The Origins and Future of Global Health Law: Regulation, Security, and Pluralism

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INTRODUCTION

The COVID-19 pandemic has presented a global health crisis unlike any seen in the seventy-five years since the United Nations and the World Health Organization were formed—"one that is killing people, spreading human suffering, and upending people's lives. But this is much more than a health crisis. It is a human crisis. The coronavirus disease (COVID-19) is attacking societies at their core."[1] It is therefore a crucial point around which to focus the capability of national and global institutions to address this essential threat to human health and life. Although the human right to the highest attainable standard of health was formally established with the adoption of the Constitution of the World Health Organization (WHO) in 1946 (entering into force in 1948),[2] the field of global health law, oriented to deal with threats like COVID-19, is much younger.[3] For many decades, WHO's implementation of its mandate was limited to technical advice on measures that states (especially developing states) should adopt to promote individual and public health, as well as a successful campaign commencing in 1967 to address first smallpox and then additional vaccine-preventable diseases in children, which has now expanded even further.[4] In the early 2000s, the World Health Assembly (WHA), the governing body of WHO, revised the International Health Regulations. These revisions gave WHO broader authority to fight disease outbreaks and other public health events of international concern. The WHA also adopted the Framework Convention on Tobacco Control,

1. U.N. SUSTAINABLE DEV. GROUP, SHARED RESPONSIBILITY, GLOBAL SOLIDARITY: RESPONDING TO THE SOCIO-ECONOMIC IMPACTS OF COVID-19 (2020), https://unsdg.un.org/sites/default/files/2020-03/SG-Report-Socio-Economic-Impact-of-Covid19.pdf [https://perma.cc/95QY-RZB9].

2. Constitution of the World Health Organization, at pmbl., *in* WHO, Basic Documents 1 (45th ed. Supp. 2006), http://www.who.int/governance/eb/who_constitution_en.pdf [https://perma.cc/Z9ZT-5CCV] ("The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.").

3. David Fidler and others rightly point out that the history of treaties with at least some "health" implications dates as far back as 1851, and often dealt with specific diseases, like cholera, or specific substances, like alcohol or opium. David P. Fidler, *The Globalization of Public Health: The First 100 Years of International Health Diplomacy*, 79 BULL. WORLD HEALTH ORG. 842, 843–46 (2001). These treaties, however, centered on the facilitation of trade. *See id.* at 846 ("The treaties were also not considered important in connection with public health law generally."). Even international labor law, much of which dated to the early part of the twentieth century, was focused on managing labor tensions, not the individual health of workers. *See id.* at 847 tbl. 5.

4. *See* WHO, *The Immunization Programme That Saved Millions of Lives*, 92 BULL. WORLD HEALTH ORG. 314–15 (2014), https://www.who.int/bulletin/volumes/92/5/14-020514/en/ [https://perma.cc/5W9K-7LQU] ("In the 1960s, smallpox was still circulating in Africa and Asia. Within a decade of the launch of the WHO's Intensified Smallpox Eradication Programme in 1967, the disease had been wiped out globally. Long before the last case of smallpox was reported in 1977, the idea that a similar approach could be taken with other vaccine-preventable diseases was gaining support.").

the first use of WHO's Article 19 authority to conclude public health treaties.[5] COVID-19 has challenged the sufficiency of even these significant global efforts.

In 2008, Lawrence Gostin and Allyn Taylor defined the field of global health law.[6] According to their analysis, global health law "encompasses the legal norms, processes, and institutions needed to create the conditions for people throughout the world to attain the highest possible level of physical and mental health."[7] Gostin and Taylor fashioned a capacious definition in order to capture five features of global health law: mission (for example, "basic survival needs"), key participants, sources, structure, and moral foundations.[8] With Gostin's *Global Health Law* in 2014,[9] the concept of an international law devoted to the realization of the highest attainable standard of health worldwide drew broad contours around the subject matter of global health law, including: major threats like infectious diseases and noncommunicable diseases;[10] socioeconomic factors like global trade, poverty, and government corruption;[11] and relevant institutions such as WHO, the World Bank, the Global Fund, the GAVI Alliance, and the Gates Foundation.[12] In *Global Health Law*, Gostin scrutinized law most relevant to global health, the International Health Regulations, and the Framework Convention on Tobacco Control, but also acknowledged the influence of human rights law, international trade law, and intellectual property law.[13] In significant measure, the establishment and growth of the field is attributable to these works.[14]

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5. The stated purpose of the International Health Regulations is "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." WHO, *International Health Regulations* 1 (3d ed. 2005), https://apps.who.int/iris/bitstream/handle/10665/246107/9789241580496-eng.pdf [https://perma.cc/5GYW-PEX3]; *see also* WHO, *WHO Framework Convention on Tobacco Control* (2005), https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf [https://perma.cc/YM2U-GH64].

6. Lawrence O. Gostin & Allyn L. Taylor, *Global Health Law: A Definition and Grand Challenges*, 1 PUB. HEALTH ETHICS 53, 55–56 (2008).

7. *Id*. at 55.

8. *Id*.

9. *See generally* LAWRENCE O. GOSTIN, GLOBAL HEALTH LAW (2014) (providing the first book-length, comprehensive survey of the field).

10. *See id*. at 34–46.

11. *See id*. at 73–74.

12. *See id*. at 129–74.

13. *See generally id*. (covering the IHR, the FCTC, human rights law, international trade and intellectual property law as they affect the right to health).

14. *See* Brigit Toebes, *International Health Law: An Emerging Field of Public International Law*, 55 INDIAN J. INT'L L. 299, 300 n.2, 301 n.10 (2016) (describing Gostin and Taylor's 2008 article as "comprehensive" and noting Gostin's *Global Health Law* as "an authoritative study"); Octavio Gomez-Dants & Julio Frenk, *The Quest for Global Justice in Health: A Review of Global Health Law by Lawrence O. Gostin*, 15 YALE J. HEALTH POL'Y L. & ETHICS 377, 380 (2015) ("Gostin is one of the pioneers and leading figures in the field of global health law."); Gian Luca Burci, Book Review, 109 AM. J. INT'L L. 691, 691 (2015) ("Research and scholarship on international legal and normative aspects were initially affected by the very limited scope of international law primarily dedicated to the protection of health, with the exception of a few pioneering scholars including Gostin [and Taylor]."); Stéphanie Dagron, Book Review, EUR. J. INT'L L. 949, 949 (2014) ("Lawrence O. Gostin's new book

The purposes of this Article are to revisit and assess the field as it has evolved since 2014 and to understand the origins of global health law and the forces now shaping its future with the benefit of new histories and analyses as well as how those forces are exerted upon the most significant infectious disease threat to face the world in the last 100 years. This Article undertakes this inquiry in order to understand how the relevant actors and subjects have changed; whether institutions established since 2000 are still optimally positioned to do the most relevant work; and whether changes in the relevant subjects of global health law (like animals and plants) are adequately prioritized. It is the first to undertake such a comprehensive review. The Article analyzes those components that Gostin detailed, like the International Health Regulations, that have become even more important (and scrutinized) with the COVID-19, Ebola, MERS-CoV, and Zika public health emergencies. It also identifies those aspects of global health law that have become ascendant, like the participation of the U.N. Security Council, which in 2014 seemed, only occasionally, concerned with HIV/AIDS, and not with wider health threats to international peace and security.

While anchored in the human rights discourse typical of post-World War II regimes, global health law has transitioned from a regime focused on the legal relationship between sovereign states and between those states and their citizens to a regulatory force increasingly composed of public–private partnerships.[15] In addition to its traditional focus on governments, global health law increasingly regulates corporations and other businesses. As discussed in sections I.A and II.A, major international treaties and regulatory instruments have become a regular component of global health law's focus. Historically occupied with measures taken regarding civilian life during times of peace, global health law is increasingly becoming intertwined with policies aimed at national or international security.[16] Traditionally focused on human health and medicine, it has now internalized the interconnectedness of domestic- and wild-animal life, along with the wider environment that humans and animals share. This has given rise to "one-health" approaches to the management of animal-, human-, and plant-health threats.[17] Indeed, the preliminary evidence suggests that COVID-19 spilled over from bats to humans, either directly or through an intermediary animal host.[18]

These changes fundamentally challenge the primacy of the historical sources of global health law (WHO and its Member State governments) and implicate a

begins with the sentence '[t]his is a unique moment to offer a systematic account of global health law' and he is right.").

15. Toebes, *supra* note 14, at 301 ("Globalisation only adds a number of new actors to our analysis in addition to the international society of states, including multinational corporations, non-governmental organisations and public-private partnerships. As international law is still primarily state-centred, it fails to call these actors to account directly.").

16. *See infra* Section I.C (identifying the increasing intervention of the U.N. Security Council on health-related international emergencies).

17. *See, e.g.*, Paul D. van Helden, Lesley S. van Helden & Eileen G. Hoal, *One World, One Health*, 14 EMBO REP. 497 (2013).

18. *See* Kristian G. Andersen et al., *The Proximal Origin of SARS-CoV-2*, 26 NATURE MED. 450, 450 (2020).

much larger cast of characters who exercise influence at multiple levels. Global health law, as it transforms over the course of the twenty-first century and as health threats like COVID-19 become more frequent and severe, will require more collaborative lawmaking efforts between U.N. agencies, mediated more often by the United Nations Security Council.

This transformation will be particularly shaped by mass urbanization and climate change. Global health law will need to be increasingly informed by the law of business organizations, including competition or "antitrust" law, as consolidation of large global firms in the agriculture, medical, and pharmaceutical sectors transform those businesses into actors with state-like reach and influence. Finally, global health law and international environmental law, especially the law of biodiversity conservation, will be shaped by current mechanisms for international lawmaking like World Trade Organization (WTO) dispute-settlement panels, international-arbitration fora, and technical, standard-setting processes at international organizations like the Organization for Animal Health (OIE), the Codex Alimentarius Commission (Codex), and the International Organization for Standardization (ISO). These mechanisms, in turn, will require modification—the creation of new lawmaking channels—as climate change renders significant stress on structures developed more than seventy years ago.

These changes offer both threats and opportunities. The increasing "securitization" of health law means it may become a primary instrument of abusive and arbitrary state power.[19] For example, several states have deployed surreptitious cell phone technologies to track persons potentially infected with COVID-19 and their contacts.[20] The growing influence of multinational enterprises may compromise access to important innovations and pharmaceuticals because of unaffordability.[21] The breadth of one-health laws—that is, laws that address health by looking comprehensively at animal, plant, and human health as well as the environments they inhabit—may make global health lawmaking slower and more complex.

Yet for each of these threats, there are corresponding opportunities for global health law to "achiev[e] global health . . . through legal instruments, legal

19. *See* Nan D. Hunter, *"Public-Private" Health Law: Multiple Directions in Public Health*, 10 J. HEALTH CARE L. & POL'Y 89, 92 (2007) ("Both the proposed new regulations for federal quarantine authority and a series of emergency planning documents are directed toward the goal of maximizing the power of government. They evidence little concern for checks against arbitrary uses of that power . . . ."); Ronald Bayer, *The Continuing Tensions Between Individual Rights and Public Health*, 8 EMBO REP. 1099, 1099 (2007) ("Biggs was but the most articulate of the new cadre of public health officials who endorsed authoritarian attitudes in the name of public health . . . .").

20. *COVID-19, Surveillance and the Threat to Your Rights*, AMNESTY INT'L (Apr. 3, 2020, 10:58 AM), https://www.amnesty.org/en/latest/news/2020/04/covid-19-surveillance-threat-to-your-rights/ [https://perma.cc/3AJP-3SMN].

21. SAM F. HALABI, INTELLECTUAL PROPERTY AND THE NEW INTERNATIONAL ECONOMIC ORDER: OLIGOPOLY, REGULATION, AND WEALTH REDISTRIBUTION IN THE GLOBAL KNOWLEDGE ECONOMY 159 (2018) ("To be sure, part of the larger problem was that monopoly rents supported by patents, trademarks, trade dress, and data exclusivity meant medicines like antiretrovirals, cancer treatments, and diabetes control drugs would lie out of reach for low- and middle-income countries.").

capacities, and institutional reforms," in the words of a recent report commissioned by *The Lancet* and the O'Neill Institute for National and Global Health Law.[22] This Article aims to articulate those opportunities and to outline the mechanisms by which they may achieve better outcomes for individual and population health worldwide through the adoption and implementation of global health law. Although many analysts of global health law have acknowledged the importance of nonstate actors like businesses,[23] none have adequately analyzed the increasing interlinkages between the U.N. Security Council and global health law, as well as the growing one-health movement as critical, course-shaping factors for global health law.

Part I of this Article traces the origins and definitions of "global health law" as that phrase has changed since the formation of the World Health Organization and the formal, legal commitment of the world's sovereign states to a human right to health. Part I challenges the conventional history of global health law, which tends to emphasize the International Health Regulations and the Framework Convention on Tobacco Control. It claims that the welfare of infants, children, and mothers reoriented the post-World War II focus of global health law and aimed it at multinational enterprises and the importance of food and agriculture; and that it did so increasingly as a function of international peace and security.

Part II first identifies the emerging and expanding sources of supranational regulation of global firms, including the regulation of their behavior imposed through contract or binding agreements and the growth in global health law formed through adjudication. Part II further analyzes the developing impact of one-health principles on global health law, and how it is likely to recharacterize global health law over this century. Finally, Part II ties these trends to the "securitization" of global health law at the U.N. Security Council, including the stalemate that has developed between China and the United States over the characterization of the COVID-19 threat to international security.

Part III concludes that global health law became increasingly focused on the protection of infant, child, and maternal health over the course of the 1950s and 1960s, a focus that expanded the diversity and number of subjects it targeted, especially multinational businesses. As disease threats expanded and became more severe, global health law also "securitized," such that the U.N. Security Council and auxiliary, security-oriented organizations became key sources of new global health law. As a result, the future of global health law lies in more supranational regulation of global firms; the influence of agreements between firms, foundations, and governments (including international organizations); and

22. Lawrence O. Gostin et al., *The Legal Determinants of Health: Harnessing the Power of Law for Global Health and Sustainable Development*, 393 LANCET 1857, 1857 (2019). "Global health" is "an area for study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide." Jeffrey P. Koplan et al., *Towards a Common Definition of Global Health*, 373 LANCET 1993, 1995 (2009).

23. *See* Gostin & Taylor, *supra* note 6, at 55; Gian Luca Burci, *Global Health Law: Present and Future*, *in* RESEARCH HANDBOOK ON GLOBAL HEALTH LAW 487, 489, 522 n.92 (Gian Luca Burci & Brigit Toebes eds., 2018).

the growing body of law generated by adjudicative bodies like international-investment and trade tribunals. COVID-19, as a dramatic illustration of these movements, has shown that biomedical interventions are being produced under the guidance of a bundle of contracts constraining firms that would otherwise seek to exploit the potential market for a therapeutic or vaccine; the response being coordinated as a fundamental threat to global security, and that response has been shaped by stakeholders ranging from regional and national governments to global financing institutions to global companies. The result of these movements is the future of global health law: regulation, security, and pluralism.

I. THE ORIGINS OF GLOBAL HEALTH LAW

The "enjoyment of the highest attainable standard of health" has been recognized as a "fundamental right[]" since the adoption of the Constitution of WHO in 1946.[24] Abbreviated, somewhat misleadingly, as the "right to health" in much of the discourse following its establishment, global health law at that time and for the next two decades was concerned with "the declaration of the right to health as a basic human right; the prescription of standards aimed at meeting the health needs of specific groups of persons; and the prescription of ways and means for implementing the right to health."[25]

This law was directed at the actions of individual countries. Reflecting on the field of global health law upon WHO's fortieth anniversary, Professor Michel Bélanger wrote that the "general objective [of international health law] is to support, guide, and coordinate national health law."[26] Working in partnership with nongovernmental organizations based in-country, WHO provided technical support to, hosted meetings for, and thereby contributed significantly to reducing the incidence of malaria, tuberculosis, poliomyelitis, and other viral diseases around the world, generally through national-level coordination.[27] It also led a number of maternal-health programs,[28] developed nutrition and sanitation guidelines,[29] and worked to ensure appropriate mental-health treatments in member states.[30]

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24. Constitution of the World Health Organization, *supra* note 2, at pbml.

25. Virginia A. Leary, *The Right to Health in International Human Rights Law*, 1 HEALTH & HUM. RTS. 24, 29 (1994) (quoting Theo C. Van Boven, Dir., United Nations Div. of Human Rights, The Right to Health, Paper for Workshop on the Right to Health as a Human Right (1978), *in* THE RIGHT TO HEALTH AS A HUMAN RIGHT: WORKSHOP BY THE HAGUE ACADEMY OF INTERNATIONAL LAW AND THE UNITED NATIONS UNIVERSITY (Rene-Jean Dupuy, ed. 1979)).

26. Michel Bélanger, *The Future of International Health Legislation*, 40 INT'L DIG. HEALTH LEGIS. 1, 2 (1989).

27. *See* WHO, THE HEALTH OF THE PEOPLE: WHAT WORKS – THE AFRICAN REGIONAL HEALTH REPORT 58–82 (2014), http://extranet.who.int/iris/restricted/bitstream/handle/10665/137377/9789290232612.pdf [https://perma.cc/RJ9K-MDKZ].

28. *See Maternal Health*, WHO, https://www.who.int/maternal-health/en/ [https://perma.cc/W8HS-EAM6] (last visited Jan. 5, 2020).

29. *See, e.g.*, WHO, ESSENTIAL NUTRITION ACTIONS: IMPROVING MATERNAL, NEWBORN, INFANT AND YOUNG CHILD HEALTH AND NUTRITION (2013), https://www.who.int/nutrition/publications/infantfeeding/essential_nutrition_actions.pdf [https://perma.cc/NB8Y-DDCH].

30. *See Mental Health: New QualityRights Modules Launched*, WHO (Nov. 29, 2019), https://perma.cc/Q8BV-ZSET.

Professor Bélanger's statement and the organization's subsequent non-lawmaking trajectory would have surprised WHO's founders.[31] When international lawmakers established the World Health Organization, they intended to give it theretofore unheard of, and robust, lawmaking and regulatory authority.[32] Article 19 of the WHO Constitution authorized it to adopt treaties relevant to its broad mandate.[33] For example, WHO was authorized to "promote and conduct research in the field of health by the personnel of the Organization," "establish such other institutions as it may consider desirable," and "take any other appropriate action to further the objective of the Organization."[34]

Article 21 gave the World Health Assembly the authority to adopt legally binding recommendations in five discrete areas: sanitary and quarantine regulations; nomenclatures on diseases, causes of death, and public health practices; standards for diagnostic procedures for international use; standards for safety, purity, and potency of biological, pharmaceutical, and similar products moving in international commerce; and advertising and labeling of biological, pharmaceutical, and similar products moving in international commerce.[35] Article 22 established the binding legal effect of these regulations unless states opted out of them within the notification period,[36] an innovation that limited the delays that accompanied traditional ratification processes.

One of the first exercises of this authority was in 1951 to adopt the International Sanitary Regulations, an international agreement that resurrected and rationalized moribund international treaties that addressed international traffic and quarantine policies oriented at plague, cholera, yellow fever, smallpox, louse-borne typhus, and relapsing fever.[37] WHO updated the regulations and renamed them in 1969,[38] eventually narrowing their reach to yellow fever, cholera, and plague by 1981, while expanding the monitoring and control mechanisms applicable to those diseases.[39] The resurgence of cholera in South America, plague in India, and Ebola in Africa, as well as the emergence of HIV as a global pandemic, encouraged the world's countries to consider further, more

31. *See* V.S. Mihajlov, *International Health Law: Current Status and Future Prospects*, 40 INT'L DIG. HEALTH LEGIS. 9, 9 (1989) ("The responses received clearly reflected the general interest shown by governments, organizations, and individuals in an analysis and study of problems relating to international medical law. It is a fact, however, that WHO paid relatively little attention to the matter thereafter.").

32. *See* George A. Codding, Jr., *Contributions of the World Health Organization and the International Civil Aviation Organization to the Development of International Law*, 59 PROC. AM. SOC'Y INT'L L. 147, 147–48 (1965).

33. Constitution of the World Health Organization, *supra* note 2, art. 19.

34. *Id*. art. 18.

35. *Id*. art. 21.

36. *Id*. art. 22.

37. Comment, *International Sanitary Regulations*, 147 J. AM. MED. ASS'N 62, 62–63 (1951).

38. *Strengthening Health Security by Implementing the International Health Regulations (2005): The International Health Regulations (1969)*, WHO, https://www.who.int/ihr/current/en/ [https://perma.cc/CGZ8-QJJ5] (last visited May 18, 2020).

39. Sam F. Halabi, *Multipolarity, Intellectual Property, and the Internationalization of Public Health Law*, 35 MICH. J. INT'L L. 715, 723–24 (2014).

extensive revision.[40] WHO was authorized to take action based on information it collected itself, even if individual countries remained important to the process of controlling these diseases.[41]

After 1969, the World Health Organization did not exercise its legal powers for over thirty years.[42] Rather, WHO embarked upon several decades of technical data collection, advice-giving, and support.[43] WHO "focused on medical and epidemiological expertise, coordinating international and non-governmental organizations" (another unique role encouraged by its constitution), "and regular use of its Article 23 recommendation-issuing authority."[44] The World Health Assembly frequently issued resolutions recommending that governments undertake multiple and diverse measures related to its technical work but avoided lawmaking and regulation-issuing alternatives available under its constitution.[45] According to David Fidler, this neglect of legal authority was largely attributable to how WHO historically viewed individual and public health problems.[46] Because those problems were medical and scientific, there was little need to do more than dedicate medical and scientific resources toward their solution.[47]

> This medical-technical ethos did not exhibit interdisciplinary sensibilities about public health problems because its focus was narrow, static, relatively inflexible, and largely nonpolitical. International law fell outside this limited focus because the medical-technical ethos did "not need international law

40. *See Frequently Asked Questions About the International Health Regulations (2005)*, WHO, https://www.who.int/ihr/about/faq/en/ [https://perma.cc/5Y9Q-JVEZ] (last visited May 18, 2020); Rebecca Katz & Julie Fischer, *The Revised International Health Regulations: A Framework for Global Pandemic Response*, 3 GLOBAL HEALTH GOVERNANCE, 1, 2 (2010).

41. *See* WHO, *International Health Regulations*, *supra* note 5, art. 9, § 1 ("WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10. To this end, WHO shall make the information received available to the States Parties and only where it is duly justified may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedure set forth in Article 11.").

42. *See* Katz & Fischer, *supra* note 40, at 2.

43. *See* David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34 J.L. MED. & ETHICS 85, 93 (2006) ("For decades, WHO has issued recommendations on many public health problems; but the mixed record of state compliance with WHO guidance should temper enthusiasm for the new IHR's recommendation provisions.").

44. Sam Halabi, Rebecca Katz & Amanda McClelland, *International Institutions and Ebola Response: Learning from the 2017 Outbreak in the Democratic Republic of Congo*, 88 ST. LOUIS U. L.J. 1, 4 (2019).

45. *See* David P. Fidler, *International Law and Global Public Health*, 48 U. KAN. L. REV. 1, 15 (1999) ("WHO operated as if it were not subject to the normal dynamics of the anarchical society; rather, it acted as if it were at the center of a transnational Hippocratic society made up of physicians, medical scientists, and public health experts. The nature and dynamics of this transnational Hippocratic society led WHO to approach international public health without a legal strategy.").

46. *See id*. at 22–23.

47. *Id*.

> because the approach mandates application of the medical or technical resource or answer directly at the national or local level."[48]

A. CORPORATIONS, FOOD, AND THE U.N. SECURITY COUNCIL

Throughout its first two decades, global health law was not effectively law at all. There were few, if any, firm commitments made by governments, and though WHO made a large body of general recommendations on a variety of individual and public health measures, it could only regulate through one weak regulatory instrument aimed at six diseases (IHR (1969)).

Important exceptions to this assessment were its early effort to eradicate malaria, and a later, more successful effort to eradicate smallpox. The latter commenced in 1961 but failed in the face of inadequate funding and the greater attention paid to malaria.[49] By 1967, the vast resources required to eradicate malaria became clear to the international community, and resources were redirected toward smallpox initiatives.[50] The smallpox program was an important turning point in global health law's trajectory. The campaign's success was the result of legal authorizations for immunization, surveillance, and quarantine first by African then South Asian governments. The campaign also committed to training healthcare workers, building laboratories, and creating regular public health reporting systems.[51] In 1974, the World Health Assembly expanded the smallpox

48. *Id.* at 23 (citing David P. Fidler, *The Future of the World Health Organization: What Role for International Law?*, 31 VAND. J. TRANSNAT'L L. 1079, 1099 (1998)).

49. *See* Edward A. Belongia & Allison L. Naleway, *Smallpox Vaccine: The Good, the Bad, and the Ugly*, 1 CLINICAL MED. & RES. 87, 88 (2003) ("The first large smallpox eradication effort was launched in 1950 with the goal of eliminating smallpox in the Americas. In 1958, the World Health Assembly passed a resolution calling for the global eradication of smallpox. Although some countries established smallpox eradication programs, there was no coordinated infrastructure. Many programs faltered due to insufficient vaccine supplies and limited resources."); WHO, WHA Res. 14.40, *Smallpox Eradication Programme* (1961), https://apps.who.int/iris/bitstream/handle/10665/89023/WHA14.40_eng.pdf [https://perma.cc/HL9K-FDU5].

50. *See* D.A. Henderson & Petra Klepac, *Lessons from the Eradication of Smallpox: An Interview with D.A. Henderson*, 368 PHIL. TRANSACTIONS ROYAL SOC'Y B 1, 1 (2013) ("During the 1960s, expenditure for the malaria programme represented 20 per cent or more of all funds available to WHO, thus constraining other control programmes."); Marcel Tanner & Don de Savigny, Editorial, *Malaria Eradication Back on the Table*, 86 BULL. WORLD HEALTH ORG. 82, 82 (2008) ("Regional malaria elimination campaigns were first conducted in the late 1940s, preparing the ground for the Global Malaria Eradication Program in 1955. This campaign succeeded in eliminating malaria from Europe, North America, the Caribbean and parts of Asia and South-Central America. But no major success occurred in sub-Saharan Africa, which accounts for 80% of today's burden of malaria. When the aspiration of global eradication was abandoned in 1969, the main reasons for failure were technical challenges of executing the strategy especially in Africa." (footnotes omitted)).

51. *See* Henderson & Klepac, *supra* note 50, at 4 ("Many weak, poorly managed primary healthcare programmes benefited from the smallpox programme, focusing, as it did, on greatly neglected vaccination initiatives. To achieve surveillance goals, weekly reports that provided feedback to field staff demonstrated a national interest in otherwise routine reports and improved morale of many in isolated primary care units."); Margalit Fox, *Dr. J. Donald Millar, 81, Dies; Led C.D.C. Mission That Helped Eradicate Smallpox*, N.Y. TIMES (Sept. 3, 2015), https://www.nytimes.com/2015/09/04/health/dr-j-donald-millar-who-led-cdc-mission-that-helped-eradicate-smallpox-dies-at-81.html (discussing

program into the Expanded Programme on Immunization (EPI), with the goal of "reduc[ing] morbidity and mortality by making immunization services available for all children of the world by 1990."[52] But WHO remained committed to the study of public health problems and use of evidence-based recommendations and resolutions, not lawmaking.[53]

Beginning in the mid-1960s, three main influences converged to change the nature and strength of global health law: the increasing influence of multinational corporations and other large private organizations on all aspects of human-health systems, the growing impact of agriculture and food systems on individual and population health, and the growing challenge that transnational health threats posed to international peace and security. These forces propelled global health law toward an increasing preoccupation with agriculture and nutrition and caused it to target corporations as proper subjects of international regulation due to their health impact. These influences also caused global health law to move to the forefront of issues that might require the attention of the most important body overseeing international peace and security: the United Nations Security Council.

Section I.A.1 analyzes how WHO's early efforts to eradicate smallpox led to an increasing focus on infant and child health as the critical points for interventions. With that focus, the practices of large firms that undermined infant and child health became increasingly urgent matters for national and international regulatory action. Damaging corporate practices included discouraging exclusive breastfeeding in the first six months of life; marketing tobacco products to all populations, but especially children and young adults; and, later, pricing certain vaccines at high rates. As business practices came into regulatory focus for infants, children, and mothers, their impact on other health sectors similarly became more salient.

Section I.B pivots to the global production of food and associated problems in ensuring its quality and safety. As markets for processed agricultural goods and packaged foods globalized over the course of the 1960s and 1970s, business practices related to livestock health, antibiotic use, and land acquisition raised the risk that novel or reemerging pathogens might infect and spread in humans through the production or consumption of food. Given the cross-border and trade-related implications of managing these threats, global health law emerged as an important source for regulating food production through international standards and legal agreements related to animal and plant health.

Section I.C situates these expansions of global health law into the international peace and security context. As health threats, often accompanying violent conflicts, increased in global significance and risk to human life, global health law

WHO's contribution of people to the smallpox campaign); *see generally* WHO, *The Global Eradication of Smallpox* (1980) (outlining measures taken by WHO during the smallpox eradication programme).

52. Ralph H. Henderson, *The Expanded Programme on Immunization of the World Health Organization*, 6 REVS. INFECTIOUS DISEASES S475, S475 (1984).

53. *See* Fidler, *supra* note 45, at 15.

increasingly became a focus of the world's most important security-focused body: the U.N. Security Council.

1. Multinational Corporations

The influence of multinational firms on individual and public health—as it came to be conceptualized and prioritized over the course of the 1970s—created conditions for these firms to be regulated at the supranational level with far more specificity than ever before. Firms' activities with respect to children and mothers became subject to the argument that—because of global reach and corresponding adverse health outcomes—regulatory mechanisms must correspondingly expand.

a. Infant and Child Nutrition.

The smallpox-eradication effort led directly to the prioritization of interventions to protect infants and children, including growth monitoring, oral rehydration, promotion of breastfeeding, and immunization, largely focused through EPI.[54] This focus facilitated a shift in global health law toward a greater openness to the regulation of corporations, both at the national level and through international mechanisms.

In 1974, the same year EPI was launched, the World Health Assembly acknowledged the declining rate of mothers exclusively breastfeeding for the first six months of life, the period WHO recommends for both maternal and child health.[55] Because the issue is frequently misunderstood and controversial, it is important to clarify why WHO recommends exclusive breastfeeding for the first six months of life. The recommendation is not driven by nutritional variation between breastmilk and infant formula, but by improper mixing practices prevalent in most of the world, often involving contaminated water. Improper mixing, administration, or nutritional balance results in life-threatening malnutrition and susceptibility to other diseases.[56] "Exclusively breastfed children are less susceptible to diarrhoea and pneumonia and are 14 times more likely to survive than

54. Mariam Claeson & Ronald J. Waldman, *The Evolution of Child Health Programmes in Developing Countries: From Targeting Diseases to Targeting People*, 78 BULL. WORLD HEALTH ORG. 1234, 1235 (2000) ("A number of specific, more vertical programmes . . . were promoted to channel relatively meagre resources into areas in which demonstrable success could be achieved in the medium-term. Furthermore, the emphasis was clearly put on programmes that would contribute to achieving decreases in mortality among infants and children . . . . The World Health Organization, for example, first developed the Expanded Programme on Immunization and subsequently the Programme for the Control of Diarrheal Diseases. UNICEF chose four specific interventions on which to focus: growth monitoring, oral rehydration therapy, breast-feeding promotion, and immunization, known by the acronym GOBI.").

55. *See* WHO, WHA Res. 27.43, *Infant and Young Child Feeding* (1974), *in* WHO, 2 HANDBOOK OF RESOLUTIONS AND DECISIONS OF THE WORLD HEALTH ASSEMBLY AND THE EXECUTIVE BOARD 58–59 (4th ed. 1981).

56. *See Marketing and Promotion of Infant Formula in the Developing Nations, 1978: Hearing Before the Subcomm. on Health and Sci. Research of the S. Comm. on Human Res.*, 95th Cong. 1–2 (1978) (statement of Sen. Kennedy).

non-breastfed children."[57] Even in wealthier countries, resource-scarce households have diluted formula in order to make quantities last longer.[58]

Although the declining rates of breastfeeding observed by the World Health Assembly in 1974 could be somewhat attributed to the inability of many new mothers in those countries to breastfeed because of their own malnutrition, and some other causes, the evidence strongly suggested that food firms' aggressive promotion of infant formula, other milk products, cereals for infants, vegetable mixes, and baby teas and juices "reversed feeding trends from primarily breastfeeding to formula feeding through pervasive marketing strategies targeting hospitals, health providers, and the general public."[59]

> During the 1970s and 1980s breastfeeding rates began to rise in the industrialised world, particularly among older, more educated mothers. Formula companies responded by vigorously seeking new markets in the developing world. They gave gifts to health workers and used saleswomen dressed as 'nurses' to provide donations of formula and advice to mothers. Poverty, illiteracy and poor sanitation often led to improper formula preparation. Mortality in very young infants from malnutrition, diarrhoea and pneumonia—virtually unknown previously—increased dramatically.[60]

Marketing strategies in poorer countries further asserted that formula was "modern" and better than breastmilk, depressing breastfeeding rates across the globe.[61] In Mexico in 1960, almost 100% of six-month-old babies were breastfed; by 1966, the number had declined to 40%.[62] In Chile, those numbers went from over 90% of thirteen-month-old babies in 1960 to less than 10% in 1968; in Singapore in 1951, approximately 80% of three-month-old babies were

57. *Nutrition: Improving Breastfeeding, Complementary Foods and Feeding Practices*, UNICEF, https://www.unicef.org/nutrition/index_breastfeeding.html [https://perma.cc/W9RC-XZ5N] (last visited Feb. 4, 2020).

58. *See* Stephen Solomon, *The Controversy over Infant Formula*, N.Y. TIMES (Dec. 6, 1981), https://www.nytimes.com/1981/12/06/magazine/the-controversy-over-infant-formula.html.

59. *See* Leif Hambraeus, *Proprietary Milk Versus Human Breast Milk in Infant Feeding: A Critical Appraisal from the Nutritional Point of View*, 24 PEDIATRIC CLINICIAN OF NORTH AM. 17, 18, 32 (1977); Derrick B. Jelliffe & E.F. Patrice Jelliffe, Editorial, *Feeding Young Infants in Developing Countries: Comments on the Current Situation and Future Needs*, 24 TROPICAL PEDIATRICS & ENVTL. CHILD HEALTH 155, 155–56 (1978); Ellen G. Piwoz & Sandra L. Huffman, *The Impact of Marketing of Breast-Milk Substitutes on WHO-Recommended Breastfeeding Practices*, 36 FOOD & NUTRITION BULL. 373, 379 (2015).

60. June Pauline Brady, *Marketing Breast Milk Substitutes: Problems and Perils Throughout the World*, 97 ARCHIVES DISEASE CHILDHOOD 529, 529 (2012) (footnotes omitted).

61. Solomon, *supra* note 58.

62. F. PHILIP RICE, HUMAN DEVELOPMENT: A LIFE-SPAN APPROACH 140 (3d ed. 1998); *see also* ALAN BERG, THE NUTRITION FACTOR: ITS ROLE IN NATIONAL DEVELOPMENT 92, 94 (1973).

breastfed.[63] By 1971, only 5% were.[64] Consequently, infant mortality from malnutrition, pneumonia, and diarrhea increased.[65]

The potential market for infant formula in developing countries was then, and remains, vast.[66] Over the 1970s, the developing-country market was estimated to run into the billions of dollars.[67] Nestlé accounted for approximately 50% of the market in that time.[68] In 2012, Nestlé bought Pfizer's baby food division for $11.9 billion.[69] Acquiring the Pfizer product line expanded Nestlé's already substantial reach into developing countries, as 85% of Pfizer's baby-food-division sales were in developing countries.[70] Its marketing investments reflected the importance of developing country markets. In August 1974, for example, Nestlé broadcasted 135 thirty-second advertisements for its infant formula Lactogen in Sierra Leone.[71]

Although its market share is smaller, Abbott's conduct was (and is) similar. In the Philippines, where only 34% of mothers exclusively breastfeed in the first six months, Abbott representatives "were described as a constant presence in hospitals."[72] There, "they reportedly hand out 'infant nutrition' pamphlets to mothers, which appear to be medical advice but in fact recommend specific formula brands and sometimes have money-off coupons."[73] In 2018 alone, Abbott Laboratories spent $790,000 on lobbying "the U.S. Trade Representative, among others, on 'proposals regarding infant nutrition marketing.'"[74]

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63. Michael C. Latham, *Infant Feeding in National and International Perspective: An Examination of the Decline in Human Lactation, and the Modern Crisis in Infant and Young Child Feeding Practices*, 300 ANNALS N.Y. ACAD. SCI. 197, 199 (1977).

64. *Id*. at 199.

65. *See* D.B. Jelliffe, *Commerciogenic Malnutrition?*, 30 NUTRITION REVS. 199, 200–01 (1972).

66. *See* Kenneth D. Rosenberg et al., *Marketing Infant Formula Through Hospitals: The Impact of Commercial Hospital Discharge Packs on Breastfeeding*, 98 AM. J. PUB. HEALTH 290, 294 (2008) ("[F]ormula is now marketed to almost all women.").

67. Pierre A. Borgoltz, *Economic and Business Aspects of Infant Formula Promotion: Implications for Health Professionals*, *in* 2 ADVANCES IN INT'L MATERNAL AND CHILD HEALTH 159 (D.B. Jelliffe & E.F.P. Jelliffe eds., 1982).

68. *Id*.

69. Tiffany Hsu, *$11.9 Billion for Baby Food? Nestle Pays Up for Pfizer Nutrition*, L.A. TIMES (Apr. 23, 2012, 12:00 AM), https://www.latimes.com/business/la-xpm-2012-apr-23-la-fi-mo-nestle-pfizer-baby-food-20120423-story.html.

70. *See id*. (identifying Pfizer's baby food division sales in "emerging markets").

71. Russell Mokhiber, *Infant Formula: Hawking Disaster in the Third World*, 8 MULTINATIONAL MONITOR para. 8 (1987), https://multinationalmonitor.org/hyper/issues/1987/04/formula.html [https://perma.cc/M3HF-UKF9].

72. Hannah Ellis-Petersen, *How Formula Milk Firms Target Mothers Who Can Least Afford It*, GUARDIAN (Feb. 26, 2018, 7:01 PM), https://www.theguardian.com/lifeandstyle/2018/feb/27/formula-milk-companies-target-poor-mothers-breastfeeding [https://perma.cc/LX3M-GP4V].

73. *Id*.

74. Olga Khazan, *The Epic Battle Between Breast Milk and Infant-Formula Companies*, ATLANTIC (July 10, 2018), https://www.theatlantic.com/health/archive/2018/07/the-epic-battle-between-breast-milk-and-infant-formula-companies/564782/.

In 1975, a Bristol Myers subsidiary enjoyed a one-year record in profits, largely because of formula sales.[75] It expanded its presence in developing countries rapidly thereafter.[76] By 2008, its Mead Johnson baby-formula business was valued between $7 billion and $9 billion.[77]

This growth was accompanied by partnerships, tie-ups, and acquisitions between market players. Well-known U.S. pharmaceutical companies and food firms like Gerber[78] worked together on marketing and promotional activities, because there was a strong incentive to increase the overall number of mothers using breastmilk substitutes.[79] "As Mead Johnson's former Chief Executive Kasper Jakobsen said: 'We have to wait for babies to be born that we can capture. That can then go through our acquisition, retention, and extension model.'"[80] "By 1980, mothers in developing countries were paying an estimated $1 billion to Nestlé, Unigate, Bristol Myers, Abbott, Wyeth, Glaxo and other infant formula companies for products which, in most instances, the mothers did not need."[81]

Between 1977 and 1979, the regulation of corporations became part of WHO's broader strategy in ensuring infant and children's health. Regulating corporations also shifted the global-health-lawmaking approach from making recommendations to states to directly regulating nonstate actors through law. This practice was bidirectional: not only did WHO seek to regulate corporations but also to negotiate the terms of the regulation with the firms themselves. With the assent of the WHA, WHO began working with UNICEF on a framework for "regulating inappropriate sales promotion of infant foods that can be used to replace breast milk."[82] In 1980, the WHA endorsed WHO's and UNICEF's findings and recommended that "there should be an international code of marketing of infant formula

75. Ann Crittenden, *Baby Formula Sales in Third World Criticized*, N.Y. TIMES (Sept. 11, 1975), https://www.nytimes.com/1975/09/11/archives/baby-formula-sales-in-third-world-criticized-some-producers-accused.html.

76. *See Marketing and Promotion of Infant Formula in the Developing Nations, 1978*, *supra* note 56, app. at 224–25 (supplementary testimony of James E. Post, Sch. of Mgmt., Bos. Univ.).

77. Lina Saigol & Christopher Bowe, *Bristol-Myers Sounds Out Baby Food Sale*, FIN. TIMES (Mar. 16, 2008), https://www.ft.com/content/e6356bb0-f387-11dc-b6bc-0000779fd2ac.

78. Gerber was acquired by Sandoz in 1994 and later by Novartis. *See* Associated Press, *Nestlé to Buy Gerber for $5.5 Billion*, N.Y. TIMES (Apr. 13, 2007), https://www.nytimes.com/2007/04/13/business/13gerber.html. In 2007, its baby food unit was then sold to Nestlé. *Id.*

79. *See* Heather Clancy, *Gerber to Introduce Baby Formula in Deal with Bristol-Myers*, UNITED PRESS INT'L (June 15, 1989), https://www.upi.com/Archives/1989/06/15/Gerber-to-introduce-baby-formula-in-deal-with-Bristol-Myers/2260613886400/ [https://perma.cc/G3UB-HJKS].

80. SAVE THE CHILDREN, DON'T PUSH IT: WHY THE FORMULA MILK INDUSTRY MUST CLEAN UP ITS ACT, at vi (2018), https://www.savethechildren.org.uk/content/dam/gb/reports/health/dont-push-it.pdf [https://perma.cc/KB9W-6QJZ].

81. Mokhiber, *supra* note 71, ¶ 14.

82. WHO, INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES 4 (1981) (quoting WHO, WHA Res. 31.47 (1978)), *in* WHO, 2 HANDBOOK OF RESOLUTIONS AND DECISIONS OF THE WORLD HEALTH ASSEMBLY AND THE EXECUTIVE BOARD 62 (4th ed. 1981), https://www.who.int/nutrition/publications/code_english.pdf [https://perma.cc/5LD5-GAYB].

and other products used as breast-milk substitutes."[83] In early 1981, WHO endorsed a draft of the International Code on the Marketing of Breast-milk Substitutes (International Code) and recommended it to the WHA, which adopted it by an overwhelming vote.[84]

> The extensive involvement of all major actors in negotiations contributed to the development of detailed, meaningful regulations. WHO and UNICEF ensured the participation and consultation of all interested parties while limiting the actual drafting to the secretariats. . . .
>
> The final negotiations between Nestlé and the INBC [(the International Nestlé Boycott Committee)] were carried out at UNICEF in New York. . . . UNICEF's role as a facilitator of the negotiations and the final agreement between Nestlé and its critics was also a departure from the customary activities of international organizations.
>
> The final joint agreement between Nestlé and the INBC guarantees that the corporation will abide by a voluntary code of conduct worked out in an international organization.[85]

As a result of these efforts, the International Code in many countries now prevents companies from advertising, subject to constitutional limitations; implements strict labeling requirements, including a proscription on infant images or other pictures that idealize breastmilk substitutes; limits influence on healthcare workers; and prohibits distribution of free samples of breast milk substitutes.[86] The International Code, together with subsequent recommendations, represents an evidence-based minimum standard that informs human-rights obligations for both states and companies.[87]

> As of March 2016, 135 countries had at least some form of legal measure in place covering some provisions of the Code. This represents significant progress since 2011, when only 103 countries had relevant legal measures in place. A total of 39 countries have comprehensive legislation or other legal measures reflecting all or most provisions of the Code. An additional 31 countries have legal measures incorporating many provisions of the Code, and a further 65 countries have legal measures that contain a few provisions. 49

83. *Id*. at 5 (quoting WHO, WHA Res. 33.32, *Infant and Young Child Feeding* (1980), *in id*. at annex 2).

84. *Id*. at 5 & n.7.

85. Kathryn Sikkink, *Codes of Conduct for Transnational Corporations: The Case of the WHO/UNICEF Code*, 40 INT'L ORG. 815, 833 (1986).

86. *Id*. at 822.

87. *See* U.N. Convention on the Rights of the Child, *General Comment No. 15 on the Right of the Child to the Highest Attainable Standard of Health*, art. 24, ¶ 2(e) (Apr. 17, 2013); Sami Shubber, *The International Code of Marketing of Breast-Milk Substitutes*, 36 INT'L DIG. HEALTH LEGIS. 877, 884–85 (1985).

> countries have non-legal or no measures in place. No information was available for 10 countries.[88]

b. Tobacco Marketing and Promotion.

Although it is far more lethal and far more tied to the activity of multinational corporations, tobacco did not become a major focus of global health law until after litigation in the United States exposed the breadth and depth of industry practices aimed at marketing, promotion, and deception.[89] Tobacco consumption annually kills approximately 8 million people around the world and represents the principal preventable threat to individual and public health worldwide.[90] Though consumption of tobacco products, especially combustible types like cigarettes, causes various cancers, cardiovascular disease, and chronic obstructive pulmonary disease, second-hand smoke increases risks for disease in non-smokers as well.[91]

"Between 1970 and 1998, the [WHA] . . . had adopted 17 resolutions on different aspects of tobacco control."[92] In its first major assessment of the evidence on the relationship between smoking and health, WHO acknowledged the "useful role of legislation" in addressing the threat but hardly mentioned the role of international tobacco companies as targets of regulation or as causes of the problem.[93] By 1979, WHO had reached a far firmer conclusion on the role of tobacco companies:

> It must be recognized that the tobacco industry has presented, and will continue to present, a formidable barrier to smoking control. . . . [N]o worthwhile progress can be achieved unless governments are prepared to put the interests of public health before those of private tobacco enterprise . . . . The international tobacco industry's irresponsible behaviour and its massive advertising and promotional campaigns are . . . direct causes of a substantial number of unnecessary deaths. The Committee expressed particular concern at the tobacco industry's expansionary approach to the developing countries.[94]

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88. WHO, UNICEF & IBFAN, MARKETING OF BREAST-MILK SUBSTITUTES: NATIONAL IMPLEMENTATION OF THE INTERNATIONAL CODE STATUS REPORT 2016, at 1 (2016).

89. *See* Sam Foster Halabi, *The World Health Organization's Framework Convention on Tobacco Control: An Analysis of Guidelines Adopted by the Conference of the Parties*, 39 GA. J. INT'L & COMP. L. 121, 129–30 (2010).

90. *See Tobacco*, WHO (July 26, 2019), https://www.who.int/news-room/fact-sheets/detail/tobacco [https://perma.cc/PD5G-GDSX].

91. *See id.*; Gro Harlem Brundtland, Dir.-Gen., *Burden of Disease and Best Practices: High-Level Roundtable on Tobacco Control and Development Policy*, WHO (Feb. 3, 2003), http://www.who.int/dg/speeches/2003/brussels/en/ [https://perma.cc/7837-E8EC].

92. Heather Wipfli & Jonathan M. Samet, *One Hundred Years in the Making: The Global Tobacco Epidemic*, 37 ANN. REV. PUB. HEALTH 149, 155 (2016).

93. EXPERT COMM., WHO, SMOKING AND ITS EFFECTS ON HEALTH, TECHNICAL REPORT NO. 568, at 25 (1975), https://apps.who.int/iris/bitstream/handle/10665/41157/WHO_TRS_568_eng.pdf [https://perma.cc/6YCC-V9SJ].

94. EXPERT COMM. ON SMOKING CONTROL, WHO, CONTROLLING THE SMOKING EPIDEMIC, TECHNICAL REPORT NO. 636, at 8–9 (1979), https://apps.who.int/iris/bitstream/handle/10665/41351/WHO_TRS_636.pdf [https://perma.cc/XX7Z-3ZWF].

Not until 1980 did those resolutions identify the role of tobacco companies in perpetuating a public health epidemic.[95]

WHO and large tobacco companies became more antagonistic over the course of the 1980s and 1990s—indeed, WHO compiled an entire report on industry efforts to undermine the tobacco industry's work.[96] But it was not until litigation in the United States uncovered the extent of companies' tactics worldwide that WHO determined that a regulatory instrument at the international level was needed.[97] The release of correspondence between parent companies and foreign subsidiaries as part of the Master Settlement Agreement in U.S. litigation opened a window into the operations of transnational tobacco companies.[98] "Accordingly, tobacco control advocates, researchers, and litigants working outside the United States have made extensive use of the documents to support their own health policy efforts."[99]

Because multinational tobacco corporations represented a critical barrier to the adoption of tobacco-control regulation, Canada, Finland, Mexico, and Tanzania sponsored the idea of an international agreement[100] to regulate tobacco

95. *See* WHO, *WHA33.35 WHO's Programme on Smoking and Health* (1980), https://www.who.int/tobacco/framework/wha_eb/wha33_35/en/ [https://perma.cc/9CSC-VJTD].

96. *See generally* COMM. OF EXPERTS ON TOBACCO INDUS. DOCUMENTS, WHO, TOBACCO COMPANY STRATEGIES TO UNDERMINE TOBACCO CONTROL ACTIVITIES AT THE WORLD HEALTH ORGANIZATION (2000), https://www.who.int/tobacco/en/who_inquiry.pdf [https://perma.cc/6D85-TMBP] (reviewing strategies deployed by tobacco companies to discredit WHO and derail efforts at forming a tobacco control treaty).

97. *Id.* at 242; Derek Yach, *The Origins, Development, Effects, and Future of the WHO Framework Convention on Tobacco Control: A Personal Perspective*, 383 LANCET 1771, 1771 (2014) ("In May 1998, the WHO noted the document and a related resolution in words that would support the WHO FCTC: 'as global interdependence increases, so will the need for global, ethical, and scientific norms, standards and commitments, including some that are legally binding.'").

98. *See* Jeff Collin, Kelley Lee & Karen Bissell, *The Framework Convention on Tobacco Control: The Politics of Global Health Governance*, 23 THIRD WORLD Q. 265, 267 (2002); Ruth Roemer et al., *Origins of the WHO Framework Convention on Tobacco Control*, 95 AM. J. PUB. HEALTH 936, 938 & nn.8–9 (2005); *An International Tobacco Control Policy: Policy Number 9809*, AM. PUB. HEALTH ASS'N (1998), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/08/29/11/06/an-international-tobacco-control-policy.

99. Richard D. Hurt et al., *Open Doorway to Truth: Legacy of the Minnesota Tobacco Trial*, 84 MAYO CLINIC PROC. 446, 451 (2009).

100. Hiroshi Nakajima, Dir.-Gen., WHO, *The Feasibility of Developing an International Instrument for Tobacco Control*, EB97/INF.DOC./4 (Nov. 30, 1995); Collin, Lee & Bissell, *supra* note 98, at 266 (finding a transnational approach to be necessary because the tobacco industry benefitted from globalization through "facilitated access to markets worldwide by the tobacco industry through trade liberalisation and specific provisions under multilateral trade agreements; enhanced marketing, advertising and sponsorship opportunities via global communication systems; greater economies of scale ranging from the purchase of local cigarette manufacturers, improved access to ever larger markets and the development and production of global brands; and the ability of transnational corporations (TNCs) to undermine the regulatory authority of national governments"); Yach, *supra* note 97, at 1771 ("Transnational tobacco control gained support as countries with effective policies recognised their progress could be undermined by cross-border advertising and illicit trade, resulting in an unintended consequence: the rapid expansion of tobacco use in resource-poor countries."); Roemer et al., *supra* note 98, at 937.

companies at the WHA in 1995.[101] In 1998, Member States of the World Health Organization established a Working Group to draft provisions of a treaty—the first in WHO's history—to address the major supply-and-demand factors contributing to tobacco consumption.[102] The Framework Convention on Tobacco Control (FCTC) was adopted by the WHA in 2003 and entered into force on February 27, 2005.[103] One hundred and eighty-one parties have ratified or acceded to the FCTC, with the most recent to do so in July 2017.[104]

Whereas large multinational corporations negotiated directly with WHO on aspects of the International Code of Marketing of Breast-milk Substitutes, the nature of industry interference in tobacco control and its essential interest in undermining public health caused WHO to determine that tobacco firms should not participate in the FCTC drafting process.[105] When the Conference of the Parties, the governing body of the FCTC, convened in 2008 to elaborate guidelines for implementation, it declared, pursuant to Article 5.3 of the treaty, that there was a "fundamental and irreconcilable conflict" between the treaty and the tobacco industry.[106] Though the FCTC regulates a wide range of supply-and-demand factors affecting tobacco consumption, core aspects of its nonprice provisions are aimed at eliminating or limiting business practices crucial to tobacco firms. Article 11 (packaging and labeling) and Article 13 (promotion) limit firms' ability to use advertisement and color schemes to deceive consumers.[107] The

101. WHO, *WHA48.11: An International Strategy for Tobacco Control* (May 12, 1995), http://www.who.int/tobacco/framework/wha_eb/wha48_11/en [https://perma.cc/AXD8-26P8].

102. *See Working Group Preceding the Intergovernmental Negotiating Body on the WHO FCTC (1999–2000)*, FCTC: WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, https://www.who.int/fctc/about/pre_neg_working_group/en/ [https://perma.cc/2TVZ-EHE5] (last visited Jan. 6, 2020); WHO, *WHO Framework Convention on Tobacco Control*, *supra* note 5, at v.

103. WHO, *WHO Framework Convention on Tobacco Control*, *supra* note 5, at vi, 35.

104. *Parties to the WHO Framework Convention on Tobacco Control*, WHO (Nov. 23, 2017), http://www.who.int/fctc/signatories_parties/en/index.html [https://perma.cc/AT28-DHGY].

105. *See* Collin, Lee & Bissell, *supra* note 98, at 267, 276, 279; Yach, *supra* note 97, at 1772 ("An inquiry initiated by WHO in collaboration with the World Bank led to a report showing well-financed and effective industry efforts to stop, slow, or delay the introduction of effective tobacco control policies within WHO and member states. The inquiry yielded outcomes in two areas without which there might have been no WHO FCTC. The World Health Assembly adopted *Transparency in tobacco control*, a 2001 resolution warning governments about tobacco industry tactics, and developed language supportive of making tobacco companies liable for harm in the final adopted text of the WHO FCTC. It also galvanised a global network of nongovernmental organisations linked to major media, which reframed the tobacco control debate in terms of corporate accountability rather than human frailty. Public access to industry records also led to the discovery that some critics of tobacco control were on the industry payroll—notably Roger Scruton, whose opinion pieces appeared in *The Wall Street Journal* and *Financial Times*. In a lengthy email exchange, he quibbled with his Japan Tobacco International paymasters about his fees for editorials and commentaries related to tobacco." (footnotes omitted)); Gregory F. Jacob, *Without Reservation*, 5 CHI. J. INT'L L. 287, 297 (2004) ("The NGOs complained vociferously about a supposed tobacco industry lobbying campaign aimed at sinking the Convention, but other than a couple of representatives of the duty-free lobby, the tobacco industry was nowhere to be found.").

106. WHO, *Guidelines for Implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control* 2 (Nov. 2008), https://www.who.int/fctc/guidelines/article_5_3.pdf [https://perma.cc/M76J-DMHT].

107. WHO, *WHO Framework Convention on Tobacco Control*, *supra* note 5, arts. 11, 13.

Conference of the Parties has issued additional guidelines that go further in limiting tobacco business practices and keeping those firms away from public health policymaking.[108]

c. Vaccines.

As with legal challenges to the marketing of infant foods and tobacco, the introduction of vaccines was one of the principal interventions that elevated the health of children in not only the developing but also the wealthy world.[109] Vaccines are not only critical for the prevention of illnesses in children but are one of the most important lines of defense against the emergence of pandemics.[110] Indeed, giving researchers as much time as possible to develop a vaccine is one of the principal justifications for the significant social distancing and lockdown measures now imposed by governments in response to COVID-19.[111]

Although many vaccines distributed through the Expanded Programme on Immunization were not patented, later vaccines, especially influenza vaccines, were.[112] Seasonal and pandemic influenza vaccines are possible in significant part because developing countries share influenza samples with the WHO's Global Influenza Surveillance and Response System (GISRS).[113] Access to viruses is crucial to the development of vaccines and other treatments. WHO's system allows countries to effectively coordinate surveillance efforts for influenza outbreaks.[114] Through the GISRS, national influenza centers submit local virus samples to WHO for monitoring and research.[115]

As was the case with infant foods and tobacco, multinational corporations' involvement with vaccines created barriers to, rather than facilitated, improved

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108. *See* Halabi, *supra* note 89, at 125.

109. *See* Christopher Ingraham, *In 2013, Measles Killed More Kids than Car Accidents or AIDS*, WASH. POST (Feb. 25, 2015), www.washingtonpost.com/blogs/wonkblog/wp/2015/02/25/in-2013-measles-killed-more-kids-than-car-accidents-or-aids/.

110. *See* Seth Berkley, *Global Vaccine Access as a Critical Intervention to Fight Infectious Disease, Antibiotic Resistance, and Poverty*, *in* GLOBAL MANAGEMENT OF INFECTIOUS DISEASE AFTER EBOLA 179, 179 (Sam Halabi, Lawrence Gostin & Jeff Crowley eds., 2017); Eileen M. Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137, 1145 (2009).

111. Joe Pinsker, *The Four Possible Timelines for Life Returning to Normal*, ATLANTIC (Mar. 30, 2020, 4:40 PM), https://www.theatlantic.com/family/archive/2020/03/coronavirus-social-distancing-over-back-to-normal/608752/.

112. *See* Kane, *supra* note 110, at 1158.

113. Kumanan Wilson, Barbara von Tigerstrom & Christopher McDougall, *Protecting Global Health Security Through the International Health Regulations: Requirements and Challenges*, 179 CANADIAN MED. ASS'N J. 44, 46 (2008); *see also* Fidler & Gostin, *supra* note 43, at 90 (describing the IHR requirement that WHO share information relating to public health risks with all states).

114. *See* Sam Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Human Pathogens for Infectious Disease Research*, 28 ANNALS HEALTH L. & SCI. 101, 109–10 (2019).

115. Marie Wilke, *The World Health Organization's Pandemic Influenza Preparedness Framework as a Public Health Resources Pool*, *in* COMMON POOLS OF GENETIC RESOURCES: EQUITY AND INNOVATION IN INTERNATIONAL BIODIVERSITY LAW 315, 316–17 (Evanson Chege Kamau & Gerd Winter eds., 2013).

health outcomes. The infrastructure and technology for vaccine development is overwhelmingly located in a small number of firms based in wealthy states.[116] Five large firms generate approximately 80% of global vaccine sales across all products.[117] Many of the markets for individual vaccine products operate as monopolies or oligopolies.[118] This concentration renders many developing states dependent on wealthier states to manufacture and distribute vaccines in sufficient quantities to address their needs in routine and emergency circumstances.[119] These states must therefore be willing to share disease samples and biological material relevant to risk assessment, risk management, disease research, and vaccine development. When firms patent shared samples to produce unaffordable vaccines, the willingness to share is undermined.[120]

In 2006, Indonesia withheld H5N1 avian-flu samples from the WHO system, compromising efforts to monitor and produce vaccines in response to an avian-flu outbreak that had not only spread worldwide but threatened to become easily transmissible from birds to humans and then between humans.[121] Indonesia asserted that its decision was a response to an Australian company's development of a vaccine derived from a virus sample Indonesia provided to WHO.[122] The cycle demonstrated the inequities inherent in the global vaccine-distribution system: "Developing countries provided information and virus samples to the WHO-operated system; pharmaceutical companies in industrialized countries then obtained free access to such samples, exploited them, and patented the resulting products, which the developing countries could not afford."[123]

"The resolution to Indonesia's complaints about [GISRS] was the 2011 Pandemic Influenza Preparedness Framework (PIP Framework)."[124] WHO negotiated the PIP Framework, and the World Health Assembly passed it as an Article

116. Sam F. Halabi & John Monahan, *Regulatory Capacity in Low- and Middle-Income Countries: Lessons from the H1N1 Influenza Pandemic*, *in* FOOD AND DRUG REGULATION IN AN ERA OF GLOBALIZED MARKETS 63, 65, 66 fig.6.1 (Sam F. Halabi ed., 2015).

117. *Immunization, Vaccines, and Biologicals: Vaccine Market*, WHO, http://www.who.int/immunization/programmes_systems/procurement/market/global_supply/en/ [https://perma.cc/N2FK-YEF5] (last visited Jan. 6, 2020).

118. *Id.*

119. *See, e.g.*, David P. Fidler, *Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1*, 7 PLOS MED., May 2010, at 1–2.

120. *See id.*

121. David P. Fidler, *Influenza Virus Samples, International Law, and Global Health Diplomacy*, 14 EMERGING INFECTIOUS DISEASES 88, 88 (2008).

122. *Id.*

123. *Id.*

124. Sam Halabi & Rebecca Katz, *Introduction*, *in* VIRAL SOVEREIGNTY AND TECHNOLOGY TRANSFER, AND THE CHANGING GLOBAL SYSTEM FOR SHARING HUMAN PATHOGENS FOR INFECTIOUS DISEASE RESEARCH 49 (Sam Halabi & Rebecca Katz eds., forthcoming 2020) (manuscript at 49).

23 resolution in May 2011.[125] The PIP Framework was committed to "increas[ing] the access of developing countries to vaccines and other pandemic related supplies."[126] Under the PIP Framework, firms retain their ability to access samples shared through GISRS, but now they must contribute towards half the cost of its maintenance.[127] Firms must also promise to share either intellectual property, products developed through use of the system, or other medical countermeasures critical to pandemic response.[128]

The International Code, the FCTC, and the PIP Framework facilitated what is now a fundamental shift in the course of global health law: direct relationships between lawmaking processes and corporations, not only through their national governments.[129] Moreover, the direct relationship between firms and international regulatory instruments has been channeled to international dispute resolution fora like the WTO Dispute Settlement Understanding, ICSID arbitral tribunals, and national courts.[130] It has also been directed toward major standard-setting organizations like Codex (described in section I.B.1) and the Organization for Animal Health (OIE), where health standards must meet both consumer-protection and trade-liberalizing objectives.[131] The future of global health law is therefore at the intersection of international-regulatory bodies and international-dispute-settlement bodies, as much as or more than it is at international health organizations like WHO.

2. Private Foundations

Not only for-profit entities have reached the size and influence of states or international organizations. Prominent nongovernmental organizations like the Bill and Melinda Gates Foundation; the Bill, Hillary and Chelsea Clinton Foundation; and the Bloomberg Family Foundation have prioritized individual and public health initiatives, earned seats at important decisionmaking tables, and regulated through contract the behavior of firms, governments, and international

125. WHO, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, WHA 64.5 (May 24, 2011), *in* PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK: FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS 1 (2011) [hereinafter WHO, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*], https://apps.who.int/iris/bitstream/handle/10665/44796/9789241503082_eng.pdf [https://perma.cc/FQ4U-7BUG].

126. *Pandemic Influenza Preparedness (PIP) Framework*, WHO, http://www.who.int/influenza/pip/en/ [https://perma.cc/ZF7Q-9RR2] (last visited Jan. 6, 2020).

127. *See* Lawrence O. Gostin et al., *Virus Sharing, Genetic Sequencing, and Global Health Security*, 345 SCIENCE 1295, 1296 (2014); WHO, PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK: DISTRIBUTION OF PARTNERSHIP CONTRIBUTION AMONG COMPANIES 1 (2013), https://www.who.int/influenza/pip/pc_distribution.pdf [https://perma.cc/D9MV-BG46].

128. *See* WHO, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, *supra* note 125, at 33–35 art. 4.1.1.

129. *See* HALABI, *supra* note 21, at 217–26.

130. *Id*. at 76.

131. *See* Sam F. Halabi & Ching-Fu Lin, *Assessing the Relative Influence and Efficacy of Public and Private Food Safety Regulation Regimes: Comparing Codex and GlobalG.A.P. Standards*, 72 FOOD & DRUG L.J. 262, 282–83 & n.164 (2017).

organizations.[132] For example, in a renewed effort to complete the work begun with the WHO's Expanded Programme on Immunization, the Bill and Melinda Gates Foundation together with WHO, UNICEF, the World Bank and several large pharmaceutical firms established the Global Alliance for Vaccines and Immunizations (GAVI).[133] GAVI is funded through the International Finance Facility for Immunisation (IFFIm), which is itself funded by the governments of Australia, Brazil, France, Italy, the Netherlands, Norway, South Africa, Spain, Sweden, and the United Kingdom.[134]

Under the GAVI model, low- and middle-income states identify immunization needs, apply for funding, and implement approved vaccination programs.[135] Under GAVI's program, donors guarantee the price of eligible vaccines.[136] Pharmaceutical firms, in turn, guarantee the vaccines at an affordable price to participating countries.[137] The relationships in GAVI are governed by contract. Through these contracts and the surrounding negotiations and relationships, foundations can exercise significant influence on the firms that participate.[138]

> The creation of Gavi . . . facilitated the use of breakthrough technologies to expand access to new vaccines, as well as traditional immunizations that may have been delayed for decades without Gavi support. For example, between Gavi's inception and 2014, DTP3 coverage in Gavi-supported countries rose from 60% to 81%. This change had a direct impact on disease burden: between 1980 and 2014, cases of diphtheria declined by 92%, pertussis by 91%, and tetanus by 90%.[139]

GAVI is just one example of a public–private partnership, which in the global health space number in the hundreds.[140] The participation of nongovernmental organizations in global public health lawmaking will continue to shape the

132. *See* Lisa Clarke, *Responsibility of International Organizations Under International Law for the Acts of Global Health Public-Private Partnerships*, 12 CHI. J. INT'L L. 55, 59–60 (2011).

133. *History of GAVI*, GAVI, https://perma.cc/2ZTP-YFK4 (last visited Jan. 7, 2020).

134. *Overview*, IFFIM, https://perma.cc/4GJM-C4GL (last visited Mar. 18, 2020).

135. *See* GAVI, HOW WE WORK TOGETHER 14 (2019), https://www.gavi.org/sites/default/files/document/2019/How%20we%20work%20together.pdf [https://perma.cc/Y7GY-3952] (last visited Mar. 18, 2020).

136. *See id*. at 6.

137. *See* Ilona Kickbush, Wolfgang Hein & Gaudenz Silberschmidt, *Addressing Global Health Governance Challenges Through a New Mechanism: The Proposal for a Committee C of the World Health Assembly*, 38 J.L. MED. & ETHICS 550, 554 (2010) ("The parallels to the dominant position of the Bill & Melinda Gates Foundation today—who in 2007 spent roughly as much on global health as WHO's budget for that year—are obvious. . . . They now have a significant impact on setting agendas, shaping global health policies and implementing programs.").

138. *See id*. Also relevant is the Global Fund's regulation of "suppliers," "including bidders, suppliers, agents, intermediaries, consultants and contractors and representatives of each of the above." *Sanctions Panel Procedures Relating to the Code of Conduct for Suppliers*, GLOBAL FUND 1 (June 19, 2015), https://www.theglobalfund.org/media/6015/corporate_sanctionsprocedures_policy_en.pdf [https://perma.cc/99SM-2MNE].

139. Berkley, *supra* note 110, at 181 (footnote omitted).

140. Kickbush, Hein & Silberschmidt, *supra* note 137, at 554.

direction of global health law as contracts between firms, governments, and international organizations internalize regulatory norms.[141]

B. FOOD AND AGRICULTURE

For the most part, concerns with food and agriculture after World War II focused on food shortages, growing populations, and regular famine.[142] In response, scientists from India, Mexico, the Philippines, and the United States partnered with international organizations and foundations to create a system of cross-country research experiments focused on producing high-yield varieties of cereal grains to feed more people.[143] This scientific collaboration created a system that could sustain further research in poorer countries in the future. Alongside the research collaborations, wealthier countries committed to transferring technologies like tractors, fertilizers, and pesticides for higher-yield crops to continue.[144] Farmers were able to adopt the new high-yield varieties quickly, and food production was able to keep up with local population growth.[145] Known as the "Green Revolution," the production of high-yield grains, establishment of research centers in poorer countries, and technology transfer boosted average caloric intake in emerging regions as food prices declined, leading to better health outcomes and longer lives.[146] The Green Revolution also ushered in the global mechanization and industrialization of food production, with effects for global health law detailed below.

1. The Global Law of Food Safety

As mechanization supported increased global trade in food throughout the 1950s, food additives in processed fruits, vegetables, and milk became significant areas of concern for individual and public health.[147] Between 1971 and 2001, the growth in food imports was especially notable in low- and middle-income countries, which saw a rise of 115%, compared to wealthier countries at 45%.[148] Food imports into all countries are increasingly processed; from 1991 to 2000, trade in processed food products accounted for some 66% of agricultural trade.[149] Along with imports come risks for spoilage, adulteration, and contamination. "An estimated 600 million—almost 1 in 10 people in the world—fall ill after eating

141. *See, e.g.*, Sam F. Halabi, Michelle Rourke & Rebecca M. Katz, *The Law and Ethics of Data Sharing During Infectious Disease Emergencies*, 8 J. HEALTHCARE L. & POL'Y (forthcoming 2020) (manuscript at 4–5) (identifying instances where large foundations swayed large pharmaceutical firms during the Ebola emergency through the use of their data sharing agreements).

142. *See* W.B. Dickinson Jr., *World Food Shortages*, 2 EDITORIAL RES. REP. 1–2 (1965).

143. *See* Derek Byerlee & Harvey Jesse Dubin, *Crop Improvement in the CGIAR as a Global Success Story of Open Access and International Collaboration*, 4 INT'L J. COMMONS 452, 456 (2010).

144. *See id.*

145. *See id.*

146. R. E. Evenson & D. Gollin, *Assessing the Impact of the Green Revolution, 1960 to 2000*, 300 SCIENCE 758, 758, 761 (2003).

147. *See* Sam F. Halabi, *The Codex Alimentarius Commission, Corporate Influence, and International Trade: A Perspective on FDA's Global Role*, 41 AM. J.L. & MED. 406, 408 (2015).

148. FOOD & AGRIC. ORG., THE STATE OF AGRICULTURAL COMMODITY MARKETS 14 (2004).

149. *Id.* at 26.

contaminated food and 420,000 die every year, resulting in the loss of 33 million healthy life years (DALYs)."[150]

In the 1960s, globally accepted international standards were proposed as the solution to the food adulteration and contamination problems that accompanied trade in food.[151] Those standards would, in theory, ensure that quality measures adopted in one country could be verified in a second or third country where the food was ultimately sold. The Codex Alimentarius Europaeus, a forerunner of the international regulatory framework that exists today, issued standards and guidelines for producers, regulators, and courts that achieved some of these aims in the European context.[152] By 1963, the Food and Agricultural Organization of the U.N., WHO, and Codex Alimentarius Europeaus partnered to form the Codex Alimentarius Commission (Codex), with a goal of creating a global set of food safety, testing, labeling, and nutrition standards.[153] Codex sets standards on food quality and safety, including food commodity standards and codes of hygienic or technological practice.[154] "In addition, Codex evaluates pesticides, food additives and veterinary drugs, establishes limits for pesticide residues, and creates guidelines for contaminants."[155] There are now hundreds of standards, guidelines, and codes of conduct regulating the international food trade.[156]

Although Codex's standard development process is meant to "ensure fair practices in food trade" and "protect the health of consumers,"[157] it has leaned toward the trade liberalization component of that mission. Section II.A.3 explains how Codex will become an important channel for global health law as it becomes a more detailed, administrative body of law, not only with respect to its traditional standard-issue areas but also with respect to broader and steepening global health threats like antimicrobial resistance. Because Codex standards provide the benchmark against which food quality and safety measures are assessed when disputed under international-trade rules, the incorporation of health protections into Codex processes will become more important as "global health common law" develops through adjudicative bodies.

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150. *Food Safety*, WHO (Apr. 30, 2020), https://www.who.int/news-room/fact-sheets/detail/food-safety [https://perma.cc/GM9T-QTDF].

151. *See* Halabi & Lin, *supra* note 131, at 267.

152. Franz Vojir et al., *The Origins of a Global Standard for Food Quality and Safety:* Codex Alimentarius Austriacus *and FAO/WHO* Codex Alimentarius, 82 INT'L J. VITAMIN & NUTRITION RES. 223, 226 (2012).

153. *See id*.

154. *See* A.W. Randell & A.J. Whitehead, *Codex Alimentarius: Food Quality and Safety Standards for International Trade*, 16 REVUE SCIENTIFIQUE ET TECHNIQUE DE L'OFFICE INT'L DES EPIZOOTIES 313, 316–17 (1997).

155. Halabi, *supra* note 147, at 407.

156. *See generally Codex Alimentarius International Food Standards*, FOOD & AGRIC. ORG., http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/ [https://perma.cc/N7PL-N7PA] (last visited Jan. 7, 2020).

157. Halabi & Lin, *supra* note 131, at 271.

2. The Global Law of Animal and Plant Health

Though there were nascent efforts to address threats to animal health (the Office International des Epizooties (OIE) or Organization for Animal Health) as early as 1924, and for plants as early as 1929 (the International Convention for the Protection of Plants),[158] global health law from its establishment in 1948 was primarily concerned with humans stripped from the environment—including plants and animals—in which they lived. As this anthropocentric model appeared to succeed, with more humans living longer and healthier, the result was expanded encroachment into the environment. This, in turn, caused significant changes to the nature and severity of threats to human health.

For example, one consequence of the Green Revolution's success meant that land yielding greater quantities of cereals and grains could be rededicated to livestock production.[159] Global livestock production has consequently exploded since the 1960s—"[b]eef production has more than doubled, while over the same time chicken meat production has increased by a factor of nearly 10, made up of increases in both number of animals and productivity."[160] In low- and middle-income countries, "[t]he share of the world's poultry meat consumed . . . rose from 43 to 54 percent between 1990 and 2005 . . . . Further, the proportion of the world's poultry meat produced in developing countries rose from 42 to 57 percent."[161] This production and consumption "will increase by 3.6 percent and 3.5 percent, respectively," annually until at least 2030 "because of rising incomes, diversification of diets and expanding markets."[162]

More land dedicated to more livestock has resulted in increased interactions between humans and animals, both domesticated and wild. As those parts of the ecosystem interact, they give rise to increased channels for pathogens to migrate from wild animals to livestock to humans. The 2005 H5N1 avian-influenza outbreak produced a terrifying 50% fatality rate, primarily among humans who

158. Shakeel Bhatti, *The International Treaty on Plant Genetic Resources*, *in* NAT'L RESEARCH COUNCIL, DESIGNING THE MICROBIAL RESEARCH COMMONS: PROCEEDINGS OF AN INTERNATIONAL SYMPOSIUM (Paul F. Uhlir ed., 2011), https://www.ncbi.nlm.nih.gov/books/NBK91499/pdf/Bookshelf_NBK91499.pdf [https://perma.cc/FAC4-7W9E]; 3 HORTICULTURE: PLANTS FOR PEOPLE AND PLACES 1179 (Geoffrey R. Dixon & David E. Aldous eds., 2014); Alejandro B. Thiermann, *International Animal Health Regulations and the World Animal Health Information System*, *in* INST. OF MED., INFECTIOUS DISEASE MOVEMENT IN A BORDERLESS WORLD: WORKSHOP SUMMARY 246 (2010), https://www.ncbi.nlm.nih.gov/books/NBK45728/pdf/Bookshelf_NBK45728.pdf [https://perma.cc/89LN-DXF7].

159. *See* Food & Agric. Org., *Lessons from the Green Revolution: Towards a New Green Revolution*, WORLD FOOD SUMMIT para. 4.7 (1996), http://www.fao.org/3/w2612e/w2612e06a.htm [https://perma.cc/7843-KQBV].

160. Philip K. Thornton, *Livestock Production: Recent Trends, Future Prospects*, 365 PHIL. TRANSACTIONS ROYAL SOC'Y B 2853, 2854 (2010).

161. CLARE NARROD, MARITES TIONGCO & ACHILLES COSTALES, FOOD & AGRIC. ORG., GLOBAL POULTRY SECTOR TRENDS AND EXTERNAL DRIVERS OF STRUCTURAL CHANGE 2 (2007), http://www.fao.org/ag/againfo/home/events/bangkok2007/docs/part1/1_1.pdf [https://perma.cc/JLJ8-QPUQ].

162. *Id.*

worked directly with infected birds.[163] Although the precise origin remains unknown, the COVID-19 coronavirus is likely to have emerged from a live animal market or from agricultural animals.[164]

Moreover, the overuse of antibiotics in the livestock-raising process has made even old pathogens more dangerous as bacteria develop resistance to inappropriately used antibiotics.[165] OIE, FAO, and WHO, as a result, have increasingly focused on global legal instruments to control these threats to human health.

a. New and Reemerging Pathogens.

In addition to poultry, much of this growth has revolved around pigs, another important host for human pathogens.[166] "Pathogens" refer to bacteria, viruses, and other microorganisms that cause disease.[167] The problems of new and reemerging pathogens have arisen because of aforementioned shifts in human population growth, behavior, and consumption. New or "emerging" pathogens are those that have newly appeared in a population or have been present but swiftly increase in incidence or geographic range.[168] Recent examples include COVID-19, HIV/AIDS and Lyme disease.[169] Many of these pathogens emerge at convergence points between humans, livestock, and wildlife. Today, more than 50% of known pathogens infectious to humans are shared with animals (zoonotic diseases) and occur through recurring transmission or an initial spillover event.[170] Worldwide, "more than 1 billion infections and 1 million deaths annually are attributable to zoonoses[] and vector-borne diseases."[171]

As the human population grows, more land is claimed for food production, and more interactions between humans and animals (including their parasites) result. For example, infected bats are important carriers of the Nipah virus, which is

163. *See* Samson S.Y. Wong & Kwok-yung Yuen, *Avian Influenza Virus Infections in Humans*, 129 CHEST 156, 156 (2006).

164. Graham Readfearn, *How Did Coronavirus Start and Where Did It Come From? Was It Really Wuhan's Animal Market?*, GUARDIAN (Apr. 27, 2020, 8:46 PM), https://www.theguardian.com/world/2020/apr/13/how-did-the-coronavirus-start-where-did-it-come-from-how-did-it-spread-humans-was-it-really-bats-pangolins-wuhan-animal-market [https://perma.cc/V72H-CCV8].

165. *See* Michael J. Martin & Thomas B. Newman, *Antibiotics Overuse in Animal Agriculture: A Call to Action for Health Care Providers*, 105 AM. J. PUB. HEALTH 2409, 2409 (2015).

166. *See* WORLD BANK, MINDING THE STOCK: BRINGING PUBLIC POLICY TO BEAR ON LIVESTOCK SECTOR DEVELOPMENT, REPORT NO. 44010-GLB 47–49 (2009), http://documents.worldbank.org/curated/en/573701468329065723/pdf/440100ESW0whit10Box0338899B1PUBLIC1.pdf [https://perma.cc/AR62-2HYJ].

167. Liise-anne Pirofski & Arturo Casadevall, *Q&A: What Is a Pathogen? A Question That Begs the Point*, 10 BMC BIOLOGY, Jan. 2012, at 1.

168. Stephen S. Morse, *Factors in the Emergence of Infectious Diseases*, 1 PERSP. 7, 7 (1995).

169. *Id.*; Ali M. Messenger et al., *Reverse Zoonotic Disease Transmission (Zooanthroponosis): A Systematic Review of Seldem-Documented Human Biological Threats to Animals*, 9 PLOS ONE, Feb. 2014, at 6.

170. *Cf.* van Helden, van Helden & Hoal, *supra* note 17, at 498.

171. *Advancing a 'One Health' Approach to Promote Health at the Human-Animal-Environment Interface: Policy No. 201712*, AM. PUB. HEALTH ASS'N (Nov. 7, 2017), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2018/01/18/advancing-a-one-health-approach [https://perma.cc/KL53-PB9H].

transmitted through contact with infected livestock or by eating fruit contaminated with bats' urine or saliva.[172] As those interactions multiply in the context of climate change and urbanization, both of which contribute to emergence and spread, conditions for outbreaks ripen.[173] Indeed, annual population growth is exploding in areas that surround wildlife reserves, where these transmissions are likely to occur.[174]

The ease with which humans cross the world means those outbreaks are more likely to become epidemics or pandemics than in previous decades.[175] For most of history, human populations have been isolated from one another. Transcontinental exploration, the expansion of communication, and armed conflict have fundamentally changed these circumstances. The frequency, velocity, and volume of passengers by air, land, and sea transportation modes facilitate transfer of pathogens and vectors further, faster, and in significantly larger numbers than ever before.[176] A person's ability to reach almost any part of the world within the incubation period of disease with multiple stops and layovers means that travelers are important carrier risks for diseases.[177] The increased transportation of bacteria through global travel and trade can turn what would have been a local outbreak into a pandemic.

The future of global health law is therefore necessarily the law of the human environment, in ways detailed in section II.B.

b. Antimicrobial Resistance.

Linked to the problem of new and reemerging pathogens and the growth in livestock agriculture worldwide is the overuse of antibiotics and the accompanying rise of antimicrobial resistance, one of the most serious and worsening threats to the fight against infectious disease. "Antimicrobial" agents or therapies kill or slow the spread of bacteria, viruses, or other microorganisms that may cause disease, or pathogens. "Antibiotics" specifically act against bacterial infections. Properly administered antibiotics kill illness-causing bacteria or limit bacteria's ability to multiply, allowing the immune system to effectively respond.[178]

172. *Nipah Virus*, WHO (May 30, 2018), https://www.who.int/news-room/fact-sheets/detail/nipah-virus [https://perma.cc/4AJV-5N9Q].

173. Johanna F. Lindahl & Delia Grace, *The Consequences of Human Actions on Risks for Infectious Diseases: A Review*, 5 INFECTION ECOLOGY & EPIDEMIOLOGY, Nov. 2015, at 2.

174. Lucas N. Joppa, Scott R. Loarie & Stuart L. Pimm, *On Population Growth Near Protected Areas*, 4 PLOS ONE, Jan. 2009, at 1.

175. *See Why It Matters: The Pandemic Threat*, CTRS. DISEASE CONTROL & PREVENTION, https://www.cdc.gov/globalhealth/healthprotection/fieldupdates/winter-2017/why-it-matters.html [https://perma.cc/L46Z-AN6A] (last updated May 4, 2020).

176. *See* Mary E. Wilson, *Global Travel and Emerging Infections*, *in* INST. OF MED., *supra* note 158, at 90.

177. *Id.*

178. *Antibiotic Resistance and the Industrial Animal Farm*, PEW CHARITABLE TRS. (Feb. 8, 2010), http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2010/02/08/antibiotic-resistance-and-the-industrial-animal-farm [https://perma.cc/C2AT-3RFY].

"Antimicrobial resistance" describes traits and genetic elements, developed and then disbursed, by which infectious bacterial pathogens survive current antibiotic treatments and then pass on those traits.[179] This development threatens not only the infected animal or human but also the broader community that now collectively faces pathogenic bacteria that are more difficult to fight.

Antimicrobial resistance renders current, relatively inexpensive medicines for treating infectious diseases "less effective or useless."[180] The decline in efficacy of these medicines endangers lives and raises the costs of medical treatment, because infections from resistant pathogens prolong illness, increase the likelihood of hospitalization (where hospitals are available), and enlarge financial losses attributable to inability to work and redirection of family care.[181] "These drug-resistant bacteria, or 'superbugs,' present a serious and worsening threat to human health."[182]

Although there are multiple sources from which antibiotic-resistant bacteria may develop, "[f]arming practices are largely to blame for the rise of antibiotic-resistant strains."[183] Significant quantities of antibiotics have been used for promotion of growth and treatment of infections among farm animals and in aquaculture.[184] Antibiotics are commonly used for routine, nontherapeutic application in food animal production to promote growth and to anticipate the effects of crowded and unhygienic conditions.[185] Industrial farm animals release resistant bacteria in their feces, and resistant bacteria may be secreted into the environment through the animal's feces or contaminated skin.[186] When manure is applied to farmland as fertilizer, it may contaminate crops with antibiotic resistant bacteria.[187] Water runoff from industrial farms can carry resistant bacteria and unmetabolized antibiotics into the water supply and, as a result, contaminate drinking water.[188]

The World Health Organization has noted the public threat posed by excessive antibiotic use in animals, declaring that "widespread use of antimicrobials for disease control and growth promotion in animals has been paralleled by an increase in resistance in those bacteria . . . that can spread from animals, often through

179. *See What Is Microbial Resistance?*, WHO (July 2017), https://www.who.int/features/qa/75/en [https://perma.cc/NV48-DKQN].

180. *See* Gail Hansen, *Antibiotic Resistance*, *in* GLOBAL MANAGEMENT OF INFECTIOUS DISEASE AFTER EBOLA 87, 87 (Sam Halabi, Lawrence O. Gostin & Jeffrey S. Crowley eds., 2016).

181. *Id*. at 87.

182. *Id*. at 88.

183. Donald Kennedy, Editorial, *Time to Deal with Antibiotics*, 342 SCIENCE 777, 777 (2013).

184. *See* Vangelis Economou & Panagiota Gousia, *Agriculture and Food Animals as a Source of Antimicrobial-Resistant Bacteria*, 8 INFECTION & DRUG RESISTANCE 49, 50 (2015).

185. *See* Timothy F. Landers et al., *A Review of Antibiotic Use in Food Animals: Perspective, Policy, and Potential*, 127 PUB. HEALTH REP. 4, 6 (2012).

186. *See* Hansen, *supra* note 180, at 89.

187. Romain Marti et al., *Impact of Manure Fertilization on the Abundance of Antibiotic-Resistant Bacteria and Frequency of Detection of Antibiotic Resistance Genes in Soil and on Vegetables at Harvest*, 79 APPLIED & ENVTL. MICROBIOLOGY 5701, 5701 (2013).

188. Fabio Kaczala & Shlomo E. Blum, *The Occurrence of Veterinary Pharmaceuticals in the Environment: A Review*, 12 CURRENT ANALYTICAL CHEMISTRY 169, 170 (2016).

food, to cause infections in humans."[189] WHO has advocated that the "[u]se of antimicrobial growth promoters . . . in humans and animals should be terminated or rapidly phased-out in the absence of risk-based evaluations."[190] Although scholars have advocated for the use of an Article 19 treaty to address antimicrobial resistance, to date WHO has only issued Article 23 recommendations, primarily because they "offer a nimbler, more adaptive option" in the current state of political sensitivities on the issue.[191]

C. INTERNATIONAL PEACE AND SECURITY

The United Nations Charter is the foundational post-World War II treaty oriented toward a peaceful international order, where the regulation of armed force to settle international disputes, albeit with important qualifications, is vested in the U.N. Security Council.[192] The powers given to the Council under Chapter VII do not expressly address global health threats.[193] Article 39 of the U.N. Charter authorizes the Council to counteract "threats to the peace, breaches of the peace, and acts of aggression."[194] Yet global health challenges are emerging as a recurrent and critical component of the Security Council's agenda.

The 1980s and 1990s witnessed the emergence of new infectious diseases like HIV and viral hemorrhagic fevers, both of which have become subjects of U.N. Security Council action.[195] Scientists discovered the virus that caused AIDS in 1983.[196] By the end of 1986, 85 countries had reported 38,401 cases of AIDS to WHO: 2,323 in Africa, 31,741 in the Americas, 84 in Asia, 3,858 in

189. *How Antibiotic Resistance Happens*, PEW CHARITABLE TRS., https://www.pewtrusts.org/~/media/legacy/uploadedfiles/phg/content_level_pages/issue_briefs/antibioticresistancepdf.pdf [https://perma.cc/33LK-7798] (last visited Feb. 2, 2020).

190. WHO, WHO GLOBAL PRINCIPLES FOR THE CONTAINMENT OF ANTIMICROBIAL RESISTANCE IN ANIMALS INTENDED FOR FOOD 5 (2000), https://apps.who.int/iris/bitstream/handle/10665/68931/WHO_CDS_CSR_APH_2000.4.pdf [https://perma.cc/E28T-BG4M].

191. Ponnu Padiyara, Hajime Inoue & Marc Sprenger, *Global Governance Mechanisms to Address Antimicrobial Resistance*, 11 INFECTIOUS DISEASES: RES. & TREATMENT, 2018, at 3.

192. U.N. Charter ch. V. art. 24, ¶ 1 ("In order to ensure prompt and effective action by the United Nations, its Members confer on the Security Council primary responsibility for the maintenance of international peace and security, and agree that in carrying out its duties under this responsibility the Security Council acts on their behalf.").

193. Chapter VII of the Charter authorizes the Council to counteract threats to peace, breaches of peace, and acts of aggression. U.N. Charter art. 39. Article 42 empowers the Council with the power to "take such action . . . as may be necessary to maintain or restore international peace and security." *Id.* art. 42. To invoke its Article 42 powers, the Council need only "consider that measures provided for in Article 41 would be inadequate or have proved to be inadequate." *Id.*; Gian Luca Burci, *Ebola, the Security Council and the Securitization of Public Health*, 10 QUESTIONS INT'L L. 27, 27 (2014) ("This [UN Security Council Resolution on Ebola] is an unprecedented step in expanding the concept of threat to international peace and security and implicitly the scope of the powers of the Council under the UN Charter.").

194. U.N. Charter ch. VII; *see id.* ch. V. art. 24, ¶ 2 (granting to the Council the powers in Chapter VII).

195. *See* Fidler & Gostin, *supra* note 43, at 85.

196. Robert C. Gallo & Luc Montagnier, *The Discovery of HIV as the Cause of AIDS*, 349 NEW ENG. J. MED. 2283, 2284 (2003).

Europe, and 395 in Oceania.[197] By the early 1990s, the HIV/AIDS-afflicted population exploded in sub-Saharan Africa, which became home to the vast majority of people living with HIV/AIDS worldwide.[198] By 2005, approximately 20 million people had died from AIDS, and another 40 million people were infected.[199] Over the following decade, HIV/AIDS posed a burden of death and disability on those it afflicted and a threat to international peace and security.

> The precursor to the Security Council debate [(in 2000)] was a US National Intelligence assessment of the security threat posed by infectious diseases, which singled out HIV/AIDS as the gravest such peril. The National Intelligence Council report sounded the alarm: "the persistent infectious disease burden is likely to aggravate and in some cases, may even provoke economic decay, social fragmentation and political destabilisation of the hardest hit countries in the developing world."[200]

Other infectious diseases also posed significant risks to global security. Between 1994 and 2000, for example, there were more outbreaks of Ebola Virus Disease in Africa than there had been in the twenty years before.[201] The outbreak in West Africa between 2014 and 2016 spread to Italy, Spain, and the United States.[202] As of this writing, COVID-19 had infected over 1.9 million people worldwide, and caused more than 119,000 deaths.[203]

These infectious disease threats caused the U.N. Security Council to act upon both HIV/AIDS and Ebola, deeming them threats on the order of militarized threats the Council was established to regulate. Between 1981—when the members of the World Health Assembly adopted the International Code—and 1994, when the World Trade Organization was established, the relationship between free movement of goods, global health law, and human welfare was focused

197. *History of HIV and AIDS Overview*, AVERT, https://www.avert.org/professionals/history-hiv-aids/overview [https://perma.cc/299J-4GYJ] (last visited Jan. 8, 2020).

198. AIDS IN THE WORLD II: GLOBAL DIMENSIONS, SOCIAL ROOTS, AND RESPONSES 18–23 (Jonathan M. Mann & Daniel J.M. Tarantola eds., 1996).

199. Thomas Goliber, *The Status of the HIV/AIDS Epidemic in Sub-Saharan Africa*, POPULATION REFERENCE BUREAU (July 2, 2002), https://www.prb.org/thestatusofthehivaidsepidemicinsubsaharanafrica/ [https://perma.cc/9J2A-D63F]; *The Global HIV and AIDS Epidemic, 2001*, 50 CDC MORBIDITY & MORTALITY WKLY. REP. 434 (June 1, 2001), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5021a3.htm [https://perma.cc/KCH7-KDGP].

200. Alex de Waal, *The Art of Medicine: HIV/AIDS and the Challenges of Security and Conflict*, 375 LANCET 22, 22 (2010).

201. Martiner, *Chronology of Ebola Virus Disease Outbreaks, 1976–2014*, HEALTH INTELLIGENCE (June 10, 2014), http://publichealthintelligence.org/content/chronology-ebola-virus-disease-outbreaks-1976-2014 [https://perma.cc/L4WZ-UEYY].

202. *2014–2016 Ebola Outbreak in West Africa*, CTRS. DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html [https://perma.cc/96PE-2M3Q] (last updated Mar. 8, 2019).

203. *Coronavirus Resource Center*, JOHNS HOPKINS U. & MED., https://coronavirus.jhu.edu/ [https://perma.cc/3Q9V-J86C].

through not only the HIV/AIDS crisis, but a broadening spectrum of health threats faced primarily by poor populations.[204]

In 1994, the U.N. Economic and Social Council (ECOSOC) passed resolution 1994/24, which endorsed the establishment of a Joint United Nations Programme on HIV/AIDS, UNAIDS.[205] UNAIDS was founded to be the successor of the Global Programme on AIDS of WHO, which had led the fight against AIDS since 1986.[206] The creation of UNAIDS came as the result of the recognition of the insufficiency of the medically based AIDS approach of WHO's Global Programme and "the need for a multisectoral response to the complex challenges of the HIV/AIDS pandemic, including the social, economic, and development issues contributing to the spread of the virus."[207]

In 2000, the U.N. Security Council unanimously adopted Resolution 1308, marking the first time that a health issue was deemed a threat to international peace and security.[208] The Security Council tied its own recommendations for action to the integrity of international peacekeeping operations, but it was clear that the resolution was more broadly intended, noting as it did "that the spread of HIV can have a uniquely devastating impact on all sectors and levels of society."[209] In 2011, the U.N. Security Council expanded its recommendations, emphasizing that "urgent and coordinated international action continues to be required to curb the impact of the HIV epidemic in conflict and post-conflict situations."[210]

In 2014, the U.N. Security Council adopted Resolution 2177 in light of the International Health Regulations' failure to adequately address the Ebola epidemic in Guinea, Liberia, and Sierra Leone.[211] Neighboring and distant states implemented trade and travel restrictions inconsistent with the WHO Director–General's recommended measures after a public health emergency of international concern was declared (the triggering acknowledgement for legal authorities under the International Health Regulations), and the U.N. Security Council stepped in as a "Global Health Keeper," establishing the U.N. Mission for Ebola Emergency Response (UNMEER) as a temporary measure to meet immediate needs related to the fight against Ebola.[212]

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204. *See, e.g.*, UN MILLENNIUM PROJECT, PRESCRIPTION FOR HEALTHY DEVELOPMENT: INCREASING ACCESS TO MEDICINES 9 (2005).

205. Economic and Social Council Res. 1994/24 (July 26, 1994).

206. UNAIDS, *Facts About UNAIDS* 1 (Oct. 1996), http://data.unaids.org/publications/irc-pub03/una96-2_en.pdf [https://perma.cc/5PCW-GWJV].

207. U.S. GEN. ACCOUNTING OFFICE, GAO-01-625, JOINT U.N. PROGRAMME ON HIV/AIDS NEEDS TO STRENGTHEN COUNTRY-LEVEL EFFORTS AND MEASURE RESULTS 4–5 (2001).

208. S.C. Res. 1308 (July 17, 2000).

209. *Id.*

210. S.C. Res. 1983 (June 7, 2011).

211. S.C. Res. 2177 (Sept. 18, 2014).

212. *See* Ilja Richard Pavone, *Ebola and Securitization of Health: UN Security Council Resolution 2177/2014 and Its Limits*, *in* THE GOVERNANCE OF DISEASE OUTBREAKS 301, 302, 323 (Leonie Vierck, Pedro A. Villarreal & A. Katarina Weilert eds., 2017).

As of this writing, the U.N. Security Council held its first meeting about declaring COVID-19 a threat to international peace and security.[213] The failure of it to do so was not for lack of consensus about the threat but about the disagreement between the United States and China regarding the wording of its origin.[214]

II. THE FUTURE OF GLOBAL HEALTH LAW

The shifts in global health law have driven it from its twentieth-century home in the lawmaking authorities of the WHO Constitution and toward a wider, more diverse range of international actors, including other U.N. agencies, the WTO, international arbitral tribunals, the U.N. Security Council, and large enterprises in health-related sectors like food, medicine, and tobacco. Whereas the origins of global health law were in formal treaties and regulatory instruments like the International Sanitary Regulations and the International Health Regulations, the future of global health law lies in what would have formerly been understood as "private" or quasi-private law: administrative law, the law of contracts between large entities, and the law of tort. Just as influential as the number of players in global health law is the scope of its applicability. Urbanization and climate change have made the surveillance and regulation of animals (domesticated and wild) critical components of "one-health" approaches to human health and therefore the kinds of issues that global health law must address.

A. REGULATING FIRMS AND THEIR PARTNERSHIPS

Section I.A analyzed how WHO activities over the course of the 1950s and 1960s led to increasing focus on infant and child health and the corresponding influence, much of it adverse, that large firms exercised upon infant, child, and adolescent health. This section explicates the international dynamics that will facilitate the development of additional supranational regulatory regimes, legal frameworks for public–private partnerships, and administrative changes in world investment and trade law that will correspondingly make regulation more integrated with, and influenced by, global health law.

1. Supranational Regulation

There are two fundamental dynamics that will push global health law toward the development of more international treaties and supranational legal instruments aimed at directly regulating firms.[215] The first is the increasing importance of low- and middle-income markets to global firms with products and services

213. *UN Security Council to Discuss COVID-19 Pandemic in Closed Session on Thursday*, ECON. TIMES (Apr. 7, 2020, 10:23 AM), https://economictimes.indiatimes.com/news/international/world-news/un-security-council-to-discuss-covid-19-pandemic-in-closed-session-on-thursday/articleshow/75020783.cms [https://perma.cc/6SD6-WU9H].

214. *Id.*

215. "Supranational law" has been defined as "law which goes beyond the national law and prevails." Kristi Joamets, Gender as an Element of Marriage Capacity in the Context of National and Supranational Law in the European Union 10 (Oct. 7, 2014) (unpublished Ph.D. thesis, Tallinn University of Technology).

uniquely affecting individual and public health.[216] The second is the persistent need and desire for low- and middle-income countries to use collective action to address firm behavior. Theoretically, it is possible for each country, as a sovereign lawmaker, to regulate firm behavior within its jurisdiction. Practically, laws like the Framework Convention on Tobacco Control and the International Code of Marketing of Breast-milk Substitutes have emerged because those countries realize that their internal lawmaking processes are vulnerable to influence from global firms. They further realize that they are likely to achieve greater gains vis-à-vis those firms through collective, global health law instruments.

"The 1981 International Code of Marketing of Breastmilk Substitutes is effectively a Nestlé-specific treaty."[217] Even in 1981, Nestlé controlled 50% of the global infant formula market.[218] Developing countries were unified in their positions with respect to Nestlé (and to some extent, the small number of competitor firms all based in wealthy countries) that breastmilk substitutes contributed little to their national economies and, by increasing infant morbidity and mortality, generated unnecessary healthcare costs. This unity of position, and the necessity of a supranational regulatory instrument to give effect to their consensus, is expressed in the strength of the Code vote (118 in favor, 1 against, and 3 abstentions).[219] Similarly, not only Nestlé, but diplomats from wealthier countries, viewed the Code as a regulatory assertion from WHO and understood it to be the first of more such regulatory instruments to follow.[220]

The lessons of the International Code informed the debate leading to the negotiation and adoption of the Framework Convention on Tobacco Control.[221] Nongovernmental organizations pointed to the International Code as showing the pathway toward civil-society engagement with the treaty-making process.[222] As with the formula sector as it existed in the late 1970s and the early 1980s, the

216. *See* Anna Gilmore, *Big Tobacco Targets the Young in Poor Countries – with Deadly Consequences*, GUARDIAN (Dec. 1, 2015, 6:57 AM), https://www.theguardian.com/global-development/2015/dec/01/big-tobacco-industry-targets-young-people-poor-countries-smoking [https://perma.cc/XRX5-5535].

217. HALABI, *supra* note 21, at 220.

218. Solomon, *supra* note 58.

219. *See* Sikkink, *supra* note 85, at 822.

220. *See id.* at 820 ("Kenneth L. Adelman, when U.S. deputy representative to the United Nations, wrote that 'it appears that the infant formula drive was just the opening skirmish in a much larger campaign. . . . And this larger campaign could reach beyond regulation of pharmaceuticals to encompass United Nations codes on hazardous chemicals, transborder data flow, and an array of so-called consumer protection activities.'").

221. *See* Roemer et al., *supra* note 98, at 937.

222. *See* WHO, Framework Convention on Tobacco Control, Technical Briefing Series Paper 3, *Mobilizing NGOs and the Media Behind the International Framework Convention on Tobacco Control*, at 17–20 (1999), https://apps.who.int/iris/bitstream/handle/10665/65357/WHO_NCD_TFI_99.3.pdf [https://perma.cc/G2CV-ALGA].

tobacco industry in the late 1990s and early 2000s was highly consolidated, with common overlapping practices worldwide.[223]

When Canada, Finland, Tanzania, and Mexico introduced the idea of a global tobacco control treaty at WHO, four corporations controlled 75% of the global market and the broad perception was that only a supranational regulatory instrument could effectively address their international activities.[224] The global tobacco industry put the conceptual notion of supranational regulation at the core of its fierce resistance to the Framework Convention on Tobacco Control.[225] Philip Morris endeavored generally to discredit WHO as a tobacco regulatory body and sought to weaken the treaty through its influence on national delegations.[226]

Supranational regulation has now moved beyond product sectors that affect individual and public health and toward the broader healthcare sector. Less oligopolistic, but nevertheless global, firms have long recruited healthcare workers trained abroad to fill understaffed areas in the United States, especially in rural regions and other underserved populations.[227] Active recruitment by private recruitment agencies greatly contributes to the depletion of health workforces in many low- and middle-income countries.[228] "Australia, Canada, the United Kingdom (UK) and United States (USA) account for 72% of foreign-born nurses and 69% of foreign-born physicians."[229] Those countries have collectively saved billions in costs "by recruiting physicians from countries in sub-Saharan Africa—countries that lose 30% of their trained health workers annually to medical emigration."[230] In 2010, WHO adopted the Global Code of Practice on the International Recruitment of Health Personnel, which makes clear that it is applicable to "recruiters, employers, health-professional organizations, relevant subregional, regional and global organizations, whether public or private sector,

223. Katherine DeLand et al., *The WHO Framework Convention on Tobacco Control and the Tobacco Free Initiative*, *in* THE GLOBAL TOBACCO EPIDEMIC AND THE LAW 11, 13 (Andrew D. Mitchell & Tania Voon eds., 2014).

224. *Id.* at 13–14; Thomas Bollyky & David Fidler, *Has a Global Tobacco Treaty Made a Difference?*, ATLANTIC (Feb. 28, 2015), https://www.theatlantic.com/health/archive/2015/02/has-a-global-tobacco-treaty-made-a-difference/386399/.

225. *See, e.g.*, Brown & Williamson Tobacco Corporation, Comments on the World Health Organization Framework Convention on Tobacco Control 2–3 (Mar. 29, 2000), http://legacy.library.ucsf.edu/tid/uri45a99 [https://perma.cc/DAZ6-K87X].

226. *See* H.M. Mamudu & S.A. Glantz, *Civil Society and the Negotiation of the Framework Convention on Tobacco Control*, 4 GLOBAL PUB. HEALTH, 2009, at 10.

227. Giorgio Cometto et al., *Health Workforce Brain Drain: From Denouncing the Challenge to Solving the Problem*, 10 PLOS MED., Sept. 2013, at 1.

228. Lisa A. Eckenwiler, *Care Worker Migration and Transnational Justice*, 2 PUB. HEALTH ETHICS 171, 173–74 (2009); Christoph Aluttis et al., *The Workforce for Health in a Globalized Context – Global Shortages and International Migration*, 7 GLOBAL HEALTH ACTION, 2014, at 3.

229. Vivian Tam et al., *Empirically Evaluating the WHO Global Code of Practice on the International Recruitment of Health Personnel's Impact on Four High-Income Countries Four Years After Adoption*, 12 GLOBALIZATION & HEALTH, 2016, at 2.

230. *Id.*

including nongovernmental, and all persons concerned with the international recruitment of health personnel."[231]

Calls for similar supranational or international agreements have followed on other global health law matters such as excessive alcohol consumption, antibiotic resistance, counterfeit medicines, and corruption in health systems.[232]

2. Public–Private Partnerships

Global health law will not only be characterized by additional supranational regulation of global firms but also by the contractual agreements that regulate relationships between firms and public-sector partners. Because public–private partnerships have proliferated since 2000 (with the establishment of GAVI, followed by the Global Fund to Fight AIDS, Tuberculosis and Malaria in 2002), the contractual relationships between firms, governments, and large health-oriented foundations will serve as a significant source of global health law. Consider the Pandemic Influenza Preparedness Framework described in section I.A.1.c. On one hand, pharmaceutical firms viewed the arrangement as a form of supranational regulation: "The negotiations over the establishment of the WHO Pandemic Influenza Preparedness Framework Agreement were viewed, at least by the IFPMA, as fundamentally about what level of supranational regulation would be imposed for them to participate in the Global Influenza Surveillance and Response System for virus samples with pandemic potential."[233] On the other hand, the system works through standard material-transfer agreements establishing the rights and obligations between the companies and WHO.[234]

GAVI similarly operates under agreements between itself (technically a Swiss foundation), vaccine manufacturers, and governments procuring the vaccines.[235] The procuring agency is UNICEF (and, for some stockpiles of vaccines, WHO), and the terms of UNICEF acquisition are imposed on firms as well.[236] These terms include responsibility for other aspects of vaccines that may affect health, like side effects or adverse reactions.

The Global Fund similarly administers its mandate through contractual arrangements. The Global Fund is the main multilateral funder in global health

231. WHO, *WHO Global Code of Practice on the International Recruitment of Health Personnel*, WHA63.16, art. 2.2 (May 2010); *see also* Amani Siyam et al., *Monitoring the Implementation of the WHO Global Code of Practice on the International Recruitment of Health Personnel*, 91 BULL. WORLD HEALTH ORG. 816, 816 (2013) ("The adoption in 2010 of the WHO Global Code of Practice . . . furnished a guide to international cooperation and facilitated a platform for continuing dialogue on the critical problem of health worker migration.").

232. Bollyky & Fidler, *supra* note 224.

233. HALABI, *supra* note 21, at 220.

234. WHO, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, *supra* note 125, at 14.

235. *See* Susan K. Sell, *The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions*, 77 TEMP. L. REV. 363, 371 (2004).

236. *See generally* United Nations Children's Fund [UNICEF], *UNICEF Vaccine Procurement Overview: Priorities, Status and Way Forward*, https://perma.cc/QFU4-WK4Q (explaining UNICEF's procurement role).

and channels 69% of the international financing for TB[237] and more than 20% of the international financing against AIDS.[238] It also funds "health systems strengthening, as inadequate health systems are one of the main obstacles to scaling up interventions to secure better health outcomes for HIV, TB and malaria."[239] Grants are awarded to Principal Recipients, entities that enter into agreements with the Fund.[240] The Principal Recipients are the grants' lead implementers and are responsible for program management.[241] Country Coordinating Mechanisms (CCMs) evaluate proposals within a particular country and send coordinated proposals to the Global Fund.[242] The CCMs also share governance with Principal Recipients, who are also members of the CCMs.[243]

Large, influential foundations like the Bill and Melinda Gates Foundation and the Wellcome Trust similarly use legally binding agreements to shape the behavior of health-related actors. The Gates Foundation is part of the governance of GAVI, the Global Fund, and other public–private partnerships specific to disease research like HIV/AIDS. Gates Foundation funding is accompanied by requirements that recipients allow "unrestricted access and reuse of all peer-reviewed published research funded, in whole or in part, by the foundation, including any underlying data sets."[244] These requirements similarly inform agreements entered into by the organizations in which the Gates Foundation plays a management role, like the Global Fund and GAVI. The Wellcome Trust also requires the disclosure of research and the publication of data in open-access fora.[245] The future of global health law is therefore not only likely to be shaped by supranational regulation, primarily by WHO, but also by the tightening network of agreements required by international funders.[246]

The Coalition for Epidemic Preparedness Innovations (CEPI), an international public–private partnership committed to developing vaccines for otherwise

237. *Tuberculosis*, GLOBAL FUND (May 2, 2019), https://www.theglobalfund.org/en/tuberculosis/ [https://perma.cc/VD3P-DMDF].

238. *Funding for HIV and AIDS*, AVERT (May 25, 2018), https://www.avert.org/professionals/hiv-around-world/global-response/funding [https://perma.cc/8XJ6-46FJ].

239. *Fighting AIDS, Tuberculosis and Malaria*, GLOBAL FUND, https://perma.cc/CK6T-DNE4 (last visited May 18, 2020).

240. Anna Triponel, *Global Fund to Fight Aids, Tuberculosis and Malaria: A New Legal and Conceptual Framework for Providing International Development Aid*, 35 N.C. J. INT'L L. & COM. REG. 173, 198 (2009).

241. *Id*.

242. *Id*. at 197.

243. *Id*. at 197–98.

244. *Bill & Melinda Gates Foundation Open Access Policy*, BILL & MELINDA GATES FOUND. https://www.gatesfoundation.org/how-we-work/general-information/open-access-policy [https://perma.cc/JTA6-NKWP] (last visited Jan. 9, 2020).

245. *See Open Access Policy*, WELLCOME, https://wellcome.ac.uk/funding/guidance/open-access-policy [https://perma.cc/QC7Y-RNGP] (last visited Feb. 3, 2020).

246. *See, e.g.*, Michelle Rourke, Sam Halabi, Gian Luca Burci & Rebecca Katz, *The Nagoya Protocol and the Legal Structure of Global Biogenomic Research*, 41 YALE J. INT'L L. 1 (forthcoming 2020) (manuscript at 2).

neglected diseases, now funds eight vaccine candidates against COVID-19.[247] CEPI's equitable-access policy requires that vaccines it funds "will be priced and include affordability commitments or standards."[248]

3. The World Trade Organization, ICSID, and Other Adjudicatory Bodies

Supranational regulation and the agreements forging public–private partnerships for health may be thought of as *ex ante* forms of global health law that will grow in importance and influence. *Ex post* global health law may be understood to be how lawmaking or law-shaping adjudicative bodies integrate *ex ante* global health law into their decisions affecting rights between parties—both governments and firms—when disputes arise that implicate application of that body of law.[249] These bodies are most likely to be arbitral panels like those convened under the auspices of the International Centre for Settlement of Investment Disputes (ICSID), courts dedicated to disputes between sovereigns like the International Court of Justice and the WTO's Dispute Settlement Understanding, and, of course, national courts. These adjudications have already occurred at a limited level and are likely to increase, thus expanding the body of global health law that is judicially informed and shaped.

The most significant incorporation of global health law in one of these tribunals to date was the Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health.[250] In 1996, Brazil adopted a "local-working" requirement as part of its Industrial Property Law, which permitted the Brazilian government to license patented medicines and technology to other firms for production if the patent was not "worked" in Brazil.[251] Pharmaceutical firms, which had exported patented medicines to Brazil but not produced them there, protested the law and encouraged the U.S. government to bring a formal dispute at the WTO for violating TRIPS, the intellectual property law in the broader WTO Agreements.[252] In response to the U.S. complaint, Brazil raised issues of U.S. patent policy that provided allegedly discriminatory support for its pharmaceutical industry.[253] As a result of the WTO dispute

247. Dave Kovaleski, *CEPI Invests $4.9M in Consortium to Develop COVID-19 Vaccine*, HOMELAND PREPAREDNESS NEWS (Mar. 23, 2020), https://homelandprepnews.com/stories/46200-cepi-invests-4-9m-in-consortium-to-develop-covid-19-vaccine/ [https://perma.cc/MVD2-2ZDR].

248. Brenda Huneycutt et al., *Finding Equipoise: CEPI Revises Its Equitable Access Policy*, 38 VACCINE 2144, 2144, 2146 (2020).

249. *See generally* Leonie Vierck, *The Case Law of International Public Health and Why Its Scarcity Is a Problem*, *in* THE GOVERNANCE OF DISEASE OUTBREAKS, *supra* note 212, at 113 (arguing that more *ex post* law is needed in the global public health field).

250. *See generally* James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 293–95 (2002); John S. Odell & Susan K. Sell, *Reframing the Issue: The WTO Coalition on Intellectual Property and Public Health, 2001*, *in* NEGOTIATING TRADE: DEVELOPING COUNTRIES IN THE WTO AND NAFTA 85, 94–96 (John S. Odell ed., 2006).

251. *See* Article 68 of Law No. 9,279 of May 14, 1996, effective May 1997.

252. Request for the Establishment of a Panel by the United States, *Brazil – Measures Affecting Patent Protection*, WTO Doc. WT/DS199/3 (Jan. 9, 2001).

253. *See* 35 U.S.C. §§ 204, 209 (2012).

and pressure exerted by African countries bearing the burden of the HIV/AIDS crisis, WTO Member States adopted the Declaration on the TRIPS Agreement and Public Health (Doha Declaration) at the Fourth Ministerial Conference, held in Doha, Qatar, in November 2001.[254]

Developed to protect access to medicines for HIV/AIDS, tuberculosis, malaria and "other epidemics," the Doha Declaration established that treatments for diseases affecting low- and middle-income countries required that normal rules of trade defer to global health interests.[255] The United States and Brazil terminated their dispute in 2001 in the wake of the Doha Declaration, which they jointly drafted.[256] Although accomplished through ministerial action, the Doha Declaration was effectively the result of international litigation.[257]

Similarly, the International Code of Marketing of Breast-milk Substitutes has been incorporated into WTO-relevant instruments to protect infants from trade challenges to products the Code covers. The Code is specific to a "corporation" or "any other entity" in the business of breastmilk substitutes and covers not only infant formula but also "cow's milk, fruit juices, cereals, vegetables, or any other fluid, solid or semi-solid food intended for infants" when those foods are "marketed or otherwise represented to be suitable" as a substitute.[258] The Code authorizes countries to prevent companies from advertising breastmilk substitutes; implement strict labeling requirements, including a proscription on infant images or other pictures that idealize breastmilk substitutes; limit influence on healthcare workers; and prohibit distribution of free samples of breast milk substitutes.[259] Large infant formula markets like Brazil, China, and India have banned the use of images on infant formula containers,[260] while a growing number of developing and wealthy countries are considering stronger measures toward limiting the appearance or use of trademarks in connection with infant formula.[261]

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254. WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2 [the Doha Declaration].

255. *Id*. ¶ 1; *see* Elizabeth Chien-Hale & Frederick M. Abbott, *Intellectual Property Rights in Global Trade Framework: IP Trends in Developing Countries*, 98 PROC. ANN. MEETING AM. SOC'Y INT'L L. 95, 96 (2004).

256. *See* Notification of Mutually Agreed Solution, *Brazil – Measures Affecting Patent Protection*, WTO Doc. WT/DS199/4 (July 19, 2001).

257. *See* Sam F. Halabi, *International Intellectual Property Shelters*, 90 TUL. L. REV. 903, 908 (2016) (arguing that events leading to the Doha Declaration reflect "a single, cohesive phenomenon that has emerged in response to intellectual property protections expanding through trade and investment agreements").

258. WHO, INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES, *supra* note 82, arts. 2–3, annex 3.

259. *Id*. arts. 5, 7, 9.

260. WHO, COUNTRY IMPLEMENTATION OF THE INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES: STATUS REPORT 2011 26–38 (2013), https://apps.who.int/iris/bitstream/handle/10665/85621/9789241505987_eng.pdf [https://perma.cc/4NLW-ZD7W].

261. *See, e.g*., Jessica Samakow, *Baby Formula Ads in Sweden May Soon Be Banned from Featuring Babies*, HUFF POST (Nov. 8, 2012, 5:03 PM), http://www.huffingtonpost.com/2012/11/08/baby-formula-ads-sweden-_n_2092920.html [https://perma.cc/E3UW-H5WL]; Aideen Sheehan, *EU Bans Photos of Babies on Formula Milk*, IRISH INDEP. (June 12, 2013, 3:04 AM), http://www.independent.ie/irish-news/eu-bans-photos-of-babies-on-formula-milk-29337896.html [https://perma.cc/4LCD-84G6].

Measures implementing the International Code are protected from the WTO's dispute-settlement mechanism, so challenges under TRIPS would be unusually difficult.[262] At the time of WTO's establishment, as well as the TRIPS Agreement's establishment, countries needed an efficient mechanism by which to evaluate whether public health and regulatory measures that already existed, and those that might be adopted in the future, appropriately served regulatory purposes, rather than as hidden means to discriminate against foreign goods.

The answer, at least for food and plant safety, was the list of standards already adopted by Codex, analyzed in section I.B. Since 1963, Codex had adopted standards on food quality and safety, including food-commodity standards and codes of hygienic or technological practice, in an effort to "ensure fair practices in food trade" and "protect the health of consumers."[263] Codex was designated WTO's official standard reference body for challenges to food safety or labeling measures under the Sanitary and Phytosanitary (SPS) Agreement.[264] All countries that have acceded to the WTO Agreements may be bound by WTO panel decisions regarding SPS and TBT measures. Therefore, these countries may be constrained by Codex standards.[265] The Agreement instructs WTO Members to "'base their sanitary or phytosanitary measures on international standards' (Article 3.1) and presumes those international standards to 'be consistent with the relevant [provisions] of this Agreement and of GATT [General Agreement on Tariffs and Trade] 1994' (Article 3.2)."[266]

By 1994, Codex had already adopted the International Code into its "Standard for Infant Formula and Formulas for Special Medical Purposes Intended for

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262. *See* Halabi, *supra* note 147, at 414 ("Codex standards on infant formula . . . not only tightly regulate the components of formula (for example, vitamins, minerals, and essential nutrients) but also incorporate key aspects of the 1981 World Health Organization's International Code on the Marketing of Breastmilk Substitutes. This is to enable regulatory authorities to require manufacturers to include labels stating the superiority of breastfeeding for infants, prohibiting pictures of infants or women that idealize formula use, and advising consumers that they should use formula only on the advice of an independent health worker, without falling afoul of the SPS Agreement." (citing Codex Alimentarius Commission, Codex Standard 72-1981 § 9.6 (2011))).

263. *Id*. at 407 (citing FOOD & DRUG ADMIN., FDA'S INTERNATIONAL FOOD SAFETY CAPACITY-BUILDING PLAN 21 (2013)).

264. *Id*. at 412. "The WTO's SPS Agreement was established in 1995 to regulate food, plant, and animal safety and health regulations. The adjudicatory arm . . . of the WTO resolves trade disputes regarding such issues and can impose or permit trade-based punitive measures for violations of the SPS Agreement." *Id*. at 412 n.58.

265. Michael A. Livermore, *Authority and Legitimacy in Global Governance: Deliberation, Institutional Differentiation, and the Codex Alimentarius*, 81 N.Y.U. L. REV. 766, 768–70 (2006). "The WTO's near codification of Codex Alimentarius standards regarding sanitary and phytosanitary measures likely casts Codex's SPS-related actions as the organization's most significant activity." Halabi, *supra* note 147, at 413 n.60; *see* Randell & Whitehead, *supra* note 154, at 316–17.

266. Halabi, *supra* note 147, at 413 n.61 (quoting Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154, art. 3); *see also* David A. Wirth, *The Transatlantic GMO Dispute Against the European Communities*, *in* EU AND WTO LAW: HOW TIGHT IS THE LEGAL STRAIGHTJACKET FOR ENVIRONMENTAL PRODUCT REGULATION? 175, 191 (Marc Pallemaerts ed., 2006).

Infants."[267] Although the Codex standard operates separately from measures sanctioned by TRIPS, the standard effectively creates a safe harbor for strong measures regulating infant formula and other foods that might be used as substitutes.

Though global health law has been increasingly incorporated into adjudications under international trade law, one of the most significant changes has occurred in the field of international investment law.[268] Between 2008 and 2010, the small, South American country of Uruguay implemented a number of tobacco-control measures, including two that addressed the manipulation of packaging and labeling to shape health perceptions of tobacco products.[269] First, the state required that pictorial warnings cover 80% of a cigarette pack's surface.[270] Second, the Ministry of Health limited the sale of cigarettes to only one variety per brand, the so-called single-presentation requirement.[271] That part of the law prevented a firm from selling multiple varieties of cigarettes under a single trademark. For example, Philip Morris International (PMI), whose most important asset is the Marlboro brand, could no longer sell Marlboro "Reds" and Marlboro "Greens," leaving "Marlboros" as its only authorized variety.[272] At the time the measures were adopted, Uruguay had one of Latin America's highest smoking rates.[273] As of 2009, more than 5,000 Uruguayans died each year from diseases linked to tobacco consumption, mainly due to cardiovascular diseases and cancer.[274]

The FCTC effectively protected Uruguay's measures from what would have, prior to the FCTC's existence, been strong claims that the new laws wrongly diminished the value of PMI's investment—that is, its trademarks. Philip Morris International first challenged the regulations in Uruguayan courts, seeking an injunction based in part on Uruguay's law adopting TRIPS, the treaty at issue for

267. Codex Alimentarius Commission, FAO & WHO, Codex Standard 72-1981, *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* § 9.6.2 (2016).

268. *See, e.g.*, Prathana Rebecca Knapp & Nutthakarn Phongphunpunya, *Striking a Balance: Public Health vs IP Rights in Thailand's Cigarette Package Rules* (2014), http://gip-asean.com/information/newsletter201404th.pdf [https://perma.cc/JSY2-FQJS].

269. *See* Susy Frankel & Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, 46 VAND. J. TRANSNAT'L L. 1149, 1158–59 & n.31 (2013).

270. Uru., Presidential Decree No. 287/009 (June 5, 2009); *see* FTR Holding S.A. v. Uruguay, ICSID Case No. ARB/10/17, Request for Arbitration, ¶ 5 (Feb. 19, 2010), http://www.smoke-free.ca/eng_home/2010/PMIvsUruguay/PMI-Uruguay%20complaint0001.pdf [https://perma.cc/P34R-55N3].

271. Uru., Ministry of Public Health Ordinance No. 514 art. 3 (Feb. 14, 2009).

272. FTR Holding S.A. v. Uruguay, Request for Arbitration, ¶ 45 ("As of 31 December 2009, Article 3 of Ordinance 514 has resulted in an approximately 15 per cent decrease in Abal's sales. The hardest hit brand has been 'Marlboro,' of which the discontinued 'Marlboro Gold,' 'Marlboro Blue' and 'Marlboro Green (Fresh Mint)' varieties represented 40.5 per cent of total sales in 2008. . . . As a result of Ordinance 514, Philip Morris has been prevented from introducing these innovations in Uruguay and accordingly has been deprived of the use of its intellectual property.").

273. PAN AMERICAN HEALTH ORGANIZATION [PAHO] & WHO, TOBACCO CONTROL REPORT FOR THE REGION OF THE AMERICAS 3 chart 2 (2013).

274. PAHO, GLOBAL ADULT TOBACCO SURVEY: GATS URUGUAY 2009, at 15, 22 (2011), https://www.paho.org/hq/index.php?option=com_docman&view=download&category_slug=reports-9464&alias=16757-gats-uruguay-report-2009-757&Itemid=270&lang=en [https://perma.cc/P9NN-EYH2].

the Doha Declaration dispute described above.[275] Unsuccessful in Uruguayan courts, PMI initiated (through Swiss corporate entities it controlled) arbitration proceedings under Switzerland's bilateral-investment treaty with Uruguay.[276] That treaty included not only broad definitions of "investor" and "investment," but it also established narrow exceptions for public health regulation and required laws to compensate an investor for an "indirect" expropriation, even when those laws were passed under the public health exception and according to due process.[277]

The international arbitration panel hearing the dispute determined that Uruguay's measures fell within its obligations under the FCTC, which itself provided an independent basis that Uruguay's measures were evidence-based and in the public interest.[278] Citing Articles 2, 4, 11, and 13 of the FCTC, the arbitration panel concluded that:

> [The single-presentation requirement (SPR)] is part of Uruguay's comprehensive tobacco control policies and is in line with WHO Recommendations and Uruguay's express obligations under Article 11 of the FCTC as well as in accordance with Art. 8 of Law 18,256. The SPR thus draws upon the scientific evidence of the FCTC and its implementation guidelines, and constitutes a sound policy that advances important public health objectives.[279]

Similarly, the panel cited Article 11 of the FCTC for support of larger graphic warnings. After the adoption of Uruguay's measures, other developing countries followed with laws increasing the required size of warnings on tobacco packaging: Namibia (55% of a cigarette pack must be covered with warning labels), Burkina Faso (60%), Ecuador (60%), Moldova (65%), Turkey (65%), Uganda (65%), Chad (70%), Brunei (75%), Canada (75%), and Sri Lanka (80%).[280] Thailand, Pakistan, and India now require warning labels that cover 85% of the front and back of cigarette packs.[281]

B. GLOBAL "ONE-HEALTH" LAW

If enterprises and foundations represent new actors and sources of global health law, and international adjudicatory bodies represent the future of how global health law is applied, then animals, both domesticated and wild, represent the

275. FTR Holding S.A. v. Uruguay, Request for Arbitration, ¶ 1.

276. *Id.*

277. Agreement on the Reciprocal Promotion and Protection of Investments (with Protocol), Switz.-Uru., arts. 1, 5, Oct. 7, 1988, 1976 U.N.T.S. 389.

278. Philip Morris Brands Sàrl v. Uruguay, ICSID Case No. ARB/10/7, Award, ¶ 391 (July 8, 2016).

279. *Id.* ¶ 360.

280. *Id.* ¶¶ 372–73.

281. *Id.* ¶ 373; *see UP Court Recommends Plain Packaging for Cigarettes*, HINDUSTAN TIMES (July 25, 2014), https://www.hindustantimes.com/india/up-court-recommends-plain-packaging-for-cigarettes/story-2et7l356qUSKE4KZKTgvEM.html [https://perma.cc/8YSH-F9HT].

expansion of global health law's subjects. Human health, narrowly defined, prevailed throughout most of the twentieth century. In some ways, the comprehensive approaches to animal, human, and plant life should have been obvious and inevitable from the earliest days of WHO. Its most ambitious, early eradication effort focused on malaria.[282] This effort made extensive use of DDT, which "appeared to be effective everywhere, making eradication of malaria a feasible objective. However, DDT's effectiveness against agricultural pests and household insects made prices soar, and its widespread application rapidly led to" resistance in some pests.[283] Beyond those effects, it also imposed significant toxic risks on wildlife and posed serious health risks to humans as well.[284] It was banned in most developed countries during the 1970s.[285]

The need to widen the reach of global health law to include not only the health of humans but also the health of the animals they raised and ate as well as the environment in which they lived grew over the course of the 1970s. In 1972, the U.N. held the first of many global conferences on environmental issues: the Conference on the Human Environment in Stockholm, Sweden.[286] In the decade after the 1972 conference, scientists and nongovernmental organizations had sounded the alarm on biodiversity losses generally and in the Amazon River basin specifically.[287] Logging, extraction, and agriculture explained much of the loss.[288] In 1987, the governing council of the United Nations Environmental Programme created a working group to explore the possibility of developing a legally binding treaty to protect biological resources.[289] In 1991, formal multilateral negotiations began for a Convention for Biological Diversity.[290]

The interconnectedness of habitat loss, pathogen emergence, and ecosystem collapse led researchers, governments, and public health scholars to develop what has been known as "one-health" approaches to animal, human, and plant health.[291] That humans, animals, and the environment are interdependent and that their respective welfare is mutually supportive has been acknowledged for

282. José A. Nájera et al., *Some Lessons for the Future from the Global Malaria Eradication Programme (1955–1969)*, 8 PLOS MED., Jan. 2011, at 1.

283. *Id.* at 2.

284. Thieu Thi Thuy, *Effects of DDT on Environment and Human Health*, 2 J. EDUC. & SOC. SCI. 108, 108 (2015).

285. *Id.*

286. Roger A. Coate, *Civil Society as a Force for Peace*, 9 INT'L J. PEACE STUD. 57, 59–60, 66 (2004).

287. *See* Daniel H. Janzen, *The Future of Tropical Ecology*, 17 ANN. REV. ECOLOGY & SYSTEMATICS 305, 317 (1986).

288. *See* Michael J. Heckenberger et al., *The Legacy of Cultural Landscapes in the Brazilian Amazon: Implications for Biodiversity*, 362 PHIL. TRANSACTIONS ROYAL SOC'Y B 197, 197 (2007); *Land Use and Agriculture in the Amazon*, GLOBAL FOREST ATLAS, https://globalforestatlas.yale.edu/amazon/land-use [https://perma.cc/CT7G-3K56] (last visited Feb. 3, 2020).

289. Environment Programme Res. 14/26 (June 17, 1987).

290. *International Day for Biological Diversity 22 May*, U.N., https://perma.cc/GY83-H6EB (last visited Feb. 3, 2020).

291. *Advancing a 'One Health' Approach to Promote Health at the Human-Animal-Environment Interface*, *supra* note 171.

centuries.[292] Yet it is relatively recently that public health policies have focused on the nexus between humans, animals (domesticated and wild), and the environment.[293] After the severe acute respiratory syndrome (SARS) epidemic (which led to the revision of the International Health Regulations) and the H5N1 avian influenza outbreaks, one-health approaches expanded to include health-service delivery, environmental health, and ecosystem services.[294] As Dr. Robert Breiman has explained in the context of COVID-19:

> Recent studies indicate that there may be parallels between SARS and the current pandemic. Scientists have found coronaviruses, genetically similar to the Covid19 virus, in pangolins, leading to a hypothesis that they served as an intermediate host, much like civet cats did with SARS. . . .
>
> We have affected these creatures in more ways than poaching them. As human populations grow, our incursion into a variety of habitats expands even as our appetite for certain animals remains unabated. As it has with civets, deforestation has dramatically affected the areas available for pangolins' foraging, putting them in closer contact with other animals including bats, which are reservoirs for other dangerous viruses like Nipah virus, and possibly Ebola. This may have facilitated the spread of disease.[295]

This one-health strategy means establishing systems that acknowledge the close relationship between animal and human health.[296] These systems are oriented toward areas where rapid intensification of agriculture systems, especially with livestock keeping, have increased interactions between animals and humans, and consequently caused significant changes in habits and practices of proximate human communities.[297]

The most significant manifestation of global health law at the nexus of animals, humans, and the environment is the Joint External Evaluation (JEE) process. The JEE is a "voluntary, collaborative, multisectoral process" that assesses countries' capacities to identify the most critical gaps within their human and animal health systems, in order to prioritize opportunities for enhanced preparedness and response.[298] The JEE "bring[s] together national representatives from key sectors,

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292. van Helden, van Helden & Hoal, *supra* note 17, at 497.

293. *See id*.

294. Nita Madhav et al., *Pandemics: Risks, Impacts, and Mitigation*, *in* 9 DISEASE CONTROL PRIORITIES: IMPROVING HEALTH AND REDUCING POVERTY 315, 315 (Dean T. Jamison et al. eds., 3d ed. 2018).

295. Robert F. Breiman, *The COVID-19 Culprit Is Us, Not Pangolins*, CNN (Mar. 27, 2020, 7:42 PM), https://www.cnn.com/2020/03/27/opinions/pangolin-coronavirus-pandemic-breiman/index.html [https://perma.cc/8JXW-TQP3].

296. *See generally* Justin Lessler et al., *What Is a Hotspot Anyway?*, 96 AM. J. TROPICAL MED. HYGIENE 1270 (2017) (analyzing currently used definitions of "hotspot" and recommending more specific application to animal-human interactions).

297. Lindahl & Grace, *supra* note 173, at 2.

298. *Strengthening Health Security by Implementing the International Health Regulations*, WORLD HEALTH ORG. (2005), https://www.who.int/ihr/procedures/joint-external-evaluations/en/ [https://perma.cc/28SY-WU2E].

including human and animal health, agriculture, wildlife, finance, defence, security, environment, communication, disaster management board, transportation, customs, civil aviation, universities or institutes, and political leadership."[299] The JEE exercise identifies whether a country has adopted laws specific to the International Health Regulations, maintains surveillance systems for animal health, and monitors the use of antibiotics and signals for the emergence of antimicrobial resistance.[300]

The JEE process itself is a function of the increasing "securitization" of global health law. The Global Health Security Agenda (GHSA), described in more detail in section II.C, was launched in 2014 to help build countries' capacities to address infectious disease and other threats. The GHSA external assessment tool was developed in collaboration with relevant international organizations with mandates committed to one-health approaches—WHO, FAO, and OIE—as well as member countries. In early 2016, the WHO IHR monitoring and evaluation teams began working with the GHSA secretariat to introduce the Joint External Evaluation tool (JEE). The JEE tool includes the original components of the GHSA tool but also adds in eight other key technical areas from the International Health Regulations.

C. GLOBAL HEALTH LAW AS INTERNATIONAL PEACE AND SECURITY LAW

The formation of the GHSA coincided with the emergence of the Ebola outbreak in Guinea, Liberia, and Sierra Leone, which lasted through 2016 and claimed over 11,000 lives. Its formation signaled the tightening relationship between global health law and international peace and security, further intertwined with the U.N. Security Council's intervention into the Ebola outbreak in September 2014. The 2014 establishment of the GHSA represents the rise of a new kind of governance that blends the trends outlined in sections II.A and II.B. The GHSA is a broad-based partnership comprised of approximately sixty countries who work with international organizations, foundations, and businesses.[301] It explicitly acknowledges equivalence between infectious disease and biosecurity threats and integrates into its partnership not only WHO, FAO, and OIE but also security-oriented international organizations like Interpol.[302] According to the GHSA, the fight against COVID-19 has been significantly enhanced by "national plans supported by the International Health Regulations and Joint External

299. Nirmal Kandel et al., *Joint External Evaluation Process: Bringing Multiple Sectors Together for Global Health Security*, 5 LANCET 857, 857 (2017).

300. *See generally* WHO, INTERNATIONAL HEALTH REGULATIONS (2005) COUNTRY IMPLEMENTATION GUIDE: VOLUNTARY JOINT EXTERNAL EVALUATION (2017).

301. *The U.S. Government Engagement in Global Health: A Primer*, KAISER FAM. FOUND. (Feb. 5, 2019), https://www.kff.org/global-health-policy/report/the-u-s-government-engagement-in-global-health-a-primer/view/print/ [https://perma.cc/646Z-54YX].

302. *About the GHSA*, GLOBAL HEALTH SECURITY AGENDA, https://ghsagenda.org/home/about-the-ghsa/ [https://perma.cc/SCQ7-ZGXD] (last visited Feb. 3, 2020).

Evaluations [which are] are guiding action and providing resources for decision making, prioritisation, and actions."[303]

Although there had been global health emergencies before the International Health Regulations were adopted and expanded in the early 2000s (for example, pandemic influenza), they had never before been considered as proper concerns of the world's most important authority for securing international peace and security. With the global threat posed by both HIV/AIDS and Ebola, the U.N. Security Council became a more regular player in the scope and applicability of global health law. It issued recommendations, established response organizations, and played a more coordinating role between relevant U.N. agencies. In 2014, the U.N. Security Council established the U.N. Mission for Ebola Emergency Response (UNMEER) to meet immediate needs related to the fight against Ebola.[304] U.N. Security Council Resolution 1983 established that "United Nations troops and police are part of prevention, treatment and care" in countries battling HIV/AIDS.[305] Given the lack of adherence to recommendations issued by the WHO Director–General during declared public health emergencies, one possibility, even likelihood, is for the Security Council to implement those measures with the greater force of the U.N. Charter.[306]

The enhanced role of the U.N. Security Council means that global health law is more likely to be "securitized"—that is, "the risk of international spread of infectious diseases is seen not so much as a public health problem to be dealt with by civilian authorities but a security threat to be addressed primarily by security, military and intelligence authorities at the national and international levels"—in the future than it has been in the past.[307] Indeed, the U.N. Security Council appears poised to intervene in the current Ebola outbreak in eastern Democratic Republic of the Congo (DRC). On August 2, 2019, the U.N. Security Council expressed "grave concern" about the Ebola virus outbreak in the DRC and "stressed the urgency of broad cooperation in the response, as 'the disease could spread rapidly, including to neighbouring countries, possibly having serious

303. Roland Driece, *COVID-19 Chair's Statement: What Is the Role of GHSA2024 in This Pandemic?*, GLOBAL HEALTH SECURITY AGENDA (Mar. 17, 2020), https://ghsagenda.org/2020/03/17/covid-19-chairs-statement-what-is-the-role-of-ghsa2024-in-this-pandemic/ [https://perma.cc/897P-AE4Z].

304. Pavone, *supra* note 212, at 323.

305. Press Release, Security Council, Unanimously Adopting 1983 (2011), Security Council Encourages Inclusion of HIV Prevention, Treatment, Care, Support in Implementing Peacekeeping Mandates, U.N. Press Release SC/10272 (June 7, 2011), https://www.un.org/press/en/2011/sc10272.doc.htm [https://perma.cc/V7LB-A8XH]; S.C. Res. 1983 (June 7, 2011).

306. *See* 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* THE GOVERNANCE OF DISEASE OUTBREAKS, *supra* note 212, at 327.

307. Burci, *supra* note 193, at 33.

humanitarian consequences and impacting regional stability.'"[308] In other words, the Security Council appeared ready to assume once again leadership on a specifically health-related crisis. It is now contemplating international action against COVID-19.

The "securitization" of health carries with it significant threats to other human rights. At the national level, measures curtailing civil liberties, like isolation and quarantine, have long been used pretextually to detain those who may not in fact be infectious but may be politically unpopular, like migrants.[309] Indeed, COVID-19-based measures have brought global migration to a grinding halt.[310] At the international level, the securitization of health may mean the stigma or isolation of entire countries. This explains in significant part the dispute between the United States and China at the U.N. Security Council, with the former demanding at some points to refer to a "Wuhan" virus or a "China" virus.[311]

On the other hand, the intervention of the U.N. Security Council in the contexts of HIV/AIDS and Ebola has been associated with a significant acceleration of the mobilization of international resources and a more rapid containment of epidemics once they are determined to fundamentally challenge international peace and security. The same is hoped for COVID-19.

CONCLUSION

This Article has endeavored to identify the origins of global health law with the major human-rights agreements that emerged in the post-World War II era, situated, as it is, in the most significant health threat to face the world since those institutions were formed. It has argued that global health law became increasingly focused on the protection of infant, child, and maternal health over the course of the 1950s and 1960s, a focus that expanded the diversity and number of subjects

308. Lindsay Mackenzie, *Security Council Gravely Concerned by Ebola Outbreak in DR Congo, Demands Immediate End to Violence Hampering Response*, UN NEWS (Aug. 2, 2019), https://news.un.org/en/story/2019/08/1043651 [https://perma.cc/EWF3-LWJV].

309. Eugenia Tognotti, *Lessons from the History of Quarantine, from Plague to Influenza A*, 19 EMERGING INFECTIOUS DISEASES 254, 258 (2013) ("Quarantine and other public health practices are effective and valuable ways to control communicable disease outbreaks and public anxiety, but these strategies have always been much debated, perceived as intrusive, and accompanied in every age and under all political regimes by an undercurrent of suspicion, distrust, and riots. These strategic measures have raised (and continue to raise) a variety of political, economic, social, and ethical issues (*39*,*40*). In the face of a dramatic health crisis, individual rights have often been trampled in the name of public good. The use of segregation or isolation to separate persons suspected of being infected has frequently violated the liberty of outwardly healthy persons, most often from lower classes, and ethnic and marginalized minority groups have been stigmatized and have faced discrimination. This feature, almost inherent in quarantine, traces a line of continuity from the time of plague to the 2009 influenza A(H1N1) pdm09 pandemic.").

310. *See* John Letzing, *How COVID-19 Is Throttling Vital Migration Flows*, WORLD ECON. F. (Apr. 8, 2020), https://www.weforum.org/agenda/2020/04/covid-19-is-throttling-vital-migration-flows/ [https://perma.cc/N9NM-T5AG].

311. *See* John Bowden, *China: Pompeo Has 'Sinister Motive' for Pushing 'Wuhan Virus' Language*, HILL (Mar. 26, 2020, 7:47 AM), https://thehill.com/policy/international/489605-china-pompeo-has-sinister-motive-for-pushing-wuhan-virus-language [https://perma.cc/LB7K-8Z4R].

it targeted to include multinational enterprises. As disease threats expanded and became increasingly understood to originate with animals, and therefore the environment in which those animals lived, global health law also "securitized," such that the U.N. Security Council and auxiliary security-oriented organizations became key sources of new global health law. As a result, the future of global health law lies in more supranational regulation of global firms, the influence of agreements between firms, foundations, and governments (including international organizations), and the growing body of law generated by adjudicative bodies like international investment and trade tribunals. The result of these movements is the future of global health law: regulation, security, and pluralism.