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Global Health Law: International Law and Public Health Policy

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Introduction

The growth and elaboration of the field of global health law over the last two decades has been a notable development in global health policy. Traditionally, public health was viewed as a realm of almost exclusive national jurisdiction, and multilateral cooperation in this realm was restricted to discrete areas. Public health law today remains predominantly domestic and national, but the field of global health law is extant and growing. Through the codification of binding global health law standards that regulate interstate behavior and national conduct as well as the creation of other global norms that influence state actions, global health law has expanding significance in national public health law and policy.

The domain of global health law now encompasses increasingly diverse concerns, including aspects of biomedical science and human reproduction/cloning; organ transplantation and xenotransplantation; infectious and noncommunicable diseases; the control of the safety of health services; food and pharmaceuticals in international trade; access to medicines; and the control of addictive and harmful substances such as tobacco and narcotics. Global health law is also increasingly linked to other traditional areas of international legal concern. Environmental law and the control of toxic pollutants, arms control and the banning of weapons of mass destruction, human rights law, nuclear safety and radiation protection, international drug control, customs law, and occupational health and safety are increasingly recognized as inextricably connected to public health. [Table 1](#) hereto provides a variety of examples of the wide domain of international law related to public health, including international agreements that have positive as well as negative implications for public health.

This article provides an overview of the field of global health law. It examines the historical origins of the field and the factors contributing to its contemporary evolution. In addition, the article briefly reviews the nature and the significance of international law and the contribution of international organizations to the codification of global health law. Finally, the role of two international organizations, the World Health Organization (WHO) and the World Trade Organization (WTO), in the contemporary development of international law is considered in connection with examples of lawmaking with important public health and public health policy implications.

The Evolution of Global Health Law

Although public health is one of the earliest fields of international cooperation and one of the first domains in which an intergovernmental organization was created, the scope of international legal cooperation in public health was, until recently, highly limited.

Disease has been the unwelcome traveling companion of international commerce throughout history and international

public health cooperation from the beginning was as concerned with facilitating trade as with protecting public health. The functions of the early international health organizations of the nineteenth and twentieth centuries centered on combating infectious and communicable diseases and preventing their spread across international boundaries ([Pannenburg, 1979](#)). For example, the Conseil supérieur de santé (Superior Council of Health) of Constantinople, composed of delegates of the Ottoman Empire and the chief maritime states, was established in 1838 to supervise sanitary regulation of the Turkish ports to prevent the spread of cholera. As a further example, the international legal activities of the first permanent international health organization, L'Office International d'Hygiène Publique, were restricted to the administration of international sanitary conventions, including the international exchange of epidemiological information. International communicable disease control remained the predominant area of international legal cooperation throughout the mid-nineteenth century and most of the twentieth century.

With a focus limited to international communicable disease control, public health law remained a relatively neglected field of international legal concern throughout most of the twentieth century. In particular, the WHO, established in 1948 as the specialized agency of the United Nations in the field of health, stood out as unique among such UN agencies in that the Organization traditionally neglected the use of international legislative strategies to promote its global public policies ([Taylor, 1992](#)). WHO Member States also paid little attention to the potential contribution of international law in advancing global health during most of the last century. Although public health remained a narrow realm of multilateral cooperation for over 150 years, the long-standing historical connection between international law and communicable disease control pointed to the larger role that international law could serve in future international health diplomacy.

Global health law has been defined as a “field that encompasses the legal norms, processes, and institutions needed to create the conditions for people throughout the world to attain the highest possible level of physical and mental health” ([Gostin and Taylor, 2008](#)). In the last couple of decades, the field of global health law has expanded significantly. The breadth and depth of contemporary international health law can be traced to a number of recent and interconnected developments, including (1) the impact of globalization on public health diplomacy; (2) the growth of global concern with economic and social rights, including the right to health; and (3) expanding appreciation of the nexus between global health law and other realms of international legal concern.

Globalization and the Expanding Domain of International Health Law

It is widely recognized that contemporary globalization is contributing to the expansion of the field of global health

Table 1 Examples of international legal instruments and public health

| <i>Category of public health concern</i> | <i>Date</i> | <i>International agreement</i> | |
|--|-------------------------|--|---|
| Disability | 2006 | Convention on the Rights of Persons with Disabilities | |
| Communicable disease control | 2005 | International Health Regulations (revised) | |
| Global tobacco control | 2011 | Pandemic Influenza Preparedness Framework | |
| | 2003 | WHO Framework Convention on Tobacco Control | |
| Human rights | 2012 | Protocol to Eliminate Illicit Trade in Tobacco Products | |
| | 1966 | International Covenant on Economic, Social and Cultural Rights | |
| | 1966 | International Covenant on Civil and Political Rights | |
| | 1979 | Convention on the Elimination of All Forms of Discrimination Against Women | |
| | 1980 | Convention on Certain Conventional Weapons | |
| | 1984 | Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment | |
| Arms control | 1989 | Convention on the Rights of the Child | |
| | 1968 | Treaty on the Non-Proliferation of Nuclear Weapons | |
| | 1972 | Biological Weapons Convention | |
| | 1993 | Chemical Weapons Convention | |
| | 1982 | UN Convention on the Law of the Sea | |
| Environmental health | 1996 | Comprehensive Test Ban Treaty | |
| | 1985 | Vienna Convention for the Protection of the Ozone Layer | |
| | 1987 | Montreal Protocol to the 1985 Vienna Convention for the Protection of the Ozone Layer | |
| | 1992 | UN Convention on Climate Change | |
| | 1994 | Convention to Combat Desertification | |
| | 1992 | Convention on the Transboundary Effect of Industrial Accidents | |
| | 1997 | Kyoto Protocol to 1992 UN Convention on Climate Change | |
| | 1998 | Convention on Prior Informed Consent for Certain Hazardous Chemicals and Pesticides in International Trade | |
| | Health worker migration | 2001 | Stockholm Convention on Persistent Organic Pollutants |
| | | 2013 | Minamata Convention on Mercury |
| International narcotic drug control | 2010 | WHO Global Code of Practice on the International Recruitment of Health Personnel | |
| | 1961 | Single Convention on Narcotic Drugs | |
| | 1971 | Convention on Psychotropic Substances | |
| Occupational health and safety | 1988 | UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances | |
| | 1921 | White Lead (Painting) Convention | |
| | 1932 | Protection Against Accidents (Dockers) Convention | |
| | 1960 | Radiation Protection Convention | |
| | 1974 | Occupational Cancer Convention | |
| International trade law | 1981 | Occupational Safety and Health Convention | |
| | 2006 | Convention Concerning the Promotional Framework for Occupational Safety and Health | |
| | 1994 | General Agreement on Tariffs and Trade (GATT 1994) | |
| | 1994 | General Agreement on Trade in Services (GATS) | |
| | 1994 | Agreement on the Application of Sanitary and Phytosanitary Measures | |
| | 1994 | Agreement on Trade-Related Aspects of Intellectual Property Rights | |
| | 1994 | Agreement on Technical Barriers to Trade | |

law. Although increasing global integration is not an entirely new phenomenon, contemporary globalization has had an unprecedented impact on global public health and is creating new and increasingly difficult governance needs and health policy-making challenges. Globalization has contributed to the rapid decline in the practical capacity of sovereign states to address public health challenges through unilateral national action alone and expanded the need for health governance structures that transcend traditional and increasingly inadequate national approaches.

Treaty law, often referred to as conventional international law, has received new prominence as a mechanism or a tool that can be used by states to facilitate multilateral

cooperation in this era of globalization, as states increasingly recognize the need for international cooperation to attain national public health objectives for which domestic law and other policy responses are increasingly inadequate (Taylor, 2004). For example, rapid worldwide dissemination of recent advances in scientific knowledge and technology has encouraged international cooperation in a wide range of treaties, including those concerning the safety of chemicals, pesticides, and food, and the disposal of hazardous wastes.

Globalization has increased the need for new, formalized frameworks for international cooperation, including international law, to address emerging global health threats. For

example, the dynamics of globalization have created fertile global breeding conditions for the cross-border spread of emerging threats to health, such as weapons of mass destruction, including bioterrorism; emerging and reemerging infectious diseases; and the vectors of noncommunicable diseases including tobacco, alcohol, and obesity.

In addition, globalization has expanded global interest in codifying new international commitments to protect the health status of populations in low-income and emerging market states that have not benefited from globalization – the so-called losers of globalization. For example, the need to promote more equitable innovation and universal access in health-care products, including medicines, pharmaceuticals, diagnostics, and medical devices, is generating ongoing debate about the efficacy of codifying a new international instrument on medical research and design.

Because of the momentum of globalization, states must increasingly turn to international cooperation in order to protect and promote domestic health. Consequently, we are likely to see wider use of international legal instruments in this century to control the risks and threats to health associated with globalization and, perhaps, to take advantage of the opportunities to improve world health that have been afforded by global change. For example, the WHO International Health Regulations (IHRs), the sole international legal instrument designed to provide a framework for multilateral efforts to combat infectious diseases, were revised in 2005 to address the increasing threat posed by the transnationalization of infectious diseases and to incorporate newly developed mechanisms for international coordination and response. As a further example, in 2010 WHO Member States adopted the first international legal instrument to address the challenges increasingly raised by health worker migration in the WHO Global Code of Practice on the International Recruitment of Health Personnel. In addition, in 2011, the Member States of WHO adopted the Pandemic Influenza Preparedness (PIP) Framework to facilitate the sharing of influenza viruses and increase access to vaccines and antiviral medications in low- and middle-income countries.

Health and Human Rights

The evolution of global health law in the last two decades is very much tied to the protection and promotion of human rights related to physical and mental integrity. Although global health law is largely utilized as a mechanism to protect and expand state interests in an era of global interdependence, it is also conceived of and employed as a framework or tool for protecting the rights of individuals and, perhaps, creating a more just and equitable world (Meier, 2011).

The preamble to the WHO Constitution, the first international expression of the right to health, declares that “[t]he enjoyment of the right of the highest attainable standard of health is one of the fundamental rights of every human being without distinction or race, religion, political belief, economic or social condition.” The principal international legal basis for the right to health is found in the core instruments of international human rights law promulgated under the auspices of the United Nations: the International Bill of Rights, which consists

of the Universal Declaration of Human Rights (1948), the International Covenant on Economic, Social and Cultural Rights (1966) (ICESCR), and the International Covenant on Civil and Political Rights (1966).

Read in conjunction with Article 2, Article 12 of the ICESCR, the most significant binding legal expression of the right to health, provides, among other things, that each state ‘undertakes to take steps,’ to the maximum extent of its available resources and with a view toward progressive achievement, toward “the highest attainable standards of physical and mental health of all individuals, without discrimination.” Beyond this broad formulation, however, Article 12 is replete with ambiguity. The Covenant neither defines ‘health’ nor the particular obligations of states necessary to realize the right to health.

No subsequent binding international legal instrument has provided an authoritative interpretation of the Covenant. In 2000 the Committee on Economic, Social and Cultural Rights to the ICESCR adopted General Comment 14, a detailed explanatory commentary on the right to health under Article 12 of the Covenant. Among other things, the broadly formulated General Comment 14 sets forth that the right to health is not simply a right to be healthy, but rather a robust human right extending not only to access to health-care services but also to the underlying determinants of health, including an access to safe water and adequate sanitation, occupational health and environmental conditions, and access to health-related education and information. Although highly influential, the legal significance of General Comment 14 remains controversial. The General Comment is not binding international law. In addition, some observers, including the United States, have directly questioned the legal authority of the Committee on Economic, Social and Cultural Rights, a committee established by a decision of ECOSOC and not pursuant to the Covenant, to issue authoritative interpretations of the ICESCR.

An important concern with the formulation of the right to health is whether it is an individual or a collective standard reflecting the health-related interests of communities. As a human right, the conventional interpretation of the right to health pertains to individual and not collective claims. However, in public health practice, the right to health is often used to refer to public or community health. There can also be tension between the idea of the collective right to health and the exercise of other human rights, including liberty, physical integrity, and privacy.

Despite the long historical linkage, the strong connection between health and human rights has only recently received significant attention. A number of emerging global concerns, including HIV/AIDS and women’s health issues, including rape and other forms of violence against women, brought the intrinsic connection between health and human rights to the forefront of international policy concern beginning in the late 1980s and early 1990s. Of particular importance was a pioneering human rights approach to the global HIV/AIDS pandemic adopted by WHO in the late 1980s. It is widely recognized that this novel emphasis on the linkage between public health and human rights law had a groundbreaking impact in that it compelled governments to be publicly accountable on an international stage for their actions against persons living

with HIV/AIDS. (Ultimately, this innovative global political approach to public health issues publicly highlighted for the very first time the underlying legal responsibility of governments to protect and promote the health of their populations and has served as a forerunner for increasingly widespread links between human rights and other public health issues (Mann and Tarantola, 1998).)

The domain of health and human rights has expanded significantly under the auspices of agencies and organs of the United Nations and other international organizations. Specific international legal instruments addressing the rights of particular populations, such as persons with HIV/AIDS, women, children, migrant workers, and refugees, have been adopted. For example, on 13 December 2006 the United Nations General Assembly adopted the Convention on the Rights of Persons with Disabilities.

Other contemporary developments are contributing to the further elaboration of international legal instruments in the realm of health and human rights, including, in particular, globalization. For example, widespread recognition of growing inequalities in health status and differential access to medical advances in rich and poor states has expanded interest in the relationship between social and economic rights and health. Of particular concern is the impact of international intellectual property protection under the WTO Trade-Related Aspects of Intellectual Property (TRIPS) Agreement, discussed in the section titled 'The World Trade Organization, International Law and Global Health,' in restricting access to essential medicines, particularly HIV/AIDS antiretrovirals, in low-income countries. The unprecedented human catastrophe posed by HIV/AIDS led the international community to adopt a number of nonbinding resolutions at the United Nations General Assembly, the former United Nations Commission on Human Rights and the WHO specifying the relationship between HIV/AIDS, human rights, and access to medicines. In June 2006, the United Nations General Assembly adopted a Political Declaration on AIDS (UN Res. 60/262) reaffirming that access to medicines in the context of pandemics, including HIV/AIDS, is one of the fundamental elements to achieving full realization for everyone of the international right to health. In May 2013 the UN Special Rapporteur on the right to health issued a report analyzing existing international challenges toward realizing access to medicines within a right to health framework and called upon the international community to shift from the 'dominant market-oriented paradigm' to promote access to medicine (A/HRC/23/42). Following the release of the report in June 2013, the UN Human Rights Council adopted a resolution on access to medicines (A/HRC/RES/23/14) broadly recognizing that access to medicines is one of the fundamental elements in achieving progressively the full realization of the right to everyone to the enjoyment of the highest attainable standard of physical and mental health.

Globalization is also furthering the elaboration of international instruments in this realm because increasing global integration is compounding the impact of other contemporary global developments associated with health status and human rights. An interesting recent development in this realm is the negotiation and adoption of the 2010 WHO Global Code of Practice on the International Recruitment of Health Personnel discussed in the section 'The World Health Organization.'

As a further example, the links between scientific progress, global diffusion of new technologies and human rights is also receiving increased attention in the elaboration of international legal instruments. For instance, the implications of advances in biotechnology for the protection of human rights and human dignity have been a topic of interest by international and regional organizations, including consideration of bans on novel technologies. In 1997 the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted a nonbinding instrument, the Universal Declaration on the Human Genome and Human Rights, and in 2003 it adopted the International Declaration on Genetic Data. In addition, in the wake of failed treaty negotiations, in 2005 the United Nations General Assembly adopted a declaration urging Member States to prohibit reproductive cloning as incompatible with human rights. At the regional level, the Council of Europe adopted a Convention on the Protection of Human Rights and Human Dignity with regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine in 1997. Four protocols to the Convention – separate agreements – on human cloning, biomedical research, transplantation of organs and tissues, and genetic testing for health purposes have also been adopted by the Council of Europe between 1998 and 2008. Biomedical research is emerging as important topic in global and regional nonbinding and binding international legal instruments. For example, the European Union adopted a directive on clinical practice in the conduct of clinical trials on medicinal products for human use in 2001 and investigational medicinal products in 2005.

The biotechnology revolution is putting continuing pressure on the international community to develop international law, including human rights law, to effectively govern this realm, and we are likely to see further developments in the future. Notably, the elaboration of international law on biotechnology is exemplary of how the international community develops regulatory responses. Rather than codifying a comprehensive instrument in this realm, existing international agreements on biotechnology have been adopted in a piecemeal and, at times, incoherent fashion and today consist of different instruments, including guidelines, code of conduct, resolutions, and treaties adopted under the auspices different international organizations.

Linkage and the Scope of Global Health Law

The expanding domain of global health law can be understood, in part, as a product of enhanced appreciation of the interconnectedness of contemporary global concerns and, concomitantly, the linkage of health to other legal issues. International legal scholars traditionally compartmentalized and treated substantive subject matters such as human rights, environmental protection, arms control, and public health as discrete self-contained areas with limited connections. Rapid global integration propelled by contemporary globalization has contributed to the recognition of the nexus among different realms of international law.

As a consequence of issue linkage, international law and global health is increasingly understood to be a central component of other international legal regimes, including labor law, human rights, arms control, and international trade. The recent

connection between health and human rights in contemporary international law and practice discussed in the preceding section is an important example of the linkage of two traditionally distinct realms of international law.

The evolution of the concept of human security provides another interesting example of this development. The traditional understanding of human security has come under increasing pressure in recent years, with growing support for a comprehensive approach to human security that addresses the wide-ranging factors that impact upon the vulnerability of people. In 2003, the UN Commission on Human Security released a report proposing a new security framework and recognizing the linkage between health and human security ([United Nations Commission on Human Security, 2003](#)).

WHO's 2005 IHRs described further herein have been at the center of discussion of the linkage between global health and security. The IHRs are designed to facilitate countries and the WHO working together to identify contain and control health risks. For example, at the time of the drafting of the revised IHRs expanding global concern with weapons of mass destruction and terrorism underscored the strong interconnection between public health and security and legal commitments established under the Regulations are clearly designed to apply to releases of biological, chemical, and radiological events, accidental and deliberate. Recent disease outbreaks, epidemics, natural disasters, and other health emergencies have reinforced the linkage between global health and security. For example, the recent Ebola outbreak discussed further herein has revitalized discussions of global health security, including a range of proposals for reframing the global health governance to strengthen the global health security regime ([Kickbush, 2016](#)).

The linkage between health, security, and other traditionally defined legal realms is also exemplified in the contemporary global threat of counterfeit medicines. Expanding international trafficking in counterfeit medicines, including substandard, defective or adulterated medicines has underscored the interconnections among global health law, international customs law, international criminal law, and international trade law and led to expanding support for the adoption of an international legal instrument in this realm ([Attaran, 2012](#)).

The nexus between global health law and other traditionally distinct realms of international law is further exemplified by the rapidly evolving field of biotechnology described in the preceding section. Biotechnology closely interlinks many quarters of the law including, global health, human rights, intellectual property, trade regulation, and environmental law. For example, advances in biotechnology have prompted debate and development of the field of international environmental law with the main area of environmental concern being the potential effect of intentional or unintentional releases of genetically modified organisms (GMOs) for health and the environment. International instruments of relevance in this field include the Convention on Biological Diversity and its 2010 Cartagena Biosafety Protocol, the International Plant Protection Convention, and the WHO/FAO Codex Alimentarius. International trade law, particularly the General Agreement on Tariffs and Trade, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), and the Technical Barriers to Trade Agreement (TBT Agreement),

functions to discipline or restrict the authority of member states of the WTO to take food, safety, health, environmental and food security considerations into account in making regulatory decisions on the import and use of GMOs. Among regional instruments, the European Union regulatory framework in this realm is one of the most extensive, covering issues including import, cultivation, monitoring, and labeling of GMOs and GMO-derived material. The main piece of European legislation regarding GMO food is EU Directive 2001/18/EC, which was amended in 2008 by Directive 2008/27/EC and again in 2015 by Directive (EU) 2015/412. These directives govern 'the deliberate release of GMOs in the environment' and consequently cover both cultivation and imports of GMO crops. In addition, EU regulations set forth detailed rules regarding the authorization, labeling, and placing on the market of GMOs meant for food and feed.

An Introduction to Public International Law

The Nature and Sources of International Law

Understanding the implications of recent developments in global health law, including those for domestic public health policy, requires some appreciation of the nature of international law and the international political system. Since the end of the Thirty Years War in 1648, the global political system has principally involved the interactions of sovereign states. Consequently, the elaboration of international law has focused on the establishment of consensual rules concerning the status of states and their fundamental rights and obligations as well as commitments. International law, therefore, is primarily focused on the interactions of sovereign states and can broadly be defined as the rules that govern the conduct and relations of states.

International law is traditionally understood as consisting of two core realms: public international law and private international law. While public international law is primarily concerned with the relations of states, private international law focuses on the law of private transactions of individuals and corporations. The traditional distinction between public and private international law persists even though it is not fully accurate. For example, much of private international law concerns the transactions of public entities. In addition, while states are the primary subjects of public international law, they are not the only subjects. International organizations and, through the development of international human rights law, individuals, are also considered subjects of public international law.

In international law, the sources of legal rules are very different than in most domestic legal systems because the global political system of sovereign states differs fundamentally from domestic political systems. While there are important differences in the sources of law among countries, domestic law generally comes from national constitutions, municipal statutes, parliamentary or executive regulations, and decisions of municipal courts. In contrast to domestic political systems, there is generally no supranational authority within the global system to develop and enforce law against sovereign states. In the absence of a supranational authority, states establish the rules of international law. Article 38(1) of the Statute of the

International Court of Justice is generally regarded as an authoritative list of the sources of international law (Table 2).

Although there is a wide and complex array of binding international legal sources, most international law today, including global health law, can be found in treaties. The word treaty is a generic term that encompasses all written instruments concluded between states by which states establish obligations by and among themselves. Treaties function essentially as contracts between states whereby states make binding written rules to govern their own conduct and the conduct of their individual and corporate nationals. When states become parties to treaties, they explicitly agree to limit their sovereign freedom of action in some respect to achieve mutually agreed-upon goals. Generally, treaties are only binding upon states that give their express written consent.

Treaties are also subject to a significant corpus of international law: the 1969 Vienna Convention on the Law of Treaties (the Vienna Convention). The Vienna Convention, the so-called law of treaties, provides general rules of treaty implementation and interpretation. The Vienna Convention confirms the generic use of the term treaty by defining a treaty as "an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation." The terms treaty, convention, protocol, and pact are largely used interchangeably in international legal parlance. Article 19 of the Vienna Convention sets forth the basic legal principle concerning the observance of treaties, *pacta sunt servanda*: "Every treaty in force is binding upon the parties to it and must be performed in good faith."

A second important source of international law is customary international law. Analogous to domestic legal concepts such as usage of the trade and course of dealing, the idea behind customary international law is that widespread international practice undertaken out of a sense of legal duty creates reasonable expectations of future observance and constitutes implicit consent to the creation of legal rules. The determination of whether or not a particular practice constitutes customary international law is a complex analysis that is more like an art than a science. But, generally, the determination requires near-uniform-state practice undertaken because of a sense of legal obligation. With some important exceptions, once a rule is recognized as part of customary international law, it is generally considered binding upon all states. For example, the Vienna Convention is accepted as declaratory of

customary international law and binding for all states, including those that have not formally ratified it. Like treaty law, customary international law is said to emanate from the consent of states. States party to a treaty explicitly consent to be bound by codified rules, whereas with customary international law states implicitly agree to be bound to particular rules through consistent state practice.

In addition to binding international law, states produce a wide variety of nonbinding international legal instruments that can have an important impact on state behavior. Such instruments include resolutions, declarations, codes of conduct, guidelines, or standards. However named, general declaratory resolutions are, for the most part, intended to be nonbinding instruments expressing the common interest of many states in specific areas of international cooperation. Significantly, these nonbinding international legal instruments are not comparable to voluntary instruments adopted at the national level or by industry. To begin with, nothing in such nonbinding intergovernmental resolutions prohibits states from incorporating the terms of the instruments into national law. Although generally nonbinding, such instruments are not without legal or political significance. Like treaties, these nonbinding instruments can be mechanisms for advancing international consensus on rules and for promoting consistent state action. There are prominent examples of nonbinding instruments in public health with important policy impacts developed under the auspices of different international organization. For example, the WTO Doha Declaration on Trade and Public Health, discussed below, is widely considered to have advanced global understanding and, perhaps, action on trade and health matters, particularly in relation to access to essential medicines, even though the legal significance of the declaratory instrument is unclear. Another well-known example of a nonbinding international code with a significant public health impact is the 1981 WHO Code of Marketing Breastmilk Substitutes that was designed to protect and promote breastfeeding through the provision of adequate information on appropriate infant feeding and the regulation of the marketing of breastmilk substitutes, bottles, and teats. Additional Health Assembly resolutions adopted over the years since the adoption of the Breastmilk Code have further defined and strengthened the instrument and, according to UNICEF, as of 2016 over 84 countries have adopted legislation implementing all or part of the Code. Another example of a nonbinding legal regime that has had an impact on state practice is the legal framework established by 2001 United Nations General Assembly Special Session (UNGASS) Declaration of Commitment on HIV/AIDS and the monitoring mechanism mandated under its auspices and under two other subsequent UN General Assembly resolutions.

At times, nonbinding intergovernmental resolutions have been highly persuasive, and the conduct of states has tended to follow the principles embodied in these resolutions. The effectiveness of some nonbinding intergovernmental resolutions in promoting international cooperation has led some commentators to refer to them as *soft-law*, although the term is highly controversial. Such instruments are often carefully negotiated and, at times, drafted with the intention to influence state practice. Nonbinding legal instruments, at times, have

Table 2 Statute of the International Court of Justice

The Court, whose function it is to decide in accordance with international law such disputes as are submitted to it, shall apply:

- a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
- b. international custom, as evidence of a general practice accepted as law;
- c. the general principles of law recognized by civilized nations;
- d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

also paved the way for the evolution of treaty law by generating an ongoing diplomatic forum.

Not all resolutions lead to the development of formalized treaty obligations or are a significant factor in state practice. However, intergovernmental resolutions, particularly resolutions of the UN General Assembly that are supported by influential states often, have a political significance that can stimulate national behavior and lead to the eventual development of binding international law.

The Limitations of Global Health Lawmaking in International Health Policy

It is important to recognize that international law is an inherently imperfect mechanism for international cooperation. The innate weakness of international law stems in large part from the core principle of state sovereignty. The law that is made and the law that is implemented depend upon the will of states. In the treaty-making process, states are explicitly agreeing to make rules to govern and, thereby, limit their own conduct and that of their nationals through the development and implementation of legislation and other policies, depending upon the terms of the treaty, which are consistent with their international commitments. The concept of sovereignty looms large in the international system, and states are generally loath to sacrifice their freedom of action through the development of binding international obligations. A related weakness stemming from the principle of sovereignty is the general lack of formal enforcement mechanisms in most contemporary economic and social agreements. In contrast to the dispute resolution mechanism established under the WTO, described below in the section on the 'World Trade Organization,' in most social and economic treaties and other instruments states do not include machinery to compel parties to comply with their international legal commitments.

The fact that many treaties tend to be well respected in practice largely reflects the fact that they are generally seen as mutually beneficial for states' parties. In addition, there is increasing awareness that the failure of states at times to implement international commitments may reflect more a lack of capacity than political will. Many states, particularly developing countries, face acute problems of limitations of resources and capacity in implementing contemporary treaties. Recent advances in the international legislative process have expanded mechanisms to address these problems of domestic capacity through international technical and financial assistance programs incorporated in the texts of relevant conventions.

International law and the international legislative process suffer from other important difficulties. Notably, the international legislative process itself is characterized by numerous challenges and limitations – including challenges to timely national commitment by states through timely treaty ratification and implementation – although considerable advances have been made in the last few decades.

An emerging challenge in international health lawmaking is the limited scope of entities that are subjects of international law and thereby entitled to participate in international agreements and hold rights and duties thereunder. As described above in the 'Nature and Sources of International Law' section, states have traditionally been the sole subjects of international

law. The scope of international law was only expanded in the twentieth century to include individuals and international organizations. However, the nature of global health and the major actors in health policy are changing in such a way that challenges this restricted approach to international legal cooperation. To begin with, in an era of globalization, the exclusive focus on territorial statehood is irrelevant to global health policy. Nonstates ranging from Taiwan to Palestine are excluded from a range of international agreements because of lack of statehood. In addition, the major actors in global health policy today, including foundations, most notably the Bill and Melinda Gates Foundation, and a wide range of significant public-private partnerships, such as the Global Alliance for Vaccines and Immunizations and the Global Fund for AIDS, Tuberculosis and Malaria, or civil society organizations, such as Medicines sans Frontiers, are also excluded from the international lawmaking process. A major challenge for this century is to establish mechanisms to promote more effective cooperation between states and the other major health actors under international law. Recognition of the limitations of treaty making is contributing to growing interest in nonbinding legal mechanisms for global governance in health and other realms of international concern.

Despite the conspicuous limitations of the formal international lawmaking process and the inherent challenges of using treaties to promote collective action, treaties can be useful for raising global awareness and stimulating international commitment and national action. As an increasing number of health threats are global in scope or have the potential to become so, international legal agreements, including treaties, are likely to become of increasing importance and an essential component of global health governance. Consequently, international legal agreements, both binding and nonbinding, are likely to become an increasingly important factor underpinning and guiding national policy and action on health.

The International Lawmaking Process and the Role of International Organizations

The process of international lawmaking, such as the identification of international legal rules, is very different than it is in most domestic legal systems. The unique character of the international lawmaking process, such as the international legal rules themselves, can be understood as a consequence of the core principle of state sovereignty. In the international political system, there generally exists no supranational authority to make binding international rules.

International health law is largely treaty-based, and most international treaty making today is typically conducted under the auspices of international organizations. The vast majority of international legislative projects tend to be undertaken at public international organizations because such institutions function as formal mechanisms for multilateral negotiation and cooperation for their member states. International organizations can anchor and facilitate treaty-making efforts because their organizational structures and administrative arrangements enable them to serve as stable and ongoing negotiating forums.

In recent years, there has been considerable development in the field of international organization with a significant increase in the number of international organizations active in the domain of health. Within the United Nations system, for example, organizations with significant involvement in the health sector include WHO, UNICEF, FAO, UNEP, UNDP, UNFPA, and The World Bank. Overall, an increasing number of international organizations have served as platforms for the codification of international health law, while others have had a significant influence on the development of international law in this field.

It is important to recognize that not all international organizations have lawmaking authority or the legal mandate to serve as a platform for international health negotiations. The World Bank, for example, is an organization that is highly influential in the field of health but has no actual legal authority to serve as a framework for treaty negotiations. In the international legal system, lawmaking authority is always expressed and never implied. The existence and scope of lawmaking authority can generally be identified by carefully examining an organization's constituent instrument, typically its constitution.

Today there is considerable jurisdictional overlap in the field of international health lawmaking. Unlike most domestic systems where lawmaking efforts are largely coordinated into an integrated legal system, in the international legal system lawmaking efforts among different international organizations are notoriously uncoordinated. In the absence of an umbrella organization to manage lawmaking efforts, the proliferation of international organizations with overlapping legal authority and ambitions is creating the risk of institutional overload and inconsistent standard setting (Taylor, 2004).

For example, during the early stages of the WHO Framework Convention on Tobacco Control (FCTC) negotiation process, other international organizations initiated novel efforts to negotiate binding instruments on global tobacco control. In 1998, for example, the Pan American Health Organization, a regional office of WHO with separate constitutional status, initiated efforts to develop a regional treaty on tobacco control under the auspices of the Organization of American States. As a further example, in 2000 the Secretary General of the World Customs Organization (WCO), an international organization outside of the United Nations framework, advanced efforts to develop a WCO treaty on global tobacco control. While both of these overlapping treaty-making efforts ultimately failed, problems of jurisdictional overlap and inconsistent standard setting are occurring in other realms.

Forum shopping is also a widely used policy tool in international standard setting generally and of increasing importance in the domain of global health. A host of factors that may influence the outcome of negotiations may shape the choice of negotiating forum, including differences in composition, jurisdiction, decision-making procedures, working methods, and other characteristics of international organizations. Rising institutional density is contributing to expanded use of forum shopping in global health and other realms of international legal concern. In some cases forum shopping is aimed at gaining a single favorable agreement. In other contexts, however, forum shopping is part of an iterative long-term strategy aimed at

"broadening the policy spaces within which relevant decisions are made." International relation scholars have sought to distinguish this broader strategy of forum shopping by defining it as 'regime shifting' (Helfer, 2004).

An important example of potential 'regime shifting' in global health revolves around intellectual property and access to medicines, a topic of fierce political and legal battles in the international community. The WTO TRIPS, discussed in the section entitled 'The World Trade Organization,' ushered in a new era of powerful international intellectual property law that has had a critical impact on access to medicines, particularly in low-income countries. TRIPS is also at the core of a wave of international legal instruments and processes seeking to redefine the law of international intellectual property. Dissatisfaction with TRIPS and shifting power bases at the WTO has led those who support stronger and weaker intellectual property protections in search of alternative and more favorable venues to promulgate treaties and other legal instruments. For example, some countries, along with nongovernmental organizations, have undertaken efforts since 2005 to initiate the development of a proposed treaty on medical research and development under the auspices of the WHO. While public health efforts to shift debate and codification to WHO have thus far stalled, other global health actors have undertaken steps to establish more robust intellectual property than provided by TRIPS in a number of forums. Most well-known are the so-called 'TRIPS-plus' bilateral and multilateral agreements that establish intellectual property rights and obligations that are more stringent than required under TRIPS. A significant recent example of a TRIPS-plus agreement is the Trans-Pacific Partnership Agreement among 12 Pacific Rim countries that was adopted in October 2015 and, at the time of this writing, has not yet entered into force. Less well-known than TRIPS-plus agreements are a range of global standard-setting initiatives that act below the level of formal international law through global networks of international regulators. Although not formally international law, such standard-setting initiatives, can at times have a powerful impact in harmonizing state practice. In the field of intellectual property, the most important are best practice standards for custom authorities established by the WCO. The WCO also cooperates with Interpol and the Universal Postal Union to strengthen the enforcement of intellectual property law.

The Process of International Lawmaking

International law allows considerable flexibility in the process by which multilateral agreements are developed. The primary source of international law governing the creation of treaties, the Vienna Convention, provides a limited number of ground rules for the conclusion of treaties, concerning the capacity of states to enter into agreements, adoption, and authentication of a treaty by a valid representative, and expressions of consent to be bound by a treaty. Beyond these few basic requirements, the Vienna Convention does not mandate any particular methods of negotiation or ratification.

In the absence of binding international rules, international organizations have adopted a wide variety of strategies to initiate, negotiate, and conclude international agreements.

Despite the differences in legal processes, the treaty-making process generally consists of four stages: initiation, negotiation, adoption, and entry into force (Szasz, 1997). Negotiations are the most difficult and generally the longest substage of the treaty process. In practice, all recent public health negotiations have been open to participation by all states or all states' members of the international organization sponsoring the negotiations.

Examples of International Organizations and International Lawmaking

The World Health Organization

The WHO, the largest international health agency and one of the largest specialized agencies of the United Nations system, has wide-ranging responsibilities to address global public health concerns based upon responsibilities assigned by its constitution and by its affiliation with the United Nations.

The structure of the relationship between WHO and the United Nations, a separate international organization, is grounded in the United Nations Charter and, in particular, those sections that describe the objectives of the United Nations. Article 55 of the Charter describes the goals that the United Nations has pledged to promote among its members, including solutions to international economic, social, health, and related problems. As the United Nations specialized agency with the constitutional directive to act as 'directing and coordinating authority' on international health work, WHO has the cardinal responsibility to fulfill the aims of the Charter with respect to health.

WHO's broad authority to serve as a platform for international health lawmaking is expressly established by the terms of its Constitution. Article 19 of the WHO Constitution specifies that the World Health Assembly, WHO's legislative body composed of all of its Member States, "shall have the authority to adopt conventions or agreements with respect to any matter within the competence of the Organization." Article 1 of the Constitution defines the objective of WHO as "shall be the attainment by all peoples of the highest possible level of health." The broad scope of WHO's mandate under Article 1 vests the Organization with the legal authority to serve as a platform for conventions and agreements that potentially address all aspects of national and global public health, as long as advancing human health is the primary objective of such instruments.

Although vested with broad legal authority to protect global health and serve as a platform for global health lawmaking, the WHO has undergone severe financial and political challenges and has been in the process of instituting a reform agenda since 2011. The splintering of WHO's political and financial capacity is contributing to the process of forum shopping in global health governance. Elsewhere I have argued that expanded use of WHO's extensive normative authority could help solidify an integral position for the Organization in the increasingly crowded and complex global health institutional landscape of global health (Taylor, 2004).

Framework Convention on Tobacco Control

Despite WHO's wide authority in the field of international health lawmaking, it has only recently used its constitutional

authority to develop conventions by serving as a platform for the negotiation of the 2003 WHO FCTC. Initiated in the early 1990s by Taylor and Roemer, the WHO FCTC was envisioned as a mechanism to promote national public health interventions and multilateral cooperation on aspects of tobacco control that transcend national boundaries. Formally negotiated between 1999 and 2003 in six negotiation rounds open to all WHO Member States, the text of the treaty was adopted by the World Health Assembly in May 2003 and entered into force in February 2005. The final text of the Convention cuts across a wide range of tobacco control topics, including advertising, production, smuggling and counterfeit cigarettes, warning labels, clean indoor air policies, and health education (Roemer et al., 2005). In 2012 the State Parties to the FCTC adopted the first protocol to the treaty – the Protocol to Eliminate Illicit Trade in Tobacco Products.

As of October 2015, 180 countries have ratified the FCTC making it one of the most widely subscribed to treaties in the history of the United Nations. One of the important lessons from WHO's first treaty negotiation is the significance of the international lawmaking process itself in promoting national action and international cooperation during negotiations before the treaty is adopted and after it has formally entered into force. I have described this phenomenon elsewhere as the 'power of the process.' It is widely recognized that WHO's efforts to achieve global public support for an international regulatory framework for tobacco control, stimulated national policy change in a number of countries and thus made an important, albeit limited, contribution to curtailing the epidemic well before global consensus on binding tobacco control norms was secured. The FCTC negotiations were also the *raison d'être* for the establishment of the first global alliance of tobacco control activists, the Framework Convention Alliance – a coalition of over 300 nongovernmental organizations worldwide – and thus further influenced the strengthening and deepening of tobacco control legislation in many states around the world. Despite the significance of the treaty in mobilizing national and international action, the record of implementation has been mixed. The treaty has some key weaknesses that limit its effectiveness. As a consequence of the lack of consensus during the formal negotiation process, broadly drafted with significant wiggle room for interpretation. In addition, the instrument does not include a robust monitoring mechanism to supervise and encourage national action. Finally, the tobacco industry and state interests that support it have pushed back against strong tobacco control measures in national and international fora, including disputes brought to the WTO and pursuant to investment treaties against Australia and Uruguay for their use of plain packaging of tobacco products. At the time of this writing, these disputes have not been settled. As discussed further below, the conflict between international trade and public health is increasingly an important theme in the realm of global health law.

International Health Regulations

In another recent lawmaking initiative, on 23 May 2005 the World Health Assembly adopted the new IHRs. As described above in the 'Evolution of International Public Health Law' section, virulent infectious diseases have a long history in civilization, and international disease control was one of the

earliest areas of international cooperation. WHO, upon its founding, inherited the responsibility for the management of the international legal regime for the control of the international spread of diseases. The IHRs, first adopted by the Health Assembly in 1951 and last modified in 1981, were designed to provide an effective framework for addressing the international spread of disease while ensuring minimum interference with world traffic. However, the IHRs were ineffective in ensuring national action and global cooperation to stop the spread of disease. The IHRs only applied to a highly narrow subset of infectious diseases and were routinely ignored by states. The magnitude of the global impact of catastrophic appearances of new infectious diseases and the virulent reemergence of old contagions during the 1980s and 1990s underscored the irrelevancy of the old IHRs in global health initiatives and initiated global interest in securing more effective international cooperation to control infectious diseases.

Although the IHR revision process had been underway since 1995, the negotiations were galvanized by the well-publicized global threats of severe acute respiratory syndrome (SARS) in late 2002 and 2003 and outbreaks of both human (H3N2) and avian (H5N1) influenza less than a year later. The SARS epidemic spread rapidly from its origins in Southern China until it had reached more than 25 countries within a matter of months. The magnified public attention to these recent epidemics jolted global awareness of the global vulnerability spurred by the rapid spread of disease in this era of globalization as well as the necessity of international cooperation in halting the spread of deadly agents. As such, the SARS epidemic provided a mobilizing vision for coordinated health action. Consequently, the IHR revision process provides an important lesson in the significant role played by a galvanizing event, and associated global public and media attention, in bringing states to the table in contemporary international law negotiations.

The new IHRs are also an important example of the linkage of traditionally distinct subject matters for the protection of global public health. The new Regulations bring together under one treaty intertwined concerns of public health, security, international trade, and human rights. The complex regulations include 66 articles divided into 10 parts as well as 9 annexes. The new IHRs expand the scope of disease coverage, incorporate human rights principles, and institute demanding obligations for state surveillance and response.

The IHRs were adopted pursuant to Article 21 of WHO's Constitution, a fairly unique lawmaking device in the international system. Article 22 of the WHO Constitution provides that regulations adopted under Article 21 are adopted pursuant to a contracting-out procedure designed to simplify and expedite the lawmaking process. Regulations come into force automatically for all WHO Member States, except for those states that notify WHO's Director-General, the Organization's executive head, of any rejection or reservations. The drafters of the WHO Constitution severely circumscribed the scope of this simplified lawmaking process, however, by limiting the scope of the regulatory authority under Article 21 to traditional public health concerns (Table 3). In the case of the new IHRs, WHO Member States who do not opt out of the IHR pursuant to WHO's Constitution are legally required to update policy and law to comport with the provisions of the new instrument. The IHR core capacities required of countries are

Table 3 Article 21 of the Constitution of the World Health Organization

The Health Assembly shall have the authority to adopt regulations concerning:

- a. sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease;
- b. nomenclatures with respect to diseases, causes of death, and public health practices;
- c. standards with respect to diagnostic procedures for international use;
- d. standards with respect to the safety, purity, and potency of biological, pharmaceutical, and similar products moving in international commerce;
- e. advertising and labeling of biological, pharmaceutical, and similar products moving in international commerce.

to detect, assess, report, and to respond to public health risks and emergencies of national and international concern. However, progress toward implementing the core capacity provisions of the instrument has been slow at the country level, and the Health Assembly has extended the deadlines for implementation. Significantly, the IHRs do not include any financial mechanism to assist states that lack capacity to implement the broad public health system and reporting obligations of the instrument.

The emergency provisions of the new IHRs have been invoked four times since the entry into force of the agreement, each time raising criticisms both of the instrument and WHO. Recently, the Organization, Member States, and the Regulations themselves faced considerable criticism in the context of the outbreak of Ebola in 2013 in West Africa and, ultimately, the United Nations led the global response to this epidemic. The Ebola outbreak, such as the H1N1 2009 outbreak, evidence that the global community is not prepared to respond to global health emergencies. In the wake of the flawed response to Ebola, commentators have called for major reforms to prevent future disasters and repair the global system for outbreak prevention and response (Moon, 2015). WHO solicited an independent assessment of its efforts during the Ebola crisis and agreed to major reforms at the 2015 World Health Assembly, including an overhaul of the IHR. Most recently, in February 2016 the WHO Director-General declared a public health emergency of international concern in the context of the outbreak of the Zika virus in order to institute a coordinated international response.

Global Code of Practice on the International Recruitment of Health Personnel

The loss of highly skilled personnel, colloquially referred to as 'brain drain,' has been a central concern of low-income countries for the last half century. In the context of health personnel, the global workforce shortage and the inequitable distribution of workers among and within nations has expanded in the last few decades and has now reached crisis proportions. The WHO Global Code, adopted by consensus by the World Health Assembly in 2010, marks the first time that the world community has considered and sought to respect critical and, at times, conflicting issues in this realm, including human rights issues. Such policy concerns incorporated in the Code include honoring the right to health of all persons, the right of

low-income countries to strengthen their health systems and the right of health workers to migrate to countries that wish to admit and employ them (Taylor and Dhillon, 2011). The WHO Global Code of Practice on the International Recruitment of Health Personnel also reflects the increasing significance of nonbinding instruments in contemporary global health governance. It is only the second instrument of its kind adopted by the World Health Assembly since the 1981 WHO Code of Marketing Breastmilk Substitutes described in the section entitled 'The Nature and Sources of International Law.' In 2015 WHO held its first formal review of the nature and significance of the Global Code, finding that while the Code was highly relevant for global health, it was not yet widely significant in global practice due, in part, to a lack of national and international resources devoted to its implementation.

PIP Framework

An interesting example of a recent nonbinding international legal instrument in communicable disease control is the PIP Framework adopted as a resolution by the World Health Assembly in 2011. The PIP Framework was designed to address the controversy that erupted in 2007 when Indonesia refused to share samples of influenza A (H5N1) with WHO collaborating centers. Indonesian officials claimed sovereignty over a virus that was identified within its jurisdiction in part because of concerns that the country's population would not receive a fair share of the benefits of any vaccine developed. Notably, the IHRs do not address the thorny issue of access to vaccines and other medications in the context of influenza pandemics. The PIP Framework attempts to resolve the controversy. Article 2 of the Framework sets forth the objective to improve pandemic preparedness and response systems with a benefit sharing system for influenza viruses that have human pandemic potential, and access to vaccines and other benefits including antiviral medications. Viewed as an international legal instrument, the PIP Framework has several interesting features. In particular, although adopted as a resolution of the World Health Assembly, the framework is a hybrid instrument that includes contractual instruments, designated as Standard Material Transfer Agreements, and other mechanisms designed to legally bind members of WHO's Global Influenza Sharing Network and pharmaceutical companies involved in the production of vaccines.

The World Trade Organization

This article would be remiss if it did not discuss the significant role of the WTO in international health law and policy. The connection between international trade and health is an important example of the contemporary linkage of two traditionally distinct realms of international legal concern discussed above. The growth of international trade means that the link between WTO treaties is becoming increasingly manifest in a wide range of areas, including access to medicines, health services, food security, nutrition, infectious disease control, and biotechnology.

The WTO, formed at the conclusion of the Uruguay round of the General Agreement on Tariffs and Trade (1994), is the primary international institution governing international trade with over 90% of world trade conducted according to its rules.

The Uruguay round brought about a complete overhaul of the international trading system by the conclusion of a number of new international agreements addressing trade issues and by the establishment of the new WTO.

Certain organizational features of the WTO make it uniquely powerful in contemporary international relations and international law. First, as a condition of membership in the new Organization, member states were required to agree and bind themselves to 24 different agreements, contained in Annexes 1–3 of the Marrakesh Agreement. Second, the WTO established a powerful dispute resolution procedure with a structured process, a prompt timetable, and the capacity to enforce rulings that is very rare in the international legal system. Pursuant to the WTO Dispute Settlement Understanding, a WTO Dispute Settlement Body is authorized to formally adjudicate trade disputes between members and can authorize the winning party to apply trade sanctions if the losing party does not modify the violating law or policy. This mandatory and enforceable dispute resolution process stands in sharp contrast to the limited implementation mechanisms established by most treaties.

Notably, the WTO does not have a direct legal mandate in international health. Article III of the Marrakesh Agreement that established the WTO specifies that the Organization shall "provide a forum for negotiations among its Members concerning their multilateral trade relations" The WTO's impact on health law and policy is collateral to its role in establishing a legal framework for international trade relations. Since the principal aim of the WTO is the reduction of barriers to trade and not the protection of public health, the pervasive and growing influence of WTO agreements on national and international health policy has been a subject of increasing concern.

A number of the WTO trade liberalization agreements have a significant impact on health policy. For example, the WTO's General Agreement on Trade in Services (GATS) has resulted in the liberalization of international trade in health services and has exacerbated concerns about equity and quality in the health sector in developing countries. The GATS may be applied to the international trade in health services, including health insurance and health-care provision. As a further example, the Agreement on Agriculture has had an important impact on food security through its downward pressure on nontariff barriers to trade, opening up developing country markets to food imports from industrialized states. Similarly, the General Agreement on Tariffs and Trade (1994) has expanded international trade in harmful commodities, such as tobacco, by mandating that states lower tariff and nontariff barriers to trade. The TRIPS Agreement, SPS Agreement, and TBT Agreement are discussed further below.

Trade-Related Aspects of Intellectual Property Agreement

The impact of the WTO's TRIPS in impeding drug development capacity and access to medicines in developing countries has received the most public attention during the last decade. As discussed above in the 'Health and Human Rights' section, the concern about TRIPS has arisen particularly in the context of global access to HIV/AIDS antiretrovirals in poor nations. It is estimated that the vast majority of the world's population of 36 million people living with HIV live in low- and middle-income countries, particularly in sub-Saharan Africa. Despite

important accomplishments over the last decade, according to UNAIDS as of 2013, only one in three persons with HIV/AIDS in sub-Saharan Africa who was eligible for treatment under WHO guidelines had access to prevention, care, or treatment with life-saving antiretrovirals.

The 1994 TRIPS Agreement brought intellectual property rights under one common set of international rules for the first time and established minimum levels of protection that all members of the WTO must accord to the intellectual property of fellow members. According to the WTO, TRIPS attempts to balance long-term social objectives of providing incentives for future inventions with short-term access to such inventions. TRIPS is the most comprehensive agreement ever reached on intellectual property. Notably, TRIPS is one of the mandatory agreements that all WTO members, including developing countries, were required to ratify. Developing countries were given transition periods to bring their national intellectual property legislation in compliance with TRIPS. By 2005, all member states of the WTO, except for the poorest, were required to be TRIPS compliant.

The most significant aspect of TRIPS, for public health purposes, is that it strengthened international protection of pharmaceutical patents. Prior to TRIPS, most developing countries did not recognize patents on pharmaceuticals in order to promote widespread and cost-effective access to medicines through generic competition and to strengthen the development of the local pharmaceutical industry. TRIPS requires patent protection of pharmaceuticals for 20 years. The patent monopolies established by TRIPS are a significant concern to many countries because such monopolies tend to increase the price of medicines and restrict generic competition.

The TRIPS Agreement contains a wide range of safeguards that can be used to protect public health at the national level, including the possibility of overriding patents through compulsory licensing or parallel imports. These and other TRIPS flexibilities as well as the legal authority of developing countries to use them to protect public health were battled out in the WTO. A large part of the concern was settled in November 2001 in the Declaration on the TRIPS Agreement and Public Health, the so-called Doha Declaration, discussed above, in which WTO members reaffirmed the right of states to use TRIPS flexibilities to protect public health and, in particular, promote universal access to essential medications. Although it is beyond the scope of this article to provide a detailed analysis of TRIPS, it should be noted that the Doha Declaration did not solve all of the problems associated with intellectual property protection and public health. As described in the section 'The International Lawmaking Process and the Role of International Organizations,' dissatisfaction with TRIPS has encouraged both those who favor stronger and those who favor weaker intellectual property protection to search for alternative venues to forge agreement. Most significantly, are the 'TRIPS-plus' bilateral and multilateral agreements that establish intellectual property rights and obligations that are more stringent than required under TRIPS, including the recently adopted 2015 Trans-Pacific Partnership Agreement that has not entered into force at the time of this writing.

The conflict between the imperatives of ensuring access to essential medications, particularly in the poorest countries and providing incentives to industry to develop

new products through the TRIPS framework continues to dominate international public health law discourse. Despite the Doha Declaration and a subsequent, related WTO decision for countries that lack domestic generic capacity, few countries have instituted TRIPS flexibilities to expand access to essential medicines and many have come under pressure from industrialized countries to provide broader intellectual property protection than that required by TRIPS, particularly through the use of bilateral agreements. In addition, the transition period for most developing countries to become TRIPS-compliant has recently come to an end in 2005, meaning that all new medicines are patentable in export-capable countries. The deadline for TRIPS-compliance has been extended several times for the poorest members, and in November 2015 the TRIPS Council agreed to an extension until 2033 for the least developed country members of the WTO allowing such members to maintain flexibility in their approach to pharmaceutical patents.

The battle over universal access to antiretroviral therapy is symptomatic of the overall challenge of securing access to essential medicines for developing nations. One-third of the world's population lacks access to basic medicines. The introduction of patent protection for drugs has made efforts to promote universal access more difficult by raising prices and reducing access. Moreover, it is estimated that, between 2000 and 2011, only 4% of new drugs or vaccines developed were designed for neglected diseases. An increasingly significant related legal challenge is the issue of patent protection for repurposed medicines. Whether called repurposing, reusing, reprofiling, or rescuing, the process of reusing previously patented medicines is expanding as an avenue for providing cost-effective and timely access to drugs in low- and middle-income countries. Granting another patent on a known product for a newly discovered use or form adds an additional layer of exclusive rights on the same chemical entity, although only for the new use. Opponents of patentability, such as MSF, have argued that granting such a new patent is a classic example of 'ever-greening' that considerably extends the period of patent protection for a known substance. Notably, TRIPS is silent on the issue of providing patents on new uses for old medicines. Debate on the issue of patentability of repurposed drugs is being taken up in other national and international venues, and there is no commonly accepted international legal practice. However, the Trans-Pacific Partnership Agreement, which was adopted in 2015 by 12 states and has been designed as a platform agreement for other states to join, explicitly requires patentability for new uses, new forms, and new methods of use subject to some exceptions.

Finding the right balance between health, trade, and intellectual property policies to sustain innovation and ensure widespread access to life-saving technologies is one of the primary public policy challenges of our time. The failure of the international community to secure an effective mechanism under TRIPS to ensure the production and export of essential medicines to meet the health needs of developing states as well as growing recognition of the link between access to medicines and human rights has led to proposals for a radical shift in the way in which pharmaceutical research and development is undertaken, including proposals for a new research and development treaty described above.

The WTO SPS and TBT Agreements

The need to find an appropriate balance between free trade rules and the rights of states to implement measures to protect public health is a continuing challenge of the WTO regime. WTO law includes an array of constraints on domestic measures that go beyond its basic principle of nondiscrimination. In particular, the WTO codified the SPS Agreement and the TBT Agreement to address the emerging debate over the use of standards, including public health standards, in international trade. These agreements are designed to balance the competing demands for domestic regulatory autonomy and the global harmonization of product standards as well as prevent imposition of protectionist policies. Some critics contend that the harmonization provisions of these global agreements interfere with the sovereign authority of states to implement domestic public health standards and stop nations from taking preventive measures against health risks in the absence of scientific certainty. Others favor the harmonization provisions arguing that higher and more costly safety standards in high-income states can be protectionist measures that act as barrier to access to the markets of high-income states. This issue has been hotly contested, particularly in the realms of environmental health and of product standards for food safety.

The SPS Agreement defines SPS measures basically as all measures instituted by states to (1) protect animal or plant life or health in its territory from the spread of pests or disease; (2) protect human or animal life or health in its territory from the risk arising from the presence of an additive, contaminant, or disease-causing organism in a food, beverage, or foodstuff; (3) protect human life or health in its territory from the risk arising from a disease-causing organisms carried by an animal or plant; and (4) prevent or limit other damage in its territory from the spread of a pest. The SPS Agreement prohibits states from imposing measures that “arbitrarily or unjustifiably discriminate between Member where identical conditions prevail” and authorizes WTO members to impose SPS measures to protect public health that may impact international if such measures are based upon internationally established guidelines and risk assessment procedures and scientific justification. When existing scientific evidence is insufficient to determine risk, states are authorized under the agreement to adopt SPS measures on the basis of available information as an interim measure, but must objectively ground their assessment of risk within a reasonable period of time.

The WTO divided the issue of technical standards or barriers between the SPS and the TBT agreement, and the scope of these two treaties are mutually exclusive with the TBT Agreement applicable to all regulations not covered by the SPS Agreement. Like the SPS Agreement, the TBT Agreement is designed to balance the policy goals of national autonomy in technical regulations and free trade by obligating states to ensure their technical regulations, including product standards, do not unreasonably restrict international trade. Public health and environmental health national standards have been the subject of dispute in a number of recent TBT cases, including cases involving a ban on clove cigarettes, regulations on labeling tuna as dolphin-safe and a country-of-origin labeling scheme for meat. Most recently, Cuba and others challenged Australia’s tobacco plain packaging standards under the WTO dispute resolution mechanism primarily based on allegation that the plain packaging regulation violates TBT obligations.

Conclusion

This article has provided a broad overview of the rapidly expanding field of global health law. This is an era of significant change in health policy. Over the last decade and a half, public health has emerged as an issue central to virtually all areas of multilateralism, ranging from arms control to security to human rights to trade. At the same time, the global dimensions of public health are transforming traditional approaches to public health. Globalization has limited the capacity of governments to protect health within their sovereign borders through unilateral action alone and national and international health are increasingly recognized as intertwined and inseparable. In addition, the idea that governments have human rights responsibilities to protect and promote public health and can and should be held accountable domestically and internationally for their actions is gaining widespread acceptance. In this new era of global health governance, international law has an important role to play in promoting and coordinating international cooperation and national action. Through the establishment of international health commitments, states legally bind themselves to establish, implement and, at times, coordinate national health laws and national health policy.

The effective design and management of international health law will be one of the major challenges for global health governance in this century. Recent developments in international health law and diplomacy have led to increasing calls for international lawmaking in an expanding number of areas related to public health. It is important to recognize that international law is not an appropriate policy instrument for all global health problems. Given the substantial limitations of international law and the international legislative process, careful consideration should be given to the selection of global health concerns and the construction of legal regimes in future international health lawmaking enterprises. Policy-makers must give high priority to identifying if and how legal strategies can contribute to the agenda in international health cooperation, including, most importantly, the major challenges that plague many developing nations. At the same time, increased attention should be paid to the impact, both positive and negative, of existing international law on population health. It is hoped that increased attention to the impact of international law, most notably international trade law, will open up critical avenues for advancing human health.

See also: Foundations in Public Health Law; Health and Human Rights: Overview; Legal Issues in Public Health.

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