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Global Health and the Law

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REVIEW ARTICLE

GLOBAL HEALTH

Global Health and the Law

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THE PAST TWO DECADES HAVE BROUGHT REVOLUTIONARY CHANGES IN global health, driven by popular concern over the acquired immunodeficiency syndrome (AIDS), new strains of influenza, and maternal mortality.¹ International development assistance for health — a crucial aspect of health cooperation — increased by a factor of five, from \$5.6 billion in 1990 to \$28.1 billion in 2012, with the private and voluntary sectors taking on an ever-increasing share of the total.² Given the rapid globalization that is a defining feature of today's world, the need for a robust system of global health law has never been greater.

Global health law is not an organized legal system, with a unified treaty-monitoring body, such as the World Trade Organization. However, there is a network of treaties and so-called “soft” law instruments that powerfully affect global health, many of which have arisen under the auspices of the World Health Organization (WHO). Global health law has been defined as the legal norms, processes, and institutions that are designed primarily to attain the highest possible standard of physical and mental health for the world's population.³

Global health law can affect multiple spheres, ranging from national security, economic prosperity, and sustainable development to human rights and social justice. Each global health problem is shaped by the language of rights, duties, and rules for engagement used in the law (see Glossary).

UNDERSTANDING THE LAW AND GLOBAL HEALTH

Safeguarding the population's health traditionally occurs at the national level, with a web of laws and regulations governing health services, injury and disease prevention, and health promotion.⁴ However, in a globalized world in which pathogens and lifestyle risks span borders, the need for collective action has intensified interest in international legal solutions.⁵

The law relating to global health rests primarily within the domain of public international law, which can be broadly characterized as the rules that govern the conduct and relations of countries, including their rights and obligations. Countries remain the major subjects of international law, but international organizations and (through human rights law) individuals are also considered to be subjects of international law.

There is a complex array of international norms, including those that are binding, or “hard” (e.g., treaties), and those that are nonbinding, or “soft” (e.g., codes of practice). Hard and soft legal instruments have many similarities and often take similar forms, since both forms of instruments are negotiated and adopted by countries, are administered by international organizations, and have similar compliance mechanisms, such as setting targets, monitoring progress, and reporting to governmental agencies. Soft instruments can influence domestic law and policy and are often viewed as part of the corpus of international law (Fig. 1; and the interactive timeline, available at NEJM.org).⁶



An interactive
timeline
is available
at NEJM.org

Glossary

International Law

Treaty: A binding agreement between countries that is intended to create legal rights and duties. Treaties can often have substantial effects on private parties, such as corporations (e.g., trade law) and individuals (e.g., human rights).

Customary international law: Legal norms established by consistent practice among countries.

WHO Treaty-Making Powers

Convention: An international agreement under Article 19 of the WHO Constitution, which empowers the World Health Assembly to “adopt conventions or agreements” by a two-thirds vote on “any matter within the competence of the Organization.” The Framework Convention on Tobacco Control (adopted in 2003) is the Assembly’s only convention.

Regulation: An international rule under Article 21, which empowers the World Health Assembly to adopt regulations on a range of health topics. The two Assembly regulations are the Nomenclature with Respect to Diseases and Causes of Death (adopted in 1948) and the International Health Regulations (revised in 2005).

WHO “Soft” Law

“Soft” law: An instrument that creates health norms without the binding nature of international law. Article 23 empowers the WHO to issue formal recommendations, but the organization has developed norms through a range of soft instruments, such as global strategies, action plans, and guidelines.

Recommendations: Norms under Article 23, which empowers the World Health Assembly “to make recommendations to members.” Two Assembly recommendations are the International Code of Marketing of Breast-Milk Substitutes (adopted in 1981) and the Global Code of Practice on the International Recruitment of Health Personnel (adopted in 2010).

Global strategies: Proposals that offer a strategic vision of how to tackle health challenges, listing specific objectives and guidance to stakeholders — for example, the WHO Global Health Sector Strategy for HIV/AIDS, 2011–2015. Global strategies often stress the comparative advantages of the WHO, such as its ability to leverage its strengths through partnerships and coordination.

Global action plans: Proposals that outline specific steps or activities for a strategy to succeed — for example, the Global Action Plan for the Prevention and Control of Noncommunicable Diseases, 2013–2020. Global plans often specify detailed tasks, time horizons, and resources.

Guidelines: Policies or methods of professional practice that are approved by the Guidelines Review Committee and designed to promote evidence-based health policies or clinical interventions — for example, guidelines on patient safety.

International Human Rights Law

International Covenant on Civil and Political Rights: An agreement that requires governments to safeguard civil and political rights, including the freedom of expression and religion, freedom from slavery and torture, and rights to privacy.

International Covenant on Economic, Social, and Cultural Rights: An agreement that guarantees “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,” as well as capturing social determinants: “an adequate standard of living . . . including adequate food, clothing and housing, and to the continuous improvement of living conditions.”

General Comment 14: The interpretation of the Committee on Economic, Social, and Cultural Rights of the right to health, including health goods, services, and facilities that should be available, accessible, acceptable, and of good quality.

In recent years, the international community has moved toward a new language of global governance.⁷ Neither global health law nor governance is well defined, but the central feature of global health law is the negotiation, adoption, and monitoring of normative rules among countries. Both law and broader governance require institutions to do much of the work, including creating norms, mobilizing resources, guiding multiple stakeholders to work collaboratively, and ensuring accountability for results. The WHO is the most important institution for negotiating international health agreements.⁸

WHO AS A NORMATIVE AGENCY

The WHO has constitutional authority to negotiate and monitor normative instruments — both treaties and soft instruments, such as recommendations. The constitution of the WHO enunciates the universal value of the right to health — a widely adopted international legal entitlement.^{9,10}

The WHO uses a variety of policy tools to set soft norms, with varying levels of institutional support. A World Health Assembly resolution expresses the will of 194 member countries. The

agency has constitutional authority to adopt formal recommendations; the two most prominent are the International Code of Marketing of Breast-Milk Substitutes (adopted in 1981)¹¹ and the Global Code of Practice on the International Recruitment of Health Personnel (adopted in 2010).¹² The Assembly has also adopted influential global strategies and action plans.

The treaty-making powers of the WHO are extraordinary, with separate processes for negotiating agreements, or conventions, and regulations. Member countries must accept or reject a convention within 18 months after its adoption by the Assembly.¹⁰ This is a powerful mechanism requiring countries to consider the treaty in accordance with national constitutional processes. The WHO, however, lacks the authority to enforce compliance and thus relies on governmental implementation through domestic law and policy.

The WHO can negotiate regulations on a range of health topics, including sanitation and quarantine, nomenclatures of diseases, and standards for the safety, purity, and potency of pharmaceuticals. Regulations enter into force after

adoption by the Assembly, except for members that notify the director-general within a specified time.¹⁰ Consequently, countries must proactively opt out or they are automatically bound. The first WHO regulations — on nomenclature for diseases — date back to the late 19th century as the International List of Causes of Death; these regulations are now implemented through the International Classification of Diseases.¹³ The second WHO regulations date back to 1892, when European countries adopted the International Sanitary Convention, a predecessor to the International Sanitary Regulations (now called the International Health Regulations).³

The constitution of the WHO creates ongoing governmental obligations to report annually on actions taken on recommendations, conventions, and regulations.¹⁰ Despite the normative powers of the WHO, modern international health law is remarkably thin, with only two major treaties adopted since the creation of the agency.

FRAMEWORK CONVENTION ON TOBACCO CONTROL

The WHO did not negotiate a convention until the Framework Convention on Tobacco Control

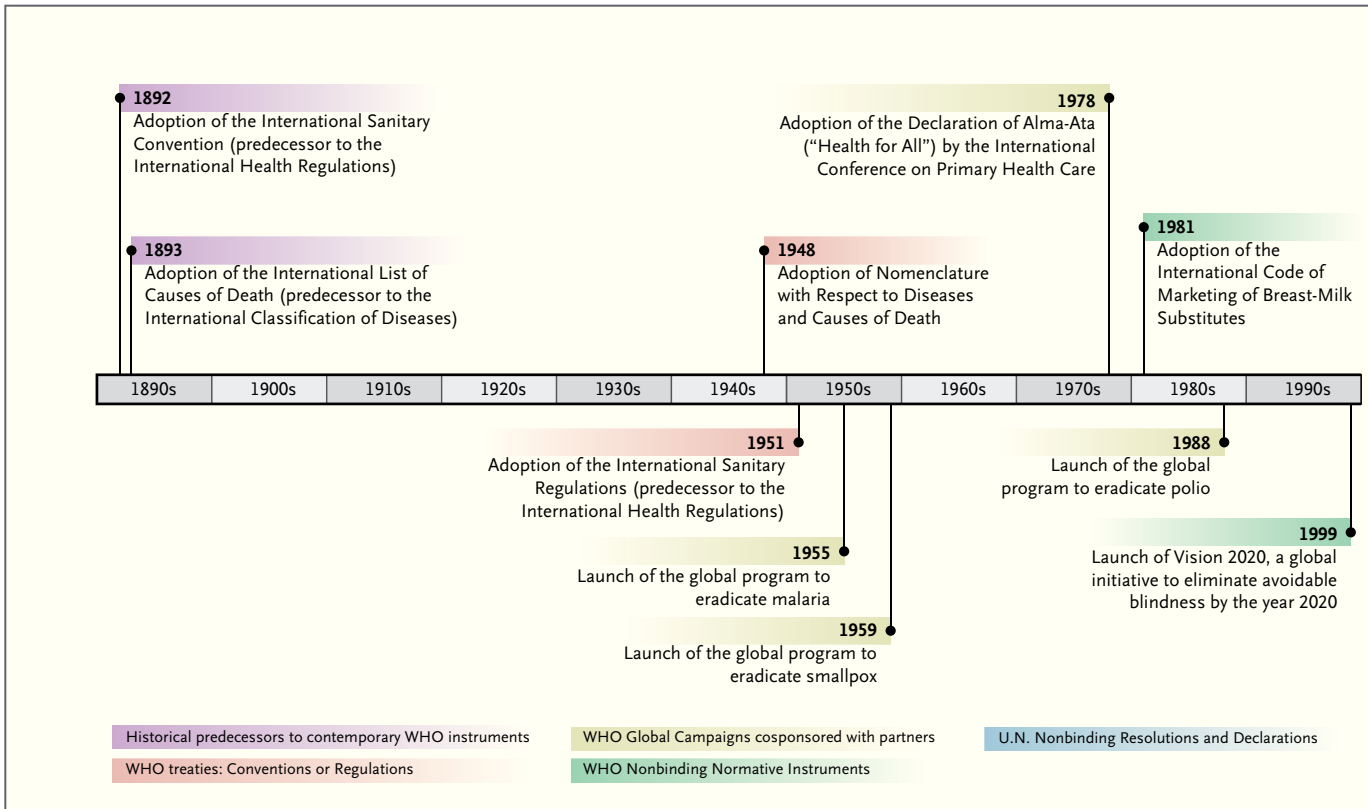


Figure 1. Timeline of Major Milestones in Global Health Law.

(FCTC), which was adopted in 2003.¹⁴ The FCTC, which remains the only convention adopted by the World Health Assembly, was ratified by 177 countries that are home to 88% of the world's population, although the convention was not ratified by 2 countries, the United States and Indonesia, which have the third and fourth largest populations, respectively, worldwide.¹⁵ In 2012, the Secretariat of the FCTC estimated that nearly 80% of the 159 countries that submitted reports had strengthened national tobacco-control laws after ratification.¹⁶ However, overall progress masks unequal performance — for example, China showed “an alarming lack of progress,” whereas India's implementation was “slow.”¹⁶

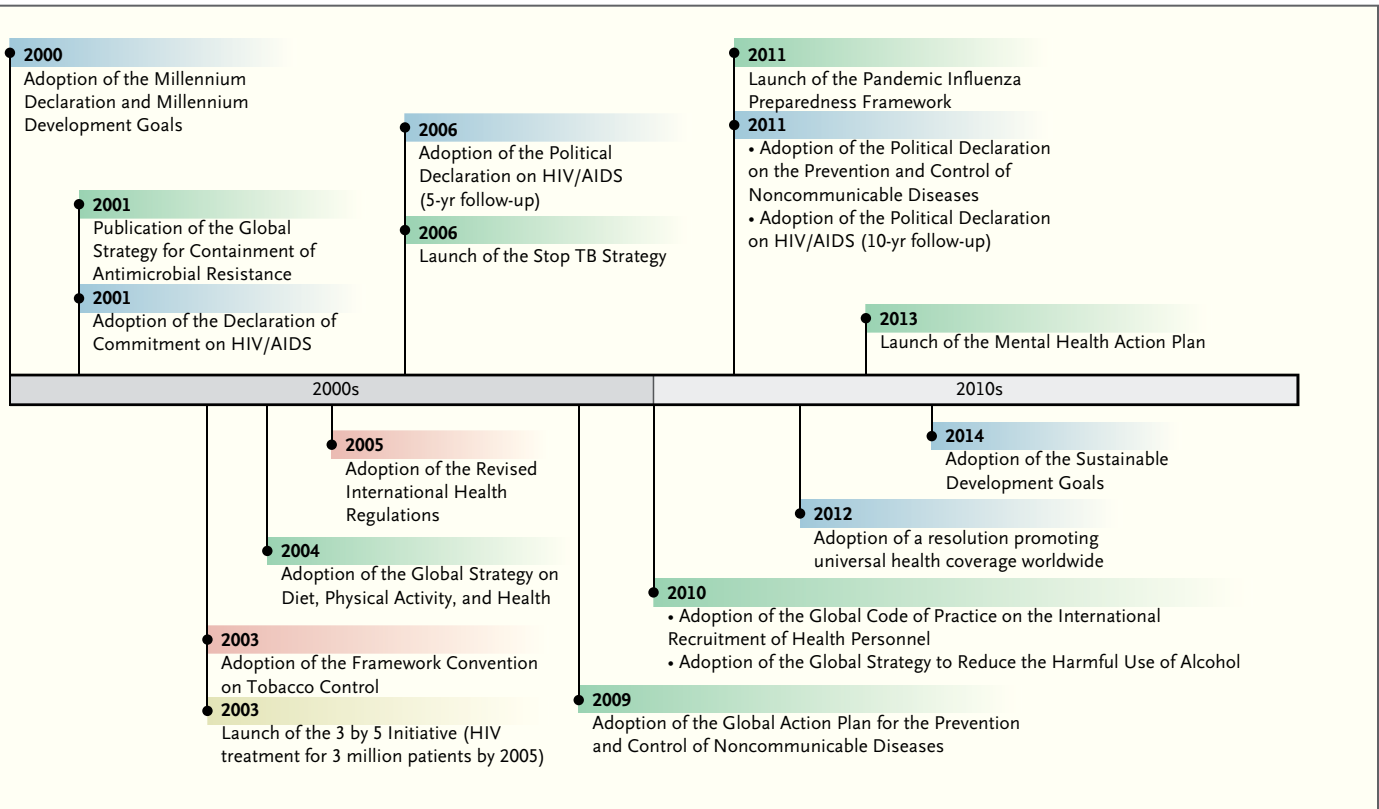
The FCTC created binding norms to reduce the demand for, and supply of, tobacco products and to share information and resources. Efforts to reduce demand include taxing and pricing guided by health objectives, the provision of 100% smoke-free environments, disclosures of contents and emissions of tobacco products, large warning labels on packaging of tobacco products, comprehensive marketing bans, and tobacco cessation and treatment programs. Re-

ducing the supply of tobacco focuses on illicit trade (e.g., smuggling and counterfeiting), which was estimated to account for 11.6% of global cigarette consumption in 2009, resulting in lost tax revenues of \$30 to \$50 billion per year.¹⁷

Despite the success of the FCTC in mobilizing governmental action and civil-society engagement, the treaty has major weaknesses. First, it contains ambiguous language, affording countries broad discretion in implementation. Second, it does not provide resources to give low- and middle-income countries sufficient capacity to implement and enforce policies outlined in the convention. In addition, the tobacco industry has fought back against the FCTC, bringing cases under the World Trade Organization and investment treaties against Australia and Uruguay for their use of plain packaging of tobacco products and adoption of tobacco-control legislation — a classic conflict between health and commerce regimes.^{18,19}

INTERNATIONAL HEALTH REGULATIONS

The World Health Assembly adopted a substantially revised version of the International Health



Regulations in 2005 in the aftermath of the severe acute respiratory syndrome (SARS) outbreak, establishing a framework for global health security.²⁰ The aim of the regulations is to enhance the monitoring and reporting of international health threats and to improve the coordination of the response while avoiding unnecessary interference with traffic and trade.²¹ The regulations govern surveillance and containment of disease within countries, at borders, and in international travel.²²

The regulations encompass a broad spectrum of health hazards of international concern, regardless of their origin or source — biologic, chemical, or radionuclear. Using a decision instrument as a guide, governments must monitor health hazards and notify the WHO within 24 hours after events that may constitute a public health emergency of international concern. The director-general has the exclusive power to declare an emergency and has done so only once — during the 2009 influenza A (H1N1) pandemic. The regulations permit the WHO to take into account unofficial sources, such as nongovernmental organizations, scientists, and social networks in print and electronic media. Countries also agreed to develop core capacities — including legislation, national focal points, and pandemic planning — to implement the regulations.

PANDEMIC INFLUENZA PREPAREDNESS (PIP) FRAMEWORK

Although not a treaty, the WHO PIP Framework is an innovative hybrid — a soft law instrument that nonetheless can create binding obligations. Adopted in May 2011, the PIP Framework resolved the nearly 5-year controversy that erupted when Indonesia refused to share samples of influenza A (H5N1) virus with WHO collaborating centers. Claiming sovereignty over a virus that was identified in their territory, Indonesian officials expressed concern that their country would not receive a fair share of the benefits of scientific discoveries.^{23,24}

The PIP Framework facilitates sharing of influenza viruses that have human pandemic potential and increases access to vaccines and antiviral medications in developing countries. The agreement incorporates “standard material transfer agreements” between the WHO and biotechnology companies or universities. When such agreements are signed, they create contractual duties to provide certain benefits in exchange

for access to biologic materials. Recipients of such materials make monetary and in-kind commitments, including commitments to donate vaccines to WHO stockpiles, offer products at affordable prices, and make intellectual-property rights available. Sharing the benefits of scientific progress is a vital aspect of global security and justice. However, the intellectual-property controversy associated with the novel coronavirus that causes the Middle East respiratory syndrome (MERS) reminds the international community that the PIP Framework applies only to pandemic influenza, with no WHO-negotiated agreement covering other emerging diseases.²⁵

INTERNATIONAL HUMAN RIGHTS LAW

The constitution of the WHO proclaims, “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”¹⁰ Reflecting the same sentiment, the International Covenant on Economic, Social, and Cultural Rights, which complements the International Covenant on Civil and Political Rights and which 161 countries have accepted as binding international law, guarantees “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” It also spells out governmental obligations to reduce infant mortality, promote the development of healthy children, improve environmental and industrial hygiene, prevent and treat diseases, and ensure the provision of medical services.²⁶ In a demonstration of the universal value of such provisions, all countries except South Sudan have joined at least one treaty recognizing the right to health.²⁷

The right to health requires that governments meet “minimum core obligations,” including the provision of health facilities, goods, and services, without discrimination and distributed equitably; nutritious and safe food; shelter, housing, sanitation, and safe and potable water; and essential medicines. Health goods, services, and facilities must be available in sufficient quantity, with public accessibility, ethnic and cultural acceptability, and good quality, as outlined in General Comment 14 of the U.N. Committee on Economic, Social, and Cultural Rights.²⁸

Whether human rights law influences governmental practices is disputed.²⁹ However, health rights are incorporated into statutes and consti-

tutions in many countries and have formed the basis for landmark judicial rulings.³ The real-world effect of human rights law depends on an active civil society, which can highlight governmental violations, lobby parliaments, and litigate health rights.³⁰ The most successful national litigation has involved access to essential medicines. For example, in 2002, the Constitutional Court in South Africa struck down government limits on access to nevirapine for pregnant women with human immunodeficiency virus (HIV) infection. As a result of this ruling, the government had to begin to realize the rights of mothers and infants to HIV prevention.³¹

Judicial decisions are increasing access to underlying determinants of health, such as food, water, and housing. In 2001, the Indian Supreme Court held that nutrition programs were legal entitlements and required that cooked meals be provided for primary school children. In later orders, the court set timetables for action on subsidized grain, maternal and child health, and food for the homeless and rural poor.³ Table 1 shows country-level court cases that illustrate the effect of human rights law on health policy.

CHALLENGES IN GLOBAL HEALTH LAW

Despite the potential of soft and hard instruments to set norms and mobilize multiple actors, global health laws have major limitations (Table 2). First, governments are loath to constrain themselves and, therefore, often reject international law or agree only to weak norms. Second, high-income countries are reluctant to finance capacity building in lower-income countries or to provide funding to the WHO without specific earmarks. And third, compliance mechanisms for such laws are often weak or nonexistent.

Because international law primarily addresses the rights and duties of countries, it cannot easily govern nonstate actors, which range from individuals and civil-society groups to foundations and private enterprises. Although newer global health institutions (e.g., UNAIDS, Global Fund, and GAVI Alliance) include civil-society representatives on their governing boards, the WHO has resisted nonstate participation in its governing structures.³²

The harmonization of governmental interests, moreover, can be difficult because of the dispa-

rate perspectives.³³ Although high-income countries often favor trade liberalization, low- and middle-income countries seek greater access to drugs and the fruits of technological progress. In 2001, World Trade Organization members adopted the Doha Declaration on TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights) and Public Health, which allowed countries to issue a compulsory license during a public health emergency, granting to itself or a third party the right to produce or import a patented drug without authorization from the patent holder.³⁴ So-called “TRIPS flexibilities” were designed to ensure that intellectual property should not prevent countries from providing affordable access to essential medications in a public health emergency.

Increasingly, the reconciliation of these interests occurs at the national level. For example, in 2013, the Supreme Court of India held that Novartis did not have a valid patent in India on the lucrative cancer drug Gleevec.³⁵ The court ruled that Indian law grants patents only to new compounds and that modified drugs must improve treatment for patients. The decision could embolden other emerging economies to reject similar intellectual-property claims. At the same time, developed countries are seeking stricter intellectual-property protection in trade agreements, such as the Trans-Pacific Partnership, which seeks to promote trade and investment among the partner countries.³⁶

Trust in international organizations to act impartially and demonstrate leadership is crucial to the future of global health law. As new health security challenges arise, the integrity and efficient functioning of the WHO becomes ever more important. The WHO, however, is struggling with a small group of donors that contribute approximately 80% of its total budget.³⁷ The term for this type of financing is “multi-bi” aid — donors’ earmarking of noncore funding for specific sectors, diseases, or regions through multilateral agencies.³⁸ Since the leadership of the WHO is unable to control most of its budget, these aid arrangements endanger the perceived independence and normative influence of the WHO.

Financing is intricately related to the challenge of building capacity to fulfill duties created by global health law. The 2011 review committee on the functioning of the International Health Regulations stressed that many countries lacked capacity and were not on a path to fulfill their

Table 1. Human Rights Court Cases Showing the Influence of International Law on Domestic Health Policy.

Case	Year	Country	Basis for Decision	Court Decision
<i>Cruz del Valle Bermúdez v. Ministerio de Sanidad y Asistencia Social</i>	1999	Venezuela	Freedom from discrimination; rights to health, security, life, and the benefits of scientific progress	Requires government to cover treatment expenses for persons living with HIV and to develop information campaigns
<i>People's Union for Civil Liberties v. Union of India</i>	2001	India	Rights to health, food, and life	Requires free and universal nutrition programs (midday meal), setting standards and timetables for action
<i>Minister of Health v. Treatment Action Campaign</i>	2002	South Africa	Right to health	Strikes down government limits on access to nevirapine for pregnant women
<i>A.V. et al. v. Estado Nacional</i>	2004	Argentina	Rights to bodily integrity, health, and life	Mandates universal, free treatment for persons living with HIV
<i>Roa Lopez v. Colombia</i>	2006	Colombia	Rights to life and health	Finds unconstitutional a prohibition on abortions to protect the life or health of the mother or in cases of rape, even when the fetus is not viable
<i>Judgment T-760/08</i>	2008	Colombia	Right to health	Requires the government to unify two insurance plans with fewer benefits for indigent persons into a single plan with equal benefits for all
<i>Lindiwe Mazibuko v. City of Johannesburg</i>	2009	South Africa	Rights to water and sanitation	Finds no immediate duty to provide a specific amount of water but only reasonable measures within the country's resources
<i>Caceres Corrales v. Colombia</i>	2010	Colombia	Rights to life and health	Upholds a complete ban on tobacco advertising and sponsorship
<i>Canada (Attorney General) v. PHS Community Services Society</i>	2011	Canada	Right to liberty and security of person, right to life	Finds unconstitutional the failure to exempt drug users and staff at a supervised safe-injection site from bans on possession of and trafficking in illicit drugs
<i>Matsipane Mosethanyane et al. v. The Attorney General</i>	2011	Botswana	Freedom from torture and cruel, inhuman, or degrading treatment; right to water and sanitation	Protects water rights of an indigenous community living in the Kalahari desert
<i>5000 Citizens v. Article 3 of Law No. 28705</i>	2011	Peru	Right to health	Upholds a ban on smoking in all public places
<i>British American Tobacco South Africa v. Minister of Health</i>	2012	South Africa	Freedom of expression; rights to information, a clean environment, and health	Upholds the constitutionality of restrictions on tobacco advertising and marketing
<i>Novartis AG v. Union of India</i>	2013	India	Rights to health and life	Invalidates the patent for Gleevec because it was not materially better than the existing drug

obligations.³⁹ The same failure to mobilize resources has plagued WHO normative development in such areas as achieving ambitious goals set forth in action plans on noncommunicable diseases and mental health.⁴⁰⁻⁴²

STRATEGY FOR GLOBAL HEALTH LAWS

Given the undoubted need for global cooperation, international norms are accepted as impor-

tant global health tools. The more difficult question is whether to pursue hard or soft routes to address health challenges. This debate plays out in international forums ranging from alcohol control and biomedical research to broader reforms such as the Framework Convention on Global Health.^{30,43-45} However, there are strengths and weaknesses to both approaches.

Soft agreements are easier to negotiate, with countries more likely to accede to far-reaching norms if there is no formal obligation to comply.

Table 2. Limitations of Global Health Law.

Challenge	Description	Example
National sovereignty	Countries are reluctant to forgo self-governance or cede authority to international actors.	The Global Code of Practice on the International Recruitment of Health Personnel is voluntary, despite active recruitment from high-income countries.
Rise of nongovernmental actors	Businesses, foundations, and civil-society groups have major effects on health but are hard to govern at the international level.	The Global Strategy on Diet, Physical Activity, and Health does not govern marketing of food.
Divergent interests of emerging economies and high-income countries	High-income countries defend trade liberalization (e.g., intellectual property), whereas low- and middle-income countries focus on health justice (e.g., access to medicines and fair allocation of scientific benefits).	The Pandemic Influenza Preparedness Framework struggled to reconcile Indonesia's claim for fair sharing of benefits with the desire of high-income countries to receive viral samples.
Funding earmarked by private donors for specific sectors, diseases, or regions through multilateral agencies ("multi-bi" financing)	Countries route assistance through the WHO and other multilateral agencies but hold tight control over its use, limiting WHO control of its resources and ability to set priorities and diminishing the perceived independence of the WHO.	Approximately 80% of the WHO's funding is voluntary, with targets that are incongruent with the priorities of the World Health Assembly and the major causes of disability and death.
Funding for capacity building	Global health law rarely requires high-income countries to build capacities in lower-income countries to fulfill international obligations.	A committee on functioning of the International Health Regulations (2011) found that many countries lacked capacity and could not fulfill their obligations.
Compliance and incentives	WHO norms (whether soft or hard) rarely contain effective methods for holding countries and stakeholders accountable.	The Global Strategy to Reduce Harmful Use of Alcohol does not require governmental action or prevent industry from lobbying against alcohol control.
Adjudication and enforcement of norms	The WHO lacks power to adjudicate most disputes and enforce norms.	The tobacco industry uses the World Trade Organization and investment treaties to challenge plain packaging of tobacco products and the initiation of tobacco-control campaigns.

Countries can assent to a soft norm without the national constitutional processes entailed in ratifying a treaty. In addition, soft norms can be negotiated more quickly with the use of fewer resources. Resolutions of the WHO Health Assembly represent a major expression of political will and can lead to progressive deepening of norms — enacted into domestic law, referenced by treaty bodies, or incorporated into international law. The WHO, moreover, is building accountability mechanisms into soft agreements, with targets, monitoring, and timelines for compliance.

However, national governments can largely ignore soft instruments, and as a result, civil society often urges treaty development.³⁹ No hard norms have been enacted, for example, relating to food, alcohol, physical activity, injuries, pain medication, or mental health. If the WHO acts principally through voluntary agreements, while other sectors develop hard law, this weakens and sidelines the agency. Civil society often points to

the obligatory nature of international trade law and its binding dispute-settlement mechanism, which often trumps WHO norms.⁴⁶

Even with all the funding and celebrity power that has entered the global health space, key health indicators lag, whereas the health gap between rich and poor has barely abated.^{47,48} A renewed attention to lawmaking efforts by the WHO and the human right to health are crucial elements of progress. It is only through law that individuals and populations can claim entitlements to health services and that corresponding governmental obligations can be established and enforced. It is through law that norms can be set, fragmented activities coordinated, and good governance ensured, including stewardship, transparency, participation, and accountability. Global health law, despite its limitations, remains vital to achieving global health with justice.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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