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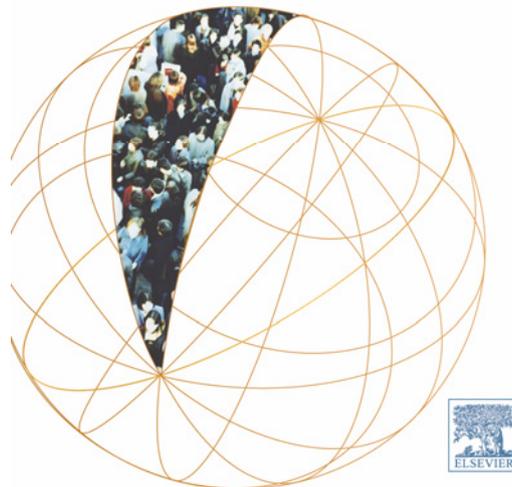
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## PUBLIC HEALTH

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## Relevant Websites

[http://www.icn.ch/icnp\\_def.htm](http://www.icn.ch/icnp_def.htm) – International Classification for Nursing Practice.

<http://www.who.int/classifications/icf/site/> – International Classification of Functioning, Disability and Health.

<http://www.iarc.fr/WHO-BlueBooks> – WHO Classification of Tumours: Pathology and Genetics.

<http://www.rivm.nl/who-fic/ICECleng.htm> – WHO Family of International Classifications, International Classification of External Causes of Injuries.

<http://www.globalfamilydoctor.com/WICC> – WONCA, International Classification Committee.

<http://www.who.int/classifications> – World Health Organization, The WHO Family of International Classifications.

<http://www.who-icps.org/> – World Health Organization, World Alliance for Patient Safety.

## International Law, and Public Health Policy

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### Introduction

The growth and elaboration of the field of international public health law in the last decade and a half 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 international public 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, international public health law has expanding significance in national public health law and policy.

The domain of international public 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, and the control of addictive and harmful substances such as tobacco and narcotics (Grad, 2005). International 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, and occupational health and safety are increasingly recognized as 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 international public 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 international public health law. Finally, the role of two international organizations, the World Health Organization and the World Trade Organization, in the contemporary development of international law are considered in connection with recent examples of lawmaking with important public health and public health policy implications.

### The Evolution of International Public 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 (Pannenberg, 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

**Table 1** Examples of international law 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	2003	WHO Framework Convention on Tobacco Control
Human rights	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
	1989	Convention on the Rights of the Child
Arms control	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
	1996	Comprehensive Test Ban Treaty
Environmental health	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
	2001	Stockholm Convention on Persistent Organic Pollutants
International narcotic drug control	1961	Single Convention on Narcotic Drugs
	1971	Convention on Psychotropic Substances
	1988	UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances
	1921	White Lead (Painting) Convention
Occupational health and safety	1932	Protection Against Accidents (Dockers) Convention
	1960	Radiation Protection Convention
	1974	Occupational Cancer Convention
	1981	Occupational Safety and Health Convention
	1994	General Agreement on Tariffs and Trade (GATT 1994)
International trade law	1994	General Agreement on Trade in Services (GATS)
	1994	Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)
	1994	Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

d'Hygiene 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 World Health Organization (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.

In the last decade and a half, the field of international public 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 public 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 international public health 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 (Lee *et al.*, 2002).

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 non-communicable diseases including tobacco use and obesity.

In addition, globalization has expanded global interest in codifying new international commitments to protect the health status of poor 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, 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. The International Health Regulations are discussed in detail in the section titled “The World Health Organization: The 2003 Framework Convention on Tobacco Control and the 2005 International Health Regulations.”

### **Health and Human Rights**

The evolution of international health law in the last decade and a half is very much tied to the protection and promotion of human rights related to physical and mental integrity. 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), and the International Covenant on Civil and Political Rights (1966). Despite the historic 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 (Gruskin and Tarantola, 2002). 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 recently been adopted. As a further example, on December 13, 2006, the United Nations General Assembly adopted the Convention on the Rights of Persons with Disabilities, a Comprehensive and Integral International Convention on the Protection and Promotion of the Rights and Dignity 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 economics rights and health. Of particular concern is the impact of international intellectual property protection under the World Trade Organization TRIPS Agreement, discussed in the section titled 'The World Trade Organization: 1994 Trade Related Aspects of Intellectual Property Agreement and Access to Essential Medicines,' in restricting access to essential medicines, particularly HIV/AIDS antiretrovirals, in most developing countries. The unprecedented human catastrophe posed by HIV/AIDS has 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 World Health Organization specifying the relationship between HIV/AIDS, human rights, and access to medicines. Most recently, 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.

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. For example, the spread of communication and information technologies has dramatically accelerated the rate of scientific progress as well as its global diffusion. For instance, the implications of recent advances in biotechnology for the protection of human rights and human dignity have also been a topic of recent 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. 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. Protocols to the Convention – separate agreements – on human cloning, biomedical research, and transplantation have also been adopted by the Council of Europe.

Finally, it is important to note that the rapid expansion of the domain of health and human rights also serves as an important illustration of another interconnected factor contributing to the breadth of contemporary international health law: The increasingly recognized nexus between public health and other international legal concerns.

### Linkage and the Scope of International Health Law

The expanding domain of international health law can be understood, in part, as a product of recently enhanced appreciation of the interconnectedness of contemporary global concerns and, concomitantly, the linkage of health to other legal issues. International legal scholars have 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 fairly recent recognition of the nexus among different realms of international law.

As a consequence of issue linkage, international 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). In addition, expanding global concern with weapons of mass destruction and terrorism has underscored the strong interconnection between public health and security. For example, legal commitments established under WHO's new International Health Regulations, described further herein, are clearly designed to apply to releases of biological, chemical, and radiological events, accidental and deliberate.

## An Introduction to Public International Law

### The Nature and Sources of International Law

Understanding the implications of recent developments in international 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, as discussed above, are now 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 international 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 international legal sources, most international law today, including international public 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

**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

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. Of course, nothing in such resolutions prohibits states from incorporating the terms of the instruments into national law. One well-known example of a nonbinding international code in the public health field is the WHO Code of Marketing Breastmilk Substitutes. Although generally nonbinding, such instruments are not without significance. Like treaties, these nonbinding instruments can be mechanisms for advancing international consensus on rules and for promoting consistent state action. 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.

At times such 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. Soft-law instruments,

at times, have also paved the way for the evolution of treaty law by generating an on-going diplomatic forum. It is important to recognize that not all resolutions lead to the development of formalized 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 International 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 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 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 law-making 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. Non-states 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.

Despite the conspicuous limitations of the 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 are likely to become of increasing importance and an essential component of global health governance. Consequently, international legal agreements 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, like 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, like 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 negotiation process, other international organizations initiated novel efforts to negotiate binding instruments on global tobacco control. In 1998, 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.

### 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 2003 Framework Convention on Tobacco Control and the 2005 International Health Regulations

The World Health Organization, 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 co-ordinating 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.

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 Framework Convention on Tobacco Control (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).

One of the important lessons from WHO's first treaty negotiation process is the significance of the international lawmaking process itself in promoting national action and international cooperation long before the treaty is adopted and formally entered into force, 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 non-governmental organizations worldwide – and thus further influenced the strengthening and deepening of tobacco control legislation in many states around the world.

In another recent lawmaking initiative, on May 23, 2005, the World Health Assembly adopted the new International Health Regulations (IHR). 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 IHR, 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 IHR were ineffective in ensuring national action and global cooperation to stop the spread of disease. The IHR 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 re-emergence of old contagions during the 1980s and 1990s underscored the irrelevancy of the old IHR in global health initiatives and initiated global interest in securing more effective international cooperation to control infectious diseases.

Although the IHR revision process has 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 IHR 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 ten parts as well as nine annexes. The new IHR expand the scope of disease coverage, incorporate human rights principles, and institute demanding obligations for state surveillance and response (Fidler and Gostin, 2006).

The IHR 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 IHR, 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 World Trade Organization: 1994 Trade-Related Aspects of Intellectual Property Agreement and Access to Essential Medicines

This article would be remiss if it did not discuss the significant role of the World Trade Organization 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 World Trade Organization treaties is becoming increasingly manifest in a wide range of areas, including

**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

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 World Trade Organization 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 World Trade Organization 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. As a further example, the Agreement on Agriculture has had an important impact on food security through its downward pressure on non-tariff 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 non-tariff barriers to trade.

The impact of the World Trade Organization's Trade Related Aspects of Intellectual Property Agreement (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 95% of the world's population of 40 million people living with HIV live in developing countries and that most do not have access to 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 during this decade. 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.

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. This means that all new medicines are and will be patented in all export-capable countries and will in all likelihood limit the supply of generics of new essential medicines in the poorest countries that depend on such imports.

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. 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 have 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. A critical global public health challenge for the coming years will be to ensure pharmaceutical research and access to essential medicines for the benefit of all.

## Conclusion

This article has provided a broad overview of the rapidly expanding field of international 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; Human Rights, Approach to Public Health Policy; Legal Issues in Public Health.

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## Further Reading

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## Internet, Health Information on the

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## Introduction

The Internet has had a pervasive impact on communities, directly or indirectly affecting the way the majority of people in technologically advanced societies work, communicate, become informed, entertain themselves, or buy goods and services. The public health impact of the Internet is also wide reaching, affecting many aspects of people's social lives and practices. The Internet might be exacerbating some public health problems. For example, extensive use of the Internet can increase hours of sedentary activity and contribute to obesity (Lajunen *et al.*, 2007) and the Internet increases the accessibility of gambling and purchase of drugs. But it has also become central to health information for patients and the public, as well as a core element in health promotion and the provision of health care (including telemedicine).

Telemedicine has been defined as “the use of telecommunications technology for medical diagnostic, monitoring, and therapeutic purposes where distance and/or time separates the patient and health care provider” (Hersh *et al.*, 2006: 1). However, telemedicine raises a large number of issues that are more germane to the delivery and organization of clinical services, and therefore is not further considered in this article. As well, the use of the

Internet in public health practice is considered elsewhere. It is the personal use of websites for information, communication, and support that is the focus of this article. Access to health information is a key public health and health promotion issue, and the Internet is becoming the key source of information for the community.

Websites can incorporate a wide variety of content, including:

- Static website pages (e.g., information, personal stories, blogs)
- Tools to enable self-help or best use of health care (e.g., decision aids, referral information)
- Directories of other public web sources
- Interactive materials (including tests, online diaries, or monitoring tools)
- Audiovisual communication (sound and/or video)
- Moderated or unmoderated online peer support (bulletin boards, chatrooms, online forums)
- Systematic instructional programs via modules
- Open public access to an expert reply to emails
- Access to a therapist or health practitioner as part of an interactive module
- Real-time group meetings or classes online (National Institute of Clinical Studies, 2003).