of the WHO International Health Regulations, examining contemporary responses from HIV/AIDS to COVID-19, and considering the importance of ongoing law reforms to face future threats to global health security. This infectious disease response is distinct from policy approaches to addressing non-communicable disease, with the global trade of unhealthy products leading to a series of hard and

soft law approaches to the regulation of commercial determinants of health, and Chapter 7 examines policies to shape smoking, eating, and drinking behaviors throughout the world. Recognizing the underlying conditions that contribute to physical, mental, and social well-being, Chapter 8 explores changing approaches to mental health under global health policy, analyzing how global health governance has shifted from institutionalization to medicalization to community-based rehabilitation. In focusing on the environmental threats of an industrializing world, Chapter 9 investigates policy frameworks to support environmental health through the regulation of environmental pollutants and the establishment of a "One Health" approach to global health governance.

Section III considers the influence of economic governance on the public's health, examining the role of global health law in shaping economic development, international trade, corporate regulation, and health funding for the realization of a healthier world. Where economic development underlies public health, the Sustainable Development Goals provide a foundation for all global efforts to ensure sustainable development, with Chapter 10 delineating the wide range of health-related goals and targets. This focus on economic development is extended through international economic governance under the International Monetary Fund and World Bank, and Chapter 11 analyzes the evolving influence of these development institutions in alleviating poverty to promote global health. Expanding to international trade governance, Chapter 12 looks to efforts to liberalize international trade through the World Trade Organization, considering the harmful consequences of trade agreements and examining rising efforts to challenge intellectual property protections to ensure access to essential medicines. This focus on essential medicines requires transnational corporations, and Chapter 13 looks to the rising influence of transnational corporations on commercial determinants of health, analyzing models for regulating harmful corporate actions and considering whether corporate social responsibility doctrines can support corporate engagement in global health governance. In bringing these economic actors together to support global health, Section III ends by focusing on international assistance and cooperation in health, with Chapter 14 examining the establishment of new global health funding agencies, bringing state and non-state actors together to pool resources to meet basic needs and distribute essential medicines.

Globalization has fundamentally altered public health, raising an imperative for international law to address rising health threats, and Section IV analyzes these issues at the leading edge of global governance. Recognizing the importance of anti-microbials to the treatment of infectious disease, Chapter 15 confronts the rising challenge of anti-microbial resistance and the need for collective action through international law to prevent and respond to resistant strains. This focus on the infectious disease response is extended in Chapter 16, considering the rise of international agreements to ensure pathogen sharing as a basis for both responding promptly to disease threats and ensuring access to medicines and vaccines. Chapter 17 looks to the evolution of international law to safeguard sexual and reproductive health and rights, exploring how human rights advocacy has reframed health policy and transformed health institutions. Framing international humanitarian law as global health policy, Chapter 18 examines international efforts to protect public health and human rights in the context of armed conflict and humanitarian emergencies, looking to health protections for refugees and ethical responsibilities of health professionals in avoiding harm and upholding human rights. Climate change is affecting the health of the entire planet, and given the cataclysmic threat to planetary health, Chapter 19 considers climate change mitigation and adaptation under the UN Framework Convention on Climate Change. Bringing together efforts across sectors to advance public health through global health law, Chapter 20 concludes Section IV by examining evolving policies to promote Universal Health Coverage, seeking a multisectoral approach to addressing health in all policies.

Conclusion

Global health law is rapidly expanding, creating new governance institutions to alter behaviors, sustain funding, and coordinate partnerships for justice in global health. This foundational text reflects on the dramatic development of the field of global health law, highlighting the advancements of law and policy in promoting health equity, the challenges exposed by the COVID-19 pandemic, and the need for new legal and governance frameworks in responding to the threats of the 21st century.

Out of the ashes of World War II, institutions of global health have brought the world together in unprecedented cooperation through global health law, giving rise to the successes and opportunities detailed throughout this text. This expansion of international law to encompass global health law has laid out a legal framework to structure efforts by the global community to advance global health. However, the current age of rising nationalism amid emerging threats has cast doubt on many of these successes and raised obstacles to future progress. In violent contrast with the shared goals of a globalizing world, populist nationalism seeks to retrench nations inward, with rising nationalist movements directly challenging norms of human rights, violating tenets of international law, and spurring isolationism in global affairs. These challenges to global health law have coincided with sweeping new global health threats, as nationalist retrenchment has led to a rejection of global health law as a basis for global health solidarity. Such compounding crises offer a unique opportunity to reform global health law to effectively coordinate pandemic preparedness and strengthen legal authorities to advance global health.

Global health law remains necessary—now more than ever before. As infectious disease threats expand, the global climate changes, and humans, animals, and environments are increasingly interconnected, bold law and governance have become vital to a world that is safer and fairer. Global governance provides hope for the future, with these governance institutions facilitating the durability of global health law through the unprecedented challenges ahead. In preparing for future threats, a wide range of crucial global health law reforms are being undertaken simultaneously in the coming years, with the chapters of this book grappling with these ongoing reforms. These reforms of global health law, while each responding to distinct concerns, must be considered as interrelated instruments across an interconnected legal landscape, with the reforms undertaken in the coming years shaping the next generation of the field.

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FRAMEWORKS & INSTITUTIONS OF GLOBAL HEALTH

Shifting Actors & Norms in a Globalizing World

Global Health

Global Determinants, Global Governance, and Global Law

Lawrence O. Gostin and Alexandra Finch

Introduction

Global health reflects efforts to achieve population health throughout the world. Looking to public health principles as a basis for global health, the advancement of health has shifted from a focus on individual medical care to approaches that address broad underlying determinants of health for entire populations. In an increasingly globalized world, national responses are no longer sufficient to address these determinants of health. Globalization has enabled the spread of disease and proliferation of a vast range of health hazards, from unhealthy foods and unsafe products to global poverty and environmental degradation, highlighting the limitations of domestic public health interventions. Responding to these global threats requires global efforts to address global determinants of health. These global efforts rely upon global governance, bringing together actors throughout the world to address health threats that transcend national boundaries, and states have come to look to the United Nations (UN) system as a central pillar of global governance.

Where advancing public health in a globalizing world requires global governance, global health governance has sought to address political, social, commercial, and behavioral determinants of health through global health law. Drawing from a long history of international cooperation to address infectious disease, states worked through the UN after World War II to develop international health governance under the World Health Organization (WHO). In establishing WHO as the first UN specialized agency, states envisioned it as the world's health champion, granting it sweeping authority to bind states together through international law to coordinate national governments to prevent disease and promote health. WHO emerged as the early leader of global health governance. This system of global health governance has evolved to encourage global coordination to promote public health and mitigate health threats, codifying these efforts in global health law and policy. Law and policy have thus become a foundation of good governance for health.

This chapter examines the contested meaning of global health, the health implications of a globalizing world, and the importance of global governance for health. Part I describes how global health reflects the practice of public health, examining the progression of the field of public health and government efforts to promote public health through public policy. In a globalizing world, such public policy to address global threats would require global governance. Examining the shift from international health to global health, Part II traces the evolving field of global health, the rise of international health governance, and the birth of global governance for health after World War II. Part III analyzes global health governance under the UN, with the establishment of WHO giving rise to the contemporary system of global health law. This chapter concludes that global health governance has become the foundation for advancing global health law in a globalizing world, bringing together state and non-state actors to realize the highest attainable standard of health for all.

I. Global Health Is Public Health

As populations first came into contact with each other, public health practice came to be seen as critical in preventing disease and promoting health. Rising public health movements for social medicine in the progressive era of the 19th century would focus both on prevention of injury and disease and on a broad population-based understanding of health. Governments, in recognizing their central responsibility to secure health and safety, evolved their governance to develop policies to protect public health. These policies would look to address underlying determinants of health, shaping the living conditions that ultimately determine the health of populations.

A. From Individual Health to Public Health

Health entails a state of complete physical, mental, and social well-being. This standard of health is not inherent in the individual but is derived from interpersonal, community, and institutional factors that interact with local, national, and global environments. Reflecting determinants of the public's health, health is strongly influenced by underlying social, political, and economic conditions at the population level (Birn, Pillay, and Holtz 2017). Public health is thus

focused on the health of entire populations, reflecting societal actions that promote health and prevent disease by focusing on the improvement of underlying determinants of health. These determinants—across a range of social, economic, and political factors—encompass an expansive array of sectors and conditions in both the natural and built environments.

From the earliest civilizations, humans have faced a myriad of determinants that impacted the health of the public. As early civilizations looked from divine forces to natural forces as the cause of disease, rulers sought to monitor potential physical and environmental factors that influence health, with Greco-Roman philosophers theorizing that poor health and disease were the result of an "imbalance between man and his environment" (Rosen 1958, 33). As science advanced, thinkers of the Middle Ages (from the late 5th century through the 15th century) began to theorize that disease could spread between individuals, giving rise to concerns around infectious disease. These infectious diseases repeatedly threatened populations in the Middle Ages, as rapid population growth left cities overcrowded and unhygienic. Following the fall of the Roman Empire, municipalities across Europe moved to introduce some of the first public health measures. Municipalities sought to prohibit dead animals and other waste from being dumped in rivers and streams, placing restrictions on manufacturing to protect the water supply. By the late Middle Ages, cities introduced policies for street cleaning and refuse pickup. With the Bubonic Plague ravaging much of Europe in the 14th century, governmental entities moved to combat this deadly infectious disease threat, implementing the first quarantine and isolation strategies to prevent the spread of disease (Porter 1999). The rise of educational systems during the Middle Ages established the knowledge base to promote individual and societal medicine during the Enlightenment era.

Scientific advancements during the Enlightenment (from the late 17th century through the 18th century) would set the stage for health advancements transitioning from individual medicine for specific ailments to societal efforts to promote public health. As industrial and urban population centers rapidly grew, so did the threat of dangerous living conditions and poor health outcomes (Tulchinsky and Varavikova 2014). This recognition of disease threats would give rise to the field of epidemiology, the study of the determinants and distribution of health and disease across populations. Yet, to curb disease, societal efforts would require policy reforms. Early public health was centralized and focused on bettering health among the upper levels of the social and economic hierarchy. However, this focus would shift as the wealthy realized they could no longer ignore the impoverished in neighboring districts (Goudsblom 1986). Public health movements looked across social hierarchies to address the plight of the impoverished, establishing the modern elements of public health through the fight for "social medicine" (Mackenbach 2009).

Case Study: Social Medicine and 1848 Revolutions: From Medicine to Public Health

Born out of the Industrial Revolution and working class movements across Europe, the rise of social medicine examined how economic inequalities shape the rise and experience of disease. Prussian researcher Rudolf Virchow gave rise to this movement in analyzing the socioeconomic causes of a typhus epidemic in Upper Silesia, concluding that "the government has rendered impossible the mental and material development of these people through the most preposterous neglect of this country, and by its equally dilatory internal and external politics." With Virchow holding that "medicine is a social science, and politics is nothing more than medicine on a grand scale," this focus on health inequities would shape revolutionary movements across Europe, with the summer of 1848 bringing armed revolts, calling on governments to guarantee safe water and health standards amidst cholera and other infectious disease outbreaks. While these 1848 revolutions failed to overthrow the political order, they would lead to new social policies to institute public health governance. Laying the groundwork for these policies, Friedrich Engels would consider the inequalities of Industrialization in England, posing the question: "How is it possible, under such conditions, for the lower class to be healthy and long lived?" These inequitable determinants of health would become a focus of government responsibility and public policy-beginning in Europe and spreading well beyond-to address economic development as a basis for health promotion. Even as some policymakers argued that central governments could not guarantee health, others looked to governments to establish policies that could, through financial and legal standards, create a social medicine system for reforming conditions to improve underlying determinants of health.

Building from the early days of social medicine, scientific discoveries in the late 19th century supported the identification of disease-causing agents, allowing for the realization of societal goals to prevent disease.

In drawing from epidemiology, government record keeping led to statistical analysis that would provide insights on health at the population level. Disease surveillance could trace diseases back to their initial source, with epidemiology seeking to reveal the causal connections between environmental conditions, disease outbreaks, and individual morbidity. Epidemiologists began to study the influence of societal ills, including poverty and malnutrition, on mortality and morbidity (Sand 1934).¹ The 20th century began with efforts to preserve and promote the well-being of populations, spawning the modern field of public health. Even as modern medicine rose alongside public health, epidemiological data undercut the "triumphalist myths of clinical medicine" (Porter 1997, 102), highlighting the overwhelming role of public health measures in driving health improvements. Governments recognized that medical interventions alone could not sufficiently promote health, with public health improvements occurring largely as a result of the "modification of the conditions which led to disease, rather than from intervention in the mechanism of disease after it occurred" (McKeown 1979, 198). This holistic approach to disease prevention—looking at improvements in nutrition, education, and living conditions—would seek to address underlying determinants of public health.

Public health has come to take a broader view of the conditions for health and well-being, focusing on underlying determinants of health and the policy interventions necessary to improve them. From the birth of early reforms to the seeds of modern-day public health, it has been clear that government efforts are necessary to address underlying determinants of health. By addressing these underlying determinants, health is shaped across government sectors, and at all levels of society, through various laws and policies. Through public health law and policy, governments authority is central in structuring public health.

B. Government Authority for Public Health

Governments have come to accept responsibility to address the underlying conditions that affect public health. Public health is integral to government functioning, making promoting public health and well-being a significant government interest (Gostin and Wiley 2016). Government authority is seen as necessary to propel the collective action required to protect and promote public health. To operationalize this societal goal, governments develop public policy to prevent disease and promote health, taking on responsibilities that individuals alone cannot (Carey 1970). Collective action through public policy is necessary

¹ This new study would eventually give rise to the field of social epidemiology, utilizing statistical evidence to display health inequities and examine disproportionate harms impacting those living in poverty. Through this focus on underlying social determinants of health, it became apparent that public health cannot be dissociated from socioeconomic factors, with poverty serving as a fundamental underlying determinant of health and well-being, and thus—no matter the disease or its origin—health threats will inevitably descend the social gradient to disproportionately threaten the poor (Marmot, Kogevinas, and Elston 1987).

to secure public health and general welfare. Government entities dedicated to promoting public health have accordingly arisen through public policy and play a central role in developing and implementing standards for health and well-being.

The development of public policy in public health evolved slowly, with government concern for population health largely ignored for centuries. Amid the sanitary movements of the 19th century, many governments for the first time looked to public policy to advance public health, with rapid population growth and unprecedented levels of disease leading to popular calls for clean water systems, refuse removal, and hygiene protocols (Porter 1999). As seen in France, which first operationalized health councils, the formalization of health institutions would address hygiene and sanitation through public policy to prevent disease across populations—as a government responsibility (De Feo et al. 2014).² However, these health councils operated at a local level, and it would take until the turn of the 20th century for governments to advance public health through national policy.

As national governments across the globe began to embrace an obligation to prevent disease and promote health, they enacted national policies across sectors to protect public health. The United States implemented some of the strongest early examples of national policy to promote public health. The 1911 Triangle Shirtwaist Factory fire would result in the death of 146 people (largely immigrant women and girls), as the factory had locked exit doors to prevent workers from taking breaks and leaving their workstations. Following from this preventable tragedy, the U.S. government strengthened labor laws to protect public health.³ Such responsive government actions across countries would solidify national authority in central aspects of public health policy. The continuing need for government action would lead to the establishment of the first health departments, tasked with overseeing public health policy on a continuing basis (Winslow 1923). By instituting these public health departments, national health systems moved toward a focus on permanent health institutions, capable of adapting to changing policy needs and providing for rapid policy responses.

² These French health councils maintained some of the first modern-day sewage systems. Centralized in Paris, these reforms shifted populations from open air waste disposal to closed, underground sewage systems. Under Napoleon III, Paris in the 1830s underwent major city developments to lay these underground sewage pipes and ducts. By ensuring proper methods of both cleaning the sewage system and disposal of waste products, Parisian infrastructures achieved drastic decreases in cholera and other waste-borne diseases (De Feo et al. 2014).

³ Similarly, the public recognition of unsanitary food conditions reached public consciousness in the United States through the writings of Upton Sinclair in *The Jungle*, leading to the Meat Inspection Act of 1906. The United States would go on in the decades that followed, and amid the Great Depression in the West, to create sweeping public policies that brought about new regulations in daily lives and commercial industries to promote public health and well-being (McEvoy 1995).

As national governments came to recognize an imperative to develop governing institutions to protect and promote the health and well-being of people within their borders, it became increasingly important to apply this focus to public health across nations. With the rise of globalized trade and international relations, governments came to see the rise of health threats and destructive behaviors abroad as a threat to domestic prosperity (Fidler 2001). Diseases and disease vectors once relegated to specific nations and continents now spread rapidly across national borders. This rapid change in human interaction necessitated the adoption of health governance across nations. Developments in international affairs led to the birth of "international health," which framed early efforts to prevent the spread of disease across national borders, with governments recognizing a corollary need for international governance to establish laws that would protect public health throughout the world.

II. Global Health Requires Global Governance

To advance public health in a globalizing world, health institutions and instruments must look beyond the actions of singular nations to address a larger set of global health determinants. Rising from international principles drawn up to prevent the spread of epidemic disease, the evolution of international sanitary regulations led to a series of early treaties that served as the foundation of the modern global health order. Early institutions of international health governance soon followed. Yet these institutions were unable to bring the world together to address public health challenges, and as the bloodshed of two world wars left nations and their populations decimated, states sought to lay a new foundation for global health governance. Seeking to overcome the limitations of international health governance, global health governance brought states together following the atrocities of World War II to take collective action to build a healthier world under the UN.

A. Origins of International Health

National governments first came together formally to address international health in the 19th century, looking across nations to understand international determinants of public health and develop common regulations to protect populations. The earliest measures to limit the spread of disease had relied on isolating populations through the formation of a "cordon sanitaire," where armed guards surrounded towns stricken by illness, but it was not until the 14th century that measures were introduced to prevent the introduction of disease into a population (Goodman 1952). These measures required those entering a community

to isolate for a period of time in order to observe whether the visitor developed signs of illness. (Such requirements came to be known as "quarantine" based on the forty-day "quarantino" isolation period required by Venice.) The Venetian quarantine practice served as a model for other European governments over the course of the next two centuries (Goodman 1952). Governments came to understand that preventing infectious disease outbreaks would require international cooperation, but they long failed to work together to advance their common needs. Yet, with an increase in disease outbreaks driven by international commerce amid industrialized production in the mid-1800s, states looked to "international health" partnerships to protect their own self-interests (Goodman 1952). Recognizing the cross-border threat of disease, the European trading powers began efforts to standardize international health cooperation to prevent the spread of epidemics across national borders and throughout their colonies. Creating new avenues to report disease outbreaks and secure cross-border traffic, cooperative efforts to ensure mutual self-interest would lead to the first international health agreements to prevent the spread of disease (Kelley 2011).

However, with powerful nations basing these early international health agreements on exploitative colonial systems and economic self-interest, governments failed to ensure cooperation across nations and overlooked rising threats in the environmental, physical, social, and cultural space. Agreements among European powers often excluded the lands and peoples they had colonized, which were governed instead through a focus on "tropical disease"encompassing diseases that originate from temperate or tropical areas with no previous origin point within Europe and the Western world (Hewa 1995). Leading to the development of the field of "tropical medicine," this focus on disease in colonized lands in Africa, Asia, and the Middle East sought to keep European colonizers free of diseases that they had not faced previously (Coghe 2020).⁴ Notwithstanding these imperialistic motives, efforts to prevent, control, and treat "tropical disease" were framed as humanitarian efforts, which helped to justify colonial oppression while furthering colonial expansion (Bump and Aniebo 2022). Yet this narrow focus on tropical diseases and tropical medicine neglected to address the broader set of health concerns that continued to plague the colonies and beyond, including non-communicable diseases and wider determinants of health such as basic sanitation, nutrition, and housing.

Despite an imperative for greater cooperation across nations, national governments were slow to adapt to public health conditions that demanded

⁴ This understanding of "tropical medicine" arises out of the colonial history of health, and these colonial legacies of global health have persisted in global health practice to this day. Where major Western organizations still embrace a focus on "tropical diseases," offering "innovative" solutions to the lands they once colonized, this anachronistic term reflects the continuing influence of colonial power dynamics in global health (Lang 2001).

international cooperation to address health threats across all nations, rather than to protect the economic interests of wealthy nations (Fidler 2001). These international health threats were increasing, exacerbated by increasing interconnections in a rapidly globalizing world, bringing nations together in shared vulnerability (Birn, Pillay, and Holtz 2017). 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. These threats would challenge all nations, and no single nation could respond to them alone. States began to look to new health frameworks to bolster cooperation—in a shift toward international health (McMichael and Beaglehole 2009). This focus on international health encompassed broad notions of collective action and underlying determinants of health for all (Brown, Cueto, and Fee 2006). To coordinate national health interventions at the international level, a new international governance landscape arose for public health advancement throughout the world.

B. Rise of an International Health Order

Drawing from increasing attention to international health, an international health order arose, looking to international law to drive collective action and harmonize national public health measures. International cooperation was becoming essential to coordinate national policies across states-to prevent the spread of disease without undermining economic and security interests (Aginam 2005). The Industrial Revolution had propelled international trade, and with it, the spread of disease across borders. The development of the steamship and the railway in the early 19th century hastened travel, which led to a growing frustration over quarantine measures. In an effort to reduce the spread of disease, travelers were held for inspection at borders and goods were regularly destroyed, slowing the movement of people and goods. Powerful economic interests began to grow weary of trade delays incurred by distinct health policies at each port of entry. Governments faced pressure to establish reformed quarantine laws that were less burdensome on tradespeople and private interests. By the late 1840s, governments in Europe began to organize international conferences in an effort to establish international cooperation for resolving technical questions on quarantine methods and other public health measures (Goodman 1952).

The first International Sanitary Conference, held in Paris in 1851, sought to bring together physicians and diplomats to reach consensus among those states with trade interests in the Mediterranean region. Additional conferences would be held over the next fifty years, and this rising international health order would ultimately establish the international legal foundation upon which permanent international health institutions could be constructed (Gostin and Meier 2019).

Case Study: International Governance: From Sanitary Conferences to Permanent Institutions

With national governments recognizing the nature of disease and spread of infection across populations, states saw that disease prevention could not be undertaken only at the domestic level, raising an imperative to coordinate responses internationally. European trading powers gathered for the first International Sanitary Conference in 1851, and this groundbreaking meeting would establish a cooperative architecture to address the threat of infectious disease, seeking to harmonize quarantine regulations across nations without causing undue interference with international travel or trade. However, state agreements could not garner the widespread national ratification necessary for adoption of a binding convention. It would take until the end of the 19th century for states to reach sufficient consensus on epidemiological methods and public health practice to work together to prevent the spread of infectious disease. The preamble of the first International Sanitary Convention of 1892, establishing quarantine requirements for ships traveling along the Suez Canal, recognized that national governments must gather regularly "to establish common measures for protecting public health during cholera epidemics without uselessly obstructing commercial transactions and passenger traffic." Subsequent conventions would seek to require states to notify other states of potential outbreaks of diseases, outlining public health measures at national borders to identify diseases at points of entry. Subsequent international sanitary conventions at the start of the 20th century would establish binding provisions to ensure the practice of public health and safety from infectious disease. At the eleventh International Sanitary Conference in Paris in 1903, delegates drafted the first International Sanitary Convention of widespread applicability. This Convention not only established international obligations but also laid the foundations for permanent international health institutions-calling for the creation of an international health office.

These international sanitary conventions during the first decades of the 20th century, focusing on specific infectious diseases,⁵ provided

⁵ Early sanitary conventions had concerned cholera, plague, and yellow fever—diseases not considered endemic to Europe and North America but whose spread from Asia and the Middle East was of deep concern to the trade and colonial powers. The International Sanitary Convention of 1926 added notification requirements for typhus and smallpox—diseases endemic to Europe.

opportunities for states to develop governance institutions to ensure permanent public health leadership across nations. Given the recurring threat of infectious diseases—as trade, travel, and industrialization continued to expand—such permanent institutions would allow for monitoring and surveillance across the world to prevent the spread of disease at the earliest possible time. Building from early sanitary conventions and moving toward permanent international bodies, collaborative frameworks were formed to establish communication between nations and give rise to international public health bureaucracies.

C. New Governance Institutions

Public health was among the earliest fields to seek international cooperation through international institutions, born out of an understanding that disease transmission required states to collaborate-for the health of their populations and advancement of their economic interests. To protect public health as a foundation of national security, early international health councils and meetings concerning infectious diseases would soon evolve into standing health bureaucracies, guided by multilateral treaties and seeking to maintain the public health order (Jacobson 1979). During the fifth International Sanitary Conference in 1881, states recommended improvements in disease notification procedures-through weekly epidemiological bulletinsproviding a foundation for sanitary authorities from different countries to communicate (Goodman 1952). By the end of the 19th century, health professionals began to appreciate the need for permanent international governance to coordinate disease control measures across countries, recognizing the recurring disease threats that faced increasingly interconnected states (Pannenborg 1979).

The first permanent institutions emerged in the early 20th century. In the Americas, states in 1902 would form the Pan American Sanitary Bureau, seeking to standardize national regulations in the Western Hemisphere and control infectious disease at regional ports (Meier and Ayala 2015). European states thereafter established the *Office International d'Hygiène Publique* (OIHP) in 1907, building from commitments in the 1903 International Sanitary Convention. The OIHP soon expanded across regions to encompass nearly sixty nations, as member states sent representatives to Paris to discuss and circulate key epidemiological information and coordinate international sanitary conferences (WHO 1958). Yet, these nascent governing bodies would soon be challenged by unprecedented public health threats, as the "Great War" caused suffering unlike any the world had ever seen, giving rise to new international institutions of public health.



Figure 1.1 LNHO Members Meet in 1925 to Address Malaria (United Nations Archives at Geneva)

World War I brought about numerous new public health challenges widespread famine, refugee crises, and pandemic threats⁶—and the aftermath of the war would give rise to new institutions of international governance. In a postwar effort to maintain and promote peace and security throughout the world, the League of Nations was founded in 1920, with founding states seeking to establish a stable political order governed under international laws and institutions (Borowy 2009). These states understood that addressing the world's growing public health challenges would be central to their international efforts. Going beyond OIHP's mandate to collect, validate, and publish epidemiological data, the League of Nations would also address health conditions within countries and across regions, as seen in Figure 1.1, through the establishment of a health-specific agency under the League's umbrella: the League of Nations Health Organization (LNHO) (Cueto, Brown, and Fee 2019).

Despite an already crowded landscape of international health organizations, the LNHO became the preeminent hub for public health, cooperating

⁶ These wartime challenges were exacerbated by the 1918 influenza pandemic, which would kill over fifty million people—more than the war itself. In the face of one of the worst pandemics in human history, governments employed public health strategies developed over the centuries, implementing measures such as isolation, quarantine, and suspension of mass gatherings, but without international institutions in place to coordinate these national measures (Bootsma and Ferguson 2007).

with high-level health officials in virtually every member country, convening panels of experts, and even leveraging new communications technologies (i.e., telephone and telegraph) to rapidly transmit epidemiological data to member states around the world. The LNHO developed international commissions on diseases, shared epidemiological surveillance, and published technical health reports. However, the LNHO was constrained by its narrow diseasecentered mandate, lack of funding and membership, and mounting geopolitical pressures (Borowy 2009). Just as new sweeping threats to underlying determinants of health were emerging, requiring LNHO leadership amid a "Great Depression" in the West,7 the League of Nations was collapsing amid a deterioration in the international order. By the late 1930s, the rise of fascist regimes and a wave of imperialistic repression had brought nations once again to the edge of war. The spirit of multilateral cooperation that had led to the League's creation would yield to these divisive ideologies. As armies mobilized across Europe and Asia, states rapidly withdrew from the League of Nations, with international health and international institutions hanging in the balance of another world war.

D. World War II Challenges Governance Regimes

World War II saw renewed atrocities throughout the world, and new international governance institutions would be formed in response to this cataclysmic suffering. As the German army marched through European nations, the Nazi regime's genocidal plans became a horrific reality. The Nazi regime carried out mass extermination of entire populations—including millions of Jews, Roma, homosexuals, and people with disabilities—with millions of others imprisoned and forced into concentration camps. This complete Nazi disregard for the value of human life arose out of the German medical field's widespread promotion of "eugenics," a distortion of public health principles that posited the genetic inferiority of entire peoples, with physicians voluntarily aiding in theorizing, planning, and operating death camps that would slaughter all those deemed "unworthy of life" (Bachrach and Kuntz 2004).⁸ War simultaneously spread across eastern Asia, as the Japanese Empire sought colonial domination

⁷ The Great Depression was a long and pronounced economic downturn in the 1930s that led to rising unemployment, food insecurity, and widespread immiseration in the industrialized world— and required novel government programs to provide labor rights and public assistance to millions facing poverty.

⁸ Beyond this genocidal horror, Nazi doctors furthered their disregard for the value of human life by conducting medical experiments on healthy individuals in countries under German occupation. These experiments occurred without consent and led to murder, brutality, cruelty, torture, and other atrocities that would come to be seen as "crimes against humanity" (Constantin and Andorno 2020).

over the region, subjugating peoples across Korea, Manchukuo, southeast Asia, and Micronesia. The world was again at war, touching almost every nation, with this unprecedented violence threatening international governance and health advancements.

As war raged unchecked, international governance was unable to respond to the escalating slaughter and suffering, leading to the rise of new wartime health institutions. The League of Nations had collapsed, and OIHP was unable to operate effectively as the Nazi army descended upon its headquarters in Paris (Cueto, Brown, and Fee 2019). Amid this absence of international health governance, forty-four nations came together in 1943 to form the United Nations Relief and Rehabilitation Administration (UNRRA). UNRRA rapidly assumed wartime responsibility for public health, establishing offices across the world that would provide technical assistance to prevent disease outbreaks, rebuild national health agencies, and assist with the procurement of medical supplies (Sawyer 1947). Although UNRRA was only intended to be a temporary governance body, it provided essential public health coordination during a time of international crisis, developing flexible local responses during one of the most difficult times in humanity's history and creating a model for a new permanent international governance body.

It was out of the destruction of World War II that the current global governance structures would arise. From these atrocities, states sought a path forward to create a healthier world. In the autumn of 1944, state delegations (led by the United States, the United Kingdom, the Soviet Union, and the Republic of China) held a series of meetings at the Dumbarton Oaks Estate in Washington, D.C. to begin planning for the postwar period. These allied states sought to provide a framework for a new international organization to replace the League of Nations. This new organization, as they envisioned it, would maintain peace and stability by safeguarding human rights and facilitating collective governance over the world's most pressing challenges (Meier 2010). Less than a year later, their vision would come to fruition with the birth of the UN. States looked to the UN as a renewed institutional basis for global governance, with the 1945 Charter of the United Nations (UN Charter) bringing nations together to develop international laws to ensure global cooperation. New institutions of public health would be developed under the UN, establishing a global governance foundation for the development of global health law.

III. Global Governance Requires Global Law

The UN system of global governance plays a crucial role in coordinating the activities and defining the objectives of global actors to promote global health.

At the end of World War II, the international community was more interconnected than ever before—and more vulnerable to international health threats. States recognized that a more robust international law framework would be necessary for international health governance. International health law under the UN would seek to codify common values across states, binding them to mutual obligations and providing an international legal foundation for national law reforms to address public health challenges of global significance (Meier and Gostin 2018). With public health increasingly impacted by a range of global determinants and international bodies, global health law would become necessary for collective governance throughout the world, with the establishment of WHO providing new centralized legal authorities to advance global health and unite state and non-state actors in common cause.

A. Birth of the UN and Governance under International Law

The 1945 UN Charter would frame the global governance landscape for health. This constitutional framework for UN governance was the culmination of two months of deliberations at the San Francisco Conference, where representatives from fifty countries defined the structure and powers of a new international organization. The UN's framers built on the proposals from the Dumbarton Oaks Conference, entrusting the UN with legal authorities and funding support that far surpassed the League of Nations. The resulting UN Charter provided an institutional foundation to develop international law, representing necessary and unprecedented cooperation to further global solidarity in the postwar world (Gostin, Moon, and Meier 2020). This cooperation would allow for the implementation of a broad range of collective health responses by states in accordance with international law (Bélanger 1989).

In drafting the UN Charter, states did not initially address health; however, late-breaking additions at the San Francisco Conference would mainstream health authorities across the text of the UN Charter (Lancet 1945).⁹ These diplomatic efforts to incorporate health authorities under UN governance would form the legal foundation for the world's governance architecture for health. Yet, notwithstanding this invocation of international health in the UN Charter, it would fall to subsequent international negotiations to frame the international governance regime for health, with the UN proposing an International Health

⁹ These initiatives to incorporate health in the UN Charter arose out of collaborative efforts between physicians in the Brazilian and Chinese delegations to the 1945 San Francisco Conference on International Organization, who worked to establish the word "health" as a matter of international cooperation through the UN General Assembly, mandate the UN to promote solutions to international health problems, and propose a UN specialized agency to govern health (Sze 1988).

Conference that would give rise to WHO as the first UN specialized agency (Doull 1949).

B. Establishment of WHO

This International Health Conference brought together technical experts from around the world to develop the Constitution of the World Health Organization (WHO Constitution). In late 1945, the U.S. government worked with public health scholars to create a draft constitution, with that early draft serving as an outline for the UN's Technical Preparatory Committee. The Preparatory Committee's work in Paris, in turn, served as the foundation for the 1946 International Health Conference in New York, where state delegates deliberated for four and a half weeks before officially adopting the WHO Constitution pursuant to the UN Charter (Sharp 1947). In establishing WHO, the delegates agreed that this new international organization would assume the responsibilities of all the leading international health organizations—OIHP, LNHO, and UNRRA's Health Division—positioning WHO alone at the center of the global health landscape. Under this expansive global health mandate, states inaugurated WHO in 1948, launching its operations as the leading institution of global health governance.

1. Governing Structure

In facilitating this governance, states developed WHO's governing structure under the three organs diagrammed in Figure 1.2: an Assembly of member states to serve as the principal legislative and policy-making body of the organization; an Executive Board to set the agenda of the Assembly and implement its decisions; and a Secretariat made up of appointed professional staff and led by the elected Director-General (Cueto, Brown, and Fee 2019).

The World Health Assembly is WHO's ultimate policy-making body. Made up of all WHO member states, the Assembly has the authority to set WHO's agenda, approve its budget, and instruct the Executive Board and Director-General. It thus has wide-ranging authority to respond to global health concerns. Assembly resolutions, while not legally binding, reflect the will of WHO member states and have the potential to be effective tools in spurring action across nations. Most resolutions and decisions of the World Health Assembly can be adopted by a



Figure 1.2 WHO's Governing Structure (Gostin and Finch)

majority vote during annual plenary sessions, with each member state having an equal vote in all Assembly decision-making.¹⁰

Operating as a subset of the World Health Assembly, the WHO Constitution stipulates that WHO's Executive Board implements the decisions and policies set forth by the Assembly. Executive Board members are elected by the Assembly, taking into consideration an equitable geographic distribution, with members serving a term of three years. The Executive Board meets twice each year to guide the Assembly agenda, submit WHO's general program of work, and carry out decisions by the Assembly. Where immediate action is required, including in efforts to combat epidemics, the Constitution provides Executive Board authority to take emergency measures.

The WHO Secretariat, comprised of appointed technical staff and an elected Director-General, plays a crucial administrative role in coordinating the agency's day-to-day activities—convening technical experts, setting global standards, and supporting member states. The Secretariat is led by the Director-General, elected to a five-year term by the World Health Assembly and responsible for raising funds; coordinating with member states, partners, and other actors; and maintaining the credibility of the Organization. Serving as the public face of WHO, the Director-General is called upon to play a diplomatic role, balancing the interests of WHO's member states, mediating disputes in global health, and carrying out WHO's mission and core functions.

2. Mission and Core Functions

The WHO Constitution has provided WHO with an unprecedented mandate: "the attainment by all peoples of the highest possible level of health"—a lofty, if not unattainable, goal that seeks to achieve for every person "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO 1946, preamble). This sweeping mission represented a significant expansion from the limited scope of authority held by previous international health governance bodies (Gostin and Meier 2020), entrusting WHO not just with controlling the spread of disease but also achieving a state of global well-being—and, in the process, safeguarding health as a "one of the fundamental rights of every human being" (WHO 1946, preamble).¹¹

¹⁰ While a majority vote is sufficient for most Assembly resolutions, the WHO Constitution provides that more consequential decisions—including those proposing amendments to the WHO Constitution, suspending a member's voting privileges, or adopting conventions or agreements have a higher voting threshold of two-thirds for adoption. In practice, however, virtually all decisions by the Assembly are adopted on a consensus basis without a formal vote (OECD 2014).

¹¹ This right to health, first declared in the WHO Constitution, was later echoed across international human rights treaties, as discussed in Chapter 4, laying a foundation for the field of health and human rights (Gostin and Meier 2020).

The WHO Constitution positioned WHO as the world's leader in international health governance, stating that, among other functions, it is to "act as the directing and co-ordinating authority on international health work" (WHO 1946, art. 2). Drawing from this expansive authority to govern public health across nations, the WHO Constitution provided specific authority for a wide range of technical functions, tasking WHO with furnishing technical assistance and emergency aid, eradicating disease, promoting the prevention of injury, improvement of nutrition, and cooperation among scientific and professional groups (Gutteridge 1963). Beyond these technical functions, WHO was endowed with expansive normative functions, unique among global governance institutions, that provide WHO with extensive lawmaking authority.

3. Legal Authorities: Conventions, Regulations, and Recommendations To enable WHO to carry out its wide-ranging mandate, drafters of the WHO Constitution granted the agency unprecedented legal authority in international health. WHO's quasi-legislative powers were a key innovation in international governance, allowing the World Health Assembly to adopt different types of legal instruments and thereby offering WHO flexibility in addressing distinct public health challenges with varying degrees of legal authority (Sharp 1947).

Case Study: Legal Authorities of the World Health Organization

The WHO Constitution confers legal authorities that are both robust and varied, delineating separate authorities to develop conventions, regulations, and recommendations. The World Health Assembly, under Article 19 of the WHO Constitution, has broad authority to adopt conventions or agreements with respect to "any matter within the competence of the Organization"-a major departure from predecessor organizations. A rare feature in international law, the WHO Constitution thus allows for the development of binding obligations, with the Assembly authorized to adopt legally binding treaties and agreements that set standards to promote public health and provide paths for state ratification. Similarly providing means to bind all WHO member states, Article 21 of the WHO Constitution empowers the Assembly to adopt regulations in specific areas of global health: the international spread of disease, public health nomenclature, and standards for diagnostic procedures and the international trade and advertising of biological and pharmaceutical products. In these specific areas, regulations promulgated by the World Health Assembly automatically bind WHO member states unless they specifically opt out, with this "contracting out" approach requiring member

states to either accept or reject a regulation. Yet, not all health threats require binding obligations. For areas where non-binding obligations are sufficient (or at least politically expedient) to support global action, Article 23 of the Constitution confers authority on the World Health Assembly to develop non-binding recommendations, with these recommendations offering guidance to member states on any matter within the competence of WHO. These three distinct lawmaking authorities under Articles 19, 21, and 23 of the WHO Constitution put WHO in a position to achieve maximum possible adherence from WHO member states, with varied legal authorities providing the flexibility to pursue the most expedient legal path to advance global health.

The drafters of the WHO Constitution expected that this lawmaking authority would enable WHO to develop international health law across various global health threats, creating binding public health obligations for states and more effectively aligning national public health actions with international public health strategies—providing the uniformity under international law that had been missing in the work of previous organizations (Bélanger 1989). However, this hope that international health law would bind the world came to be challenged by the rapid rise of non-state actors in global health governance, raising an imperative to look beyond international law for lawmaking authority in global health (Gostin 2014).

C. Norm Setting Beyond Treaty Law: An Imperative for Global Health Law

Building from the development of international law to bind WHO member states in the prevention, control, and response to diseases, global health law has come to address a larger set of global health determinants that require globally coordinated action. Global health law supports WHO in binding states to shared commitments under "hard law" instruments, but also provides a path under "soft law" to unite state and non-state actors in the pursuit of global health goals (Meier et al. 2020). These non-binding soft law instruments— including resolutions, guidelines, protocols, global strategies, declarations, and recommendations—do not offer the enforceability of binding international law but are nonetheless authoritative, providing a path to incorporate non-state actors (from non-governmental organizations to private sector organizations) in global health governance (Fidler 1999).

Expanding the range of law and policy instruments in responding to global health crises, soft law norms have offered flexibility in structuring responsibilities for the full range of state and non-state actors in global health. The increasing health threats of a globalizing world have required global governance institutions to look beyond international treaties, utilizing soft law frameworks and innovative policy partnerships to enable the attainment by all peoples of the highest possible level of health (Gostin 2014). WHO has come to look largely to soft law approaches in establishing its policy agenda, regulating issues as broad as unhealthy diets, breastmilk substitutes, and environmental health. Soft law instruments dominate WHO governance because they are faster and easier to adopt than treaties and their non-binding nature may encourage actors to accept them more readily-precisely because they are not legally bound (Sekalala and Masud 2021). This advantage in developing soft law has thus served as an important building block for more ambitious instruments in global health law and policy—beyond international law and across the global health landscape.

Conclusion

The advancement of public health has changed dramatically over the centuries. Globalization has woven together the fates of people from different countries and the health challenges they face. The world must act together to address common threats. Addressing public health in a globalizing world requires efforts to understand global governance. Global governance for health is essential to coordinate actors throughout the world, with the end of World War II and establishment of the UN giving rise to WHO as the world's directing and coordinating authority on health. The WHO Constitution reflected a groundbreaking effort to establish international health governance in a world torn apart by war. Under WHO governance, the global community recognized that the most pressing health threats require international responses, and that belief is reflected in the development of international health law—from the first sanitary conventions to the postwar birth of WHO's legal authorities.

While the WHO Constitution would provide the organization with sweeping legal authorities to shape norms and address global health under a range of law and policy approaches, threats to global health have continued to evolve, requiring new legal authorities to promote public health. Under WHO governance, the application of law to global health has grown from a narrow set of international legal obligations for responding to specific infectious diseases to a wide-ranging field of practice that strives to prevent disease and promote health and well-being. These responses to global health challenges implicate a vast number of sectors and actors, and are influenced by developments in science and underlying social environments, requiring global health law to encompass both binding "hard" and non-binding "soft" law instruments. Global health law now seeks to establish mutual obligations across state and non-state actors to face new threats—looking beyond the spread of infectious disease and recognizing our common humanity and shared vulnerability.

The history of global health law provides a path to understand the importance of law and policy as a foundation of global health governance. As in the past, global health threats can only be solved through global health cooperation, and that cooperation can only be achieved through global health law. Global health law, like the public health science that underpins it, has evolved through iterative processes. Only by reflecting on the past successes and failures of legal responses to public health challenges is it possible to understand how global health law has come to shape global health governance. Law has provided a path for populations to claim entitlements to health services and systems, with corresponding obligations developed, implemented, and enforced. These obligations provide a foundation for fragmented national responses to be harmonized, looking to global health governance to bring the world together to respond to global health challenges under global health law.

Questions for Consideration

- 1. How does public health differ from the practice of medicine? How did social medicine expand the definition of public health?
- 2. Why do governments bear responsibility for addressing public health? How do governments meet this responsibility through public policy?
- 3. How did states first come to see the need for international cooperation to address public health threats? Why did these early international efforts fail to achieve true cooperation?
- 4. What did early institutions of international health governance provide that was lacking in international sanitary conferences? Why did nations develop competing institutions across the Pan American Sanitary Bureau, *Office International d'Hygiène Publique* (OIHP), and League of Nations Health Office (LNHO)?
- 5. How did the United Nations Relief and Rehabilitation Administration (UNRRA) succeed in providing international health governance amid the challenges of World War II?
- 6. How did the horrors of World War II shape the development of the United Nations (UN) as a new system of global health governance? Why

did states see the UN as necessary to the postwar development of international law?

- 7. Given the establishment of the UN, why was it necessary to develop the World Health Organization (WHO) as a separate organization? How did WHO governance draw from previous institutions of international health governance?
- 8. Why was WHO's mandate so much broader than that of previous institutions? Was this mandate realistic, encompassing WHO efforts to realize for all people "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"?
- 9. Why was it necessary to endow WHO with expansive normative functions to develop global health law? Why did states delineate multiple types of legal authorities (binding and non-binding) for multiple types of global health challenges?
- 10. Why does global health law need to look beyond international treaty law (applicable to states) to encompass global health law (over a larger set of state and non-state actors)?

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