

The Changing Structure of Global Health Governance

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Abstract

This article examines whether and how certain trends in global health governance, such as privatization, fragmentation and de-formalization, change the governance structure and modify the legal framework in which the right to health is protected. Particular attention is given to the role played by International Organizations, in order to show how a specific nature and functioning of certain organizations has been one of the reasons for failures of global health regulation in addressing global health crises, which prompted structural changes in global health governance.

However, the article also shows that recent structural changes and in particular the emergence of new actors, policies and instruments of global health regulation results in a selective, fragmented and donor-driven regulation, produces structural deficiencies and escapes some of the most essential standards for an effective and legitimate governance. The article therefore analyzes how diverse powers, obligations and responsibilities of the more prominent actors in the health sector relate to each other, and explores both the risks and potentials of the present global health governance.

Thereby, it shows that while International Organizations can indeed be considered as part of the problem that prompted structural changes in global health governance, they can, under certain conditions, also offer a solution to the systemic deficiencies that now arise from the new governance structure. That would require, however, that governance by International Organizations becomes more inclusive in order for them to cope with global health risks in a more effective and legitimate way.

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I Introduction

Some of the recent global health crises, in particular the outbreak of epidemics such as HIV/AIDS, SARS, Ebola and Zika, revealed challenges and limitations in global health regulation and its inability to cope with large-scale risks and global problems that adversely affect health. At the forefront of the critique have been International Organizations (IOs) like the World Health Organization (WHO) and some other UN agencies, which increasingly need to compete with new global governance actors for financial and human resources, expertise and novel regulatory instruments. Many of these new governance actors belong to the private sector or feature public-private partnerships (PPPs), such as The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).¹ While sociologists, medical experts, political scientists and many other scholars have already addressed the interplay between the changing structure of global health governance, on the one hand, and insufficient protection and promotion of the right to health, on the other hand, legal scholarship still lacks more comprehensive research on that topic.²

The present paper therefore aims to contribute to that discussion by examining whether and how certain trends in global health governance, such as privatization, fragmentation and de-formalization, change the governance structure and modify the legal framework in which the right to health is protected. A specific nature and functioning of certain IOs has been one of the reasons for the failures of global health regulation in coping with global risks that adversely affect health and for prompting structural changes in global health governance, but that IOs might also offer a solution to the systemic deficiencies that now arise from the new governance structure.

For the purposes of the present paper, the term “global” health governance is used in order to a) analyze an increase of intergovernmental as well as transnational actors and activities in the health sector, the latter being carried out by civil society and private sector; b) to address an increase of non-formal instruments that these various actors deploy, which generally do not amount to legal instruments that are subject to regulation by inter-

1 For further examples see Section III of this paper.

2 For an analysis of the belated discussion on the link between health and human rights as well as for an introduction into some fundamental international legal aspects of the right to health see Tobin, J, *The Right to Health in International Law*, 2011.

national or domestic law; and to c) underline interdependence of different legal systems and different governance levels in the health sector.

In order to explore some of the elements of the present global health governance and to examine the role that IOs have played in that respect, Section II examines the structural changes that have occurred in the past decades, the extent to which these changes have been part of broader developments in global governance, and the aspects in which they could have been prompted by the failures of IOs. In Section III, these insights are used to show how new governance actors and their goals lead to an increased contestation of the normative content of the right to health, why competing instruments of the multitude of actors result in selective regulation and structural defects of global health governance, and how diverse powers, obligations and responsibilities of the more prominent actors in the health sector relate to each other, especially those of states and IOs. Section IV aims to address general risks and potentials of the present governance structure, especially the trend of privatization of the health sector,³ which weakens certain IOs, but also pressures the respective IOs to become more inclusive, thus acting as proper global public institutions that have been given the formal mandate to engage in global health regulation. Section V summarizes some of my main findings.

II The Fall of International Organizations

1 Structural Changes in Global Governance

In recent decades, traditional governance mechanisms of the nation state have lost their dominance as new government arrangements have emerged. The changes in governance have occurred at the local, regional, national, transnational and international levels, and have transformed decision-making, implementation, supervision and enforcement mechanisms. Vertically, an increased shift in the exercise of public authority has first taken place from the nation state to international and supranational organizations, such as the United Nations (UN), the World Trade Organization (WTO) and the

3 See also the contribution of *Christian R. Thauer*, “The Governance of Infectious Diseases. An International Relations Perspective” in this volume.

European Union (EU).⁴ That shift of governance from the state to international and supranational organizations has been visible in most, if not all policy sectors, but also within particular branches of government, giving rise to global administration⁵ and boosting international adjudication.⁶

Somewhat less attention has been given to the increased downward vertical shift of public authority from the national to sub-national and regional levels, resulting in empowerment of regional and local communities. The downward shift has also taken place at the international and supranational level, in that organizations commonly entrust tasks and powers to lower governance levels and rely not merely on states, but also increasingly on regional and local communities to implement and enforce their acts.⁷

The exercise of public authority has also been re-allocated horizontally. The shifts from the legislature to the executive have been prompted in particular by increased international cooperation by states: Since the executive has traditionally represented the state at the international level, the increased exercise of public authority at these governance levels commonly strengthens the executive at the expense of the domestic legislature.⁸ More recently, the judiciary has likewise gained a more prominent role vis-à-vis legislature and the executive, especially due to increasing juridification of social relations.⁹

4 Sarooshi, D, *International Organizations and their Exercise of Sovereign Powers*, 2005.

5 Kingsbury, B, Krisch, N & Steward, R B, "The Emergence of Global Administrative Law" (2005), 68 *Law and Contemporary Problems*, 15.

6 Bogdandy, A von & Venzke, I, *In Wessen Namen? Internationale Gerichte in Zeiten globalen Regierens*, 2014, Introduction.

7 That shift has been most visible in the European context, where the so-called principle of subsidiarity of the powers exercised by the EU institutions and by the European Court of Human Rights (ECHR), respectively, has found its place in the founding treaties; for the EU, see Article 5(3) of the Treaty on European Union and Protocol No. 2 on the application of the principles of subsidiarity and proportionality; for the ECHR, see Article 1 of Protocol No. 15 amending the Convention on the Protection of Human Rights and Fundamental Freedoms (adopted in 2013, not yet in force); compare also with the West-African regional structures described by the contribution of Edefe Ojomo, "Fostering Regional Health Governance in West Africa: The Role of the WAHO" in this volume.

8 See for the critique of that trend Wheatley, S, *The Democratic Legitimacy of International Law*, 2010, 23-31.

9 For identifying the trend by a comparative analysis, see Tate, C N & Vallinder, T, *The Global Expansion of Judicial Power*, 1995.

Particular attention in the present paper is given to the re-allocation of the exercise of public authority away from public institutions towards semi-public and private entities. As decision-making, implementation, supervision and enforcement become more complex and require ever greater expertise, the reasons of efficiency and effectiveness demand greater specialization and delegation of particular tasks to expert bodies, market agents and other agencies of public-private and private character. In fact, the tendency towards functional specialization because of the need for technical expertise has been seen as one of the main reasons for the proliferation of governance actors on national and international levels.¹⁰

Thus, an increasing number of states as well as international and supranational organizations establish PPPs with private actors, thereby allowing such actors to take part in the exercise of public authority in the respective policy field. Examples include agencies regulating areas as diverse as environmental protection, social security, telecommunication and security.¹¹ Most examples of PPPs, however, are found in the health sector and, more specifically, in the context of regulating the production of drugs, where partnerships have been established with the pharmaceutical industry.¹²

Some critics have termed that phenomenon as “the flight from international governmental organizations”¹³ and warned against global governance being increasingly entrusted to the private sector, or to informal international or transnational institutions, whose regulation escapes some of the

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- 10 Wessel, R A & Wouters, J, “The Phenomenon of Multilevel Regulations: Interactions between Global, EU and National Regulatory Spheres” (2007), 4 *International Organizations Law Review*, 257; for the critique of that shift see Koskeniemi, M, “The Fate of Public International Law: Between Technique and Politics” (2007), 70 *The Modern Law Review*, 1.
 - 11 Dickinson, L A, “Public Law Values in a Privatised World” (2006), 31 *The Yale Journal of International Law*, 367; for the specific features of that trend in the developing countries see Leadership and Social Transformation in the Public Sector, *Moving from Challenges to Solutions*, Public Administration, the United Nations, 2003.
 - 12 Benvenisti, E, *The Law of Global Governance*, 2014, 55; for a critical assessment of that trend see also Börzel, T A & Risse, T, “Public-Private Partnerships: Effective and Legitimate Tools of International Governance?” in Grande, E & Pauly, L W (eds.), *Complex Sovereignty. Reconstituting Political Authority in the Twenty-First Century*, 2005, 195.
 - 13 Benvenisti, *The Law of Global Governance*, above Fn. 12, 37 et seqq.

most essential standards for a legitimate governing, including certain basic human rights and the rule of law standards.¹⁴

2 The Specific Nature of Global Health Governance

While privatization of governance can be analyzed as a general trend that transcends individual states, institutions, and policy areas, there is scarcely any other field where the new governance forms have gained comparable significance as in the public health sector.¹⁵ One important reason for that tendency has been subscribed to the traditional engagement of non-state actors in health affairs, ranging from private physicians, insurances, pharmaceutical companies, to church-related organizations, charity and relief organizations like the Red Cross Federation.¹⁶

Many actors of global health governance are thus rooted in the private sector, including professional associations, such as Médecins Sans Frontières (MSF), PPPs, such as the International Conference on the Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), or the Global Fund as well as certain global human rights organizations, such as Amnesty International. That strong presence of private actors in health affairs might be closely related to the ethical pressure that underlies the concern for ill and vulnerable people, which in the last decades gained prominence in light of the growing awareness of widespread poverty-related diseases.¹⁷ On the other hand, the trend of privatization has been subject to market forces, including the interests of pharmaceutical companies and healthcare providers in selling their products and services, thereby pursuing their own business models.

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- 14 Pauwelyn, J, Wessel, R A & Wouters, J, “When Structures Become Shackles: Stagnation and Dynamics in International Law” (2014), 25 *European Journal of International Law*, 733 (752).
 - 15 Hein, W & Kohlmorgen, L, “Global Health Governance: Conflicts on Global Social Rights” (2008), 8 *Global Social Policy*, 80 (84).
 - 16 Kohlmorgen, L, “International Organisations and Global Health Governance. The Role of the World Health Organization, World Bank and UNAIDS” in Hein, W, Bartsch, S & Kohlmorgen, L (eds.), *Global Health Governance and the Fight Against HIV/AIDS*, 2007, 119.
 - 17 For the historical account of that feature see Riedel, E, “The Human Right to Health – Conceptual Foundations” in Clapham, A (ed.), *Realising the Right to Health*, 2009, in particular at 21.

The health sector has been marked in a specific way by the four global crises: Climate change as well as economic, food and epidemic crises have all adversely affected health and thereby revealed limitations in global health regulation to cope with large-scale political, economic and environmental problems. For example, the outbreak of pandemic influenza A (H1N1) led the WHO to acknowledge the lack of a “global framework” that would ensure equitable access to the influenza vaccines.¹⁸ The global economic crisis has reportedly undermined efforts to achieve the Millennium Development Goals (MDGs), most of which concern health problems or address policy areas affecting health.¹⁹ Thereby, the four crises exposed the economic, social and environmental determinants of health and showed that global health regulation required a stronger cross-sectoral approach.²⁰

However, not only socio-economic factors have become acknowledged as some of the determinants of health. Health has also become, in turn, defined as one of determinants of social and economic development.²¹ That new understanding of health can be identified in particular in more recent policies aiming at poverty reduction, whose agendas increasingly integrate strategies for combating infectious diseases that are commonly referred to as “diseases of the poor”.²² Moreover, the normative content of the right to health seems to have overstepped the confines of the economic and social rights, and has become part of a more general human rights discourse, including the civil and political rights discourse.²³

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- 18 Fidler, D P, “Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1” (2010), 7 *PLoS Medicine*, 1.
 - 19 Benatar, S R, Gill, S & Bakker, I, “Global Health and the Economic Crisis” (2011), 101 *American Journal of Public Health*, 646; see also for the impact of financial crises Ruckert, A & Labonté, R, “The financial crisis and global health: the International Monetary Fund’s (IMF) policy response” (2013), 28 *Health Promotion International*, 357 (357), with further references.
 - 20 For the impact of the climate change, see Luber, G & Lemery, J, *Global Climate Change and Human Health: From Science to Practice*, 2015.
 - 21 See also the contribution of Michael Marx, “Ebola Epidemic 2014-2015: Taking Control or Being Trapped in the Logic of Failure – What Lessons Can Be Learned?” in this volume.
 - 22 See for example WHO, *Global Report for Research on Infectious Diseases of Poverty*, 2012.
 - 23 That development has been importantly influenced by the case law of the ECHR on health-related issues; see Council of Europe, *Thematic Report on Health-related issues in the case law of the European Court of Human Rights*, 2015.

Most importantly, health risks in the form of the global spread of infectious diseases, but also health threats in the area of biological terrorism, have resulted in global health being defined also in terms of national and security interests. That insight has pushed health issues up to the level of high politics, foreign policy goals and even the UN Security Council agenda.²⁴ Such broader understanding of the notion of health and its implications for national and global security requires a new legal framework, which gives rise to new global health actors and instruments, including those of the UN Security Council.²⁵ Quite tellingly, such a paradigmatic turn in conceptualizing global health governance has been considered in political science as nothing less than “a political revolution”.²⁶

3 The Flaws of International Organizations in the Health Sector

As the global crises exposed a too narrow approach in seeking to secure global health, they have also revealed the inability of IOs and the WHO in particular to respond adequately to global health threats, which required a more holistic approach and development of strategies that would reach far beyond the health sector. The lack of flexibility to react to the new challenges of globalization and undergo necessary reforms particularly hampered the WHO in retaining the central role in securing global health. Its decline can be subscribed to factors internal as well as external to the organization and relate, *inter alia*, to the WTO’s institutional setting, the growing influence of non-state actors as well as other UN agencies in the

24 The UN Security Council took up for the first time the HIV/AIDS issue in 2000, when it adopted a resolution recognizing the potential of the epidemic, if unchecked, to pose a risk to stability and security; see Resolution 1308 (2000) on the Responsibility of the Security Council in the Maintenance of International Peace and Security: HIV/AIDS and International Peace-keeping Operations, S/RES/1308 (2000); for the health securitization debate see also the contributions of *Robert Frau*, “Combining the WHO’s International Health Regulations (2005) with the UN Security Council’s Powers: Does it Make Sense for Health Governance?” and *Ilja Richard Pavone*, “Ebola and Securitization of Health: UN Security Council Resolution 2177/2014 and its Limits” in this volume.

25 For the distinction between high and low politics in political science see for example Jackson, R H & Sørensen, G, *Introduction to International Relations: Theories and Approaches*, 6th edition, 2015, 105.

26 Kickbusch, I & Reddy, K S, “Global health governance – the next political revolution” (2015), 129 *Public Health*, 840 (840 et seq.).

health sector and the interest of certain countries to shift health regulation towards other actors.²⁷

There are thus several more or less related reasons for the failures of IOs in governing global health. Some reasons seem to be organization-specific and relate to the mandate and management of the respective IOs, in particular some UN organizations, which rely on very formalized decision-making processes and procedures involving all Member States. Their regulation tends to be highly bureaucratic and slow, complicated, and not best suited to react effectively to crises that demand swift response.²⁸ The proposals to reform their mandates, structure and functions themselves initiate lengthy and complex decision-making processes, that may be protracted by the IO's inertia as well as by the Member States themselves.²⁹

In addition, by ensuring a voice and a vote to all Member States, IOs with a universal membership function to a large extent on behalf of the interests of developing countries, which do not always reflect the interests of industrialized countries.³⁰ The latter are, however, likely to be the main contributors or donors to the IO's budget, as the examples of the WHO and some other universal IOs show. That asymmetry prompted some of the powerful states to pursue their agendas rather within the IOs such as the World Bank, where higher financial contributions provide for greater voting powers.³¹

The interest of powerful actors in retaining control over the expenditure has also manifested itself in the shift from IOs towards the private sector. Thus, while the WHO has been severely obstructed by a freeze of contributions to its budgets,³² an increased number of PPPs in the field of global

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- 27 Lidén, J, "The World Health Organization and Global Health Governance: post-1990" (2014), 128 *Public Health*, 141.
 - 28 These features have been identified as one of the main reasons for certain states to favor informal cooperation to cooperation within International Organizations; see for example Pauwelyn, Wessel & Wouters, "When Structures Become Shackles", above Fn. 14, 25 et seqq.
 - 29 Kickbusch & Reddy, "Global health governance", above Fn. 26, 838.
 - 30 Benvenisti, E & Downs, G W, "The Empire's New Clothes: Political Economy and the Fragmentation of International Law" (2007), 60 *Stanford Law Review*, 595.
 - 31 The World Bank has however also been subject to criticism due to financial mismanagement; see for example Garret, L, "The Challenge of Global Health" (2007), 86 *Foreign Affairs*, 14.
 - 32 Brown, T M, Cueto, M & Fee, E, "The World Health Organization and the Transition from 'International' to 'Global' Health" in Bashford, A (ed.), *Medicine at the Border: Disease, Globalisation and Security*, 2014, 76.

health governance evidences the rise in financial and other resources given at disposal to the private sector. A telling example is the Global Fund, which was established in 2002 in close collaboration with the G8 countries. While it has been labelled as a PPP, its financial structure discloses that the majority of its funds are provided by states, making it function as a multilateral funding mechanism rather than a semi-private actor.³³

The comparison in the functioning and influence between some social policy oriented IOs such as the WHO, on the one hand, and PPPs, private actors, but also some governmental global economic institutions, on the other hand, also suggests that the rise of global economy increases competition in regulation among various actors in the field of global health and advances those actors whose power is based on financial resources. Thus, among IOs, the World Bank has become almost undisputedly the most important IO of global health governance, exercising its public authority by lending and granting activities and winning the status of being the greatest single donor in the field of health.³⁴ In the private sector, the lead has been taken over by financially heavily buttressed philanthropic foundations such as the Bill and Melinda Gates Foundation, which has been reported as becoming one of the most prominent funders in promoting global health.³⁵

But global health governance has not been restructured merely under the demands of the global market. Its development seems to reflect also the need for new governance modes and instruments, which have been promoted as more flexible, context-oriented and inclusive, and therefore more effective in attaining global health than those traditionally employed by IOs. That assumption will be examined in the following section.

33 For the latest figures see Pledges and Contributions, available at www.theglobal-fund.org/en/financials/.

34 The World Bank has been considered as one of the most powerful actors in global health governance according to different indicators; compare Abasi, K, "The World Bank and World Health: Changing Sides" (1999), 318 *British Medical Journal*, 865; Thomas, C & Weber, M, "The Politics of Global Health Governance: Whatever Happened to Health for All by the Year 2000?" (2004), 10 *Global Governance*, 187; Ruger, J P, "The Changing Role of the World Bank in Global Health" (2005), 95 *Am J Public Health*, 50.

35 Dodgson, R, Lee, K & Drager, N, "Global Health Governance, A Conceptual Review" (2002), *Discussion Paper No. 1 Department of Health & Development WHO*, 22.

III The New Legal and Political Architecture

1 New Actors, Instruments and Policies

The current structure of global health governance demonstrates an increase in the quantity and diversity of actors engaged in global health issues and manifests the preference for private actors established under domestic private law and for informal instruments of regulation, which escape the traditional public law domain. However these two phenomena are only partly related. The present section will first address the relationship between the emergence of new actors and new types of regulatory instruments that they employ in pursuing their particular policies. Afterwards, the new regulatory instruments that are not necessarily adopted by these new actors, but by traditional actors that have changed their governance mode will be examined.

New actors in the field of health governance include a variety of civil society organizations, ranging from private foundations and professional associations to business actors such as multinational corporations. Some of the larger civil society organizations, such as Oxfam and MSF, have gained a more prominent role since the 90's, by campaigning for social rights in general and for global health in particular. They are using a wide variety of instruments to co-determine the regulation of public health, including lobbying, issuing recommendations, or organizing protests. Their political weight can be well illustrated by the Nobel Peace Prize that was awarded to the MSF in 1999.

Furthermore, large foundations such as the Gates Foundation, the Rockefeller Foundation and the Ford Foundation play an ever more important role, based primarily on their extensive resource-based power.³⁶ Their main regulatory instrument is their funding activity, which enables them to co-determine the health policies that shall be fostered, the people that shall be subject to health care programs and other goals of health governance. The scope and relevance of their instruments transpires from the

36 For a critical assessment of that trend see Stuckler, D, Basu S & McKee, M, "Global Health Philanthropy and Institutional Relationships: How Should Conflicts of Interest Be Addressed?" (2011), 8 *PLoS Medicine*, 1.

reports stating that today national and global health programs are becoming largely funded by private actors.³⁷

Certain private business actors likewise continue to gain importance in the field, especially transnational pharmaceutical companies from some of the most developed countries, who have managed to develop most PPPs with states.³⁸ For example, the ICH was established in 1991 by drug regulatory authorities from the US, the EU and Japan, as well as by associations of domestic pharmaceutical companies from these countries, with the aim to harmonize technical requirements for ensuring the quality, efficacy and safety of drugs. Their main regulatory instruments are the issued guidelines, which have become *de facto* global standards, since they have been adopted by its members as well as by non-member countries and companies.³⁹

The establishment of the Global Fund, which was inspired by the G-8 summit in 2000, similarly reveals the emergence of new actors conceived by cooperation of states with private actors. Its structure aims at greater inclusiveness of the private sector and provides for the main organ of the Fund (the Foundation Board) to consist of seven representatives from donor states, seven from developing states and five members representing civil society organizations and the private sector. The primary instrument used by the Fund is disbursement of funds, which is regulated by individual grant agreements implementing international law and the Trade-Related Aspects of Intellectual Property Rights (TRIPs) in particular. Such instruments amount to very effective regulatory mechanisms and enable business actors to significantly shape the policies concerning public health.⁴⁰

However, despite such a shift from public to private forums, IOs remain among the central actors of the new legal and political architecture, although they have been affected by structural changes in global governance in several ways. Universal IOs, such as the UN, the WHO, the World Bank, the International Labour Organization (ILO), the United Nations Children's

37 Buissonniere, M, "The New Realities of Global Health: Dynamics and Obstacles" in Carbonnier, G (ed.), *Aid, Emerging Economies and Global Policies*, 2012, 60.

38 Benvenisti, *The Law of Global Governance*, above Fn. 12, 53.

39 Berman, A, "Informal International Lawmaking in Medical Products" in Berman, A, Duquet, S & Pauwelyn, J et al. (eds.), *Informal International Law-Making: Case Studies*, 2012, 353.

40 For the critique of that development see Berman, A, "The Role of Domestic Administrative Law in the Accountability of IN-LAW: The Case of the ICH" in Pauwelyn, J, Wessel, R & Wouters, J (eds.), *Informal International Lawmaking*, 2012, 468.

Emergency Fund (UNICEF) and the WTO, as well as regional IOs, such as the Organization for Economic Cooperation and Development (OECD), the EU, the African Union and the Association of Southeast Asian Nations (ASEAN), are becoming increasingly prominent as venues for negotiation and coordination among the multiple global health governance actors. Many of them cooperate with a wide range of stakeholders, securing their voice in the IO's own decision-making processes and procedures. The establishment of the Joint United Nations Program on HIV/AIDS (UNAIDS) may serve as a prime example for such negotiation and coordination efforts at the international level, whereas the EU boosts a number of mechanisms for ensuring inclusive health governance at a regional level.⁴¹ Moreover, some IOs rely on particularly effective instruments of regulation, with the World Bank providing an example of applying conditionality of structural adjustment policies as a means of fostering the IO's goals in the field of public health.⁴²

The new instruments and modes of governance are therefore also used by IOs and states in particular. Their shift towards public-private networks and their concessions to the private sector suggests that certain states increasingly favor informal governmental regulation. First, they prefer to transfer the regulation on less formal international and transnational institutions, and second, they prefer informal and private instruments to broad, integrative international agreements.⁴³ That tendency has been identified especially with the most developed states, some of which explicitly adhered to the strategy of adopting informal non-binding instruments as a matter of their national policy.⁴⁴ While that shift is part of a general trend in global

41 For the EU strategy see Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, *The EU Role in Global Health*, COM(2010)128 final, under 4.1; for a comparative account see Lamy, M & Hong, P K, "Southeast Asian cooperation in health: A comparative perspective on regional health governance in ASEAN and the EU" (2012), 10 *Asia Europe Journal*, 233.

42 See however for controversies surrounding the bank's structural adjustment programs in Breman, A & Shelton, C, "Structural Adjustment Programs and Health" in Kawachi, I & Wamala, S (eds.), *Globalisation and Health*, 2007, 219.

43 For the controversial legal nature of these instruments see Ruiter, D W P & Wessel, R, "The Legal Nature of Informal International Law: A Legal Theoretical Exercise" in Pauwelyn, J, Wessel, R & Wouters, J (eds.), *Informal International Lawmaking*, 2012, 162.

44 For examples of national policy statements and their comparative analysis see Benvenisti, *The Law of Global Governance*, above Fn. 12, 37 et seqq.

governance, it is particularly evident in the field of health regulation.⁴⁵ Ever since the most developed states identified global health risks as their own national security risks, they increasingly engage in so-called strategic health diplomacy and afford development assistance.⁴⁶ The US President's Emergency Plan for AIDS Relief (PEPFAR), launched in 2004, thereby counts among the most noted foreign aid programs and has made the US one of the biggest donor states.⁴⁷

2 Structural Deficits in Ensuring the Right to Health

The developments discussed above manifest the trend of privatization of health governance, which may lead to the weakening of IOs and thus to a decline of those global public institutions that have been given the formal mandate to engage in global health regulation. While more general concerns about the legitimacy of the present system are discussed in Section IV, the present section seeks to show, first, that those who are ultimately affected by the present trends are developing countries and other weaker global actors, such as less organized civil society groups.⁴⁸ That deprivation follows in particular from the shifting of the forums of decision-making from traditional universal IOs, in which developing countries seek to minimize the power disparities, to the forums, in which developing countries have less of a voice and a vote – if they can participate in them at all. Less formal structures, processes and forums may likewise affect those non-profit civil society organizations, whose inclusion into the decision-making procedures is put at the discretion of the more powerful actors, thus those actors who

45 Examples include also cooperation between national governments, International Organizations and private actors, such as the Global Alliance for Vaccines and Immunisation (GAVI), established in Davos in 2000.

46 Brown, M D, Mackey, T K & Shapiro, C N et al., "Bridging Public Health and Foreign Affairs: The Tradecraft of Global Health Diplomacy and the Role of Health Attachés" (2014), 3 *Science and Diplomacy*, available at <http://bit.ly/2l3lhas>.

47 Fidler, D P, "The Challenges of Global Health Governance", (2010) *Council on Foreign Relations, International Institutions and Global Governance Program*, 10.

48 On the problem of underrepresented groups and individuals in global governance see Steward, R B, "Remedying Disregard in Global Regulatory Governance: Accountability, Participation and Responsiveness" (2014), 108 *American Journal of International Law*, 211.

might least be interested in the participation of the weaker actors in the global governance structures. Circumvention of some of the traditional IOs can therefore result in insulation of weaker actors, in particular developing countries and their populations – indeed those who are suffering most from poor health standards.

Second, the functioning of some of the present actors and instruments results in a donor-driven development, as most technical assistance, grants and loans that are provided for the health sector need to comply with donors' priorities, goals, values and policies, and not with those of the receiving countries or communities.⁴⁹ Since donor funding is often determined by donors' preferences, which tend to be disease- and program-specific, it may fail to address broader socio-economic determinants of health or weak institutional capacity in the country.⁵⁰ At the same time, these trends shift the focus of global health governance from primary health care to fighting specific diseases, in particular infectious diseases that have been considered by the powerful countries as a risk to the health of their own population.⁵¹ That leads towards reducing the protection of the right to health as a universal right to the fighting of infectious diseases, or, even narrowly, towards the "fighting the diseases of the poor".⁵²

Third, the multiplication of actors, instruments and policies can lead to fragmentation in global health governance, lacking general and universal norms, effective coordinating actors and comprehensive solutions addressing the overall health standard in countries. Instead, the present system faces overlapping mandates, competition and duplication of health activities, conflicting standards on the global and national level, and forces recipient

49 Certain PEPFAR funding conditions have even been found by the US Supreme Court to be contrary the US Constitution; see *Agency for International Development et al. v Alliance for Open Society International, Inc, et al.* 570 U. S. (2013).

50 Walt, G & Buse, G, "Global Cooperation in International Public Health" in Merson, M, Black, R & Mills, A (eds.), *International Public Health: Diseases, Programmes, Systems and Policies*, 2nd edition, 2006, 649.

51 For an example as to how infectious diseases are perceived as a national security threat to a powerful state see the 1992 Report of US Institute of Medicine "Emerging Infections: Microbial Threats to Health in the United States", cited in Feldbaum, H, *US Global Health and National Security Policy, A Report of the CSIS Global Health Policy Center*, 2009.

52 See also Section II.2.

countries and actors to struggle with demands of multiple donors.⁵³ Ultimately, the present system of global health governance risks becoming ineffective, being impaired by diverging norms and conflicting goals.

3 Competing Goals, Shared Responsibilities

The multiple actors that take part in global health governance are driven by diverse interests, which these actors seek to translate into the normative framework of public health regulation. Particular actors may thereby pursue several, more or less interdependent goals, which may possibly complement or conflict with the interests of other actors. For example, states and certain IOs can regulate the health sector *inter alia* with human rights objectives, recognizing the right to health as one of the fundamental human rights and a common public good. Under this normative framework, they meet the goals pursued by a number of civil society organizations, such as human rights Non-Governmental Organizations (NGOs), charity and humanitarian relief organizations.

But states, IOs and other non-state actors pursue other goals as well. Once health has become recognized as a determinant for economic and social development, states started to protect health more distinctively with the goal of reaching social and political stability and have focused on eradication of poverty-related diseases. Moreover, when the right to health became defined as a determinant for global economy and for fully functioning global markets, the focus was further modified towards the prevention of international spread of infectious diseases.⁵⁴ Under the global economy paradigm, the goals of states, especially those of the most powerful ones, can meet the goals of other powerful global economic actors, including certain international economic IOs, such as the WTO, and transnational corporations, such as pharmaceutical companies, that seek to secure their profits by selling drugs. However, since a pricey medicine inhibits accessibility to that medicine, these goals often conflict with the goal of securing health for all

53 Brugha, R, Donoghue, M & Starling, M et al., “The Global Fund: Managing Great Expectations” (2004), 364 *Lancet*, 95.

54 The 2005 WHO International Health Regulations thus provide in Article 2 (Purpose and scope): “The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.”

and undermine the right to health as a universal human right, as promoted by some other actors.

In addition to economic interests, security interests also play a role in defining the goals of global health governance actors. Thus, in the most recent and comprehensive understanding, global health has been considered as being a matter of national and international security. The recent global health challenges, posed by epidemics such as HIV/AIDS, SARS, Ebola and Zika, that have arisen in developing countries and speedily spread in developed countries, lead to infectious diseases being defined by developed states and some IOs as a new threat to international peace and security. That understanding has further modified the normative framework under which global health is regulated and triggered the powers of the UN Security Council, which for the first time in history acted under Article 39 of the UN Charter in order to promote and protect the right to health.⁵⁵

The diversity of goals pursued in global health governance and multiplicity of actors operating in this field thereby produce continuous contestations as to how the right to health is to be understood, which values it ultimately protects, how it should be regulated and the goals of which actors should be given priority in the global regulation.⁵⁶ The above discussion suggests that states have the capacity to endorse the widest range of goals, values and purposes implied in the right to health, while non-state actors, including IOs, commonly pursue only specific goals. That state capacity to entertain a wide range of social goals and values is based on the state's general competence in regulating social relations and on its fundamental function to govern different interests and values. The distinctive character of the states vis-à-vis non-state actors such as IOs, which function according to the so-called principle of specialization, was well expressed by the International Court of Justice (ICJ) in the WHO Advisory Opinion by the statement that “[u]nlike states, which have a general competence to act, an International Organization can only act where it has been entrusted by the states with the power to act”.⁵⁷

55 UN Security Council Resolution 2177(2014); for more details see the contribution of *Robert Frau*, “Combining the WHO’s International Health Regulations (2005) with the UN Security Council’s Powers: Does it Make Sense for Health Governance?” in this volume.

56 See the contribution of *A. Katarina Weilert*, “The Right to Health in International Law – Normative Foundations and Doctrinal Flaws” in this volume.

57 ICJ Reports, *The Legality of the Use by a State of Nuclear Weapons in Armed Conflict*, 1996, 78-89, para. 25.

Moreover, the state is also the actor who carries the primary obligation to promote and protect the right to health, being bound by human rights treaties and customary international law. Thus, every state is bound by at least one treaty containing a provision on the right to health, and is subject to customary human rights norms, including Article 25 of the Universal Declaration of Human Rights.⁵⁸ That primary obligation of the state continues even when the state entrusts non-state actors with the mandate to act in the relevant field, as analyzed in the first sections of this paper. Therefore, despite such re-allocation of the exercise of public authority, the state does not escape its obligations under international law but remains bound by them, including by its obligations relating to the right to health.⁵⁹

The obligations of non-state actors in the health sector, in particular those of IOs and PPPs, are therefore subsidiary to the state obligations under international law.⁶⁰ As regards private actors such as companies and NGOs, on the other hand, there are at present no binding rules governing their obligations under international law.⁶¹ In that case, the applicable obligations under international law are merely those of the state and involve state duty to protect against abuses of human rights by third parties.⁶² The obligations of non-state actors are thus defined in relation to the scope of the state's powers, competences and limits to promote and protect the right to health, and in relation to the scope of transfer of such powers to other actors, including IOs.⁶³

58 Marks, S P, "The Emergence and Scope of the Human Right to Health" in Zuniga, J M, Marks, S P & Gostin, L O, *Advancing the Human Right to Health*, 2013, 2 (20).

59 See in that respect Article 61 of the UN ILC Draft Articles on the Responsibility of International Organizations, in particular the references to the case law of the ECHR; Report of the International Law Commission, 63rd Session, April 26 - June 3 and July 4 - August 12, 2011 GAOR 66th Session, Suppl. No. 10 (A/66/10 and Add. 1).

60 For the obligations of these actors and their relationships see Clarke, L, *Public-Private Partnerships and Responsibility under International Law. A Global Health Perspective*, 2014.

61 Alston, P (ed.), *Non-State Actors and Human Rights*, 2005.

62 See, however Guiding Principles on Business and Human Rights, Implementing the United Nations "Protect, Respect and Remedy" Framework; Ruggie, J, Special Representative of the Secretary-General Human Rights Council, UN Doc A/HRC/17/31 (2011).

63 For implied powers, see the Reparations for Injuries Suffered In the Service of the United Nations, Advisory Opinion, ICJ Reports (1949), (at 182-183): "Under International law, the Organization must be deemed to have those powers, which

The obligations of IOs – be they in the health sector or any other policy field – thus necessarily depend on the nature and scope of the mandate, powers and competences of each particular IO, and are to be determined in accordance with the principle of specialty and subsidiarity.⁶⁴ Consequently, the state cannot escape its obligations relating to the right to health by delegating tasks to IOs or other non-state actors.⁶⁵ However, IOs are also themselves bound to promote and protect public health to the extent provided for by their mandate, the rules of the IO, and other applicable norms and thus share with states the responsibilities in the health sector.⁶⁶

In that context, it is important to note that regulatory instruments adopted by an IO, even if non-binding vis-à-vis its members, may have binding effect within the IO. For example, the standards and regulations on health and safety adopted by the International Atomic Energy Agency (IAEA) are recommendations vis-à-vis the members. Under the Agency's Statute, however, they are binding with regard to its own operations.⁶⁷ In the next section, some of the features of the emerging normative framework under which IOs may, and should, participate in global health governance will be sketched.

IV The Rise of International Organizations?

1 Organizations as Public Forums

If the potential of the state rests in its general competence to regulate social relations in the country and to manage diverse interests, goals and values of

though not expressly provided for in the Charter, are conferred upon it by necessary implication as being essential to the performance of its duties.”

64 For the principle of subsidiarity see Feichtner, I, “Subsidiarity” in Wolfrum, R (ed.), *The Max Planck Encyclopedia of Public International Law*, 2007, available at <http://opil.ouplaw.com/home/EPIL>.

65 See also Benvenisti, E, “Sovereigns as Trustees of Humanity: On the Accountability of States to Foreign Stakeholders” (2013), 107 *The American Journal of International Law*, 295.

66 On the exercise of public powers by international institutions see Bogdandy A von, Wolfrum, R & Bernstorff, J von et al. (eds.), *The Exercise of Public Authority by International Institutions: Advancing International Institutional Law*, 2009.

67 Schermers, H G & Blokker, N M, *International Institutional Law*, 5th edition, 2011, 766, 780 and 792.

the various *national* actors, the potential of IOs seems to lay in their potential to host diverse *global* actors, serving them as a public forum for discourse and organization, by giving them a formal voice, or in the case of membership even a vote, at the international level. With the multiplication of actors in global health governance, diversification of the goals and purposes pursued in the name of the right to health, and the more complex and competitive environment in which these actors operate, IOs become prominent as possible venues for inclusion, contestation, negotiation and cooperation. In that capacity, they can offer an important counterpart to the regulation of the health sector by the global market and can moderate the privatization of global health governance, in particular by including private actors into the decision-making processes and procedures of particular IOs.⁶⁸ On the other hand, private actors, once participating in the decision-making structures of an IO as a public forum, are not subjected anymore merely to market competition, but also to deliberative processes and normative constraints of legitimate exercise of public authority by the respective IO.

In that respect, the WHO as a public health IO has never been more important. Having been confronted with the loss of its significance, in particular in relation to some new actors such as the Global Fund and PEPFAR, the WHO started to engage itself in forms of hybrid regulation and cooperation with private actors, for example by launching its own HIV/AIDS strategy, which is defined as a movement initiated and coordinated by the WHO, in cooperation with national authorities, UN agencies, multilateral agencies, foundations, non-governmental, religious and community organizations, private sector, labor unions and people living with HIV/AIDS.⁶⁹

An even clearer attempt to coordinate fragmented activities and to embrace new forms of governance may be found in the establishment of the UNAIDS, which has been set up by the UN and its eleven agencies, including the WHO, the World Bank and the United Nations Development Program (UNDP), with an aim to coordinate the response of the UN system to the HIV/AIDS epidemic. Besides these IOs, delegates of 22 governments

68 For the initiatives taken in this respect by the WTO see Hein & Kohlmorgen, "Global Health Governance", above Fn. 15, 97.

69 For the so-called 3 by 5 Initiative see WHO, *Treating 3 Million by 2005, Making it Happen, The WHO Strategy*, 2003.

from all geographic regions and five NGOs (including associations of people living with HIV) are members of the governing body of the UNAIDS.⁷⁰ Due to its coordinating function and the inclusion of civil society organizations, UNAIDS is often seen as an example for a promising UN reform that could minimize ineffectiveness and duplication of structures in global health governance.⁷¹

Other IOs, whose core mandate is not to promote global health but other objectives, have also adapted themselves to the emergence of new actors, powers and structures in the field of global health governance. The World Bank, which has been charged with global economic development and only indirectly with social rights, has been at the forefront of promoting PPPs, for example by conditioning the financing of health services with the inclusion of private actors into public health structures.⁷² Similarly, the WTO's objective has been to regulate and facilitate world trade, rather than global welfare, and yet, free trade has been promoted on the assumption that expanding trade has a generally positive impact on all participants. The preamble of the Agreement Establishing the World Trade Organization thus refers to the goals supporting development and improving standards of living.⁷³ The WTO has accordingly responded and adapted itself to the new governance actors, and developed a number of mechanisms for inclusion of and interaction with these actors, including with civil society groups.⁷⁴

70 For its coordinating function, see Article 1 (Objectives) and Article 2 (Functions) of the WHO.

71 See, however, for a skeptical view Bartsch, S, "The Global Fund to Fight AIDS, Tuberculosis and Malaria" in Hein, W, Bartsch, S & Kohlmorgen, L (eds.), *Global Health Governance and the Fight Against HIV/AIDS*, 2007, 146.

72 World Bank Group, *Strategic Framework for Mainstreaming Citizen Engagement in World Bank Group Operations*, 2014.

73 The first paragraph of the Preamble states, *inter alia*: "The Parties to this Agreement, recognizing that their relations in the field of trade and economic endeavor should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, [...]."

74 For the variety of mechanisms see Grasstek, C van, *The History and Future of the World Trade Organization (WTO)*, 2013, 180 et seqq.

2 International Organizations as Autonomous Actors

While IOs can play an important role in serving as public forums to other actors operating in the field of global health, they function also as autonomous actors and can be charged with promoting health in their own right, as noted in Section III.3. In that respect, IOs function also as independent international bureaucracies, pursuing their own goals, policies and interests, which is particularly evident in the organs and bodies of IOs not composed of state officials, but organization's members of staff.⁷⁵

For example, the WHO was established as a classical intergovernmental IO with states as its members, all of them being represented in the World Health Assembly and 34 of them being represented also in the Executive Board. In that regard, the WHO functions as a forum for intergovernmental discourse and cooperation. Yet, the WHO's Secretariat can be considered as enjoying a semi-autonomous status, being actively engaged in shaping the WHO's strategies, standards and policies.⁷⁶ Similarly, the World Bank cannot be described merely as a venue for hosting a discourse among states, as it is functioning as a development bank, aiming at the fight against poverty in poor countries. Capital contribution and shares of course give economically stronger countries greater voting power; nevertheless, the bank's overall decision-making processes and procedures, its internal structure and its mandate to provide for financial resources grant the bank an autonomous position, distinct from the legal and economic position of any particular Member State.

Due to their relatively autonomous position in relation to their Member States, IOs are capable of possessing their own legal personality under international and national law and can acquire rights and obligations of their own, independent from the rights and obligations of their members. They can also institute legal proceedings against other actors, negotiate and conclude international agreements in their own name, or become members of other IOs.⁷⁷ IOs can also partner with the private sector in their own right, the way the WHO, World Bank and UNAIDS became non-voting members of the hybrid Global Fund.

75 Venzke, I, "International Bureaucracies from a Political Science Perspective – Agency, Authority and International Institutional Law" (2008), 9 *German Law Journal*, 1401, in particular 1410 et seqq.

76 See also the contribution of *Pedro A. Villarreal*, "The World Health Organization's Governance Framework in Disease Outbreaks: A Legal Perspective" in this volume.

77 Brownlie, I, *Principles of Public International Law*, 6th edition, 2003, 57.

As autonomous actors, IOs are obliged to protect and promote the right to health in their own right and as their own obligation. That obligation is to be carried out in accordance with their mandate, powers and competences, and goes beyond providing a mere forum for inclusion, coordination and contestation by other actors, and implies – depending on the mandate – an active support of, and participation in, decision-making, implementation, dispute settlement or even enforcement of global health standards. IOs, although serving a subsidiary role in promoting and protecting the right to health, represent the community of their members and as such by definition cannot function merely in the service of national interests of any individual country, but are required to act in the interest of all their members and their populations and to pursue their aims on the regional or even global scale.

By acquiring rights and obligations under international law vis-à-vis their members as well as third parties, such as non-Member States, other IOs and private parties, IOs can also acquire rights and obligations towards individuals. In the field of public health, these may include obligations towards the sick, poor and other individuals exposed to health risks. However, commitments of IOs are often formulated as declarative and programmatic norms, guidelines and standards, rather than rules with clearly defined obligations for the IO and its members. Moreover, many obligations are defined as obligations of conduct, rather than obligations of result, leaving a broad scope for interpretation of IOs' responsibilities.⁷⁸ Furthermore, in case an IO breaches its obligations, the affected party might have difficulties in enforcing the claim against it, in particular due to the lack of dispute settlement mechanisms that would entertain claims against IOs and award a remedy to the affected party.⁷⁹ Obligations of IOs, either arising directly from their mandate, from their contractual obligations, or from their actions in tort, are therefore often hard to enforce, especially by individuals – indeed those ultimately affected by IOs activities.⁸⁰

78 For a comparative analysis, see Clapham, A, *Human Rights Obligations of Non-State Actors*, 2006, Ch. 4 and 5, addressing the obligations of the UN, the WTO and the EU.

79 Wellens, K, *Remedies against International Organisations*, 2002.

80 For the immunities that International Organizations enjoy before domestic courts see Reinisch, A, *International Organizations Before National Courts*, 2004, 278; for the position of individuals see Bogdandy, A von & Steinbrück Platise, M, "ARIO and Human Rights" (2012), 9 *IOLR*, 67.

One of the recent examples includes the dispute involving cholera outbreak in Haiti, where the United Nations Stabilization Mission in Haiti (MINUSTAH) has been claimed responsible for causing the outbreak. The outbreak has been attributed to poor construction of the sanitation system in the UN base, which resulted in contamination of the primary water source of Haitian residents.⁸¹ The claim by the NGOs representing thousands of victims before the US courts has been rejected by the first- and second-instance courts, which both recognized UN immunity in the domestic proceedings.⁸² Thus, even when the failure to protect the human right to health could be attributed to an IO, and could even amount to an epidemic, the obligation of the IO to remedy the situation will be hard to enforce.⁸³

However, the existence of obligations of IOs should clearly be distinguished from the lack of monitoring and enforcement mechanisms that could ensure compliance of IOs with their obligations, and from the lack of possibility of third parties, including individuals, to enforce these obligations. That distinction is based on the fundamental difference between primary and secondary rules of international law, whereby the primary rules concern the substantive rights and obligations binding upon IOs, whereas the secondary rules determine when an IO is responsible for a breach of primary obligations and what are the means of redress.⁸⁴ Difficulties in *enforcing* the right to health against an IO do not therefore affect the *existence* of the corresponding IO's obligation to protect that right.

3 The Risks and Potentials

The new legal and political landscape in global health governance that was analyzed in the previous sections opens a number of risks, but also potentials for an effective and legitimate governance of the health sector in which

81 Cravioto, A, Lanata, C F & Lantagne, D S et al., *Final Report of the Independent Panel of Experts on the Cholera Outbreak in Haiti*, 2011, 29, available at www.un.org/News/dh/infocus/haiti/UN-cholera-report-final.pdf.

82 *Delama Georges et al. v. The United Nations et al.*, 13-cv-7146 (JPO), opinion and order of January 9, 2015; for the decision on the appeal see *Delama Georges et al. v. The United Nations et al.*, No. 15-455-cv (2nd Cir 2016), decision of August 18, 2016.

83 See also the contribution of *Leonie Vierck*, "The Case Law of International Public Health and Why its Scarcity is a Problem" in this volume.

84 For the distinction see the Draft Articles on the Responsibility of International Organizations with commentary, above Fn. 59, General Commentary para. 3, 2.

IOs could play a prominent role. Some of the current structural deficits in health governance, described in Section III, are due to the multiplication of actors with overlapping mandates, duplication of work, competition and lack of coordination of their activities in the health sector. Such a deficiency results in selective regulation of specific diseases, rather than in a comprehensive promotion and protection of health worldwide, and primary health care in particular.⁸⁵ Proliferation of actors with overlapping mandates, coupled with poor coordination, also leads to duplication of governance structures and can produce conflicting priorities, standards and policies. The current structure of global health governance therefore risks ever-greater institutional and regulatory fragmentation.

More importantly, fragmented governance structures, strategies and norms hamper effectiveness of global health governance. Some observers therefore criticize the current governance patchwork as incapable of producing a convergence of interests, resources and strategies, and warn that it prevents in particular developing countries from effective participation.⁸⁶ Instead of pooling available resources and knowledge to address health risks as collective action problems, various actors need to compete for financial and human resources. Such competition especially weakens those actors whose functioning is not market-oriented, such as the WHO and some other UN agencies. Moreover, the actors' success and effectiveness in their functioning is measured against organizational criteria, such as the number of loans dispersed or amount of funding provided, rather than in terms of their ultimate impact on health and disease control.⁸⁷

If duplication of tasks, confusing priorities and poor coordination impede effectiveness of global health governance and thereby its *output* legitimacy, the exercise of public authority by some of the most powerful actors, which lack democratic governance structure, puts into question also the *input* legitimacy of global health governance. According to this distinction, the input legitimacy of an actor is secured in particular by democratic guarantees such as participation, representation and transparency in the actor's deci-

85 For the critique concerning the World Bank and the Global Fund see UNAIDS, *The Global Task Team on Improving AIDS Coordination Among Multilateral Institutions and International Donors (Final Report)*, June 14, 2005, 15.

86 Fidler, "The Challenges of Global Health Governance", above Fn. 47, 12 et seq.

87 Brooks, A, Cutts, F T & Justice, J et al., *Policy Study of Factors Influencing the Adoption of New and Underutilized Vaccines in Developing Countries, CVI and USAID*, 1999, 33 et seqq.

sion-making, whereas the output legitimacy concerns the actor's performance and is obtained in particular by providing effective solutions to collective problems.⁸⁸

The concern for the input legitimacy has been raised especially with respect to private actors, who dominate and control resource allocation in the health sector and determine health policies in accordance with their own preferences, goals and interests. In particular, the involvement of the pharmaceutical industry in the regulation and standard-setting has been harshly criticized in that it has been too prone to engage in merely profit-oriented activities, as the decision-making of private business actors necessarily follows their own private interests and cost-benefit analysis, rather than health needs and interests of larger communities or indeed of the international community.⁸⁹ Moreover, many not-for-profit NGOs have been considered as representing merely themselves and their own interests, thus not representing their constituencies in any formal, accountable or participatory way.⁹⁰ This observation is relevant also for a number of actors of a public-private character, including the Global Fund, whose national-level mechanisms such as the Country Coordinating System do not represent the constituencies in which they operate.⁹¹ The new forms of governance like self-regulation and hybrid regulation therefore lack external and internal accountability mechanisms, yet they increasingly compete with the public and – more or less – democratically legitimized IOs.

Indeed, IOs have likewise been criticized for lacking legitimacy, in particular for failing to meet many of the standards of democratic decision-

88 For the notion of input and output legitimacy of International Organizations, see Steffek, J, "The Output Legitimacy of International Organizations and the Global Public Interest" (2015), 7 *International Theory*, 263 (263 et seqq.); see also Bexell, M, "Global Governance, Legitimacy and (De)Legitimation" (2014), 11 *Globalizations*, 289 (291 et seqq.).

89 Benvenisti, *The Law of Global Governance*, above Fn. 12, 54, with further references.

90 See also the contribution of Hunter Keys, Bonnie Kaiser & André den Exter, "The Real Versus the Ideal in NGO Governance: Enacting the Right to Mental Healthcare in Liberia During the 2014-2016 Ebola Epidemic" in this volume.

91 Kageni, A, Mwangi, L & Mugenyi, C et al., *Representation and Participation of Key Populations on Country Coordinating Systems in Six Countries in Southern Africa*, Final Report, AIDSPAN, 2015.

making⁹² and for giving greater regard to the interests of some actors, especially powerful states and well-organized economic actors, and lesser regard to the interests of more weakly organized groups and vulnerable individuals.⁹³ Nevertheless, due to their dual capacity to serve as public forums for other governance actors and as autonomous actors, they may carry, first of all, the potential for inclusion and integration of diverse actors and interests, especially those of weaker countries, less represented peoples and marginalized groups and individuals. The inclusion of state and non-state actors, NGOs, business actors, local organizations and other stake-holders can enable political processes that are closer to the needs of the affected individuals and communities, and can therefore increase the legitimacy of the respective IO, and of global health governance more generally.

Second, due to their public nature, IOs are well endowed with powers and competences for addressing collective action problems. They are *the* actors that have been entrusted with protecting global common goods and given the mandate for promoting and protecting the right to health on the international level, for coordinating international response to health risks and for regulating the health sector in the interest of global population. They are the actors who are competent for pooling available resources, skills and knowledge and who are charged with facilitating integrative agreements. The establishment of the UNAIDS and the WHO's launching of its own initiative to fight HIV/AIDS may therefore be seen as an attempt towards a better inclusion of underrepresented stakeholders, prevention of further privatization of global health governance, and coordination and cooperation in the fight against certain infectious diseases through a public – and thus more legitimate – international forum.

Third, if IOs will be able to embrace the private sector, engage more actively in forming partnerships and networks with other actors, including business actors and not-for-profit NGOs, and enable them to participate in the IOs' own decision making processes and procedures, IOs may not only gain higher input legitimacy, but also higher acceptance and thus better implementation of their policies and decisions on the national and local level,

92 Compare Wheatley, S, *The Democratic Legitimacy of International Law*, 2010; Wouters, J, Braeckman, A & Lievens, M et al. (eds.), *Global Governance and Democracy, A Multidisciplinary Analysis*, 2015; Klabbbers, J, Peters, A & Ulfstein, G, *The Constitutionalization of International Law*, 2009.

93 Particularly forceful Stewart, R B, "Remedying Disregard in Global Regulatory Governance: Accountability, Participation and Responsiveness" (2014), 108 *The American Journal of International Law*, 211.

which could improve their effectiveness. Such changes, however, require reforms of institutional structures, instruments and policies within each IO.

Thereby, it seems that apart from an IO's inertia, one of the greatest challenges to successful reforms might be the hesitance of powerful states and powerful private actors to support such changes, as they seem to prefer bilateral and informal agreements to the broader collective actions. Still, IOs such as the WHO show that also international public institutions – precisely because they are public – have the potential to accommodate diverse competing interests, enhance cooperation between public and private actors and build networks with and between them, thereby contributing towards greater legitimacy and effectiveness of the global health sector.

V Conclusion

In recent decades, several structural changes have occurred in global health governance, in which traditional regulation by international governmental organizations has increasingly been replaced by new government modes and structures, in particular by bilateral arrangements, PPPs and less formal instruments.⁹⁴ The shift of governance away from IOs has been prompted by different factors, including by certain failures of IOs such as the WHO, which to a large extent have been lacking flexible, context-oriented and inclusive governance modes and instruments, and were unable to respond swiftly and adequately to some of the recent global crises. On the other hand, the decline of IOs has been part of a more general trend of shifting the exercise of public authority towards informal international or transnational institutions and entrusting global governance to the private sector, whereby the health sector has manifested more examples of PPPs than any other policy sector. However, the new global health governance architecture produces a number of structural deficiencies, such as selective and donor-driven regulation, fragmentation and ineffectiveness of the global health sector. In addition, the regulation by some of the most powerful global actors, such as those dominated by pharmaceutical companies, escapes some of the most essential standards of legitimate governance, including certain basic democratic, human rights and the rule of law standards. What is more, informal governance arrangements, be they adopted by state or

94 See also Pauwelyn, J, "Is it International Law or Not and Does it Even Matter?" in Pauwelyn, J, Wessel, R & Wouters, J (eds.), *Informal International Lawmaking*, 2012, 125.

non-state actors, remain below the threshold of legally binding instruments and can therefore escape the requirements for a legitimate exercise of public authority. In view of such structural deficiencies, IOs carry the potential to redress the lack of effectiveness and legitimacy of global health governance, in that they could more prominently use their dual character of public forums and of autonomous actors, by hosting – and moderating – the contestation, negotiation and cooperation between multiple actors, goals, interests and values. Thereby, they have the potential to bring public governance back to public forums and subjecting the global health governance to the normative framework for a legitimate and effective exercise of public authority. That would require, however, that governance by IOs becomes more inclusive, if in the future IOs are to prevent global health risks in a more coordinated, effective and legitimate way.

