THE SOFT LAW ALTERNATIVE TO THE WHO’S TREATY POWERS

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ABSTRACT

As a recent decision of the World Health Assembly makes clear, many in the global health movement advocate mobilizing the World Health Organization’s (WHO) treaty-making powers to address the world’s great health challenges. The hard lawmaking power granted to the WHO in the 1940s was unprecedented, but is antiquated now given contemporary international relations and global health concerns. This Note argues that the WHO can better facilitate the development of global health ‘law’ by promulgating soft law instruments containing specific, concrete provisions. These mechanisms are different from treaties because the instruments are soft, but distinguished from ‘mere declarations’ because their contents are hard. Practitioners in other fields have deployed such instruments effectively when (1) sovereignty costs are intractable and yet normative experimentation is needed, (2) agreements are meant to coordinate rather than constrain, perhaps through a centralizing international institution, (3) non-state actor participation is essential, and (4) agreements will require constant updating to keep current with substantive developments in the subject matter. Finally, durable soft law provisions may harden into binding customary international law, thus achieving the status so desired by hard law enthusiasts. Consequently, this form of soft law instrument provides a useful and modern means to craft agreements that, while not binding legally, may have relatively more power to affect conduct and help achieve global health’s social justice ends.

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I. Introduction

In 1947, the world “recognized that the solution of certain problems in the field of health depends on international action”1 and needed a “powerful and competent international body [to] apply[] modern remedies . . . .”2 In this spirit, the Constitution of the World Health Organization (WHO) bestowed on its highest decision-making body, the World Health Assembly (WHA),3 the power to adopt binding international agreements.4 However, it has used this power only three times.5 Some commentators label this inaction “myopia,”6 argue it damages the WHO’s institutional legitimacy,7 and advocate greater

2. Id. at 3.
3. See WHO Const. art. 18.
5. See id.
Perhaps in response to this criticism, in May 2012, the WHA unanimously resolved to begin work on a fourth agreement. However, “soft law” agreements are also used to coordinate and organize international activity. This Note argues that instead of energizing its mostly dormant treaty-making authority, the WHO can better facilitate the development of global health ‘law’ by promulgating soft law instruments containing specific, concrete provisions. Practitioners in international financial and environmental law have deployed such instruments effectively to decrease the barriers to entry, articulate norms, facilitate coordination, involve non-state actors, and respond to rapid change.

Section II of this Note analyzes the WHO’s experience with its constitutional treaty-making power, revealing significant drawbacks to hard lawmaking. Section III defines soft law, reviews its relative benefits, and explains why it works with international financial and environmental agreements. Section IV analyzes the characteristics of soft law in light of the goals of global health law, concluding that it provides an effective basis for coordinating international health efforts and potentially creates binding customary law. Section V will critique the recent WHA decision to pursue another binding agreement and explain why the choice of instrument may hinder, rather than foster, its noble aims.

8. See, e.g., Ilona Kickbusch et al., 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, 551 (2010); see generally Fidler, supra note 6, at 1079.


11. See infra Part III.A-D.

12. There is considerable literature drawing a distinction between “international health” and “global health.” See, e.g. Gorik Ooms, Global Health: What It Has Been So Far, What It Should Be, and What It Could Become 9-39 (Inst. Of Tropical Med., Antwerp, Working Paper No. 2, 2011). In short, “international health is the practice of richer countries trying to enable poorer countries to address their own health issues, thus advancing the interests of poorer countries,” id. at 24, whereas “global health” is “the practice of richer countries co-financing health efforts in poorer countries with the explicit intention of advancing shared interests . . . .” Id. It is argued that in certain discrete areas, there has been a shift from international health paradigms to global health frameworks, while in other areas, the international health mindset has remained. See id. at 25. It is beyond the scope of this Note to comment on soft law’s relative impact to forward either of these paradigms, but the reader should be aware that in this Note, “international health” and “global health” are used interchangeably and should be read in the context of the definition of global health law posited by Lawrence O. Gostin and Allyn L. Taylor. See Lawrence O. Gostin & Allyn L. Taylor, Global Health Law: A Definition and Grand Challenges, 1 PUB. HEALTH ETHICS 53, 55 (2008).
II. THE WHO’S EXPERIENCE WITH HARD INTERNATIONAL HEALTH LAW

The mission of the WHO is “to act as the directing and coordinating authority on international health work.”\footnote{See WHO Const. art. 2(a).} Much global health research concerns the WHO’s activity.\footnote{See John J. Kirton, Introduction to Global Health, at xviii (John J. Kirton ed., 2009).} Due to its position, some commentators have lamented the “untapped” potential of the WHO’s role in crafting global health law,\footnote{See Christine P. Bump, Close but No Cigar: The WHO Framework Convention on Tobacco Control’s Futile Ban on Tobacco Advertising, 17 Emory Int’l L. Rev. 1251, 1264 (2003) (“The WHO is widely criticized for not utilizing its legal powers.”); Fidler, supra note 6, at 1089 (“Since 1948, the potential for international legal activity created by the WHO Constitution has remained untapped”).} defined as:

[A] field that encompasses the legal norms, processes, and institutions needed to create the conditions for people throughout the world to attain the highest possible level of physical and mental health. The field seeks to facilitate health-promoting behavior among the key actors that significantly influence the public’s health, including international organizations, governments, businesses, foundations, the media, and civil society. The mechanisms of global health law should stimulate investment in research and development, mobilize resources, set priorities, coordinate activities, monitor progress, create incentives, and enforce standards. Study and practice of the field should be guided by the overarching value of social justice, which requires equitable distribution of health services, particularly to benefit the world’s poorest populations.\footnote{Gostin & Taylor, supra note 12, at 55.}

Specifically, they point to the WHO’s scarce use of its treaty-making authority,\footnote{See Bump, supra note 15, at 1264 n.89.} which could create binding international law.\footnote{See Gostin, supra note 4, at 240-42.} Inherent in this argument is the notion that if the WHO’s treaty power remains unused, international health law as a whole will remain underdeveloped and this would impede global health action and commitment.\footnote{See Allyn L. Taylor, Governing the Globalization of Public Health, 32 J.L. Med. & Ethics 500, 502 (2004).}

However, the incremental benefits to treaty-making are rarely impli-
cated in global health agreements while the potential costs remain significant. In this Section, the substantive and procedural benefits to crafting and implementing treaties are examined and applied in the context of the three existing agreements adopted under the WHO Constitution.

A. Hard Law: Uses and Drawbacks

Traditionally, hard international law refers to the “rules that govern relations between states.”20 Rules are acknowledged by the “international community of states” in one of three forms: a treaty obligation, customary law, or derived from general principles common to major domestic legal systems.21 While contemporary definitions recognize the roles and relationships of international organizations, private entities, and human beings,22 states are the main subjects of international law23 and, generally speaking, requisite obligations fall on them alone.24

Generally, states use treaties for one or more of the following reasons: (1) to credibly commit themselves to promises; (2) to enforce obligations; (3) to develop mechanisms for later interpretation and compulsory conflict resolution; or (4) in certain countries, to produce self-executing domestic obligations.25 In trade law, for instance, treaty instruments dominate26 because market behavior needs to be constrained and disputes between parties arbitrated.27 Seemingly, restricting the ability of all parties to make certain choices in their own interests will deliver benefits to each in excess of those that could be achieved without a binding agreement.

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22. See, e.g., id. § 101.
23. See Franck et al., supra note 20, at 98.
26. See e.g., Shaffer & Pollack, supra note 25, at 715.
However, there are significant drawbacks to pursuing agreement by treaty. As indicated above, constraints on behavior, known as “sovereignty costs” serve to “limit a state’s ability to follow its own national prerogatives.” This drawback is accentuated because treaties take years to conclude, and require heads of state to execute. It is especially onerous because coordination and standard setting tend to be the province of technocrats, not chief executives. Salient private actors cannot become parties to treaties either, meaning agreements can exclude critical partners (or potential underminers). Rapid scientific advances can undercut static international agreements, which cannot be amended quickly. Consequently, hard law instruments work less well in environmental and financial contexts.

Further, treaties are not necessarily harder than other international agreements simply because the instrument is hard. Many treaties contain vague obligations, seemingly drafted to ensure that parties will ratify the document without actually imposing concrete obligations.

All told, treaties are not the panacea they are sometimes advocated to be. Bearing in mind their benefits and shortcomings, the following subsections briefly review the three instances in which the WHA exercised its treaty powers, demonstrating how the costs can be pervasive.

**B. The WHO’s Article 19 Power and Experience**

Article 19 of the WHO Constitution states that the WHA may “adopt conventions or agreements with respect to any matter within the..."
Because the scope of the provision is so broad, it has been described as having “virtually limitless potential.” From the start, however, the WHO and its member states were hesitant to use this power due to the costs outlined above. The WHO’s founders considered several entry-into-force provisions, eventually choosing one that left considerable discretion to member states whether to accede to an Article 19 measure after WHA adoption. In fact, Article 19 only requires that member states consider signature and ratification. The apparent sovereignty concerns underlying this sleight-of-hand result in a power that is softer than advertised.

Even with this blunted apparatus, Article 19 sat dormant for over half a century. Finally, in the mid-1990s, a growing tobacco pandemic sparked interest in its mobilization. Even then, nearly ten years elapsed between the WHA decision to begin work on an Article 19 agreement and the entry into force of the Framework Convention on Tobacco Control (FCTC). A lack of political will from state parties, and the ineligibility of non-state actors to participate as potential signatories, contributed to this delay. In fact, the secondary status of non-state actors resulted in backroom campaigns to influence state delegates and active undermining of the agreement once it was
adopted.\textsuperscript{48} Today, states themselves circumvent some of the FCTC’s requirements, resulting in calls for the Convention’s refinement.\textsuperscript{49}

Several lessons can be learned from this experience. First, states can be reluctant to negotiate and complete binding Article 19 instruments, thus delaying normative identification and experimentation. Second, as a method for quickly responding to an epidemic, conventions may take many years and require senior political leadership to finalize. Third, participation (or non-participation) of cogent non-state actors can undermine negotiations and implementation. Finally, if a treaty does not work as intended, it can be difficult to refine or rescind later. These concerns are implicated again in relation to WHO’s other treaty power.

\textbf{C. The WHO’s Article 21 Power and Experience}

Article 21 allows the WHA to enact “regulations” concerning a number of enumerated items including sanitary requirements, disease names, and product labeling.\textsuperscript{50} As opposed to Article 19, regulations would “come into force for all Members” upon WHA adoption, though parties could affirmatively opt out.\textsuperscript{51} However, Article 21 is also blunted because the universe of potential topics is restricted to five discrete subjects.\textsuperscript{52} Even so, the WHA has adopted regulations in only two areas, and the WHO’s experience with their adoption and implementation highlights the limitations of these hard instruments.

WHO Regulations 1, known as the “Nomenclature Regulations,”\textsuperscript{53} sought to unify classifications of morbidity and mortality data.\textsuperscript{54} Preceding the WHO’s formation, their 1948 adoption was the sixth iteration


\textsuperscript{49.} See, e.g., Bump, supra note 15, at 1308-09 (“Despite [Article 13] restrictions on advertising, tobacco manufacturers have steadily increased their advertising and promotional expenditures in the United States over the past three decades . . . . In order to be a valid attempt at curbing exposure to tobacco advertising and promotion, the Framework Convention should specifically direct states to ban or restrict point-of-sale advertising.”).

\textsuperscript{50.} See WHO Const. art. 21.

\textsuperscript{51.} See WHO Const. art. 22.

\textsuperscript{52.} See Burci & Vignes, supra note 39, ¶ 266, at 131.

\textsuperscript{53.} See id. ¶ 268, at 132.

\textsuperscript{54.} See id.
in a century, updated each time to keep up with medical science. However, when it became difficult to update the regulations using Article 21, the WHA employed a workaround by turning the Nomenclature Regulations into a de facto reference statute to the International Classification of Diseases, the latter being updated and endorsed by the WHA from time to time under a different constitutional power. In other words, Article 21 showed itself to be an impediment to crafting responsive and timely global health law.

WHO Regulations 2, the “International Health Regulations” (IHR) have suffered from similar shortcomings. The purpose of the IHR is “to prevent the international spread of disease” in proportion to the health, trade, and travel risks at stake. Like the Nomenclature Regulations, the IHR derived from a pre-WHO set of rules, but also suffered interpretational and compliance issues. Though the WHO set up a committee to propose updates from time to time, the WHO recognized it would have trouble consistently using Article 21 to keep the regulations’ technical aspects up to date.

By the 1990s, the world community recognized that the regulations had become marginalized and that the universe of covered diseases was too small. State compliance with the supposedly hard instrument was waning. The chair of a commission tasked to revise the IHR admitted progress was “quite slow” because the technocratic negotiators needed to constantly consult the political leadership at home. It

55. See id. ¶ 270, at 133.
56. See id. ¶¶ 270-71, at 133.
59. See GOSTIN, supra note 4, at 242.
60. See WHO, THE FIRST TEN YEARS OF THE WORLD HEALTH ORGANIZATION 264 (1958) (“There were naturally difficulties in the first year of their application—not so much in the application of the technical provision for the diseases as in regard to the interpretation of definition, the notifications required...[Also,] national practice in some countries does not yet conform to the Regulations.”).
61. See id.
63. See BURCI & VIGNES, supra note 39, ¶ 288, at 138.
64. Cf. GOSTIN, supra note 4, at 246.
65. See Fidler, supra note 6, at 1090.
67. See id. at 14.
took ten years and the SARS outbreak to craft and adopt a more flexible instrument. 68

Even so, the experience after the 2005 revision has been mixed. For example, the international community praised Mexico for fulfilling its treaty obligations when it reported the genesis of the H1N1 outbreak. 69 Nevertheless, the country experienced significant adverse collateral consequences as a direct result of its notification. 70 Because of this, there are already calls for another revision of the IHR, 71 which will be challenging given past experience.

D. Summary

The WHO’s experience with Articles 19 and 21 lawmakers have provided strong evidence that health treaties have serious deficiencies. State parties hide behind their sovereignty concerns, hard law agreements take too long to find consensus, and issues are too dynamic for health treaties to remain relevant.

When considering alternatives, it should not be lost that Article 23 of the WHO’s Constitution allows the WHA to “make recommendations to Members with respect to any matter within the competence of the Organization.” 72 Whether the WHO’s founders anticipated it or not, nonbinding agreements would come to play a substantial role in much international activity. The next Section turns to the attributes of a form of soft law popular in other areas of international lawmakers, to see whether it might be pertinent to global health challenges.

III. The Soft Law Alternative: Attributes and Prospects

Soft law provides a viable instrument for key actors to create expectations and facilitate follow-through. Its “primary objective is to produce dominant norms with which to coordinate behavior,” 73 as international finance 74 and environmental 75 practitioners have learned.

68. See id. at 3.
70. See Bruce D. Greenberg, Mexico and the Price of Economic Consequence, MEXIDATA.INFO (May 25, 2009), http://www.mexidata.info/id2273.html.
71. See e.g., WHO Director-General, Report of the Review Committee on the Functioning of the International Health Regulations (2005) in Relation to Pandemic (H1N1) 2009: Report by the Director-General, ¶¶ 20-22, at 12, WHA 64/10, Provisional Agenda Item 13.2 (May 5, 2011).
72. See WHO Const. art. 23.
73. See BRUMMER, supra note 28, at 128.
74. See generally id.
However, soft law has broad and diverse meanings. In this context, soft law comprises “nonbinding rules or instruments that . . . represent promises that in turn create expectation about future conduct.”

Though states do not intend to be legally bound by these instruments, their provisions can be quite “hard” because of their specificity and the expectations that concrete arrangements enable. More succinctly, they are different from treaties because the instrument is soft, but distinguished from “mere declarations” because the contents are hard. Parties enter these agreements because they have incentives to comply, and can realistically evaluate adherence (or defection). These factors create normative force.

Soft law tends to work well when (1) sovereignty costs are intractable and yet normative experimentation is needed, (2) agreements are meant to coordinate rather than constrain, perhaps through a centralizing international institution, (3) non-state actor participation is essential, and (4) agreements will require constant updating to keep current with substantive developments in the subject matter. Finally, durable soft law provisions may harden into binding customary international law, thus achieving the status so desired by Article 19 and 21 enthusiasts.

A. Sovereignty Costs and Normative Experimentation

Soft law increases the willingness of states to articulate and experiment with norms by lowering the sovereignty costs involved with negotiating, ratifying, and following an agreement. Though a treaty

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75. See generally Dupuy, supra note 32.
76. See CARTER & WEINER, supra note 10, at 131.
78. See id. at 187-88.
79. See Brummer, supra note 27, at 624.
80. See Dupuy, supra note 32, at 429.
81. See Alexandre Kiss, Commentary and Conclusions, in COMMITMENT AND COMPLIANCE, supra note 34, at 223, 239; see also Dupuy, supra note 32, at 429.
82. See Peter M. Haas, Choosing to Comply: Theorizing from International Relations and Comparative Politics, in COMMITMENT AND COMPLIANCE, supra note 34, at 43, 58-61.
83. See id.
can provide instant law,\textsuperscript{85} knowledge that a legal obligation lays at the finish line of a successful negotiation creates enormous barriers to entry, which can stifle the law’s development.\textsuperscript{86} These sovereignty costs cause countries to approach each phase with skepticism, knowing that legal obligations cannot be undone easily.\textsuperscript{87} Alternatively, soft law helps parties move past the start line by limiting barriers to entry to allow normative testing.\textsuperscript{88} For example, the Basel Committee, a consortium of state central banks, provided an excellent case study when it adopted the Basel Capital Accord in 1988 to set a concrete, specific minimum capital standard for banks.\textsuperscript{89} The Committee chose not to construct a hard law agreement because it thought state parties would be dubious that an agreement could be forged without significant alteration to domestic banking regulations.\textsuperscript{90} By constructing a softer instrument, it allowed the Committee to propose specific provisions\textsuperscript{91} and tough supervisory measures.\textsuperscript{92} Having crossed the start line, adherence developed remarkably quickly,\textsuperscript{93} with even non-member countries deciding that compliance was in their interests.\textsuperscript{94}

In addition, unlike treaties in which “nothing [is] agreed until everything [is] agreed,”\textsuperscript{95} soft law negotiators can move forward with incremental and indicative principles, understanding that they will continue to evolve as states build a record of compliance\textsuperscript{96} and mutual

\textsuperscript{85} See Vienna Convention, \textit{supra} note 31, art. 24(1).
\textsuperscript{86} See Brummer, \textit{supra} note 28, at 125.
\textsuperscript{87} See Vienna Convention, \textit{supra} note 31, art. 54.
\textsuperscript{88} See Brummer, \textit{supra} note 28, at 128.
\textsuperscript{91} For example, the 1988 Basel Capital Accord required that banks “maintain a ratio of 8% capital to the total amount of risk-weighted assets and credit-converted [off-balance sheet] items.” Heath Price Tarbert, \textit{Are International Capital Adequacy Rules Adequate? The Basle Accord and Beyond}, 148 U. PA. L. REV. 1771, 1793 (2000).
\textsuperscript{93} See Lee, \textit{supra} note 90, at 5.
\textsuperscript{94} See id.; Brummer, \textit{supra} note 28, at 77.
\textsuperscript{95} See Whelan, \textit{supra} note 66, at 14.
For example, after adopting a revised, non-binding “Basel II” accord, the Basel Committee “expect[ed] its members to move forward with appropriate adoption procedures.”

This example demonstrates the value of lowering sovereignty costs by negotiating a soft instrument. Of course, both hard and soft law provisions can be ambiguous, but soft law creates the space needed to articulate concrete norms and try them out in practice.

### B. Coordination and Central Coordinator

Soft law instruments work effectively to coordinate behavior when coercive measures are inappropriate. They have been used to propagate best practices, share regulatory reports and information, cooperate on domestic enforcement, and set the rules for technical and financial assistance.

Further, a central organizing international institution can provide an important locus for soft lawmaking. Though central institutions can also assist with constructing treaties and are not essential to making soft law, they can influence the choice of instrument and provide a ready mechanism to implement and monitor agreements. For instance, the Basel Committee had been in place for over a decade when it suggested the need to establish minimum capital standards through a soft instrument. Also, the U.N. and Organization of American

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97. See Dupuy, supra note 32, at 424.
99. See Bilder, supra note 96, at 70.
100. See Brummer, supra note 28, at 117-18.
101. See id. at 118-19.
102. See id. at 119.
104. See Brummer, supra note 28, at 97.
105. See Jan Klabbers, An Introduction to International Institutional Law 251 (2d ed. 2009).
108. See generally Lee, supra note 90.
109. See Beth Simmons, International Efforts against Money Laundering, in COMMITMENT AND COMPLIANCE, supra note 34, at 244, 250 (Legal Assistance Money Laundering Model Law).
States have served as sponsoring organizations for other financial soft law agreements. Because international institutions possess a convening power and can coordinate behavior, it is not surprising that the advent of soft lawmaking has tracked the growth of international institutions.

C. Participation of Non-State Actors

Soft law agreements can include parties not traditionally recognized under international law. While treaties shun the parties most responsible for globalizing many areas of modern life, soft law actively courts private entities and human beings, understanding that state participation alone can undermine the effectiveness of an agreement. For example, the standards propagated by the International Organization for Standardization are crafted through a process involving both governments and the private sector. Non-state participation helps the rules achieve legitimacy in the commercial sector, and incentivizes watchdog groups to hold violators to account. In addition, the privately governed IFRS Foundation provides a key coordinating mechanism for crafting financial reporting standards, which are subsequently incorporated into the domestic law of many countries. This sampling shows that non-state actors can be critical to creating effective commitments that are nevertheless non-binding as a matter of international law.

D. Nimble and Responsive to Rapid Scientific Change

Soft law approaches are more nimble and responsive than hard law agreements. They have simpler finalization procedures given that...
technocrats, rather than heads of state, negotiate and conclude them.120 They can stimulate further development and provide the flexibility to incorporate associated changes.121

Because of this, if parties craft an agreement in a subject area that undergoes rapid scientific evolution, they can use soft law instruments that can adapt in concert to those developments.122 For instance, the International Atomic Energy Agency propagates nonbinding but persuasive codes of good practices that are constantly updated as approaches to nuclear facility safety are refined.123 In fact, states often perceive pertinent soft agreements as more legitimate than hard pacts because they can be updated in line with scientific understanding.124

E. Customary International Law

Beyond soft law’s power to influence states in the ways explained above, it can serve as a stepping-stone to the formation of customary international law,125 which is legally binding upon nations.126 Customary international law is defined as a consistent practice among states that is followed out of a sense of legal obligation.127 These rules start as “customary practices,”128 followed out of moral obligation,129 natural incentive,130 or comity.131 However, once a state performs a practice because it believes it is legally required to do so (known as opinio juris), it becomes customary international law.132 In this spirit, soft instruments that are meant to coordinate behavior may ripen into customary

120. See Brummer, supra note 27, at 631.
121. See Hillgenberg, supra note 119, at 124.
122. See Dupuy, supra note 32, at 421.
123. See Kiss, supra note 81, at 238.
124. See id. at 238-59.
127. See Lepard, supra note 126, at 6.
128. See id.
130. See Kenneth A. Oye, Explaining Cooperation Under Anarchy, 38 World Politics 6 (1985), referenced in Lepard, supra note 126, at 62 (explaining that when parties are naturally in harmony, that “no incentive to cheat exists”).
132. See id.
international law, and do so relatively quickly.133

As one example, the International Law Association propagated a non-binding environmental agreement called the Helsinki Rules on the Use of Waters of International Rivers.134 This influential agreement led to a significant UN General Assembly resolution.135 Though GA resolutions are not binding law per se, they are evidence of legal obligation.136 Additional evidence of opinio juris can be derived from domestic law incorporation,137 International Court of Justice opinion,138 scholarly identification,139 and, occasionally, sufficient repetition.140 Soft law norms will not always turn into customary international law, but this factor can provide additional incentive to use soft instruments.

F. Summary

Soft law agreements can provide a viable alternative to formal treaties in terms of reduced sovereignty costs, normative articulation, coordination activities involving a central institution, engagement of non-state actors, and scientific relevance. The next Section will consider their usefulness to pertinent areas of international health law, concluding that the WHO is well positioned to craft effective agreements using this method.

IV. Application of Soft Law to the WHO and International Health Law

Parsing the definition of global health law and the WHO’s stated purpose immediately reveal soft law’s relative advantages to Article 19 and 21 treaties. As a cross-cutting matter, soft law’s less threatening sovereignty costs would allow the WHO to get over the start line and pursue concrete normative provisions without stoking anxiety over pending legal encumbrances. Second, even beyond WHO’s inherent

133. See LEPARD, supra note 126, at 224.
135. See Dupuy, supra note 32, at 423.
137. See KLABBERS, supra note 105, at 190.
139. See LEPARD, supra note 126, at 116.
140. See GOLDSMITH & POSNER, supra note 131, at 23.
141. See id. at 24.
convening power, it can serve as the locus for crafting agreements meant to “coordinate activities,” which is the WHO’s stated purpose.142 Third, proposing a soft law instrument would allow non-state actors to participate in negotiations, make morally binding commitments, and implement concrete provisions. Fourth, because soft agreements are nimble and responsive, they can adapt and change as research yields new health solutions. Finally, if provisions within the WHO-sponsored agreements prove durable and lasting, it could set the stage for practices to become customary international health law.

A. Lowering Sovereignty Costs and Establishing Health Norms

Soft lawmaking would lower the barriers to entry, thus allowing relevant actors to articulate and test new norms. When compared to the WHO’s historical reluctance to use Article 19 and 21 powers,143 soft lawmaking can allow negotiators to propose concrete health standards without the apprehension associated with the perceived potential loss of sovereign power.

In the case of the FCTC, the WHO could have pursued a softer instrument.144 Of course, such a strategy would be bound to frustrate impatient negotiators longing for an instant legal solution to a pandemic problem. But the FCTC experience shows that even if the final instrument is hard, the provisions within it can be nonspecific145 and take a long time to negotiate,146 calling into question its eventual effectiveness.147 Instead, if parties build a record of adherence to tangible soft law provisions, they can agree to take further steps in the future. If they do not comply, there is no legal violation but at least the norm was articulated and tested, rather than never tried.

B. Global Health Coordination and the WHO as Coordinator

Soft law agreements can work because much of health law seeks to coordinate behavior, which is the “essential purpose” of the WHO.148 Like the Basel Committee, the WHO is a centralized institution that

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142. See WHO, supra note 13.
143. See Roemer et al., supra note 45, at 937 (noting that some WHO official recommended a nonbinding “code of conduct[.]”).
144. See id.
145. See GOSTIN, supra note 4, at 255.
146. See BURCI & VIGNES, supra note 39, at 126-27.
147. See GOSTIN, supra note 4, at 258.
148. See BURCI & VIGNES, supra note 39, at 156.
can convene parties to set standards.\footnote{149}{See Kickbusch et al., supra note 8, at 551.} It has also been argued that it has the ability to bring together the diversity of global health efforts, serve as the forum to establish the norms soft law agreements can generate, and monitor and report whether parties are complying with agreements set in place.\footnote{150}{See Lawrence O. Gostin, Redressing the Unconscionable Health Gap: A Global Plan for Justice, 4 HARV. L. & POL’Y REV. 271, 274 (2010).}

Interestingly, the WHO has had experience as a norm-setter even when it has not meant to take on this role. For example, the WHO inadvertently became the global standard-setter in assessing the quality, safety, and efficacy of medicines when it created its prequalification program in 2001.\footnote{151}{See generally Prequalification Programme: A United Nations Programme Managed by WHO, WORLD HEALTH ORGANIZATION (Apr. 26, 2012, 10:30AM), http://apps.who.int/prequal/ [hereinafter WHO Prequalification].} Originally intended to advise other UN procurement agencies, it organically grew to “a useful tool for anyone bulk purchasing medicines,”\footnote{152}{See id. (follow “About us” hyperlink in left menu bar) (last visited Dec. 31, 2012).} and is now viewed as a global standard setter for safety and effectiveness.\footnote{153}{See Yousef A. Vawda, Ensuring Access Through the Medicines and Related Substances Amendment Act 72 of 2008: Another Lost Opportunity?, 126 S. Afr. L.J. 667, 674 (2009).} State regulators have found the prequalification program compelling,\footnote{154}{See Barry Kellman & Zachary Clopton, A Global Architecture for Medical Counter-Measure Preparedness Against Bioviolence, 6 U. ST. THOMAS L.J. 550, 574-75 (2009).} even though there is no international legal obligation to follow its decisions. Had pursuing this global role been the WHO’s intention, it is difficult to imagine that an Article 19 treaty would have been constructed quickly, considering that the regulation of pharmaceutical products is viewed as central to state sovereignty.\footnote{155}{See id. at 575.} Instead, this unintentionally soft approach to norm setting may have allowed the program to prove itself, resulting in its current reputation and legitimacy.

C. Participation of Non-State Actors

Next, soft law agreements allow the participation of “businesses, foundations, the media, and civil society.”\footnote{156}{Gostin & Taylor, supra note 12, at 55.} The WHO itself admits that “[t]he private sector has strong advantages that enable the WHO to reach wider and to have a more significant impact on global public
health. Pharmaceutical companies develop and supply medicines, foundations invest in research to develop new health technologies, and civil society organizations are often best positioned to reach rural areas where health interventions are desperately needed. The WHO has a role in ensuring that non-state actors, as full participants in the global health landscape, are also full participants in crafting global health norms.

Also, inclusion makes the influence of non-state actors more transparent. Soft law negotiations actively engage these stakeholders in the outcome by inviting them to become signatories. It has been argued that the current global health governance system has been unable to cope with the number and diversity of actors participating in it. Hard law mechanisms foreclose many of these actors from participating, and the FCTC experience shows that non-state actors could alternatively participate by subterfuge if an issue is pertinent but they are not full partners.

D. Nimble and Responsive Health Agreements

Ongoing scientific analysis has been proposed as a key component of a global health governance framework. In tandem, soft law instruments can be updated to keep pace with health science. In recent years, the WHO has modernized its health data collection methods, updated guidelines on HIV testing, and developed strategies for vector-

162. See Gostin, supra note 150, at 273.
164. See BURCI & VIGNES, supra note 39, ¶¶ 544-46, at 215.
borne diseases.\textsuperscript{166} Agreements to coordinate behavior in these areas must be amendable or they risk going out of date quickly. This is a particular problem facing the WHO as it begins work on a possible fourth agreement concerning research and development (a topic that will be explored in the final Section).

E. Customary International Health Law

Finally, soft health law agreements have the potential to become binding through consistent state practice, eventually followed out of a sense of legal obligation. The WHO has noted that “[t]he setting of a wide variety of ... non-binding standards is without doubt the most prolific and successful normative activity of the Organization.”\textsuperscript{167} Durable soft law provisions can become customary international law if the WHO’s normative power is properly wielded.

Much of this Note has shown that the WHO can meaningfully affect and coordinate state practice, so the question remains as to whether this activity can harden into \textit{opinio juris}. The potential is significant. As stated above, the WHO has significant coordinating capability, and coordination activities can ripen into customary law.\textsuperscript{168} In addition, the General Assembly takes decisions on international health matters from time to time\textsuperscript{169} and countries consistently rely on the WHO prequalification decisions in making bulk purchasing choices. This implies remarkable potential to stimulate \textit{opinio juris}.

To take advantage of this positioning, the provisions within the soft instruments will need “definite content.”\textsuperscript{170} The method proposed here allows for precision because the instrument itself does not serve as an impediment.

F. Summary

To review, negotiating soft instruments with hard provisions provide the WHO with a viable alternative to Articles 19 and 21. However, the institutional reluctance to negotiate binding instruments shows signs of weakening. As the final Section will demonstrate, the WHA took the


\textsuperscript{167} See Burci & Vignes, supra note 39, ¶ 293, at 141.

\textsuperscript{168} See Lepard, supra note 126, at 224.


advice of an expert committee to begin work on a health research and development convention. Unfortunately, many of the pitfalls to hard lawmaking remain present and could threaten both the speed of this important work, and the quality of the result.

V. A FOURTH AGREEMENT: WILL HISTORY REPEAT?

In May 2012, the World Health Assembly considered a report from a “Consultative Expert Working Group,” which recommended that the “Member States... begin a process leading to the negotiation of a binding agreement on R&D” to address “the current situation of R&D for health needs in developing countries.” Its purpose would be to provide “effective financing and coordination mechanisms to promote R&D.” The Working Group submitted an exhaustive list of potential components, noting that “[t]he framework for a possible convention has in many ways already been agreed... in the [Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property],” namely: assessing developing countries’ public health needs, promoting research and development activities, building and promoting innovative capacity for R&D activities in developing countries, accelerating the transfer of technology between developed and developing countries, encouraging and managing intellectual property in a manner that maximizes health-related innovations, improving delivery of health products and medical devices, enhancing sustainable financing mechanisms for R&D, and crafting monitoring mechanisms.

Interestingly, the Working Group considered both hard and soft instruments, but it recommended an Article 19 agreement believing that “Article 23 is not sufficient due to the collective action problem of providing global public goods and since stronger commitments and monitoring and enforcement mechanisms are needed.” In the end, the WHA adopted the recommendation.

172. See id. at 111.
173. See id. at 7.
174. See id. at 114.
175. See id. at 114-16.
176. See id. at 113.
177. See id. at 113-14.
178. See id. at 113.
179. See id.
180. See Daily Notes, supra note 9.
Leaving aside the substantive arguments (such as whether the World Trade Organization is better situated to address some of the components of the proposed treaty and whether the Marrakesh Agreement provides a more sophisticated foundation), the Working Group’s choice of instrument is difficult to reconcile with the potential agreement’s aims. First, any multilateral agreement, hard or soft, addresses a collective action problem, a circumstance in which the rationality of one party’s choice is conditioned on rationality of the concurrent choices made by all the other parties. More colloquially, this could be labeled a coordination problem, and as demonstrated above, soft law agreements work well in coordination contexts. The Working Group also does not explain why the particular “global public good” involved requires a hard instrument for effective distribution, rather than a soft instrument with hard provisions.

In addition, it is not clear that an R&D treaty could be enforceable (i.e. coercive) in the manner the Working Group anticipates. The activities listed above implicate a potential series of grantor-beneficiary relationships among state parties in which the benefits flow from industrialized countries to developing countries.

Given this, the pursuit of a hard instrument is risky. As advocated above, treaties work well when all parties receive some incremental benefit as a result of their legal obligations to each other. In this case, only one set of parties receive any benefit. It is therefore unclear why industrialized countries would voluntarily incur the sovereignty costs involved or, if a treaty were enacted, how the beneficiary countries could meaningfully enforce industrialized country obligations. For industrialized countries, the barriers to entry cannot be wished away. Given the Working Group’s recommendation to use a hard instrument, it should have presented a clearer strategy for enticing these countries to succumb to concrete legal obligations. Not having a strategy risks either never getting past the start line or concluding a hard instrument with only soft provisions.


182. “Public goods” are “products, program[s], activities, or services” that “are nonrivalrous and nonexclusive.” Comm’n on Macroeconomics & Health, Global Public Goods for Health: The Report of Working Group 2 of the Commission on Macroeconomics and Health, presented to the WHO Director-General, 4 (2002). The global public good in this case is a financial transaction tax or a solidarity tobacco contribution meant to generate funds to support “health and health R&D relevant to developing countries.” See R&D Working Group, supra note 171, at 72. However, the Working Group does not analyze why these taxes, or a country’s commitment to apportion a part of these taxes to health R&D requires a binding agreement under international law.
In addition, the beneficiary countries may be wary of a treaty that relies on enforcement mechanisms to guarantee compliance. Unlike some trade treaties in which noncompliance by one party can be rebuffed by others through a meaningful retaliation mechanism, a beneficiary country will likely not have the means, or the political incentive, to retaliate against a noncompliant state.

There are additional risks as well. By recommending an Article 19 agreement, the Working Group announced to non-governmental actors that they were not welcome as full participants to the negotiating table. Admittedly, it argued that the negotiators should “solicit[] inputs as necessary from . . . funders, researchers, the private sector, civil society and academics as necessary,” and that the eventual treaty “should define which research entities in the public and private sectors . . . should be eligible for funding.” Although the Working Group appears on its face to desire non-governmental views and to support private work, this language indicates that private actors are to be consulted, but not invited as full partners.

Finally, while any health R&D agreement will take time to complete, a hard instrument will take relatively longer than a soft approach. The Working Group itself admitted that “conventions can take a long time to negotiate and can involve quite complex governance arrangements and enforcement mechanisms.” It also noted that it took time to reach the current stage, and that “[t]he issues that will need to be addressed in a negotiation of a binding agreement are many and complex.”

These acknowledgements are difficult to reconcile with the Working Group’s admission that “[t]he issue we were asked to investigate was identified at least two decades ago,” the Working Group’s mandate had its genesis in 2003, and that the WHA had characterized the

183. For example, the WTO can authorize a state party to retaliate against another state party if the latter does not comply with adverse arbitration rulings. See generally WTO, UNDERSTANDING THE WTO 55-61 (5th ed. 2011). The mechanism has a track record of success, see Jide Nzelibe, The Case Against Reforming the WTO Enforcement Mechanism, 2008 U. ILL. L. REV. 319, 320 (2008), but some argue it also favors industrialized countries. Id.
185. See id. at 115.
186. See id. at 110.
187. See id. at 21.
188. See id.
189. See id. at 7.
190. See id.
need to move this work forward as “urgent” in 2008.191 And yet, when the FCTC was at a similar stage, it would be seven more years until the WHA approved the treaty192 and almost another two years until it entered into force.193 Considering that R&D activities evolve quickly,194 another nine years is a long time to persist without an agreement just to finalize a hard instrument that is bound to fall out of date.

Even if all of these considerations are managed and the WHA adopts a hard instrument with hard provisions, Article 19 only obligates countries to consider entry.195 While proponents may point to the unanimous WHA decision to begin work on a treaty, such decision did not obligate countries to do anything; it was truly a ‘mere declaration.’ A potential treaty’s durability would be tested in the legislatures of every country of every WHO member, and the resulting reservations, understandings, declarations, and refusals to ratify could gut the most important provisions that had taken years to negotiate.

Alternatively, a soft approach, while not guaranteeing a result, potentially increases the chance for a meaningful plan of action. By taking international legal obligations off the table, expert technocrats could negotiate and conclude an agreement under their existing domestic remits and authorizations. They can attempt to set in place hard provisions for normative testing. The WHO could use its convening power to organize and coordinate negotiations and monitor progress on deliverables, thus giving parties important feedback to calibrate their activities. These calibration exercises would be enabled by a living document that can also be updated as science evolves. Non-state actors would also be invited to participate in crafting the agreement, and perhaps sign on to it. The most durable practices, having been tried, tested, and found to have accrued benefits to all may eventually be followed out of legal obligation, thus adding to customary international health law. Other norms may be followed for a while but fade away (appropriately) as the public health needs of the world evolve. Finally, we know a soft law agreement can work because they have often been used to set the rules for financial assistance in other areas of interna-

191. See id. at 11.
192. See Burci & Vignes, supra note 39, at 126-27.
193. See FCTC, supra note 44, at vi.
195. See Gostin, supra note 4, at 604. Note that Article 21, which authorizes legal agreements that become effective unless affirmatively opted out of, does not include research and development among its enumerated subjects. See WHO Const. art. 21.
These benefits cannot be brushed aside lightly. However, the R&D Working Group advocated hard law seemingly based upon its positive perception of the FCTC’s implementation and its negative view of the time it took for the UN to adopt an irrelevant declaration containing soft provisions. While this Note does not argue that the FCTC is ineffectual at all, the choice of instrument has posed significant drawbacks in construction and compliance without clear benefits. Further, as the IHR experience has shown, health treaties can take years to update due to “unique factors which [are] very difficult to replicate.”

Consequently, while the unanimous decision of the WHA to move forward with treaty negotiations on R&D could seem to be a significant milestone, no meaningful law or tangible benefit to developing countries has yet emerged and may not for some time. Pursuing a soft law agreement with hard provisions might have allowed the parties to move past the start line to test new norms of interaction, include relevant private actors, and guard against obsolescence. Instead, one is left to wonder when crossing the start line will occur, and whether any negotiated provisions will be significant enough to matter.

VI. CONCLUSION

If the international community believes that development of global health law will ensure the “enjoyment of the highest attainable standard of health” for “all peoples,” it needs to pursue this activity by the most effective means. The hard lawmaking power granted to WHO in 1948 was unprecedented, but is now outdated. The global health law landscape needs tools that can help articulate norms, include salient actors, and stay current with advances in medical science. It does not generally need instruments that are hard to enter or that enforce behavior.

Instead, soft law provides a useful and modern means to craft agreements that, while not binding legally, may have relatively more

196. See Mekouar, supra note 103, at 155.
197. The Committee noted it took twelve years for the UN to negotiate and adopt the Declaration on the Rights of Indigenous Peoples. See R&D Working Group, supra note 171, at 110. Beyond the fact that the declaration is a different kind of soft law instrument than that advocated in this Note, the Committee fails to demonstrate why this particular experience is relevant to its analysis.
198. See Whelan, supra note 66, at 5.
199. WHO Const. pmbl.
power to affect conduct. There are many global health issues left to address. 200 Soft law agreements can be effective tools to help achieve global health’s social justice ends.

200. See R&D Working Group, supra note 171, at 112 (“In recent times suggestions have been made for the adoption of international legal instruments on health-related issues. These include, for instance, alcohol (10,11), obesity control (12), counterfeit drugs (13), impact evaluation (14), and a framework convention for global health (15).”).