Current Debates on Realizing Health and Human Rights:

An Annotated Bibliography on the Human Rights Roles and Responsibilities of the Pharmaceutical Industry
THE PROGRAM ON INTERNATIONAL HEALTH AND HUMAN RIGHTS

The Program on International Health and Human Rights (PIHHR) at the Harvard School of Public Health is at the forefront of expanding research in the field of health and human rights, and is a leader in developing health and human rights tools for analysis, programmatic intervention, monitoring and evaluation. PIHHR works to strengthen the practical implementation of human rights for public health programming in a variety of ways – from the design and application of specific analytic and programmatic tools to conducting trainings in various areas of health and human rights. The Program works closely with international agencies, governments and non-governmental organizations to assist in policy development and programming initiatives.

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PURPOSE OF THE BIBLIOGRAPHY

This annotated bibliography reviews relevant legal, public health, medical, and social science peer-reviewed literature to shed light on what are understood to be the human rights roles and responsibilities of the pharmaceutical industry and other non-state actors.

The ultimate goal of the review is to contextualize and provide an overview of the principal debates and discussions surrounding the roles and responsibilities of the pharmaceutical industry in the context of health-related human rights. During the conceptualization of this project, it was determined that this review would focus on issues outside the realm of intellectual property and human rights given the plethora of work that already exists in this area. Abstracts of articles are included as they appear in the literature and are followed by relevant annotations.

LITERATURE REVIEW METHODOLOGY

Articles relating to corporate responsibility, human rights obligations of non-state actors (particularly transnational corporations and the pharmaceutical industry), the right to health, and essential medicines were culled from databases specializing in the social sciences, law, and medicine. These included: Social Citations Index, JSTOR, PubMed, Westlaw, Sociological Abstracts, and Article First. As the principles of ‘Availability’, ‘Accessibility’, ‘Acceptability’ and ‘Quality’ outlined in General Comment 14 on the Right to the Highest Attainable Standard of Health (jointly referred to as the 3AQ) form the key conceptual framework for this project, and the provision of ‘essential medicines’ is a right to health standard, these words formed the basis of the original search terms. However, initial searches revealed that these words singly or in combination did not sufficiently bring to light the expected range of issues of concern. In the end, the following search terms were used in multiple combinations: “pharmaceutical,” “human rights,” “UN Global Compact,” “public private partnership,” “justice,” “equity,” “non-state actor,” “corporate responsibility,” ”social responsibility,” “right to health,” “essential medicines,” “drug,” “multinational corporations,” “access,” “affordability,” “acceptability,” and “quality.” (see footnote #3 for a more detailed definition of the 3AQ).

Several search terms deserve a word of explanation. The search term

1 This project’s objectives as outlined in the original proposal are to: 1) identify issues relevant to the potential roles and responsibilities of the pharmaceutical industry with regard to human rights in order to focus and stimulate discussion among experts in the field and to catalyze thinking; and 2) utilize a conceptual framework that includes the key concepts of the 3AQ (Availability, Accessibility, Acceptability, Quality), framing them broadly in discussions on human rights, models for collaboration, lessons learned and ways forward.
“affordability” was used because it is a sub-component of accessibility as defined in General Comment 14, and appears to be more commonly used in the literature. As the project focuses on intersections between the pharmaceutical sector and human rights, databases were also searched for articles analyzing the UN Global Compact – a well-established initiative exploring the confluence of corporate conduct and human rights – and corporate social responsibility frameworks. Public-private partnerships were examined as they have become increasingly common and it was thought they could highlight different and relevant human rights issues.

From the search results, articles relevant to the project goal of clarifying the roles and responsibilities of the pharmaceutical industry in the context of health-related human rights were selected based on title and abstract content. Articles were eliminated if the abstract clearly did not relate to the objectives of this bibliography, such as articles on illicit drugs. Articles without abstracts were also included. This first round of searches identified a total of 111 articles of potential interest.

These articles were then reviewed in more detail. Only those articles published between 1993 and 2008 were included. The year 1993 was used as a cut-off because of the project’s interest in recent discourse, which was defined as the last fifteen years. Further, due to limitations in access only articles written in English were selected. Articles whose focus was not relevant to the scope of the project, including those dealing primarily with intellectual property issues, were removed. Forty articles in total were excluded as they focused on: intellectual property (11); litigation (2); genetic research (5); clinical trials (6); the US legal system (5); and other topics considered to fall outside the specific aims of this project (11). Four articles were not available in English, three were not available at all, and two were published prior to the 1993 cutoff date. These were all removed from the review. Four additional articles were removed because they were editorials or transcripts of speeches and thus not peer-reviewed.

Based on title and abstract content, the 58 remaining articles were grouped according to topics determined to constitute distinct focus areas in the literature, and to be useful groupings for further analysis and discussion. These include: Corporate Social Responsibility and Human Rights (12); UN Global Compact (7); Essential Medicines (10); Public-Private Partnerships (12); Accessibility of Drugs and/or Services (6); Affordability of Drugs and/or Services (7); and Quality of Drugs and/or Services (4).
ANALYTICAL FRAMEWORK USED FOR ANNOTATIONS

First, articles were analyzed for whether and how they addressed the right to health and other health-related human rights (e.g., the right to education). The ways in which articles examined human rights-related norms and standards were also considered in this analysis, primarily with respect to how the elements of availability, accessibility, acceptability and quality (the “3AQ”) were discussed.2 These elements help to define and delineate the approach to services and

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2 The 3AQ are normative components of the right to health and are defined below:
(a) Availability. Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party. The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party’s developmental level. They will include, however, the underlying determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical and professional personnel receiving domestically competitive salaries, and essential drugs, as defined by the WHO Action Programme on Essential Drugs.

(b) Accessibility. Health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State party. Accessibility has four overlapping dimensions: Non-discrimination: health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any of the prohibited grounds. Physical accessibility: health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS. Accessibility also implies that medical services and underlying determinants of health, such as safe and potable water and adequate sanitation facilities, are within safe physical reach, including in rural areas. Accessibility further includes adequate access to buildings for persons with disabilities. Economic accessibility (affordability): health facilities, goods and services must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households. Information accessibility: accessibility includes the right to seek, receive and impart information and ideas concerning health issues. However, accessibility of information should not impair the right to have personal health data treated with confidentiality.

(c) Acceptability. All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned.

(d) Quality. As well as being culturally acceptable, health facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation.

goods as articulated under the right to health. Throughout this examination the distinction between explicit and implicit analyses of rights norms and standards was highlighted. Explicit analyses are those that refer directly to human rights, while implicit analyses are those that address health-related rights issues without making explicit reference to human rights norms and standards. Arguments used to elucidate the specific responsibilities of both state and non-state actors to address human rights norms and standards were specifically highlighted in the annotations.

Second, analyses were carried out to highlight the interactions between state and non-state actors and between the pharmaceutical industry and governments in particular, in the context of health-related human rights. Interactions between state and non-state actors, in particular in relation to both legal and operational levels, were noted. The legal level comprises the relationships between state and non-state actors as shaped by international human rights law and other international commitments with human rights content. The operational level is used here to refer to practical initiatives undertaken by states and pharmaceutical companies with implications for advancing health and health-related human rights, such as public-private partnerships to provide free medicines. The relationships between pharmaceutical companies and NGOs in the context of such operational initiatives were also examined.

Third, a distinction was made between articles that analyze the specific roles and responsibilities of the pharmaceutical industry, and articles that deal with multinational corporations (MNCs) and non-state actors more broadly. For example, many analyses of corporate social responsibility (CSR) refer to MNCs more broadly and are applicable beyond the pharmaceutical industry. The annotations make it clear when this is the case.

Taken together, these three focus areas provide a useful overview of current understanding of the human rights roles and responsibilities of the pharmaceutical industry as they relate to states and other non-state actors. An assessment of the explicit or implicit reference to human rights, norms, and standards reveals the extent to which the selected literature addresses human rights directly, the responsibilities of state and non-state actors in this context, and how under-explored topics regarding pharmaceuticals and the pharmaceutical industry may relate to the right to health and other human rights. This analysis of the relationships between state and non-state actors is needed to clarify how their interactions are shaped both by legal instruments and by the practical realities of operating on the ground, and to identify potential entry points for collaboration promoting the right to health and related norms and standards.
ORGANIZATION OF THE BIBLIOGRAPHY

The bibliography is organized into the following sections based on the topic areas of each group of articles: Corporate Social Responsibility and Human Rights; the UN Global Compact; Essential Medicines; Accessibility of Drugs and/or Services; Affordability of Drugs and/or Services; and Quality of Drugs and/or Services.

Each annotation is presented with the following information: article name, citation, abstract, and annotation. Based on the focus areas noted above, the annotation is divided into 3 parts: Human Rights Norms and Standards; Interactions Between State and Non-State Actors; and Distinctions Between Pharmaceutical Companies and other MNCs. Where abstracts were unavailable, the introduction or published summary of the article is used instead. These are clearly demarcated in the bibliography as necessary. The bibliography also signals where no abstract or equivalent was available.
SUMMARY OF FINDINGS

Introduction

This summary of findings is based on the cross-cutting themes emerging from the reviewed articles. An examination of the articles included in this bibliography leads to several conclusions, which are organized into five sections according to the following themes:

2. Voluntary Self-Regulatory Regimes;
3. Integrating Human Rights into Voluntary Self-Regulatory Regimes: Why and How;
4. National Drug Programs and Public-Private Partnerships: Opportunities for Promoting Human Rights; and

A summary of findings relevant to each theme is presented below. At the end of each section, a bulleted summary of emerging key issues and entry points for future research and analysis emerging from the literature is presented.

In the context of access to medicines and the right to health, the articles address and distinguish between state obligations and the responsibilities of non-state actors. Moreover, the articles address the theoretical aspects of voluntary self-regulatory regimes while simultaneously revealing potential entry points for integrating human rights norms and standards into such regimes. Another major theme emerging from the bibliography is the significance of national drug programs and public-private partnerships for advancing the availability of and access to medicines while implicitly promoting the right to health. Finally, the articles draw attention to government initiatives aimed at realizing their right to health obligations by improving access to and quality of essential medicines and in doing so highlight entry points where the pharmaceutical industry can provide support. Taken together, these cross-cutting themes provide a summary of the ways in which the reviewed articles address the human rights roles and responsibilities of the pharmaceutical industry, and lend themselves to further analysis and discussion.

The articles that address access to medicines clarify the various obligations of states to provide essential medicines (EM) under the right to health and the fact that this duty has been reaffirmed by courts at national and international levels. However, all are clear that the reality of gross disparities in access to EM persists nonetheless.³

As recognized in international documents, states have the obligation to respect, protect, and fulfill rights, including the right to health, provided the state has ratified the international treaties that lay out those rights. In relation to access to medicines, this has been understood to mean that states must not block access or impose discriminatory criteria that would discourage the supplies of drugs coming into their borders. States must also take positive steps to fulfill their obligations relating to accessibility under the right to health. Obligations that authors note as taking immediate effect under the International Covenant on Economic, Social and Cultural Rights (ICESCR) include prohibiting discrimination in access and cooperating at the international level to realize the right.⁴ With the obligation to protect the right to health, states also have to prevent infringement of the right by third parties by ensuring, for example, that drugs are safe and of a high quality.⁵

The state obligation to promote and protect the right to health, i.e., to take affirmative steps towards the realization of this right and to prevent rights violations committed by non-state actors in its jurisdiction, has had a particular influence on the relationship between governments and the pharmaceutical industry. First, this obligation means that states must support third parties in their actions to realize the right to health. Second, it means that non-state actors including the private sector cannot be permitted to violate rights. Third, this obligation almost inevitably requires states to regulate the actions of pharmaceuticals and other non-state actors in order to ensure that their actions do not prevent access to EM. Examples of such regulations undertaken by governments include anti-competition legislation that promotes the use of generic drugs and the reduction of taxes imposed on generics.⁶

With regard to EM, and according to the right to health, states have the obligation to ensure that EM are available, accessible, acceptable, and of quality. It has also been argued that, under the right to health obligation to provide access to EM, states are required to develop Essential Medicines Lists (EMLs) whereby they can use the WHO Model List as guidance.\(^7\)

Overall, as noted in the literature reviewed, human rights obligations are borne solely by states and not by non-state actors.\(^8\) Nevertheless, non-state actors including pharmaceutical companies are understood to hold responsibilities regarding the realization of the right to health and related rights. In this respect, as stated in the literature, human rights bodies have emphasized the responsibilities not only of state and non-state actors, but of inter-governmental organizations like the World Bank and the IMF to modify their lending policies and programs so that they are more favorable to realization of the right to health.\(^9\) The Committee on Economic, Social, and Cultural Rights (CESCR)\(^10\) has specifically noted the responsibilities of the private business sector and other non-state actors in the realization of the right to health, and has declared that states should provide an environment conducive to meeting these responsibilities. One article emphasized the importance of clarifying the content and scope of non-state actors’ responsibilities in the context of the right to health and the state obligation to provide EM, including the pharmaceutical industry.\(^11\) This distinction between responsibilities and legally-binding obligations is important and requires further exploration and clarification.


\(^10\) The Committee on Economic, Social and Cultural Rights (CESCR) is the body of independent experts that monitors implementation of the International Covenant on Economic, Social and Cultural Rights by its States parties. All States parties are obliged to submit regular reports to the Committee on how the rights are being implemented. The Committee examines each report and addresses its concerns and recommendations to the State party in the form of “concluding observations.” The Committee also publishes its interpretation of the provisions of the Covenant, known as general comments. Source: Office of the United Nations High Commissioner for Human Rights. http://www2.ohchr.org/english/bodies/cescr/ (Accessed: 2 June 2008).

In exploring the underlying thinking attributing responsibilities to the pharmaceutical industry under the right to health, the articles highlight the industry’s critical role in ensuring access to medicines because of its technical capacity, resources, and sphere of influence. An underlying assumption appears to be that pharmaceutical companies have a moral duty to help ensure access to the medicines and technologies they produce and to share their advances with the public because they are partly financed by states, and because they have themselves acknowledged their responsibilities to society at large. Moreover, while pharmaceutical companies have intellectual property rights, these must in some way be reconciled with their right to health responsibilities, and their general commitment to social good. While extensively stated in general terms, at this point in time the literature remains unclear about what these specific responsibilities amount to in practice, both for pharmaceutical companies specifically and for non-state actors more broadly.

Overall, with regard to the Right to Health and Access to Medicines, the literature reviewed raises the following key issues and entry points for further exploration:

- Under the right to health, states have a legal obligation to ensure that essential medicines (EM) are available, accessible, acceptable, and of quality, and are thought to do so in part by developing an Essential Medicines Lists (EMLs).
- A state has a legal duty to prevent rights violations committed by non-state actors in its jurisdiction, which is thought to almost certainly require regulating the activities of the pharmaceutical industry and other non-states actors to ensure that they do not restrict access to EM.
- Legally binding human rights obligations apply solely to state actors, whereas non-state actors, including the pharmaceutical industry, are seen to hold human rights responsibilities.
- The distinction between human rights responsibilities and legally-binding obligations requires further analysis and clarification, particularly in the context of the pharmaceutical industry and health-related human rights.

2. Voluntary Self-Regulatory Regimes

One approach to clarifying the right to health responsibilities of the pharmaceutical industry has been to examine the content and processes of their voluntary commitments to human rights and social responsibility. A number of the articles reviewed analyzed the human rights and legal dimensions of voluntary self-regulatory regimes adopted by businesses. These regimes include

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corporate social responsibility (CSR) frameworks as well as international non-binding commitments such as the UN Global Compact (UNGC).

CSR centers on the idea that a corporation may be held socially and ethically accountable to a wide range of stakeholders such as customers, employees, governments, communities, NGOs, media, investors, unions, and supply chain constituents. CSR frameworks are those adopted voluntarily by companies and often encompass dimensions of business ethics including philanthropy, community, workplace diversity, human rights, and the environment.\textsuperscript{13} The UNGC, originally proposed by former UN Secretary General Kofi Annan, asks businesses to voluntarily sign on and adopt ten core principles which are divided into four categories dealing with human rights, labor standards, the environment, and anti-corruption.\textsuperscript{14}

Overall, the literature reviewed was fairly critical of voluntary self-regulatory regimes because of their vague human rights commitments, limited transparency about industry adherence, and a lack of independent evaluations of industry compliance.\textsuperscript{15} Moreover, a number of reviewed CSR initiatives were found to operate more like charitable programs rather than efforts to actually identify and address human rights and corporate activity.\textsuperscript{16} A major critique of CSR frameworks was that they embraced rights in their discourse but were very limited in promoting equality and empowerment in practice.\textsuperscript{17} Because of these limitations, several articles noted the importance of external regulations that would bind non-state actors to certain standards, including human rights


standards. By contrast, others argue that an international legally binding approach may be unfeasible and would have a limited impact because of several factors: treaties addressing corporate conduct may have low rates of ratification by both state and non-state actors; states have differing views on the desirability of an international convention open for ratification by MNCs; and resistance exists to increasing the binding laws and regulations that already target both states and MNCs.\(^{18}\)

As such, some argue that states should create incentives to encourage corporations to adopt self-regulatory frameworks, e.g. by having more lenient penalties on companies with codes of conduct or linking the existence of such codes to government financing of MNCs. States may also promote the transparency of self-regulatory codes through truth in advertising legislation, for example, in order to limit companies from misinforming the public about their conduct and commitment to social good.\(^{19}\)

**The UN Global Compact (UNGC)**

A number of the articles reviewed deal with the human rights dimensions of the UNGC and its potential impact on corporate conduct. The articles are mixed in their analyses of the UNGC. There is general agreement that the UNGC is non-binding, yet some authors argue that the Compact is insufficient as a mechanism for regulating or supporting corporate conduct precisely because it lacks any enforcement mechanisms and fails to place legal obligations on participating parties.\(^{20}\) One survey of companies participating in the UNGC revealed that they join the Compact not only because of their interest in supporting sustainable development, but also to improve their corporate image and strengthen market performance.\(^{21}\) In contrast, others argue that the UNGC enables corporations to promote universal human rights principles through its built-in mechanism of learning networks, policy dialogues, and public-private partnership projects (PPPs).\(^{22}\) Moreover, some argue in bringing together


\(^{19}\) Ibid.


corporations and states, the UNGC may, in the future, be developed to serve as a forum for clarifying and defining the role of business in society, including perhaps the right to health responsibilities of the pharmaceutical industry and MNCs in general.23

Overall, with regard to Voluntary Self-Regulatory Regimes, the literature reviewed raises the following key issues and entry points for further exploration:

- Voluntary self-regulatory frameworks are seen as often lacking transparency and detail regarding their human rights content, and evaluation of their impact on business practices has been limited. At the same time, the feasibility of an internationally binding regime to regulate corporate conduct remains questionable.
- States can continue to create incentives for corporations to adopt or strengthen voluntary self-regulatory regimes, and it may be that this offers a practical approach for advancing health-related human rights.
- While it has been argued that the UN Global Compact (UNGC) can be a self-serving platform which lacks enforcement mechanisms, understanding how the UNGC can function as a forum for addressing the health-related human rights responsibilities of the pharmaceutical industry remains an area for further analysis.

3. Integrating Human Rights into Voluntary Self-Regulatory Regimes: Why and How

The general consensus of the articles analyzed is that states are the key actors holding human rights obligations while corporations and the private sector are more accurately seen as moral agents with a critical but still loosely defined responsibility to promote and protect human rights. At the same time, some argue that corporate responsibility frameworks which take into account human rights principles will over time contribute to industry reputation and sustainability.24 States are held accountable for all conduct of MNCs based in

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their jurisdiction both at home and abroad because they exercise fundamental influence over the ways in which MNCs operate across borders. Therefore, the ways in which states interact with and regulate MNCs will likely continue to be reviewed by commentators and civil society more generally from a human rights perspective—a dynamic which it can be assumed will impact the future behavior of states and consequently state-MNC relations and regulations. In order to address this and related long-term challenges, some argue that the private sector could incorporate human rights principles into their own self-regulatory codes of conduct in a meaningful manner.

Along these lines, some authors present approaches for modifying voluntary self-regulatory regimes so that they better embrace human rights principles without significantly undermining business interests. One such approach is to strengthen the transparency in corporate codes of conduct by introducing mandatory disclosure of human rights impact evaluated by independent auditors, as well as requiring companies to promote human rights internally by holding training and educational sessions on the application of human rights norms and standards to their areas of work. While many details remain to be defined, companies would then receive a certification of some sort acknowledging their compliance with human rights responsibilities.

In an assessment of the UN “Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights” (UN Norms), one of the articles suggested a similar approach to building in accountability mechanisms. The UN Norms were approved by the United Nations Sub-Commission on the Promotion and Protection of Human Rights in 2003 and consist of a comprehensive summary of the international legal principles deemed relevant to businesses, including those that draw from human rights law, environmental law, international labor law, and other areas. While the UN Norms are not legally binding, they do focus more on specific human rights than the UNGC, including, for example, the right to health. It is assumed that their authority is likely to grow as they are adopted and referred to by businesses and inter-governmental agencies, which may in turn be useful for clarifying their potential impact and legal weight. One suggested approach for strengthening business accountability for the rights

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26 Ibid.
embodied by the UN Norms is to enable those treaty bodies with individual communications procedures to take up complaints about governments which have failed to take effective action in response to corporate violations of the provisions of the UN Norms. It is unclear what effect this ultimately would have but is something to monitor in the future.

Only one of the articles focused specifically on self-regulation of the pharmaceutical industry, but it did not deal with CSR frameworks or the UNGC. Nonetheless, the article highlighted various forms of intrafirm and interfirm regulations as effective checks on corporate conduct in the pharmaceutical sector. Intrafirm mechanisms include internal compliance groups such as the office of the medical director and quality assurance groups. Interfirm self-regulation includes codes adopted by national and international business associations that may overlap with CSR frameworks. These intrafirm and interfirm regulatory mechanisms may provide useful entry points for integrating human rights norms and standards into operational practice.

Human Rights as part of the UN Global Compact
The impact of the UNGC on the application of specific human rights seems to have been relatively unexplored in the articles analyzed, with one exception. One article argued that gender equality is embedded in the UNGC, though not explicitly, as women and women’s human rights are ignored in the UNGC itself, because the UNGC derives its principles from human rights instruments containing gender equality provisions. The article suggested that, through its learning networks, the UNGC can introduce a gender equality lens into the corporate responsibility discourse, and in doing so can provide an opportunity to discuss a number of issues from a human rights and gender perspective leading to an assessment of specific rights, including the right to health. It is worth considering the potential impact this approach may have over time in clarifying the human rights roles and responsibilities of the pharmaceutical industry.

Overall, with regard to Integrating Human Rights into Voluntary Self-Regulatory Regimes, the literature reviewed raises the following key issues and entry points for further exploration:

31 Ibid.
The interactions between states and multinational companies are likely to continue to be critiqued from a human rights lens by civil society and international agencies. Thus, approaches for modifying voluntary self-regulatory regimes by integrating human rights principles without significantly undermining business interests are thought to be a useful approach for operationalizing human rights responsibilities.

Intrafirm and interfirm regulatory mechanisms are also seen as serving as effective checks of pharmaceutical industry conduct and therefore to hold potential for integrating human rights norms and standards into operational practice.

The UN Global Compact’s learning networks can serve as a platform for discussing a number of issues from a human rights perspective, and it is thought that this may contribute to better understanding the specific health-related human rights responsibilities of the pharmaceutical industry.


The articles make clear how the actions of pharmaceutical companies contribute to shaping the success of national drug programs. The right to health norms of availability and financial accessibility (affordability) of medicines are often implicit criteria relevant to the ultimate success of these national programs. Consequently, the role of the pharmaceutical industry in national drug programs has implications for understanding their right to health responsibilities.

Two examples emerge from the literature, which are worth highlighting for the light they may shed in this area. In Argentina, the Remediar program’s success was due in part to: strong monitoring and surveillance to prevent unlawful diversion of drugs and blocked access; training to improve prescription practices among pharmacists; and working closely with local NGOs to implement and deliver EM. However, the lack of evaluation of the demand side of prescription practices, or whether patients were retaining health information received from providers, was considered a major limitation of the program.\(^{33}\) In Mali, the government-introduced cost recovery scheme is believed to have led to improved affordability in the public sector, with consequent reduction in drug prices in private facilities, highlighting the interaction between private and public sectors.\(^{34}\) The pharmaceutical industry’s

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working relationship with both sectors can be understood to place it in an advantageous position for supporting improved access to EM across the health system. An examination of the roles that the pharmaceutical industry plays in supporting national drug programs may serve as a useful entry point for better defining its right to health responsibilities.

**Public-Private Partnerships**
The bibliography includes a series of articles highlighting the rise in the number of public-private partnerships (PPPs). In general, the PPPs discussed appear to focus on drug development and delivery, including drugs for neglected diseases, which has several implicit human rights benefits including promoting accessibility of drugs (under the right to health) and the right to benefit from scientific progress. PPPs are useful to consider because they represent a nexus of interactions between states, intergovernmental and multilateral agencies, civil society, and for-profit institutions including the pharmaceutical industry.

In one interesting example of a PPP focusing on TB research in South Africa, the partnership between civil society and the private sector placed pressure on the state to prioritize TB as a health issue. In this manner, the private sector was involved in supporting state accountability for its right to health obligations. In another example of a PPP between the government and NGOs in Cambodia, improving equity in childhood immunization was an explicit partnership goal, as well as a component of the monitoring and evaluation strategy. These examples show how PPPs can shape state and non-state interactions in unorthodox ways in relation to right to health obligations and responsibilities.

The articles accessed offer several critiques of PPPs which require some consideration. First, PPPs tend to revolve around product development for diseases with significant economic incentives and not those which pose the greatest burden to health. Second, the literature identified sustainability as another major limitation of PPPs, given that their funding is not always guaranteed in the long-run, and that they are dependent on exogenous expertise. Third, the complexity of defining the responsibilities of partners

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involved and ensuring accountability and transparency within PPPs were identified as major challenges. Finally, PPPs are also thought to be plagued by a lack of alignment between basic research and translational research, which in turn is thought to lead to a lack of delivery of the drugs to poor communities.

One suggestion made is that pharmaceutical companies engaged in PPPs could use their technical expertise to strengthen the links between basic, translational, and operational research to promote the accessibility component of their partnerships.

The articles demonstrate that the success of these sorts of partnerships has been dependent on the active involvement of disease-endemic countries and researchers from those countries, and in some cases also the active participation of community members. However, the articles do not clarify how and in what capacity individual partners can or should contribute to PPP effectiveness. While it is clear that PPPs, as any other health promotion efforts, can contribute to the right to health in their objective of achieving positive health outcomes, more research is needed to understand how PPPs can integrate human rights principles to strengthen pre-established determinants of partnership success, such as community participation and internal accountability structures, as well as how human rights principles necessary for achieving the right to health can be used to tackle some of the well-known drawbacks of PPPs. For example, it may be that a human rights focus on community participation and empowerment may contribute to local ownership and capacity to take up product development and distribution after PPP resources have been exhausted.


Overall, with regard to National Drug Programs and Public-Private Partnerships, the literature reviewed raises the following key issues and entry points for further exploration:

- **Further examination of the ways that the pharmaceutical industry supports or hinders national drug programs, including its working relationship with both the public and private health sectors, is thought to be a useful approach to gain clearer understanding of its right to health responsibilities.**

- **Public-private partnerships (PPPs) aimed at improving access to medicines are thought to be useful for examining how the operational relationships to medicines between states, the pharmaceutical industry, and other non-state actors can contribute to advancing the right to health and human rights responsibilities more broadly.**

- **More research is needed on how some well-known obstacles to PPP success may be addressed in part through the systematic integration of human rights principles into partnership processes.**

5. Essential Medicines Under the Right to Health: Entry Points for Supporting State Obligations

The availability, accessibility, acceptability, and quality (3AQ) elements of the right to health overlap closely with the WHO statement that EM should be of appropriate quality, and available in adequate quantities at all times at an affordable price.\(^{42}\) In addition, emphasis of WHO’s strategy on universal access to EM complements the human rights principle of non-discrimination.\(^{43}\) Four articles in the bibliography primarily and explicitly addressed the relationship between human rights and EM. Overall, these analyses highlight the synergy between a human rights perspective and global objectives regarding EM.

Although the focus of these articles is on human rights principles for states to use in the processes of strengthening their EM programs, the recommendations are worth considering as they may point to useful entry points for the engagement of non-state actors. The role of the private sector, including the pharmaceutical industry, in assisting states to integrate human rights into the processes shaping EM programs is unclear but may be worth exploring. For example, one human rights-based recommendation is that states ensure all vulnerable groups have access to EM by collecting data and statistics pertinent to them.\(^{44}\) Another recommendation is that transparency and accountability mechanisms be integrated into EM programs so that they include clear


\(^{44}\) Ibid.
objectives and specific roles and responsibilities for all actors involved. A third recommendation is that the international treaty body system for monitoring compliance with human rights commitments be increasingly used to hold states specifically accountable for their EM obligations. One option here is the development of indicators of EM which explicitly take right to health considerations into account.

Supporting National Essential Medicines Lists and Committees
While the provision of EM which adhere to the 3AQ norms is a clear component of the right to health, the definition of what actually constitutes an essential medicine is more contentious requiring an evidence-based process, technical expertise and assessment of quality, safety, and public health relevance. The development of national essential medicines lists (EMLs) and national EML committees provides a useful entry point for undertaking right to health responsibilities. Although EMLs are primarily seen as a tool for the public sector, the pharmaceutical industry could potentially work with states to provide the necessary training and capacity building to enable EML committees to undertake evidence-based selection processes using a right to health framework with attention to cost-effectiveness analysis and other techniques.

Essential Medicines Affordability and Pricing
This bibliography was explicitly limited in its focus on affordability barriers outside ongoing debates on intellectual property and trade law. The high cost of many EM is nonetheless a well-documented barrier to ensuring access, particularly among the poor or disenfranchised populations. In one article, multi-country surveys revealed significant increases in EM prices resulting from taxation and price-markups as medicines moved down the supply chain. Further, the same surveys revealed wide variations in the median-price ratio of drugs, which suggested inconsistent price mark-ups along the supply chain. The researchers conducting these surveys noted several options for improving the financial accessibility of EM including improving management efficiency, securing adequate and sustainable financing, pooling procurement to improve purchasing efficiency, lowering taxes, changing regulatory mark-ups and monitoring distribution chains. Some aspects of the discussions around generics

45 Ibid.
48 Ibid.
could usefully be considered for what they suggest with respect to affordability of EM more broadly. For example, policies promoting affordability of EM by addressing the education of health professionals and increasing consumer awareness warrant consideration.\textsuperscript{50}

Likewise, to reduce price mark-ups on generics and innovator brands in Malaysia, authors of another analysis recommended that the country review and monitor its purchasing practices and regulate pharmaceuticals by printing maximum prices on drug packages.\textsuperscript{51} Strong civil society engagement in decision-making around drug pricing and legislation ensuring free access to certain treatments were also identified as critical to improved financial accessibility to anti-retroviral therapies in Brazil and Thailand.\textsuperscript{52} Furthermore, as pricing policies are often a product of, and complicated by, the competing interests of those ministries devoted to promoting industry and those in charge of health,\textsuperscript{53} policy alignment between various ministries aimed at protecting the right to health is required. One article’s grouping of pricing policies as supply-side, proxy-demand side, and demand side categories\textsuperscript{54} may be a useful framework for identifying the financial accessibility dimension of the right to health. These points may all be of use in considering support for right to health responsibilities.

The bibliography’s wide range of policy recommendations sets out multiple entry points for pharmaceutical companies to explore opportunities for assisting states with their right to health obligation to provide affordable or financially accessible EM, thereby operationalizing their political commitment to social good and moving towards clarifying their right to health responsibilities.

\textit{Researching Policies and Pharmaceutical Use}

While a number of studies examined the affordability and cost of EM and suggested key policy areas for taking action, very few have looked at the impact of national drug policies on drug use, albeit a methodologically challenging

\textsuperscript{50} Ibid.
\textsuperscript{54} Ibid.
As noted by the articles reviewed, recent developments in this area include the increasing number of product patents and the growth of national pharmaceutical insurance policies. Studies are needed to examine the impact of these emerging developments on drug access and use.

**Neglected Diseases**

Three articles reviewed for the bibliography focus on barriers to the development of drugs for neglected diseases. Notably here, the definition of neglected diseases is unclear, and often shifts between those diseases with minimal public health impact in terms of morbidity and mortality and diseases for which drug development is assumed to be undermined by limited economic incentives. Barriers to access to medicines for neglected diseases as identified in these articles include: the high cost of research and development; strict and complex regulatory framework; counterfeit drugs; and mandatory patent protections. While interesting, these barriers do not appear to be specific to neglected diseases but rather to affect access to medicines in general.

With the exception of a general recommendation to develop a Neglected Diseases Treaty and a specific international legal and regulatory framework, the recommendations from the reviewed articles on neglected diseases focus on very broad policy changes that impact access to drugs in general. Moreover, nearly all the recommendations for overcoming the barriers to neglected diseases are directed at governments. The role of the pharmaceutical industry came up only twice in recommendations that the industry work more closely.

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56 Ibid.


with international organizations and PPPs on this issue.\textsuperscript{60} Working with international organizations who are actively engaged in using human rights to guide their EM work may be one opportunity for exploring the contribution of the private sector and the pharmaceutical industry in this area. One article pointed to various financial push and pull mechanisms that could be initiated by governments and inter-governmental organizations to engage the pharmaceutical industry in developing medicines for neglected diseases. These include tax credits and advance purchase funds. However, it was also emphasized that these approaches be reviewed with caution as their actual impact on drug development and access remains unclear.\textsuperscript{61} Additional thought could be given to how right to health concepts could be used to inform the role of the pharmaceutical industry more generally in relation to neglected diseases and to help shape the development of appropriate push and pull mechanisms.

\textit{Barriers to the Quality of Essential Medicines}

Under the right to health, states have a duty to ensure that EM are not only affordable to communities and individuals, but that they are also of appropriate quality. Counterfeit and expired drugs are recognized as presenting major barriers to quality. One article recommends that, to improve quality, states put into place legislation and other initiatives to combat the flow of substandard medicines including consumer education and increasing criminal penalties.\textsuperscript{62} The author goes on to specify two potential roles the pharmaceutical industry could play in helping ensure quality of medicines in this regard: launching or assisting in low-cost high-quality drug donation programs, and providing training to prevent the expiration or improper storage of pharmaceuticals.\textsuperscript{63} Another article highlights three ways in which states, civil society, and the private sector can regulate the quality of drugs: establishment of professional associations for pharmacies and drug dispensaries to improve credibility; accreditation of pharmacies’ drug dispensaries by the state; and improved consumer education which may lead to regulations on the part of consumer and community organizations.\textsuperscript{64} All of these could be useful approaches for


\textsuperscript{63} Ibid.

pharmaceutical companies wishing to support implementation of the human rights norm of quality.

In an effort to maintain the affordability of medicines, as noted by the articles, states often implement cost-containment strategies when purchasing drugs, which sometimes results in compromising the quality of drugs which amongst other things leads to an increase in the long-term costs borne by the state and by individuals.\textsuperscript{65} While the literature does not specify the role of non-state actors in this area, pharmaceutical companies and other non-state actors, could potentially assist countries in developing cost-containment tools that use human rights principles that systematically take into account quality and equity issues.

Overall, with regard to Essential Medicines under the Right to Health, the literature reviewed raises the following key issues and entry points for further exploration:

- While the use of human rights principles to strengthen essential medicines (EM) policies and programs has been analyzed extensively in terms of government accountability, the role of the private sector in this context remains unclear and calls for further analysis.
- More research is needed to understand the role of states and civil society in creating push and pull incentives for the pharmaceutical industry to develop new drugs for neglected diseases, and to alleviate known barriers which limit access to these new drugs and EM in general.
- Working with National Essential Medicines Committees, addressing supply chain price-markups, poor consumer knowledge, and other obstacles to EM affordability and quality, and undertaking research on the impact of drug policies on access to quality EM, are all considered to be potential entry points for the pharmaceutical industry to support states’ right to health obligations, as well as opportunities for clarifying its own human rights responsibilities.

CONCLUSIONS

Outside the realm of intellectual property, the debate on the right to health responsibilities of non-state actors is important and yet relatively unexplored. The overall consensus in the literature reviewed is that states have the primary obligation to realize the right to health along with all human rights, while the pharmaceutical industry and other non-state actors can at this point in time be seen primarily as having moral, social, and legal responsibilities in this regard.\textsuperscript{66}


\textsuperscript{66} The bibliography identifies a number of human rights which are useful for understanding the responsibilities of the MNCs in general, with implications for pharmaceutical companies. The following rights were explicitly mentioned in the peer-reviewed literature: right to health; freedom from harm; right to benefit from scientific progress; right to property; right to benefit
This distinction between obligations and responsibilities is important. It is generally accepted that under the right to health, states have an obligation to ensure the availability, accessibility, acceptability, and quality of EM and other health goods and services. However, highlighting an important gap in the literature, the articles reviewed do not specify the human rights responsibilities of the pharmaceutical industry with regards to EM or other health issues, nor clarify the specific role for the industry in state-led efforts to use human rights as a “tool” to advance public health. In spite of this gap, it remains clear that initiatives aimed at realizing the human rights responsibilities of the pharmaceutical industry are inextricable from state obligations, including state duties to regulate MNCs.

The bibliography highlights the ongoing debate on whether voluntary or legally-binding regimes are the best way for corporations to consider their corporate responsibilities. Arguments looking at the responsibility of MNCs for their conduct seemed to focus primarily on corporate accountability for direct violations of rights and not give sufficient attention to what exists or could be done with respect to working with governments and communities to help promote and fulfill rights. Voluntary self-regulatory regimes may provide opportunities for meaningfully integrating human rights principles while serving as a participatory platform for clarifying the pharmaceutical industry’s right to health responsibilities. The reviewed articles outlined potential mechanisms for strengthening corporate transparency and accountability. Moreover, using UNGC mechanisms such as learning networks to explore rights and equality issues may be a useful way to promote discussion and clarify the specific human rights responsibilities of MNCs in relation to state obligations, including the responsibilities of the pharmaceutical industry in the context of the right to health.

Those articles dealing primarily with voluntary self-regulatory regimes did not take up the issue of how regimes can further the realization of specific rights or rights-related issues, nor the human rights content of such regimes, with more research needed on these topics. Overall, a major gap exists in the literature on CSR and related regimes, which mainly focuses on the theoretical relationships of CSR and human rights without reference to practical implications for different sectors, including pharmaceutical companies.

The bibliography also highlights the ways in which states and civil society are taking operational steps to promote access to medicines and the right to

from moral and material interests of scientific production; right to work; right to education; right to life; and non-discrimination.
health. These efforts provide useful entry points for exploring the pharmaceutical industry’s right to health responsibilities. National drug programs provide a venue for non-state actors to support the state in fulfilling its EM obligation, while PPPs provide a platform for atypical interactions between civil society, for-profit organizations, governments and multilateral agencies. Promoting human rights sensitivity in PPP processes remains an unexplored option for pharmaceuticals seeking to operationalize their right to health responsibilities and their concern for human rights more broadly.

A significant number of articles address EM and the role of governments in ensuring their availability, accessibility (including financial accessibility or affordability), and quality. The majority of these articles incorporate human rights implicitly in their analysis, providing examples of operational efforts undertaken by states and pharmaceutical companies on these issues. Those articles that did take up human rights tended to explicitly focus on the general use of rights principles such as accountability and non-discrimination for use by states in their EM programs, and did not specify the role of the private sector.

While the bibliography identifies a host of policy recommendations and operational entry points for improving access to essential medicines, how pharmaceutical companies can best contribute to realizing the right to health remains an area to be explored. One option may be for the pharmaceutical sector to identify and support ongoing EM initiatives with a pre-existing and specific human rights component. Doing so may lead to useful lessons to help clarify their right to health responsibilities. Another option may be for the pharmaceutical industry to apply the 3AQ normative framework or draw upon other human-rights based frameworks to identify novel entry points for collaborating with states and civil society, or to structure research studies in other ways. For example, the 3AQ framework could be used to identify and categorize health laws and regulations, policies, and programs (including EM-related ones) based on how they impact each right to health normative component. Pharmaceutical companies could then undertake concrete steps to advance the right to health by working with governments in these areas. In using the 3AQ framework explicitly, pharmaceutical companies would be applying human rights principles to shape their interactions with governments — an approach that is distinct from the philanthropic initiatives dominating CSR agendas. Further research on these issues would be a contribution to the process of elucidating the human rights roles and responsibilities of the pharmaceutical industry.
INDEX OF ARTICLES REVIEWED

I. Corporate Social Responsibility and Human Rights


II. The UN Global Compact


### III. Essential Medicines


Drug Programs Improve Drug Use?: A Review of Experiences in Developing Countries.” *Social Science and Medicine* 53(7):831-844.


10. Trouiller, Patrice; Torreele, Els; Olliaro, Piero; White, Nick; Foster, Susan; Wirth, Dyann and Bernard Pécoul. 2001. “Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure?” *Tropical Medicine and International Health* 6(11):945-951.

**IV. Public-Private Partnerships**


IV. Accessibility of Drugs and/or Services


V. Affordability of Drugs and/or Services


VI. Quality of Drugs and/or Services


I. CORPORATE SOCIAL RESPONSIBILITY AND HUMAN RIGHTS

1. Transnational Regulation of the Pharmaceutical Industry
   Braithwaite, John

Abstract: While the pharmaceutical industry arguably has the worst record of serious corporate crime of any industry, international law evasion rather than outright law violation has been the biggest problem in the industry. To understand how these problems can be and are being brought under control, a legal-pluralist analysis is needed that decenters criminal enforcement by the state. Consumer and professional activism and a variety of levels of self-regulation in combination with state, regional, and international regulation are all important to understanding how progress is possible. Creative work within this web of controls can actually transform lowest-common-denominator regulation into highest-common-factor regulation and self-regulation when actors are capable of thinking strategically in world-system terms.

Human Rights Norms and Standards
The article does not explicitly deal with human rights norms and standards. Nonetheless, the article is of use because it implicitly addresses the 3AQ as it focuses on regulations to ensure that drugs are of a high quality.

Interactions Between State and Non-State Actors
The article generally highlights how formal regulation of the safety and efficacy of pharmaceutical products by states occurs at the national, regional and international level. However, the article focuses primarily on forms of regulation that do not involve states directly. To improve regulation of the pharmaceutical industry, the article recommends criminal law support, as well as intrafirm, interfirm, and consumer forms of regulation. It notes that intrafirm regulation is one of the most effective checks on pharmaceutical companies. For example, internal compliance groups such as the office of the medical director or a quality assurance group that can support the intent of regulatory laws.

Interfirm self-regulation also plays a substantial role in keeping standards high in the industry. The codes of conduct of national and international industry associations may be more effective than government regulation. Individual firms can also raise standards. Lastly, consumer activism through lobbying by consumer groups and other stakeholders such as doctors can be very effective.
Distinctions Between Pharmaceutical Companies and other MNCs
The article focuses entirely on the pharmaceutical industry.

2. Responsibility for Global Health
Buchanan, Allen and Matthew DeCamp

Abstract: There are several reasons for the current prominence of global health issues. Among the most important is the growing awareness that some risks to health are global in scope and can only be countered by global cooperation. In addition, human rights discourse and, more generally, the articulation of a coherent cosmopolitan ethical perspective that acknowledges the importance of all persons, regardless of where they live, provide a normative basis for taking global health seriously as a moral issue. In this paper we begin the task of translating the vague commitment to doing something to improve global health into a coherent set of more determinate obligations. One chief conclusion of our inquiry is that the responsibilities of states regarding global health are both more determinate and more extensive than is usually assumed. We also argue, however, that institutional innovation will be needed to achieve a more comprehensive, fair distribution of concrete responsibilities regarding global health and to provide effective mechanisms for holding various state and nonstate actors accountable for fulfilling them.

Human Rights Norms and Standards
The article explicitly refers to the right to health, and implicitly to the related norms of financial accessibility or affordability, non-discrimination, and availability. The authors not only emphasize the role of states as primary agents of distributive justice, but also highlight their responsibility to address the disease burden of their countries. They go on to propose a minimal right to health standard that all states must be obliged to provide: removing barriers to access and refraining from discrimination in planning health services; and ensuring a set of basic health entitlements for all citizens, such as clean drinking water and a sanitation system. Further, the article explicitly refers to human rights discourse as providing the normative basis for taking global health seriously and as a moral issue. The authors posit that responsibilities of states regarding global health are both more determinate and more extensive than is usually assumed. They especially caution against allocating duties to address global health concerns to specific actors without offering adequate justification as to why those actors are responsible. Moreover, they mention how “duty dumping”, for instance on pharmaceutical companies might be politically convenient but ultimately counterproductive as it drives attention away from the importance of collective responsibility and fails not only to tackle the roots of
the problem but also allows states to get away from their own responsibility of ensuring the right to health of their citizens.

The authors contend that pharmaceutical companies do not bear a particular moral obligation under the right to health simply because they have the capabilities to improve health care significantly. They suggest that global corporations have a responsibility to: avoid actions and policies that significantly harm health; withdraw support from governments engaged in unjust activities that are harmful; and not impede health-promoting efforts by states or other organizations that have a more direct responsibility for public health.

**Interactions Between State and Non-State Actors**

The article explicitly refers to the interaction of states, non-state actors, and global governing agencies and agencies that promote health. It also refers to the role of individuals in promoting global health, specifically emphasizing the importance of individual action in the political process. Thereby, it suggests a role for civil society in monitoring the responsibilities of states, corporations, and institutions.

The article implies that human rights frameworks could be useful guides for setting up institutions for collective action and these institutions could then assign duties to individual actors and promote CSR. For example, such institutions could propose that pharmaceutical companies contribute to a fund for subsidizing the purchase of medicines in exchange for receiving patent protection for their drugs. In addition to proposing that global governance institutions should be created to clarify and fill in “responsibility gaps,” the article argues that existing institutions that have assumed responsibilities for global health explicitly (e.g., the WHO) or implicitly (e.g., the WTO) should be held accountable.

**Distinctions Between Pharmaceutical Companies and other MNCs**

The article explicitly talks about the potential roles pharmaceutical companies can play in promoting global health. Although the article does not explicitly refer to MNCs more generally, it discusses the role of cross border and global governing bodies which may have authority over MNCs outside of the pharmaceutical sector.

3. **Thinking for the Future: Global Corporate Responsibility in the Twenty-First Century**

Collier, Jane and Lilian Wanderley

Abstract: This paper reflects on the kinds of responsibility businesses today must exercise in order to be part of the solution to the problems of a globalizing world. These problems are to a large extent rooted in the dynamics of a globalization that is driven by business objectives and operations. They are brought to the fore of global consciousness by civil society protest on the one hand and investor pressure on the other in a manner that reminds us of Adam Smith’s anxieties concerning the threats posed by corporate power. It is clear that in our time the systemic complexities of global interdependence magnify these threats in ways beyond the control of governments and nation states. The remedy must thus lie with the companies themselves. Businesses, whether global or local, must recognize that as agents of global change they are acting not simply as economic but also as moral agents. They must assume the responsibility for the effects of their actions, and we argue that the best way to do this is to commit to the primacy of human rights as an overarching value governing all their internal and external dealings. This has its difficulties, as we discuss in the latter part of the article: we use the example of a Brazilian study to illustrate some of the problems of acting out such a commitment. This study also illustrates the point that the futures of business and of the communities in which they exist are intertwined; shareholder value and human rights are interactive elements of ‘good’ business.

Human Rights Norms and Standards
The article suggests that addressing human rights is theoretically the responsibility of the state, but globalization has made it the moral responsibility of corporations as well. Without mention of specific human rights norms and standards, it argues that human rights principles and concepts should be integrated into CSR frameworks. The authors claim that a CSR framework, underpinned by human rights, can help companies manage risks if it is embedded in corporate practices and not just used for its public-relations value. Such a framework would also be good for business by protecting the company’s reputation and making growth more sustainable.

Interactions Between State and Non-State Actors
The article focuses on the problems corporations face when working in states where there are significant human rights violations but where corporations are not directly or even indirectly involved. The authors argue that corporations will need to delineate responsibility between businesses, states, and NGOs, and must also strengthen the international legal obligations of non-state actors in using human rights when developing CSR frameworks. On an operational level, the article suggests that companies often lack expertise on human rights and that tools will need to be developed collaboratively to incorporate human rights elements into business activity and operations.
Distinctions Between Pharmaceutical Companies and other MNCs
The article does not distinguish between pharmaceutical companies and MNCs.

4. Do Firms with Unique Competencies for Rescuing Victims of Human Catastrophes Have Special Obligations? Corporate Responsibility and the AIDS Catastrophe in Sub-Saharan Africa
   Dunfee, Thomas W

Abstract: Firms possessing a unique competency to rescue the victims of a human catastrophe have a minimum moral obligation to devote substantial resources toward best efforts to aid victims. The minimum amount that firms should devote to rescue is the largest sum of their most recent year's investment in social initiatives, their five-year trend, their industry's average, or the national average. Financial exigency may justify a lower level of investment. Alternative social investments may be continued if they have an equally compelling rationale. These duties apply to the global pharmaceutical companies in the context of the AIDS pandemic in sub-Saharan Africa.

Human Rights Norms and Standards
The article is based on an ethical analysis and does not explicitly reference human rights norms and standards. The author argues that the pharmaceutical industry has a moral obligation to help address the AIDS pandemic due to its unique competencies in this area.

Interactions Between State and Non-State Actors
While the author stresses that the pharmaceutical industry has a moral duty and not a legal one, he does suggest that divergence between what is moral and what is legal may lead society to impose such a duty to act in a way that would harm the business interests of the industry.

Distinctions Between Pharmaceutical Companies and other MNCs
The article deals specifically with pharmaceutical companies and not MNCs more broadly.

5. Corporate Transparency and Human Rights
   Mock, William BT

No abstract available
**Introduction:** In order for corporate support for human rights to become a routine of corporate commitment, it must cease to be a matter of corporate grace and rise to the level of corporate obligation. In other words, corporate support for human rights must operate on the level of social, political, and economic activity, however inspired such commitment may be from the moral level. The essential practical distinction between the social, political, and economic levels, on the one hand, and the moral level, on the other, is that accountability for one’s actions arise temporally in the former spheres of action, whereas accountability or credit for moral actions must await another, less visible world. Corporations must, therefore, be made accountable in the coin of the temporal, workaday world for their actions or inactions on issues of human rights. Human rights activists and their supporters have long sought to make corporations feel the consequences of their human rights abuses. Such efforts, however, are largely sporadic and incidental (in the sense of relating to particular incidents) or limited to one particular corporation or another.

**Human Rights Norms and Standards**
The article examines how transparency can help structure corporate codes of conduct such that those companies that violate human rights can be clearly identified by the public. The article does not address explicit human rights norms and standards. Nonetheless, the article implicitly deals with human rights, given that transparency is central to realization of the right to information and a concept fundamental to human rights more broadly. The author suggests that regulatory codes such as CSR frameworks, regardless of their efficacy, have fallen short of human rights norms because of a lack of appropriate reporting systems.

**Interactions Between State and Non-State Actors**
The article does not discuss the specific role of states in promoting the transparency of corporate codes of conduct. However, it does present three recommendations for promoting transparency that may involve collaboration between MNCs and other non-state actors: (1) establishing mandatory disclosure evaluated by independent auditors paid for by companies; (2) requiring companies to take steps to promote human rights internally by paying for training sessions and other educational opportunities; and (3) a system of “metamarks”, or certification, indicating a company’s overall compliance with human rights responsibilities. While the article does not clarify the specific human rights responsibilities of non-state actors, it does posit that applying transparency, a principle central to human rights, can operationally improve CSR and similar frameworks.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article does not refer specifically to pharmaceutical companies.
Human Rights Norms and Standards
The author provides a brief overview of the benefits and justifications for holding multinational enterprises (MNEs) responsible for human rights violations under international law, and contextualizes these arguments using three intellectual strands that have shaped the evolution of human rights discourse: the emergence of human rights doctrine in response to protecting property rights from the state; the splintering of human rights ideology between the West and the Soviet bloc; and the current rise of identity and lifestyle politics. While the analysis does not focus on specific human rights norms and standards, it presents several different rationales that justify the relevance of human rights responsibilities to MNEs: (1) society believes that corporations have social responsibilities; (2) human rights are good for business by protecting a company’s reputation and securing a stable environment for its operation; (3) the legal context in which MNEs operate has changed making their private status irrelevant (such as the break-down and increasing regulation of the private sphere and the creation of new institutions that have allowed MNEs to bypass the state entirely); (4) MNEs can affect the human rights its workers and the wider community enjoy; and (5) concerns that NGOs will arbitrarily target MNEs are exaggerated. In this manner, the author explicitly presents justifications for MNEs’ moral and social responsibilities for human rights, which may have implications for corporate social responsibility frameworks and initiatives. However, with the exception of not violating rights directly, the article is unclear as to what these responsibilities entail, and whether any legally binding obligations exist. The author recognizes the primacy of states as duty-bearers with human rights obligations.

Interactions Between State and Non-State Actors
In terms of the legal relationship between states and corporations, Muchlinski notes the significance of state control and regulation of MNEs and their actions in order to protect human rights, and that efforts to place legal responsibilities on MNEs should not in any way absolve states of their human rights obligations. The author also raises the issue of how to differentiate between resistance by resource-poor countries to the importation of strict international standards regulating MNEs for economic development reasons, and resistance stemming from government unwillingness to take human rights seriously.
Distinctions Between Pharmaceutical Companies and other MNCs
The article does not refer to pharmaceutical companies specifically.

7. Taking Multinational Corporate Codes of Conduct to the Next Level
Murphy, Sean D

Abstract: Over the course of the past thirty years, numerous nonstate actor codes of conduct have emerged that seek to promote socially responsible conduct of multinational corporations (MNCs), especially in the developing world. The objective of such codes is to prevent harm or mistreatment of persons or things caused by MNC operations (e.g., the existence of unhealthy worker conditions in an MNC factory). Such harm or mistreatment need not be a core concern for the corporate actor. Indeed, the MNC – in theory driven to maximize its profits, although in practice driven by various factors – may benefit far more by inflicting the harm or mistreatment than by engaging in socially responsible behavior. Only in reaction to outrage and discontent by other actors (governments, nongovernmental organizations, or civil society groups) might the MNC see a value in developing a code of conduct that, if adhered to, would reduce the harm or mistreatment the MNC inflicts on others. This article briefly summarizes the rise of these codes of conduct, with particular attention to certain highly visible examples. Many criticisms have been leveled against such codes, suggesting that, over the long term, they may not survive in their present form. Consequently, this article suggests a new approach to thinking about these codes, one that might enhance their legitimacy, effectiveness, and credibility. Greater thought should be given by all stakeholders to an increased role for governments in the development and implementation of such codes. While transforming the codes wholesale into binding law is not politically feasible at this time, and may never be economically desirable, other means of governmental involvement should be considered. For instance, governments can play a better role in bringing stakeholders together to form such codes and do better at identifying which types of codes are effective and which are not. Governments might do better at using national laws and regulations to make adherence to such codes more attractive, such as by using the codes to help reduce regulatory uncertainty and as safe harbors for MNCs against criminal or civil penalties. At the same time, governments might use national laws to regulate better MNC use of the codes, such as by compelling disclosure of information about MNC adherence to the code. The role of governments would not be one of state control of corporate activity, but rather one of helping empower the individual autonomy of corporations within certain bounds of justice, fairness, and equity.
Human Rights Norms and Standards
The article does not explicitly address any human rights norms and standards, despite the fact that it makes some reference to the United Nations Global Compact (UNGC).

Interactions Between State and Non-State Actors
The article notes that voluntary self-regulatory codes adopted by corporations have been heavily criticized for not being legally enforceable. At the same time, it argues that a binding legal solution is not feasible for a number of reasons: treaties addressing corporate conduct have had low rates of ratification; countries have different views on the desirability of such a convention; states are reluctant to constrain their own MNCs and therefore are unlikely to enact national legislation to address CSR; and MNCs will resist any move to binding law. Consequently, the article proposes a “middle of the road” approach to CSR whereby the state plays a central role in encouraging MNCs to adopt codes through various measures without making them strictly legally binding. The article suggests that states can help bridge the gap between a voluntary and legally binding solution and satisfy both corporations and other civil society actors by offering a number of incentives for corporations to create and abide by effective codes as well as penalties for misusing a corporate code, noting that governments would be appropriate brokers between the two camps of non-state actors. Furthermore, the article suggests that states can also set the criteria different codes must fulfill to be recognized, encourage the creation of codes by having more lenient regulatory, civil, or criminal penalties for corporations that have a code, and tie the existence of a code to government procurement and financing. Moreover, states may choose to promote transparency in the codes through truth in advertisement legislation and the creation of an oversight process for the CSR codes and frameworks.

Distinctions Between Pharmaceutical Companies and other MNCs
The article analyzes MNCs and does not deal with the pharmaceutical industry.

8. The Right to Food: Holding Global Actors Accountable Under International Law

Narula, Smrita

No abstract available

Human Rights Norms and Standards
The author argues that resource-rich countries have duties under international law to respect and protect the right to food under article 25 of the Universal
Declaration of Human Rights and article 11 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which include the regulation of those international financial institutions (IFIs) and transnational corporations (TNCs) over which they are assumed to exercise significant control

Interactions Between State and Non-State Actors
On a legal level, the author suggests resource-rich countries have a different relationship with TNCs and IFIs than developing countries do. While rich countries control TNCs and IFIs, these entities control poor states. Therefore, in terms of legal liability, the article posits that these states should be held responsible for human rights violations committed by TNCs and IFIs in developing countries. Although recognizing that states are typically only held responsible in situations where they exercise “effective control” and non-state actors are not liable under international law, the article argues that states can be held accountable through their relationship to IFIs and TNCs both under the ICESCR and through customary international law. As noted, under the ICESCR, states must respect and protect the right to food extraterritorially and the article argues that this includes an obligation to regulate the TNCs and IFIs which they control. The author further contends that home states should be held accountable for violations by TNCs since they exercise “decisive influence over the ability of TNCs to operate in an unregulated manner abroad.”

Ultimately, the author argues that states are primarily responsible for human rights violations while also mentioning that NGOs play an important role in raising awareness of states’ obligations and any violations that may occur.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not discuss the pharmaceutical industry and refers to MNCs generally.

Ratner, Steven R

No abstract available

Human Rights Norms and Standards
The article presents a theory of corporate responsibility for human rights violations under international law, arguing that corporations need to be held responsible under international law for human rights violations since they are global actors who can have enormous influence on states and/or participate in abuses by states. While the article contends that corporations should be
accountable for human rights violations, it does not clarify their responsibilities in supporting states to fulfill these same rights. The article mentions examples of environmental and labor laws where companies may have responsibilities but does not refer explicitly to any specific human rights norms and standards.

**Interactions Between State and Non-State Actors**
The article notes that international law has taken a number of different approaches to regulating corporations depending on the political and economic conditions of the time and the relationship between four key actors – the home state of the corporations; the host state for the corporation’s activities, investor(s), and the affected population of the host state. The author’s proposed theory is based on a methodology for deriving norms of corporate social responsibility that consists of identifying how corporations are similar or different to states or individuals in order to determine what human rights responsibilities they actually have using four factors: the corporation’s ties to the government; its ties or nexus to the affected population; the existence of countervailing business interests; and the corporation’s control over agents involved in human rights abuses.

The author suggests several entry points for operationalizing his theory including using it in corporate codes of conducts such as CSR frameworks, national legal regimes, soft international law, and binding treaties on corporate conduct.

The author only briefly mentions the role of NGOs by asserting that they can use the theory to determine when corporations have committed human rights abuses.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article deals with MNCs and does not take up the pharmaceutical industry.

**10. Corporate Voluntarism and Human Rights: The Adequacy and Effectiveness of Voluntary Self-Regulation Regimes**

*Simons, Penelope*


**Abstract:** In response to increasing public concern over the accountability of transnational corporations (TNCs) for violations of human rights in the states in which they operate, governments, corporations, and NGOs have promoted the development and implementation of voluntary self-regulatory regimes. However, TNC practices under these regimes call into question their adequacy and effectiveness in preventing complicity in egregious violations of human
rights by corporations operating in conflict zones and repressive regimes. This article reviews and assesses the language, human rights content, and compliance mechanisms of the voluntary policies and/or codes developed by a number of corporations, industry groups, intergovernmental organizations, and multistakeholder initiatives, as well as associated corporate practices. The analysis shows that these voluntary regimes are flawed and inadequate, and therefore unable to ensure that TNCs are not complicit in human rights violations in their extraterritorial activities.

Human Rights Norms and Standards
The author deals specifically with human rights violations as they relate to MNCs, but does not explicitly deal with specific human rights norms and standards. The focus on civil and political rights is implicit in the analysis of “egregious human rights violations” involving forced displacement, extrajudicial killings, disappearances, rape and abduction. The analysis also implies that non-state actors, including businesses, hold responsibilities for not violating rights directly, and that voluntary self-regulatory regimes are inadequate in terms of holding businesses accountable for these responsibilities.

Interactions Between State and Non-State Actors
Overall, the voluntary self-regulatory policies analyzed in the article are found to be inadequate primarily because they are vague, use permissive language in defining the corporations’ human rights responsibilities, and focus on labor and environmental protections to the exclusion of other concerns. These policies also lack effective compliance mechanisms and do not require corporations to conduct a self-evaluation with results that are made available to the public. When corporations have revealed information on their performance, their reports still lack transparency, neutrality, and an outline of the broader context of human rights violations. Last of all, verification of compliance to self-regulatory policies either does not take place or, when it does, transparency, auditor independence, and auditor expertise are very limited. Upon analyzing the limitations of CSR frameworks and related self-regulatory policies, the author concludes that mandatory legislation at the state level is needed and self-regulation is of minimal importance, highlighting the significance of the underlying legal relationship between states and MNCs.

Distinctions Between Pharmaceutical Companies and other MNCs
The article deals with human rights and CSR as they relate to MNCs generally. It draws on examples from oil companies but does not refer to the pharmaceutical industry.
11. CSR and Equality
Utting, Peter

Abstract: Institutional reforms associated with neoliberalism and ‘good governance’ have altered the roles and responsibilities of states and transnational corporations (TNCs) in relation to social development. Increasingly such firms are engaging more directly in social service provisioning through privatisation, claiming to be more responsive to the concerns of multiple ‘stakeholders’ through ‘corporate social responsibility’ (CSR), positioning themselves as ‘partners’ in poverty reduction, and becoming more proactive in standard setting and ‘privatised governance’. Given the extent of anecdotal or piecemeal ‘evidence’ regarding the impacts of CSR, attention has turned in recent years to developing frameworks that identify a range of policies, practices and effects that need to be examined to adequately assess social and developmental aspects. This paper attempts to contribute to this discussion by focusing on the contribution of CSR to equality and equity, understood here in terms of minimising deprivation; enhancing equality of opportunity; correcting gross imbalances in the distribution of income, wealth and power; and social justice. While the primary responsibility for promoting equality belongs to state and multilateral institutions, the CSR agenda, with its emphasis on such aspects as improvements in working conditions, community support, labour and human rights, and stakeholder participation, clearly has implications for equality and equity. Four central components of equality are considered: social protection, rights, empowerment and redistribution. It is argued that the contribution of CSR in relation to these different elements varies considerably. Most CSR initiatives focus on social (and environmental) protection. Belatedly CSR discourse has embraced issues of labour and other human rights but CSR practice associated with the realisation of rights lags well behind. Other dimensions of equality related to empowerment and redistribution remain relatively marginal in the CSR agenda.

Human Rights Norms and Standards
The author uses human rights explicitly in analyzing the impact of CSR initiatives on promoting equality and equity using four components of equality—social protection (the well-being of stakeholders), rights, empowerment, and redistribution. The article is critical of CSR initiatives because while they have focused on social and environmental protection by addressing working conditions and assistance for social issues such as HIV/AIDS, there are still gaps between intention and implementation in the few companies that embrace CSR.
In addition, the article argues that corporations appear to pick and choose which rights to include in their CSR codes, with the right to health and an adequate living standard seldom appearing in the codes. The lack of monitoring is also posited to have undermined CSR initiatives. The article implicitly deals with the human rights principle of non-discrimination in arguing that vulnerable groups have not been empowered by the codes as they are seldom involved in their construction.

Interactions Between State and Non-State Actors
The article does not address the interactions of states and MNCs in the context of CSR. Nonetheless, the suggestion is made that the involvement of vulnerable groups in CSR construction may require cooperation between MNCs and organizations within which vulnerable populations are represented.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not refer specifically to pharmaceutical companies.

Weissbrodt, David and Muria Kruger

No abstract available

Summary: ...On August 13, 2003, the United Nations Sub-Commission on the Promotion and Protection of Human Rights approved the “Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights” (Norms) in its Resolution 2003/16. ... The working group is to receive information from governments, NGOs, business enterprises, individuals, groups of individuals, and other sources on the negative impacts of businesses, and especially data on the implementation of the Norms. ... The Norms and Commentary, however, require further efforts with regard to implementation and enforcement, and the working group and others will continue to address these issues in the future. ... The working group defines the phrase “other business enterprise” as “any business entity, regardless of the international or domestic nature of its activities, including a transnational corporation, contractor, subcontractor, supplier, licensee or distributor; the corporate, partnership, or other legal form used to establish the business entity; and the nature of the ownership of the entity.” ... A further mechanism not mentioned specifically in the Norms or the Commentary would be for the four treaty bodies with individual communications procedures to receive communications about governments that have failed to take effective action in
response to business abuses under the respective treaties, as elaborated by the Norms as well as related general comments and recommendations. ... 

**Human Rights Norms and Standards**

In analyzing the content of the UN Norms, the article explicitly mentions that the right to health, the right to equal opportunity and treatment, and rights related to consumer protection are all addressed. While the article states that the UN Norms are more focused on human rights than other existing international codes for corporate conduct, the article does not provide a critique of the UN Norms as much as explain its background and content.

**Interactions Between State and Non-State Actors**

According to the authors, as a restatement of legal principles applicable to companies, the UN Norms have some legal authority which is likely to grow with increasing adoption and implementation by businesses, the UN, and other intergovernmental organizations such as the WTO. The article further states that the UN Norms are not meant to erode any duties that states have to protect these rights, and that they encourage best practices for CSR while allowing standards to evolve. On a legal level, the article notes that states can enforce the UN Norms by implementing legislation to hold corporations accountable, but that states are not the sole actors responsible for enforcement.

**Distinctions Between Pharmaceutical Companies and other MNCs**

The article does not explicitly address pharmaceutical companies but the applicability of the UN Norms to their conduct is implied.

II. THE UN GLOBAL COMPACT

1. **Corporate Social Responsibility Practices and Environmentally Responsible Behavior: The Case of the United Nations Global Compact**

   Cetindamar, Dilek and Kristoffer Husoy


   **Abstract:** The aim of this paper is to shed some light on understanding why companies adopt environmentally responsible behavior and what impact this adoption has on their performance. This is an empirical study that focuses on the United Nations (UN) Global Compact (GC) initiative as a Corporate Social Responsibility (CSR) mechanism. A survey was conducted among GC participants, of which 29 responded. The survey relies on the anticipated and actual benefits noted by the participants in the GC. The results, while not conclusive, indicate that companies have more than one reason for adopting environmentally responsible behavior and that ethical and economic reasons
co-exist. In terms of performance, the impact of participation in the GC seems to be particularly high in securing network opportunities and improved corporate image. The results indicate that companies that have participated many years in the GC, have submitted the most projects and have attended the most GC meetings also regard their CSR involvement as having had a strong, positive influence on their market performance. GC participation does not result in significant cost advantages, but this does not seem to have been regarded as a goal anyway. Costs seem to be affected to a large extent by existence of in-house research and development and the capability of developing environmentally sound technologies. Overall, the company receives both ethical and economic benefits from joining the GC.

**Human Rights Norms and Standards**
The article does not explicitly deal with human rights norms or standards. Nonetheless, the right to health is implicated through the discussion of clean water and other underlying determinants of health in the analysis of corporations’ environmentally responsible conduct.

**Interactions Between State and Non-State Actors**
The article depicts the UNGC as a forum for dialogue and mutual learning and networking among companies and between companies and UN agencies. The authors describe three basic corporate social responsibility (CSR) concepts that they consider characteristic of the UN GC: (1) voluntarism as opposed to government regulations; (2) stakeholder management; and (3) networking and dissemination of information. The article notes that the desire to participate in sustainable development efforts was the most commonly cited reason for signing onto the UNGC. In addition, the networking opportunities (mainly for companies in resource-rich countries), improved corporate image, and the benefit of UN CSR experience were the three aspects of the UNGC reported to have had the greatest impact on company performance.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article deals with MNCs in general and does not refer specifically to the pharmaceutical industry.

**2. The Global Compact Selected Experiences and Reflections**

*Kell, Georg*


**Abstract:** In this paper, the Executive Head of the Global Compact shares some of his own reflections on the evolution of the Global Compact initiative – United Nations Secretary-General Kofi Annan’s voluntary corporate citizenship
initiative in the area of human rights, labor, the environment and anti-corruption. Two main themes are addressed. The first considers the Global Compact’s institutional context, examining how such an initiative is even possible in the historically hierarchical and traditionally business-unfriendly UN. The second concerns the voluntary nature of the initiative and how it interacts with regulatory approaches. It explains what the Global Compact has to offer as a voluntary initiative, as well as how it can make a unique and complementary contribution to regulation-backed initiatives. The paper concludes with a brief consideration of what the future holds for the Global Compact.

**Human Rights Norms and Standards**
The article does refer to any specific human rights norms and standards.

**Interactions Between State and Non-State Actors**
The article argues that the UNGC has been an innovative and successful initiative in spite of the bureaucratic nature of the UN system. Moreover, the article highlights that the UNGC is not meant to be a legally enforceable commitment. On the other hand, it is meant to encourage learning, dialogue and cooperation between businesses and states as well as other non-state actors. Moreover, the article contends that the UN’s political climate makes a binding approach unfeasible, and a regulatory framework is unlikely to have the additional learning opportunities that are available with the Compact. The article also argues that the voluntary nature of the UNGC is misjudged because it is backed by states and there are strong business incentives for corporations to comply. For the continued success of the UNGC, the author states that the UN and corporations will need to continue their support and states will need to play an even greater role in the initiative.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article does not address the pharmaceutical industry and focuses on the UNGC and its applicability to a wide range of companies.

**3. The UN Global Compact and Substantive Equality for Women: Revealing a ‘Well Hidden’ Mandate**

*Kilgour, Maureen A*


**Abstract:** The achievement of women’s equality is an elusive goal, especially in developing economies, where states have been unable or unwilling to protect and promote women’s human rights and gender equality. Many argue that globalization has heightened gender inequality. One response to this crisis is the United Nations corporate citizenship initiative: the Global Compact. This
paper argues that the Global Compact has a strong gender equality mandate, which has not been fulfilled. The paper advances a number of reasons why this may be the case, including the lack of women’s participation at many levels, the pervasive nature of women’s inequality and the fact it may not be in the interests of Global Compact signatories to address this inequality. Despite the limitations of this voluntary initiative, it does have some potential to effect positive change. However, unless the pervasive and continued violation of women’s human rights is addressed by the Global Compact, the claim that it is a viable new form of global governance for addressing major social and economic problems is severely weakened.

**Human Rights Norms and Standards**
The article argues that the UNGC has failed to address women’s human rights, but without reference to what this constitutes in terms of specific rights as outlined in international legal instruments. In analyzing gender equality and the UNGC, the article implicitly makes reference to the right to non-discrimination.

The author argues that there is a gender equality mandate embedded in the UNGC for the following reasons: the documents from which the ten UNGC principles are derived contain specific gender equality provisions; rights related to gender equality are part of the “internationally proclaimed human rights” that businesses should support and respect under Principle One of the UNGC; the UNGC is part of the UN system which is committed to achieving gender equality; and gender equality is necessary to solve development challenges – a central purpose of the UNGC. Nonetheless, the article suggests that the UNGC should play a role in addressing gender equality issues, particularly through its built-in learning networks.

**Interactions Between State and Non-State Actors**
The article posits that very few civil society organizations working on women’s issues have engaged operationally with the UNGC in part because they see it as ineffective and sanctioning a neoliberal agenda. However, the article argues that these reasons are short-sighted and the UNGC can be an effective tool for addressing gender equality. The role of states in these contexts is not discussed.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article does not address the pharmaceutical industry and focuses on the UNGC and its applicability to a wide range of MNCs.
4. Human Rights, the UN Global Compact, and Global Governance
Meyer, William and Boyka Stefanova

No abstract available

Introduction: The new Global Compact proposed by Secretary General Kofi Annan seeks to improve corporate responsibility in the areas of human rights, labor standards, and environmental protection. As such, the Global Compact is a new effort that has been added to a long list of activities at the local, national and international levels to make transnational corporations (TNCs) better corporate citizens. In this article, the authors put the Global Compact into a larger empirical and theoretical context. This article discusses the Global Compact (GC or Compact) in relation to similar efforts in other quarters, and then ties these various political and legal activities to larger issues raised by theories of international relations. Over the past two decades, international relations (IR) theory has become increasingly occupied by studies of international regimes and global governance. To gain an understanding of the GC’s potential for success, we must think of the Compact as a case study for the IR theory topics of international regimes and global governance.

Human Rights Norms and Standards
The article does not refer explicitly to human rights norms and standards.

Interactions Between State and Non-State Actors
The article argues that the Global Compact is a “necessary but not sufficient” tool used to encourage corporations to follow higher labor and environmental standards. Even though the Global Compact has set standards for behavior and monitoring, there are no legal obligations to abide by these standards. The authors go on to note that unlike the human rights regime governing states, there is no international regime to govern corporate responsibilities, and that setting-up such a regime would not be feasible since the issue cuts across a number of different areas and the response to the problem has been so mixed. Instead, they posit that CSR is better understood using a global governance framework as it is managed through the combined efforts of different actors in various spheres of authority such as a local courtroom, regional treaty, or UN convention. In terms of future developments, the authors recommend that the World Trade Organization should play an important role in improving corporate responsibility and propose a number of operational reforms to the organization such as a working group on labor rights and increased transparency.
Distinctions Between Pharmaceutical Companies and other MNCs
In its analysis of the UNGC, the article does not discuss the role of the pharmaceutical industry.

Ruggie, John Gerard

Abstract: This article draws attention to a fundamental reconstitution of the global public domain – away from one that for more than three centuries equated the ‘public’ in international politics with sovereign states and the interstate realm to one in which the very system of states is becoming embedded in a broader and deepening transnational arena concerned with the production of global public goods. One concrete instance of this transformation is the growing significance of global corporate social responsibility initiatives triggered by the dynamic interplay between civil society actors and multinational corporations. The UN Global Compact and corporate involvement in HIV/AIDS treatment programs are discussed as examples. The analytical parameters of the emerging global public domain are defined and some of its consequences illustrated by the chain of responses to the Bush Administration’s rejection of the Kyoto Protocol by a variety of domestic and transnational social actors.

Human Rights Norms and Standards
Using the UNGC as an example, the author argues that the actions of MNCs have created a new global public domain that has given rise to new systems of governance that lie outside international and national law. There is no explicit reference to human rights norms and standards. However, in using the example of corporate programs that provide health information on HIV/AIDS to both their workers and customers, the article implicitly deals with outcomes related to the rights to health and information.

Interactions Between State and Non-State Actors
The article suggests that a new global public domain has emerged which requires the active participation of MNCs to address various issues such as environmental pressures. At the same time, the rights of MNCs have expanded greatly through multilateral trade agreements. The author suggests that corporations, under pressure from civil society organizations, are addressing the imbalance between corporate rights and responsibilities. The article highlights several mechanisms of the UNGC which promote engagement between MNCs and civil society organizations: participation in learning networks where companies communicate their progress in internalizing the UNGC’s ten
principles; “policy dialogues” where members develop shared understandings on particular issues; and public-private partnership projects in developing countries. Moreover, the article argues that MNCs can compensate for governance gaps and failures by other actors, again using the example of HIV/AIDS information provided by corporations.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article deals with MNCs and does not specifically address the pharmaceutical industry.

### 6. The United Nations Global Compact and the Continuing Debate about the Effectiveness of Corporate Voluntary Codes of Conduct

**Shaughnessy, Meaghan**


*No abstract available*

**Introduction:** The gulf between Unocal’s action in Burma and its principles, as illustrated in its voluntary code of conduct, highlights the potential problems with using voluntary codes of conduct to help solve international human rights and environmental abuses. First, this paper will explore how the use of voluntary codes of corporate compact was enhanced in July 2000, when the United Nations created the Global Compact, a voluntary coalition formed by nearly fifty corporate charter members to promote human rights and environmental standards in business. Second, it will describe critics’ concerns with the Global Compact. Third, the paper will highlight several reasons corporations have implemented voluntary codes of conduct. Fourth, it will consider critical assessments of voluntary codes of conduct, including the lack of legal mechanisms to enforce compliance, the lack of incentive to implement voluntary codes, especially for corporations selling products to other corporations, the use of voluntary codes as public relations gimmicks, and the problem of varying degrees of compliance. Finally, it will consider a variety of potential legal remedies, including use of the Alien Tort Claims Act, the independent federal subject matter jurisdiction statute state law claims such as negligence, intentional tort, nuisance, and unfair competition laws, and enforcement through section five of the Federal Trade Commission Act.

**Human Rights Norms and Standards**
The article does not address specific human rights norms and standards, referring only broadly to human rights in the context of UNGC commitments and violations committed by corporations.
Interactions Between State and Non-State Actors
The article highlights the role of human rights and environmental groups in critiquing the UNGC and corporate voluntary codes of conduct for their lack of legal enforceability. The article further posits that corporations join the UNGC in part because of the benefits of being associated with the UN, while also noting that the drafters of the UNGC argue that it is meant to complement the efforts of governments to oversee corporations and realize human rights, not replace the responsibilities of the state.

Distinctions Between Pharmaceutical Companies and other MNCs
The article deals with corporations and businesses in general and does not refer to the pharmaceutical industry.

7. The UN Global Compact: The Challenge and the Promise
Williams, Oliver F

Abstract: The UN Global Compact is a voluntary initiative designed to help fashion a more humane world by enlisting business to follow ten principles concerning human rights, labor, the environment, and corruption. Although the four-year-old Compact is a relatively successful initiative, having signed up over eleven hundred companies and more than two hundred of the large multinationals, and having begun some important projects on globalization issues, there is a serious problem in that very few of the major U.S. companies have joined. While the premier U.S. companies are interested in meeting the legitimate expectations of society, there is concern centering around accountability issues. The accountability issues are in four major areas: 1. Accountability showing that the globalization of the economy actually helps the poor. 2. Accountability showing the corporate performance matches rhetoric. 3. Accountability that provides legitimacy to a two-tier pricing system and other measures that are designed to assist the poor in developing countries. 4. Accountability in the human rights area; what societal expectations are multinational companies accountable for? The article outlines the problems that the Compact brings to the fore and offers some insight from the ethical literature that may address U.S. company concerns or provide new ways of thinking about the issues. It further argues that the forum provided by the Compact may be the most effective means to gain consensus of the role of business in society.

Human Rights Norms and Standards
The article does not refer to specific human rights norms and standards. Nonetheless, it does take up the issue of accountability, a fundamental and
cross-cutting human rights principle, in analyzing the various critiques of the UNGC and its accountability to its commitments, including the accountability of MNCs to human rights.

Interactions Between State and Non-State Actors
The article argues that the criticisms made by civil society groups and United States corporations of the UNGC as failing to be accountable to its principles are unjustified. The article sees the UNGC as a useful forum for understanding and clarifying corporations’ human rights and social responsibilities through its learning networks and promotion of public-private partnerships. For example, the article notes that by encouraging countries and individual companies to develop the appropriate norms, the UNGC can help generate consensus on measures that apportion differential responsibilities in resource-rich and resource-poor settings, such as the two-tier pricing system used by pharmaceutical companies. In this manner, the interactions shaped by the UNGC serve to clarify legal responsibilities and ways in which they can be operationalized.

The author argues that under the UNGC, corporations must balance addressing human rights with potential harms to their ability to create products and engage in free enterprise. Highlighting programs corporations have put in place to help combat HIV/AIDS, such as Merck’s Botswana Comprehensive HIV/AIDS Partnership, the article suggests that such corporations appear to recognize that society believes they have some obligation to address the epidemic. However, the article contends that this does not mean they should not be expected to ensure everyone has access to medicine.

The article notes that both UNGC critics and supporters continue to debate whether a legally binding approach to corporate responsibilities is better than a voluntary one.

Distinctions Between Pharmaceutical Companies and other MNCs
The article analyzes the role of MNCs in terms of the UNGC while drawing on examples of the pharmaceutical industry efforts in this regard.

III. ESSENTIAL MEDICINES

1. Essential Medicines and Human Rights: What Can They Learn from Each Other?
   Hogerzeil, Hans V
Abstract: Most countries have acceded to at least one global or regional covenant or treaty confirming the right to health. After years of international discussions on human rights, many governments are now moving towards practical implementation of their commitments. A practical example may be of help to those governments who aim to translate their international treaty obligations into practice. WHO’s Essential Medicines Programme is an example of how this transition from legal principles to practical implementation may be achieved. This programme has been consistent with human rights principles since its inception in the early 1980s, through its focus on equitable access to essential medicines. This paper provides a brief overview of what the international human rights instruments mention about access to essential medicines, and proposes five assessment questions and practical recommendations for governments. These recommendations cover the selection of essential medicines, participation in programme development, mechanisms for transparency and accountability, equitable access by vulnerable groups, and redress mechanisms.

Human Rights Norms and Standards
The article explicitly addresses the intersections of human rights and EM, focusing primarily on the right to health and cross-cutting human rights principles of non-discrimination, transparency, and accountability. The article analyzes how the provision of EM is a key component of the right to health, and that providing EM is one of the steps State Parties must take to fulfill the right to health. The article mentions the two immediate obligations states adopt upon signing the ICESCR: to not discriminate in fulfilling their duties under the right to health, and to take deliberate and concrete steps to realize the right. In this respect, it is argued the WHO essential medicines list has put human rights into practice by emphasizing the principle of non-discrimination through its emphasis on universal access.

Although the author does not use the 3AQ directly to analyze how states can actually implement their commitments to the right to health, many of the considerations and the recommendations he proposes are targeted towards ensuring the accessibility of EM.

The article recommends that states adopt what is called a human-rights based approach in crafting development policies and medicine programs, and highlights five ways in which such an approach can strengthen an essential medicine program: establishing a national list that defines the minimum needs of individuals; consulting all the beneficiaries of the program including rural communities, NGOs, patients, consumer groups and representatives of vulnerable groups; creating mechanisms for transparency and accountability that include clear objectives for the policies and specific roles and
responsibilities for stakeholders; ensuring all vulnerable groups have access to essential medicines by collecting statistics on their access to medicine; and having safeguards, redress, and appeal mechanisms in place to deal with human rights violations. These recommendations and their underlying principles, although directed at states, may be of use for pharmaceutical companies interested in identifying and supporting specific human rights initiatives or integrating human rights into their own operations.

Interactions Between State and Non-State Actors
The article focuses primarily on the obligations of states in the context of EM and how international governmental organizations such as the WHO can support their efforts. Good governance strategies in the selection of essential medicines, procurement, management supply and rational use strategies all have helped maximize the funds available to provide basic health care to all citizens. The ways in which the WHO has played an important operational role in providing information to states on pharmaceuticals through activities such as the international prequalification program and the dissemination of information on sources and prices is highlighted.

The article discusses the importance of consulting with NGOs in developing national EM programs; however, since many of the recommendations involve issues of good governance, it is assumed civil society groups are likely to play an important role in holding the state to its commitments. The ways in which the pharmaceutical industry can and does help national essential medicine programs are not addressed.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not discuss the pharmaceutical industry or MNCs.

2. The Human Right to Medicines
Hunt, Paul and Rajat Khosla

No abstract available

Human Rights Norms and Standards
The article explicitly discuss the following components of the right to health: 1) available, accessible, acceptable, and good quality health goods and services; 2) issues of non-discrimination, equality, and vulnerability; 3) identification of indicators and benchmarks to measure progressive realization; 4) active and informed participation of individuals and communities in decision making that bears upon their health; 5) international cooperation and assistance between
resource-rich and resource-poor countries; 6) effective mechanisms for monitoring and accountability; 7) the duty of states to respect, protect, and fulfill the right to the highest attainable standard of health; and 8) identification of the relevant national and international human rights law, norms and standards.

In addition, the authors describe state obligations with regard to specific right to health norms outlined in the 3AQ. States have a duty to ensure that existing medicines are available within their borders and that much needed new medicines are also made available. The article further notes that ensuring accessibility of medicines requires that medicines be available in all parts of the country, must be affordable, and must be accessible without discrimination. The authors point out that, in developing countries, inadequate public funding in the health sector and corruption in the medical supply system often make medicines unaffordable. Additionally, reliable information about medicines must be accessible to patients and health professionals so that they can make well-informed decisions and take medicine safely (implicitly raising issues surrounding the right to information). The authors also describe states’ obligation to ensure that medicines are culturally acceptable and respectful of medical ethics, which may involve national support of traditional medicine and its integration into health-care systems or other related measures. Finally, the authors discuss the right to health standard of quality, noting its application to medicines to ensure that they are of good quality. It is argued this can be done by having states establish a regulatory system to check medicine safety and quality.

Interactions Between State and Non-State Actors
According to the article, national and international laws and policies are essential to ensuring states meet their right to health obligations and such policies require collaboration between state and non-state actors. The authors argue that fulfillment of the right to health requires a national medicines policy that must explicitly include vulnerable and disadvantaged groups, such as women and girls, people living with HIV, internally displaced persons, and others. Such laws can serve to reinforce the human rights principles of non-discrimination and equality. Using the guidance of the WHO Model List of Essential Medicines, a State is also required to prepare a national essential medicines list. State obligations are thus mediated and clarified through the work of inter-governmental organizations whose structures and decisions are influenced by the input of non-state actors, such as civil society and private corporations. In formulating these policies, a state must actively promote an inclusive and participatory process to ensure that all stakeholders are involved. The authors also emphasize the importance of monitoring and evaluation of these policies including the use of disaggregated indicators that identify and
include vulnerable groups and monitor their progress toward equal access.
Regardless of the interaction between state and non-state actors, the authors affirm that the state is the ultimate duty-bearer responsible for respecting, protecting, and fulfilling the right to health. While a state may contract the delivery of the health services to a private company, it cannot contract out of its right to health obligations.

The authors conclude by briefly discussing the role of pharmaceutical companies in ensuring access to medicines. Citing examples such as the UN Global Compact and the Organization for Economic Cooperation and Development’s Guidelines for Multinational Enterprises, they describe the emerging consensus that businesses enterprises, like all actors in society, have some legal and ethical human rights responsibilities. They suggest that applying the right to health analytical framework to pharmaceutical companies may help address two key issues: 1) clarifying the scope and content of these human rights responsibilities and 2) identifying which of these responsibilities are legal and which are ethical.

Distinctions Between Pharmaceutical Companies and other MNCs
The article refers specifically to the pharmaceutical industry as well as businesses more broadly, but does not distinguish their roles and responsibilities in its right to health analysis.

3. Rights and Practical Access to Medicines
Kahn, Johnathan

No abstract available

Human Rights Norms and Standards
The author provides two caveats to the argument that access to essential medicines is an important element of the right to health. The first is not to focus too ardently on the importance of pharmaceuticals. Attention should also be paid to the social conditions that are often responsible for many of the world’s public health problems. The second caveat is that although intellectual property rights are limited by the public interest, the boundaries of this limitation are unclear and it is difficult to assess the public interest. Outside of mentioning EM access as a component of the right to health, the article does not address any specific human rights norms and standards. Nonetheless, the analysis clearly relates to the right to health norm of accessibility.
Interactions Between State and Non-State Actors
The article mentions pharmaceutical companies in noting that they receive funding from the government to develop drugs for which the company will be a patent-holder. The article suggests that, where the state and pharmaceutical industry are partners in developing innovations, the state should have some right or claim on that product.

The author also suggests that civil society groups can have an impact on the state’s obligation to ensure EM access but currently do not because they are focused on influencing the pharmaceutical industry. The article proposes the US government should retain the power to issue compulsory licenses for drugs that are developed as the result of research partly funded by the state. This would notify patent holders and researchers that their products may be subject to a compulsory license and may allow health activists to focus on lobbying the government, which is more responsive to public complaints than private companies who have legitimate duties to their shareholders.

Distinctions Between Pharmaceutical Companies and other MNCs
No distinctions are made between the pharmaceutical industry and other MNCs.

4. 25 Years of the WHO Essential Medicines Lists: Progress and Challenges
Laing, Richard; Waning, Brenda; Gray, Andy; Ford, Nathan and Ellen ‘t Hoen

Abstract: The first WHO essential drugs list, published in 1977, was described as a peaceful revolution in international public health. The list helped to establish the principle that some medicines were more useful than others and that essential medicines were often inaccessible to many populations. Since then, the essential medicines list (EML) has increased in size, and defining an essential medicine has moved from an experience to an evidence-based process, including criteria such as public-health relevance, efficacy, safety, and cost-effectiveness. High priced medicines such as antiretrovirals are now included. Differences exist between the WHO model EML and national EMLs since countries face varying challenges relating to costs, drug effectiveness, morbidity patterns, and rationality of prescribing. Ensuring equitable access to and rational use of essential medicines has been promoted through WHO’s revised drug strategy. This approach has required an engagement by WHO on issues such as the effect of international trade agreements on access to essential medicines and research and development to ensure availability of new essential medicines.
Human Rights Norms and Standards
The article implicitly deals with the right to health norms of availability, accessibility and quality as it traces the history and evolution of the WHO’s Essential Medicines List (EML) and ways to improve its implementation in future.

Interactions Between State and Non-State Actors
The article deals with the operational interactions between state and non-state actors in its analysis of the roles the pharmaceutical companies and NGOs have played in shaping EMLs. According to the authors, while states, international organizations, and civil society appear to be advocates of EMLs, pharmaceutical companies remain skeptical of the idea. Moreover, the article contends that the pharmaceutical industry has historically been opposed to EMLs, stating that they threaten health care and investment in research. The industry, it is argued, has seen EMLs as a tool meant for the public sector of poor countries and opposes their expansion to developed countries and the private sector. At the same time, pharmaceutical companies have been involved in PPPs that have focused on diseases where there are economic incentives for drug development such as AIDS, malaria, and tuberculosis. Furthermore, the article notes that NGOs have been strong advocates of EMLs and have helped strengthen the political will and capacity of states to adopt the measure. Since many NGOs provide treatment in a number of countries, they also actively use EMLs in the selection and procurement of medicines.

Citing experiences of South Africa and Eritrea, the authors note the importance of having input from a wide variety of health programs and professionals as states develop their EMLs as well as the need to maintain the list so that it reflects the evolving needs of a nation and developments in medicine. The authors also suggest that in future, training and international assistance may be needed to help national EML committees use evidence-based approaches and conduct cost-effectiveness analyses. Given the expertise of the pharmaceutical industry in this regard, their potential roles in development of national EMLs warrants further exploration.

Distinctions Between Pharmaceutical Companies and other MNCs
The article explicitly deals with pharmaceutical companies but there is no reference to MNCs.
5. The Availability and Affordability of Selected Essential Medicines for Chronic Diseases in Six Low- and Middle-Income Countries

Mendis, Shanthi; Fukino, Keiko; Cameron, Alexandra; Laing, Richard; Filipe, Antonio, Jr; Khatib, Oussama; Leowski, Jerzy and Margaret Ewen

Abstract: Objective: To assess the availability and affordability of medicines used to treat cardiovascular disease, diabetes, chronic respiratory disease and glaucoma and to provide palliative cancer care in six low- and middle-income countries. Methods: A survey of the availability and price of 32 medicines was conducted in a representative sample of public and private medicine outlets in four geographically defined areas in Bangladesh, Brazil, Malawi, Nepal, Pakistan and Sri Lanka. We analysed the percentage of these medicines available, the median price versus the international reference price (expressed as the median price ratio) and affordability in terms of the number of days’ wages it would cost the lowest-paid government worker to purchase one month of treatment. Conclusion: Context-specific policies are required to improve access to essential medicines. Generic products should be promoted by educating professionals and consumers, by implementing appropriate policies and incentives, and by introducing market competition and/or price regulation. Improving governance and management efficiency, and assessing local supply options, may improve availability. Prices could be reduced by improving purchasing efficiency, eliminating taxes and regulating mark-ups.

Human Rights Norms and Standards
This study implicitly deals with right to health norms in its empirical analysis of the availability, economic accessibility and quality of EM. Based on the results of their study, the authors highlight several relevant areas where states can take measures to improve the availability, economic accessibility, and quality of EM. Improved management efficiency, and realistic assessment of local supply options can improve availability. Measures to lower EM prices include securing adequate and sustainable financing, improving purchasing efficiency, lowering taxes, regulating price mark-ups, and monitoring distribution chains. Generics could also be promoted through such measures as educating health professionals, making generic substitutes mandatory, and increasing consumer awareness. To address EM quality, guidelines for medicine selection by suppliers should be reviewed and essential medicines lists should be revised to reflect current evidence on the rational use of drugs. In suggesting these measures, the authors implicitly refer to the rights to education and information. The potential roles of non-state actors are not addressed.
Interactions Between State and Non-State Actors
The article alludes to interactions between governments and foundations, pharmaceuticals, and other non-state actors with respect to drug donations by highlighting the limited sustainability of donation programs which improve EM affordability in the short run.

Despite recommending initiatives requiring the involvement of non-state actors, the article does not address the collaboration envisioned as necessary between states and other actors for achieving such measures.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not specifically discuss pharmaceutical companies.

Nygren-Krug, Helena and Hans Hogerzeil

No abstract available

Human Rights Norms and Standards
The article implicitly deals with the availability and accessibility of essential medicines. Further, the article explicitly takes up a number of human rights principles, presenting them collectively as a framework aimed at improving access to EM. Namely, the rights and related principles discussed are: the rights to health, information, and education; non-discrimination; attention to vulnerable populations; redress for right to health violations; and state accountability for accessible EM by using indicators to monitor the right to health. According to the article, state governments would benefit from using these principles to guide their EM strategies. As an example, policy alignment between the various ministries responsible for safeguarding the right to health – such as the finance, trade, planning, and health ministries – would be enhanced. The roles of the pharmaceutical industry are not addressed.

Interactions Between State and Non-State Actors
The article focuses on actions that states can take alone or with the assistance or support of inter-governmental organizations and civil society groups. On a legal level, inter-governmental organizations can provide assistance for states in complying with their human rights obligations in the context of EM and also hold them accountable for violations. Civil society groups could play an important operational role by highlighting areas where states need to improve, connecting the government to vulnerable populations, and raising awareness.
about EM and the right to health in general. Specific roles for the pharmaceutical industry are not presented.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not explicitly mention pharmaceutical companies or MNCs.

7. Access to Essential Drugs in Poor Countries: A Lost Battle?
Pécoul, Bernard; Chirac, Pierre; Trouiller, Patrice and Jacques Pinel

Abstract: Drugs offer a simple, cost-effective solution to many health problems, provided they are available, affordable, and properly used. However, effective treatment is lacking in poor countries for many diseases, including African trypanosomiasis, Shigella dysentery, leishmaniasis, tuberculosis, and bacterial meningitis. Treatment may be precluded because no effective drug exists, it is too expensive, or it has been withdrawn from the market. Moreover, research and development in tropical diseases have come to a near standstill. This article focuses on the problems of access to quality drugs for the treatment of diseases that predominantly affect the developing world: (1) poor-quality and counterfeit drugs; (2) lack of availability of essential drugs due to fluctuating production or prohibitive cost; (3) need to develop field-based drug research to determine optimum utilization and remotivate research and development for new drugs for the developing world; and (4) potential consequences of recent World Trade Organization agreements on the availability of old and new drugs. These problems are not independent and unrelated but are a result of the fundamental nature of the pharmaceutical market and the way it is regulated.

Human Rights Norms and Standards
The article does not explicitly address human rights norms and standards. Nonetheless, its analysis of barriers to accessing quality essential drugs for diseases primarily affecting developing countries has implications in particular for the right to health norms of availability, accessibility, and quality of EM. In focusing on essential medicines for overlooked or neglected diseases, the article also implicitly deals with the human rights principle of non-discrimination.

Interactions Between State and Non-State Actors
The article recommends several concrete actions for overcoming barriers to EM access: the creation of a permanent agency within WHO to oversee drug control measures and states centralizing procurement in order to prioritize essential drugs; a centralized purchase fund to guarantee manufacturers a large sales volume to help address the availability of drugs; operational research in the field involving health care professionals to develop simple and effective protocols for
EM; and the encouragement of developing countries to take advantage of exceptions in WTO agreements, with the WHO being more vocal in making the case for public health and essential drugs at the international level, and a clear role for the pharmaceutical industry. Outside of this final recommendation, the role of the pharmaceutical industry is not explored in detail.

Distinctions Between Pharmaceutical Companies and other MNCs

The article refers specifically to the role of the pharmaceutical industry in recommending that it collaborate with international organizations since both actors share a common interest in assuring high quality drugs.

8. Do National Medicinal Drug Policies and Essential Drug Programs Improve Drug Use?: A Review of Experiences in Developing Countries

Ratanawijitrasin, Sauwakon; Soumerai, Stephen B and Krisantha Weerasuriya


Abstract: Increasing concerns regarding access to and appropriateness of medicinal drug use have led many governments in developing countries to develop national policies and regulations intended to increase the affordability, supply, safety, and rational use of pharmaceuticals. However, little is known about the intended and unintended impacts of these social experiments on actual drug use. We conducted a critical review and synthesis of the international literature in an attempt to define the current state of knowledge regarding drug policy effects on drug use, and to extract from the evidence important lessons for future policy and research. Literature sources included the archives and computerized databases, articles published in medical and pharmacy journals, as well as published annotated bibliographies. The evaluated interventions included three broad categories: (1) multi-component national drug policies including essential drug programs; (2) drug supply and cost-sharing programs; and (3) regulatory measures. Most of these studies utilized weak research designs that evaluated programs solely on the basis of post-intervention measures. Only two studies measured pre-policy utilization, but did not include a control group. Thus, none of the results are conclusive, and the findings represent, at best, hypotheses for more rigorous studies of policy impacts. Some suggestive findings include an association between increases in the supply of essential drugs (combined with training) and more appropriate use of medications in primary care settings. In addition, preliminary data suggest some unintended effects of de-registration of drugs or upward reclassification of specific medicines. Similarly, loosening restrictions have sometimes been accompanied by increased dispensing of specific drugs by unqualified personnel. The available studies focused only on a few categories of
national and regulatory policies. Because of poor study design, the results do not provide valid data to determine whether national drug policies improve drug use. Moreover, no studies have evaluated the effects of major and recent changes, such as increased use of product patents, national pharmaceutical insurance policies, and increased privatization of pharmaceutical products and services. Future studies need to explore the consequences of these emerging developments on drug access and use. Despite the difficulties inherent in evaluation of national policies, stronger research designs can and should be carried out. Interrupted time-series analysis and other more rigorous designs should become standard designs for policy evaluation in the same way that standard treatment guidelines are intended to guide medical practice.

**Human Rights Norms and Standards**
The article implicitly deals with the right to health norms of availability, accessibility and quality, as well as the right to information, as it critically reviews studies of the effect of national drug policies on EM use and prescription practices. The article notes that accessing information on EM is problematic since the staff in pharmacies may not be trained to advise consumers on the effects of downwardly reclassified drugs and consumers may not be able to understand information even if it is regulated. While admitting the limitations of the studies reviewed, the authors suggest that policies and programs that were combined with an educational component were more successful, suggesting that training health workers is important for successful policy implementation.

**Interactions Between State and Non-State Actors**
The article explicitly analyzes the interaction between states, health workers in the public and private sector, and individual patients or consumers, while discussing how national drug policies, and a lack of information and training can be barriers to accessing quality EM. The authors do not directly assess the role of the pharmaceutical industry in this regard. However, given their expertise in this field, pharmaceutical companies and other non-state actors may be able to assist with training of health professionals, and educating and providing information to consumers.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article does not distinguish between the pharmaceutical industry and MNCs in general.

**9. A Human Rights Approach to the WHO Model List of Essential Medicines**
*Seuba, Xavier*
Abstract: Since the first WHO Model List of Essential Medicines was adopted in 1977, it has become a popular tool among health professionals and Member States. WHO’s joint effort with the United Nations Committee on Economic, Social and Cultural Rights has resulted in the inclusion of access to essential medicines in the core content of the right to health. The Committee states that the right to health contains a series of elements, such as availability, accessibility, acceptability and quality of health goods, services and programmes, which are in line with the WHO statement that essential medicines are intended to be available within the context of health systems in adequate amounts at all times, in the appropriate dosage forms, with assured quality and information, and at a price that the individual and the community can afford. The author considers another perspective by looking at the obligations to respect, protect and fulfill the right to health undertaken by the states adhering to the International Covenant of Economic, Social and Cultural Rights (ICESCR) and explores the relationship between access to medicines, the protection of intellectual property, and human rights.

Human Rights Norms and Standards
The article uses the 3AQ framework to briefly review how the four normative elements of the right to health relate to WHO’s EM program. Attention is primarily paid to the obligations to respect, protect, and fulfill the right to health and access to EM in particular, under the ICESCR. Given that access to EM is part of the right to health, the author argues states must not block or impose discriminatory criteria that would discourage the supplies of drugs in order to respect the right to health and access to EM. With the obligation to protect the right to health, states have to prevent infringement of the right by third parties by ensuring, for example, that drugs are safe and of a high quality. States must also take positive steps to fulfill its obligations under the right to health and EM access.

Interactions Between State and Non-State Actors
The author concludes that conceiving of access to EM as a right strengthens the patient’s position, provides the tools to report violations, and guides states’ pharmaceutical policies. The role of non-state actors is not explored outside of the indirect reference of patient rights.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not explicitly discuss the pharmaceutical industry or other MNCs
10. Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure?

Trouiller, Patrice; Torreele, Els; Olliaro, Piero; White, Nick; Foster, Susan; Wirth, Dyann and Bernard Pécoul


Abstract: Infectious diseases cause the suffering of hundreds of millions of people, especially in tropical and subtropical areas. Effective, affordable and easy-to-use medicines to fight these diseases are nearly absent. Although science and technology are sufficiently advanced to provide the necessary medicines, very few new drugs are being developed. However, drug discovery is not the major bottleneck. Today’s R&D-based pharmaceutical industry is reluctant to invest in the development of drugs to treat the major diseases of the poor, because return on investment cannot be guaranteed. With national and international politics supporting a free market-based world order, financial opportunities rather than global health needs guide the direction of new drug development. Can we accept that the dearth of effective drugs for diseases that mainly affect the poor is simply the sad but inevitable consequence of a global market economy? Or is it a massive public health failure, and a failure to direct economic development for the benefit of society? An urgent reorientation of priorities in drug development and health policy is needed. The pharmaceutical industry must contribute to this effort, but national and international policies need to direct the global economy to address the true health needs of society. This requires political will, a strong commitment to prioritize health considerations over economic interests, and the enforcement of regulations and other mechanisms to stimulate essential drug development. New and creative strategies involving both the public and the private sector are needed to ensure that affordable medicines for today’s neglected diseases are developed. Priority action areas include advocating an essential medicines R&D agenda, capacity-building in and technology transfer to developing countries, elaborating an adapted legal and regulatory framework, prioritizing funding for essential drug development and securing availability, accessibility, distribution and rational use of these drugs.

Human Rights Norms and Standards

The article implicitly deals with the right to health norms of availability, accessibility and quality, as well as the principle of non-discrimination, as it outlines barriers to EM development for neglected diseases and suggests strategies to overcome them. The article also highlights three barriers that contribute to the poor facing greater burdens in accessing EM. First, the cost of research and development is high. Second, current regulatory barriers are stricter and more complex than in the past as the International Conference on Harmonisation (ICH) focuses on drug development in rich countries where
safety is the primary concern. Insistence on strict compliance with ICH guidelines is a disadvantage to small companies and increases development costs. The authors argue, however, that concerns for the quality, efficacy and safety of drugs for neglected diseases should be put in the context of the massive public health failure caused by the current lack of treatment. Third, the protection of intellectual property rights likely limits access despite industry claims that stronger patent protection in developing countries would create incentives for research on the health needs of poor countries. Furthermore, broad patenting of basic technologies and common resources could hinder research into neglected diseases and/or increase costs by requiring multiple licenses.

Interactions Between State and Non-State Actors
To overcome these barriers and stimulate drug development the authors argue that the global economy needs to be restructured so that public health needs are addressed. The authors propose four approaches, both legal and operational, that can be used to encourage EM development: 1) an EM R&D agenda with a prioritized, regularly updated list of what is needed. Government subsidized industrial R&D can then require the inclusion of research on neglected diseases as a condition for funding; 2) a supportive international policy, legal, and regulatory framework for capacity building and technology transfers. Within this approach, drug development can also help drive development; 3) improvements in the legal and regulatory environment through a Neglected Diseases Treaty that encourages R&D and ensures access. It is asserted that such a treaty would address the imbalance between the rights and obligations in international treaties, include intellectual property issues, and address differential pricing, licensing strategies, quality, efficacy and safety standards, as well as access and affordability criteria; and 4) increased financing of drug development for neglected diseases and ensured access to drugs. This could be achieved through PPPs, centralized purchases, or by requiring pharmaceutical companies to use some of their profits on EM before granting a patent on a new product.

The authors note that the pharmaceutical industry should play a role in addressing the lack of drugs for neglected diseases. However, their specific recommendations focus primarily on actions that can be implemented by states, including the need for governments to create incentives and disincentives to encourage the industry to act on these issues. The role of the pharmaceutical industry in the context of the article’s four proposed approaches warrants further exploration.
Distinctions Between Pharmaceutical Companies and other MNCs
The article explicitly refers to pharmaceutical companies without addressing the role of other MNCs.

IV. PUBLIC-PRIVATE PARTNERSHIPS

1. Public-Private Partnerships: From There to Here
Croft, Simon L

No abstract available

Summary: Major changes in research and development (R&D) for drugs to treat tropical and neglected diseases have occurred in the past five years. Public-private partnerships for product development (PD PPPs) have emerged since rising drug development costs pushed pharmaceutical companies out of R&D for these diseases of the developing world and are now having an impact on the discovery and development of new medicines to treat them. PD PPPs can be an efficient model for bridging the translational research gap between basic research and clinical development by bringing together expertise from academia, the pharmaceutical industry and the public sector. Sustainability of funding is a serious problem. At present, one or two key philanthropic organisations provide a large proportion of the funding. Drug development typically takes 10 years and only 10 per cent of initial projects make it into the clinic. The partnerships need to widen their funding base and ensure that the funders understand the high level of attrition. Public-private partnerships have proved that they can move compounds quickly through the R&D pipeline. The challenge is to ensure that the products are delivered to the people who need them and to ensure that scientists in endemic countries are involved in the whole process.

Human Rights Norms and Standards
The article does not explicitly discuss the human rights dimensions of PD PPPs, even as the programs can presumably help both consumer and manufacturing states meet their obligations to provide accessible health goods and services under the right to health.

Interactions Between State and Non-State Actors
In reviewing the rise of product development private-public partnerships (PD PPPs), and analyzing four case studies, the article mentions that the involvement of disease endemic countries is important for their success, but
does not discuss why such involvement is necessary. It is also unclear whether the state needs to be directly involved or whether the involvement of local scientists and communities is necessary.

The article argues that while PD PPPs already involve pharmaceutical and biotech companies, more engagement with the industry is needed. Highlighting the existence of problematic drug procurement and delivery strategies in countries, the article implies that states should also be more involved in PPPs in order to ultimately ensure access to emerging new products.

Distinctions Between Pharmaceutical Companies and other MNCs
The article refers to both the pharmaceutical and biotech industries as critical partners in PPP operations but does not distinguish between them nor mention MNCs more generally.

2. Collaboration Between Private Pharmacies and National Tuberculosis Programme: An Intervention in Bolivia
Lambert, ML; Delgado, R; Michaux, G; Vols, A; Speybroeck, N and P Van der Stuyft

Abstract: Background: Public–private partnerships are felt to be necessary for tuberculosis (TB) control in some developing countries. Objectives: To evaluate the potential of a collaboration between the National TB Programme (NTP) and private pharmacies in Bolivia, the country with the highest TB incidence in Latin America. Methods: We contacted the local Pharmacists' Association in the city of Cochabamba, and designed a two phase intervention. The objectives of the first phase were to decrease the availability of TB drugs in private pharmacies on a voluntary basis, and to improve referral of clients seeking TB drugs to the NTP. A survey of all pharmacies allowed for a before–after comparison with a baseline survey. The objectives of the second phase were to obtain referral of pharmacy clients with chronic cough for TB screening in the NTP. This phase was started in 70 pharmacies and evaluated after 2 months using the referral slips issued by the pharmacists. Results: The proportion of pharmacies selling TB drugs decreased (rifampicin: 23–11.5%; isoniazid: 16–3.1%; P < 0.001) and the proportion of pharmacies referring to the NTP clients seeking TB drugs increased (22–58%; P < 0.0001). In the second phase, 26 of 70 pharmacies (38%) referred a total of 41 clients for screening in the NTP (i.e. an average of 0.29 clients per pharmacy and per month); 11 of 41 (27%) were screened and three of 11 (27%) diagnosed with smear-positive TB. Conclusion: The first phase of the intervention proved effective in reducing the availability of the main TB drugs in pharmacies, and in improving referral of
clients seeking TB drugs. Key factors in this success were not specific to Bolivia, and collaboration between private pharmacies and public services appears possible in that respect. However, collaboration with pharmacies does not seem an efficient way to increase the number of patients screened for TB, and to shorten delays to TB diagnosis and treatment.

Human Rights Norms and Standards
The article implicitly addresses the right to health norms of availability, accessibility, and quality of TB drugs in its assessment of the PPP interventions. The objective of the first-phase intervention shifted the availability of TB drugs from the private to the public sector in an attempt to improve quality. The objectives of the second-phase intervention attempts to improve quality of health service delivery. Additionally, by increasing diagnosis of TB within the NTP, the intervention aimed to promote availability and accessibility of TB drugs.

Interactions Between State and Non-State Actors
The authors analyze the interactions between the Bolivian government and the private health sector as the PPP aimed to direct clients from private pharmacies to NTP affiliated public institutions. The authors note an inverse relationship between private and public sector care in Bolivia: apparently, TB drug sales in private pharmacies have been decreasing in parallel with improved NTP visibility and coverage. Although losing clients could be a disincentive for pharmacies to refer out TB patients to NTP sites, the study finds that pharmacists appreciated the collaboration with public services as an opportunity to improve their image as “fully-fledged” health professionals. However, the authors also recognize that unsolicited advice from pharmacists may not be enough to ensure that targeted clients actually access NTP services.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not mention pharmaceutical companies or other MNCs.

Maïga, Fatoumata Ina; Haddad, Slim; Fournier, Pierre and Lise Gauvin

Abstract: Many African countries have introduced cost recovery mechanisms based on the sale of drugs and measures aimed at improving drug supply. This study compares prescribing and selling practices in Mali, in 3 cities where the public sector contributes differentially to the supply of drugs on the market.
Multilevel models are used to analyse the content and cost of 700 medication transactions observed in 14 private and public legal points of sale.

Results show that the objective of improving access to drugs seems to have been achieved in the sites studied. Costs of prescriptions were lower where public health services had been revitalized. Affordable generic drugs were accessible and widely used, even in the private sector. However, measures intended to rationalize the prescription and delivery of drugs did not always have the desired effect. While agents in the public sector tended to prescribe fewer antibiotics, injectables, or brand-name drugs, the data confirm the virtual absence of advice concerning the use or the side effects of the drugs in both public and private sectors. In addition, data supported the notion that the public and private sectors are closely intertwined. Notably, availability of drugs in the public sector contributed to diminishing the prices charged in the private sector. Similarly, the use that agents in the public sector made of the opportunities afforded by the presence of the private pharmaceutical sector provided another illustration of interrelatedness. Finally, the data showed that the presence of a private sector, which has not been affected by measures aimed at rationalizing prescription and sales practices, limits the effects of measures implemented in the public sector. More assertive policies, based on strategies encompassing actors in the private sector, are needed to increase the safety and effectiveness of prescription and sales practices.

**Human Rights Norms and Standards**

The study does not address human rights norms and standards in an explicit manner. Nonetheless, in its analysis of prescription and selling practices in Mali, the article implicates right to health norms of availability, financial accessibility or affordability, and quality. The study also implies that national drug plans help states fulfill their obligations under the right to health while their reliance on generic medicines suggests that the right to benefit from scientific progress is implicated in these programs.

**Interactions Between State and Non-State Actors**

The authors discuss how, in Mali, drugs in generic form are more accessible because they are cheaper and the careful promotion of essential drugs may help increase the demand for generics. The authors draw some generalizations from the results of their study, which have implications for states seeking to realize their obligation to ensure access to medicines, as well as the interactions between the public and private health sectors. In sum, they suggest that states should play a heavy role in providing access to medicine by providing drugs at a cost lower than what currently exists on the market.
At the same time, the authors highlight some challenges that may face states in their efforts to ensure access to drugs. Efforts to rationalize the prescription and delivery of drugs were not successful in Mali as professionals in the public sector did not prescribe fewer antibiotics, injections, or brand-name drugs than in the private sector. Moreover, the study reveals that drug sellers in Mali did not inform consumers of the side-effects of the drugs prescribed.

The authors conclude that the availability and accessibility of essential drugs can be improved though the implementation of national drug plans and by suppressing prices in the private sector. As the public and private sectors are related, it is important to broaden the scope of national drug plans to include the private sector so that they can be better involved and regulated. The study emphasizes that changing prescription habits remain a difficult problem to solve. Outside of general reference to the private sector, the role of other non-state actors is not examined.

Distinctions Between Pharmaceutical Companies and other MNCs
The role of MNCs and pharmaceutical companies is not discussed.

4. Stimulating Pharmaceutical Research and Development for Neglected Diseases
   Mrazek, Monique F and Elias Mossialos

Abstract: New vaccines and drug treatments are needed for tackling the neglected diseases (NDs) of poor countries. These diseases are associated with high levels of mortality and/or morbidity, but lack appropriate vaccines and drug treatments because of bacterial resistance, toxicity, long-treatment protocols, problems with administration or because none are available. Current initiatives directed at research and development (R&D) of NDs are being led predominantly by the governmental, inter-governmental and private not-for-profit sectors implemented by way of public–private partnerships. Push and pull mechanisms targeted at the pharmaceutical industry have also been proposed as another way to stimulate R&D of NDs; however, these should be viewed with some caution. Stimulating R&D for NDs is important as part of a wider long-term public health strategy and must be addressed simultaneously with resolving more immediate problems of access to medicines and health system sustainability in less developed countries (LDCs).

Human Rights Norms and Standards
Although they do not specifically discuss right to health norms or standards, the authors recognize that drug availability and accessibility in LDCs is limited due
to lack of affordable prices, sustainable financing, rationale selection and use, and reliable systems of drug supply and health care. Additionally, they describe limitations in quality and appropriateness of drug treatment, which include lack of diagnostic tools, necessary follow-up, and increased resistance associated with over-prescribing, inappropriate prescribing or inadequate prescribing. In these ways, the authors’ implicitly relates to the right to health norms of accessibility, economic accessibility or affordability, and quality. The focus on neglected diseases also relates indirectly to the human rights principles of equality and non-discrimination. The article argues that PPPs should be transparent, accountable to public interest, have a clear governance structure, and delineate specific short term and long-term objectives. R&D of ND must also be seen as part of a wider public health strategy and not viewed in isolation.

Interactions Between State and Non-State Actors
The authors describe several PPP initiatives that bring together funds and/or expertise from governmental, inter-governmental and not-for-profit organizations along-side funds and/or expertise from the for-profit sector. The authors mention the need for better monitoring and evaluation of these PPPs to determine the precise impact of these actors. The challenges these initiatives face include reconciling differing research objectives, product selection, addressing intellectual property rights and product pricing, focusing funding and project objectives, exchanging information, and ensuring that R&D developments are followed by commitment to ensure world-wide access to any new product. To alleviate some of these challenges, the authors assert the need for clear guidelines to govern the interactions between governmental, NGO, and private sectors. Additionally, the authors call for coordination and collaboration between different PPPs, not just within the various actors of a given PPP.

The article’s discussion about stimulating R&D revolves around push and pull financial mechanisms for researchers and pharmaceuticals. Push mechanisms aim to reduce the costs of R&D by providing direct funding or tax credits, for example. Pull mechanisms focus on improving the attractiveness of the market to investors by strengthening intellectual property rights, advance purchase funds, and other approaches that intend to correct for the market’s failure to attract for-profit investors. Ultimately, the authors note that while sustained funding for R&D of ND is needed, push and pull mechanisms should be assessed carefully.

Distinctions Between Pharmaceutical Companies and other MNCs
The article specifically mentions pharmaceutical companies on several occasions, though it does not distinguish them from other MNCs.
5. Control of Tuberculosis in an Urban Setting in Nepal: Public-Private Partnership

Newell, James N; Pande, Shanta B; Baral Sushil C; Bam Dirgh S and Pushpa Malla

Abstract: Objectives: To implement and evaluate a public–private partnership to deliver the internationally recommended strategy DOTS for the control of tuberculosis (TB) in Lalitpur municipality, Nepal, where it is estimated that 50% of patients with TB are managed in the private sector.

Methods: A local working group developed a public–private partnership for control of TB, which included diagnosis by private practitioners, direct observation of treatment and tracing of patients who missed appointments by nongovernmental organizations, and provision of training and drugs by the Nepal National TB Programme (NTP). The public–private partnership was evaluated through baseline and follow-up surveys of private practitioners, private pharmacies, and private laboratories, together with records kept by the Nepal NTP. FINDINGS: In the first 36 months, 1328 patients with TB were registered in the public–private partnership. Treatment success rates were >90%, and <1% of patients defaulted. Case notification of sputum-positive patients in the study area increased from 54 per 100 000 to 102 per 100 000. The numbers of patients with TB started on treatment by private practitioners decreased by more than two-thirds, the number of private pharmacies that stocked anti-TB drugs by one-third, the number of pharmacies selling anti-TB drugs by almost two-thirds, and sales of anti-TB drugs in pharmacies by almost two-thirds. Private practitioners were happy to refer patients to the public–private partnership. Not all private practitioners had to be involved: many patients bypassed private practitioners and went directly to free DOTS centres.

CONCLUSIONS: A combination of the strengths of private practitioners, nongovernmental organizations, and the public sector in a public–private partnership can be used to provide a service that is liked by patients and gives high rates of treatment success and increased rates of patient notification. Similar public–private partnerships are likely to be replicable elsewhere, as inputs are not large and no special requirements exist.

Human Rights Norms and Standards

Although this article does not explicitly discuss human rights in general or the right to health in particular, the right to health norms of availability, accessibility and quality are implicitly central to the description of the PPP. Essentially, the authors contend that private health services are generally more convenient and holistic, but TB patient retention and cure rates are generally poor. Public services under National TB Programmes (NTPs), on the other hand, are generally of good quality, but less convenient in terms of time and location...
and treat diseases rather than people. Therefore, the public-private partnership aimed to capitalize upon the strengths of each approach to health services. The methods used to establish the PPP in Nepal were related to the promotion of the right to information, although the right was not explicitly mentioned in the article.

Interactions Between State and Non-State Actors
The authors discuss specific operational aspects of the relationships between state and non-state actors in the context of the piloted PPP. The intervention aimed to increase private practitioner’s referrals to the other private institutions, NGOs and the public sector that had been selected and were willing to provide DOTS treatment. This aim evolved from the initial intention, which sought to have private practitioners directly provide the DOTS, but it became clear that private practitioners were not interested in becoming providers of DOTS. This strategy required private practitioners to have confidence in the public/non-governmental institutions in order to refer patients to participating DOTS centers. Interestingly, the authors point out that long-term sustainability of the program rests in the hands of the local municipality since support from NGOs for advocacy and late patient tracing could cease. While the authors conclude that similar PPPs are likely to be replicated elsewhere, they also warn that such initiatives should only be considered when a country’s national TB program is strong. An ineffective PPP may have irreversible adverse consequences, such as multi-drug resistance in the case of TB and other infectious diseases.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not specifically mention pharmaceutical companies or MNCs.

6. Drug Discovery and Beyond: The Role of Public-Private Partnerships in Improving Access to New Malaria Medicines
   Nwaka, Solomon

No abstract available

Summary: Traditional pharmaceutical research and development (R&D) strategy has failed to address the desperate need for new antimalarial drugs. The populations affected are too poor to attract commercially-driven R&D. Over the last few years, a new model, the public-private partnership for product development, has radically changed the antimalarial R&D landscape. The partnerships bring together academic and industry expertise with funding
from governmental, philanthropic and charitable sources. The Medicines for Malaria Venture, a not-for-profit foundation based in Geneva, aims to develop new antimalarials for developing countries through public-private partnership. It is currently managing a portfolio of around 20 projects at various stages of development. However, as in all drug R&D, some of these projects will fail. The portfolio approach helps to maximize the chances of success, but there are obvious challenges, including financial and managerial ones. Proactive management of the two vital interfaces in the drug supply chain is important for success. Upstream, basic research must be aligned with translational research in order to ensure a continuous supply of leads into the development pipeline. Meanwhile, downstream, drug discovery and development must be aligned with access to ensure optimal health impact. All stages require partnership, sustainable financing and the engagement of disease-endemic countries. The recent G8 report on Africa has lent support to mechanisms aimed at improving health and achieving the Millennium Development Goals.

Human Rights Norms and Standards
In reviewing one PPP’s effort to address the lack of access to new antimalarials through research and delivery, the article analyzes operational efforts which indirectly relate to the right to health norms of availability and accessibility, as well as the right to benefit from scientific progress.

Interactions Between State and Non-State Actors
The article highlights the need for PPPs to coordinate translational research with basic research with access and delivery so that there is a constant supply of new products that actually reach the poor, noting the significant role of pharmaceutical companies in doing so. The article further argues that obstacles to basic research need to be improved by giving academics access to the facilities necessary to conduct such research, addressing regulatory hurdles, and engaging with policymakers to ensure that there is no delay in delivery. Moreover, the shortage of clinical trial sites should be addressed to improve access. The role of the state is not directly discussed in the article; however, it would appear to be an important factor at both the basic research stage – through the funding of academic and other research – and at the delivery stage discussed. Although the article argues that building capacity and engaging scientists in the epidemic country is also crucial to the success of the PPPs, it does not provide specific reasons for the importance of their involvement.

Distinctions Between Pharmaceutical Companies and other MNCs
The article highlights the role of various pharmaceutical companies in the Medicines for Malaria Venture but does not address MNCs in broad terms.
Ramiah, Ilaveil and Michael R. Reich

Abstract: The African Comprehensive HIV/AIDS Partnerships (ACHAP) played a major role in initiating Botswana's antiretroviral (ARV) program in 2001. ACHAP is a prominent public-private partnership involving Merck and its foundation, the Bill and Melinda Gates Foundation, and the government of Botswana. This paper analyzes ACHAP's efforts to assist Botswana with its ARV program, the first and most advanced in sub-Saharan Africa. It identifies five features of the model and shows how they contributed to the ARV program. It also raises questions about ACHAP's role in scaling up and sustaining the program, as Botswana faces the challenges of treating growing numbers of HIV-infected people.

Human Rights Norms and Standards
The article implicitly discusses right to health norms of availability, accessibility, and quality as relates to ACHAP's objectives of improving access to ARV treatment for HIV positive individuals in Botswana. The ACHAP PPP with Botswana increased availability of ARVs, particularly given Merck’s provision of two ARV drugs, Crixivan (indinavir) and Strocrin (efavirenz). Additionally, ACHAP provided financial support for KITSO, a training initiative for health care workers in the ARV treatment program, to improve quality of care.

Interactions Between State and Non-State Actors
Given the close collaboration between ACHAP and the Botswana government, the authors raise several significant points regarding interactions between state and non-state actors. According to the authors, the political stability and leadership in Botswana helped to attract support from ACHAP. The authors attribute much of the success of the PPP to the active engagement of ACHAP sponsors with the Botswana government in the design and implementation of the ARV programs that focused on building institutional capacity in country. The access to global networks afforded by ACHAP played a major role in the establishment of the program. One of the strengths of the PPP model, the streamlining of operating procedures, derived in large part from adaptation of the private sector approach. It is worth noting in this regard the private sector is not generally held to the same standards of public accountability and transparency that are part of a human rights approach and apply to government. While ACHAP has provided essential resources that are being used to promote the right to health, the authors raise concerns about sustainability. The role of civil society organizations is not explored.
Distinctions Between Pharmaceutical Companies and other MNCs
The article explicitly discusses the role of the pharmaceutical industry as it analyzes the PPP between Merck (as part of ACHAP) and the Botswana government. It does not address MNCs in general.

8. Improving Immunization Equity through a Public-Private Partnership in Cambodia.
Schwartz, J. Brad and Indu Bhushan.

Abstract: Objective: To examine the effects on immunization equity of the large-scale contracting of primary health-care services in rural areas of Cambodia. Methods: Data were obtained pre-intervention and post-intervention from a large-scale quasi-experiment in contracting with nongovernmental organizations to provide primary health care in nine rural districts of Cambodia between 1999 and mid-2001. Coverage targets and equity targets for all primary health-care services, including immunization of children, were explicitly included in the contracts awarded in five of nine rural districts, which together have a population of over 1.25 million people. The remaining four districts used the traditional government model for providing services and were given identical targets. Findings: After the 2.5 years of the trial, bivariate and multivariate analyses of the results suggested that although there was a substantial increase in the proportion of children who were fully immunized in all districts, children in the poorest 50% of households in the districts served by contractors were more likely to be fully immunized than poor children living in similar circumstances in districts using the government's model, all other things being equal. Conclusion: The contracting approach described in this paper suggests a means of moving towards a more equitable distribution of immunization services in developing countries.

Human Rights Norms and Standards
The article implicitly addresses the human rights principles of equality and non-discrimination in its analysis of a PPP that targeted poor rural households in Cambodia. The PPP aimed to increase the overall proportion of children who are fully immunized to 70% with the “equity goal” to target the children from the poorest 50% of households. Given that the PPP aimed to improve access to immunizations services in rural areas of Cambodia, the article also relates indirectly to the right to health norm of accessibility. More specifically, the authors dealt with two aspects: physical accessibility and economic accessibility or affordability. They found that children living in contracted districts that had a higher likelihood of being fully immunized. Not surprisingly, after controlling
for relevant variables, children from wealthier households have higher likelihoods of being fully immunized.

**Interactions Between State and Non-State Actors**
The operational interactions between state and non-state actors in this PPP derived from three different models for service delivery: 1) contracting-out, in which contractors had complete line responsibility for service delivery; 2) contracting-in, in which the contractors worked within the government’s system to strengthen the existing district administrative structure; and 3) the government model, in which management of services remained with the government, and drugs and supplies were provided through normal government channels. In implementing the PPP intervention, the government randomly assigned districts to one of these three service delivery models. The authors demonstrate that, all other factors being equal, living in a contracted district is positively correlated with more equitable distribution coverage.

The PPP also used guidelines from the World Health Organization (WHO) to define new operational districts and to strengthen and broaden the services provided by the primary health care system, highlighting the interaction between states, non-state actors and inter-governmental organizations.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article does not directly address pharmaceutical companies or MNCs.

**9. A Political Analysis of Corporate Drug Donations: The Example of Malarone in Kenya**
Shretta, R; Walt, G; Brugha, R and RW Snow

**Abstract**: This paper describes the introduction of the Malarone Donation Programme in Kenya. Using a policy analysis approach it illustrates the political nature of donation programmes and how they are affected by a large and varied group of national, regional and international stakeholders, with different levels of influence and experience. The paper shows that interaction between these different groups may affect the development and implementation of the donation programme. It ends by raising some more general questions about public/private partnerships and corporate donation programmes, and their potential impact on national drug policies.

**Human Rights Norms and Standards**
As one of the primary objectives of the Malarone Donation Program (MDP) was to donate up to one million treatment courses of Malarone globally per year for
patients with uncomplicated malaria, the program’s intentions are implicitly related to the right to health norms of availability and accessibility of medicines.

Interactions Between State and Non-State Actors
The Malarone Donation Program is a PPP between the pharmaceutical company Glaxo-Wellcome and the Task Force for Child Survival and Development (TFCSD), which formed an International Advisory Committee with expert international malariologists, WHO-Geneva, UK Department for International Development (DFID), the World Bank, Glaxo-Wellcome, and TFCSD. The membership did not initially extend to regional representatives from AFRO or to DFID’s East Africa Office. The authors specifically examine four areas related to governance that also all play into the acceptability of the intervention: accountability, representation, competence and appropriateness, and respect for due process. These four areas implicitly relate to cross-cutting human rights principles of accountability, transparency and participation. Overall, the authors’ analysis indicates that much of the initial conflict between the early members of the IAC and critics of the intervention (local scientists, AFRO, WHO country and DFID-EA representatives) derived from a lack of open dialogue between and involvement of all stakeholders. They also suggest that the intervention may have been overreaching given the under funded and weak public sector infrastructure.

Much of the author’s analysis focuses on power differentials between various actors in the PPP. In the end, the authors raise questions about the sustainability and equity of a PPP such as the MDP and emphasize the need for an inclusive and participatory process that takes into account the local resources and capacity so as to make effective use of the increased access to medicines.

Distinctions Between Pharmaceutical Companies and other MNCs
This article addresses the specific role of pharmaceutical companies in the context of the MDP between Glaxo-Wellcome and TFCSD. It does not discuss other MNCs.

10. **TB: A Partnership for the Benefit of Research and Community**
*Walzl, Gerhard; Beyers, Nulda and Paul van Helden*

*No abstract available*

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67 Candidates for Malarone must have also failed initial treatment and live in areas with highly endemic malaria and known resistance to standard, first-line therapy
Summary: A public-private partnership (PPP) involving Stellenbosch University in South Africa and GlaxoSmithKline (GSK) has benefited both research and a local community where tuberculosis (TB) is endemic. The venture, part of GSK’s Action TB programme, enabled the University’s Desmond Tutu TB Centre to establish an epidemiological field site in two suburbs of Cape Town where the annual risk of TB infection is 3.5%. Collaboration between the centre and GSK focused on the development of a surrogate marker model able to predict patient outcome with relative accuracy. Such models may be useful tools for diagnosis/prognosis and for shortening clinical trials of novel TB agents. Other research findings stemming from the Action TB partnership suggest that exogenous reinfection is responsible for the majority of relapse cases and that adults often have infection with multiple strains. The local community has been empowered by the implementation of the Directly Observed Treatment, Short-course (DOTS) programme and benefited from improved education about health in general and TB in particular. The centre has also provided employment for many local people in field work and other roles. Meanwhile, national and international publicity about the centre’s work has aided in generating the essential political will to allocate resources and shape healthcare priorities, benefiting this impoverished community.

Human Rights Norms and Standards
The article does not discuss the PPP in terms of human rights. Nonetheless, the right to health norms of accessibility and availability are implicitly related to the partnership’s goals of exploring new diagnostics and strengthening the local DOTS program. At the same time, the right to information and the right to benefit from scientific progress are also indirectly related to the partnership’s educational and research objectives.

Interactions Between State and Non-State Actors
The article highlights the significance of the operational relationship between a pharmaceutical company and civil society, in this case an academic institution, to promote development of new TB diagnostics as well as local access to DOTS. According to the article, this partnership has helped increase awareness of the disease through its educational work and influenced how politicians prioritize healthcare and allocate resources. In this manner, the relationship between the civil society and the private sector put pressure on the state to prioritize health issues including access to treatment and diagnostics for TB.

Although not a direct partner in the PPP, the article briefly mentions that the local community participated and benefited from increased employment, and improved communication with healthcare providers. The ways in which human
rights frameworks and approaches can contribute to community engagement with the PPP is not discussed.

Distinctions Between Pharmaceutical Companies and other MNCs
The article deals directly with the experience of one pharmaceutical company and does not elaborate on potential implications for MNCs.

11. Facing the Challenge: the Symposium in Context
Widdus, Roy

No abstract available

Human Rights Norms and Standards
Summarizing the results of a symposium on PPPs, the author suggests some steps partnerships should now take in order to achieve their goal of providing access to medicine for the world’s poor and improve their sustainability. In doing so, the article implicitly deals with the right to health norm of accessible goods and services.

Interactions Between State and Non-State Actors
To secure access, the article argues PD PPPs will need to engage policymakers, scientists and other healthcare professionals in the disease-endemic country as well as access PPPs where appropriate. The biggest problem facing PD PPPs is unrealistic expectations. Given the high rate of turnover among staff in funding organizations, the article argues partnerships will need to continually re-educate new staff. This is particularly necessary as additional funding is needed just to move the products that PD PPPs are currently working on through the development pipeline. Moreover, translational research will need to be aligned with basic research to improve delivery of new products. The ways in which human rights issues may relate to the sustainability of PPPs is not explored.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not address MNCs while the role of pharmaceuticals as key players in access and PD PPPs is implied.

12. Public-Private Partnerships: An Overview
Widdus, Roy
Abstract: The development and marketing of medicines needed specifically to combat diseases of the developing world are commercially unattractive because the populations concerned are among the poorest on earth. Partnerships which bring together pharmaceutical companies, academics, not-for-profit organizations, philanthropists, governmental and inter-governmental agencies are an increasingly popular solution. These partnerships result in a complementarity of skills and resources that can accelerate the development and delivery of new medicines to those in need. Over the last 10 years or so, these public-private partnerships (PPPs) have grown significantly in number and diversity. However, they tend to cluster into two main groups: those dealing with product development (PD PPPs), and those concerned with improving the access of new medicines to target populations (Access PPPs). The Initiative on Public-Private Partnerships for Health was set up four years ago to monitor the performance of these new partnerships. After a series of studies of Access PPPs, it concluded that they provide significant benefits with very few side effects, particularly in the case of tropical diseases.

Human Rights Norms and Standards
The article implicitly analyzes the right to health norms of availability and accessibility in its assessment of how PPPs can overcome access barriers to drugs by bringing together the skills and resources necessary to address these issues successfully. The focus of PPPs on neglected and overlooked diseases is indirectly related to the human rights principle of non-discrimination.

Interactions Between State and Non-State Actors
PPPs are based on operational collaboration between state and non-state actors. The article defines PPPs as consisting of partnerships between three sectors- the public sector (including international governmental organizations controlled by states such as the WHO), the for-profit sector, and civil society (which includes academia). The author distinguishes between two types of PPPs – product development PPPs (PD PPPs) and access PPPs. PD PPPs use a “portfolio” approach similar to that used in the pharmaceutical industry where a number of different products are promoted and developed in parallel. Pharmaceutical companies often use their own facilities to carry out the tests, giving a PD PPP greater flexibility and lowering the investment it has to make in its own staff and infrastructure. Because PD PPPs are relatively new, the article notes that it remains hard to forecast what impact they will actually have, and that, in the future, expanded funding and performance measures to judge the “success” of the partnerships will be needed. The role of the pharmaceutical industry in monitoring and impact of PD PPPs in explored.

Access PPPs mostly involve donations from pharmaceutical companies or discounted pricing. These partnerships are older than the product development
partnerships and the article contends that they have generally been very successful. Moreover, the article argues that continued support from donors and integration of the PPPs into the local health system from the very beginning is crucial for the success of these programs.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article specifically analyzes the pharmaceutical industry’s role in PPPs while providing an operative definition of PPPs that includes the private sector more broadly.

**V. ACCESSIBILITY OF DRUGS AND/OR SERVICES**

1. **Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally**
   **Dominguez-Urban, Ileana**

*No abstract available*

**Introduction:** This article will concentrate on two aspects of human rights implicated in the regulation of pharmaceuticals: first, the effect of the regulatory process on the availability to consumers of safe and efficacious drugs, and second, the use of human subjects for clinical drug trials or investigational research. The need to distribute potentially beneficial drugs to the sick as expeditiously as possible and the need to protect research subjects are competing forces. In Part I, this article will describe the interdependency of world health care and the globalization of the pharmaceutical market, and will advocate that pharmaceutical products be regulated with a global focus. Part II of this article will describe the international movement to harmonize pharmaceutical regulations, its origins, and goals. Part III will recommend that, in keeping with global human rights concerns, including the need to ensure that safe and efficacious drugs are available to consumers on a global basis, “total harmonization” should not be the goal of harmonization efforts. Part IV will address the effects of harmonization on human subjects in international research, and will advocate greater international protection for subjects through the development of binding, minimum standards, which should include obtaining informed consent and proceeding with human subject research only after oversight by representatives of the scientific and lay communities.
Human Rights Norms and Standards
The article discusses global human rights concerns in broad terms and also explicitly mentions “freedom from harm” as a basic human right in its analysis of pharmaceutical regulation and human subject research (even as this is not legally recognized). The article implicitly deals with the right to health norm of accessibility in its characterization of unnecessary delays in the approval of safe and efficient drugs as a denial of access to medicine. The author’s suggestion that research subjects should also benefit implicitly invokes the right to benefit from scientific progress while informed consent provisions implicate the right to information.

Interactions Between State and Non-State Actors
The article focuses on state action through its regulatory agencies and mostly ignores the role of non-state actors, including pharmaceutical companies who may be pushing for harmonization. Because of the impact of harmonization on developing countries, the article argues that they should be consulted and considered in the discussions manufacturing countries have on streamlining the regulatory process. The author argues that a binding document governing research on human subjects is needed to promote ethical research, which would set out minimum, universal standards but allow countries to tailor standards and enforcement to fit the local culture.

Distinctions Between Pharmaceutical Companies and other MNCs
The author mentions pharmaceutical companies and they are clearly implicated in the focus of the article, but MNCs in general are not discussed.

2. Improving Access to Pharmaceuticals in Brazil and Argentina
Homedes, Nuria and Antonio Ugalde

Abstract: The population of many Latin American countries is having increasing difficulty in accessing needed medicines due to the rise in their unitary cost and the growing number of poor in most countries of the region. A number of countries have taken steps to increase access to pharmaceuticals and have had different levels of success. This article reports on two country-wide programmes: the AIDS programme in Brazil, which has been judged as being highly successful, and the Remedia programme that has been implemented recently in Argentina. Both programmes have significantly increased access to needed pharmaceuticals, and Argentina has done it in a record time. In the discussion, we suggest that pharmaceutical interventions are successful when there is a firm political commitment, they are comprehensive, include the participation of
civil society, and use a combination of methods to control the rising cost of medicines, including centralized international competitive bidding processes for drug procurement and reliance on multi-source drugs.

**Human Rights Norms and Standards**
This study implicitly deals with right to health norms in its analysis of the availability, accessibility and quality of medicines in Brazil and Argentina. The review of Brazil’s national program highlights how state efforts relate to both financial accessibility and non-discrimination. Reducing or eliminating the costs of HIV/AIDS drugs by strengthening the local pharmaceutical industry improves financial accessibility, while the lack of adequate treatment for pregnant women suggests that access is not provided equally. The rights to information and education are implicated in the article’s analysis of the difficulty of assessing the therapeutic impact of Argentina’s program without information on how patients use the medicines they receive and the extent to which they understand the advice provided by their physician. The authors do not address human rights as they relate to non-state actors, implicitly or explicitly.

**Interactions Between State and Non-State Actors**
The authors emphasize the importance of civil society and inter-governmental organization participation in the national programs of both countries. In Brazil, a civil society group helped the government reach remote communities. Argentina’s Remedi care program relied on state-run training seminars for pharmacologists and the use of NGOs, Caritas and the Red Cross, to implement the program. The operational relationship between the Brazilian government and the local pharmaceutical industry to strengthen local production and procurement was critical to producing low cost generic medicines and ultimately to improving their accessibility. Moreover, the relationship between Brazil’s government and UNDP helped solidify the international bidding process which was critical to improving access to procured drugs. The role of multi-national pharmaceutical corporations in relation to state and non-state actors is not addressed.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article does not deal with MNCs and only refers to the role of the local pharmaceutical sector in Brazil.

3. **When ‘Development’ Devastates: Donor Discourses, Access to HIV/AIDS Treatment in Africa and Rethinking the Landscape of Development**

   *Jones, Peris S*
   
**Abstract:** If globalization is the mighty tremor shaking the landscape of the 'project of development,' then, in certain regions of the world, HIV/AIDS is surely its epicenter. Nonetheless, for all the burden of the disease, Western donor policy on HIV/AIDS still remains largely silent about the provision of antiretroviral treatment. This paper seeks explanations for this pervasive medical neglect and donor preference for prevention programs over treatment. The postcolonial approach taken in the paper is to regard donor policy on HIV/AIDS -- as illustrated by the UK's Dept for International Development and the Norwegian Agency for Development Co-operation -- as cultural and political exchanges framed by prevailing representations of Africa. The different 'logics' that skew policies toward prevention are identified. For donors and African states alike, HIV/AIDS policies -- like development interventions more generally -- would benefit immensely by foregrounding the human right to health, including critically promoting treatment within a genuine 'prevention-care-treatment' policy continuum.

**Human Rights Norms and Standards**
The article analyzes the approaches donor countries have taken to HIV/AIDS programs in Africa from a post-colonial and developmentalist point of view. The article explicitly invokes the right to health and the right to life in arguing for expansion of HIV/AIDS treatment services in Africa. The article also implicitly refers to discrimination, especially as the author argues donor policies make it difficult for the poor to access Essential Medicines (EM). The author notes that an integrated approach to the disease is necessary since treatment can help reduce the stigma attached to the disease encourage people to get tested, and reduce the economic and social impact of the disease. However, the article points out that due to globalization, civil and political rights have been favored resulting in international trade agreements and debt repayment schemes that have impaired the access of the poor to EM.

**Interactions Between State and Non-State Actors**
The article explicitly deals with interaction between state actors when it discusses donor policies and how it shapes subsequent state and donor interaction. According to the author, there are a number of post-colonial/developmentalist rationales for donors' overemphasis on prevention of HIV/AIDS in Africa: Africa is too poor and too unsophisticated for treatment since health care systems are poor and prices are too high and donors worry that any resources used for treatment will be taken away from prevention efforts; donors worry that corruption will lead to an unequal distribution of drugs; and donors emphasize behavioral modification and changes in sexual behavior. The author’s perception of the roles played by the pharmaceutical industry or the private sector in these interactions are not explored.
Distinctions Between Pharmaceutical Companies and other MNCs
The article does not explicitly refer to pharmaceutical companies or MNCs.

4. Access to HIV Drugs: Are We Changing the Two World Paradigm?
   Lazzarini, Zita

No abstract available

Introduction: This paper examines some aspects of this paradigm shift, whereby we have gone from assuming that combination therapy for HIV could never be given in India or Africa, to asking “Why not? Why is it that millions of people who could benefit from something are being denied it?” First, the paper will review the current situation, the global disparities that frame this debate, and then it will look at potential barriers to and opportunities for improving HIV care. Next, it will consider, specifically, the role of international law and human rights in changing the landscape and the roles of state and non-state actors in making change possible.

Human Rights Norms and Standards
The article takes up human rights explicitly as a framework for analyzing access to HIV drugs, arguing that it can help frame the debate by recognizing both a general right to benefit from scientific progress and an individual right to benefit from “the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” The author claims these two rights are not in tension with each other and suggests that property protections and wider access to drugs can be reconciled.

Interactions Between State and Non-State Actors
Framing access to HIV/AIDS pharmaceuticals as a right, the article argues that states have an obligation to uphold existing treaties that allow them to respond to a health crisis. They should also use human rights as a tool to reform international law, finance and trade agreements in order to promote more equitable accessibility. The article also discusses how pharmaceutical companies are important partners in making access to care possible, arguing that they are responsible to shareholders as well as the public at large, in part because their research is financed by governments. The article suggests that this gives rise to a moral and possibly legal duty for companies to share these advances with the public; therefore, pharmaceutical corporations should take their role as global citizens seriously and realize that their interest in protecting property rights is limited and should only be pursued to the extent that it does not cause harm.
Moreover, the article states that the academic research community should also
affirm that their primary goal is to create knowledge for all of society to benefit and only secondly to promote business and wealth.

The article posits that a human rights discourse can also be used to make multinational corporations more accountable under international law as they are the most powerful constituents in international trade and financial organizations. In reconciling the right to property and the right to health, the article notes that a strategy should be adopted that recognizes that the right to property is limited. Civil society, the article contends, should push for international finance, trade and human rights regimes to be better coordinated so that human rights obligations regarding accessibility to HIV/AIDS drugs are not subordinated to commercial concerns.

Although the article claims that the right to benefit from scientific progress can be reconciled with the right to property, it does not attempt to reconcile these rights in this paper beyond stating that the right to property is limited. The author does not explore the basis for her claim that pharmaceutical companies may have a legal responsibility to share their advances with the public.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article analyzes the roles of the pharmaceutical industry and does not discuss MNCs in general.

5. Access to Essential Drugs in Guyana: A Public Health Challenge
Seoane-Vazquez, Enrique and Rosa Rodriguez-Monguio

**Abstract:** Guyana's pharmaceutical sector faces major challenges that limit access to essential drugs. This study analyzes Guyana's drug policy and regulation, public financing, and drug procurement and delivery. The study also identifies main barriers to drug access and proposes alternatives to strengthen the country's public health functions. Data were collected from the country's regulatory agencies, public procurement agency, pharmacies, wholesalers, and pharmaceutical companies. The information was supplemented with interviews with a convenient sample of Guyanese health authorities and stakeholders. Data were also compiled from scientific databases, and web pages of the country's Ministries of Health, Commerce and Finance, the Bureau of Statistics, and international organizations. Major barriers to drug access include: (1) lack of national drug policy and regulation, and limited role of the regulatory authority; (2) inefficient drug selection and irrational drug use; (3) insufficient financial resources and lack of drug pricing policy; (4) inefficient planning and managing
public supply system; (5) deficient epidemiological and information systems; and (6) inadequate infrastructures and human resources shortage. Improving drug access in Guyana requires the strengthening of the country’s public health functions and the implementation of a national drug policy and pricing policy, streamlining the drug financing, procurement, and planning and managing drug supply; and adequate infrastructures and human resources. Copyright (c) 2008 John Wiley & Sons, Ltd.

Human Rights Norms and Standards
In assessing the resource-limited public health and essential medicines situation in Guyana, the article provides specific recommendations for improvement which are based both explicitly and implicitly on the right to health and the 3AQ specifically. The article refers to Guyana’s constitutional commitment to the right to free medical attention. However, the government does not provide for all the health needs of its citizens. The authors suggest various recommendations, which implicitly apply aspects of the 3AQ and recognize the right to health. First, they suggest a national drug policy that “promotes equitable access” because access to drugs is curtailed by the lack of supply and manufacturing capabilities.

Second, the authors recommend a series of initiatives to harmonize regulations and standards at a regional level, even as they recognize that regulation capabilities are limited (and consequently the degree to which quality can be monitored). Distribution to rural areas of the country is also limited for a variety of reasons. Private financing occurs through out of pocket expenditures, and some larger employers also finance drugs for their workers. All these challenges lead to decreased economic accessibility or affordability. Additionally, although generics are not regulated, the Guyanese pharmacist’s ethical code does not allow for generic substitution. Finally, the strengthening of existing bodies as well as the development of health capabilities and infrastructure is recommended by the authors, as is competitive procurement to increase economic accessibility or affordability.

Interactions Between State and Non-State Actors
The article focuses primarily on the interactions between Guyanese national institutions. In doing so, however, it notes several implications for the engagement of pharmaceutical companies and the private health sector. Resource limitations jeopardize the regulatory capabilities of relevant government bodies, and subsequently impact the functioning of the pharmaceutical industry and other private non-state actors under regulation. The details of the potential consequences for the actions of non-state actors are not explored in this article.
Distinctions Between Pharmaceutical Companies and other MNCs
The article deals solely though minimally with the pharmaceutical industry and does not refer to other MNCs.

6. Not Just A Tragedy: Access To Medications As A Right Under International Law

Yamin, Alicia Ely

No abstract available

Introduction: This article first sets out the principal norms under international human rights law that relate to access to medications. No issue more starkly illuminates the egregious inequalities that exist in the world today between and within countries and demands that we address such inequalities as urgent matters of social justice in accordance with international human rights law. At the same time, no issue more clearly demonstrates the indivisibility of civil/political and economic/social/cultural rights and challenges national courts and international human rights bodies to evolve in their definitions and approaches toward different rights categories. Part II discusses how the right to life has increasingly been expansively interpreted to include conditions that promote and sustain life with dignity, as well as both the minimum core content and progressive realization of the right to health. Part II also sets out the connections between access to medications and the rights to an adequate standard of living, to work, and to education, as well as between access to medications and the right to enjoy the benefits of scientific progress and the disproportionate effects on children and marginalized groups of failure to ensure access to medications. In Part III, the article examines the obligations that flow from those human rights provisions, which could provide the practical basis for policy-making and legislation. Primarily focusing on the right to health, as defined by the International Covenant on Economic, Social and Cultural Rights (“ICESCR”), the article analyzes governmental obligations according to the tripartite framework of duties that is now well-established under international law: to respect, to protect, and to fulfill. That is, first, states have obligations to respect the right to health by refraining from adopting laws or measures that directly infringe upon people’s health. Second, states have obligations to adopt measures to protect the population from the effects of policies imposed upon states by pharmaceutical companies, third-party states, and international institutions, such as the World Trade Organization (“WTO”). Third, the normative framework of human rights requires adequate progress to fulfill universal access to essential medications. At a minimum in this regard, international human rights law requires a clear plan to be made and deliberate
steps to be taken toward the progressive realization of the right to health and does not permit policies or acts, even under pressure from other actors, which would entail regression in terms of availability or affordability of medications.

**Human Rights Norms and Standards**
The article analyzes how access to medicine relates explicitly to the rights to life, health, benefit from scientific progress, an adequate standard of living, social security, education, and work. Access to essential medicines is highlighted as a legally established right to health standard. The principles of non-discrimination and protection of vulnerable and marginalized groups (particularly children) are also discussed. The article explicitly mentions right to health norms in noting that the obligation to protect, as elaborated upon by the ICESCR, encompasses the state responsibility to ensure essential medicines are available, accessible, acceptable and of a high quality.

**Interactions Between State and Non-State Actors**
Focusing primarily on the right to health, the author examines the obligations states, third-party states, and international institutions have to provide access to medicine under international human rights law, highlighting how they have been established by court decisions at the national, regional and international level as well as in various human rights treaties. The author notes that the state obligation to respect the right to health in part requires preventing pharmaceutical companies from abusing their patents as well as developing regulatory systems to do so. To meet their obligation to fulfill the right to health, states must satisfy the “minimum essential level” of the right to health which includes providing essential drugs as defined by the WHO. The article mentions a number of inexpensive measures that may help states meet their obligations to respect, to protect, and to fulfill the right to health and access to medicine in particular, such as passing anti-competition legislation that promotes the use and development of generic drugs or reducing taxes on inputs for generics.

The article also suggests that other actors also have responsibilities to uphold the right to health under international law. For example, the ICESCR has stated that the World Bank and IMF should consider the right to health in their lending policies and programs and that intellectual property rules should be modified in developing countries. The article suggests that the responsibilities of non-state actors emanate from the treaties that they have signed as well as resolutions of the UN and other regional human rights organizations to which they are members. Furthermore, as members of the WHO they must support the missions and declarations of that organization. As a result, states have a duty not to restrict the availability or accessibility of medicine, to protect the public’s access to medication from threats imposed by pharmaceutical companies and
other third parties, and to take steps to realize access to medicine for all without discrimination.

Although it is never made explicit, the article strongly implies that human rights obligations are born solely by states and that other actors, including pharmaceutical companies, cannot be held responsible for hampering access to medicine under international human rights law. Rather, the article focuses on how states can use their influence on these companies to prevent them from restricting access to medications and violating other human rights.

Distinctions Between Pharmaceutical Companies and other MNCs
The article directly addresses the responsibilities of the pharmaceutical industry. Its analysis is also applicable to other MNCs that may impact access to medicines.

V. AFFORDABILITY OF DRUGS AND/OR SERVICES

1. Evaluating Drug Prices, Availability, Affordability, and Price Components: Implications for Access to Drugs in Malaysia
   Babar, Zaheer Ud Din; Ibrahim, Mohamed IM; Singh, Harpal; Bukahri, Nadeem Irfan and Andrew Creese

   No abstract available

Background: Malaysia’s stable health care system is facing challenges with increasing medicine costs. To investigate these issues a survey was carried out to evaluate medicine prices, availability, affordability, and the structure of price components. METHODS AND FINDINGS: The methodology developed by the World Health Organization (WHO) and Health Action International (HAI) was used. Price and availability data for 48 medicines was collected from 20 public sector facilities, 32 private sector retail pharmacies and 20 dispensing doctors in four geographical regions of West Malaysia. Medicine prices were compared with international reference prices (IRPs) to obtain a median price ratio. The daily wage of the lowest paid unskilled government worker was used to gauge the affordability of medicines. Price component data were collected throughout the supply chain, and markups, taxes, and other distribution costs were identified. In private pharmacies, innovator brand (IB) prices were 16 times higher than the IRPs, while generics were 6.6 times higher. In dispensing doctor clinics, the figures were 15 times higher for innovator brands and 7.5 for generics. Dispensing doctors applied high markups of 50%-76% for IBs, and up to 316% for generics. Retail pharmacy markups were also high-25%-38% and
100%-140% for Ibs and generics, respectively. In the public sector, where medicines are free, availability was low even for medicines on the National Essential Drugs List. For a month’s treatment for peptic ulcer disease and hypertension people have to pay about a week’s wages in the private sector.

CONCLUSIONS: The free market by definition does not control medicine prices, necessitating price monitoring and control mechanisms. Markups for generic products are greater than for Ibs. Reducing the base price without controlling markups may increase profits for retailers and dispensing doctors without reducing the price paid by end users. To increase access and affordability, promotion of generic medicines and improved availability of medicines in the public sector are required.

Human Rights Norms and Standards
The article implicitly deals with the right to health norms of availability and economic accessibility as the study investigates the sources of increasing drug prices and low availability of medicines in public hospitals in Malaysia. The study found that prices in Malaysia, which has a free market pricing system for pharmaceuticals, were high in terms of international pricing, especially when compared with India and Sri Lanka who are more efficient in procurement and pricing. Availability of drugs, including essential medicines, was low in all sectors and particularly in the public sector, thereby forcing patients to buy from private pharmacies or dispensing doctors. In terms of affordability and pricing, markups were higher than in comparison countries, particularly for generics.

Interactions Between State and Non-State Actors
The article explicitly addresses the interactions between the pharmaceutical industry and the state. Given what they perceive to be the failures of the free market system, the authors urge the Malaysian government to regulate the pharmaceutical industry and implement a system to monitor such regulation by, for example, printing maximum prices on the packages of drugs. They also suggest improving the targeting of spending on medicines, increasing the budget, and reviewing purchasing practices. Additionally, they recommend a generics policy that attempts to increase consumer awareness and provide incentives for other actors to prescribe and dispense generic medicines. While there is reference to the need for consumer awareness, the role of civil society and the pharmaceutical industry in this regard is unexplored.

Distinctions Between Pharmaceutical Companies and other MNCs:
The article explicitly refers to the pharmaceutical companies but there is no reference to MNCs. The article also differentiates between generic and other pharmaceutical companies.

Ford, Nathan; Wilson, David; Costa Chaves, Gabriela; Lotrowska, Michel, and Kannikar Kijtiwatchakul

Abstract: Antiretroviral rollout in Brazil and Thailand: Brazil and Thailand are among few developing countries to achieve universal access to antiretroviral therapy. Three factors were critical to this success: legislation for free access to treatment; public sector capacity to manufacture medicines; and strong civil society action to support government initiatives to improve access.

Local production of affordable, non-patented drugs: Many older antiretroviral drugs are not patented in either country and affordable generic versions are manufactured by local pharmaceutical institutes.

Efforts to ensure access to expensive, patented drugs: Developing countries were not required to grant patents on medicines until 2005, but under US government threats of trade sanctions, Thailand and Brazil began doing so at least ten years prior to this date. Brazil has used price negotiations with multinational pharmaceutical companies to lower the price of newer patented antiretrovirals. However, the prices obtained by this approach remain unaffordable. Thailand recently employed compulsory licensing for two antiretrovirals, obtaining substantial price reductions, both for generic and brand products. Following Thailand’s example, Brazil has issued its first compulsory license.

Lessons learned: Middle-income countries are unable to pay the high prices of multinational pharmaceutical companies. By relying on negotiations with companies, Brazil pays up to four times more for some drugs compared with prices available internationally. Compulsory licensing has brought treatment with newer antiretrovirals within reach in Thailand, but has resulted in pressure from industry and the US government. An informed and engaged civil society is essential to support governments in putting health before trade.

Human Rights Norms and Standards
This article analyzes the experience of two countries, Brazil and Thailand, in achieving universal access to antiretroviral treatment. While it does not explicitly mention the right to health, it does implicitly address the importance of the right to health norms of accessibility and affordability of drugs. The article refers generally to human rights principles as the foundation for Thai civil society and notes the government’s challenge of drug patents in court.
Interactions Between State and Non-State Actors
The article deals extensively with the operational relationships between state and non-state actors, principally between national governments and multinational as well as national drug companies. Both Brazilian and Thai governments engaged in price negotiations with the pharmaceutical industry for newer drugs subject to patent. At the same time, private national and state owned pharmaceutical industries were authorized by both governments to produce generic drugs. The article also notes the significance of national legislation mandating free access to treatment in defining the legal duties of the state, and subsequent regulation of and operational engagement with the pharmaceutical industry through, for example, compulsory licensing and the challenging of patents. The role of civil society in pressuring governments and pharmaceutical companies to improve access to drugs is also identified.

Distinctions Between Pharmaceutical Companies and other MNCs
The article deals with the pharmaceutical industry, including generics and state-owned pharmaceuticals. It does not discuss MNCs more broadly.

3. Financing Pharmaceuticals in Transition Economies
Kanavos, Panos

Abstract: This paper (a) provides a methodological taxonomy of pricing, financing, reimbursement, and cost containment methodologies for pharmaceuticals; (b) analyzes complex agency relationships and the health versus industrial policy tradeoff; (c) pinpoints financing measures to balance safety and effectiveness of medicines and their affordability by publicly funded systems in transition; and (d) highlights viable options for policy-makers for the financing of pharmaceuticals in transition. Three categories of measures and their implications for pharmaceutical policy cost containment are analyzed: supply-side measures, targeting manufacturers; proxy demand-side measures, targeting physicians and pharmacists; and demand-side measures, targeting patients. In pursuing supply side measures, we explore free pricing for pharmaceuticals, direct price controls, cost-plus and cost pricing, average pricing and international price comparisons, profit control, reference pricing, the introduction of a fourth hurdle, positive and negative lists, and other price control measures. The analysis of proxy-demand measures includes budgets for physicians, generic policies, practice guidelines, monitoring the authorizing behavior of physicians, and disease management schemes. Demand-side measures explore the effectiveness of patient co-payments, the impact of allowing products over-the-counter and health promotion programs. Global policies should operate simultaneously on the supply, the proxy demand, and
the demand-side. Policy-making needs to have a continuous long-term planning. The importation of policies into a transition economy may require extensive and expensive adaptation. Otherwise it may lead to sub-optimal policy outcomes.

**Human Rights Norms and Standards**
In its analysis of drug financing and pricing policies, the article implicitly addresses the right to health norms of affordability, quality, and accessibility. It does not clarify human rights concerns more generally nor specific right to health obligations or responsibilities in its analysis of various policy options.

**Interactions Between State and Non-State Actors**
The article focuses primarily on the role states play in setting or shaping drug prices as well as the competing interests the states try to balance through their pricing policies. It notes that several parties with different interests are involved in the distribution, payment and availability of drugs: third party insurers, wholesalers, prescribing physicians, dispensing pharmacists, the Ministry of Finance who taxes the drugs, and regulatory agencies who assess the quality, efficacy and safety of drugs. The article posits that state regulation of the pharmaceutical industry is complicated by the competing interests of those ministries devoted to promoting industry and those in charge of health. In terms of industrial policies, a number of policy areas are important: research and development support, employment, academic research, IP protection, and, possibly, the promotion of a local generics industry. Governments, therefore, have to balance the need to control pharmaceutical costs in order for the public to afford treatment while still encouraging industry to develop new drugs. The article suggests that the health and industrial interests that states have in the pharmaceutical industry may lead to a number of areas in which states and the industry should be able to cooperate, even though manufacturers often want to set prices higher than the states would like.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article discusses specific aspects of the pharmaceutical industry that may have unique implications on state policies and regulations. It notes that economic factors particular to the industry, the large number of intermediary agency relationships, and the lack of competition are particular to the pharmaceutical industry. The number of parties involved in the drug development and distribution may make problems affecting access, affordability and quality control extremely difficult to solve, but also reveals that there is a diverse set of actors who can contribute to tackling these issues. The framework used by the author to classify policies into demand-side, proxy demand-side, and supply side categories may be useful for identifying entry points for the engagement of the industry and other non-state actors.
4. Differential Pricing of Drugs: A Role for Cost-Effectiveness Analysis? 
Lopert, Ruth; Lang, Danielle L; Hill, Suzanne R and David A Henry 

Abstract: Internationally, the high costs of pharmaceutical products limit access to treatment. The principle of differential pricing is that drug prices should vary according to some measure of affordability. How differential prices should be determined is, however, unclear. Here we describe a method whereby differential prices for essential drugs could be derived in countries of variable national wealth, and, using angiotensin-converting enzyme inhibitors provide an example of how the process might work. Indicative prices for drugs can be derived by cost-effectiveness analysis that incorporates a measure of national wealth; such prices could be used internationally as a basis of differential price negotiations.

Human Rights Norms and Standards
The article implicitly deals with the human rights norm of economic accessibility or affordability while proposing a methodology for calculating differential pricing of essential drugs taking into account a nation’s wealth. The authors use the World Bank standard of health interventions that buy a year of healthy life for less than the nation’s per capita GDP as cost-effective. The authors calculate an incremental cost a country should pay for a drug using this measure and weighting it with a country’s per capita GDP. The article goes on to say that even in the absence of differential pricing, this method is still useful as this knowledge about the value of a drug can be used by state parties in negotiations. However, a limitation of the proposed method identified is that it only takes into account mortality and not morbidity.

Interactions Between State and Non-State Actors
The article does not deal in detail with the interaction between state and non-state actors. Nonetheless, the proposed methodology for states to negotiate differential pricing of pharmaceuticals and determine their cost-effectiveness implies a necessary and useful engagement with the pharmaceutical industry and other relevant actors.

Distinctions Between Pharmaceutical Companies and other MNCs
The article does not deal with MNCs and but refers to pharmaceutical companies specifically.
   Morgan, Steve; McMahon, Meghan and Devon Greyson

Abstract: Introduction: Policy-makers worldwide struggle to balance health with industrial policy objectives in the pharmaceutical sector. Tensions arise over pricing and reimbursement in particular. What health plans view as necessary to maintain equitable access to medicines, industry views as inimical to R&D and innovation. Australia has grappled with this issue for years, even incorporating the goal of "maintaining a responsible and viable medicines industry" into its National Medicines Policy. Methods: This case study was conducted via a narrative review that examined Australia's experiences balancing health and industrial policy objectives in the pharmaceutical sector. The review included electronic databases, grey literature and government publications for reports on relevant Australian policy published over the period 1985-2007. Results: While pharmaceutical companies claim that Australia's pricing and reimbursement policies suppress drug prices and reduce profits, national policy audits indicate these claims are misguided. Australia appears to have secured relatively low prices for generics and "me-too drugs" while paying internationally competitive prices for "breakthrough" medicines. Simultaneously, Australia has focused efforts on local pharmaceutical investment through a variety of industry-targeted R&D incentive policies. Discussion: Despite the fact that policy reviews suggest that Australia has achieved balance between health and industrial policy objectives, the country continues to face criticism from industry that its health goals harm innovation and R&D. Recent reforms raise the question whether Australia can sustain the apparent balance.

Human Rights Norms and Standards
The article does not explicitly take up human rights norms and standards. Nonetheless it does implicitly mention several right to health norms, namely accessibility, including affordability, and quality. Australia’s National Medicines Policy is founded on four central pillars: timely and affordable access to medicines; appropriate quality control; appropriate use of medicines; and the maintenance of a viable medicines industry. The Pharmaceutical Benefits Scheme (PBS) is the main policy instrument for reaching NMP goals, and implicitly relates to the right to health norms of quality and affordability. The PBS Schedule (a national formulary) lists all subsidized medicines and provides additional information regarding aid. For medicines to make the Schedule, they must meet certain quality and cost-effectiveness criteria.
Interactions Between State and Non-State Actors
The article focuses mainly on the operational relationships between the national and international pharmaceutical industry and the Australian state, and their contributions to what the authors argue is a successful balance between drug affordability and incentives for research and development. In the government or public sector, the Department of Health promotes a health agenda, while the Department of Industry, Tourism and Resources (DITR) seeks to promote and attract research and development initiatives of the pharmaceutical industry. Medicines are regulated by the Pharmaceutical Benefits Advisory Committee (PBAC)-a statutory independent advisory body to the PBS-which is comprised of representatives of both the private and public sector including health professionals, economists, pharmacologists, and consumers. Moreover, the Pharmaceutical Benefits Pricing Authority (PBPA), a non-statutory body, is responsible for conducting price negotiations with pharmaceutical companies. In addition to consolidating bargaining clout in a central body, the PBS provides affordable medicines by other various pricing and reimbursement policies.

Distinctions Between Pharmaceutical Companies and other MNCs
The article focuses primarily on the pharmaceutical industry and does not distinguish it from other MNCs.

6. Negotiating Antiretroviral Drug Prices: The Experience of the Andean Countries
Seoane-Vazquez, Enrique and Rosa Rodriguez-Monguio

Abstract: Objectives: This study analyses the effect of the Andean countries' June 2003 negotiation of antiretroviral drug (ARV) prices. The objectives were to assess the problems faced during the negotiation process, to evaluate the impact of the negotiation on ARV prices, and to identify factors that could make it difficult for countries to implement the results of the negotiation.
Methods: Price information of ARVs purchased by public programmes during 2004 was collected from the ministries of health. A survey of the ministries of health was conducted using a questionnaire with information related to the countries' health care and drug regulations and policies. Interviews with a convenient sample of key Andean health authorities and other stakeholders were also conducted.
Results: Study results show that the negotiation did achieve lower prices and higher quality and bioequivalence standards for ARVs. However, in general, the public health care programmes of the six countries analysed did not purchase ARVs from the companies that participated in the negotiation, nor did they
base purchases on the prices or quality and bioequivalence criteria established in the negotiation. Prices paid by the Andean countries' public programmes in 2004 were a weighted average of 65% higher than the negotiated prices; and this difference in negotiated prices vs. actual prices represented 39.5% of the programmes' ARV expenditures in 2004, or US$18 million in ARV expenditures. Conclusion: The successful development and implementation of multinational price negotiations requires that participant countries coordinate pharmaceutical regulations and policies, and pool procurement processes.

Human Rights Norms and Standards
The article implicitly deals with the right to health norms of economic accessibility or affordability and quality as it evaluates the impact and process of a negotiation undertaken by the Andean countries to reduce ARV prices and improve quality.

Interactions Between State and Non-State Actors
The article explicitly deals with the interactions among states, and between state and non-state actors, as in this case the negotiation was taking place between states and pharmaceutical companies. The authors found that in spite of an agreement for the reduction of prices, the cost of the drugs did not decline. The authors highlighted five problems that prevented implementation of the agreement: there was no contractual obligation for companies who wanted to bid on supplying any of the states with ARVs to participate in the negotiation; states did not guarantee to buy ARVs at the prices set; the agreement did not conform to the rules and regulations in each country and was not adapted to address procurement; states did not have enough information on the epidemiology of the disease and the market; and, there was a lack of coordination between different agencies within individual countries and not enough resources dedicated to buying ARVs. The article highlights three major operational lessons learnt that can be used to shape future efforts. First, countries could share expertise and pool ARV purchases to increase leverage at the negotiation table. Second, states could make an advance commitment to purchase the drugs at the negotiated price. This would eliminate the need for domestic bids and encourage more companies to participate, which would reduce prices further. Finally, coordination of drug regulations and policies between states is necessary and could be undertaken.

Distinctions Between Pharmaceutical Companies and other MNCs
The article explicitly deals with the pharmaceutical companies but no distinction between MNCs and pharmaceutical companies is made. The article only distinguishes between generic and originator companies.
Tetteh, Ebenezer Kwabena

Abstract: Medicines are integral of any healthcare system, and limited access to medicines undermines health systems' objectives of equity, efficiency and health development. In African countries, where it is estimated that 50-60% of the populace lack "access" to essential medicines, health problems associated with limited drug benefits are more damaging. However, there is no single solution to medicine access problem given its multiple dimensions: availability, acceptability, affordability and accessibility. This paper explores affordability dimension of medicine access and concentrates solely on price regulatory policies and institutional structures that national and international policy makers may consider in making prices of essential drugs compatible to the purchasing power of African households. The main theme is the application of the concept of bilateral dependence in creating price-sensitive purchasers to exert countervailing market power on drug price setting in African healthcare systems.

Human Rights Norms and Standards
In exploring different pricing schemes aimed at providing affordable essential medicines in Africa, the article implicitly considers the right to health norms of accessibility, affordability, acceptability, and quality as dimensions of what the authors call “access to medicines.” It does not refer explicitly to the human right to health.

Interactions Between State and Non-State Actors
The article highlights the interactions between states and pharmaceutical companies in examining pricing schemes imposed by national governments to regulate drug prices in local markets set by both national and multinational companies in order to increase drug affordability. One such pricing scheme is the government’s use of a pharmaceutical benefit manager (PBM), a public agency, or series of public agencies, which establish a national formulary and negotiate prices with pharmaceutical companies. The author ultimately recommends a bilateral monopoly, where there is only one buyer (the government) and several competing sellers (pharmaceutical companies). Additionally, as a means of keeping prices down, the article suggests confidential negotiations between the government and drug companies, to ensure that companies do not band together to raise drug prices. On the flip side, it proposes several measures to satisfy transparency and accountability standard including the publication of relative prices and the publishing of discounted prices.
Distinctions Between Pharmaceutical Companies and other MNCs
The article focuses primarily on the pharmaceutical industry and does not distinguish it from other MNCs.

VI. QUALITY OF DRUGS AND/OR SERVICES

1. Drug Shop Regulation and Malaria Treatment in Tanzania--Why Do Shops Break the Rules, and Does it Matter?
   Goodman, Catherine; Kachur, S Patrick; Abdulla, Salim; Bloland, Peterand Anne Mills

Abstract: Regulatory infringements are extremely common in low-income countries, especially with respect to retail pharmaceutical sales. There have been few practical suggestions on public policy responses other than stricter regulatory enforcement, which governments are often unable, or unwilling, to do. This paper explores the challenges of regulating retail drug sellers, and potential solutions, through a case study of malaria treatment in rural Tanzania where small drug shops are a common source of medicine. Infringement of health-related regulation was extremely common. Most stores lacked valid permits, and illegal stocking of prescription-only medicines and unpackaged tablets was the norm. Most stocked unregistered drugs, and no serving staff met the qualification requirements. Infringements are likely to have reflected infrequent regulatory inspections, a failure of regulatory authorities to implement sanctions, successful concealment of regulatory violations, and the tacit permission of local regulatory staff. Eliminating regulatory infringements is unlikely to be feasible, and could be undesirable if access to essential medicines is reduced. Alternatives include bringing official drug regulation closer into line with locally legitimate practices; greater use of positive incentives for providers; and consumer involvement. Such a change in approach has the potential to provide a firmer platform for public-private collaboration to improve shop-based treatment.

Human Rights Norms and Standards
In examining the problems of drug regulation through a drug shop and malaria case study, the authors implicitly refer to the right to health norm of quality. Researchers recorded several violations, including failure to display permits in all drug stores, under-qualified staff, stocking of prescription-only medicines, unregistered imported antimalarials, expired antimalarials, sales of loose painkillers and antimalarials, and inadequate dosing instructions. All of these regulatory violations negatively impact the quality of these drugs. The authors also implicitly refer to the right to health norm of economic accessibility or
affordability and the importance of balancing this component with quality in policy recommendations.

**Interactions Between State and Non-State Actors**
In their discussion of suggested policy options, the authors stress an approach that allows the experience of the private sector (specifically local drug stores) to inform policy making. The authors suggest three ways in which the interactions between state and non-state actors are necessary for creating incentives and regulations to improve access and use of malaria drugs. First, they suggest the establishment of professional associations that may grant members greater credibility. Second, they suggest the accreditation of drug stores by government agencies. Finally, they suggest increased consumer education may lead to regulation by consumers and community organizations.

**Distinctions Between Pharmaceutical Companies and other MNCs**
This article does not deal specifically address pharmaceutical companies or other MNCs.

2. The Quality Quandary
   **Langston, Edward L**

**Abstract:** America's physicians write over three billion prescriptions a year for patients—and they need to know that when patients fill those prescriptions, the drugs they take are safe. Physicians want their patients to be able to get those drugs at the lowest price possible. Patient safety and drug quality are the overriding issues, as physicians work with their patients to make prescription drugs more available and affordable. Patients are rightly concerned over the cost of prescription medication and are seeking alternative sources to fulfill their prescription drug needs. Many are turning to international pharmacy outlets as a resource and the Internet. The Internet option creates a special concern for physicians, as not all Internet sources are reliable or ethical. Further, importation creates safety issues. Using Canada as an example, there is considerable misunderstanding within the general public regarding the authenticity of medications imported or reimported from Canada. Many drugs sold there are manufactured in other countries where the U.S. Food and Drug Administration (FDA) has no authority. These issues and others become even more complex and are not easily addressed simply by contracting with an international pharmaceutical drug distributor, as many states have done or are considering. Therefore, to ensure that patient safety is the primary concern, drugs should be FDA-approved, the distribution chain should remain closed, products should be subject to track and trace technology, and FDA resources
should be adequate to ensure authenticity and integrity of imported or re-imported drugs.

**Human Rights Norms and Standards**
The article implicitly deals with right to health norms of quality and financial accessibility or affordability of prescription drugs, especially for vulnerable populations who are more likely to purchase counterfeit drugs. The article emphasizes the difficulty physicians have in balancing pricing issues with affordability, access, and safety of drugs prescribed to patients. The author remarks on how the concerns over cost are pushing patients to seek alternate sources to fulfill their prescription drugs needs, exposing them to international pharmacy outlets as well as other resources over the internet that are often unreliable and may lead to other safety issues linked to importation of drugs.

**Interactions Between State and Non-State Actors**
The article refers implicitly to interaction between state and non-state actors while referring to the need for consumer education and cross border collaboration. Moreover, the article recommends specific measures states can take to ensure patient safety including closure of distribution chains, use of track and trace technology, regulation of wholesale distributors, strengthening consumer education, collaboration with foreign governments and setting strict standards on the importation and reimportation of pharmaceuticals, most of which necessitate the involvement of the pharmaceutical industry.

**Distinctions Between Pharmaceutical Companies and other MNCs**
The article explicitly refers to international pharmacy outlets as well as resources over the internet. It also implicitly talks about the possible role the pharmaceutical industry might have in regulation, price control and safety of drugs.

3. **Fade to Black: Importation and Counterfeit Drugs**
   Liang, Bryan A

*No abstract available*

**Human Rights Norms and Standards**
The study implicitly deals with the right to health norm of quality and also discusses the tension between quality and financial accessibility in the context of importation of counterfeit and expired drugs. The article emphasizes the harmful effects of counterfeit drugs on patients, the difficulty of detecting these drugs and their easy availability due to ease of manufacture, less stringent
criminal penalties and gray markets allowing them easy entry into pharmaceutical distribution networks.

Interactions Between State and Non-State Actor
The study explicitly refers to the interaction between state and non-state actors to combat counterfeit and expired drugs.

The author highlights the fact that often consumer demand pressurizes governments to purchase drugs beyond national boundaries, making it easier for counterfeits to enter the domestic market. As a recommendation to combat the inflow of substandard medicines, the author emphasizes the rights to education and information of the consumers as often consumers are not fully informed. The author also proposes that states undertake legislative and other strategic efforts like increasing criminal penalties and fostering cooperation for standardized regulation between international law enforcement and safety agencies as well as health care providers. Two potential roles of the pharmaceutical industry are also specified: launching or assisting in low-cost high-quality drug donation programs, and providing training to prevent the expiration and improper storage of pharmaceuticals.

The study directly addresses the role of consumers and the possible roles that pharmaceutical industries can play in combating substandard drugs. It goes further to emphasize the need to go beyond national boundaries and foster international cooperation and regulatory frameworks to ensure accessibility and affordability of safe, good quality drugs.

Distinctions Between Pharmaceutical Companies and other MNCs
The article refers to pharmaceutical companies and proposes roles they could play in combating counterfeit and expired drugs. The article does not explicitly analyze MNCs but refers to cross border and international trading.

4. Pharmaceutical Cost Containment and Quality Care - Conflict or Compromise?
   Redwood, H

Abstract: Existing methods of pharmaceutical cost containment are relatively primitive weapons of expenditure restraint. Their effectiveness is generally limited to short term savings. The conflict between cost containment and quality is epitomized by the 'Drug Budget', which conditions payers to regard pharmaceuticals solely as a cost input without considering the results of their
use in terms of integrated health outcomes, crossing the budgetary boundaries between drugs, hospitals, ambulatory and other forms of healthcare.

A further problem, also related to the separation of inputs from outcomes, is the contention by healthcare payers that, even if 'expensive' innovative drugs offer Value for Money, budget holders cannot afford the required Money for Value. The limits of affordability are real in poor countries. In rich industrialized nations, the affordability of quality is in essence a political rather than an economic issue. In making choices and determining priorities, elected governments are usually responsive to public opinion, which is coming to regard the issue of quality in healthcare as one of the highest social priorities.

Pharmaceutical innovation has much to contribute to quality in healthcare. A compromise between pharmaceutical cost containment and quality is feasible, based on input/outcome considerations, rational drug pricing, and re-engineering decision-making by payers away from the simplistic notion that the cheapest drug budget is necessarily the best.

Human Rights Norms and Standards
The study implicitly deals with the right to health norms of quality, affordability and accessibility to pharmaceutical innovations, specifically in the context of the tension between cost-containment strategies and quality of drugs. The article emphasizes how cost containment measures undertaken by the states often result in unnecessary expenditures and poor quality of care through prescription of cheaper and less effective drugs leading to prolonged illness and suffering of patients. The study emphasizes that a compromise between pharmaceutical cost containment and quality is feasible, based on input/outcome considerations, rational drug pricing, and re-engineering decision-making by payers away from the simplistic notion that the cheapest drug budget is necessarily the best. Furthermore, the study posits that the pharmaceutical industry should not be expected to provide society with new drugs at the price of older therapies. The study states that quality should be an important part of cost-containment analysis and implies that doing so requires the development of tools by states that systematically take into consideration quality and equity in access to drugs.

Interactions Between State and Non-State Actors
The study does not explicitly deal with the interaction between state and non-state actors while determining cost-containment strategies but does refer to the role of public opinion as an important factor in shaping decision making around quality in industrialized nations.
Distinctions Between Pharmaceutical Companies and other MNCs

Overall, the article implicitly relates to the pharmaceutical industry. It directly refers to the industry only once when discussing the cost of new drugs and does not deal with MNCs.
The Program on International Health and Human Rights at the Harvard School of Public Health promotes practical and effective responses to global public health challenges through the innovative application of human rights. This is done through a combination of research, capacity building, policy development and health programming in a variety of areas focusing on HIV/AIDS, reproductive and sexual health, and child and adolescent health.