The Concept of the Book

Leonie Vierck, Pedro A. Villarreal, and A. Katarina Weilert

The following pages introduce the present edited volume on "The Governance of Disease Outbreaks - International Health Law: Lessons from the Ebola Crisis and Beyond" and provide a concept of the book within the still under-researched and vaguely defined field of international health law. While the edited volume consists of several stand-alone contributions (and not chapters), these have been brought into correspondence with each other with a red thread described in the following lines. The reader will also be guided in detail by cross-references between the articles. Still, all authors bear responsibility for their contributions, and individual contributions do not necessarily reflect the view(s) of the editors. While the chosen title already makes clear that the angle of the book is international health law, this legal angle is, and has to be informed by other disciplines. This is reflected in contributions written from public health, political science, and anthropological perspectives. Of course, readers should be aware of the heterogeneous methodological choices within the contributions. We close this introduction with an outlook for future research questions in the area of international health law and governance.

I What is the Theme of the Book?

1 The Red Thread of the Book

Disease outbreaks occur regularly, and will present an even greater threat to humanity in the future; we know that major disease outbreaks will be increasing, but we do not know which ones and where exactly.[1] The Ebola

1 See the contribution of *Christian R. Thauer*, "The Governance of Infectious Diseases. An International Relations Perspective" in this volume showing how globalization increases demands for international health governance. Trade, investment, and travel allow infections to spread more easily. Population growth and urbanization are other highly important factors. All websites last accessed April 9, 2017.

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crisis was unexpected in that previous Ebola disease outbreaks had never been that intense, as shown in *Michael Marx*'s contribution in this edited volume. Ebola could have become more globalized, but luckily the epidemic's peak is now over, even if additional cases have emerged afterwards.[2] Ebola especially hit those countries with extremely weakened health systems.[3] As a result, studying the Ebola crisis will ideally equip us with knowledge on managing future crises with similar potential. Ebola could serve as a wake-up call for the international community, but while reports on the Ebola response broadly agree on action plans concerning compliance with the International Health Regulations (IHR) and strengthened international institutions, preparedness is yet insufficient, as a very recent study indicates.[4] Next to Ebola, other major epidemics and pandemics include cholera, various influenza outbreaks, yellow fever, and the Zika virus in the Americas.[5] In 1980, the World Health Assembly (WHA) declared the eradication of smallpox following surveillance and vaccination campaigns[6] – a unique case. Ebola has been classified as either an epidemic referring to a disease outbreak rapidly spreading from one person to another, or even as a pandemic referring to a global disease outbreak.[7] However, Ebola was by and large contained within the West-African region. Those preferring to declare Ebola a pandemic disease outbreak usually wish

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2 WHO Ebola Response Team, "After Ebola in West Africa – Unpredictable Risks, Preventable Epidemics" (2016), 375 *The New England Journal of Medicine*, 587 (593-594). See also Gates, B, "The Next Outbreak? We're not Ready" (March 2015), *TED Talks*, available at http://bit.ly/2sOc0rI.

3 In its World Health Report (WHR) 2000, the WHO comparatively ranked health system performance from 191 countries. Guinea was placed 161, Liberia 186, and Sierra Leone 191 of 191. The ranking was so controversial that it has not yet been repeated. Yet, single indicator data for individual countries could still lead to similar conclusions, see http://www.who.int/gho/en/ and http://www.who.int/healthinfo/indicators/en/.

4 See Moon, S, Leigh, J & Woskie, L et al., "Post-Ebola Reforms: ample analysis, inadequate action" (2017), 356:j280 *The British Medical Journal (BMJ)*.

5 See only for WHO's work on epidemic and pandemic diseases: http://www.who.int/csr/disease/en/.

6 See Resolution "Declaration of Global Eradication of Smallpox" WHA 33.3 of 1980, adopted at the 33rd WHA, available at http://apps.who.int/iris/handle/10665/155528.

7 See entries for "Epidemic" (339), "Epidemic Diseases" (339), and "Pandemic" (1082) in Kirch, W (ed.), *Encyclopedia of Public Health*, 2008; see also Morens, D, Folkers, G & Fauci, A, "What is a Pandemic?" (2009), 200 *The Journal of Infectious Diseases*, 1018 (1018-1020).

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to emphasize the global factors shaping any disease outbreak currently.[8] In turn, the WHO declared Ebola to be a Public Health Emergency of International Concern (PHEIC), in light of its spread throughout several countries.[9] The Ebola crisis hit countries with highly unstable health systems particularly hard. Authors diverge in their opinion of classifying Ebola as either an epidemic or a pandemic, which can be considered as the result of an unclear distinction between both terms that emerges from long-lasting scientific debates.[10] Similar to this classification problem, the exact duration of the Ebola crisis is to an extent disputed. The WHO and also the Centers for Disease Control and Prevention of the United States (CDC) refer to the first relevant reported cases as occurring in March 2014.[11] However, some scientific articles refer to the year 2013 as the initial outbreak year.[12] The WHO officially declared the end of the Ebola crisis at different points of time for various countries: On November 7, 2015 for Sierra Leone; on December 25, 2015 and once again on June 1, 2016 for Guinea; and on June 9, 2016 for Liberia.[13] Consequently, and depending on how diverse factors are weighed, the end of the Ebola crisis is stated as occurring either in the year 2015 or 2016. Individual contributions in this edited volume mirror this diversity in interpreting scientific evidence and the factual issues related to the chronology of Ebola-related developments in West Africa.[14]

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8 See for example Richardson, E, Bailor Barrie, M & Kellie, J et al., "Biosocial Approaches to the 2013-2016 Ebola Pandemic" (2015), 18 *Health and Human Rights Journal (HHR)*, 115 (115).

9 See WHO, *Statement on the 1st meeting of the IHR Emergency Committee on the 2014 Ebola outbreak in West Africa*, available at http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/.
For a more detailed overview of the Ebola crisis' chronology, see WHO Ebola Response Team, "After Ebola in West Africa", above Fn. 2, 587-591.

10 Consequences of the lack of clarity in the use of terms during the 2009 H1N1 Influenza Pandemic are further discussed in Abeysinghe, S, *Pandemics, Science and Policy. H1N1 and the World Health Organization*, 2015, 7-16.

11 See WHO, *Ebola challenges West African countries as WHO ramps up response*, Note for media, available at http://www.who.int/mediacentre/news/notes/2014/ebola-response/en/ and CDC, *Outbreaks Chronology: Ebola Virus Disease*, available at https://www.cdc.gov/vhf/ebola/outbreaks/history/chronology.html.

12 See Richardson, Bailor Barrie & Kellie et al., "Biosocial Approaches", above Fn. 8, 115.

13 See an overview in *WHO Press Releases on Ebola*, available at http://www.who.int/mediacentre/news/ebola/press-releases/en/.

14 On this issue, the contribution of *Wolfgang Hein*, "The Response to the West African Ebola Outbreak (2014-2016): A Failure of Global Health Governance?" in this volume is of particular relevance. A series of subsequent facts leading to

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The individual contributions in this book are inter-connected, clustered, and corresponding to the broader theme outlined. The book starts with introductory perspectives on the field of Ebola within the setting of international health law (*"Framing the Field"*). It continues with contributions on *"The Role of the Human Right to Health"* as a cornerstone of international health law generally, and infectious disease governance particularly. Afterwards, the role of *"International and Regional Organizations and the Securitization of Health"* is analyzed, also in light of the fact of their relevance in managing the Ebola crisis. The edited volume closes with contributions on *"Governance Beyond the Law"*.

The introductory contribution (*"Framing the Field"*) to this edited volume is given by *Marx* from a public health perspective. In his contribution titled "Ebola Epidemic 2014-2015: Taking Control or Being Trapped in the Logic of Failure – What Lessons Can Be learned?", he provides for an account of the Ebola crisis, regards the disease outbreak within the context of larger public health trends, and describes it as a wake-up call for the international community. Health systems strengthening (HSS) is at the core of his argument, also by taking stock of the new Sustainable Development Goals (SDGs). *Wolfgang Hein* responds to *Marx* as a scholar rooted in public health as well as political science with his contribution "The Response to the West African Ebola Outbreak (2014-2016): A Failure of Global Health Governance?". When characterizing the Ebola disease outbreak, and taking the complexities of the disease into consideration, he questions if the international response really can only be captured as a failure. After addressing *Marx*'s overview of the dire scenario of the national health systems most affected by Ebola as well as the lack of effective response by international stakeholders, *Hein* wonders how the final success in combating the regional disease outbreak can be adequately captured. The broader international background is then taken up by *Mateja Steinbrück Platise* in her contribution, "The Changing Structure of Global Health Governance". She scrutinizes how international organizations are increasingly sidelined in favor of alternative fora. This is reflected in debates on major trends such as privatization, fragmentation, and de-formalization. She seeks to analyze how international organizations could become more legitimate by incorporating diverging interests within a public space. *Steinbrück*'s findings are followed by *Leonie Vierck*, who examines "The Case Law of International

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the Ebola crisis are quoted for assessing the dynamics and failures of the response by institutions, such as the WHO and the CDC, as part of the overall global health governance setting.

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Health and Why its Scarcity is a Problem". In a first step, she takes stock of the fragmented body of case law existent in international infectious disease law, and shows in a second step how this is a phenomenon in international health law generally. In a third step, she enquires into the function of case law in legal systems, and argues that the virtual absence of coherent case law makes the legal argument too invisible with the governance system favoring empirical science arguments.

The second section of the book (*"The Role of the Human Right to Health"*) reflects on the role of the human right to health as entry to a broader system of international health governance. In her article titled "The Right to Health in International Law – Normative Foundations and Doctrinal Flaws", *A. Katarina Weilert* focuses on the human right to health, and explores its various dimensions, especially as concerns its complex legal interpretation. The contribution is innovative in exploring the tensions between individual health rights claims and public health policy – both dimensions are normatively enshrined in the right to health, and become especially pertinent during infectious disease outbreaks. The realization of the right to health, especially in its public health dimension, is exceeding a classical individual right and therefore is also seen as a policy strategy which asks for a broader approach of International Health Governance. In order to clarify in how far a human right to health can serve as a basis of obligations for states to engage beyond their territory, *Elif Askin* specifies the "Extraterritoral Human Rights Obligations of States in the Event of Disease Outbreaks". She argues that state obligations are not limited to the IHR, and presents a framework in order to understand if and under what conditions states, which are not the territorial states of right-holders, have legal duties *vis-à-vis* individual right bearers. *Askin* makes a strong claim that such obligations are not of a mere moral or political, but legal character. This is especially the case as concerns individual entitlements of rights holders in developing countries. One aspect of the right to health is often neglected, which is in this volume given special attention by *Hunter Keys*, *Bonnie Kaiser*, and *André den Exter* who present an interdisciplinary article on (the right to) mental healthcare, and the role of non-governmental organizations (NGOs) as healthcare providers. In their piece "The Real Versus the Ideal in NGO Governance: Enacting the Right to Mental Healthcare in Liberia During the 2014-2016 Ebola Epidemic", they mix anthropological and international law insights and provide a case study on international "soft law" guidelines such as the Inter-Agency Standing Committee (IASC)'s Guidelines on Mental Health and Psychosocial Support in Humanitarian Settings governing such NGO activities. Such guidelines can be traced back

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to the human right to health. They are brought alive and to their limits when testing their application – using anthropological methods – during their utilization.

The third section of this edited volume is reflecting upon *"International and Regional Organizations and the Securitization of Health"*. A particular emphasis is given to the legal analysis of the WHO's governance. In his article "The World Health Organization's Governance Framework in Disease Outbreaks: A Legal Perspective", *Pedro A. Villarreal* describes the institutional set-up of the WHO infectious disease governance framework, and explains the factors contributing to shortcomings when responding to the Ebola crisis. The WHO is often seen as a bureaucracy based on rational authority which, ultimately, exercises discretion when interpreting legal instruments such as the IHR. Initial questions on how it has exercised this authority in recent outbreaks could subsequently pave the way for normative debates in the future. When dealing with trans-border outbreaks of infectious diseases like Ebola in West Africa, regional organizations are also a part of the picture. *Edefe Ojomo* provides significant insights into "Fostering Regional Health Governance in West Africa: The Role of the WAHO". *Ojomo* does not only describe the institutional set-up of the West African Health Organisation (WAHO) as a specialized agency of the Economic Community of West African States (ECOWAS) in the case of the Ebola crisis, but also explains them against a backdrop of capacity and legitimacy concerns. She shows that regional institutions can support capacity building, and enhance the legitimacy of both national and global institutions. Next to the WHO and WAHO, which are already by their mandate concerned with an improvement of international health structures, another institution has come into focus on the occasion of the extreme dimensions of Ebola which gave rise to security concerns: *Ilja Richard Pavone* turns to the role of the United Nations (UN) Security Council in his article "Ebola and Securitization of Health: UN Security Council Resolution 2177/2014 and Its Limits". For the first time in history, this Resolution authoritatively qualified an infectious disease as a threat to international peace and security according to Article 39 of the UN Charter. *Pavone* wishes to understand whether this was an isolated decision or rather an indicator for the process of the securitization of health. He reflects on the underlying conceptual implications, especially in consideration of the concept of human security. *Pavone*'s considerations are also related to those by *Robert Frau,* who in his article "Combining the WHO's International Health Regulations (2005) with the UN Security Council's Powers: Does it Make Sense for Health Gover-nance?", connects the same Security Council Resolution with the

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WHO's legal regime, particularly the IHR. *Frau* is convinced that rendering the IHR legally binding would not have a game-changing effect. However, con- necting the WHO legal framework to the Security Council, as has been evidenced for the first time during the Ebola crisis, would create legal impact – especially if combined with a human right to health approach in the interest of the individuals affected.

The fourth and last section of this book (*"Governance Beyond the Law"*) opens the floor for non-legal governance approaches which can at times even challenge a law oriented view. A specifically critical voice is included with *Susan L. Erikson's* article "The Limits of the International Health Regulations: Ebola Governance, Regulatory Breach, and the Non-Negotiable Necessity of National Healthcare". From an anthropological point of view, she questions the very idea of bindingness of the IHR in light of on-the-ground realities that considerably diverge from normative standards designed at the international level. *Erikson* refers to fieldwork done during the Ebola crisis in order to substantiate her thesis. She calls for shifting more attention towards national healthcare systems, particularly that of Sierra Leone, and not primarily to international instruments such as the IHR. Notably, she emphasizes how this need for strengthening health systems should pre-date promoting regulations deriving from the international community. Thus, her arguments aim towards framing the IHR as guidelines for other operational programs, instead of being legally binding regulations. Namely in this sense, her standpoint diverges from that of other contributions in this volume, including the current introductory chapter. Although not specifically mentioned, *Erikson*'s first-hand experiences are drawn from areas characterized by limited statehood. These areas pose a challenge to common law categories as law presupposes effective state-actors. Questions around this field are taken up by *Christian R. Thauer*, who closes the edited volume with his article "The Governance of Infectious Diseases: An International Relations Perspective". He scrutinizes global health governance in the context of limited statehood, especially in so-called developing countries. *Thauer* shows that limited statehood has been largely ignored as a contextual factor of international disease outbreaks, and especially suggests assigning new roles to non-state actors, including the private sector, in global health governance. His argument also builds upon prior research on the HIV/AIDS pandemic in South Africa.

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2 The Development of the Book Project and the Broader Context

The IHG project is connected to the broader International Public Authority (IPA) framework. IPA provides a theoretical basis for analyzing the public authority exercised by international institutions. These institutions have been distinguished by world public opinion as ambivalent actors which are necessary, but raise serious legitimacy concerns at the same time. IPA proposes a theory of international public law, and not only public international law when identifying, reconstructing, and developing the law governing international institutions.[15] Earlier IPA works include publications on diverse international institutions,[16] and international courts as multifunctional judicial institutions.[17] While IPA is a theory-building contribution in order to scrutinize international institutions from an international law perspective, not all articles touch upon public international law theory building, and some are decidedly devoted to its practical application.

Also, IPA corresponds with other approaches such as Global Administrative Law (GAL).[18] *Ojomo* from New York University (NYU) adopts a typical GAL approach in her contribution within this volume. While contributions from other disciplines – public health, political science, and anthropology – inform the overall international public law methodology chosen for this edited volume, inter- or trans-disciplinary approaches were off limits for the explorative nature of the project. The IPA methodology as well as a specific interest in and knowledge of the system of the WHO from the MPIL's side merged with health-related research at the FEST. *Weilert* was leading an interdisciplinary working group at the FEST-Institute, which was centered around questions of responsibility for health within the national arena. Leading questions in this working group include "what is health and to what extent is the answer to this dependent on one's culture?", "what are the social determinants of health?", "how does the international human right to health relate to the national health system?",

15 See most recently Bogdandy, A von, Goldmann, M & Venzke, I, "From Public International Law to International Public Law: Translating World Public Opinion into International Public Authority" (2017), 28 *EJIL*, 115-116.

16 See especially Bogdandy, A von, Wolfrum, R & Bernstorff, J von et al. (eds.), *The Exercise of Public Authority by International Institutions: Advancing International Institutional Law*, 2010.

17 See most notably Bogdandy, A von & Venzke, I, *In Whose Name? A Public Law Theory of International Adjudication*, 2014, 8 et seq.

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

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"how far does the health responsibility of the state extend and where is the individual responsibility of every person coming in?" and finally "is there a duty for a state to empower the individual in order to take over responsibility for one's health?". It became obvious that many questions arising in the national context needed further discussion in an international context. A few examples may illustrate this finding: While in the national context, the principle of solidarity can be seen as solidarity between the inhabitants of this country, in the international sphere the principle of solidarity plays a role between states. Also, unequal health opportunities are already a challenge within one country and even more so between the people of different states. Likewise, the question of whether states can restrict the freedom of the individual in order to improve health (and health security) can be seen as both an internal matter as well as an international problem. Broadly speaking, in the national context we are looking at the spheres of the state, private entities and the individual and query their responsibilities. In the international context, questions of responsibility also refer to the relationship of further international actors such as the community of states, international institutions (in particular international organizations), NGOs, transnational corporations and other private entities.

3 The West African Ebola Crisis as a Central Focus

Against the background of these research interests of the institutes involved and due to the failed international governance at the early stage of the Ebola outbreak, a workshop was set up (March 3-4, 2016) which identified many questions as to the state of international law in the context of international health governance. About 20 scholars from different parts of the world and different academic backgrounds were selected following a call for abstracts. The devastating effects of Ebola were reinforced not only by poor health systems and poor management of the affected states; the lack of organization to fight such an epidemic on the international level also became obvious. Epidemics control at the international level questions a traditional view of public international law in two ways: First, two different logics are at stake. On one hand, states feel challenged to fight Ebola for *security* reasons as epidemics easily transgress borders by people traveling all over the world. On the other hand, besides the concern for their own people, the idea of *development aid* has been growing since the 1970s due to an increasing sense of responsibility for other countries in a globalized world. This means

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that the same action can be rooted in the traditional idea of state security as well as being motivated by a human rights perspective.

Secondly, there is – as in many other fields of international law today – a great variety of actors and a confusion as to their roles, responsibilities and duties with regard to epidemics control. States are the main addressees of the right to health but their role is unclear if it comes to a cross-border situation. The WHO should fill in this gap, but seemed to suffer from several structural shortcomings which hindered a better handling of the situation. The WHO has a large administrative responsibility that affects individuals, private associations, public institutions and states. Its organs can enact binding regulations (such as the IHR) and more extensive non-binding regulations (such as recommendations, resolutions, and standards). The latter are often observed even though they are not legally binding. Therefore, the workshop partially pursued an actor-oriented approach. Such an approach is aimed at understanding the roles, responsibilities, legal duties and actions of states, international organizations (as the WHO or corresponding regional organizations) and non-state actors. The workshop consisted of the following components, which differed from the structure that later evolved for the present edited volume: In its first section, the Ebola crisis was analyzed and we primarily covered sustainable health and development policies. Policies and law are intertwined, yet distinct from each other. In international law, we face the fact that the rule of law is relatively fragile. The shortcomings in enforcing international law were especially referred to in Section II from different disciplinary perspectives. These ranged from a skeptical view towards norms over the particular challenges for the rule of law in areas of limited statehood to a mirror of ineffectiveness of the right to health under the African Charter on Human and People's Rights. However, new developments towards an even stronger international law were also discussed while reflecting upon the extraterritorial obligations of states in cases like Ebola. The potential of international law was further developed in Section III, which was dedicated to the role of two major players in international law: The WHO and the Security Council. Here, questions of international health governance directly met questions as to the development of international law. In its last section (IV), the workshop dealt with the role of regional organizations and private actors in disease outbreaks. The workshop made obvious that it is not easy to have a common language and common way of addressing the open questions in this field. Recognizing the considerable research deficit in this discipline, we decided to engage in the arduous work of publishing articles presented at the workshop not as they stood, but only after a thorough revision.

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All articles provided by participants of the workshop were peer reviewed and commented upon, so that the authors could further develop their argumentation. The approach of this book is a legal one stemming from public international law and international public law, which is necessarily informed by other disciplines, but not generally interdisciplinary. In the future, developing a more advanced interdisciplinary approach could be a further step for intensifying the IHG project as such. As IHG is a very peculiar field of law, the edited volume mainly addresses the public international law community, including practitioners next to researchers, and especially those already concerned with phenomena of international administrations. If disciplines close to public international law, especially international relations, also find an interest in this publication, this would create an additional value. Given how legal obligations often collide with political and moral ones, it may be of some interest from the political theory audience, too. Last but not least, the international public health community is particularly important for obvious reasons – yet bridging the divide between predominantly empirical science and largely normative research is a challenge on its own.

II Conceptual Thematic Inputs

1 International Health Law and Infectious Disease Governance: What is it and why is it Important?

Discussing a specialized field for international health law evokes the idea of the fragmentation of international law.[19] It currently consists of a dispersed set of norms, standards and regulations which, strictly speaking, might not be limited to health issues. Although the WHO possesses the authority to create norms related to health,[20] it has only exceptionally been used.[21] And even health-specific legal instruments such as the IHR and the Framework Convention for Tobacco Control (FCTC) have considerable overlaps with fields such as trade and investment law, or even human rights

19 See the International Law Commission Report, *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*, finalized by Martti Koskenniemi, A/CN.4/L.682, 2006.

20 Gostin, L, Sridhar, D & Hougendobler, D, *The normative authority of the World Health Organization*, 2015, 854 (856-857).

21 Burci, G L & Vignes, C H, *World Health Organization*, 2004, 141.

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law. The rationale changes in each one, meaning that health arguments might enter into tension or even conflict with economic ones.

Due to the non-autonomous nature of international health law *vis-à-vis* other fields,[22] there is still a pending task of defining its contents without reference to another field. An ensuing consequence of its autonomy could be a growing group of specialized research addressing very specific topics, which means it would be directed at a particular audience.[23] But initially, the conceptual arguments for considering a legal field as autonomous would need to be convincing. This endeavor would extend beyond the scope of this edited volume, requiring a full-fledged textbook instead. Nevertheless, it is already possible to identify an ongoing academic discussion dealing with attempts to draw more concrete components of the field.[24] Whether or not this specialization will become entrenched throughout the academic community remains to be seen.[25]

In light of these unclear conceptual boundaries, suffice it to say that the control of the spread of infectious diseases has been at the core of international health ever since the first interstate meetings on this topic took place in the 19th Century. While the International Sanitary Conference of 1851 marked the first time in which twelve countries met for dealing with health matters, it did not give way to a lasting legal document.[26] Even after

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22 An argument put forward by Fidler, D, "International Law and Global Public Health" (1999), 48 *The University of Kansas Law Review*, 1 (27-40).

23 Already a trend identified in the United States of America by Posner, R, "Legal Scholarship Today" (2002), 115 *Harvard Law Review*, 1314 (1319-1322).

24 See Toebes, B, "International health law: an emerging field of public international law" (2015), 55 *Indian Journal of International Law*, 299. By contrast, within international relations and political science the strand of "global health governance" has been developed to a larger extent, see Hein, W, "The New Dynamics of Global Health Governance" in Kickbusch, I, Lister, G & Told, M et al. (eds.), *Global Health Diplomacy: Concepts, Issues, Actors, Instruments, Fora and Cases*, 2013, 56-59.

25 For instance, recently an Interest Group on International Health Law has been founded at the European Society of International Law (ESIL). See http://www.inthealthlaw.com/. Another outstanding example is the O´Neill Institute for National and Global Health Law at Georgetown University, located in Washington, D.C., the existence of which already spans ten years. See http://www.law.george-town.edu/oneillinstitute/about/index.cfm.

26 For more on this event, see Goodman, N, *International Health Organizations and Their Work*, 1971, 46-51; likewise, see Kickbusch, I & Ivanova, M, "The History and Evolution of Global Health Diplomacy" in Kickbusch, Lister & Told et al. (eds.), *Global Health Diplomacy*, above Fn. 24, 12-13.

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the adoption of the International Sanitary Convention of 1893, infectious disease epidemics control was addressed through *ad hoc* meetings and an overall "patchwork" legal process of updating lists of diseases subjected to quarantine procedures.[27]

After several reviews and iterations of the Sanitary Conventions, this inconsistent trend seemed to shift with the adoption of the Constitution of the WHO in 1946, particularly with the inclusion of extraordinary legal powers to the WHA for adopting regulations in the area of infectious disease outbreaks.[28] But throughout its first five decades and despite the creation of the International Sanitary Regulations in 1951 and the 1969 version of the IHR, these legal powers of the WHO were only rarely resorted to, leading some to consider them as "underutilized".[29]

In the same vein, the emergence of the 2005 version of the IHR was meant to explicitly address existing gaps in infectious disease epidemics control through an innovative governance framework for the WHO's authorities.[30] However, several years and outbreaks later, as this book's contents highlight, the shortcomings of this legal framework are evident on multiple levels. And, as seen also in several contributions in this edited volume, the role of law in global health governance is relatively limited in its reach, as states continuously resort to informal channels for addressing core issues of international health.[31]

Against this backdrop, events such as the 2014-2016 West African Ebola crisis or the 2016 Zika epidemic are health issues at the core, even if they also involve economic or human rights aspects. Under this assumption, a health-based legal framework would prevail over others. Yet, since there is

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27 Fidler, D "From International Sanitary Conventions to Global Health Security: The New International Health Regulations" (2005), 4 *Chinese Journal of International Law*, 325 (329-333).

28 See also Lee, K, *World Health Organization (WHO)*, 2009, 16-18; others emphasize how this is one of the core issues where the WHO has an explicit mandate, as opposed to other institutions. See Ooms, G & Hammonds, R, "Global constitutionalism, applied to global health governance: uncovering legitimacy deficits and suggesting remedies" (2016), 12 *Globalization and Health*, 1 (11), available at http://europepmc.org/articles/PMC5135750.

29 Aginam, O, G*lobal Health Governance. International Law and Public Health in a Divided World*, 2005, 71.

30 Fidler, "From International Sanitary Conventions", above Fn. 27, 358 et seq.

31 See the contribution of *Mateja Steinbrück Platise*, "The Changing Structure of Global Health Governance" in this volume.

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a scarcity of case-law related to these health issues, there is no data concerning the application of law to particular cases through adjudication, whether it is provisions from the IHR or other legal regimes that also deal with health issues.[32] Consequently, it is difficult to speak of a consistent legal field, which would encompass an ever-growing body of criteria for interpretation coupled with the consolidation of specialized professionals within epistemic communities.

For the sake of the thematic contributions and the legal perspective joining them, it is necessary to discuss the applicable law of international public health. How to define it? And what are the conceptual difficulties faced? International health law is not governed by any multilateral umbrella treaty, but builds upon an underlying concept ("international public health") across diverse public international law regimes.[33] International health law would rather be an example of a fragmented public international law regime. Some authors see international health law as an evolving body of law, especially fulfilling demands of so-called developing countries – an old attestation, which still holds true today.[34] Why then make it the focal point for considerations within public international law? There are different lines of argument. Globalization renders public health more international, and creates ever more pressing social needs – as can be evidenced above for infectious disease outbreaks. Law is one tool used in responding to these increasing needs – public health specialists, for example, advocated for the WHO FCTC as an important, multilateral treaty in the area.[35] In this edited volume, international health law can include legal norms and institutions concerned with international public health. There are diverging opinions whether or not these norms and institutions necessarily have to be geared towards the human right to health – also across the contributions. In this approach, we also consider actors that may not be subjects of international law (for example, NGOs and private businesses) to be important players if governed by public international law. The IPA approach can allow one to

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

33 Ibid.

34 See in particular Bélanger, M, "Une nouvelle branche du droit international: Le droit international de la santé" (1982), 13 *Études internationales*, 611 as an article written probably way ahead of its time, calling for a New International Economic and Health Order in the 1970s.

35 See Toebes, "International health law", above Fn. 24, 299. Toebes also makes the point for the intrinsic fragmentation of this wider field of law.

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bypass many of these questions by centering the analysis on concrete authoritative actions. These are understood as actions which have an impact on others' freedom(s), either at an individual or at a collective level, by modifying a legal situation or even factually affecting persons or, considering the international level, even states.[36]

Additionally, some definitions of global health law include an ethical component, and result in a research agenda to increase social and global justice.[37] This clearly goes beyond a positivist approach to global or international health law. While law can be a tool to reach justice, an even broader domain for analyzing justice demands is political theory.[38] Another approach to define international public health law is a descriptive listing of relevant legal instruments (like treaties) according to issue areas (such as drug control or occupational health and safety).[39] While the relevance of legal instruments in specific areas of international public health law is undisputed, the general recognition of international health law as a special regime of public international law still has to be built. Research on international health law can play an important role in advancing legal concepts, which can eventually be taken up by practice.[40]

2 The Role of the Right to Health for Shaping the Field?

The right to health, as elaborated in the contribution of *Weilert*, comprises an individual right to health and an obligation to promote public health

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36 Bogdandy, Goldmann & Venzke, "From Public International Law to International Public Law", above Fn. 15, 139-140.

37 See Gostin, L & Taylor, A, "Global Health Law: A Definition and Grand Challenges" (2008), 1 *Public Health Ethics*, 53 (55).

38 See for an introduction (on different philosophical streams) Prah Ruger, J, "Health and social justice" (2004), 364 *The Lancet*, 1075, and more specifically for example the "Special Issue: Health Justice and the capabilities approach: Essays on Sridhar Venkatapuram's work" (2016), 13 *Bioethics*, 1. The health justice approach is very rich, and in the international realm particularly relevant as concerns justice between the people of different states and in different areas of the world.

39 See for example Taylor, A, "International Law, and Public Health Policy" in Quah, S & Heggenhougen, K (eds.), *International Encyclopedia of Public Health*, 2008, 667 (668). For more detail see the discussion in the contribution of *Leonie Vierck*, "The Case Law of International Public Health and Why its Scarcity is a Problem" in this volume.

40 It should be noted this is not the only function of legal research. See Taekema, S, "Relative Autonomy. A Characterisation of the Discipline of Law" in Klink, B von & Taekema, S (eds.), *Law and Method*, 2011, 33 (37-39).

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(standards). As an individual human right, the right to health should be perceived in a narrower sense focusing primarily on medical care. As an obligation to promote public (population) health, the human right to health can be seen in a broader context, embracing also the underlying determinants of health. The prevention and combat of epidemics is one of the main fields of public health. The most important source for the right to health is Article 12 International Covenant on Economic, Social and Cultural Rights (ICESCR). Thereby, states are obliged to respect, protect and (to a certain degree) fulfill the requirements under the right to health. In the well-known interpretation in General Comment 14, the Committee on Economic, Social and Cultural Rights (CESCR) stresses that the state's obligations are not restricted to the national context, but that

> "States parties should recognize the essential role of international cooperation and comply with their commitment to take joint and separate action to achieve the full realization of the right to health. In this regard, states parties are referred to the Alma-Ata Declaration which proclaims that the existing gross inequality in the health status of people, particularly between developed and developing countries, as well as within countries, is politically, socially and economically unacceptable and is, therefore, of common concern to all countries."[41]

Therefore, the right to health also has a transnational dimension of health justice and can be one catalyst for international public health and international health law. The commitment to the right to health is one reason (next to security and economic interests in health) for the motivation of states and other actors to enable health for everyone worldwide. As mentioned before, *Lawrence Gostin* defines global health law as encompassing all hard-law and soft-law instruments "that shapes norms, processes, and institutions to attain the highest attainable standard of physical and mental health for the world's population".[42] International public health and international health law imply a variety of actors and are not related merely to states and international organizations. In this respect, they go beyond the classic shape of the human right to health which is so far primarily state-based as they are the parties to the respective treaties.[43] However, the contents of the right to health as developed under Article 12 ICESCR is also

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41 CESCR, *General Comment No. 14 on the right to the highest attainable standard of health E/C.12/2000/4*, para. 38.

42 Gostin, L, *Global Health Law*, 2014, 59.

43 Ibid., 61 et seq. Gostin sees the state-centric orientation of international law as a "serious limitation". Since international organizations and also individuals could be seen as subjects of international law, the shortcoming of international law especially refers to non-state actors.

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referred to as a standard by other actors and serves as a driving force for the WHO[44] with its instruments, which can even be binding.[45] The human right to health can perhaps even be seen as a catalyst for the further development of WHO instruments. And the right to health might even serve as a "constitutional right" (not, of course, in its proper legal understanding, but more as a portrayal of the factual situation) in so far as it gives the broad picture and the threshold for other programs, institutions, actions, and (mainly soft-) law mechanisms. Without the underlying right to health as laid down in various treaties, international public health and international health law might only consist of policy concepts. Therefore, the right to health is a "vital aspect"[46] of international health law. On the downside, in international law, policy strategies and soft-law mechanisms are much more important than in national law due to the shortcomings of the limitations of treaty law (often only vague standards, lack of enforceability and no direct obligations for non-state actors).[47] Thus, a term like "international/global health law" needs to take into account the fact that international health governance is only somewhat law-related and partly follows a political agenda.

The response of the international community to the Ebola crisis also gave rise to question the role of ethics and ethical responsibilities. A prominent position to help in the affected countries was taken by Médecins Sans Frontières (MSF), an influential and well-financed NGO, who happened to be in the field early during the outbreak of Ebola. NGOs are not subject to international law and, therefore, are not bound by any treaties or customary rules. MSF's motivation to help is rooted in the "belief that all people should have access to healthcare regardless of gender, race, religion, creed or political affiliation, and that people's medical needs outweigh respect for national boundaries."[48] This is an ethical and political statement, but at the same time also an acknowledgement of a human right to health. Likewise, when states or the European Union provided bilateral or multilateral help to countries affected by Ebola, they did not solely act out of security interests or due to any international legal obligation, but also out of a sense of moral

44 It is also to be noted that the preamble of the Constitution of the WHO declares that the "enjoyment of the highest attainable standard of health" to be a fundamental right of every human being.
45 Compare Article 21 of the Constitution of the WHO.
46 Gostin, *Global Health Law*, above Fn. 42, 68.
47 Ibid., 64.
48 *MSF History*, available at http://www.msf.org/en/msf-history.

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obligation.[49] Therefore, international health law is closely connected to the ethical conviction that powerful international entities (such as states, NGOs or other private actors) have a moral obligation to help others in need. The ICESCR has carefully maintained that this moral obligation of states is even a legal one in Article 2 para. 1, which is also read as a duty of the states to cooperate for the sake of human beings beyond their own borders.[50] The CESCR draws attention to the latter provision when fleshing out the right to health according to Article 12 ICESCR and asks State Parties to "recognize the essential role of international cooperation and comply with their commitment to take joint and separate action".[51] This is closely connected to the far reaching idea of international health justice,[52] a strong ethical claim. Although this is not the place to dwell on any theory concerning the relationship between ethics and international law,[53] a few observations can be made. Ethical claims can have a stronger impact within the international arena than in the national sphere. In the national realm, ethics can influence law-making processes (parliaments might enact a special law due to the prevailing ethical opinion of the majority). In international politics, ethical claims can also lead to binding treaty law. Ethical claims can, however, also be observed by states and other international actors. Since there are weaker mechanisms for enforcement in international law, ethical claims can have considerable weight compared to treaty law. Furthermore, the premises of human rights are based on strong ethical convictions about the position and worth of the individual human being after mankind had experienced the

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49 EU Commissioner *Tonio Borg* spoke of a moral obligation of the EU to help Ebola-affected countries (September 3, 2014), available at http://bit.ly/2tcWhl7. The question was also raised at the 51st Munich Security Conference 2015, which took place along the theme of "collapsing order, reluctant guardians". Namely, whether or not states have a moral obligation to defend human rights (in a cross-border sense), also including multilateral aid against Ebola. See http://bit.ly/2rEa1F5.

50 Compare for a transnational legal obligation to help the contribution of *Elif Askin*, "Extraterritorial Human Rights Obligations of States in the Event of Disease Outbreaks" in this volume.

51 CESCR, *General Comment 14*, above Fn. 41, para. 38.

52 See already above Fn. 38.

53 Compare here Boldizar, A & Korhonen, O, "Ethics, Morals and International Law" (1999), 10 *EJIL*, 279-311; Jones, D, "Law, morality and international affairs" in Nardin, T & Mapel, D R (eds.), *Traditions of International Ethics*, 2008, 57 et seq.

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consequences of two world wars in the first half of the 20th century. However, international law today is usually not consciously rooted in natural law thinking[54] anymore. Nevertheless, the far reaching and well received interpretation of the human right to health as put forward by the CESCR[55] shows that a strong ethical drive is having an impact on the development of international law.[56]

3 Why Use Governance as a Basis?

The idea of governance emerged as a possible frame for the contents of this book, in so far as it can contribute to open a space beyond the distinctions of what is considered "law" and what is not. The seminal work of *James Rosenau* on the topic can provide a starting point.[57] Although the post-Cold War world order in which the expression proliferated has been in continuous flux, its use still holds in many regards. The locus of authority at the international level is scattered beyond the nation-state, encompassing more than just governments and their actions.[58] The flexibility of the term governance allows for the inclusion of phenomena which would otherwise be lost under blunt binary distinctions of state vs. non-state, government vs. private actors, or legally binding vs. non-binding. It can also be noted, however, that this conceptual broadness has been the source of criticisms.[59] Its wide formulation can risk putting diverse actions under the same aegis, subsequently omitting important distinctions, for instance, between acts of authority from exclusively private acts.[60]

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54 Compare Boyle, J, "Natural law and international ethics" in Nardin & Mapel (eds.), *Traditions of International Ethics*, above Fn. 53, 12 et seq.

55 CESCR, *General Comment 14*, above Fn. 41.

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

57 Rosenau, J, "Governance in the Twenty-first Century" (1995), 1 *Global Governance*, 13 (13).

58 Rosenau, J, "Governance, Order, and Change in World Politics" in Rosenau, J & Czempiel, E-O (eds.), *Governance Without Government: Order and Change in World Politics*, 1992, 4-5.

59 See already Finkelstein, L, "What is Global Governance?" (1995), 1 *Global Governance*, 367 (367-369).

60 This criticism of (global) governance is already made in Bogdandy, A von, Goldmann, M & Dann, P, "Developing the Publicness of Public International Law: Towards a Legal Framework for Global Governance Activities" in Bogdandy,

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Nevertheless, given how the field of international health is highly fragmented, the term governance can, beyond its pitfalls, be suitable for analyzing phenomena that take place beyond the scope of states. The presence of both NGOs and even the private sector, requires a broader grasp that is not hindered by a state-centered approach. As the WHO is not alone in the international arena, rather acting in the field of health alongside other actors,[61] this requires a step forward from the institutional approach. Usually governance presupposes a certain degree of organization, authority and hierarchy. *Lawrence Gostin* describes governance as the "method by which organized society directs, influences, and coordinates the activities of multiple private and public actors to achieve collective goods".[62] However, there is no "organized society" in a strong sense in the international arena.

In addition, the idea of governance has a direct link to legal theory, as they both address an international order composed of states and other actors, as well as their relationships of power with individuals, i.e. their exercise of authority.[63] However, whereas the flexibility of the term governance further enables the analysis of a complex international arena, a positivist legal approach related namely to international law operates mostly on binary distinctions aimed precisely at reducing such complexity: either an act is legally binding, or it is not.[64] Consequently, a legal theory grounded on formal sources of (international) law cannot provide a comprehensive answer, whereas alternative proposals have to deal with problems of "relative" normativity.[65] By contrast, in so far as governance studies tend to focus on

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Wolfrum & Bernstorff et al. (eds.), *The Exercise of Public Authority*, above Fn. 16, 10.

61 Already on the point of how the WHO has entered into partnerships with groups of non-state actors, see Burci, G, "Public/Private Partnerships in the Public Health Sector" (2009), 6 *International Organizations Law Review*, 359 (381-382). This circumstance is also referred to as marking the "golden era" of global health by Kickbusch, I & Cassar, M M, "A new governance space for health" (2014), 7 *Global Health Action*, available at https://www.globalhealthaction.net.

62 Gostin, *Global Health Law*, above Fn. 42, 72.

63 On the role of private actors as authorities through a governance perspective, see Sinclair, T J, "A private authority perspective on global governance" in Hoffmann, M & Ba, A D (eds.), *Contending Perspectives on Global Governance*, 2005, 179.

64 Although not every author would agree with this view. For an overview of the discussion dealing with this distinction, see Goldmann, M, "We Need to Cut Off the Head of the King: Past, Present and Future Approaches to International Soft Law" (2012), 25 *Leiden Journal of International Law*, 335 (341-346).

65 On the issue of the relationship between positivism and relative normativity in international law, see already the seminal work of Weil, P, "Towards Relative

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continuous processes and not on identifying particular acts which may be legally relevant,[66] this means that there is a lack of direct translation between research on governance and legal theory. Similarly, the presence of actors of a varied background, as well as the formal and informal nature of their acts, have thus far not been framed under a comprehensive legal framework at the international level.[67] While this is also the case for the national level, absence is even more salient at the international level, with the lack of a central government[68] capable of issuing norms, regulations, administrative acts in an exclusive manner, or considering the uncertain legal personality of non-state actors at the international level as subjects of public international law, also with regards to their possible obligations.[69] Afterwards, the goal of making descriptive sense of this puzzle is followed by a need for devising normative answers. It is precisely at this point where there is a juncture between governance and law. Here, the IPA conceptual framework comes to the fore as an attempt to provide such answers, though it is by no means the only one.[70]

With the above in mind, the idea of governance for understanding the field of international health aims, firstly, at describing a very specific problem. Disease outbreaks such as the West African Ebola crisis of 2014-2016, or the more recent Zika epidemic of 2016, involve a mixed set of actors. International and regional organizations composed by Member States, such as the WHO or the West African Health Organisation, interact with non-

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Normativity in International Law?" (1983), 77 *American Journal of International Law*, 413 (421).

66 Bogdandy, Goldmann & Venzke, "From Public International Law to International Public Law", above Fn. 15, 122-123.

67 The need for legal approaches capable of responding to this context is already put forward in Krisch, N, "Global governance as public authority: An introduction" (2012), 10 *ICON: International Journal of Constitutional Law*, 976 (982-983); see also the other articles comprising this special edition.

68 Taken from Frenk, J & Moon, S, "Governance Challenges in Global Health" (2013), 368 *The New England Journal of Medicine*, 936 (937).

69 For the case of multinational corporations, see Weilert, A K, "Taming the Untamable? Transnational Corporations in United Nations Law and Practice" (2010), 14 *Max Planck UNYB*, 445 (454 et seq.) and Weilert, A K, "Transnationale Unternehmen im rechtsfreien Raum? Geltung und Reichweite völkerrechtlicher Standards" (2009), 69 *Zeitschrift für ausländisches öffentliches Recht und Völkerrecht*, 883 (885, 915-916).

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

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state actors such as NGOs (like MSF) and even the private sector (pharmaceutical companies). Although the role of each of them tends to be analyzed separately, they also engage in occasional partnerships.[71] Additionally, these actors within the field of health do not always issue legally binding acts, rather opting for informal arrangements and *ad hoc* political agreements. In fact, states themselves can resort to alternate venues with the explicit purpose of sidelining formal venues of international organizations.[72] Since they escape any attempt at binary classifications, facts within international health can be addressed through the idea of governance, particularly understood as a method by which "organized society directs, influences, and coordinates the activities of multiple private and public actors to achieve collective goods".[73] In this regard, governance in the field of international health is characterized by common goals of providing global public goods, one of which is the containment of the international spread of infectious diseases.[74] The notion of the "global", understood as a multi-level space, is fitting for describing the interactions between the national and the international sphere.[75] The conceptualization of global health governance has been explored with more detail elsewhere.[76] For this book, we decided to focus mostly on the international level, as there is currently no possibility to properly tackle the multi-level aspect with more depth. This does not imply there is a lack of realization of the analysis required for health issues. It is only meant to emphasize the relevance of both the inherent international

71 Notably, the recent development of an Ebola vaccine was done through a multi-partner collaboration between the WHO, governments (Guinea and Norway), NGOs (Médecins sans Frontières) and even private companies (Merck). It has been already deployed during a recent Ebola outbreak in the Democratic Republic of Congo. For journalistic reports on these issues, see McNeil, D G, "New Ebola Vaccine Gives 100 Percent Protection" (December 22, 2016), *The New York Times*, available at http://nyti.ms/2uchSOP; also, Pilling, D, "Congo to test experimental Ebola vaccine as disease re-emerges" (May 23, 2017), *The Financial Times*, available at http://on.ft.com/2rAPT9Y.

72 Benvenisti, E, *The Law of Global Governance*, 2014, 37.

73 Also espoused by Gostin, *Global Health Law*, above Fn. 42, 72.

74 Zacher, M W, "Global Epidemiological Surveillance. International Cooperation to Monitor Infectious Diseases" in Kaul, I, Grunberg, I & Stern, M (eds.), *Global public goods: International Cooperation in the 21st century*, 1999, 266-267.

75 Bogdandy, Goldmann & Dann, "Developing the Publicness of Public International Law", above Fn. 60, 7; also Zürn, M, "Global Governance as Multi-Level Governance" in Levi-Faur, D (ed.), *Oxford Handbook of Governance*, 2013, 731.

76 For a glimpse, see Kickbusch, I & Reddy, K S, "Global Health Governance - the next political revolution" (2015), 129 *Public Health*, 838 (839).

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dimension of trans-border infectious disease outbreaks, as well as the ensuing response by entities that are not limited to the borders of a country.

Nevertheless, as will be seen in several contributions of this book, this choice of scope is not restrictive. The issue of the "global" is brought up as a topic for more specific analysis.[77] The emphasis on international health governance is, at this point, more of a guiding theme than a formal endorsement of a concept as opposed to others.

III What's Next?

The process that gave way to this book has yielded the realization that there is still a need for more general textbooks on the field of international health law. Tackling the conceptual challenges requires extensive argumentation, which ranges beyond the scope of this piece. Some of the works on the subject matter adopt the idea of an expansive "global" approach, since viewing it in a stricter sense would entail that the field would be quite "sparse" if it was limited only to legally binding instruments.[78] However, as it is recognized that there are other binding sources of health-related issues, the way in which health law is understood will also determine which other legal fields that hinge upon health would be included under its aegis.[79] This way, for instance, trade and environmental law would also be addressed by the area of health law. Whereas stand-alone book chapters and research articles have also dealt with this issue, they have argued for the autonomous nature of this legal field up to a certain degree.[80] It remains unclear how and why a health approach may lead to different outcomes than one focused on trade law, environmental protection, illicit drug regulation, etc. Even though health matters are explicitly incorporated into the provisions of these fields, it remains to be discussed whether a parallel health-law field would lead to different decisions or normative conclusions.

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77 See particularly the contributions of *Mateja Steinbrück Platise*, "The Changing Structure of Global Health Governance" and *Christian R. Thauer*, "The Governance of Infectious Diseases. An International Relations Perspective" in this volume.

78 Such approach can be seen, mainly, in Gostin, *Global Health Law*, above Fn. 42, 60.

79 Ibid., 69.

80 Gostin & Taylor, "Global Health Law", above Fn. 37, 55-56; Toebes, "International health law", above Fn. 24, 301-302.

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Despite these possible objections, we believe there is still a need for more research on the topic of why there can be international health law as a particular field of law. Even though literature on global health law exists, and considering the copious contributions on global health governance, there nevertheless remains a gap in legal works. Of course, speaking of approaches with a focus on law do not entail adopting a "pure", i.e. positivistic theory[81] that casts other disciplines aside. Due to requirements imposed by the interpretation of vague health-related provisions, interdisciplinary insights are necessary for making sense of the substantive health-related claims. Problems with an overarching health dimension such as those related to tobacco control or non-communicable diseases (NCDs) in general, drug policy, and others, can already be addressed through a health-centered mindset. This means that, even if they do take aspects of trade law or even criminal law into consideration, the interpretation of the purposes of instruments and provisions would focus on the (public) health perspective. For instance, the legal assessment of whether a particular measure is justified or not touches upon matters that directly fall under the distinct fields of medicine and public health. Notwithstanding the central position of public health, the IHR provide a yardstick with which acts by the WHO, such as declarations of a PHEIC as in the case of the West African Ebola crisis, or of a pandemic in the case of H1N1 Influenza, cannot be assessed by resorting exclusively to medical criteria. Their consequences are also economic and social in nature. While not without nuances and disagreements, this is also recognized by the literature in public health.[82]

In the same sense, the broad set of interests and stakeholders needs to be provided with a legal response. Some authors deal with the limits of several approaches of international institutional law, particularly those found within a functionalist strand.[83] As long as a focus on the sources of international law prevails,[84] such limitations will continue to represent a gap in legal debates. As a result, lawyers may continue to be "left out of the equation" due to this constrained normative vision. However, since there is an existing

81 The classical formulation in this sense is by Kelsen, H, *Reine Rechtslehre*, 1960, 1-2.

82 For a list of objectives, see also the Rio Political Declaration on Social Determinants of Health, adopted at the 65th WHA in 2012 through resolution WHA65.8.

83 Notably Klabbers, J, "The EJIL Foreword: The Transformation of International Organizations Law" (2015), 26 *EJIL*, 9 (79-80).

84 Generally, to those deriving from Article 38 of the Statute of the International Court of Justice.

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(international) legal framework that begins with the Constitution of the WHO and also includes the IHR, this entails that there is room for input by legal scholarship. Whether the answer is in the sense of emphasizing the potentials of reform,[85] or rather to the limits of arguments centered in international law,[86] the inclusion of discussions on law can yield insights on how to understand the role of legal norms.

As for the WHO's role in international health governance, special mention can be made of the recent WHO Director-General election, which took place in May 2017.[87] The incoming head of the WHO's Secretariat faces a post-Ebola juncture in which many of the questions addressed in this book linger on the role of the organization in exercising its legal mandate regarding disease outbreaks. Given the authority that the WHO Director-General holds with regard to the IHR, discretion exercised by officials cannot be overlooked. Although this book is not devoted to an assessment of specific officials, the responsiveness of the whole organization – a recurring criticism of the handling of the West African Ebola crisis – depends to a large extent on the Director-General's willingness to declare a PHEIC or not. Therefore, the "new administration" is also tasked with exercising authority amidst infectious disease outbreaks that spread beyond geographical borders. Furthermore, as the spread of Zika unfolded during the stage of editing this book, there is a pending task of contrasting its emergence – mostly in Brazil – with the context of the West African Ebola crisis. There is still much to be said about the underlying conditions within which this epidemic spread, as well as how the actors of global health governance – whether international organizations, states, private companies, NGOs or even individuals – contributed to the response. For starters, both the Ebola and Zika outbreaks took place within social contexts mired with economic hardship, systemic institutional deficiencies at the international and national levels, as well as overall shortcomings of the rule of law. Thus, although future work on this matter requires broader interdisciplinary perspectives incorporating insights beyond law, legal approaches are still pertinent as to the role

85 Gostin, L, Friedman, E & Buse, K et al., "Towards a framework convention on global health" (2013), 91 *Bulletin of the World Health Organization*, 790 (790-792), available at http://dx.doi.org/10.2471/BLT.12.114447.

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

87 At the 70th WHA, which took place in May 2017, former Minister of Health of Ethiopia, *Tedros Adhanom Ghebreyesus*, was elected as the successor of *Margaret Chan* for a period of five years. He would have the possibility of running for re-election for another term in 2022.

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of the legal and institutional framework for disease outbreak preparedness and response. The arguments put forward in this book could be contrasted alongside a comparative view, all the while keeping the substantive differences in mind. As mentioned earlier, a comparative view is of high relevance in international infectious disease governance, because we do not know when exactly and which particular infectious disease will spread in the future – but we know that it will cost many lives in times of population growth. Identifying common patterns between infectious diseases in research is thus important for dealing with them.

Another major pending issue that requires deeper research is the notorious role of non-state actors – NGOs and private companies alike. Firstly, the question arises as to whether they would each need to have a different standing in international law in light of their different purposes.[88] Secondly, the growing presence of private entities, such as the Bill and Melinda Gates Foundation,[89] as important financer of – and, therefore, stakeholders within – the WHO merits a closer inspection at the very least.[90] The preference given to earmarked funds for "pet projects" raises concerns as to the autonomy with which said organization can have leeway in determining its own agenda.[91]

Last but not least, in parallel to the focus on infectious disease throughout this publication, the growing challenges stemming from NCDs also need to be taken into consideration. A sensible appraisal of current epidemiological patterns yields insights of how NCDs constitute an ever-growing cause of

88 The need to distinguish between for-profit and not-for-profit actors is also mentioned in Hanrieder, T & Kamradt-Scott, A, "Introduction. Same, Same But Different: Reforming the World Health Organization in an Age of Public Scrutiny and Global Complexity" (2017), IX *Global Health Governance*, 4 (4), available at http://bit.ly/2tcBdeE.

89 The contributions of the Bill and Melinda Gates Foundation to the WHO's finances through the Voluntary Fund for Health Promotion are sketched out, for example in the organization's Financial Reports for the year 2004. See http://bit.ly/2rYCDxO.

90 For instance, in the financial year of 2016, contributions to the WHO by non-state actors amounted to circa 37 % of the organization's total budget. See the 70th WHA document entitled *WHO Mid-Term Programmatic and Financial Report for 2016-2017, including audited financial statements for 2016*, Provisional Agenda Item 20.1, A70/40, 132-133, available at http://bit.ly/2tWbEiL.

91 The trend dates back to the 1980s. See Hanrieder, T, *International Organization in Time. Fragmentation and Reform*, 2015, 9-11.

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death within the global burden of disease.[92] Therefore, it is not possible to ignore the necessity of addressing the underlying issues that contribute to explain this fact, whether it is tobacco consumption, physical inactivity, alcohol abuse or inadequate nutrition.[93] Despite this overall trend towards the rise of NCDs, infectious diseases do not cease to be a factor of concern; to the contrary, both of these problems coexist and contribute in complicating the landscape of public health.[94] As the emergencies declared in the West African Ebola and Zika epidemics remind, the dangers posed by infectious diseases should not be underestimated, given how these are still threats requiring a global rather than a local or regional response.[95] Therefore, a comprehensive approach capable of taking this complexity into consideration seems as necessary as ever.

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92 While there are nuances in how this rate diverges across age groups depending on regions, the growing incidence of NCDs as a cause of death seems to be clear. See the detailed data in the study by the Global Burden of Disease 2015 Mortality and Causes of Death Collaborators, "Global, regional, and national life expectancy, all-cause mortality, and cause-specific mortality for 249 causes of death, 1980-2015: a systematic analysis for the Global Burden of Disease Study 2015" (2016), 388 *The Lancet*, 1459 (1482-1492).

93 See WHO, "Major NCDs and their risk factors", available at http://www.who.int/ncds/introduction/en/.

94 Frenk, J & Moon, S, "Governance Challenges in Global Health" (2013), 368 *The New England Journal of Medicine*, 936 (936).

95 Also in this sense, Heesterbeek, H, Anderson, R M & Andreasen, V et al., "Modeling infectious disease dynamics in the complex landscape of global health" (2015), 347 *Science*, aaa4339-1 (aaa4339-7).

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