

**Suerie Moon**, PhD, MPA, is Research Director and Co-Chair of the Forum on Global Governance for Health at the Harvard Global Health Institute in Cambridge, MA. She is also a lecturer in the Department of Global Health and Population at the Harvard School of Public Health, and is Project Co-Director, Innovation and Access to Technologies for Sustainable Development, in the Sustainability Science Program at the Harvard Kennedy School of Government.

Please address correspondence to the author: Suerie Moon, 104 Mount Auburn Street, 3rd Floor, Cambridge, MA 02138, email: smoon@hsph.harvard.edu.

Competing Interests: None declared.

Copyright © 2013 Moon. This is an open access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0/>), which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original author and source are credited.

## RESPECTING THE RIGHT TO ACCESS TO MEDICINES: IMPLICATIONS OF THE UN GUIDING PRINCIPLES ON BUSINESS AND HUMAN RIGHTS FOR THE PHARMACEUTICAL INDUSTRY

Suerie Moon

### ABSTRACT

*What are the human rights responsibilities of pharmaceutical companies with regard to access to medicines? The state-based international human rights framework has long struggled with the issue of the human rights obligations of non-state actors, a question sharpened by economic globalization and the concomitant growing power of private for-profit actors (“business”). In 2011, after a six-year development process, the UN Human Rights Council unanimously endorsed the Guiding Principles advanced by the UN Secretary General’s Special Representative on Business and Human Rights, John Ruggie. The Ruggie Principles sought to clarify and differentiate the responsibilities of states and non-state actors—in this case, “business”—with respect to human rights. The framework centered on “three core principles: the state duty to protect against human rights abuses by third parties, including business; the corporate responsibility to respect human rights; and the need for more effective access to remedies.”*

*The “Protect, Respect, and Remedy” Framework emerged from a review of many industrial sectors operating from local to global scales, in many regions of the world, and involving multiple stakeholder consultations. However, their implications for the pharmaceutical industry regarding access to medicines remain unclear. This article analyzes the 2008 Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines advanced by then-UN Special Rapporteur on the Right to Health, Paul Hunt, in light of the Ruggie Principles. It concludes that some guidelines relate directly to the industry’s responsibility to respect the right to access to medicines, and form a normative baseline to which firms should be held accountable. It also finds that responsibility for other guidelines may better be ascribed to states than to private actors, based on conceptual and practical considerations. While not discouraging the pharmaceutical industry from making additional contributions to fulfilling the right to health, this analysis concludes that greater attention is merited to ensure that, first and foremost, the industry demonstrates baseline respect for the right to access to medicines.*

### INTRODUCTION

What are the human rights responsibilities of pharmaceutical companies with regard to access to medicines? The state-based international human rights framework has long struggled with the issue of the human rights obligations of non-state actors, a question sharpened by economic globalization and the concomitant growing power of private, for-profit actors (“business”). In 2011, after a six-year development process, the UN Human Rights Council unanimously endorsed the UN Guiding Principles on Business and Human Rights advanced by the UN Secretary General’s Special Representative on Business and Human Rights, John Ruggie. The Ruggie Principles (for brevity) sought to clarify and dif-

ferentiate the responsibilities of states and non-state actors—in this case, “business”—with respect to human rights. The framework centered on three core principles: “(a) States’ existing obligations to respect, protect and fulfill human rights and fundamental freedoms; (b) The role of business enterprises as specialized organs of society performing specialized functions, required to comply with all applicable laws and to respect human rights; [and] (c) The need for rights and obligations to be matched to appropriate and effective remedies when breached.”<sup>2</sup>

The “Protect, Respect, and Remedy” Framework emerged from a review of many industrial sectors operating from local to global scales, in many regions of the world, and involving multiple stakeholder consultations. However, their implications for the pharmaceutical sector remain unclear.

What do these guidelines imply for the pharmaceutical industry, particularly regarding access to medicines as a part of the human right to health? What is the difference between the baseline responsibility to “respect” and other responsibilities or socially desirable practices? What are the implications of this framework for norms articulated elsewhere regarding the responsibilities of pharmaceutical companies in relation to access to medicines, in particular the 2008 Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines advanced by then-UN Special Rapporteur on the Right to Health Paul Hunt (the “Hunt Guidelines,” for brevity)? Finally, what are the implications for the respective responsibilities of States and business, including in the proposed Framework Convention on Global Health?<sup>3</sup>

This article begins with a discussion of access to medicines as a human right, describes the “Protect, Respect, Remedy” Framework, and then addresses these questions through an analysis of the “Hunt Guidelines,” followed by a discussion of broader implications.

### *Evolution of access to medicines as a human right*

Access to essential medicines has gradually come to be recognized as part of the human right to health, enforceable under both international and national laws.<sup>4,6</sup> I use the term “essential medicines” to refer broadly to the World Health Organization concept of essential medicines, defined as:

[T]hose that satisfy the priority health care needs of the population.... selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness... [and] intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.<sup>7</sup>

For the sake of brevity, I use the term “medicines” to refer broadly to health technologies such as drugs, diagnostics, vaccines, and other health-care devices. The UN Committee on Economic, Social and Cultural Rights (CESCR), authoritatively recognized access to medicines as a means of fulfilling the right to health in General Comment 14.<sup>9</sup>

Paragraph 43 of General Comment 14 stated clearly, for the first time, that state parties are obliged “to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs” and “to ensure equitable distribution of all health facilities, goods and services.” Violations of a state’s obligation to respect the right to health include, *inter alia*, “the failure of the State to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations.”<sup>9</sup> Finally, General Comment 14 makes specific reference to non-state actors in paragraph 42:

While only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society—individuals, including health professionals, families, local communities, intergovernmental and non-governmental organizations, civil society organizations, as well as the private business sector—have responsibilities regarding the realization of the right to health.

However, no further detail was provided regarding non-state actors’ specific responsibilities.

The explicit discussion of access to medicines in General Comment 14 should be understood against the historical background of the late 1990s. During that period, a number of actors began to advocate for the importance of access to medicines, particularly in relation to the HIV/AIDS pandemic and the expected negative impact of the World Trade Organization (WTO) 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on the availability of low-cost generic medicines.<sup>10</sup> In particular, TRIPS required all WTO members to adopt a minimum standard of intellectual property (IP) protection in their domestic laws, such as 20-year patent terms for medicines. It effectively required Members to adopt the IP standards of industrialized countries, which meant many developing countries would have to introduce patents on medicines for the first time. Bilateral or regional free trade agreements also often contained IP provisions that were more stringent than TRIPS, such as longer patent terms or other forms of market exclusivity.

Over the course of the next decade, a relatively strong and stable norm emerged regarding access to medicines in developing countries, particularly (but not only) regarding access to drugs for HIV/AIDS.<sup>11</sup> This norm is reflected in a broad range of political declarations, civil society initiatives, academic publications, and the discourse and practices of governments, intergovernmental organizations, and the pharmaceutical industry. For example, donors spent unprecedented billions of dollars to provide HIV treatment in developing countries; by the end of the decade, over 90% of HIV medicines in developing countries were generics; and more than 60 developing country governments made use of flexibilities in the TRIPS Agreement to authorize the use of generic versions of patented drugs in their countries.<sup>12,13,14</sup>

The pharmaceutical industry, particularly research-based, patent-holding multinational firms, has been both a major target and an influential shaper of this emerging norm. Civil society organizations, experts, governments, and intergovernmental organizations regularly call on the industry to adopt certain access policies or practices. The industry is explicitly named in the 8th Millennium Development Goal, which includes as a key target: “In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.” Indeed, often in response to public pressure

or expectations, most of the twenty largest multinational firms and a handful of the large generic firms have adopted a wide array of ‘access policies.’<sup>15</sup>

Such policies might include licensing other firms to produce lower-cost generic versions of their patented drugs, reducing prices of their own drugs in lower-income markets (“tiered-pricing”), conducting R&D into diseases that predominantly affect the poor, making product donations, or other similar practices. A 2012 study by the International Federation of Pharmaceutical Manufacturers’ Associations reported 220 “health partnerships,” 36% of which focused on increasing the availability of treatments in developing countries.<sup>16</sup>

In short, over the past decade, the norm that access to medicines formed an integral part of the right to health became widely accepted, including—at least in part—by the multinational pharmaceutical industry. However, whether such firms had specific human rights *obligations* or *responsibilities* with respect to access to medicines remained a murky question.

#### EVOLUTION OF THE HUMAN RIGHTS RESPONSIBILITIES OF BUSINESS: THE RUGGIE PRINCIPLES

At the same time as the emergence of the access norm, a parallel effort was taking place to clarify norms regarding the human rights obligations of businesses more broadly. Events such as deadly clashes between local communities and multinational oil companies in the Niger Delta highlighted the urgency of identifying more effective ways to respond to human rights violations related to business. The questions were particularly vexing in areas where poorly resourced developing country governments were challenged by large firms with daunting financial, political, and technical resources, or where states were unwilling or unable to fulfill their obligations to respect, protect, and fulfill the rights of their own populations. When states were weak or failing, should businesses be bound to step in, to self-regulate, or to provide essential public services?

Efforts in the 1990s to agree upon a set of human rights obligations for business resulted in a set of Draft Norms on Transnational Corporations and Other Business Enterprises, prepared by a subcommittee of experts at the UN Human Rights

Commission. However, Ruggie argued that these norms had two conceptual shortcomings: first, they ascribed responsibility for a subset of rights to business, raising the question of why some rights should be considered more important than others; second, in doing so, they made both states and business responsible for the protection and fulfillment of some rights, creating a confusing conflation of roles. The Draft Norms, he wrote, “emphasize precisely the wrong side of the equation: defining a limited list of rights linked to imprecise and expansive responsibilities, rather than defining the specific responsibilities of companies with regard to all rights.”<sup>11</sup>

Ultimately, the Draft Norms were not supported by enough governments, and were never endorsed by the Human Rights Commission. Instead, the Commission began a new process in 2005 by mandating Ruggie, as Special Representative of the Secretary General to first merely “identify and clarify” existing norms and practices, and ultimately, to develop a new normative framework.<sup>17</sup> Over the following six years, Ruggie developed the “Protect, Respect, Remedy” framework through a series of studies, international consultations, meetings, and field-testing.

A central principle underpinning the framework—and what distinguishes it most sharply from the preceding Draft Norms—is that states and business do not have the same obligations. While reaffirming that states have the primary responsibility to respect, protect, and fulfill human rights, Ruggie argued, “as economic actors, companies have unique responsibilities. If those responsibilities are entangled with State obligations, it makes it difficult if not impossible to tell who is responsible for what in practice.... While corporations may be considered ‘organs of society’, they are specialized economic organs, not democratic public interest institutions. As such, their responsibilities cannot and should not simply mirror the duties of States.”<sup>11</sup>

The Principles reaffirmed the primary responsibility of states to protect human rights, including against potential abuses by business, and focused on two types of responsibilities for business: respect and remedy. Ruggie explained the concept of “respect” as follows: “In addition to compliance with national laws, the baseline responsibility of companies is to respect human rights....To respect rights essentially

means not to infringe on the rights of others—put simply, to do no harm.”<sup>11</sup> He continued, “There are situations in which companies may have additional responsibilities—for example, where they perform certain public functions, or because they have undertaken additional commitments voluntarily. But the responsibility to respect is the baseline expectation for all companies in all situations.”<sup>11</sup>

What emerges from this description is an implicit two-tier framework, in which the company’s responsibility to respect is fundamental; other activities may be socially desirable and important for fulfilling the right to health, but are secondary. The primacy of the principle of “respect”—doing no harm—has important implications for the responsibilities of pharmaceutical companies. (Note that ‘respect’ may still require positive measures, and does not necessarily imply passivity; for example, an anti-discrimination policy might require pro-active recruitment programmes.) Furthermore, a key question arises regarding the extent to which pharmaceutical R&D and production should be considered “public functions” implying additional responsibilities (discussed below).

The second key part of the Ruggie Principles applicable to companies is the concept of “remedy.” Ruggie argued, “the corporate responsibility to respect requires a means for those who believe they have been harmed to bring this to the attention of the company and seek remediation, without prejudice to legal channels available.”<sup>11</sup> Finally, the Principles discussed what is required to operationalize respect and remedy within a firm, with emphasis on clear policies, due diligence, high-level leadership, and transparency. Ruggie noted, “Companies need to adopt a human rights policy. Broad aspirational language may be used to describe respect for human rights, but more detailed guidance in specific functional areas is necessary to give those commitments meaning.”<sup>11</sup> He continued that due diligence is required: “a process whereby companies not only ensure compliance with national laws but also manage the risk of human rights harm with a view to avoiding it....basic human rights due diligence process should include the following: Policies, Impact Assessments, Integration, Tracking Performance.” Finally, “Where human rights and other public interests are concerned, transparency

should be a governing principle, without prejudice to legitimate commercial confidentiality.”<sup>11</sup> This guidance has concrete implications for what “respect” for access to medicines may mean in practice.

What does this framework imply for the pharmaceutical industry?

*The pharmaceutical industry and its access to medicines responsibilities: The Hunt Guidelines*

Ruggie’s mandate (2005-2011) overlapped with that of Paul Hunt (2002-2008), the first UN Special Rapporteur on the right to health, an independent expert mandated by the Human Rights Council to explore a special theme or country situation. Among a range of topics, Hunt sought to clarify norms regarding the pharmaceutical industry and access to medicines.

In this capacity, Hunt reaffirmed the conclusion of General Comment 14 that the obligation of states to make essential medicines available was immediate and not subject to progressive realization.<sup>19</sup> However, he found that while “the human rights duties of States in relation to access to medicines were reasonably clear....the nature and scope of pharmaceutical companies’ human rights responsibilities in relation to access to medicines were not clear,” and that the CESCR had not elaborated on General Comment 14 to provide practical guidance to industry.<sup>20</sup>

At the same time, Hunt argued that the pharmaceutical industry could both positively or negatively affect access to medicines, noting, “Ministers, senior public officials and others have argued that the policies and practices of some pharmaceutical companies constitute obstacles to States’ implementation of the right to the highest attainable standard of health,” for example, through their pricing, research and marketing practices.<sup>20</sup> Hunt argued that ensuring access to medicines was a “shared responsibility” between public and private actors, and that pharmaceutical companies had an “indispensable role to play.”<sup>19</sup>

While he included both patent-holding (“innovator” and “biotechnology”) and generic pharmaceutical companies in his review, Hunt argued that patent-holders had a special set of obligations: “Society has legitimate expectations of a company holding

the patent on a life-saving medicine. In relation to such a patent, the right-to-health framework helps to clarify what these terms, and expectations, are. Because of its critical social function, a patent on a life-saving medicine places important right-to-health responsibilities on the patent holder. These responsibilities are reinforced when the patented life-saving medicine benefited from research and development undertaken in publicly funded laboratories.”<sup>21</sup>

Hunt released a set of draft Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines in September 2007 for public comment. In August 2008, after receiving input from states, investors, pharmaceutical companies, academics, and civil society organizations, the amended and finalized guidelines were submitted to the UN General Assembly.<sup>20</sup>

Some companies strongly objected. In response to Hunt’s report on a visit to GlaxoSmithKline, the company issued a statement that “the ‘right to health’ is an important issue, though not well defined, especially as it relates to non-state actors. Therefore we do not accept the suggestion—implicit in the development of this Report—that GSK’s programme and ongoing commitment is in any way required by international legal norms, whether in human rights or other areas.”<sup>22</sup> In a similar vein, Merck’s representative remarked, “we feel the approach to define guidelines specific to the pharmaceutical industry is misguided and will not result in meaningful improvements.”<sup>23</sup>

The 47 guidelines cover a broad range of areas, including transparency, management, lobbying, research, patenting and licensing, and pricing. Notably, Hunt made clear that the guidelines were exhortatory rather than obligatory, stating:

[T]he Guidelines do not use the peremptory word ‘must’, but the more modest language ‘should.’ In other words, they deliberately avoid some of the most controversial doctrinal questions (such as, ‘are businesses legally bound by international human rights law?’)... the central objective of the Guidelines is to provide practical, constructive and specific guidance to pharmaceutical companies and other interested parties,

including those who wish to monitor companies and hold them to account.<sup>20</sup>

How can this guidance be seen in light of the “Protect, Respect, Remedy” framework, which was finalized three years later?

## ANALYSIS

### *Reading the Hunt Guidelines in light of the Ruggie Principles*

The Hunt Guidelines and the initial version of the Ruggie framework were both issued in 2008. Hunt noted that “the Guidelines are consistent with and complementary to the helpful analysis recently provided by the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises.”<sup>20</sup> Indeed, the Hunt Guidelines and Ruggie Principles both unequivocally place primary responsibility for human rights protection and fulfillment on states, while also ascribing to business certain responsibilities. However, revisiting the Hunt Guidelines after the Ruggie Principles were finalized casts them in a new light. More concretely, the Ruggie Principles underscore the importance of distinguishing between companies’ responsibilities to respect human rights, and any other activities they may engage in to contribute to fulfilling human rights.

In a 2012 article, Joo-Young Lee and Paul Hunt explicitly recognized that the Hunt Guidelines extended beyond the responsibility to respect. They argued that patent-holding pharmaceutical companies had additional responsibilities, because by carrying out research and development of potentially life-saving medicines, they performed a “public function,” which Ruggie said may imply further responsibilities (see above).<sup>24</sup>

Nevertheless, it is useful to distinguish between those guidelines that primarily relate to the responsibility to respect and those that may relate to additional responsibilities, for the following three reasons. First, if “respect” forms the baseline, then it is important to ensure that companies are indeed living up to this most fundamental responsibility. Ruggie has argued that “because the responsibility to respect is a

baseline expectation, a company cannot compensate for human rights harm by performing good deeds elsewhere.”<sup>21</sup> For example, if a pharmaceutical company successfully lobbies to undermine flexibilities in patent rules or other cost-containment policies necessary to ensure widespread population access to a medicine, but then offers a voluntary price discount on that medicine, it should not be lauded for the pricing policy. Rather it should be recognized as having ‘done harm’ by undermining the state’s efforts to protect its population’s right to health. The Hunt Guidelines cover both of these policy areas—recommending that firms abstain from lobbying that undermines the right to health and that they offer voluntary price discounts for lower-income populations—but do not make clear that carrying out the latter does not absolve the firm from abiding by the former. Distinguishing between the responsibility to respect and other responsibilities helps to clarify such situations and focus attention on the most fundamental responsibilities of industry.

Second, conflating the responsibilities of state and non-state actors risks detracting attention away from state obligations, making it easier for governments to shirk their own obligations. As discussed below, several of the Hunt Guidelines seem to fall squarely under the obligations of states to protect the right to health. In other cases, relevant health objectives are more likely to be sustainably and reliably achieved with decisive state action, rather than through non-binding exhortations on firms. To be clear, this is not to discourage or devalue socially desirable actions taken by pharmaceutical companies, but rather to ensure that attention is not detracted from the clear responsibilities of states.

Finally, as Hunt has noted, the guidelines are a useful tool for “those who wish to monitor companies and hold them to account.”<sup>20</sup> But the limited resources of civil society organizations, journalists, and other watchdog entities underscore the importance of getting the baseline right, allowing such groups to focus their energies on holding companies accountable for at least their most basic human rights responsibilities, and governments for theirs.

Based on the premise that there is an important conceptual distinction between the baseline responsibility to respect and other responsibilities, I analyzed what the principle of “respect” may mean in practice for the pharmaceutical industry. This review of the 47 Hunt Guidelines found that each could be placed into one of four categories:

- 1)**Respect:** Guideline clearly falls under the responsibility to “respect”;
- 2)**Protect:** Guideline more aligned with the state duty to protect;
- 3)**Gray Area:** Guideline fell into a gray area involving both “respect” and “protect”;
- 4)**Fulfill:** Guideline more aligned with state duty to fulfill right to health.

I discuss each of these in turn.

### *Respect: Concrete implications for the pharmaceutical industry*

Over half the guidelines clearly fell under “respect.” Among these were the first four guidelines that recommend that companies “should adopt a human rights policy statement,” “integrate human rights... into the strategies, policies, programmes, projects and activities of the company,” “should always comply with the national law of the State where it operates, as well as any relevant legislation of the State where it is domiciled,” and “should refrain from any conduct that will or may encourage a State to act in a way that is inconsistent with its obligations arising from national and international human rights law,” including the right to health. These guidelines align closely with the principle of respect and Ruggie’s recommendations on how to operationalize it.

Furthermore, transparency is central to the Ruggie Principles, and is important for due diligence and effective remedy. Several of the Hunt Guidelines (6-8) explicitly address transparency, stating, “... the company should be as transparent as possible. There is a presumption in favour of the disclosure of information, held by the company, which relates to access to medicines.” Guidelines 10-13 lay out recommendations for management (“clear manage-

ment systems, including quantitative targets”) and monitoring and accountability (companies should establish a “publicly available policy on access to medicines setting out general and specific objectives, time frames, reporting procedures and lines of accountability,” “a governance system that includes direct board level responsibility and accountability,” and “publish a comprehensive annual report, including qualitative and quantitative information.”) These measures enable both the firm and third parties to assess the extent to which a firm is respecting the right to access to medicines, and as such falls clearly under the principle of “respect.”

In addition, guidelines 21-22 concerning the conduct of research state, “A company’s clinical trials should observe the highest ethical and human rights standards, including non-discrimination, equality and the requirements of informed consent. This is especially vital in those States with weak regulatory frameworks....The company should conform to the Declaration of Helsinki on Ethical Principles for Medical Research involving Human Subjects, as well as the World Health Organization Guidelines for Good Clinical Practice.” Finally, with respect to patents, the guidelines (26-29) state that companies “should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994), which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports,” “should respect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health (2001),” and, recognizing the WTO extension until at least 2016 for Least Developed Countries, the company “should not lobby for such countries to grant or enforce patents.” These guidelines advocate against doing harm (for example, through weakening public policies intended to protect access to medicines), and are therefore closely linked to the principle of “respect.”

Overall, guidelines pertaining to the adoption of human rights policies, transparency and information disclosure, adherence to national laws or widely-accepted international standards, ethical research,

and state use of patent law flexibilities, fall under the umbrella of the principle of “respect” and seem to be reasonable expectations of pharmaceutical companies.

*Protect: Beyond the baseline – additional responsibilities for business...or for states?*

However, a number of the guidelines espouse additional responsibilities that extend beyond the notion of “respect.” These guidelines raise questions on the relative responsibilities of states and firms. Unless additional responsibilities can be conceptually differentiated from baseline responsibilities, there is a risk of confusing the roles of states and firms and of weakening state and firm accountability. Some of the guidelines seemed to fall clearly under the state duty to protect, rather than under the private sector’s responsibility to respect. For example, guideline 8 calls on companies to establish an independent body “either alone or in conjunction with others...to consider disputes that may arise regarding the disclosure or otherwise of information relating to access to medicines.” Such a body, which has not yet been created, would be critical for determining whether rights have been violated and how to remedy such violations effectively. Similarly, guideline 14 calls on companies to “establish an effective, transparent, accessible and independent monitoring and accountability mechanism” to “hold the company to account” for adhering to these guidelines. Yet, it is unlikely that the establishment of an independent monitoring mechanism is (or can credibly be) the responsibility of the company, rather than that of the state or civil society.

*Gray areas: Respect, protect, or both?*

In other cases, guidelines seem to fall squarely into a gray area, involving both the state duty to protect and business responsibility to respect. Such guidelines call on firms to refrain from certain actions that would undermine access (‘do no harm’), but are likely to require state action, especially when significant profits are at stake. In their critical analysis of the Hunt Guidelines, Anand Grover (the Special Rapporteur on the right to health immediately following Hunt) and colleagues argued that since private firms have an obligation to their shareholders to maximize profit, non-binding guidelines will be insufficient to ensure respect when a firm’s adherence to such guidelines runs directly counter to profit maximization.<sup>25</sup>

For example, guideline 18 recommends that firms adhere to international quality standards in pharmaceutical production. Business compliance with national laws clearly falls under “respect,” and manufacturing quality drugs so that sub-standard medicines do not harm patients could be understood as ‘doing no harm.’ However, since adherence to quality standards is costly, firms face powerful incentives to take shortcuts on quality to increase profits, especially when competing for thin profit margins. Thus, it is widely accepted that states need to exercise strong regulatory authority over pharmaceutical production. Similarly, guidelines 39-41 call on companies to promote medicines in an ethical manner, such as by making information on side effects easily accessible. This responsibility is directly related to transparency and could easily qualify as “respect.” However, states generally regulate the promotion of medicines due to major information asymmetries between producers and consumers. Firms have strong incentives to downplay side effects or to market their medicines for indications beyond those approved by a regulatory body, as both measures can increase sales and profits. Ethical medicines promotion is more likely to be achieved by focusing on the state’s regulatory responsibilities, such as mandating the type of information that firms must disclose or restricting marketing for off-label use.

Another example is provided by guidelines (17-19) which state that a company “should disclose all current advocacy and lobbying positions, and related activities, at the regional, national and international levels that impact or may impact upon access to medicines” and “should annually disclose its financial and other support to key opinion leaders, patient associations, political parties and candidates, trade associations, academic departments, research centres and others, through which it seeks to influence public policy and national, regional and international law and practice. The disclosure should extend to amounts, beneficiaries and channels by which the support is provided.” On the one hand, transparency is a reasonable, core expectation of pharmaceutical companies; on the other hand, lobbying is politically sensitive, and when successful it can produce policies that enable significant profits. Therefore, it seems unrealistic to expect firms to adhere to this guideline in the absence of binding state regulations, which would fall under the state duty to protect.

Similarly, guidelines 31 and 32 call on firms to “waive test data exclusivity” and refrain from applying for patents “for insignificant or trivial modifications of existing medicines” in low- and middle-income countries. Both of these measures can strengthen the monopoly on a medicine and thereby increase profits. Averting such expanded monopolies (and related price increases) is more likely if states simply disallow data exclusivity and patents on trivial modifications of existing medicines in their national laws, as allowed under TRIPS.<sup>26,27</sup>

*Fulfill: What are reasonable expectations for companies and states?*

Finally, in other cases, the guidelines outlined areas where proactive company action would be socially desirable (e.g. neglected disease research, voluntary licensing, pricing), but seemed conceptually closer to “fulfilling” the right to health than “respecting” it. In such cases, it is worth noting that the responsibility to fulfill human rights falls primarily on states, and conducive public policy is likely to be required to shape firm behavior towards fulfillment. For example, guidelines 23-25 call on firms to contribute to neglected disease R&D. However, while firms may engage in some neglected disease research, by definition these diseases are ‘neglected’ because they have no commercial prospects; overall investment into neglected diseases is unlikely to be sufficient or sustainable unless states build conducive policy frameworks (such as “push” financing or “pull” incentives to subsidize costs and/or mitigate risk).<sup>28,29</sup>

Similarly, while guideline 30 calls on firms to issue voluntary licenses on all medicines in low- and middle-income countries, firms are unlikely to do so if it will significantly hurt their bottom-line. Since middle-income countries are projected to be the major source of revenue growth for the industry in the coming decade, it is highly unlikely that for-profit entities will voluntarily sign away monopoly rights in these countries. Along the same lines, guidelines 33-38 recommend that firms ensure that “all medicines manufactured by the company, including those for non-communicable conditions” “are affordable to as many people as possible” through, inter alia, voluntary price discounts to those with lower ability to pay (tiered or differential pricing), voluntary licenses, and donations.<sup>30</sup> While company efforts to

decrease the price of medicines are welcome, ensuring that price is not a barrier to access falls far beyond the responsibility to respect—in some cases, this would imply negative prices for the poorest populations; nor do the policies prescribed in the guidelines necessarily ensure affordability.<sup>31</sup>

Rather, ensuring affordability falls under the obligation of states to protect and fulfill the right to access to medicines, and is arguably more likely when governments decisively deploy a range of policy tools for this purpose, such as price negotiations, price controls, generic promotion, compulsory licensing, competition-enhancing policies, and subsidies. In particular, for the most lucrative medicines in the fast-growing (but highly unequal) middle-income countries, affordability is unlikely to be achieved without decisive public policy.

Indeed, a number of these “gray area” guidelines aim at policy objectives that are unlikely to be achieved without state action. In such cases, a practical approach would emphasize state obligations rather than the private sector’s responsibilities.

In summary, firms may reasonably be expected to take voluntary measures on R&D, licensing, or pricing when sizeable profits are not at risk, such as in the poorest countries or for certain drugs. However, they are unlikely to do so for major markets. This challenge has been clearly demonstrated in the difficulties the Medicines Patent Pool has faced in convincing companies to include the most lucrative middle-income markets, such as China and Brazil, in the scope of its voluntary licenses for HIV medicines.<sup>32</sup>

States need to provide both carrots and sticks to change the cost-benefit calculation for firms to induce them to adopt certain access-enhancing policies. Where profit potential is significant, ensuring respect for (and fulfillment of the right to) access to medicines will require state action rather than voluntary firm behavior alone.

## DISCUSSION AND CONCLUSIONS

Many of the Hunt Guidelines for pharmaceutical companies fall under the Ruggie principle of “respect,” but some fall into a gray area or even

ascribe to private actors the obligations that—for both conceptual and practical reasons—would better be ascribed to states.

Admittedly, there is significant room for debate on some of these guidelines. Does the argument that state action is required to meet certain health objectives imply that companies do not have certain responsibilities? Not necessarily. Here we return to Lee and Hunt, who argued that because of the “public” nature of the functions carried out by pharmaceutical companies, namely the development and production of essential medicines, certain additional responsibilities apply. For example, as noted, lower prices or neglected disease research would both contribute to fulfilling the right to health. Reasonable arguments could be made either that these are “additional responsibilities,” or that they fall short of “responsibility” and are merely socially desirable. However, this article has not focused on the distinction between “additional responsibilities” and other measures. Lengthier analysis of each guideline would be required to achieve greater clarity on whether certain measures cross the conceptual threshold between a “non-responsibility” (albeit one that may be socially desirable) and an “additional responsibility.” Rather, the key conclusion is that distinguishing between baseline and additional responsibilities is critical to ensure that industry meets its fundamental responsibilities to respect rights.

Indeed, greater clarity on the respective duties and responsibilities of states and pharmaceutical companies is needed. Ensuring business responsibility to respect as a fundamental baseline can sharpen the focus on the most important expectations of firms. Much attention has been paid to industry’s pricing, licensing, and neglected disease research efforts. Such attention is often accompanied by high praise, which at times is quite justifiable. However, there is insufficient information and debate regarding the ways in which firms may lobby to undermine state capacities to protect access to medicines, such as by advocating for restrictive trade agreements or the unethical promotion of medicines. Much greater attention is merited to the extent to which the industry meets its baseline responsibilities.

This analysis has primarily focused on the notion of “respect,” but further consideration of “remedy” is also merited. In a 2010 article following up on the

guidelines, Hunt and Khosla concluded that the pharmaceutical industry was failing to live up to its human rights responsibilities and called for an independent accountability mechanism, to be created by civil society if states and firms were unwilling to do so.<sup>33</sup> Grover and colleagues have also pointed to the absence of such a mechanism as a key weakness in implementing the norms contained in the guidelines.<sup>25</sup> Indeed, a major point of the Ruggie Principles is that measures to provide redress to injured parties or to prevent the reoccurrence of abuses have received too little attention. There are few institutions for remedying a pharmaceutical company’s actions to restrict access to medicines to a population. Building a more robust system to ensure industry respect for access to medicines will require greater attention to institutions for remedy—a key issue for future analysis.

Finally, what does this analysis imply for the proposed Framework Convention on Global Health (FCGH)? One of the objectives in developing the FCGH is to clarify the responsibilities of various actors. However, while the importance of clarifying the responsibilities of non-state actors is recognized, published materials have not included a detailed discussion of what obligations, if any, private for-profit actors may have within an FCGH.<sup>34</sup> Applying the Ruggie Principles would imply reinforcing the call for States to fulfill their obligations to protect the right to health when business activities may be undermining it. With regards to access to medicines, this could mean adopting the actions included in Hunt’s 2006 analysis of state responsibilities, such as making use of TRIPS flexibilities to ensure affordability of medicines and refusing to join any international agreement that would impinge on such flexibilities.<sup>19</sup> It also implies taking action to ensure that business respects the right to health, including passing national legislation to give more binding force to the responsibilities articulated here, such as disclosure requirements on R&D investments, tax benefits, marketing and lobbying activities, and pricing policies. Binding national laws requiring disclosure, especially if disclosure applies to worldwide operations, are particularly promising as the information can have global impact even if only a few states implement such laws. One of the core challenges of the FCGH proposal is to convince states to negotiate and create new binding obligations on themselves and on the firms domiciled in their territories—a tall order in a world of competitive states and firms. However, if even a

strategic handful of states negotiated an FCGH and passed disclosure and transparency requirements, the global public goods nature of information would mean that such data would be available for the benefit of all populations and countries. Overall, integrating norms on the responsibilities of business into the FCGH concept could significantly strengthen its promise as a tool for improving global governance for health.

Finally, further research, analysis and debate is required, especially to clarify the “gray areas” where both states and the pharmaceutical industry may have responsibilities, and how to define “additional responsibilities.” Furthermore, this article has focused on pharmaceuticals, but many other industries can also have profound health impacts, both within the health sector (e.g., health insurance, private hospitals) and outside it (e.g., food and beverage, oil and mining, tobacco, arms, manufacturing, finance). Further analysis is needed on the implications of the “Protect, Respect, Remedy” framework for these industries in relation to the right to health.

#### ACKNOWLEDGMENTS

I am grateful to Steven J. Hoffman, Amy Kapczynski, John-Arne Rottingen, John G. Ruggie, the participants of the American University Washington College of Law’s February 2013 Conference on Intellectual Property and Human Rights, two anonymous peer reviewers and the guest editors (especially Eric Friedman), for helpful conversations and/or insightful comments on earlier drafts of this article. All opinions, errors, and omissions remain my own.

#### REFERENCES

1. J.G. Ruggie, Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, Protect, Respect and Remedy: A Framework for Business and Human Rights, UN Doc. No. A/HRC/8/5 (2008). Available at <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G08/128/61/PDF/G0812861.pdf?OpenElement>.
2. J.G. Ruggie, Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, Guiding Principles on Business and Human Rights: Implementing the United Nations “Protect, Respect and Remedy” Framework, UN Doc. No. A/HRC/17/31 (2011). Available at <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/121/90/PDF/G1112190.pdf?OpenElement>.

3. L.O. Gostin, “A Framework Convention on Global Health: Health for all, justice for all,” *Journal of the American Medical Association* 307/19 (2012), pp. 2087-2092.
4. H.V. Hogerzeil and Z. Mirza, *The world medicines situation 2011: Access to essential medicines as part of the right to health* (Geneva: World Health Organization, 2012), pp.1-12.
5. H.V. Hogerzeil, M. Samson, J. V. Casanovas, and L. Rahmani-Ocora, “Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?” *Lancet* 368 (2006), pp. 305-311.
6. E. Friedman and L. Gostin, “Pillars for progress on the right to health: Harnessing the potential of human rights through a Framework Convention on Global Health,” *Health and Human Rights: An International Journal* 14/1 (2012), pp. 4-19.
7. World Health Organization, “Essential Medicines.” Available at [http://www.who.int/topics/essential\\_medicines/en/](http://www.who.int/topics/essential_medicines/en/).
8. A.E. Yamin, “Not just a tragedy: Access to medications as a right under international law,” *Boston University International Law Journal* 21 (2003), pp. 325-371.
9. Committee on Economic, Social and Cultural Rights. General Comment No.14, The Right to the Highest Attainable Standard of Health, UN Doc. No. E/C.12/2000/4 (2000). Available at <http://www.unhcr.org/refworld/pdfid/4538838d0.pdf>.
10. E.‘t Hoen, J. Berger, A. Calmy, and S. Moon, “Driving a decade of change: HIV/AIDS, patents and access to medicines for all,” *Journal of the International AIDS Society* 14/15 (2011).
11. W. Hein and S. Moon, *Informal norms in global governance: Human rights, intellectual property rules and access to medicines* (Aldershot, UK: Ashgate, 2013).
12. Institute for Health Metrics and Evaluation, *Financing global health 2011: Continued growth as MDG deadline approaches* (Seattle: Institute for Health Metrics and Evaluation, 2011).
13. B. Waning, M. Kyle, E. Diedrichsen, et al., “Intervening in global markets to improve access to HIV/AIDS treatment: An analysis of international policies and the dynamics of global antiretroviral medicines markets,” *Globalization and Health* 6 (2010).
14. E. ‘t Hoen, *The global politics of pharmaceutical monopoly power: Drug patents, access, innovation, and the application of the WTO Doha Declaration on TRIPS and public health* (Diemen, The Netherlands: AMB Press, 2009).
15. MSCI ESG Research, *Access to medicine index 2012* (Amsterdam: Access to Medicine Foundation, 2012).
16. International Federation of Pharmaceutical Manufacturers and Associations, “Developing world health partnerships directory reflects pharmaceutical industry’s and partners’ commitment to improving health in developing countries” (News release, September 11, 2012). Available at [http://www.ifpma.org/fileadmin/content/News/2012/FINAL\\_IFPMA\\_press\\_release\\_-\\_partnerships\\_-\\_11\\_](http://www.ifpma.org/fileadmin/content/News/2012/FINAL_IFPMA_press_release_-_partnerships_-_11_)

September\_2012.pdf.

17. J.G. Ruggie, *Just business: Multinational corporations and human rights* (New York: W.W. Norton, 2013).

18. Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Office of the United Nations High Commissioner for Human Rights. (Accessed 5/18/2010, 2010, at <http://www2.ohchr.org/english/issues/health/right/>).

18. P. Hunt, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, UN Doc. No. A/61/338 (2006). Available at <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N06/519/97/PDF/N0651997.pdf?OpenElement>.

19. P. Hunt, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, UN Doc. No. A/63/263 (2008). Available at [http://www.who.int/medicines/areas/human\\_rights/A63\\_263.pdf](http://www.who.int/medicines/areas/human_rights/A63_263.pdf).

21. P. Hunt, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Health, Paul Hunt, Annex: Mission to GlaxoSmithKline, UN Doc. No. A/HRC/11/12/Add.2 (2009). Available at [http://www.who.int/medicines/areas/human\\_rights/A\\_HRC\\_11\\_12\\_Add\\_2.pdf](http://www.who.int/medicines/areas/human_rights/A_HRC_11_12_Add_2.pdf).

22. GlaxoSmithKline, "GlaxoSmithKline statement in response to Paul Hunt's report on GSK," (June 2009). Available at <http://198.170.85.29/GSK-response-to-Paul-Hunt-report-June-2009.pdf>.

23. J.L. Sturchio, "Response from Merck & Co., Inc. (to Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines)," (February 29, 2008). Available at [http://www.merck.com/corporate-responsibility/docs/access\\_developing\\_response\\_feb08.pdf](http://www.merck.com/corporate-responsibility/docs/access_developing_response_feb08.pdf).

24. J. Lee and P. Hunt, "Human rights responsibilities of pharmaceutical companies in relation to access to medicines," *Journal of Law, Medicine and Ethics* 40/2 (2012), pp. 220-233.

25. A. Grover, B. Citro, M. Mankad, and F. Lander, "Pharmaceutical companies and global lack of access to medicines: Strengthening accountability under the right to health," *Journal of Law, Medicine and Ethics* 40/2 (2012), pp. 234-250.

26. C.M. Correa, *Guidelines for the examination of pharmaceutical patents: Developing a public health perspective* (Geneva: International Centre for Trade and Sustainable Development, World Health Organization, United Nations Conference on Trade and Development, 2007).

27. C.M. Correa, *Protection of data submitted for the registration of pharmaceuticals: Implementing the standards of the TRIPS agreement* (Geneva: The South Centre, 2002).

28. WHO Consultative Expert Working Group on Research and Development: Financing and Coordination, *Research and development to meet health needs in developing countries: Strengthening global financing and coordination* (Geneva: World Health Organization, 2012).

29. S. Moon, J. Bermudez, and E. 't Hoen, "Innovation and access to medicines for neglected populations:

Could a treaty address a broken pharmaceutical R&D system?" *PLoS Med* 9/5 (2012), p. e1001218.

30. IMS Institute for Healthcare Informatics, *Global use of medicines: Outlook through 2015* (Parsippany, New Jersey: IMS Health, 2011).

31. S. Moon, E. Jambert, M. Childs, and T. von Schoen-Angerer, "A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries," *Globalization and Health* 7 (2011).

32. Medicines Patent Pool, "Licenses in the pool 2013." Available at <http://www.medicinespatent-pool.org/licensing/current-licences/>.

33. P. Hunt and R. Khosla, "Are drug companies living up to their human rights responsibilities? The perspective of the former United Nations Special Rapporteur (2002-2008)," *PLoS Med* 7/9 (2010), p. e1000330.

34. Joint Action and Learning Initiative on National and Global Responsibilities for Health, *Preliminary answers to 5 priority questions on the Framework Convention on Global Health* (February 2012). Available at <http://www.jalihealth.org/documents/FCGH%20priority%20questions%20website%20launch.pdf>.

35. R. Laing, B. Waning, A. Gray, et al., "25 years of the WHO essential medicines lists: Progress and challenges," *Lancet* 361/9370 (2003), pp. 1723-1729.

36. S.P. Marks, "Access to essential medicines as a component of the right to health," in A. Clapham, M. Robinson, C. Mahon, and S. Jerbi (eds), *Realizing the right to health, Swiss Human Rights Book Vol. 3* (Zurich: Rüffer & Rub, 2009), pp. 80-99.

37. United Nations Development Programme, *Human development report 1999* (Oxford and New York: Oxford University Press, 1999).

38. United Nations Development Programme, *Human development report 2000: Human rights and human development* (Oxford and New York: Oxford University Press, 2000).

39. United Nations Development Programme, *Human development report 2001: Making new technologies work for human development* (Oxford and New York: Oxford University Press, 2001).

40. UN Committee on Economic, Social and Cultural Rights, Statement of the UN Committee on Economic, Social and Cultural Rights to the Third Ministerial Conference of the World Trade Organization, Seattle, November 30-December 3, 1999, UN Doc. No. E/C.12/1999/9 (1999). Available at [http://www.unhchr.ch/tbs/doc.nsf/\(Symbol\)/68300503f197ef528025683b004fbbae?Opendocument](http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/68300503f197ef528025683b004fbbae?Opendocument).

41. UN Sub-Commission on Human Rights, Intellectual Property Rights and Human Rights, UN Doc. No. E/CN.4/SUB.2/RES.2000/7 (2000). Available at <http://www.unhchr.ch/Huridocda/Huridocda.nsf/0/c462b62cf8a07b13c12569700046704e?Opendocument>.

42. S. Gruskin and Z. Raad, "Are drug companies living up to their human rights responsibilities? Moving Toward Assessment," *PLoS Med* 7 (2010), p. e1000310.