Global Health Law: A Definition and Grand Challenges

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As a consequence of rapid globalization, the need for a coherent system of global health law and governance has never been greater. This article explores the health hazards posed by contemporary globalization on human health and the consequent urgent need for global health law to facilitate effective multilateral cooperation in advancing the health of populations equitably. It sets forth the first definition of the emerging field of "global health law." After explicating the central features identified in the definition, the article examines the "grand challenges" to reaching the full potential of global health law to advance human health in just and effective ways.

It has been only recently that scholars have engaged in a serious discussion of 'public health law', (Martin and Johnson, 2001; Reynolds, 2004; Bailey *et al.*, 2005; Goodman *et al.*, 2007), including a definition and theory of the field (Gostin, 2008a.) This academic discourse examines the role of the state and civil society in health promotion and disease prevention within the country. There is an important emerging literature on the international dimensions of health (Taylor, 1992, 2004; Fidler, 2000; Aginam, 2005; Gostin, 2007a, 2008a,b; Taylor and Sokol, 2008), but no similar systematic definition and exposition of a field we call 'global health law'. In this article, we aim to fill this gap by defining global health law and characterizing the grand challenges. Given the rapid and expanding globalization that is a defining feature of today's world, the need for a coherent system of international health law and governance has never been greater. (Taylor, 2008).

We begin with a discussion of the health hazards posed by contemporary globalization on human health and the consequent urgent need for global health law to facilitate effective multilateral cooperation in advancing the health of populations equitably. We then offer a definition of the emerging field of 'global health law'. After explicating the central features identified in our definition, we turn to an examination of the 'grand challenges'—legal, political and social—to reaching the full potential of global health law to advance human health in just and effective ways.

The Globalization of Public Health and Global Health Governance

It is widely recognized that contemporary globalization is having a profound impact on the health of populations everywhere. Although increasing global integration is not an entirely new phenomenon, contemporary globalization has had an unprecedented impact on global public health (Lee *et al.*, 2002) and is creating new challenges for international law and policy.

Globalization can be broadly understood as a process characterized by changes in a range of social spheres including economic, political, technological, cultural and environmental. These processes of global change are restructuring human societies, ushering in new patterns of health and disease and reshaping the broad determinants of health. Indeed, the globalization of trade, travel, communication, migration, information and lifestyles has obscured the traditional distinction between national and global health. Increasingly human activities have profound health consequences for people in all parts of the world, and no country can insulate itself from the effects. Members of the world's community are interdependent and reliant on one another for health security.

The spread of infectious diseases in a changing and interdependent world is to be expected, given increased human migration, congregation and trade. But contemporary globalization has presented other myriad health risks that were not as predictable and are gaining the attention of political leaders. The burden of noncommunicable diseases (NCDs) was once felt disproportionately

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in industrialized countries, but NCDs are now the major causes of death and disability worldwide and increasingly affect people from resource-poor countries. Chronic diseases (e.g., cardiovascular diseases, cancers and diabetes) are exacerbated by human behaviour, such as consuming high-fat/high-caloric diets, maintaining sedentary lifestyles, smoking cigarettes and drinking alcoholic beverages. The processes of industrialization, urbanization, economic development and increasing food-market globalization lead to harmonization of behaviours. (UN Food and Agriculture Organization, 2001; World Health Organization Commission on Macroeconomics and Health, 2001; Magnusson, 2007). What was once culturally attractive primarily in industrialized countries has gained popularity all over the world (Yach and Beaglehole, 2004).

Multinational corporations, in particular, have significant influence and power over global consumption of food, tobacco, pharmaceuticals, consumer products and health care. The production and delivery of these goods and services pose health hazards that span national borders, but often escape scrutiny under national laws. The global community, therefore, needs to develop effective ways to ensure the quality and safety of goods and services that travel in international commerce. Recent cases of contaminated fish, lead in toys and tainted pet food illustrate the risks from international commerce that are effectively beyond the reach of national regulators.

Globalization profoundly affects healthcare services in multiple ways. International trade and intellectual property laws affect the ability of low- and middle-income countries to ensure access to essential drugs and vaccines. Access to antiretroviral medications for poor people living with HIV/AIDS offers an illustration of the political and humanitarian implications of robust intellectual property protection. At the same time, through unethical recruitment practices and the 'push and pull' of market forces, doctors and nurses are migrating to developed countries, leaving the poor without adequate human resources needed for well-functioning health care systems. (Pittman *et al.*, 2007).

These, and other, forces of globalization have exacerbated health disparities within and among countries. Indeed, some of the most significant impacts of globalization on health can be understood, in part, as perpetrating and deepening global inequity by compelling poor countries to, *inter alia*, privatize, impose user fees and adopt trade liberalization policies in areas, including health services and pharmaceutical distribution. In this globalized era, the world is more unequal than ever before. The United Nations Development Programme (UNDP) and the World Bank have both issued reports on human development in the past few years that highlight the spiralling problem of inequity. (UN Development Programme, 2005; World Bank 2006). Notably, the UNDP reported 'unprecedented reversals' in human development: 18 of the world's poorest countries registered lower scores on the human development index, a standard measure of well-being, than they had in 1990 (UN Development Programme, 2005, p. 21). As income is the primary determinant of health in poor countries, today's massive inequalities present the most critical global health threat of our time.

Globalization has highlighted and considerably complicated the need for effective mechanisms of global health governance. Overall, the increasing integration and the internationalization of the determinants of health have contributed to the rapid decline in the practical capacity of sovereign states to protect the health of their populations through unilateral national action and, thus, intensified the need for international cooperation among states (Taylor, 2004).

The world community's growing appreciation of the scope and scale of the challenges in global health is reflected in the multiplication of actors in global health since the founding of the United Nations in 1945. In recent years, for example, there has been a proliferation of international institutions active in the domain of health. Within the comprehensive UN system, organizations with significant involvement in health include the World Health Organization, the UN Children's Fund, the UN Food and Agricultural Organization, the UN Environment Programme, the UN Population Fund, the International Labour Organization and the World Bank.

A similar growth of interest in global health is seen within regional institutions and international organizations outside of the comprehensive UN system. Expanding concern about global health has also been fostered by and led to an increasing number of nonstate actors. These nonstate actors in international health include a wide assortment of foundations, religious organizations, nongovernmental agencies and for-profit organizations—such as the pharmaceutical industry—with a powerful influence on international health policy. Innovative health coalitions, involving diverse global health actors, such as health research networks and, most significantly, public–private partnerships, are also increasingly commonplace and have an important influence on health policy. The need for more effective collective action among governments, businesses, civil society and other actors is also intensifying as health determinants are increasingly affected by a complex web of factors outside of the health sector, including

conflict, environmental degradation, trade, investment and criminal activity.

In addition to the proliferation of actors in international health, contemporary global health is characterized by increasing amounts and sources of funding. As a consequence of a tremendous rise in public and private giving, there is more money in global health than ever before. (Garrett, 2007a). There are now multiple sources of funding in global health, including bilateral assistance, foundation and nongovernmental organization support, regular budgets of international organizations, and new specialized funding mechanisms, such as UNITAID and the International Finance Facility for Immunisation.

It is widely recognized that current system of global health governance is insufficient to meet the wide range of challenges and opportunities brought by globalization (Dodgson *et al.*, 2002). It is also increasingly understood that one necessary means of effective global health governance is a global health legal system, and that establishing such a system will require innovations in international law—of its existing rules, institutional mechanisms and forms of collaboration.

The Emerging Field of Global Health Law: A Definition

Our definition of global health law follows, and the remainder of this section explains the salient aspects of the definition:

> Global health law is a field that encompasses the legal norms, processes, and institutions needed to create the conditions for people throughout the world to attain the highest possible level of physical and mental health. The field seeks to facilitate health-promoting behaviour among the key actors that significantly influence the public's health, including international organizations, governments, businesses, foundations, the media, and civil society. The mechanisms of global health law should stimulate investment in research and development, mobilize resources, set priorities, coordinate activities, monitor progress, create incentives, and enforce standards. Study and practice of the field should be guided by the overarching value of social justice, which requires equitable distribution of health services, particularly to benefit the world's poorest populations.

The domain of global health law primarily is concerned with (i) formal sources of public international law, including, for example, treaties establishing the authority and responsibility of states for the health of their populations and duties of international cooperation, and (ii) formal subjects of international law, including states, individuals and public international organizations. However, to be an effective global health governance strategy, global health law must evolve beyond its traditional confines of formal sources and subjects of international law. It must foster more effective collective global health action among governments, businesses, civil society and other actors. Accordingly, our definition of global health law is prescriptive as well as descriptive: it sets out the sort of international legal framework needed, but still unavailable, to empower the world community to advance global health in accordance with the value of social justice. Of course, like any legal system, international law tends to evolve slowly in response to developments within the community that creates it and is subject to it. Considerable development in the nature of international law has taken place, for example, as a result of the recognition in the 20th century of universal human rights. Consequently, the evolution of international law envisioned in our concept of global health law is consistent with the progressive, historical development of international law.

Our definition of global health law captures five salient features, namely its: *mission*—ensuring the conditions for the public's health (meeting 'basic survival needs'); *key participants*—states, international organizations, private and charitable organizations and civil society; *sources*—public international law; *structure*—innovative mechanisms for global health governance; and *moral foundations*—the values of social justice, which call for fair distribution of health benefits to the world's most impoverished and least healthy populations.

The *mission* of global health law is to ensure the conditions necessary for the highest possible level of physical and mental health worldwide. To make a difference to the world's population, the international community should focus on what we call 'basic survival needs'. (Gostin, 2007a, 2008b). Basic survival needs focus attention on the major determinants of health, including functioning health systems, sanitation, clean water, uncontaminated food, safe products and services and access to essential vaccines and pharmaceuticals. Our definition posits that legal norms, processes and institutions can help create the conditions in which people can be healthy.

The *key participants* in a system of global health governance include the public and private sectors, together with civil society. National governments undoubtedly have, and will continue to have, primary authority and responsibility for the health of their people. However, as described above, multiple nonstate actors increasingly affect the public's health nationally and internationally. Charitable organizations such as the Gates Foundation and Clinton Global Initiative, and public–private partnerships, such as the Global Fund and the International

Finance Facility for Immunisation, provide resources for research, prevention and treatment. Nongovernmental organizations, such as Doctors Without Borders and Oxfam provide services on the ground. And civil society organizations, such as those working on AIDS, mental health or disability rights provide support and campaign for health reforms.

The major *source* of global health law is public international law designed to protect world health. Because state sovereignty is very important in the international system, the subjects and the sources of international law have been traditionally narrowly defined. Public international law is primarily focused on the interactions of sovereign states and can broadly be characterized as the rules that govern the conduct and relations of states, including their fundamental rights, obligations and commitments. While states remain the primary subjects of international law, international organizations and, through the development of international human rights law, individuals, are now considered subjects of international law as well. In the future, international law may evolve to address multinational corporations and other nonstate entities as direct subjects. Importantly, under existing international law, multinational corporations have, at times, been held accountable for gross violations of human rights, and some international instruments speak directly to corporations. Furthermore, international law and politics differ fundamentally from domestic law and politics. Although there is a wide and complex array of international legal sources, most international law today, including global health law, can be found in bilateral, regional or multilateral treaties. This treaty-based system bares little similarity to domestic statutes and regulations.

Global health law seeks innovative mechanisms for *global health governance*. Governance strategies include formal and informal mechanisms to promote health-producing behaviours and discourage harmful behaviours. Governance goes well beyond setting and enforcing hard legal norms for states to obey. Instead, governance involves creating incentives for a wide array of actors; setting priorities for the most cost-effective interventions; coordinating increasingly fragmented activities; mobilizing international aid and technical assistance; and stimulating research for new vaccines, pharmaceuticals and technologies. Scholars emphasize global health governance, rather than the prohibitory or regulatory products of 'government' because it allows easy movement across public/private boundaries of the state, markets, civil society and private life (Hunter, 2008). Rather than a model of top-down social control, governance theory harnesses the creativity and channels the actions, ideas and resources of multiple actors that affect health.

Elsewhere, one of us has proposed a Framework Convention on Global Health (FCGH) as a model of innovative global health governance. (Gostin, 2007a, 2008b). The framework convention–protocol approach has considerable flexibility, allowing parties to decide the level of specificity that is politically feasible now, saving more complex or contentious issues to be built in later protocols. An FCGH would represent a historical shift in global health, with a broadly imagined global health governance regime. The initial framework would establish the key modalities, with a strategy for subsequent protocols on each of the most important governance parameters. An FCGH would incorporate a bottom-up strategy substantively focused on (i) building capacity, so that all countries have enduring and effective health systems, and (ii) setting priorities, so that international assistance is directed to meeting basic survival needs.

The *moral foundation* of global health law is justice. Consistent with the value of social justice, our definition of global health law suggests that the conditions for healthy populations should be distributed fairly across social, racial, gender, economic and geographic boundaries in all countries and regions. Justice does not require rigidly equal allocation of resources, but some fair measure of health protection for every human being. Social justice includes, but is not limited to, reduction in socioeconomic disparities within and among countries. Social justice's demand for fair distribution is grounded in an equal concern for all human beings. Allowing the world's poor and less powerful to suffer needlessly and die prematurely harms the whole community by eroding public trust and undermining social cohesion. It signals to those affected and to everyone else that the basic human needs of some matter less than those of others. Social justice thus calls for policies that promote human dignity for all members of the international community equitably (Gostin and Powers, 2006).

The 'Grand Challenges' of Global Health Law

The political, legal, economic and social contours of the current international landscape present major challenges for global health governance. If ameliorating the most common causes of disease, disability and premature death require global solutions, then the future is demoralizing. The states that bear the disproportionate burden of disease have the least capacity to do anything about it. And the states that have the wherewithal are deeply

resistant to expending the political capital and economic resources necessary to truly make a difference to improve health outside their borders. When rich countries do act, it is often more out of narrowly perceived national interests or humanitarian instinct than a full sense of ethical or legal obligation. The result is a spiralling deterioration of health in the poorest regions, with manifest global consequences for cross-border disease transmission and systemic effects on trade, international relations and security. For global health law to be an effective means of stopping this disastrous dynamic, the international community must overcome four 'grand challenges' in global health law, i.e., enduring, hard-to-solve obstacles to utilizing law as an effective tool for achieving global health with justice (Gates Foundation, 2003).

- State-centricity in the international legal system.
- Skewed-priority setting.
- Flawed implementation and compliance.
- Fragmentation, duplication and lack of coordination.

State-Centricity in the International Legal System

A fundamental challenge of global health governance is the state-centric nature of international law. Although there has been significant encroachment on the power of states through the process of globalization, they remain the dominant actors in the international legal system. As discussed above, states are the primary subjects of public international law—including international public health law—and, thus, international law sources primarily address the rights and duties of state actors.

A critical limitation of the state-centric nature of international law is its inability to incorporate nonstate actors in the legal framework for global health governance. The international legal system is primarily concerned with states powers, responsibilities and relationships in the international community. However, as described above, nonstate actors ranging from civil society to foundations to private enterprises are playing increasingly important roles in global health governance. While WHO and other international organizations do interact with nonstate actors and incorporate them within global health governance through such means as public–private partnerships and participation in global health forums, international law does not provide a sufficient basis to fully realize the potential synergies of collaboration among stakeholders. Thus, international law needs to evolve to recognize their existence and to establish instruments and structures that will allow them to coordinate with each other and state actors to advance equitable global health.

The question of whether or not international law can govern the diverse entities that influence global health is the subject of intense debate in the literature (Taylor, 2004; Fidler, 2007). Indeed, a number of modern cutting-edge global health governance initiatives eschew formal international legal regimes, such as the Global Fund, Global Health Security Initiative (GHSI), International Drug Purchase Facility (UNITAID) and International Finance Facility for Immunisation.

The state-centric nature of international law poses other major obstacles to the use of global health law as an effective tool to advance global health cooperation. The idea that sovereign states are the organizing principle of international relations and, thus, are the focus of international law, has a number of important implications. The overriding principle of sovereignty makes international law fundamentally different from domestic law. In particular, international law is largely voluntary: there is generally no supranational authority to develop and enforce law against sovereign states. In treaties, the primary source of global health law today, states establish international legal rules by expressly consenting to them. Because states are generally loath to sacrifice their freedom of action through the codification of binding international law, treaties are most often far from sufficiently comprehensive and tend to incorporate limited obligations. Moreover, the drive to establish universal consensus in contemporary treaty negotiations often leads to the codification of fairly weak treaty commitments or what is known as 'lowest common denominator' standards. Overall, the implications of the voluntary and decentralized nature of the codification and implementation of international law permeate and deepen the remaining grand challenges of global health law.

Priority Setting

In contemporary global health governance, states are apparently unwilling to develop international legal instruments that create binding and meaningful obligations and incentives, and provide deep funding or services for the protection of the world's poorest people. As a consequence of the voluntary nature of international law and the overriding principle of sovereignty, states have established only a limited legal framework for national action and international cooperation to advance domestic and global public health. But this is exactly what is required to address the most intractable problems in global health.

Pursuant to international human rights law, national governments have the primary responsibility to protect and promote the health of their own populations. But what if a state is unable or unwilling to meet its

responsibilities? This is a particularly hard problem, and it can result from a combination of factors: poverty, political instability, ineffectual management, corruption or absence of political will.

Poverty is the principal obstacle to disease prevention and health promotion. Poor states are in a downward spiral, with poverty making people more vulnerable to malnutrition and disease, while deteriorating health further drags down the economy. At the same time, poor health contributes substantially to political instability, including the prospect of failing or failed states. Poor or unstable governments are ill-prepared to create viable health systems or to effectively plan and implement public health interventions. Incapacity can be devastating for the public's health, resulting in a failure to detect, prevent and ameliorate health threats, and to treat persons who are suffering and ill.

The vicious cycle of poverty, disease and political instability is the primary reason that low-income states cannot create healthy living conditions. But it is also important to stress that many countries, including developing countries, spend a minute percentage of their GDP on health, preferring to spend on armaments or other perceived needs. Furthermore, some governments misappropriate foreign health assistance, whether by excessive bureaucracy, incompetence or graft. Yet, as a consequence of the operation of the principle of sovereignty in international law, states have not created an effective legal framework to establish and hold governments accountable for investing in the health of their own populations.

More importantly, international law has not devised a method of holding rich states accountable to provide sufficient and stable international health assistance to states that lack the capacity. Developed countries have not even fulfilled their pledges made in 1975 of giving 0.7 per cent of Gross National Income (GNI) per annum on Official Development Assistance (ODA). More than 30 years later, their real contribution has only recently risen to reach a high of 0.33 per cent. For example, there has been no support to concretize and codify the bold norms of the United Nations Millennium Development Goals (MDGs), which address broad horizontal issues in global health relating to basic survival needs, including sanitation and sewage, pest control, clean air and water, diet and nutrition, essential medicines and vaccines and well-functioning health systems.

As a consequence of the state-centric system, the global health law agenda is also marked by skewed priorities. The treaty-making process today is driven by narrowly construed national interests or political expediency rather than by public health priorities (Taylor and Sokol, 2008). Much of the international community's attention in global health lawmaking is focused at the fringes and not at the core of global health problems.

A case in point is the failed negotiations for a convention to ban the reproductive cloning of human beings. In December 2001, the General Assembly established an *ad hoc* working group of the Sixth Committee to consider the elaboration of an international instrument to ban the reproductive cloning of human beings. This initiative, which was sponsored by France and Germany, was motivated by the public announcements by certain laboratories of impending attempts to begin reproductive cloning of humans. The committee met in two sessions in 2001 to 2002 to elaborate a mandate for the proposed treaty, but controversy swelled before the end of the first session. The majority of state delegations supported the original proposal, which limited the treaty's subject matter to the reproductive cloning of human beings. However, a small but vocal minority of states, led by the United States, supported extending the proposed prohibition to therapeutic cloning and embryonic stem cell research. Ultimately, the negotiations for the treaty failed, and in 2005 the United Nations General Assembly adopted a resolution calling upon member states to prohibit all forms of human cloning 'in so far as they are incompatible with human dignity and the protection of human life.' (UN General Assembly, 2005).

Even though the treaty-making effort failed, valuable time and resources of the Sixth Committee (the Legal Committee) and of member states were expended as wealthy, industrialized states, including France, Germany and the United States, fought over the content of a treaty addressing the 'global health' issue of human cloning. But codifying an international treaty on reproductive cloning was not then—and still is not—on the priority agenda of most countries, including, in particular, poor states. Indeed, at the time of the cloning treaty negotiations, only 30 states even had legislation on human cloning (Center for Genetics and Society, 2002). Nevertheless, consistent with the contemporary process for initiating multilateral negotiations, a select few states were able to initiate negotiations for such a treaty and to draw them out for years, monopolizing the law-making agenda to hammer out matters that were not even on majority of the international community's health radar screens.

Wealthy nations' skewed priorities in global health lawmaking also tend to govern their global health assistance spending as well as that of the private donors based in these countries. A relatively small number of wealthy donors currently wield considerable influence in setting the global health spending agenda—such as OECD countries, the Gates Foundation and the Global Fund—and they tend to prioritize specific diseases or narrowly

perceived national security interests, rather than larger, systemic problems, such as failing health systems, that could influence outcomes from all diseases (Garrett, 2007b). There is little doubt that the single most important way to ensure population health is to build enduring health systems in all countries. States and local communities must possess well-functioning public health and healthcare systems with sound infrastructures and human resources. If the vast preponderance of international assistance went into helping poor states develop and maintain health systems, it would give them the tools to safeguard their own populations. But the current funding streams skew priorities, diverting resources from building stable local systems to meet everyday health needs.

The experience of the cloning negotiations and other recent global health law initiatives suggests that states are not up to the hard task of using international law as an effective tool for health improvement for the world's poorest people. The few legal instruments that are in place are historically, politically and structurally inadequate to do what is needed to lift countries out of their perpetual state of extremely poor health (Garrett and Rosenstein, 2005). A global health law governance regime must effectively set priorities. A renewed focus on the health conditions that cause by far the greatest burden of illness and early death, and on achieving greater equality, is necessary. In the currently fractured environment where states, nongovernmental organizations, intergovernmental organizations and foundations all fund and prioritize different health interventions and states engage in international lawmaking that does not address the core of global health needs, establishing new and effective mechanisms to set global health lawmaking priorities is an overwhelming, but essential, task.

Implementation and Compliance

In the state-centric international legal system, the law that is made and the law that is implemented depends upon the will of states. As states are generally unwilling to subject themselves to international scrutiny and accountability, treaties by and large are typically marked by inadequate mechanisms to promote national compliance. Although perceptions of sovereignty are slowly changing, state consent to strong and meaningful implementation mechanisms remains rare because states are concerned that international institutions charged with implementing legal obligations will interpret their authority to be more expansive than that granted to them by states, thereby impinging on state autonomy.

Thus, in the state-centric international legal system, it is not surprising that there is no meaningful dispute settlement body in global health law today. Although the lack of concrete normative standards and capacity to assure effective implementation is an endemic problem in international law, it is a particularly acute problem in the economic and social arenas, including global health law. Most international instruments relating to health contain few incentives or options to encourage or promote compliance.

An important case in point is the new International Health Regulations, which mandate that states establish systems for national epidemiological surveillance. While such a system of global epidemiological surveillance is widely recognized as an essential component of effective global disease control, the new IHR does not provide any mechanism to assist poor states in establishing or maintaining their national systems (Fidler and Gostin, 2006). A further example is the WHO Framework Convention on Tobacco Control. In addition to establishing limited substantive obligations in tobacco control, the Convention drafters neglected to incorporate any mechanisms to promote national action or international review, including, most glaringly, an independent monitoring system, effective dispute resolution procedures, or a mechanism for ensuring that poor states have access to the resources necessary to implement their treaty obligations.

Perhaps the most discussed body of global health law is the field of health and human rights (Kuszler, 2007). But, even here, the norms established are vague or rhetorical, are not backed by implementation mechanisms and are silent on critically important aspects of global health. The right to health can be found in the most basic UN documents: Article 55 of the Charter ('find solutions of international economic, social, [and] health problems'); Article 25 of the Universal Declaration of Human Rights ('standard of living adequate for . . . health') and Article 12 of the International Covenant of Economic, Social, and Cultural Rights (ICESCR) ('highest attainable standard of physical and mental health'). These high-minded declarations and treaty provisions have had little impact on state practice: What is the exact content of the right to health recognized in these instruments and what corresponding obligations do states, and others, thereby assume? When is the right violated? And what are the mechanisms to promote implementation of the entitlement? In international law, it is widely recognized that ambiguity in international standard setting can vitiate a state's sense of obligation to comply with international law (Franck, 1998).

The treaty body that administers the ICESCR, known as the Committee on Economic, Social and Cultural Rights (Committee), attempted to clarify the meaning of the broad declaratory language that the ICESCR uses

to set out the right to health. In a publication called General Comment 14, the Committee parsed the right to health into norms, obligations, violations and implementation. In so doing, the Committee specified core obligations to meet basic human 'survival needs'—e.g., primary health care, essential food, adequate shelter, sanitation, safe potable water and essential drugs. Although General Comment 14 could, at least in theory, be used to make the ICESCR's right to health meaningful, that has not happened: as the Comment, issued seven years ago, has yet to be accepted as binding law by all states, its legal status remains uncertain.

The implementation challenges that riddle public international law in general and global health law in particular are not completely intractable, however, if sufficient political will exists to overcome them. This is made clear by the development of international trade law under the World Trade Organization (WTO) system. Certain organizational features of the WTO and its lawmaking apparatus make it uniquely powerful in contemporary international law and relations.

First, to become WTO members, states must consent to 24 different agreements. Second, the WTO established a powerful dispute resolution mechanism that, with a structured process (including, for example, a prompt timetable) and the capacity to enforce rulings, is an extremely rare entity in the international legal system. More specifically, WTO member states established a WTO Dispute Settlement Body that is authorized to formally adjudicate trade disputes between members. Importantly, this body is empowered to enforce its decisions by granting the winning party to right to apply trade sanctions against the losing party if the latter fails to modify its law or policy that the body found to be in violation of WTO rules. This mandatory and enforceable dispute resolution process stands in sharp contrast to the limited implementation mechanisms established by most treaties, including those in the realm of global health. Establishing effective mechanisms to promote implementation and compliance with global health law norms is an enduring challenge in global health law governance.

Fragmentation, Duplication and Lack of Coordination

One of the most striking characteristics of the emerging domain of global health law is the proliferation of organizations contributing to the elaboration of this increasingly complex and multi-faceted field. These organizations include the UN and its agencies (primarily WHO), organs and other bodies, and international and regional institutions outside the UN system. Overall, an increasing number of international organizations with lawmaking authority and relevant mandates are serving as platforms for global health law negotiations, while others are influencing contemporary lawmaking in this realm.

The proliferation and patchwork development of multilateral organizations with overlapping ambitions and without any central coordinating agency creates the risk that global health law will develop in an inconsistent and suboptimal manner. The experience of agency and treaty proliferation in the field of international environmental law in the last few decades provides a cautionary lesson that uncoordinated lawmaking among different international organizations can produce conflicting regimes and other counterproductive results. It has long been recognized that the lack of an umbrella environmental agency for global environmental governance has resulted in institutional overload in the field (Haas *et al.*, 1993).

There is growing evidence of fragmentation, duplication and inconsistency in areas of global health lawmaking ranging from biotechnology to tobacco control. The complexity of global health law governance and the need for more effective coordination of the lawmaking enterprise is further evidenced by the fact that so many agencies and institutions other than those intergovernmental organizations with a mandate closely related to global health are increasingly involved in global health law governance. Institutions with a stake in global health law governance include organizations, such as the World Bank and the World Trade Organization. The growing dominance of nonstate actors ranging from civil society to private enterprises to foundations in global health law governance further complicates effective coordination.

The proliferation of actors and institutions the field of global health law is not serving to strengthen global health law governance, but rather is leaving the field in disarray. More effective collective management of the emerging field of global health law is essential.

The WHO has a unique directive to provide leadership and promote rational and effective development and coordination in the evolving field of health law. The WHO Constitution envisaged an agency that would use law, and exercise powers, to proactively promote the attainment of 'the highest possible level of health'. (WHO Constitution, preamble). But the agency has never met these key expectations. The WHO did not serve as a platform for a health convention until 2003, when the World Health Assembly adopted the Framework Convention on Tobacco Control.

WHO has long been chastised for its reluctance to create binding norms, despite the bold mission and

sweeping powers granted in its Constitution (Taylor, 1992). At the turn of the 21st century, more than 50 years after it's founding, the agency had failed to adopt a single treaty. And its two regulations—on disease classification and epidemic control—were largely historical, were limited in scope and lacked real-world impact. Since that time, WHO has been far more proactive, suggesting that it may be prepared to exercise political power when necessary to avert global health crises. The critical question, however, is whether or not WHO can build on these recent achievements to deal with the most important, and intractable, health problems in the poorest regions of the world.

Conclusions

Amelioration of the enduring and complex problems of global health is virtually impossible without a collective response. The creation of international legal norms, processes and institutions provides an ongoing and structured forum for states to develop a shared humanitarian instinct on global health. But the problem of using international law as a tool for effective global health governance has long perplexed scholars, and for good reason.

This article has sought to set out a definition and the grand challenges in global health law today. As we have described, global health law has a number of structural inadequacies and inherent challenges—including vague standards, ineffective monitoring, weak enforcement—and a 'statist' approach that insufficiently harnesses the creativity and resources of nonstate actors and civil society more generally. Notably, international law suffers from important structural limitations that impact its effectiveness as a tool of global health governance. These limitations include challenges of timely commitment, implementation and modification of international standards. Overall, in the absence of effective mechanisms for rationalizing and coordinating the global health law system, there are serious questions about the capacity of existing and future global health law to advance global health effectively and equitably. Thus, although members of the global community are increasingly turning their attention to the idea of international law as a tool for cooperation in global health and calling for codification of new instruments, developing strategies to improve standard-setting, implementation and coordination are enduring grand challenges in global health law.

If law is to play a constructive role in global health governance in the future, new models will be required to channel more constructive and cooperative action to address one of the defining issues of our time—the health of the world's population. As described in this article, perhaps the most significant grand challenge to utilizing law as an effective tool to advance global health is the state-centricity of international law. The principle of sovereignty continues to prevail in the international legal system and states dictate whether and how law will be used to address global health problems. Importantly, however, that principle has been incrementally weakened by recent developments in the structure and the rules of the inter-state system. In particular, an increasing emphasis on human rights since the end of World War II has contributed to shifting the focus from states to individuals. At the same time, the process of globalization and the emergence of new actors on the international scene, including nongovernmental organizations, corporations and coalitions of public–private partnerships, have limited state sovereignty. Collectively, these types of changes are chipping away at the classical notion of sovereignty, providing the circumstances for the continued evolution of international law in general and global health law in particular.

The contemporary attention, funding and action devoted to global health are satisfying and show promise. Global health, no less than global climate change, is a defining issue of our time. But if the international community does not come together with a shared vision and architecture for effective self-governance, all of this interest will wane. And if it does, the vicious cycle of poverty, political instability and poor health will continue unabated.

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