Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines

Joo-Young Lee and Paul Hunt

1. Introduction

The Constitution of the World Health Organization (WHO) affirms that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being."[1] The Universal Declaration of Human Rights lays the foundations for the international framework for the right to health. This human right is now codified in numerous national constitutions, as well as legally binding international human rights treaties, such as the International Covenant on Economic, Social and Cultural Rights.[2]

Although medical care and access to medicines are vital features of the right to health, almost two billion people lack access to essential medicines, leading to immense avoidable suffering. Improving access to essential medicines could save 10 million lives each year, four million of them in Africa and South-East Asia alone.[3] Gross inequity is a shocking feature of the world pharmaceutical situation.[4]

Throughout his mandate, the first UN Special Rapporteur on the right to the highest attainable standard of health, Paul Hunt, one of the authors of this article, regularly scrutinized States' duties and practice in relation to access to medicines.[5] The issues were addressed in his thematic and country reports.[6] On numerous occasions, Ministers, senior public officials, civil society and others informed the Special Rapporteur that, when endeavoring to implement the right to health, States encounter many obstacles, among them the policies of some pharmaceutical companies, including their excessively high prices for medicines. Additionally, however, there was a widespread recognition that the pharmaceutical sector has an indispensable role to play in relation to the right to health and access to medicines. Enhancing access to medicines is understood to be a shared responsibility. If access to medicines is to be improved, numerous actors — national, international, public, and private

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— have a vital role to play. The Millennium Development Goals recognize that pharmaceutical companies are among those sharing this responsibility. Goal 8, a global partnership for development, has a number of targets; for example, "In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries."[7] In this article, we use a right to health "lens" to consider the responsibilities of pharmaceutical companies in relation to access to medicines. Of course, given space constraints, our examination is not comprehensive. Moreover, this is a new way of approaching pharmaceutical companies' responsibilities, and we recognize that it requires further discussion. Nonetheless, we hope that our analysis provides a useful introduction to the human rights responsibilities of pharmaceutical companies in relation to access to medicines.

During his tenure, the Special Rapporteur engaged in many discussions on access to medicines with numerous parties, including pharmaceutical companies. These substantive discussions took place at symposia and workshops, as well as informal visits to pharmaceutical companies. They also occurred in clinics, hospitals, and civil society consultations during the Special Rapporteur's country missions. These discussions were informed by the voluminous literature on access to medicines. During these discussions, the human rights duties of States in relation to access to medicines were reasonably clear, and these duties are now explored in the Special Rapporteur's various reports, as already mentioned. However, it became apparent that the nature and scope of pharmaceutical companies' human rights responsibilities in relation to access to medicines were not clear. The UN Committee on Economic, Social and Cultural Rights, for example, confirms that the private business sector has responsibilities regarding the realization of the right to health, but it has not taken further steps to specify these responsibilities.[8] In one of his reports, John Ruggie, the UN Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises rightly observes: "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."[9] This normative gap — the absence of "detailed guidance" — was a major impediment for all parties, including the Special Rapporteur, when considering the policies and practices of the pharmaceutical sector. Without "detailed guidance" pharmaceutical companies could legitimately remark that while they wished to comply with their right-to-health responsibilities, nobody could tell them what they were. Also, uncertainty about the contours and content of these right-to-health responsibilities made it very difficult to hold the pharmaceutical companies accountable. Thus, there was an urgent need to move from the general and abstract to the specific and operational.

The Special Rapporteur responded to this challenge in three ways. First, in 2006 he presented to the UN General Assembly a thematic report on the human right to medicines, with one section on the responsibilities of States and the other on the responsibilities of pharmaceutical companies.[10] Second, in 2008 he presented to the General Assembly *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*.[11] Finalized after a long process of research and consultation, they provide detailed guidance for all pharmaceutical companies on their right-to-health responsibilities. Third, in the same year he conducted a formal UN mission to GlaxoSmithKline (GSK), during which he gave particular attention to aspects of one crucial part of the company's portfolio: access to medicines, especially in relation to developing countries. His mission report was orally presented to the UN Human Rights Council in June 2009.[12]

The Special Rapporteur approached GSK with a view to undertaking a report because the company is regarded as one of the leading exponents of corporate social responsibility in the pharmaceutical sector. It was anticipated that a review of GSK's policies would be especially instructive, enabling the Special Rapporteur to identify good practices, as well as the obstacles facing such a company. After some months

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of research on GSK, the Special Rapporteur visited the company's headquarters in London on June 2 and 3, 2008, and also had numerous teleconferences with senior management officials based in Europe and the U.S., during June and July. The agenda of the visit to GSK's headquarters was prepared in cooperation with the company's management team. The Special Rapporteur discussed with, *inter alia*, Sir Christopher Gent, Chairman of GSK and its Corporate Responsibility Committee, Dr. Jean-Pierre Garnier, who was then stepping down as GSK's Chief Executive Officer, and five of the company's Vice Presidents. The Special Rapporteur also met with the UK Department for International Development (DFID), and he had the benefit of a half-day consultation on GSK with representatives of civil society organizations and academia working on access to medicines issues. Later, there were a number of bilateral consultations with civil society organizations and academics working in this field. While these consultations focused on the policies and practices of GSK, the Special Rapporteur's mission and report was also informed by the numerous, wide-ranging consultations he undertook between 2002-2008, including visits to clinics and hospitals in several developing countries.

The mission report is primarily based on the company's public, official policies and programs provided by staff members based at GSK's headquarters, as well as independent commentaries on those policies and programs. The Special Rapporteur neither visited GSK's country offices, nor checked the degree to which the company's policies and programs were implemented on the ground, nor scrutinized the role of GSK's subsidiaries. These are important limitations because headquarters may adopt more progressive positions than country offices are willing to implement, and some vital issues (e.g., on patents and court cases) may be decided locally. Nonetheless, a company's public, official policies and programs are important and demand scrutiny from the right-to-health perspective. A UN human rights "special procedure" had never before undertaken a formal review of, and mission to, a pharmaceutical company and so the report should be seen as one step in the long journey towards the sustained application of the right to health to the pharmaceutical sector.

The international human rights community has devoted considerable time and energy focusing on whether or not business enterprises are subject to legally binding human rights obligations.[13] This is a critically important discussion to which the Special Rapporteur on the right to health has contributed in relation to pharmaceutical companies.[14] Of course, these discussions must continue. In some quarters, however, a preoccupation with this issue has distracted from another very important question: whether legal, ethical or both, what are the practical, operational, detailed human rights responsibilities of business enterprises? This is one of the key questions that the Special Rapporteur's *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines,* and GSK report, were designed to address.

Following this Introduction, in Section 2 we consider the relationship between the *Guiding Principles on Business and Human Rights* and the *Human Rights Guidelines for Pharmaceutical Companies*. Section 3[15] outlines the right-to-health responsibilities of, first, all pharmaceutical companies and, second, patent-holding pharmaceutical companies, such as GSK; in this section, where appropriate, we will signal the relevant provisions in the *Human Rights Guidelines for Pharmaceutical Companies*. Section 4 discusses GSK and right-to-health accountability, and the chapter ends with some brief concluding remarks.

2. The Relationship between the Guiding Principles on Business and Human Rights and Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines

In 2008, John Ruggie, the UN Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises (hereinafter, the Special Representative)[16] observed:

> The root cause of the business and human rights predicament today lies in the governance gaps created by globalization — between the scope and impact of economic forces and actors, and the capacity of societies to manage their adverse consequences. These governance gaps provide the permissive environment for wrongful acts by companies of all kinds without adequate sanctioning or reparation. How to narrow and ultimately bridge the gaps in relation to human rights is our fundamental challenge.[17]

In this context, the Special Representative developed a policy framework for business and human rights — the Protect, Respect and Remedy Framework — comprising three core principles: the State duty to protect against corporate-related human rights abuse, the corporate responsibility to respect human rights, and access to effective remedy.[18] In 2011, the UN Human Rights Council unanimously endorsed the Special Representative's *Guiding Principles on Business and Human Rights: Implementing the United Nations*

"Protect, Respect and Remedy" Framework (hereinafter, the *Guiding Principles on Business and Human Rights*).[19]

Here we make a few remarks about the relationship between, on the one hand, John Ruggie's *Guiding Principles on Business and Human Rights* and, on the other hand, Paul Hunt's *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*.

The Special Representative's Protect, Respect and Remedy Framework affirms that the responsibility to respect is "the baseline expectation for all companies in all situations."[20] Moreover, it exists independently of States' duties.[21] According to the Special Representative, the corporate responsibility to respect is grounded in social expectations, or "a company's social licence to operate."[22] He suggests that the corporate responsibility to respect is not legally binding under international law, but subject to the possibility of binding obligations under domestic law.[23] He adds that the corporate responsibility to respect is recognized in "virtually every voluntary and soft-law instrument related to corporate responsibility."[24] The corporate responsibility to respect requires human rights "due diligence."[25] The Special Representative explains that "the scope of human rights-related due diligence is determined by the context in which a company is operating, its activities, and the relationship associated with those activities."[26] Crucially, the corporate responsibility to respect is "not merely a passive responsibility for firms but may entail positive steps."[27]

Ruggie's *Guiding Principles on Business and Human Rights* elaborate how the Protect, Respect and Remedy Framework applies to corporations and provide recommendations for the Framework's implementation.[28] The *Guiding Principles* clarify that the corporate responsibility to respect human rights "means that they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved."[29] In order to implement the responsibility to respect human rights, the *Guiding Principles* recommend that companies should express their commitment to meet this responsibility, carry out human rights due diligence, and put in place "processes to enable the remediation of any adverse human rights impacts they cause or to which they contribute."[30] Through the human rights due diligence process, companies should assess actual and potential human rights impacts,[31] integrate and act upon the findings,[32] track how their human rights impacts are addressed,[33] and communicate how these impacts are addressed.[34]

A key question is whether or not companies have additional responsibilities beyond the corporate responsibility to respect outlined in the Protect, Respect, and Remedy Framework. Crucially, Ruggie acknowledged that where companies perform certain public functions, "additional corporate responsibilities may arise as a result of the specific functions the company is performing."[35] He accepted that "it remains unclear what the full range of those responsibilities might be and how they relate to the State's ongoing obligation to ensure that the rights in question are not diminished."[36] The Institute for Human Rights and Business (hereinafter, IHRB), an international nongovernmental organization, in its submission to the Special Representative, noted the difficulty in defining the notion of "public functions" and suggested that "the scope of activities of a company and their effects" can be a more helpful criterion than "ownership or stated purpose — public or private."[37] Thus, the IHRB observed that:

> where there are circumstances under which a company's activities are tied closely with the fulfilment and realization of specific rights — for example, companies running healthcare facilities, food distribution, water provision, power generation or telecommunication providers — it seems reasonable, at a minimum, to consider further whether companies involved in these or other services have responsibilities beyond the scope of the corporate responsibility to respect human rights.[38]

The IHRB stressed a need for more collaborative work to "elaborate on corporate responsibilities in contexts where specific industries' core activities are critical to the realization of specific rights."[39] Also, the IHRB highlighted another area that requires further clarification: when a company is operating in an area where the State is unable to meet its human rights obligations due to, for instance, armed conflict or natural disasters or lack of capacity in situations of extreme poverty.[40] Furthermore, the IHRB observed that as "some problems go beyond national borders," developing governance mechanisms that are effective beyond borders "may require non-State actors' participation, with corresponding delineation of rights and responsibilities."[41]

In response, the Special Representative considered that in circumstances "such as natural disasters or public health emergencies, there may be compelling reasons for any social actor with capacity to contribute temporarily."[42] However, he suggests that "the proposition that corporate human rights responsibilities as a general rule should be determined by companies' capacity, whether absolute or relative to States,

is troubling" because he considers that "the proposition invites undesirable strategic gaming in any kind of country context."[43]

In order to disseminate and implement the *Guiding Principles on Business and Human Rights*, the Human Rights Council established a new expert Working Group on business and human rights and also decided to hold an annual multi-stakeholder forum under the guidance of the Working Group.[44] These new UN mechanisms provide an opportunity to enhance human rights accountabilities of companies, and to elaborate further the content of companies' human rights responsibilities, taking into account the diverse ways in which human rights are affected by the activities of companies.

In conclusion, the *Guiding Principles on Business and Human Rights* begin to articulate the baseline human rights expected of all companies. The Protect, Respect, and Remedy Framework confirms that corporate responsibility to respect human rights is "not merely a passive responsibility...but may entail positive steps,"[45] such as the introduction of anti-discriminatory policies, as well as staff training in human rights, equality and diversity. Moreover, while the *Guiding Principles* articulate the *baseline* human rights expected of all companies, where a company performs public functions, "additional corporate responsibilities may arise."[46] Sharing some common ground with Ruggie, IHRB also takes the view that companies have responsibilities beyond "the corporate responsibility to respect human rights."[47] In this article, we begin to explore some of the dimensions of these responsibilities.

Whereas the *Guiding Principles on Business and Human Rights* are general human rights standards applicable to all business entities, the *Guidelines for Pharmaceutical Companies* identify with a greater degree of operational specificity: the human rights responsibilities of one sector (pharmaceutical companies) in relation to one area of sectoral activity (access to medicines).

Moreover, taking into account the right-to-health framework, which is based on the dignity and well-being of individuals and communities, as well as globally recognized standards, the *Guidelines for Pharmaceutical Companies* encompass, but also look beyond, the corporate responsibility to respect. In our view, an examination of human rights responsibilities beyond the duty to respect is critically important because the pharmaceutical sector has highly distinctive functions directly impacting upon the life, health, and prosperity of countless individuals and communities.

3. The Right-to-Health Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines

This section begins to move beyond broad, generalized, aspirational human rights language, towards "more detailed guidance in specific functional areas."[48] Because access to medicines is a shared responsibility, whether or not a pharmaceutical company is able to fully discharge all its right-to-health responsibilities will sometimes depend upon States, donors, and others fulfilling their human rights responsibilities.

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According to the Special Representative, the corporate responsibility to respect human rights is based in "social expectations — as part of what is sometimes called a company's social licence to operate."[49] As we saw in the preceding section, while the Special Representative's focus is the "baseline" human rights responsibility of all companies, our focus is the right-to-health responsibilities of pharmaceutical companies. What are the "expectations" that society may legitimately have of a pharmaceutical company? What are the terms of a pharmaceutical company's "social licence to operate"? These are complex questions, not least because the pharmaceutical sector encompasses a range of diverse companies, including innovator, generic and biotechnology companies. For example, the "social expectations" of a company holding a patent on a life-saving medicine are different from those of a pharmaceutical company that does not hold such a patent (see below).

When approaching these important issues, it is logical to seek guidance from the right to health. Fundamentally, this human right is concerned with the dignity and well-being of individuals and communities. It is an integral part of the international bill of human rights. Every country in the world has affirmed, in one treaty or another, the right to health. Moreover, the UN Committee on Economic, Social and Cultural Rights and others have developed a framework for analyzing or "unpacking" the right to health with a view to making it easier to understand and apply. Crucially, by enhancing access to medicines, a company is making a major contribution to the realization of the right to health. For these reasons, when considering the "social expectations" and "social license to operate" of pharmaceutical companies, it is instructive to examine this compelling, fundamental human right.

The Right-to-Health Framework and All Pharmaceutical Companies

The UN Committee on Economic, Social and Cultural Rights (and others) developed the right-to-health framework as a tool to better grasp the duties of States.[50] Of course, the human rights responsibilities of pharmaceutical companies are not identical to the human rights duties of States, e.g., a State's human rights duty includes enacting appropriate legislation and, obviously, such a duty cannot fall upon private businesses. Nonetheless, the framework provides a useful tool for clarifying the right-to-health responsibilities of non-State entities. These responsibilities reflect society's "expectations" of pharmaceutical companies, and they should be read into the "social license to operate" of these companies. As already emphasized, many of these responsibilities are shared with States, donors, and others. Also, pharmaceutical companies have other responsibilities, e.g., to enhance shareholder value. Here, however, the focus is on the right-to-health responsibilities of pharmaceutical companies.[51] The following right-to-health responsibilities apply to any pharmaceutical company, whether it is an innovator, generic, or biotechnology company. The right-to-health responsibilities applicable particularly to patent-holding pharmaceutical companies are separately discussed below.

A human rights policy statement integrated throughout the company (guidelines 1-2, 14)

The right to health must be consistently integrated across all relevant policies, programs, and projects of a pharmaceutical company, including those relating to pricing, intellectual property, research and development, clinical trials, and marketing. An important pre-condition for such integration is the company's adoption of a human rights policy statement that expressly recognizes the importance of human rights generally, and the right to health, including access to medicines, in particular. Pharmaceutical companies should use impact assessments to help them ensure that their human rights policy is consistently integrated across all of the company's activities.[52] In this article, we outline some aspects of the right-to-health, and access to medicines, that companies have to take into account, and we also briefly signal how impact assessments may be used.

availability (guidelines 5, 23-25)

Pharmaceutical companies must do all they reasonably can to ensure that medicines are available in sufficient quantities in the countries where they are needed. For example, companies must not arbitrarily withhold supply of medicines over which they have a patent, or which they manufacture, from a particular country, region, or group of people. While this responsibility is discussed below in the particular context of patent holders, it must be emphasized that research and development in the pharmaceutical sector has inadequately addressed the priority health needs of developing countries, and all pharmaceutical companies have a responsibility to take reasonable measures to redress this historic imbalance. For example, they should either provide in-house research and development for neglected diseases, or support external research and development for such diseases. Sometimes known as "diseases of the developing world," neglected diseases are those that mainly afflict the poorest people in the poorest countries, such as lymphatic filariasis, sleeping sickness, and river blindness.[53]

accessibility (guidelines 5, 33-39)

In addition to being available, medicines must also be accessible. Accessibility has various dimensions; for example, medicines must be accessible in all parts of a country, including remote rural areas as well as urban centers. Of course, the responsibility to ensure access in all rural and urban areas does not fall exclusively on pharmaceutical companies, but they must do all they reasonably can. For example, pharmaceutical companies should ensure that medicines are packaged appropriately for different local climates.

Medicines must be affordable (i.e., financially accessible) to all, including those living in poverty. Medicines are often too expensive for poor communities in developing countries. In addition to the price charged by the manufacturer, other factors determining the final price paid by the patient include import tariffs, freight costs, VAT, and the mark-up added by wholesalers and retailers. While the State has a responsibil-

ity in relation to these other factors, pharmaceutical companies must ensure that their prices are affordable to as many individuals and communities as possible. In this regard, pharmaceutical companies must consider, among others, the introduction of a differential policy not only between countries, but also within the same country (e.g., market segmentation). Of course, a generic company also has a right-to-health responsibility to take all reasonable steps to make a medicine it is producing as widely accessible as possible.

Reliable information about medicines should be accessible. A pharmaceutical company should take effective measures to ensure that all statutory and other information bearing upon a medicine's safety and possible side effects is easily accessible so that individuals can make informed decisions about its possible use. (Also see the section "Transparency" in this article.)

ACCEPTABILITY (GUIDELINES 21-22)

As well as being available and accessible, medicines (and associated processes, e.g., clinical trials) must be respectful of medical ethics, culturally appropriate and sensitive to gender and life cycle issues. For example, pharmaceutical companies must ensure, where relevant, that medicines which they have developed are safe and appropriate for children and the elderly, and also ensure that clinical trials observe the highest ethical and human rights standards, including the requirements of informed consent.

QUALITY (GUIDELINE 20)

Pharmaceutical companies have a responsibility to ensure that their medicines are of good quality, safe and efficacious; for example, they must comply with national and global manufacturing standards, e.g., the current World Health Organisation Good Manufacturing Practice Guidelines.[54]

TRANSPARENCY (GUIDELINES 17-19)

Transparency is a cardinal human rights principle upon which several other human rights considerations, such as accountability, depend. In the right-to-health analysis, this principle is reflected in the requirement, already mentioned, that as much health-related information as possible should be accessible. For example, pharmaceutical companies and their subsidiaries should disclose all advocacy and lobbying positions, and related activities, at the regional, national, and international levels, that impact, or may impact, upon access to medicines. Advocacy bearing upon the public sphere must be disclosed in the public sphere. Pharmaceutical companies should also disclose the amount they spend on research and development, and research and development for neglected diseases. Of course, outputs (e.g., new medicines) are critically important, but levels of investment regarding neglected diseases are a useful indicator of corporate commitment. While there is a presumption in favor of the disclosure of information held by the company, this presumption may be rebutted on limited grounds, such as respect for the confidentiality of personal health data.

The principle of transparency not only requires that information be made publicly available, but also that the information be made available in a form that is accessible, manageable, and useful. In conjunction with other companies in the sector, a pharmaceutical company should agree to standard formats for the systematic disclosure of company information and data bearing upon access to medicines, thereby making it easier to evaluate the performance of one company against another, as well as the performance of the same company over time. This will enhance public accountability and investor confidence.

MONITORING AND ACCOUNTABILITY (GUIDELINES 9-14)

Human rights empower individuals and communities by granting them entitlements and placing obligations (or duties or responsibilities) on others. Crucially, rights and obligations demand accountability: unless supported by a system of accountability, they can become no more than window dressing. A right-

All too often, "accountability" is used to mean blame and punishment, but this narrow understanding of the term is much too limited. A right-to-health accountability mechanism establishes which health policies and practices are working and which are not, and why, with the objective of improving the realization of the right to health for all.

to-health approach emphasizes obligations and requires that all duty-holders be held to account for their conduct.[55]

All too often, "accountability" is used to mean blame and punishment, but this narrow understanding of the term is much too limited. A right-to-health accountability mechanism establishes which health policies and practices are working and which are not, and why, with the objective of improving the realization of the right to health for all. Accountability comes in many forms. In relation to a human right as complex as the right to health, a range of monitoring and accountability mechanisms are required, and the form and mix of devices will vary from one jurisdiction to another.

Although challenging issues remain, in recent years some pharmaceutical companies have made significant progress in relation to corporate social responsibility. However, there is a striking absence of accessible, effective, transparent, and independent accountability mechanisms in relation to their policies and corporate social responsibility. Some reporting initiatives are impressive such as GlaxoSmithKline's external assurance of the access to medicines chapter in its *Corporate Responsibility Report* (2007).[56] Nonetheless, the reporting of pharmaceutical companies on access to medicines is largely self-reporting, with limited exceptions such as the Access to Medicine Index.[57] While public candid self-reporting is welcome, it is no substitute for monitoring and accountability by an independent body.

An urgent need exists to devise appropriate monitoring and accountability mechanisms to monitor whether or not a pharmaceutical company is doing what it is required to do to ensure the right to health and access to medicines. Internal mechanisms are required, such as a governance system that includes direct board-level responsibility and accountability for the company's access to medicines policy. Also external (i.e., independent) mechanisms are needed, such as an Ombudsman with oversight of a company's human rights responsibilities, including those relating to access to medicines. The Ombudsman, or equivalent, may have oversight of all pharmaceutical companies, a group of companies, or an individual company. Of course, pharmaceutical companies are already subject to several forms of internal and external monitoring and accountability; however, these mechanisms rarely monitor and hold a company accountable for its human rights responsibilities to enhance access to medicines. Section 4 considers these issues in the context of GSK.

SUB-CONCLUSION

Many of the right-to-health responsibilities briefly considered here apply to all pharmaceutical companies, including innovator, generic, and biotechnology companies. For example, all pharmaceutical companies must be respectful of medical ethics; ensure their medicines are of good quality, safe, efficacious, and affordable to as many people as possible; disclose their advocacy and lobbying positions; establish internal and external right-to-health monitoring and accountability mechanisms; and so on. However, some right-to-health responsibilities only apply to some pharmaceutical companies. The next paragraphs briefly explore the particular responsibilities that apply to a company, like GSK, that holds a patent for a life-saving medicine.

The Right-to-Health Framework and Patent-Holding Pharmaceutical Companies (Guidelines 26-35)

A pharmaceutical company that develops a life-saving medicine has performed a vitally important medical, public health, and right-to-health function. By saving lives, reducing suffering, and improving public health, it has not only enhanced the quality of life of individuals, but also contributed to the prosperity of individuals, families, and communities. The company, and its employees, have made a major contribution to the realization of the rights to life and the highest attainable standard of health. The "reward" for fulfilling this critically important social function is the grant of a patent — a limited monopoly — over the relevant medicine, enabling the company to make a profit, enhance shareholder value, and invest in further research and development.

However, patent-holding companies can also negatively impact the affordability of patented medicines and thus hinder enjoyment of the rights to life and health.[58] Once a new medicine is patented, others are legally excluded from producing and selling the medicine in that jurisdiction, subject to some exceptions specified by law. Patent-holding pharmaceutical companies can charge higher prices than would otherwise be the case, because they are the only entity empowered to set the price for the patented medicine and to grant a voluntary license.[59]

Different commentators use different terms to describe the relationship between society and patent-holder. Some characterize the relationship as a "social contract."[60] Others, drawing upon the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, may regard the privileges and responsibilities arising from a patent as forming part of the patent holder's "social licence to operate."[61]

Some might describe the relationship as fiduciary, i.e., the company holds the patent — for a limited period — on trust for society. Whether characterized as contract, license, or trust, the company holds the patent on express and implied terms. 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. Due to 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.

Patent-holding pharmaceutical companies have a responsibility to ensure that their policies and practices do not negatively impact access to life-saving medicines. As discussed earlier, the UN Guiding Principles on Business and Human Rights require companies to "avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved."[62] According to the UN Guiding Principles, in order to meet this responsibility, companies should put in place policies and processes, including a policy commitment to meet their responsibility to respect human rights, a human rights due-diligence process, and a process to enable the "remediation" of any adverse human rights impacts they cause or to which they contribute. This responsibility applies to patent-holding pharmaceutical companies. Given their activities, the patent-holding pharmaceutical companies should pay particular attention to the affordability of their patented medicines in light of the rights to life and health.

Accordingly, patent-holding pharmaceutical companies should "assess the [potential and actual] impact of the company's strategies, policies, programs, projects and activities on access to medicines, especially for disadvantaged individuals, communities and populations" (Guideline 14(a)). When an impact assessment shows that a company's policies, such as on patenting, licensing and pricing, cause or contribute to an adverse impact on access to medicines or may do so, the company should take the necessary steps to avoid this impact. In order to prevent or address the potential and actual adverse impacts on access to affordable medicines, the company must use all the arrangements at its disposal, including non-exclusive commercial voluntary licenses, non-commercial voluntary licenses, donation programs, public-private partnerships, and so on.

Having developed a life-saving medicine, the company has an additional human rights responsibility to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need. Of course, the responsibility is shared with States and others. The company is not expected to make the medicine immediately accessible to all those in need; analogous to a State's responsibility of progressive realization, the company has to move expeditiously and effectively, by way of deliberate, concrete, and targeted measures, to make the medicine as accessible as possible. What is required of the company is subject to its capacity; analogous to a State's responsibility to take steps "to the maximum of its available resources," more is required of a powerful transnational company with global networks than of a smaller business. Given market realities, the company must be permitted to make a reasonable profit and enhance shareholder value; in other words, it must be allowed to operate a viable business model.

Crucially, the company may not market the medicine to social group A (i.e., wealthy urban elites), with little or no attempt to reach social groups B-E. The patent holder of a life-saving medicine has a human rights responsibility to take all reasonable steps to ensure that the medicine is accessible to all social groups. While it cannot be expected to make an overall loss, the company can sometimes be expected to operate, with respect to some of its activities, on a not-for-profit basis, such as in relation to social group E (i.e., the rural poor).[63] In such a case, the State may be required to provide a subsidy so that the company recovers its costs (e.g., freight and administrative charges) when making the medicine available to the rural poor on a not-for-profit basis. Donors may also be required to provide a subsidy, or other assistance, consistent with donors' human rights responsibilities of international assistance and cooperation in health.[64]

Pharmaceutical companies also have a responsibility to ensure that medicines are developed for children, the elderly, pregnant and lactating women, and for various climates so that the medicines are resistant to extremes of heat and humidity.

In summary, society has a legitimate expectation that the patent holder of a life-saving medicine will not only enjoy the privileges arising from the patent but also fulfill the corresponding responsibilities. The crucial right-to-health responsibility is to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need, within a viable business model. As soon as the new medicine is marketed at higher prices (usually in high-income countries), the patent holder has a right-to-health responsibility to put in place a range of mechanisms, such as differential pricing between and within countries, to enhance access for those who cannot

afford those prices. Also, the patent holder has a right-to-health responsibility to develop formulations for children, the elderly, pregnant and lactating women, and extremes of climate. For the duration of the patent, only the patent holder is authorized (with limited exceptions) to take these steps. Thus, the agreement between society and patent holder includes a responsibility on the patent holder to take these steps, expeditiously and effectively, by way of deliberate, concrete, and targeted measures. If the patent is worked without these steps being taken (i.e., without a range of mechanisms being put in place to enhance access, and without steps being taken to develop formulations for children, etc.), then the patent holder is in breach of its right-to-health responsibilities. Of course, the success of the patent holder's actions will sometimes depend upon States, donors, and others in the pharmaceutical sector fulfilling their responsibilities. Nonetheless, the patent holder has a right-to-health responsibility to do what it reasonably can.

Conclusion

Based on the dignity and well-being of individuals and communities, as well as globally recognized standards, the right-to-health framework helps to clarify what is socially expected of all pharmaceutical companies, including innovator, generic, and biotechnology companies. These paragraphs are not an exhaustive application of the framework to the pharmaceutical sector. Moreover, the elements of the framework that have been considered are only briefly discussed.

The present section has not tried to identify which are legal and which are ethical right-to-health responsibilities — that is a challenge for the future. Whether the responsibilities are legal, ethical, or both, all pharmaceutical companies have to make some critically important decisions. Have they done all they reasonably can to prevent or address the potential and actual negative impacts on access to affordable medicines in relation to those in need? Have they done all that is reasonably possible to enhance access by those in need? What is reasonable? Have they been as transparent as possible? Because of the importance and complexity of these and related questions, there must be internal and external monitoring and accountability mechanisms to provide guidance to the company and others. In the next section, by way of illustration, we briefly consider monitoring and accountability in relation to GSK and the right to the highest attainable standard of health.

4. GlaxoSmithKline and Right-to-Health Accountability

In this section, we draw from the Special Rapporteur's report on GSK.[65] As already discussed, accountability, which includes monitoring, review, and redress, is a vital feature of all human rights, including the right to health. In addition to national courts and tribunals (e.g., employment tribunals), GSK's existing internal and external (i.e., independent) accountability mechanisms include the following:

- Board of Directors and its Committees, e.g., the Corporate Responsibility Committee;
- GSK's publicly available reports, reviews, and quarterly results, including its annual *Corporate Responsibility Report*;
- Annual General Meeting;
- a company department that audits GSK's systems and processes, e.g., sales and marketing;
- internal whistle-blowing procedure;
- Integrity Helpline for "interested outside parties" who may wish to report alleged misconduct;
- independent ethical review committee on the company's clinical trials;
- PricewaterhouseCoopers' annual audits of GSK's financial statements.

Bureau Veritas, an independent third party, externally assured the information supplied in the access to medicines section of GSK's *Corporate Responsibility Report* (2007). While on mission to GSK, the Special Rapporteur was informed that Bureau Veritas asked GSK for clarification of some passages in the draft section and requested that textual changes be made. Also, they recommended that GSK "should provide greater detail on the governance, accountability and management structures for access to medicines and the relationship with external stakeholders."[66] GSK responded to these recommendations as part of its *Corporate Responsibility Report* (2008). Regrettably, GSK did not subject its 2008 *Report* to external assurance.

GSK has actively participated in independent evaluation exercises, such as *Investing for Life*, Oxfam's 2007 review of pharmaceutical companies' approach to access to medicines,[67] as well as the recent Access to Medicine Index. Launched by the Access to Medicine Foundation, the Index considers the efforts of the world's largest pharmaceutical companies, *inter alia*, to help solve the global medicines crisis. The Index scores companies according to their performance on a wide range of criteria. In the Index for 2008, and also 2010, GSK scored better than any other company.[68]

GSK's research and development strategy for diseases of the developing world was subject, in 2003,

to external review by an advisory board comprising public health and scientific experts from both developing and developed countries.[69] Although an important step in the right direction, this review did not include all those dimensions that are important from a right-to-health perspective. Moreover, it has not been repeated since 2003.

While the Special Rapporteur's GSK report does not closely examine all the accountability mechanisms mentioned above, it welcomes the external assurance of some passages in GSK's *Corporate Responsibility Report* (2007), urges all pharmaceutical companies to emulate this development as a matter of urgency, and greatly regrets GSK's failure to subject its recent *Corporate Responsibility Report* (2008) to external assurance.

The most striking feature of the accountability mechanisms briefly signalled in the preceding paragraphs is that they rarely, if ever, monitor and hold GSK accountable to its right-to-health responsibilities. None, for example, assesses how GSK is impacting on affordability of access to medicines for disadvantaged individuals and communities. While the external assurance of the *Corporate Responsibility Report* (2007) is commendable, it checked whether or not the information was accurate and sufficiently detailed, but it did not assess if GSK was fulfilling its right-to-health responsibilities.

Some of the accountability mechanisms mentioned in the preceding paragraphs are indispensable, such as those designed to ensure financial probity and shareholder confidence. But, they provide insufficient independent scrutiny of the critically important medical, public health and right-to-health functions of GSK. They do not independently assess, for example, whether or not GSK is fulfilling its responsibilities as a patent holder of life-saving medicines. Understandably, GSK robustly defends, in the courts and elsewhere, its privileges as a patent holder, but where are the independent mechanisms to check that it fulfills its corresponding responsibilities as the patent holder of life-saving medicines? To its credit, GSK is committed to upholding the Universal Declaration of Human Rights. In its human rights statement, it says: "As a marketer of pharmaceutical products with life saving and enhancing properties, we will strive to make them as widely available as possible while running our business in a sustainable way,"[70] but there are no independent mechanisms designed to monitor and hold GSK to account for this important medical, public health, and right-to-health commitment.

Whether its right-to-health responsibilities are legal, ethical, or both, GSK must strengthen its accountability in relation to access to medicines. GSK should consider, for example, appointing an independent Ombudsman with oversight of the company's right-to-health responsibilities relating to access to medicines. GSK should also work with like-minded companies to establish an independent mechanism to monitor and hold accountable the relevant companies regarding access to medicines and the right to health. In addition, GSK should consider working with an association of pharmaceutical companies with a view to establishing such a mechanism. As one step in the right direction, it may wish to establish an independent mechanism that focuses on one particular dimension of access to medicines and the right to health, such as disclosure of information. Critically, GSK needs an accountability mechanism that uses right-to-health standards and is independent, accessible, transparent, and effective.

Companies must grasp, and publicly recognize, their critically important social function and right-to-health responsibilities. They must prevent or address negative impacts of their pricing and licensing policies on access to medicines, and must demonstrably do everything possible, within a viable business model, to fulfill their social function and human rights responsibilities. Presently, this is *not* happening.

5. Conclusion

The Special Rapporteur's GSK report observes that a member of the senior management of an innovator pharmaceutical company recently remarked that the company's patents were "its crown jewels."[71] The image was revealing. In one sense, the image is legitimate — patents are immensely valuable. In another sense, the image reflects a profound misunderstanding of the role of a company that develops a life-saving medicine. As we have discussed, such a company has performed a critically important social, medical, public health, and right-to-health function. While the company's "reward" is the grant of a limited monopoly

over the medicine, enabling it to enhance shareholder value and invest in further research and development, the company also has a right-to-health responsibility to take all reasonable steps to make the life-saving medicine as accessible as possible, as soon as possible, to all those in need. For a limited period, the company holds the patent for society, but the patent must be worked, so far as possible, for the benefit of all those who need it.

The status of innovator companies would be immeasurably enhanced if they did not see, and treat, patents as their "crown jewels." Companies must grasp, and publicly recognize, their critically important social function and right-to-health responsibilities. They must prevent or address negative impacts of their pricing and licensing policies on access to medicines, and must demonstrably do everything possible, within a viable business model, to fulfill their social function and human rights responsibilities. Presently, this is *not* happening. If it were to happen, it would not only greatly enhance companies' reputation, but also pressurize States, generic manufacturers, and others to provide the environment that companies need if they are to enter into arrangements, such as voluntary licenses, that enhance access to medicines for all.

The GSK report was orally presented to the UN Human Rights Council in June 2009.[72] Informal attempts were made to ensure that GSK could orally respond to the report from the floor of the Council. Although GSK wished to speak, and a senior company representative was present, permission was not granted. This is highly regrettable and inconsistent with well-established principles of procedural fairness. However, the Council's Chairperson publicly referred to GSK's written response which was circulated in the Council.[73]

Briefly, GSK's statement "welcomes the constructive engagement" with the Special Rapporteur and signals some of its initiatives in relation to "developing country healthcare." The statement continues:

> 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 the human rights or other areas. Given the lack of legal obligation on companies relating to the right to health it is not clear to us how the Ombudsman recommended in the Report could operate.

Although predictable, these observations are misplaced because the report explicitly and tactically places on one side the complex and controversial issue of the legal status of a pharmaceutical company's right-to-health responsibilities. The statement concludes that GSK "will review the Report and its recommendations with interest."

In an editorial headed "Right-to-health responsibilities of pharmaceutical companies," *The Lancet* congratulates GSK "for subjecting themselves to the process" but disagrees with some elements of the company's written statement.[74] According to the editorial, the UN report sets out "with reasonable precision how the right to health, in the international code of human rights, applies to the pharmaceutical industry." It continues: "Pharmaceutical companies help deliver the right to health. They save lives. But with this role come responsibilities — and companies must be better held to account in relation to those responsibilities. The 2008 guidelines and the GSK report move us closer to that goal."

The GSK report generated interest among Council members. For example, the United Kingdom made a statement to the Council thanking the Special Rapporteur for the report and commending GSK for their "full engagement" with the process.[75] The statement continues: "While States bear responsibility for ensuring that human rights are protected within their jurisdiction, businesses should also ensure that they conduct their activities in a manner that is consistent with enjoyment of human rights. The Special Rapporteur rightly notes that progressively achieving access to medicines for all who need them is an objective to which both state and non-state actors can and should contribute." And the statement closes: "We agree that pharmaceutical companies should support objective reporting on their access to medicines commitments. We encourage them to develop approaches, such as external validation, to support this."

The U.K. Government was right to highlight the importance of accountability, or "external validation." In our view, it is crucial to devise appropriate mechanisms to monitor pharmaceutical companies and hold them publicly accountable for their human rights responsibilities.[76] The recently established UN expert body on business and human rights[77] may provide a forum for tackling this challenge. The revised OECD Guidelines of 2011 have incorporated the *Human Rights Guiding Principles for Business and Human Rights*,[78] and thus, the OECD implementation procedures may offer fresh possibilities. The new accountability arrangements, recently established by the UN Commission on Information and Accountability for Women's and Children's Health, are notable because

they include independent review of the commitments of state and non-state actors, including pharmaceutical companies, in relation to reproductive, maternal, new-born and child health.[79] In response to the Commission's recommendations, the UN Secretary-General has established an independent Expert Review Group to hold all stakeholders accountable.[80]

In the absence of effective, legal enforcement mechanisms, there is no alternative but to establish, and creatively use, other arrangements,[81] as illustrated above, to hold pharmaceutical companies accountable. As we have endeavored to show, the relevant human rights norms are crystallizing. Now we need independent, accessible, transparent, and effective accountability mechanisms.

References

1. The right's full formulation is "the right of everyone to the highest attainable standard of physical and mental health," from article 12, International Covenant on Economic, Social and Cultural Rights. As shorthand, we adopt either "the right to the highest attainable standard of health" or "the right to health."
2. For an introduction to the growing literature, see A. Clapham and M. Robinson, *Realising the Right to Health* (Geneva: Swiss Human Rights Book Series, Ruffer & Rub, 2008).
3. Department for International Development (U.K.), *Increasing Access to Essential Medicines in the Developing World: U.K. Government Policy and Plans*, June 2004, at 8.
4. See the Special Rapporteur on the Right to the Highest Attainable Standard of Health, UN Doc. A/61/338, September 13, 2006.
5. Unless otherwise indicated, references in this chapter to the UN Special Rapporteur on the right to the highest attainable standard of health are to Paul Hunt, the first person appointed to this mandate. One of the authors of this article, he held the post between 2002-2008.
6. For example, see the Special Rapporteur on the Right to the Highest Attainable Standard of Health, *supra* note 4 (human right to medicines); UN Doc. E/CN.4/2006/48/Add.2 (Uganda), January 19, 2006; E/CN.4/2005/51/Add.3 (Peru), February 4, 2005; and E/CN.4/2004/49/Add.1 (World Trade Organization), March 1, 2004.
7. UN Millennium Development Goals, Target 8(e).
8. Committee on Economic, Social and Cultural Rights, General Comment 14: The Right to the Highest Attainable Standard of Physical and Mental Health, UN Doc. E/C.12/2000/4, at para. 42.
9. Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, John Ruggie, "Protect, Respect and Remedy: A Framework for Business and Human Rights," A/HRC/8/5, April 7, 2008, at para. 60.
10. See *supra* note 4.
11. Special Rapporteur on the Right to the Highest Attainable Standard of Health, UN Doc. A/63/263, August 11, 2008; and R. Khosla and P. Hunt, *Guidelines for Pharmaceutical Companies in Relation to Access to Medicines: The Sexual and Reproductive Rights Context* (Colchester: University of Essex, 2009).
12. Special Rapporteur on the Right to the Highest Attainable Standard of Health, Mission to GlaxoSmithKlein, UN Doc. A/HRC/11/12/Add.2, May 5, 2009.
13. For a review of these debates and initiatives, see A. Clapham, *Human Rights Obligations of Non-State Actors* (New York: Oxford University Press, 2006).
14. See *supra* note 4, at paras 92-93.
15. Sections 3 and 4 have extensively drawn upon P. Hunt and R. Khosla, "Holding Pharmaceutical Companies to Account: A UN Special Rapporteur's Mission to GlaxoSmithKline," in G. Gilbert et al., eds., *The Delivery of Human Rights* (Oxon and New York: Routledge, 2011): at 39-67; and P. Hunt and R. Khosla, "Human Rights Responsibilities of Pharmaceutical Companies in relation to Access to Medicines," in L. Forman et al., eds., *Access to Medicines as a Human Right: What Implications for the Pharmaceutical Industry* (Toronto: University of Toronto Press, 2012): at 25-45.
16. The mandate of the Special Representative was created by the UN Commission on Human Rights in its resolution 2005/69 (April 20, 2005) and John Ruggie served the mandate from July 2005 to June 2011.
17. See *supra* note 9, at para. 3.
18. See *supra* note 9.
19. Human Rights Council Resolution 17/4, "Human Rights and Transnational Corporations and Other Business Enterprises," UN Doc. A/HRC/RES/17/4, June 16, 2011; The Guiding Principles on Business and Human Rights are annexed to the Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie, UN Doc. A/HRC/17/31, March 21, 2011.
20. See *supra* note 9, at para. 24.
21. *Id*., at para. 55.
22. *Id*., at para. 54.
23. *Id*.
24. Report of the Special Representative, "Business and Human Rights: Further Steps toward the Operationalization of the 'Protect, Respect and Remedy' Framework," UN Doc. A/HRC/14/27, April 9, 2010, at para. 55.
25. See *supra* note 9, at para. 25.
26. *Id*., at para. 24.
27. See *supra* note 9, at para. 55.
28. See Human Rights Council, Resolution 8/7, Mandate of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, adopted without a vote on June 18, 2008.
29. See the Guiding Principles, *supra* note 19, at para. 11.
30. *Id*., at para. 15.
31. *Id*., at para. 18.
32. *Id*., at para. 19.
33. *Id*., at para. 20.
34. *Id*., at para. 21.
35. Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, Business and human rights: Towards operationalizing the "protect, respect and remedy" framework, UN Doc. A/HRC/11/13, April 22, 2009, at para. 64.
36. *Id*., at para. 64.
37. Institute for Human Rights and Business, *Setting Boundaries: Clarifying the Scope and Content of the Corporate Responsibility to Respect Human Rights*, Submission to the UN Special Representative on Business and Human Rights, *available at* <http://www.ihrb.org/pdf/Setting_Boundaries-Clarifying_Scope_and_Content_of_Corporate_Responsibility_to_Respect_Human_Rights.pdf> (last visited May 16, 2012).
38. *Id*., at 5.
39. *Id*., at 9.
40. *Id*., at 5, 6, 9.
41. *Id*., at 8.
42. See *supra* note 24, at para. 63.
43. *Id*., at para. 64.
44. See Human Rights Council Resolution 17/4, *supra* note 19. For the work of the working group on Human Rights and Business, see <http://www.ohchr.org/EN/Issues/Business/Pages/WGHRandtransnationalcorporationsandotherbusiness.aspx> (last visited May 16, 2012).

45. See *supra* note 9, at para. 55.
46. See *supra* note 35.
47. See *supra* note 37, at 5.
48. See *supra* note 9, at para. 60.
49. *Id*., at para. 54.
50. See *supra* note 8; numerous reports of the Special Rapporteur on the right to the highest attainable standard of health have sought to apply the right-to-health analytical framework to specific health issues (e.g., E/CN.4/2005/51 on mental disability) and countries (e.g., A/HRC/4/28/Add.2 on Sweden).
51. Pharmaceutical companies have responsibilities arising from other human rights, such as the labour rights of their employees, but this article focuses on pharmaceutical companies' right to health responsibilities.
52. See *supra* note 9, at paras. 60-62.
53. See Special Rapporteur on the Right to the Highest Attainable Standard of Health, Mission to Uganda, UN Doc. E/CN.4/2006/48/Add.2, January 19, 2006; P. Hunt, R. Steward, J. Mesquita, and L. Oldring, *Neglected Diseases: A Human Rights Analysis*, WHO-TDR Special Topic 6, 2006; and D. H. Molyneux, "Neglected Tropical Diseases – Beyond the Tipping Point?" *The Lancet* 375, no. 9708 (January 2, 2010): 3-4, at 3.
54. WHO, *Good Manufacturing Practices for Pharmaceutical Products: Main Principles*, WHO Technical Report Series, No. 961, 2011.
55. See H. Potts, *Accountability and the Right to the Highest Attainable Standard of Health* (Colchester: University of Essex, 2008); generally, *Health and Human Rights Journal* 10, no. 2 (2008), with particular reference to A. E. Yamin, "Beyond Compassion: The Central Role of Accountability in Applying a Human Rights Framework to Health," at 1-20 and L. Freedman, "Human Rights, Constructive Accountability and Maternal Mortality in the Dominican Republic: A Commentary," *International Journal of Gynaecology and Obstetrics* 82, no. 1 (2003): 111-114.
56. GSK, *Corporate Responsibility Report*, 2007, especially chapter 5.
57. See Access to Medicine Index, *available at* <http://www.accesstomedicineindex.org/> (last visited May 16, 2012).
58. UN High Commissioner for Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, UN Doc. E/CN.4/Sub.2/2001/13, June 27, 2001, at paras. 42-43; The Special Rapporteur on the Right to the Highest Attainable Standard of Health, *Mission to the World Trade Organization*, UN Doc. E/CN.4/2004/49/Add.1, 1 March 2004, at para. 43; and The Special Rapporteur on the Right to the Highest Attainable Standard of Health, *Access to Medicines and Intellectual Property Rights*, UN Doc. A/HRC/11/12, March 31, 2009, at para. 19.
59. WHO Commission on Intellectual Property Rights, *Innovation and Public Health, Public Health, Innovation and Intellectual Property*, Geneva, 2006, at 20; and Commission on Intellectual Property (UK), Integrating Intellectual Property Rights and Development, London, 2002, at 34.
60. Pharmaceutical Shareowners Group, The Public Health Crisis in Emerging Markets, London, 2004.
61. See *supra* note 9, at para. 54.
62. See the Guiding Principles, *supra* note 19, at para. 11.
63. There are ways of ensuring that only social group E accesses these not-for-profit medicines, e.g., by only making these medicines available via designated health clinics in the public health system unfrequented by social group A.
64. Special Rapporteur on the Right to the Highest Attainable Standard of Health, "Mission to the World Bank, the International Monetary Fund, and Uganda," UN Doc. A/HRC/7/11/Add.2, March 5, 2008, J. Mesquita and P. Hunt, *International Assistance and Cooperation in Sexual and Reproductive Health: A Human Rights Responsibility for Donors* (Colchester: University of Essex, 2008); and J. Mesquita, P. Hunt, and R. Khosla, "The Human Rights Responsibility of International Assistance and Cooperation in Health," in M. Gibney and S. Skogly, eds., *Universal Human Rights and Extraterritorial Obligations* (Philadelphia: University of Pennsylvania Press, 2010): 104-129.
65. See *supra* note 12; and P. Hunt and R. Khosla, "Holding Pharmaceutical Companies to Account: a UN Special Rapporteur's Mission to GlaxoSmithKline," in G. Gilbert et al., eds., *The Delivery of Human Rights* (Oxon and New York: Routledge, 2011): at 39-67.
66. See *supra* note 56, at 49-50.
67. Oxfam International, *Investing for Life: Meeting Poor People's Needs for Access to Medicines through Responsible Business Practices*, Oxford, 2007.
68. Innovest Strategic Value Advisors, *Access to Medicine Index 2008* (Haarlem: Access to Medicine Foundation, 2008); and RiskMetrics Group, *Access to Medicine Index 2010* (Haarlem, The Netherlands: Access to Medicine Foundation, 2010).
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72. Anand Grover orally presented the report following his appointment as Special Rapporteur in August 2008. In accordance with protocol, Paul Hunt stepped down as Rapporter on completion of his second three-year term in July 2008.
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74. The Lancet, "Editorial: Right-to-Health Responsibilities of Pharmaceutical Companies," *The Lancet* 373, no. 9680 (June 13, 2009): at 1998.
75. On file with authors.
76. See Special Rapporteur, *supra* note 11, at 18-19; see *supra* note 12, at paras. 30-33.
77. See Human Rights Council Resolution 17/4, *supra* note 19.
78. See <http://www.oecd.org/document/28/0,3746,en_2649_34889_2397532_1_1_1_1,00.html> (last visited May 16, 2012).
79. Commission on Information and Accountability for Women's and Children's Health, *Keeping Promises, Measuring Results*, WHO, Geneva, 2011, at 9, *available at* <http://www.everywomaneverychild.org/images/content/files/accountability_commission/final_report/Final_EN_Web.pdf> (last visited May 16, 2012).
80. See Every Woman, Every Child, *available at* <http://www.everywomaneverychild.org/resources/independent-expert-review-group> (last visited May 16, 2012).
81. See, for "non-legal" enforcement means, A. Reinisch, "The Changing International Legal Framework," in P. Alston ed., *Non-State Actors and Human Rights* (Oxford: Oxford University Press, 2005): 37-89, at 68.