

# TRANSNATIONAL PHARMACEUTICAL CORPORATIONS' LEGAL AND MORAL HUMAN RIGHTS RESPONSIBILITIES IN RELATION TO ACCESS TO MEDICINES

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## ABSTRACT

*For decades the lack of access to needed and affordable medicines has unduly burdened developing countries worldwide. To highlight the acute need for international assistance in support of the medical plight of the sick and poor, in addition to the state's human rights obligations to fulfill the right to access medicines, scholars have manifested increasingly visible alarm over the activities and enormous power of transnational pharmaceutical corporations (TNPCs). However, requiring TNPCs to assume human rights responsibilities, in relation to access to medicines, is replete with conceptual difficulties because, as far as the right to access medicines is concerned, TNPCs' normal business operations and voluntary philanthropy form the main corporate contribution to the preservation of this right. TNPCs have only moral responsibilities to facilitate access to medicines. Moreover, it is only misleading to impose moral responsibilities, categorized in the "can" dimension, on TNPCs for pharmaceutical accessibility regardless of the heterogeneous contents on the right to access medicines. Based on the biomedical health model and Norman Daniels' theory of Just Health Care, this article proposes that, (1) TNPCs "ought to" fulfill the right to access medicines when, and only when, these medicines are necessary for restoring or*

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*maintaining “minimal health” (including life-saving)” without which, an individual cannot be a free and equal member of society and the right loses its significance, and (2) TNPCs “can” voluntarily fulfill the right to access medicines for common or insignificant physical and mental dysfunctions or for pain-killing that go beyond the level of “minimal health.”*

**KEYWORDS:** *transnational pharmaceutical corporations, right to access medicines, human rights responsibilities*

## I. INTRODUCTION

For decades the lack of access to needed and affordable medicines has unduly burdened developing countries worldwide.<sup>1</sup> For example, World Health Organization (WHO) studies show that infectious diseases kill over 14 million people per year, 90% of whom live in a developing or newly industrialized society.<sup>2</sup> Among them, approximately three million people die annually from HIV/AIDS, two million from tuberculosis, and one million from malaria.<sup>3</sup> Furthermore, vulnerable groups such as children and very young adults in sub-Saharan Africa and Southeast Asia bear a heavier burden in relation to infectious diseases, as 50% of deaths are attributable to six treatable diseases — HIV/AIDS (14%), acute respiratory syndrome (11%), diarrheal diseases (11%), malaria (8%), measles (6%), and TB (2%).<sup>4</sup> However, the tragedy of these deaths is not inevitable because most of these epidemics and diseases are preventable, treatable, or even curable with existing medications.<sup>5</sup> Despite the existence of effective medicines, millions of people in developing countries continue to needlessly suffer and die from these life-threatening conditions due to inaccessibility to affordable medicines caused by poverty, market failure (absence of affordable medicines in the private market),<sup>6</sup> unfair trade

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<sup>1</sup> Emily A. Mok, *International Assistance and Cooperation for Access to Essential Medicines*, 12(1) HEALTH & HUM. RTS. 73, 73 (2010).

<sup>2</sup> United States House of Representatives Committee on Government Reform — Minority Staff Special Investigations Division, *Trade Agreements and Access to Medications under the Bush Administration (Prepared for Rep. Henry A. Waxman)*, 1-2 (Washington DC, 2005), available at [http://www.twinside.org.sg/title2/FTAs/Intellectual\\_Property/IP\\_and\\_Access\\_to\\_Medicines/TradeAgreementsandAccessToMedicationsUnderTheBushAdmini.pdf](http://www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/TradeAgreementsandAccessToMedicationsUnderTheBushAdmini.pdf) (last visited Mar. 18, 2012).

<sup>3</sup> World Health Organization [WHO], *The Global Burden of Disease: 2004 Update*, 11 (2007), available at

[http://www.who.int/healthinfo/global\\_burden\\_disease/GBD\\_report\\_2004update\\_full.pdf](http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf) (last visited Mar. 18, 2012); UNAIDS & WHO, *AIDS Epidemic Update: Special Report on HIV Prevention*, 2 (2005), available at [http://www.who.int/hiv/epi-update2005\\_en.pdf](http://www.who.int/hiv/epi-update2005_en.pdf) (last visited Mar. 18, 2012); WHO, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, 2-3 (2006), available at <http://www.who.int/intellectualproperty/documents/therreport/ENPublicHealthReport.pdf> (last visited Mar. 18, 2012); WHO, *Towards Universal Access: Scaling up Priority HIV/AIDS Interventions in the Health Sector: Progress Report*, 5 (2009), available at [http://www.who.int/entity/hiv/pub/uaapr\\_2009\\_en.pdf](http://www.who.int/entity/hiv/pub/uaapr_2009_en.pdf) (last visited Mar. 18, 2012).

<sup>4</sup> Jonathan D. Quick, *Ensuring Access to Essential Medicines in Developing Countries and Least Developed Countries — Framework for Action*, 73(4) CLIN. PHARMACOL. & THER. 279, 279-83 (2003).

<sup>5</sup> See Mok, *supra* note 1, at 73.

<sup>6</sup> For example, the United Nation [UN] report finds that in the public sector, generic medicines are only available in 38.1% of facilities, and on average cost 250% more than the international reference price. In the private sector, those same medicines are available in 63.3% of facilities, but cost on average about 610% more than the international reference price. UN, *The Global Partnership for Development: Time to Deliver (MDG Gap Task Force Report 2011)*, 51 (2011), available at

[http://www.un.org/en/development/desa/policy/mdg\\_gap/mdg\\_gap2011/mdg8report2011\\_engw.pdf](http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2011/mdg8report2011_engw.pdf)

practice,<sup>7</sup> dependence on assistance from the global community, and flawed governance.<sup>8,9</sup>

To highlight the acute need for international assistance and cooperation in support of the medical plight of the sick's and poor,<sup>10</sup> in addition to the state's human rights obligations to respect, protect, and fulfill the right to health, established by the Universal Declaration of Human Rights (UDHR) and the International Covenant on Social, Economic and Cultural Rights (ICESCR),<sup>11</sup> scholars have manifested increasingly visible alarm over the activities and enormous power of transnational pharmaceutical corporations

f (last visited Mar. 18, 2012).

<sup>7</sup> See e.g., Sarah Boseley, *Dying for Profit*, THE GUARDIAN, Sep. 8, 2003, available at <http://www.guardian.co.uk/environment/2003/sep/08/wto.fairtrade7> (last visited Mar. 18, 2012).

<sup>8</sup> Rudolf V. Van Puymbroeck, *Basic Survival Needs and Access to Medicines — Coming To Grips with TRIPS: Conversion + Calculation*, 38(3) J.L. MED. & ETHICS 520, 520 (2010).

<sup>9</sup> The accessibility problem worsened after the implementation of the World Trade Organization [WTO] Agreement on Trade Related Aspects of Intellectual Property Rights [TRIPS Agreement], which triggered significant changes in international standards relating to intellectual property rights, and enabled pharmaceutical corporations to charge prices far above their marginal costs. Although the Doha Declaration on the TRIPS Agreement and Public Health [Doha Declaration] and the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health [2003 Decision] recognize the “gravity” of these public health problems and reflect concerns regarding the implications of the TRIPS Agreement, these documents left a number of technical legal problems unresolved. See e.g., Carlos M. Correa, *TRIPS Agreement and Access to Drugs in Developing Countries*, 3 SUR – INT’L J. HUM. RTS. 25, 25 (2004). Ellen R. Shaffer et al., *Global Trade and Public Health*, 95(1) AM. J. PUB. HEALTH 23, 23 (2005). John H. Barton, *TRIPS and the Global Pharmaceutical Market*, 23(3) HEALTH AFF. 146, 149-52 (2004). Chuan-Feng Wu, *Raising the Right to Health Concerns within the Framework of International Intellectual Property Law*, 5(1) ASIAN J. OF WTO & INT’L HEALTH L. & POL’Y 141, 148-61 (2010).

<sup>10</sup> Mok, *supra* note 1, at 73.

<sup>11</sup> In addition to Article 25.1 of the UDHR and Article 12.1 of the ICESCR, the right to health is also recognized in Article 5 (e)(iv) of the International Convention on the Elimination of All Forms of Racial Discrimination, Articles 11.1(f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women [CEDAW], Article 24 of the Convention on the Rights of the Child [CRC] of 1989, and Articles 25 and 26 of the Convention on the Rights of Persons with Disabilities. Based on the fact that people and organizations worldwide rank health as one of the greatest goods, the right to health should include both (1) the right to access health care (including medicines), and (2) the right to enjoy underlying preconditions for health (including clean water, decent housing, and proper cloth). The right to health (including the right to access medicines), like all human rights, also imposes three obligations on states: (1) States must respect the right to health, meaning that states may not interfere with the enjoyment of the right. (2) States must protect the right to health, meaning states must take measures to prevent private persons and businesses from interfering with the right. (3) States must fulfill the right to health, meaning states must facilitate and promote the right. See e.g., U.N. Econ. & Soc. Council [ECOSOC], Comm. on Econ., Soc. & Cultural Rts. [CESCR], General Comment No. 14: Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights — The Right to the Highest Standard of Health, para. 30-45, U.N. Doc. E/C. 12/2000/4 (Aug. 11, 2000) [CESCR General Comment No. 14]; Lawrence O. Gostin, *The Human Right to Health: A Right to the “Highest Attainable Standard of Health”*, 31(2) HASTINGS CENTER REP. 29, 29-30 (2001); HARVARD LAW SCHOOL HUMAN RIGHTS PROGRAM & FRANCOIS-XAVIER BAGNOUD CENTER FOR HEALTH AND HUMAN RIGHTS, ECONOMIC AND SOCIAL RIGHTS AND THE RIGHT TO HEALTH: AN INTERDISCIPLINARY DISCUSSION HELD AT HARVARD LAW SCHOOL IN SEPTEMBER 1993 17 (1995); Wu, *supra* note 9, at 168-84.

(TNPCs).<sup>12</sup> It is because of the complex, at times mystifying, forces of the new global economy<sup>13</sup> as well as the (re)emergence of these transnational corporations that have challenged the traditional understanding and functioning of human rights laws pertaining to health care.<sup>14</sup>

To be sure, TNPCs' presence may have an overall positive effect on access to medicines for all; however, they are also capable of committing human rights abuses. On the one hand, TNPCs, most of which develop life-saving and life-prolonging medicines, maintain a vitally important medical, public health, and right-to-health function in the global arena.<sup>15</sup> For example, TNPCs are capable of supporting states' efforts to protect their citizens' rights to health by making medicines affordable. More specifically, they can provide medicines at lower costs<sup>16</sup> or institute medicine donation programs,<sup>17</sup> thus helping tackle common yet deadly diseases in developing countries. On the other hand however, studies show that the cavalier conduct of TNPCs is also the primary cause of right-to-health violations, especially the right to access medicines.<sup>18</sup> For example, because pharmaceutical leaders employ strategies, such as patent protection, to maximize profits and returns on investments to benefit the corporation and its shareholders,<sup>19</sup> they are responsible for the high prices

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<sup>12</sup> Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny*, 25 HUM. RTS. Q. 425, 425-26 (2003).

<sup>13</sup> Globalization and liberalization of trade and the intensification of communication "have connected people to one another and to their environment in ways that both enhance and jeopardize public health." Carolyn Dresler & Stephen P. Marks, *The Emerging Human Rights to Tobacco Control*, 28(3) HUM. RTS. Q. 599, 634 (2006).

<sup>14</sup> August Reinisch, *The Changing International Legal Framework for Dealing with Non-State Actors*, in NON-STATE ACTORS & HUM. RTS. 37, 37-38 (Philips Alston ed., 2005).

<sup>15</sup> Paul Hunt & Rajat Khosla, *Are Drug Companies Living Up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008)*, 7(9) PLoS MEDICINE 1, 1 (2010) (published online in PLoS Medicine, e1000330. doi:10.1371/journal.pmed.1000330), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000330> (last visited Mar. 18, 2012).

<sup>16</sup> For example, after UN Secretary General Kofi Annan released a report highlighting the important role pharmaceutical corporations play in providing affordable access to HIV/AIDS drugs in developing countries, in 2001 a number of pharmaceutical corporations (including Bristol Myers Squibb, Merck, and GlaxoSmithKline) agreed to sell their drugs at lower costs to developing countries. Barbara Cochrane Alexander, *Lack of Access To HIV/AIDS Drugs in Developing Countries: Is There A Violation of the International Human Rights to Health?*, 8(3) HUM. RTS. BRIEF 12, 12 (2001).

<sup>17</sup> For example, in 2005 Novartis (a Swiss pharmaceutical corporation) concluded an agreement with WHO under which Novartis agreed to donate tuberculosis drugs worth 7 million dollars to 500,000 patients in developing countries over five-year period. Remigius N. Nwabueze, *What Can Genomics and Health Biotechnology Do for Developing Countries?*, 15 ALB. L. J. SCI. & TECH. 369, 429 (2005); Fiona Fleck, *Hopes that Novartis Deal on Tuberculosis will Spur Donations for HIV and Malaria*, 328(7431) BRIT. MED. J. 70, 70 (2004).

<sup>18</sup> M. E. Crow, *The Human Rights Responsibilities of Multinational Tobacco Companies*, 14(supp.

2) TOBACCO CONTROL ii14, ii15 (2005).

<sup>19</sup> Phoebe M. Roberts & William S. Hayes, *Information Needs and the Role of Text Mining in Drug*

charged for life-saving drugs.<sup>20</sup> Studies also show that the poor's healthcare needs are barely met in patent-based pharmaceutical markets<sup>21</sup> because patent holders (i.e., pharmaceutical corporations), who are entitled to control the prices on all sales of their products, sometimes abuse their power of market dominance by charging excessive prices.<sup>22</sup> This is notably the case in relation to the universal right to access medicines because the consumption of medicines is sensitive to price.<sup>23</sup>

The issue then arises: Should pharmaceutical corporations with life-saving medicines be obligated to prioritize the primary goal of healthcare policy, to promote access to medicines, over their economic interests and thus compromise intellectual property rights by recognizing international human rights responsibilities?

Generally speaking, requiring TNPCs to assume human rights responsibilities is replete with conceptual difficulties. First, human rights law was traditionally thought to apply almost exclusively to states, and, only in limited cases, to individuals and corporations.<sup>24</sup> Second, the regulation of corporate conduct is ordinarily treated as a matter of domestic law.<sup>25</sup> In other words, it is for the state to regulate matters of social importance, such as access to medicines, and for TNPCs to obey the law.<sup>26</sup> Since there is no clear standard for human rights to which corporations activities can be applied, holding TNPCs accountable for compliance of the right to health and requiring them to take responsibility for providing affordable medicines is difficult and confusing.

However, in view of the increasing power wielded by TNPCs and their

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*Development*, 13 PAC. SYMP. ON BIOCOMPUTING 592, 592-93 (2008), available at <http://psb.stanford.edu/psb-online/proceedings/psb08/roberts.pdf> (last visited Mar. 18, 2011).

<sup>20</sup> Joseph, *supra* note 12, at 427 (2003).

<sup>21</sup> Kevin Outterson, *Should Access to Medicines and TRIPS Flexibilities be Limited to Specific Diseases?*, 34 AM. J. L. & MED. 317, 317 (2008).

<sup>22</sup> Statement of Complaint in Terms of Section 49B (2)(b) of the Competition Act 89 of 1998, Hazel Tau et al. v. GlaxoSmithKline et al. (Competition Commission of South Africa), ¶¶ 33-44, available at

<http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf> (last visited Mar. 18, 2012).

<sup>23</sup> Price is one important determinant of the "access gap". For example, price has disproportionately severe effects on patients in developing countries because "not only are [patients] in these countries poorer on average, but they also tend to pay a greater proportion of their own medical costs than consumers in wealthy countries." COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 37 (2002). Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L. J. 1031, 1047-48 (2005).

<sup>24</sup> Maria McFarland Sánchez-Moreno & Tracy Higgins, *No Resource: Transnational Corporations and the Protection of Economic, Social, and Cultural Rights in Bolivia*, 27(5) FORDHAM INT'L L. J. 1663, 1676 (2003).

<sup>25</sup> RALPH G. STEINHARDT ET AL., INTERNATIONAL HUMAN RIGHTS LAWYERING 662 (2009).

<sup>26</sup> Peter Muchlinski, *The Development of Human Rights Responsibilities for Multinational Enterprises*, in BUSINESS AND HUMAN RIGHTS: DILEMMAS AND SOLUTIONS 33 (Rory Sullivan ed., 2003).

capacity to affect the enjoyment of the right to health, the current articulation of TNPCs' responsibilities to make medicines available and accessible is likely to be thin and weak. The growth in the role played by private non-state actors such as TNPCs, which have multimillion dollar budgets and enormous staffing, has forced a reconsideration of the boundaries between the private and the public sphere,<sup>27</sup> and brought into question the traditional notion of the corporation as a private entity with no human rights responsibilities. The scholarly debate with mounting evidence of human rights abuses by TNPCs<sup>28</sup>, has led to the conclusion that TNPCs should not remain exempt from the scope of human rights laws<sup>29</sup> and should be legally bound, or at least morally guided, by international human rights norms.<sup>30</sup>

This article thus shines the human rights spotlight on the moral and legal responsibilities of transnational pharmaceutical corporations, particularly on their business conduct that impedes pharmaceutical accessibility and affordability.<sup>31</sup> This article also contributes to the development of a systematic and analytical approach to evaluate TNPCs' human rights responsibilities in relation to access to medicines.

## II. BUSINESS AND HUMAN RIGHTS

Traditionally, international human rights laws hold the state principally liable for the full range of human rights abuses. Individuals can be held (primarily criminally) responsible only in a far smaller range of human rights abuses, mainly characterized by the gravity of the physical or spiritual assault on the individual<sup>32</sup>, such as in war crimes, genocide,<sup>33</sup> crimes against humanity, torture,<sup>34</sup> slavery,<sup>35</sup> forced labor<sup>36</sup>, apartheid,<sup>37</sup>

<sup>27</sup> *Id.* at 36.

<sup>28</sup> For example, the TNPCs have consistently misused their considerable influence to cause developed countries (such as the U.S. government) to pressure developing countries to forego generic competition. See more discussions in e.g., Lissett Ferreira, *Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations*, 71(3) *FORDHAM L. REV.* 1133, 1148-59, 1177 (2002). Patricia H. Werhane & Michael E. Gorman, *Intellectual Property Rights, Access to Life-Enhancing Drugs, and Corporate Moral Responsibilities*, in *ETHICS & THE PHARM. INDUSTRY* 260, 272-74 (Michael A. Santoro & Thomas M. Gorrie eds., 2005).

<sup>29</sup> Ferreira, *supra* note 28, at 1170.

<sup>30</sup> Sánchez-Moreno & Higgins, *supra* note 24, at 1670.

<sup>31</sup> Joseph, *supra* note 12, at 436.

<sup>32</sup> STEVEN R. RATNER & JASON S. ABRAMS, *ACCOUNTABILITY FOR HUMAN RIGHTS ATROCITIES IN INTERNATIONAL LAW: BEYOND THE NUREMBERG LEGACY* 13 (2001).

<sup>33</sup> See e.g., Convention on the Prevention and Punishment of the Crime of Genocide, Dec. 9 1948, S. Exec. Doc. O, 81-1 (1949), 78 U.N.T.S. 277.

<sup>34</sup> See e.g., Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Dec. 10 1984, S. Treaty Doc. No. 100-20 (1988), 1465 U.N.T.S. 85.

<sup>35</sup> See e.g., article 8 of the International Covenant on Civil and Political Rights [ICCPR], and Supplementary Convention on the Abolition of Slavery, the Slave Trade, and Institutions and

and forced disappearances.<sup>38</sup> The centrality of the state is one of the defining features of traditional international law, and the human rights system builds upon this by seeking to legally bind states through a network of treaty obligations to which only states can be parties.<sup>39</sup> For example, both ICCPR article 2.1<sup>40</sup> and ICESCR article 2.1<sup>41</sup> require “state parties to the present Covenant,” rather than non-state actors, to undertake steps to respect and to ensure the full realization of the rights recognized in the Covenants. Non-state actors (including corporations) are thus placed at the margins of the international legal regime.<sup>42</sup>

Furthermore, international human rights law and corporate law have historically evolved in isolation from one another.<sup>43</sup> The distance between these two legal regimes basically reflects two different legal conceptions: the notion of human rights is located in a “public” realm, binding only governments in their transactions with individuals, while the notion of corporate profits is situated in a “private” realm, governed solely by the rules of the marketplace.<sup>44</sup> Therefore, the business of private corporations is to use their resources and engage in corporate activities designed to increase their legitimate profits,<sup>45</sup> and the regulation of these corporate activities should be regarded as a matter of domestic corporate law.<sup>46</sup> Accordingly, corporations are not the principal targets for human rights concerns — only states can violate international human rights.<sup>47</sup>

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Practices Similar to Slavery.

<sup>36</sup> See e.g., article 8 of the ICCPR.

<sup>37</sup> See e.g., Programme of Action Against Apartheid, U.N. SCOR, 38th Sess., Supp. for Oct.-Dec. 1983, at 58, 63, U.N. Doc. S/16102 (1983) (calling on “corporations and employers” to “withdraw from any commercial operations in South Africa”).

<sup>38</sup> See e.g., Inter-American Convention on Forced Disappearance of Persons.

<sup>39</sup> HENRY J. STEINER ET AL., *INTERNATIONAL HUMAN RIGHTS IN CONTEXT: LAW, POLITICS, MORALS* 1385 (2007).

<sup>40</sup> Article 2(1) of the ICCPR, “Each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.”

<sup>41</sup> Article 2(1) of the ICESCR, “Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.”

<sup>42</sup> STEINER ET AL., *supra* note 39.

<sup>43</sup> STEINHARDT ET AL., *supra* note 25.

<sup>44</sup> *Id.*

<sup>45</sup> MILTON FRIEDMAN, *CAPITALISM AND FREEDOM* 133 (1962). See also Klaus M. Leisinger, *Corporate Responsibilities for Access to Medicines*, 85(1) J. OF BUSINESS ETHICS, 3 (2009) (published online in Novartis Foundation for Sustainable Development, DOI 10.1007/s10051-008-9944-4), available at <http://www.novartisfoundation.org/platform/apps/Publication/getfmfile.asp?id=612&el=2735&se=124414503&doc=184&dse=5> (last visited Mar. 18, 2011).

<sup>46</sup> STEINHARDT ET AL., *supra* note 25

<sup>47</sup> Curtis A. Bradley & Jack L. Goldsmith, *Customary International Law as Federal Common Law:*



However, international trade has connected individuals and nations to one another and to their environments<sup>48</sup>, and has also transformed governments' ability to monitor and protect human rights.<sup>49</sup> More specifically, globalization has contributed to the increasingly central role of transnational corporations (TNCs), also known as multinational enterprises (MNEs), in international and domestic economic orders.<sup>50</sup> For example, studies show that the world's 300 largest corporations account for 25% of the world's productive assets,<sup>51</sup> and 25 of them account for half of these productive assets.<sup>52</sup> TNCs also hold 90% of all technology and product patents worldwide<sup>53</sup> and are involved in 70% of world trade.<sup>54</sup> These corporations thus, have greater economic power over markets than do states in the international trade era.<sup>55</sup> Since the measure of real power in the international arena has shifted from military and political power to economic power, TNCs have become one of the most powerful economic and political entities in the world and exercise significant power over individuals, as their decisions and policies significantly impact their well-being.<sup>56</sup> Along with the growth of corporate power, TNCs have assumed major roles in relation to individuals' enjoyment of human rights.<sup>57</sup> In other words, TNCs can promote and undermine respect for human rights by wielding their power in economic and political realms — they can have an overall positive effect on human rights<sup>58</sup>, but can also

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*A Critique of the Modern Position*, 110 Harv. L. Rev. 815, 870 (1997).

<sup>48</sup> Dresler & Marks, *supra* note 13, at 634

<sup>49</sup> Shaffer et al., *supra* note 9, at 23.

<sup>50</sup> The number of TNCs in the world jumped from 7,000 in 1970 to 40,000 in 1995, and their political and economic power is continually becoming more concentrated. David C. Korten, *The United Nations and the Corporate Agenda*, EARTH ISLAND JOURNAL, Sept. 22 1997, available at [http://findarticles.com/p/articles/mi\\_hb6393/is\\_n4\\_v12/ai\\_n28696067/pg\\_2/](http://findarticles.com/p/articles/mi_hb6393/is_n4_v12/ai_n28696067/pg_2/) (last visited Mar. 18, 2012).

<sup>51</sup> MEDARD GABEL & HENRY BRUNER, GLOBAL INC.: AN ATLAS OF THE MULTINATIONAL CORPORATION 5 (2003) (citing A Survey of Multinationals, Economist, Mar. 27, 1993, at 9).

<sup>52</sup> Sol Picciotto, *Introduction: What Rules for the World Economy?*, in REGULATING INTERNATIONAL BUSINESS: BEYOND LIBERALIZATION 6-7 (Sol Picciotto & Ruth Mayne eds., 1999).

<sup>53</sup> Howard A. Kwon, *Patent Protection and Technology Transfer in the Developing World: The Thailand Experience*, 28 GEO. WASH. J. INT'L L. & ECON. 567, 570 (1995) (citing Suwanna Asavaroengchai, *Seeking a Fair Deal in Global Trade*, Bangkok Post, Oct. 19, 1994, at 31).

<sup>54</sup> David Weissbrodt, *Keynote Address: International Standard-Setting on The Human Rights Responsibilities of Businesses*, 26 BERKELEY J. INT'L L. 373, 375 (2008) (citing TOM ATHANASIOU, DIVIDED PLANET: THE ECOLOGY OF RICH AND POOR 194 (1996); DAVID KORTEN, WHEN CORPORATIONS RULE THE WORLD 132-33 (1995)).

<sup>55</sup> SUSAN STRANGE, THE RETREAT OF THE STATE: THE DIFFUSION OF POWER IN THE WORLD ECONOMY 47 (1996).

<sup>56</sup> Steven R. Ratner, *Corporations and Human Rights: A Theory of Legal Responsibility*, 111(3) YALE L.J. 443, 462 (2001).

<sup>57</sup> STEINER ET AL., *supra* note 39.

<sup>58</sup> Some scholars have argued that TNCs can help to create, mutually benefiting the world by maximizing the overall social interest and further promoting more trade liberalization, which most economists view as a means to wealth maximization. If individuals' wealth can be maximized, they

commit human rights abuses<sup>59</sup>, as will be shown in the following examples. In *Jota v. Texaco*, the defendant Texaco a transnational oil firm, which in this case was engaged in natural resources exploitation in Ecuador, was accused of affecting people's enjoyment of a healthy environment and infringing on the rights of indigenous peoples.<sup>60</sup> In *Ngcobo v. Thor Chemicals*, Thor was held responsible for human rights violations by exposing workers to mercury, causing poisoning at its South African mercury recycling plant.<sup>61</sup> Therefore, the assumption by TNCs of functions previously performed by the state has been a contentious topic in broad circles from environmental and health to legal and human rights.<sup>62</sup>

Recognizing that TNCs can and do play a significant role in human rights violations, public and scholarly awareness about TNCs' human rights responsibilities has grown rapidly.<sup>63</sup> It has been proposed that "international [human rights] law [needs to] extend the scope of liability for a violation of a given norm to a private actor such as a corporation."<sup>64</sup> International institutions sought to regulate TNCs' human rights responsibilities through a variety of mechanisms.<sup>65</sup> For example, in an attempt to promote greater corporate accountability for human rights violations, U.N. Secretary-General Kofi Annan in 1999 proposed the Global Compact,<sup>66</sup> a strategic policy initiative that requires corporations to agree to not violate human rights and also to avoid complicity in human rights abuses.<sup>67,68</sup> In 2003, the UN Sub-Commission on the Promotion and

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can then freely spend their resources to purchase social goods. In other words, TNCs' activities and increased foreign direct investment would have positive effects on human rights. See e.g., AMRITA NARLIKAR, *THE WORLD TRADE ORGANIZATION: A VERY SHORT INTRODUCTION* 2, 28-29 (2005); William H. Meyer, *Human Rights and MNCs: Theory Versus Quantitative Analysis*, 18(2) HUM. RTS. Q. 368 (1996).

<sup>59</sup> For example, Carol Bellamy, Executive Director of the U.N. Children's Fund [UNICEF], has stated that the main violators of children's right to health are tobacco and alcohol producers and distributors, which enable easy access for children. See World Health Organization, *Confronting the Epidemic: A Global Agenda for Tobacco Control Research*, available at [http://whqlibdoc.who.int/hq/1999/WHO\\_NCD\\_TFI\\_99.12.pdf](http://whqlibdoc.who.int/hq/1999/WHO_NCD_TFI_99.12.pdf) (last visited Mar. 18, 2012).

<sup>60</sup> *Jota v. Texaco, Inc.*, 157 F.3d 153, 155 (2d Cir. 1998).

<sup>61</sup> See *Ngcobo v. Thor Chemicals Holdings Ltd.*, [1995] T.L.R. 10 (Eng. C.A.).

<sup>62</sup> Sánchez-Moreno & Higgins, *supra* note 24, at 1664.

<sup>63</sup> A. A. Fatouros, *On the Implementation of International Codes of Conduct: An Analysis of Future Experience*, 30 AM. U. L. REV. 941, 951 (1981). Geoffery Chandler, *The Evolution of the Business and Human Rights Debate*, in *BUSINESS AND HUMAN RIGHTS: DILEMMAS AND SOLUTIONS* 26 (Rory Sullivan ed., 2003).

<sup>64</sup> *Sosa v. Alvarez-Machain*, 542 U.S. 692, 729 (2004). In *Presbyterian Church of Sudan v. Talisman Energy*, the court also considered that "corporations may also be held liable under international law, at least for gross human rights violations." *Presbyterian Church of Sudan v. Talisman Energy, Inc.*, 244 F. Supp. 2d 289, 319 (S.D.N.Y. 2003).

<sup>65</sup> Ferreira, *supra* note 28, at 1166.

<sup>66</sup> United Nations Global Compact, Overview of the UN Global Compact, available at <http://www.unglobalcompact.org/AboutTheGC/index.html> (last visited Mar. 18, 2012).

<sup>67</sup> Rebecca Walker Kaplan & Walker LLP, *Am I My Brother's Keeper? The Advantages and Potential Pitfalls of Extending Compliance Requirements to Suppliers and Other Third Parties*,

Protection of Human Rights further approved a new set of Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights<sup>69</sup> [Norms for TNCs], which rest on an expansive and broad theory of corporate responsibility. This initiative reaffirms TNCs' responsibility not only to respect international commercial law (particularly in relation to the rights of workers and the security of people)<sup>70</sup>, but also to “promote, secure the fulfillment of, respect, ensure respect of and protect human rights recognized in international as well as national law” within TNCs' respective spheres of activity and influence.<sup>71,72</sup> With respect to the right to health, the norms state that “[t]ransnational corporations and other business enterprises shall respect civil, cultural, economic, political, and social rights, and contribute to their realization, in particular the rights to . . . the highest attainable standard of physical and mental health; and refrain from actions which obstruct or impede the

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1703 PLI/Corp 491, 498 (2008).

<sup>68</sup> The Global Compact consists of 10 principles covering four areas: human rights, labour standards, environmental protection, and anti-corruption. TNCs are committed to aligning their operations and strategies with the following universally accepted principles: (1) Human rights: Businesses should (a) support and respect the protection of internationally proclaimed human rights, and (b) make sure that they are not complicit in human rights abuses. (2) Labour: Businesses should (a) uphold the freedom of association and the effective recognition of the right to collective bargaining; (b) work toward the elimination of all forms of forced and compulsory labour; (c) work toward the effective abolition of child labour; and (d) work toward the elimination of discrimination in respect of employment and occupation. (3) Environment: Businesses should (a) support a precautionary approach to environmental challenges; (b) undertake initiatives to promote greater environmental responsibility; and (c) encourage the development and diffusion of environmentally friendly technologies. (4) Anti-Corruption: Businesses should work against corruption in all its forms, including extortion and bribery. See United Nations Global Compact, The Ten Principles, available at <http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/index.html> (last visited Mar. 18, 2012).

<sup>69</sup> U. N. Econ. & Soc. Council, Comm. on Human Rights, Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights [Norms for TNCs], U.N. Doc. E/CN.4/Sub.2/2003/12/Rev.2 (Aug. 26, 2003).

<sup>70</sup> David Weissbrodt & Muria Kruger, *Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights*, 97(4) AM. J. INT'L L. 901, 911-12 (2003).

<sup>71</sup> Paragraph 1 of the Norms. In addition, Preamble of the Norms also states that, “transnational corporations and other business enterprises, their officers and persons working for them are also obligated to respect generally recognized responsibilities and norms contained in United Nations treaties and other international instruments.”

<sup>72</sup> Furthermore, to ensure compliance with this aspiration, the Norms also propose (1) to set corporate internal compliance regimes (paragraph 15), (2) to allow periodic monitoring of TNCs' activities by international organizations (paragraph 16), and (3) to establish a legal framework for assuring that TNCs comply with the Norms and award the necessary damages to those affected when TNCs fail to comply (paragraphs 17-18). Mara Theophila, “*Moral Monsters' Under The Bed: Holding Corporations Accountable for Violations of the Alien Tort Statute After Kiobel V. Royal Dutch Petroleum Co.*,” 79 FORDHAM L. REV. 2859, 2880 (2011). See also U.N. Report of the Special Rep. of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, Promotion of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development, ¶ 87, U.N. Doc. A/HRC/11/13 (Apr. 22, 2009).

realization of those rights.<sup>73</sup> The Organization for Economic Cooperation and Development (OECD) also drafted its own set of guidelines — the OECD Guidelines for Multinational Enterprises<sup>74</sup> [Guidelines for MNEs] — that flesh out TNCs’ responsibility to “respect the human rights of those affected by their activities consistent with the host government’s international obligations and commitments.”<sup>75</sup> <sup>76</sup> Other international institutions — such as the International Labour Organization’s (ILO’s) Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy<sup>77</sup> (Tripartite Declaration) — also call on TNCs to respect the International Bill of Rights,<sup>78</sup> including safety and health,<sup>79</sup> equality of opportunity and treatment,<sup>80</sup> minimum living wage,<sup>81</sup> and freedom of association and the right to organize.<sup>82</sup>

In addition to international institutions, because TNCs have a long-term economic self-interest to bring their practices into conformity with at least some subset of human rights standards,<sup>83</sup> TNCs have recently adopted their own codes of conduct with which make the protection of at least some essential human rights an explicit corporate objective.<sup>84</sup> For example, coalitions of TNCs in apparel, textiles, and foot-wear have

<sup>73</sup> Article 12 of the Norms for TNCs.

<sup>74</sup> Org. for Econ. Co-operation and Dev., The OECD Declaration and Decisions on International Investment and Multinational Enterprises: Basic Texts: Guidelines for Multinational Enterprises [hereinafter Guidelines for MNEs], OECD DAF/IME (2000) 20 (Nov. 8, 2000). *See also* The OECD Guidelines for Multinational Enterprises: Text, Commentary and Clarifications, DAF/IME/WPG(2000)15/FINAL (Oct. 31, 2001). The OECD Guidelines for Multinational Enterprises: Part I Recommendations for Responsible Business Conduct in A Global Context, DAF/IME/WPG(2000)15/FINAL (May 25, 2011), available at <http://www.oecd.org/dataoecd/43/29/48004323.pdf> (last visited Mar. 18, 2012).

<sup>75</sup> Section II paragraph 2 of the Guidelines for MNEs.

<sup>76</sup> By providing principles and standards for responsible business conduct in a variety of areas including human rights (Section II), employment and industrial relations (Section IV), environment (section V), information disclosure (section III), combating bribery (section VI), consumer interests (section VII), and implementation procedures of the Guidelines (such as the establishment of the Committee on International Investment and Multinational Enterprises and National Contact Points, *see* Sections I and II), the Guidelines provide much of the content of TNCs’ human rights responsibilities and have the greatest potential for effective implementation. Ferreira, *supra* note 28, at 1169. *See also* Douglass Cassel, *Corporate Initiatives: A Second Human Rights Revolution?*, 19(5) *FORDHAM INT’L L. J.* 1963, 1970 (1996).

<sup>77</sup> International Labor Organization, Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy (4th ed. 2006) [Tripartite Declaration], available at [http://www.ilo.org/wcmsp5/groups/public/---ed\\_emp/---emp\\_ent/---multi/documents/publication/wcms\\_094386.pdf](http://www.ilo.org/wcmsp5/groups/public/---ed_emp/---emp_ent/---multi/documents/publication/wcms_094386.pdf) (last visited Mar. 18, 2012).

<sup>78</sup> Paragraph 8 of the Tripartite Declaration.

<sup>79</sup> *Id.* paras. 37-40.

<sup>80</sup> *Id.* paras. 21-23.

<sup>81</sup> *Id.* paras. 33-35.

<sup>82</sup> *Id.* paras. 42-48.

<sup>83</sup> Ralph G. Steinhardt, *Soft Law, Hard Markets: Competitive Self-Interest and the Emergence of Human Rights Responsibilities for Multinational Corporations*, 33 *BROOK. J. INT’L L.* 933, 943 (2008).

<sup>84</sup> STEINHARDT ET AL., *supra* note 25, at 663.

adopted industry-wide standards to govern international labor practices<sup>85</sup> and establish unilateral codes of conduct,<sup>86</sup> “rights-sensitive” product lines and branding,<sup>87</sup> and social accountability auditing and certification.<sup>88</sup> Some TNCs have also acknowledged that their practices have had a negative impact on human rights<sup>89</sup> and are concerned about projecting “a socially responsible image”<sup>90</sup> because consumers today often choose not to purchase products that have been made in a socially irresponsible manner.<sup>91</sup> For example, transnational tobacco corporations have worked to create credibility with their customers<sup>92</sup> by agreeing, not dispute the governments’ stance, that smoking causes diseases and is addictive<sup>93</sup> and “believe in the provision of accurate, clear health messages about the risks of tobacco consumption.”<sup>94</sup>

In summary, although TNCs claim they are interested in protecting human rights, their practices and statements to this end seem more focused on their image (responsible, humane) and the bottom line (profits), and remain to be evaluated. Accordingly, it is doubtful that both international human rights institutions and TNCs, including TNPCs, fully recognize and accept their responsibilities with respect to human rights. Thus, we must reevaluate whether TNPCs should be held accountable for the rights-related

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<sup>85</sup> *Id.*; See also Marisa Anne Pagnattaro, *The “Helping Hand” in Trade Agreements: An Analysis of and Proposal for Labor Provisions in U.S. Free Trade Agreements*, 16 FLA. J. INT’L L. 845, 852 (2004).

<sup>86</sup> For example, in 1991 Levi Strauss adopted its “Global Sourcing and Operating Guidelines, which declared that it would favor business partners who also commit to improving human rights and withdraw production from any factory that violates human rights standards. STEINHARDT ET AL., *supra* note 25, at 666.

<sup>87</sup> For example, Starbucks has periodically offered “fair trade” coffees, which are not produced or marketed in countries that violate human rights of workers and communities. *Id.* at 665.

<sup>88</sup> For example, Social Accountability [SA] 8000 offers a voluntary process under which independent auditors may certify that a TNCs complies with principles in 9 essential areas: child labor, forced labor, health and safety, freedom of association, freedom from discrimination, disciplinary practices, work hours, compensation, and management systems to assure compliance. *Id.* at 667. See also Social Accountability International [SAI], SA8000® Abridged Guidance — 2008 Standard, *available at*

[http://www.sa-intl.org/\\_data/n\\_0001/resources/live/SAI\\_AbridgedGuidance\\_SA8000\\_2008.pdf](http://www.sa-intl.org/_data/n_0001/resources/live/SAI_AbridgedGuidance_SA8000_2008.pdf) (last visited Mar. 18, 2012).

<sup>89</sup> British American Tobacco, Cyprus, Social Report 2004/05, *available at* [http://www.bat.com/group/sites/uk\\_\\_3mnfen.nsf/vwPagesWebLive/9F917BD216FC90A1C12573140052F059/\\$FILE/cyprus0405.pdf?openelement](http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/9F917BD216FC90A1C12573140052F059/$FILE/cyprus0405.pdf?openelement) (last visited Mar. 18, 2012).

<sup>90</sup> Lissy C. Friedman, *Tobacco Industry Use of Corporate Social Responsibility Tactics as A Sword and A Shield on Secondhand Smoke Issues*, 37(4) J. L. MED. & ETHICS 819, 821 (2009).

<sup>91</sup> Shira Pridan-Frank, *Human-Genomics: A Challenge to the Rules of the Game of International Law*, 40 COLUM. J. TRANSNAT’L L. 619, 668 (2002).

<sup>92</sup> Friedman, *supra* note 90.

<sup>93</sup> Lissy C. Friedman, *Philip Morris’s Website and Television Commercials Use New Language to Mislead the Public Into Believing It Has Changed Its Stance on Smoking and Disease*, 16(6) TOBACCO CONTROL 9 (2007), *available at* <http://tobaccocontrol.bmj.com/content/16/6/e9.full.pdf> (last visited Mar. 18, 2012).

<sup>94</sup> British American Tobacco, Cyprus, *supra* note 89.

consequences (violations) of their activities based on the norms of the right to health — especially the right to access medicines.

### III. ACCESS TO MEDICINES AS A HUMAN RIGHT

Whether the TNPCs are obligated to improve pharmaceutical accessibility and affordability has long been debated, however, the scope of their obligations has received little examination. Therefore, to establish conceptual clarity on TNPCs' human rights responsibilities regarding access to medicines, the scope of access to medicines entitlements under international human rights law must be elucidated.<sup>95</sup>

#### A. *In Search of the Right to Access Medicines*

In a broad sense, the right to health is taken to be a repository for everything that involves health, including accessibility to medicines.<sup>96</sup> The concept that health can be a “notion of basic individual rights” was first put forth in the 18th century.<sup>97</sup> Then in the 20th century, international human rights documents (e.g., UDHR Article 25.1, ICESCR Article 12, and the WHO Constitution preamble)<sup>98</sup> along with various national constitutions<sup>99</sup>

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<sup>95</sup> Mok, *supra* note 1, at 73.

<sup>96</sup> BRIGIT C.A. TOEBES, *THE RIGHT TO HEALTH AS A HUMAN RIGHT IN INTERNATIONAL LAW* 259 (1999).

<sup>97</sup> For example, Johann Gottlieb Fichte argued that the government has the obligation to help people when they face accidents or illnesses. Van der Ven argued that the state is obligated to provide sufficient health care services to protect people's physical and mental health. G. Brunner and T. Tommandl also assert that the state is obligated to maintain the minimum standards of life, including health care services and housing for the public. See XINMIN CHEN, XIAN FA JI BEN QUAN LI ZHI JI BEN LI LUN [BASIC THEORY OF CONSTITUTIONAL BASIC RIGHTS] 95-128 (1992). See also NORMAN DANIELS, *JUST HEALTH CARE* 4 (1985).

<sup>98</sup> Article 25.1 of the Universal Declaration of Human Rights [UDHR] affirms: “Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.” In accordance with Article 12.1 of the ICESCR, state parties recognize “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,” while Article 12.2 of the ICESCR enumerates, by way of illustration, a number of “steps to be taken by the States’ parties ... to achieve the full realization of this right.” The preamble of the World Health Organization [WHO] Constitution asserts that “health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity,” and that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.” Additionally, the right to health is also recognized in Article 5(e)(iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, in Articles 11.1(f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women [CEDAW] of 1979, and in Article 24 of the Convention on the Rights of the Child [CRC] of 1989. Several regional human rights instruments also recognize the right to health, such as Article 11 of the European Social Charter of 1961, Article 16 of the African Charter on Human and Peoples’ Rights of 1981, and Article 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988.

and non-governmental organizations (NGOs)<sup>100</sup> further proposed that individuals should have the right to maintain the “highest attainable standard” of physical and mental health. This has gradually developed into the recognition of an individual’s right to health as a basic socio-economic right.

In the generally accepted framework of the right to health, access to medicines is an essential component because inaccessibility to medicines prevents individuals from obtaining the medicine they need to prevent or treat a medical condition; consequently they could fall below the highest attainable standard of health. Thus, access to needed medicines for treatment, prevention and palliative care<sup>101</sup> is a necessary condition for leading a healthy and dignified life, without which the right to health itself would be meaningless.<sup>102</sup> There is an emerging consensus among human rights scholars and advocates that access to affordable medicines is a fundamental human right under international law, and that states have an obligation to respect, protect, and fulfill this right.<sup>103</sup> For example, international human rights institutions argue that the term “medical care” described in UDHR Article 25, and the term “medical service” described in ICESCR Article 12.2, should be understood to include medicines, including both drugs and vaccines.<sup>104</sup> The U.N. Human Rights Council and the Committee on Economic, Social and Cultural Rights (CESCR) also recognize that access to medicines is a fundamental element necessary for individuals to achieve the full realization of the right to health,<sup>105</sup> and thus

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<sup>99</sup> See e.g., Section 27 of South Africa Constitution, Section 15(a) of the Finnish Constitution Act of 1995, Article 25 of Japanese constitution, and Article 157 and Amendment Article 10 of the Taiwan Constitution. Even when some countries, such as the United States, do not recognize the right to health in their constitutions, the related but subordinate issues of the right to health are present in statutes and common laws. See e.g., the Social Security Act of 1935, the Economic Bill of Rights, and the Patients’ Bill of Rights of 2005.

<sup>100</sup> See e.g., the World Medical Association’s [WMA] Declaration of Lisbon on the Rights of the Patients of 1995, the American Hospital Association’s Patient’s Bill of Rights of 1973, and the Japanese Patients’ Bill of Rights of 1984.

<sup>101</sup> African Commission on Human and Peoples’ Rights, Resolution on Access to Health and Needed Medicines in Africa, ACHPR/Res.141 (XXXVIII)08 (November 24, 2008), available at [http://www.achpr.org/english/resolutions/resolution141\\_en.htm](http://www.achpr.org/english/resolutions/resolution141_en.htm) (last visited Mar. 18, 2012).

<sup>102</sup> Joanne Csete, *Several for the Price of One: Right to AIDS Treatment as Link to Other Human Rights*, 17 CONN. J. INT’L L. 263, 265 (2002).

<sup>103</sup> *Id.* at 265. See also Ferreira, *supra* note 28, at 1171. Nitya Nanda & Ritu Lodha, *Making Essential Medicines Affordable to the Poor*, 20(3) WIS. INT’L L. J. 581, 581 (2002).

<sup>104</sup> Paul Hunt, *Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations*, 7, United Nations Health and Human Rights Working Paper Series No. 4 (2003), available at

[http://www.who.int/hhr/news/en/Series\\_4\\_neglected%20diseases\\_social\\_justice\\_human\\_rights%20Paul\\_Hunt.pdf](http://www.who.int/hhr/news/en/Series_4_neglected%20diseases_social_justice_human_rights%20Paul_Hunt.pdf) (last visited Mar. 18, 2012).

<sup>105</sup> U.N. Human Rights Council, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Expert Consultation on Access to Medicines as A Fundamental Component of the Right To Health, 5-24, U.N. Doc. A/HRC/RES/17/43 (March 16, 2011), available at

the right to health, in all its forms and at all levels, requires economic accessibility (affordability) — meaning health facilities, goods (including medicines) and services have to be accessible and affordable to everyone without discrimination.<sup>106</sup> Paragraphs 43-45 of the CESCR General Comment No. 14 further imposes a core obligation on state parties to provide essential drugs and immunization against infectious diseases occurring in the communities,<sup>107</sup> and argues that the contents of the right to health take priority over other contents.<sup>108</sup> In addition, WHO's Primary Health Care strategy also concludes that sufficient and adequate provision of essential drugs is a vital element<sup>109</sup> for the realization of a health baseline, "below which no individuals in any country should find themselves."<sup>110</sup>

Courts in various nations have ruled that states must enforce affirmative actions to uphold the right to access medicines. For example, in *Minister of Health v. New Clicks South Africa (Pty) Ltd.*, the South African Constitutional Court added significant, new, and substantive content to the right to health beyond the constitutional framework<sup>111</sup> by establishing that the right to health includes the right to access affordable medicines.<sup>112</sup> This

<http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/118/42/PDF/G1111842.pdf?OpenElement> (last visited Mar. 18, 2012). See also Committee on Economic, Social, and Cultural Rights, CESCR General Comment No. 14, ¶ 1 (E/C 12/2000/4) (2000).

<sup>106</sup> See generally Committee on Economic, Social, and Cultural Rights, CESCR General Comment No. 14 (E/C 12/2000/4) (2000).

<sup>107</sup> According to CESCR General Comment No. 14 articles 43 and 44, state parties have the following core obligations (which directly relate to health care services): (1) to ensure access to the minimum essential food which is nutritionally adequate and safe; (2) to ensure access to basic shelter, housing and sanitation; (3) to ensure access to adequate supply of safe and potable water; (4) to provide essential drugs; to ensure reproductive, maternal (pre-natal as well as post-natal) and child health care; (5) to provide immunization against the major infectious diseases occurring in the community; (6) to take measures to prevent, treat and control epidemic and endemic diseases.

<sup>108</sup> Melissa McClellan, "Tools for Success": *The TRIPS Agreement and the Human Right to Essential Medicines*, 12 WASH. & LEE J. CIV. RTS. & SOC. JUST. 153, 160-61 (2005).

<sup>109</sup> WHO, Primary Health Care, Chapter 3, ¶ 50 (1978). See also *id.* Chapter 2, at 34.

<sup>110</sup> WHO, Global Strategy for Health for All by the Year 2000, 31 (Chapter 2, ¶ 1) (1981). The other main elements of primary health care are immunization against major infectious diseases and appropriate treatment of common diseases and injuries.

<sup>111</sup> Section 27(2) of the South African Final Constitution confines the right to health to the state, which "must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights" even when Section 27(1) states that "Everyone has the right of access to (a) health care services, including reproductive health care; (b) sufficient food and water; and (c) social security, including if they are unable to support themselves and their dependents, appropriate social assistance"; and Section 27(3) states that "[n]o one may be refused emergency medical treatment." The formulation of section 27 then provides little indication of the nature or scope of the entitlement which the right to access medicines confers.

<sup>112</sup> For example, the Court stated that "prohibitive pricing of medicines ... would in effect equate to a denial of the right of access to health care," and "preventing excessive profit-taking from the manufacturing distribution and sale of medicines is more than an option for government. It is a constitutional obligation flowing from its duties under section 27(2)." *Minister of Health & Professor D. McIntyre No v. New Clicks South Africa (Pty) Ltd & Others 2006 (2) SA 311 (CC)*, ¶¶ 514, 659, 704, 706 (S. Afr.).



placed a range of obligations on the state in relation to affordability.<sup>113</sup> In *Hazel Tau et al. v. GlaxoSmithKline, Boehringer Ingelheim et al.*, the Competition Commission of South Africa confirmed that the right to access medicines is “firmly entrenched in the Constitution and [is] also recognised at international law.”<sup>114</sup> In *Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social*, the Venezuelan court also interpreted the right to HIV/AIDS treatment to be an internationally protected right<sup>115</sup> and obligated the state to ensure this right.<sup>116</sup> Brazil further committed to guarantee individuals’ universal access to medicines based on Article 196 of the Brazilian Federal Constitution.<sup>117</sup> Even though some countries, such as U.S., do not recognize the right to health in their constitutions,<sup>118</sup> through certain national policies<sup>119</sup> and cases (e.g., *Youngberg v. Romeo*,<sup>120</sup> *Estelle v. Gamble*,<sup>121</sup> *Horizon Health Center v. Felicissimo*,<sup>122</sup>

<sup>113</sup> Lisa Forman, *Justice and Juristicability: Advancing Solidarity and Justice through South Africans’ Right to Health Jurisprudence*, 27(3) MED. L. 661, 679 (2008).

<sup>114</sup> Statement of Complaint in Terms of Section 49B(2)(b) of the Competition Act 89 of 1998, *Hazel Tau et al. v. GlaxoSmithKline et al.* (Competition Commission of South Africa), ¶ 60.5, available at

<http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf> (last visited Mar. 18, 2012).

<sup>115</sup> The Cruz Bermúdez Court argued that “the right to health, as interpreted by the Court, had the broadest possible application in Venezuela, giving every HIV positive person in the country the right to access ARV therapies.”

<sup>116</sup> Mary Ann Torres, *The Human Right to Health, National Courts, and Access to HIV/AIDS Treatment: A Case Study from Venezuela*, 3 CHI. J. INT’L L. 105, 106 (2002) (citing *Cruz Bermúdez et al. v. Ministerio de Sanidad y Asistencia Social, Sala Político Administrativa, Corte Suprema de Justicia, Republica de Venezuela, Expediente Numero: 15.789* (1999) (the Venezuelan Supreme Court found that the Ministry of Health and Social Action had infringed health rights belonging to HIV-positive persons by failing to supply prescribed ART).

<sup>117</sup> Article 196 of the Brazilian Federal Constitution, “Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery.” *Constituição Federal [C.F.] Chapter II, Section II, art. 196* (Braz.).

<sup>118</sup> Kenneth R. Wing, *The Right to Health Care in the United States*, 2 ANNALS HEALTH L. 161, 163 (1993).

<sup>119</sup> For example, in the United States, Franklin D. Roosevelt’s proposed Economic Bill of Rights of 1944 introduced the idea of the right to adequate medical care and for every citizen the opportunity to achieve and enjoy good health. The National Health Planning and Resources Development Act of 1974 required federal policy to provide “equal access to quality care at a reasonable cost.” Economic Bill of Rights of 1944, 90 Cong. Rec. 55-57 (1944); National Health Planning and Resources Development Act of 1974, 42 U.S.C. § 300k et seq. (1974).

<sup>120</sup> *Youngberg v. Romeo*, 457 U.S. 307 (1982) (The Court found that have the right to adequate medical care, including mental health treatment and suicide watches).

<sup>121</sup> *Estelle v. Gamble*, 429 U.S. 97 (1976) (The Court held that under certain circumstances, it was cruel and unusual punishment for a prison to refuse to provide medical treatment, and the government has an “obligation to provide medical care for those whom it is punishing by incarceration”).

<sup>122</sup> *Horizon Health Center v. Felicissimo*, 638 A.2d 1260, 1269 (N.J. 1994) (The Court noted that “[t]he New Jersey Constitution does not guarantee explicitly a fundamental right to health” but does accord a “high priority to the preservation of health”, and thus the state “has a significant interest in

and *Right to Choose v. Byrne*<sup>123</sup>) they have developed subordinate principles to substantially protect individuals' access to healthcare as a right to health.<sup>124</sup>

In addition to the fact that the right to access medicines is considered as the core content of the right to health,<sup>125</sup> the extent of the right to access medicines is also closely linked to various human rights guarantees under international law,<sup>126</sup> such as the right to life, the right to share in scientific progress, and the right to development.

**First**, the health baseline, which is “structurally” guaranteed under the protection of the right to access affordable medicines, is directly related to life-saving, or life-maintaining, and to the right to life. On one hand, denying or withdrawing certain medicines, from people could negatively impact that respective individual's health. On some occasions though, it might even be the difference between life and death.<sup>127</sup> For example, studies have shown that HIV/AIDS drugs (e.g., anti-retroviral [ARV]) can significantly prolong the life of HIV-positive patients.<sup>128</sup> But this disease has been turned from a preventable and manageable disease into a life-threatening pandemic by ignorance, neglect, and violations of the right to access medicine.<sup>129</sup> Over the past several decades, the scope of the right to life has also gradually expanded to include a broader range of issues, such as protection against epidemics and access to medicines so as to ensure the right to life.<sup>130</sup> The international community's general acceptance of the importance of access to medicine to ensure the right to life, then makes access to medicine a human rights issue in the broader

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insuring unrestricted access to . . . medical services”).

<sup>123</sup> *Right to Choose v. Byrne*, 450 A.2d 925, 936-37 (N.J. 1982) (The court recognized that a woman's right to choose an abortion is a fundamental right of all residents, including those entitled to Medicaid reimbursement for necessary medical treatment).

<sup>124</sup> However, these contents are more precisely characterized as political rights or entitlements than constitutional rights. It is unlikely that U.S. courts would recognize access to medicines as providing a right of action justiciable under the Constitution. See e.g., Carolynne Shinn, *The Right to the Highest Attainable Standard of Health: Public Health's Opportunity to Reframe a Human Rights Debate in the United States*, 4(1) HEALTH & HUM. RTS. 114, 115 (1999). Wing, *supra* note 118, at 161 (1993). Janet O'Keeffe, *The Right to Health Care and Health Care Reform, in HEALTH CARE REFORM: A HUMAN RIGHTS APPROACH* 36 (Audrey R. Chapman ed., 1994). See also Tina S. Bhatt, *Amending TRIPS: A New Hope for Increased Access to Essential Medicines*, 33 BROOK. J. INT'L L. 597, 621-22 (2008).

<sup>125</sup> Committee on Economic, Social, and Cultural Rights, CESCR General Comment No. 14, ¶ 12 (E/C 12/2000/4) (2000).

<sup>126</sup> Ferreira, *supra* note 28, at 1171.

<sup>127</sup> TOEBES, *supra* note 96, at 259.

<sup>128</sup> Ferreira, *supra* note 28, at 1171.

<sup>129</sup> Joint Statement, The Allard K. Lowenstein International Human Rights Clinic of the Yale Law School et al., *AIDS and Human Rights: A Call for Action* (June 25, 2001), available at <http://www.hrw.org/news/2001/06/25/aids-and-human-rights-call-action> (last visited Mar. 18, 2012).

<sup>130</sup> TOEBES, *supra* note 96, at 261.

sense.<sup>131</sup> Furthermore, since the right to life is guaranteed in key human rights instruments (e.g. UDHR Article 3<sup>132</sup> and ICCPR Article 6<sup>133</sup>), the state then has a basic human rights obligation to guarantee the right to life for all by ensuring equitable access to necessary medicines.

**Second**, the right to access medicines is related to the right to share in scientific progress. Based on Article 27 of UDHR, which affirms that “everyone has the right freely. . . to share in scientific advancement and its benefits” and Article 15(1)(b) of the ICESCR, which recognizes the right of everyone both “to enjoy the benefits of scientific progress and its applications,” the individual then has the right to enjoy the benefits of scientific progress and its applications (including pharmaceutical innovations)<sup>134</sup> and the state is obligated “to promote access to the benefits of science and its applications on a nondiscriminatory basis”<sup>135</sup> and to prevent the utilization of science and technology “to the detriment of human rights . . . and the dignity of the human person.”<sup>136</sup> In addition, because the right to enjoy the benefits of scientific progress “is applicable to all fields of science and its applications,”<sup>137</sup> including scientific progress in the medical field, this right then might be violated where new treatments or medicines are available, or new methods of disease prevention have been discovered, but are kept from the public.<sup>138</sup> The right to enjoy the benefits of scientific progress thus, is inextricably linked to all human rights that reference access to science and technology,<sup>139</sup> including the right to access medicines. For example, when facing conflicts between the intellectual property right and the right to access medicines, CESCR

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<sup>131</sup> Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L. J. 103, 118 (2003).

<sup>132</sup> Article 3 of the UDHR, “Everyone has the right to life, liberty and security of person.”

<sup>133</sup> Article 6 of the ICCPR, “Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.”

<sup>134</sup> See Stephen Marks, *Out to Obscurity: The Right to Benefit from Advances in Science and Technology and Its Implications for Global Health*, 22-29, addressed at the 3rd Conference on Law, Science, and Technology: Health, Science, and Human Rights (held by Institutum Iurisprudentiae, Academia Sinica, Taipei, Taiwan) (December 18, 2010), available at <http://www.iias.sinica.edu.tw/upload/conferences/20101218/ep20101218-0b.pdf> (last visited Jan. 10, 2012). However, I want to remind readers that Article 15(c) of the ICESCR also recognizes the right “to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author,” which is the human rights basis for intellectual property protection.

<sup>135</sup> Paragraph 16(b) of the Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications (July 16-17, 2009) [hereinafter Venice Statement], available at [http://shr.aaas.org/article15/Reference\\_Materials/VeniceStatement\\_July2009.pdf](http://shr.aaas.org/article15/Reference_Materials/VeniceStatement_July2009.pdf) (last visited Jan. 10, 2012).

<sup>136</sup> *Id.* para. 15(a) and (b).

<sup>137</sup> *Id.* para. 12(a).

<sup>138</sup> Lesley Stone et al., *When the Right to Health and the Right to Religion Conflict: A Human Rights Analysis*, 12 MICH. ST. J. INT’L L. 247, 288 (2004).

<sup>139</sup> Venice Statement, para. 12(d).

explicitly states that “intellectual property rights must be balanced with the right [for all individuals] ... to enjoy the benefits of scientific progress and its applications.”<sup>140</sup> Therefore, equitable access to scientific advancements, in the form of medicines, is encompassed within the internationally guaranteed right to share in the benefits of scientific progress.<sup>141</sup>

**Third**, in the Declaration on the Right to Development, the U.N. obligates states to ensure that “every human person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realized.”<sup>142</sup> Since the right to development is strongly related to the guarantee of equal opportunity to all people in the effective availability of health services,<sup>143</sup> health, including access to medicines, should be regarded as the cornerstone for development and human rights.<sup>144</sup> Studies have identified a significant relationship between endemic mortality and fertility rates and economic growth,<sup>145</sup> and further concluded that the consumption of healthcare is positively related to household productivity and economic growth.<sup>146</sup> Likewise, Amartya Sen argues that the right to development can be regarded as a conglomeration of claims, varying from basic health care to civil rights for all.<sup>147</sup> As such, equitable access to the “health service” of medicines is a component of the right to development guaranteed under international law.<sup>148</sup>

### ***B. Content of the Right to Access Medicines***

According to CESCR, access to medicines can be further divided into the following elements:<sup>149</sup> (1) *Availability*. All individuals must have

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<sup>140</sup> Committee on Economic, Social, and Cultural Rights, CESCR General Comment No. 14, para. 4 (E/C 12/2000/4) (2000).

<sup>141</sup> Ferreira, *supra* note 28, at 1172.

<sup>142</sup> Article 1 of the Declaration on the Right to Development, G.A. Res. 41/128 (Annex), U.N. GAOR, 41st Sess., Supp. No. 53, at 186, U.N. Doc. A/41/53 (1986).

<sup>143</sup> *Id.* art. 8(1).

<sup>144</sup> See, e.g., Fourth World Conference on Women, Beijing, China, Sept. 4-15, 1995, Beijing Declaration and Platform for Action, para. 89, 92-96, U.N. Doc. A/CONF.177/20/Rev.1 (1996). See also International Conference on Population and Development, Cairo, Egypt, Sept. 5-13, 1994, Report of the International Conference on Population and Development, para. 7.3, U.N. Doc. A/CONF.171/13/Rev.1 (1995).

<sup>145</sup> Pradeep Agrawal, *Lessons from Emerging Asia*, 33(1/2) ECONOMIC AND POLITICAL WEEKLY 26, 27 (1998). See also AMARTYA SEN, DEVELOPMENT AS FREEDOM 46-51 (1999).

<sup>146</sup> Varun Gauri, *Social Rights and Economics: Claims to Health Care and Education in Developing Countries*, in HUMAN RIGHTS AND DEVELOPMENT: TOWARDS MUTUAL REINFORCEMENT 74 (Philip Alston & Mary Robinson eds., 2005).

<sup>147</sup> Amartya Sen, *Human Rights and Development*, in DEVELOPMENT AS A HUMAN RIGHT: LEGAL, POLITICAL, AND ECONOMIC DIMENSIONS 1, 5 (Bard A. Andreassen & Stephen P. Marks eds., 2007).

<sup>148</sup> Ferreira, *supra* note 28, at 1171-72.

<sup>149</sup> Committee on Economic, Social, and Cultural Rights, CESCR General Comment No. 14, para.

access to adequate public health and healthcare facilities and goods — including essential drugs, in sufficient quantity as defined by the WHO Action Programme on Essential Drugs. (2) *Accessibility*: Medicines must be accessible to all individuals without discrimination. Accessibility has four overlapping dimensions: (i) Non-discrimination: medicines must be accessible to all, in law and in actuality, without discrimination on any of the prohibited grounds. (ii) Physical accessibility: Medicines must be within safe physical reach for all. (iii) Economic accessibility (affordability): payment for medicine, which is related to the underlying determinants of health, must be based on the principle of equity, ensuring that is affordable for all, whether privately or publicly provided. (3) *Acceptability*. The mode of medicine delivery must be respectful of medical ethics and culturally appropriate (culturally, age-wise, gender-wise, etc.) for the targeted patient group. (4) *Quality*. Medicines must be scientifically and medically appropriate.

In conclusion, prevention, comprehensive care and support, including access to medications to all those infected and affected by pandemics, are inseparable elements of an effective response to the various human rights challenges.<sup>150</sup> Therefore, equitable access for all to medicines is not only an emerging independent human right, but is encompassed within a bundle of other human rights currently guaranteed under international law.<sup>151</sup>

#### **IV. PHARMACEUTICAL CORPORATIONS AND THE RIGHT TO ACCESS MEDICINES**

##### ***A. The Right to Access Medicines Norms Applicable to Pharmaceutical Corporations?***

Since TNCs' human rights responsibilities are recognized under international law (see Section II) and the issue of access to medicines is placed on the human rights agenda (see Section III), international documents start to recognize the development of TNPCs' responsibilities to protect the right to access medicines. For example, right-to-health activists refer the UDHR preamble, which states that "every individual and every organ of society . . . shall strive by teaching and education to promote respect for these rights and freedoms and by progressive measures, national

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12. Report of the Commission on Intellectual Property Rights, Innovation and Public Health 1112 (2006).

<sup>150</sup> Access to Medication in the Context of Pandemics such as HIV/AIDS, 1, Hum. Rts. Comm. Res. 2001/33, U.N. ESCOR, 57th Sess., Supp. No. 3, 71st mtg. at 169, U.N. Doc. E/CN.4/2001/167 (2001), available at <http://www.unhcr.org/refworld/docid/47d9537b2.html> (last visited March 26, 2012).

<sup>151</sup> Joanne Csete, *Several for the Price of One: Right to AIDS Treatment as Link to Other Human Rights*, 17 CONN. J. INT'L L. 263, 266-271 (2002).

and international, to secure their universal and effective recognition and observance,” as the grounds for corporate TNPCs’ responsibilities to respect the right to access medicines. They argue that the UDHR should be applied to every individual, including juridical persons and organs of society, and that it excludes no one, no company, and no market.<sup>152</sup> Paragraph 42 of the CESCR General Comment No. 14 also states that “[w]hile only States are parties to the [ICESCR] and thus ultimately accountable for compliance with it, all members of society . . . [including the] private business sector . . . have responsibilities regarding the realization of the right to health.” Paragraph 12 of the Norms for TNCs also states that “[t]ransnational corporations and other business enterprises shall respect economic, social, and cultural rights as well as civil and political rights and contribute to their realization, in particular . . . the highest attainable standard of physical and mental health . . . , and shall refrain from actions which obstruct or impede the realization of those rights.”

However, much debate rages over how to determine TNPCs’ responsibility in regards to improving overall access to medicine.<sup>153 154</sup> The major debate concerning TNPCs’ human rights responsibilities to provide affordable medicines distribution centers on whether TNPCs have moral responsibilities and/or legal responsibilities to fulfill the right to access medicines, is based on the open-ended nature of the right to access medicines under the progressive realization principle. Issues like this relate to the debate surrounding the difference between negative and positive rights<sup>155</sup> — responsibilities in the context of negative rights are subject to the criterion of “legality” and hence a part of TNPCs’ “must do” dimension, while responsibilities regarding positive rights are seen in terms of “morality” and hence a part of TNPCs’ “can do” dimension<sup>156</sup> (see Figure

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<sup>152</sup> Louis Henkin, *The Universal Declaration at 50 and the Challenges of Global Markets*, 25(1) *BROOK. J. INT’LL* 17, 25 (1999).

<sup>153</sup> Leisinger, *supra* note 45, at 4.

<sup>154</sup> For example, if corporations breach socio-economic rights (such as the right to access medicines), issues of state responsibility and sovereignty arise. States generally assert that only they may possess an obligation in international law to ensure that third parties (e.g., TNPCs/rations) do not violate human rights norms within their jurisdiction. Therefore, in a strategy for advancing the objectives of the right to access medicines, the state has traditionally been considered as the principal target for human rights violations. Paragraph 46 of CESCR General Comment No. 14 thus illustrates that “[w]hen the normative content of article 12 is applied to the obligations of States parties, a dynamic process is set in motion which facilitates identification of violations of the right to health.” In the *Minister of Health v. New Clicks* case, even though the Court recognized the right to access medicines, and indicated the impact of inaccessible medicines on the poor in particular, it nonetheless suggested state (rather than corporate) duties to take “special measures to assist those who are the most vulnerable to disease and, simultaneously the most lacking in resources” (*Minister of Health v. New Clicks SA (Pty) Ltd.* 2006 (1) *BCLR* 1, ¶ 651 & 706 (CC) (S. Afr.)).

<sup>155</sup> Negative rights are rights to be free from corporation’s intervention, and positive rights are rights to be provided by corporations with a particular action, good, or service.

<sup>156</sup> Leisinger, *supra* note 45, at 10.

1).

**First**, positive rights (or socio-economic rights, such as the right to access medicines) have not received as much respect as negative rights (most are civil and political rights),<sup>157</sup> especially in the present international context of development where social goods are thought to flow from the inexorable forward march of the market.<sup>158</sup> Fulfilling positive rights (i.e., the right to access medicines) — that is, providing essential social goods (i.e., medicines) and assisting individuals to meet their basic needs (i.e., healthcare needs) — are considered to belong to the public interventions, rather than TNCs.<sup>159</sup> Therefore, when exploring the relationships between businesses and human rights, the kind of human rights that corporations are responsible to protect are generally negative rights rather than positive rights.<sup>160</sup> For example, many of the socio-economic rights that ICESCR identifies appear to have no clear application to corporations, including the right to work, the right to receive fair wages, the right to social security, the right to an adequate standard of living and adequate food, clothing, and housing, and the right to education.<sup>161</sup> Since the right to access medicines is categorized as a positive right in the traditional human rights framework,<sup>162</sup> TNPCs then

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<sup>157</sup> Distinguishing negative and positive rights helps to identify the state's different obligations to fulfill negative and positive rights. The state is required to fulfill civil and political rights immediately ("everyone has the right to . . .") because these rights require only the state to (negatively) stay out of people's business ("no one shall be . . .") and they grant people limitless natural rights (e.g., the state does not recognize that the provision is subject to the availability of resources). On the contrary, socio-economic rights require the state's reorganization based on the availability of resources with a view to progressively achieving the goals (respecting, protecting, and fulfilling socio-economic rights) because these rights depend mainly on the state's ability to provide resources and services. According to this distinction, the fulfillment of the right to access medicines essentially depends upon the state's ability to access resources and to progressively provide these resources. This then forms the rationale behind the experts' argument that the right to access medicines is a positive right because its fulfillment requires the state to implement significant actions and to provide significant resources and/or services.

<sup>158</sup> Cass Sunstein, *Against Positive Rights: Why Social and Economic Rights Don't Belong in the New Constitutions*, 2 E. EUR. CONST. REV. 35, 35-38 (1993).

<sup>159</sup> Leisinger, *supra* note 45, at 6. (citing J.D. SACHS, COMMON WEALTH. ECONOMICS FOR A CROWDED PLANET 220 (2008)).

<sup>160</sup> Jan Wouters & Leen Chanet, *Corporate Human Rights Responsibility: A European Perspective*, 6 NW. U. J. INT'L HUM. RTS. 262, 268 (2008). Leisinger also states that when discussing corporations' human rights responsibilities, only responsibilities in the context of civil and political rights are an integral part of the "must" dimension and hence an essential ingredient of good management practices. Klaus M. Leisinger, *On Corporate Responsibility for Human Rights*, 9, available at [http://www.novartisfoundation.com/pdf/leisinger\\_contribution\\_hr\\_business.pdf](http://www.novartisfoundation.com/pdf/leisinger_contribution_hr_business.pdf) (last visited Mar. 18, 2010).

<sup>161</sup> Stephen G. Wood & Brett G. Scharffs, *Applicability of Human Rights Standards to Private Corporations: An American Perspective*, 50 AM. J. COMP. L. 531, 545 (2002).

<sup>162</sup> That is, the right to access medicines (1) is an entitlement to certain services or treatments, (2) entails progressive correlative obligations rather than immediate obligations of state parties, and (3) is irrelevant to the restriction or distribution of freedoms. Rodney Pepper, *A Defense of Rights to Well-Being*, 8(1) PHIL. & PUB. AFF. 65, 67 (1978).

should not be held legally responsible to ensure the availability and access of medicines.

**Second**, because positive rights place a specific demand on societal resources required for their fulfillment, it is unreasonable and unrealistic to assign a legal responsibility to corporations that might inevitably force them to exhaust their resources to offer social goods or services. Based on the progressive realization principle, the following reasoning shows why TNPCs assume only moral responsibilities to realize the right to access medicines (a positive right). (1) In accordance with ICESCR Article 2, the right to access medicines (under the right to health) is subject to the principle of progressive realization, meaning that, unlike civil and political rights,<sup>163</sup> the state is merely obligated to take steps toward the progressive fulfillment of the right on the premise of available resources, and the state can claim a scarcity of resources as a legitimate reason for not fulfilling the right.<sup>164</sup> Because the progressive realization of the right to access medicines means that pharmaceutical accessibility could only be progressively realized over time within available resources,<sup>165</sup> the state has only moral obligations to fulfill the right to access medicines to the extent that state resources permit. Likewise, the state has only moral obligations to provide opportunities for its citizens to access medicines and to achieve good health.<sup>166</sup> (2) Since the state has only moral obligations to protect the

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<sup>163</sup> The state is required to fulfill civil and political rights immediately (“everyone has the right to . . .”) because these rights only require the state to (negatively) stay out of people’s business (“no one shall be . . .”) and grant people limitless natural rights (e.g., the state does not recognize that the provision is subject to the availability of resources). Because civil and political rights have often been characterized as negative rights, and because civil and political rights are cost-free rights, which means that protection of these rights can be achieved without incurring significant costs, civil and political rights then are considered to be capable of full and immediate realization. All the state must do is enacting legislation that outlaws the activities that violate these rights. On the contrary, socio-economic rights only require the state’s reorganization in accordance to the availability of resources with a view to progressively achieving the goals (respecting, protecting, and fulfilling socio-economic rights) because these rights mainly depends on the state’s ability to provide resources and services. See, e.g., Cristina Baez et al., *Multinational Enterprises and Human Rights*, 8 U. MIAMI INT’L & COMP. L. REV. 183, 223 (2000). United Nations Development Programme, *Human Development Report 2000*, 93 (2000).

<sup>164</sup> According to Article 2(1) of the ICESCR, the state only need to “take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the [ICESCR] by all appropriate means, including particularly the adoption of legislative measures.” Paragraph 4 of the CESCR General Comment No. 14 also states that the state party only needs to take steps to the maximum its available resources, with a view to progressively achieving the full realization of the right to health, including the adoption of legislative measures. Committee on Economic, Social, and Cultural Rights, CESCR General Comment No. 14, ¶ 2 (E/C 12/2000/4) (2000).

<sup>165</sup> In other words, legal, administrative, operational and financial hurdles to the enjoyment of the right to access medicines are not required to be removed immediately and can be examined and, where possible, lowered over time. *Government of the Republic of South Africa v Grootboom*, 2001 SA 46, at 35 (S. Afr.).

<sup>166</sup> Emily Lee, *The World Health Organization’s Global Strategy on Diet, Physical Activity, and*



right to access medicines, analogous to so-called "soft law" obligations that have moral, but no direct legal force,<sup>167</sup> it seems unreasonable to impose legal obligations on TNPCs, which are designed to serve the primary economic purpose of profit maximization rather than to assume broad-based welfare functions.<sup>168</sup> Furthermore, given the overwhelming extent of epidemics, the pressure of their researchers, stakeholders, public opinions, and the uncertain efficacy of life-saving drugs, imposing legal obligations to promote access to medicines for all on TNPCs seems to be morally irresponsible.<sup>169</sup> (3) Therefore, TNPCs should not be expected to assume legal responsibilities to provide medicines to those who are unable to access needed medicines and to realize the right to access medicines. In other words, TNPCs' human rights responsibilities, in the context of the right to access medicines should be subject to the criterion of "morality" (rather than "legality") and should be part of the "can do" rather than "must do" dimension.

Considering the moral nature of the right to access medicines, TNPCs' responsibilities to enhance access to medicines is regarded as part of "discretionary" responsibilities, purely voluntary and not required by law.<sup>170</sup> For example, in Klaus M. Leisinger's differentiating hierarchy of corporate responsibilities<sup>171</sup> (hereinafter Leisinger's Hierarchy, see Figure 1), he placed pharmaceutical corporations' responsibilities into three dimensions by degree of importance,<sup>172</sup> and categorized "realizing the right to access medicines" as a corporate responsibility excellence, which partly has a "nice to have" character, in the "can" dimension.<sup>173</sup> In the following discussions I explore the claim that TNPCs should remain exempt from legal responsibilities under the right to access medicines framework, although I will dispute this proposition later in section (IV)(B).

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*Health: Turning Strategy Into Action*, 60 FOOD & DRUG L.J. 569, 587-88 (2005). See also Eleanor D. Kinney, *The International Human Right to Health: What Does this Mean for Our Nation and World?*, 34 IND. L. REV. 1457, 1471 (2001).

<sup>167</sup> Obijiofor Aginam, *Public Health Law in South Africa*, by Sundrasagaran Nadasen, 8 IND. J. GLOBAL LEGAL STUD. 479, 483 (2001).

<sup>168</sup> Glen Kelley, *Multilateral Investment Treaties: A Balanced Approach to Multinational Corporations*, 39 COLUM. J. TRANSNAT'L L. 483, 524 (2001).

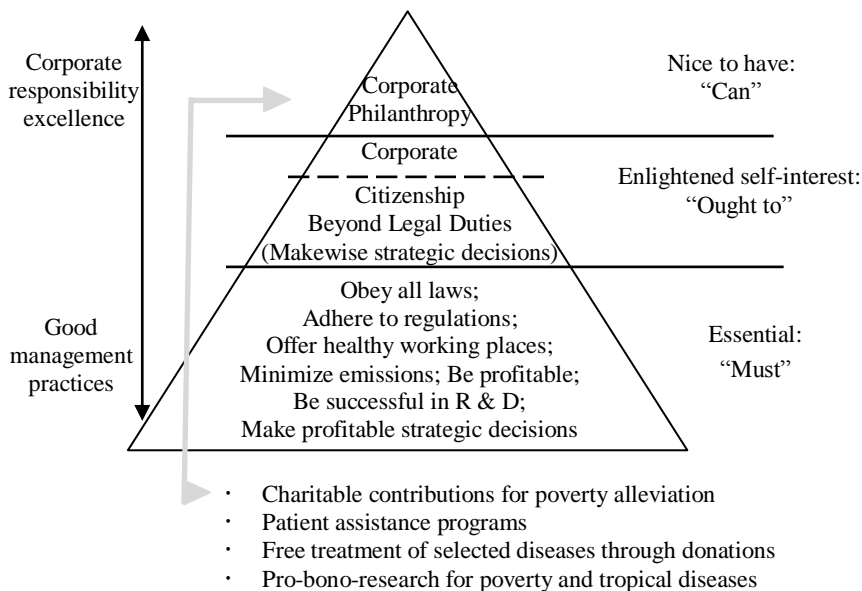
<sup>169</sup> Werhane & Gorman, *supra* note 28, at 274.

<sup>170</sup> Leisinger, *supra* note 45, at 4

<sup>171</sup> *Id.* at 13. Novartis Foundation for Sustainable Development also has similar proposal and argues that there are three dimensions of responsibility with differing degrees of commitment. See NOVARTIS FOUNDATION FOR SUSTAINABLE DEVELOPMENT, HUMAN RIGHTS AND THE PRIVATE SECTOR: INTERNATIONAL SYMPOSIUM REPORT 43-44, available at <http://www.novartisfoundation.org/platform/apps/Publication/getfile.asp?id=615&el=1432&se=9417517&doc=127&dse=2> (last visited Mar. 18, 2012).

<sup>172</sup> I want to remind readers that that the boundaries of these three degrees of corporate obligation are fluid. Leisinger, *supra* note 45, at 11.

<sup>173</sup> *Id.* at 4, 16.

FIGURE 1: Leisinger's Hierarchy of Corporate Responsibilities<sup>174</sup>

1. In the "must" dimension, corporations are obligated to realize non-negotiable essentials of human rights in the context of normal business activities, which Leisinger refers to as essential, that is, incumbent on them by social consensus.<sup>175</sup> In essence, corporations are required to do all in their power to ensure that they do not violate any legal rights/entitlements, which are categorical with judicial enforceability, within its sphere of influence. Therefore, in the "must" dimension, TNPCs' primary responsibilities are limited to the context of their normal business activities, such as complying with laws and regulations, conducting research and development, bringing innovative and effective products to the market, and providing goods and services that meet customers' needs at competitive prices.<sup>176</sup> In addition, TNPCs should comply with all laws and regulations concerning secrecy (lack of transparency), corruption, inappropriate drug promotion, and excessively high prices, because these actions would erect obstacles to the state's implementation of the right to access medicines. There is no room for the moral right to access medicines in this dimension. For

<sup>174</sup> *Id.* at 9.

<sup>175</sup> *Id.* at 13.

<sup>176</sup> *Id.* at 14.

example, in *Hazel Tau v. GlaxoSmithKline and Boehringer Ingelheim*, the pharmaceutical corporations were not held responsible for the violation of the right to access medicines by charging excessive prices for HIV/AIDS drugs, even though high drug prices substantially limited patients' access to potentially life-saving and life-enhancing treatment and violated their rights to health and to life.<sup>177</sup> However, they are held responsible for charging excessive prices (through abuse of their market dominance) to the detriment of consumers as prohibited by section 8(a) of South Africa's Competition Act.<sup>178</sup>

2. In the "ought to" dimension, corporations are expected to apply good corporate responsibility standards (ambitious corporate citizenship standards)<sup>179</sup>, which are particularly relevant in certain sensitive business areas. In other words, because TNCs' social acceptance is increasingly contingent on the degree to which they are required to respond to broader public expectations that go beyond legal minima, TNCs are gradually recognizing their "social" responsibilities regarding human rights. For example, if local legal norms are insufficient, TNCs are expected to apply higher standards for labor conditions and wages that afford employees decent lives and cover their basic needs.<sup>180</sup> But these standards, which were developed and promulgated by multilateral institutions, including states and corporations, usually indicate a consensus on TNCs' "minimum" human rights responsibilities (rather than the "maximum").<sup>181</sup> This is based on the reasoning that (a) simply extending all states' human rights obligations to TNCs would ignore the differences between the nature and functions of states and corporations;<sup>182</sup> and (b) TNCs should never be required to expend resources beyond their business activities that have no specific association with direct corporate advantage or financially measurable rewards.<sup>183</sup> Therefore, even though TNCs "ought to" apply higher

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<sup>177</sup> *Id.* ¶ 49.2.

<sup>178</sup> Statement of Complaint in Terms of Section 49B(2)(b) of the Competition Act 89 of 1998, *Hazel Tau et al. v. GlaxoSmithKline, Boehringer Ingelheim et al.* (Competition Commission of South Africa), ¶ 60.5, available at <http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmission.s.pdf> (last visited Mar.18, 2012).

<sup>179</sup> These standards are not legally binding and most of them use aspirational language (such as "strive", "seek", "work towards", "try to minimise", and "give proper regard to"). In addition, instead of explicit human rights norms, these standards also state broad and vague values of the organization, such as business integrity, openness, enriching the community, treating people with dignity, or conducting business responsibility, INTERNATIONAL COUNCIL ON HUMAN RIGHTS POLICY, BEYOND VOLUNTARISM: HUMAN RIGHTS AND THE DEVELOPING INTERNATIONAL LEGAL OBLIGATIONS OF COMPANIES 70 (2002).

<sup>180</sup> Leisinger, *supra* note 45, at 15.

<sup>181</sup> Ferreira, *supra* note 28, at 1172.

<sup>182</sup> Ratner, *supra* note 56, at 493.

<sup>183</sup> Leisinger, *supra* note 45, at 16.

standards when the quality of local legal norms is insufficient for the right to access medicines because no responsible corporation can buffer their bottom lines behind inadequate local laws,<sup>184</sup> these standards usually refer to a very limited range of human rights. In effect, only certain contents of the right to access medicines (e.g., accessibility of life-saving drugs) are categorized under the “ought to” dimension, in which responsible TNPCs ought to adopt some actions (e.g., adjust the price, produce larger quantities), on a case-by-case basis, to serve healthcare needs of the vulnerable.<sup>185</sup>

3. In the “can” dimension, corporations voluntarily assume additional responsibility based on their capacity, which represents one strand of their engagement as private actors promoting human rights norms through voluntary activity.<sup>186</sup> More specifically, since TNPCs have only moral responsibilities to progressively realize the right to access medicines based on reasonably available resources (meaning not beyond TNPCs’ capacity), delivering on moral responsibilities in the context of the right to access medicines then is a part of the “can” dimension and should be seen in terms of “corporate responsibility excellence” — that is, “accepting ambitious challenges that are mainly located in the ‘can’ dimension.”<sup>187</sup> In addition, because moral responsibilities go beyond what is legally required, as good corporate citizens, TNPCs “may” provide additional services or facilities of their own volition to respect, protect, and fulfill the right to access medicines, and they “may” carry out activities that constitute corporate responsibility excellence.<sup>188</sup> TNPCs are under no legal obligation to “exhaust” their resources to ensure that there is no violation of the right to access medicines within its own sphere of influence. Therefore, concerning the right to access medicines (as a positive right), normal business operations of TNPCs (as described in the “must” dimension) are considered adequate and enough to form the main corporate contribution to the preservation of this right.<sup>189</sup> In other words, TNPCs “can” have a significant impact on the well-being of poor people in need of medicines and hence can fulfill their right to access medicines, but TNPCs’ performance (or philanthropy) is “purely voluntary, guided only by [their] desire to engage in social activities that are not mandated, not required by law, and not generally expected of business in an ethical sense.”<sup>190</sup> TNPCs meet their human rights responsibilities for

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<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* at 13-14.

<sup>187</sup> Leisinger, *supra* note 160, at 9-10.

<sup>188</sup> *Id.* at 10.

<sup>189</sup> *Id.*

<sup>190</sup> ARCHIE B. CARROLL, BUSINESS & SOCIETY ETHICS AND STAKEHOLDER MANAGEMENT 32

access to medicines by carrying out normal business operations (but nothing more) – that is, the basic social function to produce products (medicines) and services and to sell these on the market legally.<sup>191</sup>

In conclusion, since TNPCs do not start or perpetuate epidemics and since states in which diseases flourish have responsibilities to their citizens to address this problem, it is unreasonable to hold TNPCs legally responsible to ensure access to medicines by compromising their profits and/or by freely giving out patents.<sup>192</sup> TNPCs do not have “direct” positive obligations to fulfill individuals’ entitlements or valid claims to certain sorts of goods or services.<sup>193</sup> Voluntary corporate services to improve access to medicines are classified in the “can” dimension. When, and only when, access to medicines is covered by both the right to health and other negative rights and can be structurally and indirectly achieved when realizing those negative rights (classified in the “must” dimension), TNPCs are held legally responsible to abstain from operations that may restrict individuals’ access to medicines.<sup>194</sup> Namely, TNPCs can be held legally responsible for the violations of negative rights, but not the violations of individuals’ right to access medicines. For example, the society cannot compel TNPCs, which follow principles of good corporate citizenship and do not abuse their power, to lower their drug prices based simply on the protection of individuals’ right to access medicines. However, the society can require TNPCs to comply with antitrust laws concerning abuses of dominant position in the market to deliver unfair and excessive selling drug prices, actions that would erect obstacles to the protection of competition and consumers. The implementation of antitrust laws, rather than human rights norms, would impose drug price regulations and then on some level indirectly protect individuals’ right to access medicines.

### ***B. Ignorance of Pharmaceutical Corporations’ Right to Health Responsibilities***

Because TNPCs’ voluntary actions to improve people’s access to medicines are generally classified in the “can” dimension (only life-saving cases are classified in the “ought to” dimension), they then remain

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(1993); see also Ann K. Buchholtz et al., *Beyond Resources. The Mediating Effect of Top Management Discretion and Value on Corporate Philanthropy*, 38(2) BUS. & SOC’Y 167 (1999).

<sup>191</sup> *Id.* Normal business operations generally refer to , such as hiring employees of an adult age who work voluntarily in exchange for pay as defined in legally binding contracts or collective bargaining agreements, ensuring a living wage for those people at the lowest levels of qualification, and providing safe working conditions and environments.

<sup>192</sup> Werhane & Gorman, *supra* note 28 at 274.

<sup>193</sup> ANDREW CLAPHAN, HUMAN RIGHTS OBLIGATIONS OF NON-STATE ACTORS 369 (2006).

<sup>194</sup> NICOLA JÄ GERS, CORPORATE HUMAN RIGHTS OBLIGATIONS: IN SEARCH OF ACCOUNTABILITY 87 (2002).

relatively immune from human rights responsibilities to provide access to medicines.<sup>195</sup> However, if we overlook or undervalue TNPCs' human rights responsibilities regarding the realization of the right to access medicines, we might also underestimate TNPCs' negative effects on individuals' health and equality of health in society at large. Especially, when TNPCs have demonstrated that they have used significant powers to influence healthcare policies and/or pharmaceutical patent policies, it is unreasonable that human rights institutions and states continue overlooking TNPCs' human rights responsibilities in relation to access to medicines. Basically, considering human rights responsibilities in the context of the right to access medicines as a part of the "can" dimension and relying only on the state's obligations to "regulate the activities of . . . corporations so as to prevent them from violating the right to health of others"<sup>196</sup> would improperly exclude the critical player — the pharmaceutical industry — in the protection of the right to access medicines.

Four reasons prompt me to dispute the proposition that TNPCs' human rights responsibilities for access to medicines are classified in the "can" dimension only. *First*, corporate philanthropy cannot provide a consistent response to right-to-access-medicine violations. More specifically, even though some TNPCs have acknowledged the importance and validity of human rights principles, they tend to blunt their human rights responsibilities by suggesting that these responsibilities are met via corporate social responsibility (CSR), strict adherence to employment standards, global health programmes, and participation in drug donation schemes or voluntary price reduction — not explicitly human rights activities.<sup>197</sup> But, when TNPCs attempt to blend human rights responsibilities with CSR, they are essentially weakening the protection of the right to access medicines because corporate philanthropy (e.g., drug discounts and donations) does not provide permanent solutions and a consistent response to poor people's lack of access to affordable medicines. On one hand, voluntary CSR-based drug donations and discounts can be terminated for numerous reasons and unexpectedly. For example, in 2000 Bristol Myers-Squib suddenly withdrew its commitment to reducing prices of anti-retroviral drugs due to an internal debate on its moral responsibilities to indigent people who could not afford medicines and if and how such responsibilities would be reconciled with the company's commercial objectives.<sup>198</sup> This case shows that TNPCs can fail to take

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<sup>195</sup> RALPH G. STEINHARDT ET AL., *INTERNATIONAL HUMAN RIGHTS LAWYERING: CASES AND MATERIALS* 662 (2009).

<sup>196</sup> Committee on Economic, Social, and Cultural Rights, CESCR General Comment No. 14, ¶ 51 (E/C 12/2000/4) (2000).

<sup>197</sup> Virginia Barbour et al., *Drug Companies Should be Held More Accountable for Their Human Rights Responsibilities*, 7(9) PLOS MED 1, 1 (2010).

<sup>198</sup> James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy*

seriously their “voluntary” human rights responsibilities for access to medicines in their operations,<sup>199</sup> especially to those in developing countries. On the other hand, voluntary CSR-based drug discounts have not been deep or broad enough to facilitate access<sup>200</sup> — discounted drug prices still remain far above what most poor economies can afford (inaccessibility),<sup>201</sup> and, even if price cuts are deep enough, these discounted drugs may not be produced in an adequate or sustainable quantity (unavailability).<sup>202</sup> Therefore, a system that relies on TNPCs’ capricious and unreliable voluntary actions, which are neither mandated nor necessarily guaranteed to continue, cannot result in effective protection of the right to access medicines.<sup>203</sup>

**Second**, imposing only moral responsibilities on TNPCs for pharmaceutical accessibility in the “can” dimension would leave TNPCs great flexibility and discretion in shaping and responding to social demands for accessible and affordable medicines. No doubt, many TNPCs are voluntarily making important contributions to improving access to medicines,<sup>204</sup> but they have also been criticized for trying to have it both ways — to simultaneously improve their image through corporate philanthropy, while violating their human rights responsibilities under the “soft law” standards.<sup>205</sup> For example, in 1997 the South African Parliament passed the Medicines Act Amendment,<sup>206</sup> granting the Minister of Health broad power to ensure all members of society access to affordable medicines<sup>207</sup> by requiring pharmacists to prescribe generic versions of

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*Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727, 769 (2001)

<sup>199</sup> HENRY J. STEINER, ET AL., INTERNATIONAL HUMAN RIGHTS IN CONTEXT 1397 (2007).

<sup>200</sup> Consensus Statement of Members of the Faculty of Harvard University, Antiretroviral Treatment for AIDS in Poor Countries, Mar. 2001, 14, available at [http://www.hsph.harvard.edu/hai/conferences\\_events/2001/consensus\\_aids\\_therapy.pdf](http://www.hsph.harvard.edu/hai/conferences_events/2001/consensus_aids_therapy.pdf). (last visited Mar. 4, 2011).

<sup>201</sup> *Id.* at 14-15

<sup>202</sup> For example, the Kenya Coalition for Access to Essential Medicines argued that TNPCs create the shortages of AIDS drugs in Kenya because, even though they promised to provide discounted AIDS drugs to Kenya, they curtailed the production of particular discounted drugs. Therefore, “it’s the companies that have provided these drugs at the beneficial prices are the ones that are then affected with the shortages” Katy Salmon, *Kenya-Health: Country Facing Acute Shortages of AIDS Drugs*, INTER PRESS SERV., 23 Apr. 2002.

<sup>203</sup> For example, human rights activists argue that it is better for poor nations to more dependably rely on competition from generic manufacturers than on TNPCs’ voluntary actions. *Id.* See also Kelley A. Friedgen, *Rethinking the Struggle between Health & Intellectual Property: A Proposed Framework for Dynamic, Rather than Absolute, Patent Protection of Essential Medicines*, 16 EMORY INT’L L. REV. 689, 704-05, 709-10 (2002).

<sup>204</sup> Hunt & Khosla, *supra* note 15, at 2.

<sup>205</sup> Ferreira, *supra* note 28, at 1166.

<sup>206</sup> This Act is established on the basis of South Africa’s post-apartheid Constitution that guarantees South Africans the right to health. See Section 27 of South Africa constitution.

<sup>207</sup> See Articles 10 and 14 of the Medicines and Related Substances Control Amendment, Act 90 of 1997 (S. Afr.), available at <http://www.info.gov.za/view/DownloadFileAction?id=70836> (last

drugs,<sup>208</sup> by setting up a pricing committee to recommend a transparent pricing system for medicines,<sup>209</sup> by forcing pharmaceutical corporations to justify the prices they charge, and by forbidding pharmacists from over-pricing drugs.<sup>210</sup> Since the AIDS crisis has been regarded as a national emergency in South Africa and thus can be classified in the “ought to” dimension (see Section (IV)(A)), TNPCs should have voluntarily complimented on this Act and adopted necessary actions to improve the accessibility of HIV/AIDS drugs, so as to respond to broader public expectations. However, to the contrary, the pharmaceutical industry attacked the law as unconstitutional<sup>211</sup> and a violation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) on several grounds.<sup>212</sup> Even though TNPCs eventually withdrew the legal challenges against South Africa due to the resulting negative publicity that surrounded the lawsuit (rather than concerns for the right to access medicines), they continued lobbying against the enactment of similar legislations in other developing countries.<sup>213</sup> Another example that shows the flaws of TNPCs’ humanitarian programs was a 2001 agreement to major price cuts for AIDS drugs that Merck made with the Brazilian government. In exchange for beneficial drug prices, the government agreed to prohibit local generic manufacturers to manufacture a copy of Merck-patented drugs. Therefore, Merck’s “philanthropy” apparently was not based purely on humanitarian or human rights values, but on its self-interest as highlighted in its decision — “to sacrifice prices in some poor countries in order to argue that generic manufacturers are not needed and to relieve the pressure on the patent system.”<sup>214</sup> What transpired here was that, through corporate philanthropy, Merck and other TNPCs tried to

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visited Mar. 18, 2012).

<sup>208</sup> See §14 of the Medicines and Related Substances Control Amendment, Act 90 of 1997 (S. Afr.) (inserting section 22F into original Medicines Act), available at <http://www.info.gov.za/view/DownloadFileAction?id=70836> (last visited Mar. 18, 2012).

<sup>209</sup> *Id.* (inserting section 22G into original Medicines Act).

<sup>210</sup> Statement, Treatment Action Campaign, An Explanation of the Medicines Act Amendment and the Implications of the Court Victory (Apr. 24, 2001) (describing generic substitution), available at <http://www.tac.org.za/newsletter/ns010424.txt> (last visited Mar. 18, 2012).

<sup>211</sup> The pharmaceutical industry argues that the Medicines Act Amendment would deprive pharmaceutical corporations of their constitutional right to property. See Applicants’ Notice of Motion, Pharm. Mfrs.’ Ass’n of S. Afr. v. President of the Republic of South Africa, the Honourable Mr. N.R. Mandela N.O., para. 4.3 (S. Afr. 1998) (No. 4183/98), available at <http://www.cptech.org/ip/health/sa/pharmasuit.html> (last visited Mar. 18, 2002).

<sup>212</sup> The pharmaceutical industry leveled broader challenges the validity of the Medicines Act Amendment under TRIPS, claiming, among other charges, that the amendment violated Article 28 of TRIPS by allowing parallel importing. Ferreira, *supra* note 28, at 1150-51.

<sup>213</sup> See, e.g., Andrew Pollack, *Defensive Drug Industry: Fueling Clash Over Patents*, N.Y. TIMES, Apr. 20, 2001, at A6. See also Samuel Siringi, *Generic Drugs Battle Moves from South Africa to Kenya*, 357 THE LANCET, May 19, 2001, 2001 WL 10158786.

<sup>214</sup> Andrew Pollack, *Defensive Drug Industry: Fueling Clash over Patents*, N.Y. TIMES, Apr. 20, 2001, at A6.



hinder the development of local generic-drug manufacturers in order to maintain their competitive advantages worldwide. But these actions not only compromised but also violated the right to access medicines because through these actions TNPCs were able to stave off generic competition that provided a competitive environment and improve pharmaceutical accessibility. Therefore, it is impractical to expect that the right to access medicines can be well protected or advanced by TNPCs' voluntary services, since it is doubtful whether TNPCs are truly sincere about promoting human rights in the countries in which they operate.

*Third*, focusing solely on pharmaceutical corporations' moral responsibilities to provide affordable medicines in the "can" dimension, would ignore power (economic and political) asymmetries between developing countries and TNPCs. Generally, TNPCs play a much larger and more visible role in the world and can more readily affect the right to access medicines than the powers that be in developing countries. Some of their actions can be regarded as direct violations of human rights (e.g., through the types of marketing tactics) or indirect violations (e.g., through their leverage over host governments).<sup>215</sup> However, due to the desire for foreign investment, developing countries usually have neither the economic incentive, nor the interest to negotiate with TNPCs or to set stricter regulations such as drug price controls.<sup>216</sup> Developing countries' need for foreign investment and access to industrialized country markets, then gives TNPCs considerable economic leverage over them.<sup>217</sup> Additionally, even if developing countries did not have such a great need for foreign investment, they would also lack the resources and/or political power to legislate and leverage such regulations. For example, when enacting the Medicines Act Amendment, which allows compulsory licensing and parallel importing to make HIV/AIDS drugs more affordable,<sup>218</sup> the South Africa government had to overcome the global and notional pharmaceutical industry's strong opposition and challenges to the act by threatening to withdraw from domestic markets. In 2001, South Africa agreed to redraft the law to honor TRIPS and to consult with the pharmaceutical industry on the proposed amendment, while the pharmaceutical industry agreed to withdraw the lawsuit.<sup>219</sup>

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<sup>215</sup> Mellisa E. Crow, *The Human Rights Responsibilities of Multinational Tobacco Companies*, 14 *Tobacco Control* ii14, ii15 (2005).

<sup>216</sup> The views of developing countries on foreign investment might lead them to ignore the strong relationship between pharmaceutical corporations' behaviors and the violations of the right to access medicines. Furthermore, in terms of government decision-making and priority-setting in healthcare policy, the pursuit of economic interests generally takes priority over the protection of the right to access medicines and hinders the implementation of human rights and the promotion of pharmaceutical accessibility programs.

<sup>217</sup> Susan K. Sell, *Trade Issues and HIV/AIDS*, 17 *EMORY INT'L L. REV.* 933, 944 (2003).

<sup>218</sup> Siringi, *supra* note 213.

<sup>219</sup> The pharmaceutical industry reached an out-of-court settlement with South Africa and agreed to

The situation involving power asymmetries has worsened over the past few decades because, in addition to continually exerting substantial influence on developing countries,<sup>220</sup> TNPCs also aggressively lobby authorities and politicians in developed countries to take a tough stand against developing countries that adopt drug price control measures, issue compulsory licenses for local generic drug manufacture, and/or use parallel importing. In other words, the asymmetric power relationships are reflected in continuing threats as well as the use of trade sanctions from developed countries and the proliferation of bilateral investment, which further weaken developing countries' power.<sup>221</sup> Returning to the previous example, South Africa's Medicines Act Amendment also prompted the global pharmaceutical lobby to prod developed countries to exert pressure (such as trade sanctions)<sup>222</sup> on South Africa to change or repeal its law and to forgo generic competition.<sup>223</sup> In another example, Thailand was reluctant to enforce TRIPS-exemptions (guaranteed and encouraged by the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) and to issue compulsory licenses on patented drugs that treat heart disease and cancer because TNPCs lobbied the United States Trade Representative (USTR) to place Thailand on the special 301 "priority watch list" for alleged violations of intellectual property law.<sup>224</sup> In addition, under the pressure from TNPCs and the U.S. government, the Korean government accepted Article 19.5 of the U.S.-Korea Free Trade Agreement (FTA), which requires the parties "to implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner."<sup>225</sup> However, this patent-registration linkage provision (called TRIPS-plus provision) requires intellectual property rights protection far in excess of standards set by the TRIPS Agreement, creates patent-like barriers to the accessibility of

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cooperate to provide HIV/AIDS drugs at lower costs. Gumisai Mutume, *U.S. Drug Companies Ease Up on South Africa*, INTER PRESS SERV., 12 Sept. 1999, 1999 WL 27373954, available at <http://ipsnews.net/news.asp?idnews=78086> (last visited Mar. 19, 2012). See also Ferreira, *supra* note 28, at 1156-57.

<sup>220</sup> Because enhancing access to medicines means lowering drug prices for targeted developing countries, which is antithetical to TNPCs' economic interests, TNPCs have aggressively lobbied government ministers and committees involved in drafting laws or in developing policies in less developed countries against laws and policies that set drug price controls and regulations on pharmaceutical patents

<sup>221</sup> *Id.* at 945.

<sup>222</sup> Ferreira, *supra* note 28, at 1170, 1177.

<sup>223</sup> Winston P. Nagan, *International Intellectual Property, Access to Health Care, and Human Rights: South Africa v. United States*, 14 FLA. J. INT'L L. 155, 176 (2002).

<sup>224</sup> OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2007 SPECIAL 301 REPORT 27 (2007).

<sup>225</sup> U.S.-Korea Free Trade Agreement, U.S.-Korea, June 30, 2007, available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text> (last visited Mar. 19, 2012).

affordable generic medication, and violates the right to access medicines.<sup>226</sup> These examples all show that, even if TNPCs might have a track record of providing donations in cases of medical emergencies such as contagious epidemics or pandemics, they continue to misuse their considerable influence to challenge developing countries that seek to take legal advantage of TRIPS-exemption provisions (namely via compulsory licensing and parallel importing).

Therefore, combined with structural power asymmetries between developing countries and TNPCs, imposing only moral responsibilities on TNPCs in the “can” dimension might jeopardize the protection of the right to access medicines.<sup>227</sup> To balance (or to rectify) power asymmetries and avoid the negative effects on the right to access medicines, especially when economic power is regarded as the essential power in the international arena, it is necessary to reevaluate TNPCs’ role in the framework of the right to health and consider assigning stronger human rights responsibilities to them.

*Forth*, exempting the conduct of TNPCs from their responsibilities, under the framework of the right to access medicines, would overlook essential elements of access to medicines. Generally, exorbitant profits may seem morally justifiable when there is a willing buyer and a willing seller. However, the perspective that requires the state to respect free market mechanisms, even in health care issues, has been challenged recently due to market failures. There are two reasons for this. (1) The free-market mechanism is justified when and only when consumers can freely enter the market on their equal terms.<sup>228</sup> However, due to the pharmaceutical industry’s technical expertise, complex medical information, and the broad and devastating impacts of diseases, individuals might not be able to reason and to make well-considered decisions about their healthcare in the free

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<sup>226</sup> Wu, *supra* note 9, at 157.

<sup>227</sup> Some might argue that the power asymmetries could be avoided because TNPCs “should disclose all current advocacy and lobbying positions, and related activities,” and should require all recipients to publicly disclose financial or other support from TNPCs on all occasions. In addition, TNPCs “should publicly adopt effective anti-corruption policies and measures, and comply with relevant national law implementing the United Nations Convention against Corruption.” However, even though these activities are classified in the “must” or “ought to” dimension, the problem is that, if government officials are trading off their citizens’ right to access medicines in negotiations with TNPCs, or otherwise making tradeoffs that are likely to go against the wishes of their poplaces, they are likely to hide this decision-making process from the public. Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*, Sept. 19, 2007, ¶¶ 15, 17, 19 (Draft for Consultation), available at <http://www2.ohchr.org/english/issues/health/right/docs/Guidelinesforpharmaceuticalcompanies.doc> (last visited Mar. 19, 2012) [hereinafter guidelines for pharmaceutical companies]. See also Sánchez-Moreno & Higgins, *supra* note 24, at 1670 (2004).

<sup>228</sup> Therefore, the state has the obligation to remove inequality factors, such as information asymmetry, unfair competition, and monopolization, which can cause market failures. RONALD DWORKIN, *SOVEREIGN VIRTUE: THE THEORY AND PRACTICE OF EQUALITY* 70 (2000).

market. In effect, power imbalance between TNPCs and ordinary citizens affected by the former's activities, can cause market failures and erect obstacles to access to medicines.<sup>229</sup> Unfortunately, we cannot readily expect governments (especially developing countries' governments) to effectively balance the asymmetric power relationship between TNPCs and their citizens in the healthcare market because domestic laws and regulations are often shaped by a countries' desire and need to attract investment and thus may bend to pressure from powerful TNPCs.<sup>230</sup> Therefore, it is morally unjustified to categorize the resolution of conflicts between TNPCs' pursuit of profit maximization and individuals' right to access medicines in the "private" realm governed purely by market forces. (2) Medicines are different from most other commodities because "the consumers of [life-saving] prescription drugs are often a captive rather than a willing market."<sup>231</sup> Due to the unique nature of healthcare market mechanisms, TNPCs should not be treated as other for profit businesses. More specifically, TNPCs' legitimacy cannot depend only upon their corporate taxes and taxes on profits and employment income, which contribute to state finances and hence enable the state (the primary human rights responsibility bearer) to fulfill the right to access medicines. On the contrary, TNPCs' legitimacy increasingly depends on being perceived as a societal force for good in the fight against (poverty-related) illnesses and premature mortality.<sup>232</sup> Therefore, TNPCs cannot claim that their license to operate depends primarily on complying with law and regulations and have no human rights responsibility to provide access to affordable medicines.<sup>233</sup>

In conclusion, TNPCs' human rights responsibilities to protect the right to access medicines, should not be limited to the responsibilities in the "can" dimension of Leisinger's Hierarchy and must be evaluated more carefully. Assuming the right to access medicines, as an objective to which both state and non-state actors can and should contribute,<sup>234</sup> can help us to avoid limitations of any single lens onto the protection of the right. In addition, coordinating TNPCs' right-to-access-medicines responsibilities in "must", "ought to", and "can" dimensions can also provide a more comprehensive protection of such a right because absent a strong and valid code, the nature of competition in the pharmaceutical industry and the capacity of states to regulate competition in the industry may ultimately determine the overall effect on the right to access medicines.<sup>235</sup>

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<sup>229</sup> *Id.* at 1669-670.

<sup>230</sup> Van Puymbroeck, *supra* note 8, at 520.

<sup>231</sup> Joseph, *supra* note 12, at 436.

<sup>232</sup> Leisinger, *supra* note 45, at 18.

<sup>233</sup> Pharmaceutical corporations argue that they are for-profit organizations and should not be expected to be overly altruism or charity.

<sup>234</sup> Hunt & Khosla, *supra* note 15, at 2.

<sup>235</sup> Uché Ewelukwa, *Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical*

## V. RETHINKING PHARMACEUTICAL CORPORATIONS' HUMAN RIGHTS RESPONSIBILITIES IN RELATION TO ACCESS TO MEDICINES

### A. *Why to Rethink*

In 2010 Paul Hunt drafted the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines [Guidelines for Pharmaceutical Companies] to fill the gap of TNPCs' human rights responsibilities for access to medicines. Heinz Klug addresses that the guidelines represent an "effort to use normative pressure and standards to tackle the problem" of access to medicines and argues that TNPCs "have a responsibility to promote access to medicines."<sup>236</sup> Highlights of the guidelines include:<sup>237</sup>

1. Guideline 5, which requires companies to give "particular attention to the very poorest in all markets," arises from the human rights of equality and nondiscrimination.
2. Guidelines 6 – 8, which include the rebuttable presumption "in favour of the disclosure of information, held by the company, which relates to access to medicines" is based upon the human rights principle of transparency.
3. Guidelines 17 – 19 apply transparency to the theme of public policy influence, advocacy, and lobbying.
4. Guidelines 26 – 32 address patents and licensing, including the vital role of commercial and noncommercial voluntary licenses.
5. Guidelines 33 – 37 address pricing, such as differential pricing between and within countries.
6. Other themes include management, monitoring, and accountability; neglected diseases; corruption; clinical trials; ethical promotion and marketing; and public-private partnerships.

Although the guidelines recognize that TNPCs' human rights responsibilities should not be as extensive as those of states, they do not deduce or outline specific responsibilities of TNPCs in this regard.<sup>238</sup> TNPCs' positive human rights responsibilities, to protect the right to access medicines, remain vague and unclear and cannot be applied directly to redress TNPCs' violations of the right. In addition, in the guidelines,

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*Industry, Ethics, and Global Trade*, 59 U. MIAMI L. REV. 203, 207-08 (2005).

<sup>236</sup> Heinz Klug, *Law, Politics, and Access to Essential Medicines in Developing Countries*, 36 POL. & SOC'Y 207, 239 (2008)

<sup>237</sup> Hunt & Khosla, *supra* note 15, at 2.

<sup>238</sup> Surya Deva, *UN's Human Rights Norms for Transnational Corporations and Other Business Enterprises: An Imperfect Step in the Right Direction?*, 10 ILSA J. INT'L & COMP. L. 493, 510-11 (2004).

TNPCs' voluntary philanthropies (in the "can" dimension of Leisinger's Hierarchy) still compromise an important aspect of their responsibilities for access to medicines.

However, preceding discussions in section IV(B) reveal that protecting the right to access medicines by simply imposing human rights responsibilities on TNPCs in the "can" dimension (rather than in the "must" or "ought to" dimensions) is not enough because a system that relies on TNPCs' capricious philanthropies, which can be terminated unexpectedly, cannot provide effective protection of the right to access medicine. In addition, it is also misleading to treat diverse contents of the right to access medicines as progressive realizations in the "can" dimension only because different diseases, health conditions, the severity of illnesses, and epidemics require different types of interventions and medicines. More explicit and suitable international instruments are needed to describe the relationship between business and the right to access medicines, and to define the breadth of TNPCs' human rights responsibilities to guarantee fair, reasonable, and adequate pharmaceutical accessibility.<sup>239</sup> Therefore, later in section V(B), I propose that TNPCs' human rights responsibilities for access to medicines should not all be classified in the "can" dimension, but should be differentiated and prioritized based on the contents of the right to access medicines.

But two problems create significant theoretical obstacles to clearly delineate and further TNPCs' human rights responsibilities in relation to access to medicines. *First*, the pharmaceutical industry argues that the hierarchy of TNPCs' human rights responsibilities should not be different from non-pharmaceutical TNCs'. In other words, the primary role of TNPCs in realizing the right to access medicines is through their normal business activities only (e.g., researching, developing, and producing medicines to address unmet healthcare needs).<sup>240</sup> However, the broad grouping of TNCs' human rights responsibilities cannot clearly delineate TNPCs' responsibilities for access to medicines<sup>241</sup> because "beyond the general principles of human rights, which cut across the operations of corporations, specific rights (e.g., the right to access medicines) involved,

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<sup>239</sup> Chandler, *supra* note 63, at 26.

<sup>240</sup> GERALYB S. RITTER, *Are Drug Companies Living Up to Their Human Rights Responsibilities? The Merck Perspective*, 7(9) PLOS MEDICINE, 1, 1 (2010) (published online in PLoS Medicine, e1000343. doi:10.1371/journal.pmed.1000343), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000343> (last visited Mar. 19, 2012).

<sup>241</sup> Sofia Gruskin & Zyde Raad, *Are Drug Companies Living Up to Their Human Rights Responsibilities? Moving Toward Assessment*, 7(9) PLOS MEDICINE, 1, 2 (2010) (published online in PLoS Medicine, e1000310. doi:10.1371/journal.pmed.1000310), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000310> (last visited Mar. 19, 2012).

as well as the manifestations of their violations, are obviously different.”<sup>242</sup> For example, the Norms for TNCs outline voluntary principles with a focus on equality rights, security of persons, workers rights, respect for national sovereignty and human rights, consumer protection, environmental protection, and principles of implementation. Yet these principles do not in anyway involve intellectual property rights, which are at the crux of the responsibility of TNPCs in relation to access to medicines.<sup>243</sup> It is therefore important to take a deeper look into the normative adequacy of TNPCs’ right-to-access-medicine responsibilities in the differentiating hierarchy.

**Second**, as discussed in section IV(A), in the traditional human rights approach the state has only moral obligations to progressively fulfill the right to access medicines according to resources, ability, and other relevant considerations. The pharmaceutical industry then argues that, because it is unreasonable to impose higher obligations on TNPCs than states have accepted for themselves,<sup>244</sup> TNPCs should not be expected to hold responsibilities for access to medicines beyond the “can” dimension. To go further than this position (by requiring TNPCs to take more responsibilities than philanthropy) would ignore the functional differences between states and businesses.<sup>245</sup>

However, the right to access medicines should not be categorized as one undifferentiated, universal positive right with only progressive realization regardless of its varied contents with different functions.<sup>246</sup> Even though the distinction between negative rights (freedoms) and positive rights (entitlements) is generally applied in the framework of international human rights,<sup>247</sup> some experts disagree with this distinction and argue that the right to health (including the right to access medicines) cannot easily be categorized by consensus as positive or negative.<sup>248</sup> For instance, the United Nations Development Programme (UNDP) argues that

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<sup>242</sup> See Justice C. Nwobike, *Pharmaceutical Corporations and Access to Drugs in Developing Countries: The Way Forward*, 4(3) INT’L J. ON HUM. RTS. 127, 137 (2006).

<sup>243</sup> *Id.*

<sup>244</sup> Baez et. al., *supra* note 163, at 223.

<sup>245</sup> Ratner, *supra* note 56, at 517.

<sup>246</sup> Iris Halpern, *Tracing the Contours of Transnational Corporations’ Human Rights Obligations in the Twenty-First Century*, 14 BUFF. HUM. RTS. L. REV. 129, 186-87 (2008). See also Wu, *supra* note 9, at 168-84.

<sup>247</sup> For example, the International Convention of Economic, Social, and Cultural Rights [ICESCR] employs the concept such as “state parties recognize the right of everyone to” whereas the International Convent of Civil and Political Rights [ICCPR] contains terms such as “everyone has the right to” or “no one shall be.”

<sup>248</sup> For example, Paragraph 3 of the CESCR General Comment No. 14 states that “the right to health is closely related to and dependent upon the realization of ... the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement,” and that these freedoms “address integral components of the right to health.” Committee on Economic, Social, and Cultural Rights, CESCR General Comment No. 14, ¶ 3 (E/C 12/2000/4) (2000). See also Frank B. Cross, *The Error of Positive Rights*, 48 UCLA L. REV. 857, 864 (2001).

the right to health should not be regarded as progressive realizations only,<sup>249</sup> and the state has both positive and negative duties to fulfill socio-economic rights (including the right to access medicines), which include both freedoms (resources-not-required) and entitlements (resources-required).<sup>250</sup> Article 8 of the Limburg Principles also upholds that “although the full realization of the rights [to health] ... is to be attained progressively, the application of some rights can be made justiciable immediately.”<sup>251</sup> Beauchamp and Faden argue that “if [the definition of] healthcare is broadened to include certain abstentions from actions intended as preventive and protective measures, the right to health might also contain elements of a negative right, depending ... upon one’s analysis of that notion in light of the alternatives.”<sup>252</sup> Therefore, the distinction between negative and positive rights is fading from theory and practice because no matter how we define the protection of freedom or the fulfillment of entitlements, they require the assurance of both negative (political) and positive (social) rights.<sup>253</sup>

Since the right to access medicines has various contents with different functions, and since these contents should not all be regarded as positive rights,<sup>254</sup> confining TNPCs’ responsibilities for access to (various) medicines in the “can” dimension on the basis of the traditional progressive realization principle, would overlook different functions and roles of diverse contents of the right to access medicines. More specifically, because health is a continuum of physical and mental functioning with different levels and contents of health and disease conditions, the claim of “access to medicines” in relation to human rights should contain a variety of contents.<sup>255</sup> Certain contents (e.g., the right to access essential drugs), according to Paragraphs 43 and 46 of the CESCR General Comment No. 14, are non-derogable “minimum essentials”<sup>256</sup> and should be realized

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<sup>249</sup> For example, even though creating or promoting family planning often requires the state to have adequate resources, the UNDP declared that laws that discriminate based on race, religion, and/or gender in health care must be removed immediately. UNITED NATIONS DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 2000 93 (2000).

<sup>250</sup> *Id.*

<sup>251</sup> *The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights*, UN Document E/CN.4/1987/17 (1987).

<sup>252</sup> Tom L. Beauchamp & Ruth R. Faden, *The Right to Health and the Right to Health Care*, 4(2) THE J. OF MED & PHIL. 118, 120-21 (1979).

<sup>253</sup> Stephen P. Marks, *The Human Rights Framework for Development: Seven Approaches*, 24 (2005)(unpublished manuscript, on file with author).

<sup>254</sup> In other words, the right to access medicines actually endows political and social rights with the mixed characteristics of freedom and entitlement. UNITED NATIONS DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 93 (2000).

<sup>255</sup> Emily A. Mok, *International Assistance and Cooperation for Access to Essential Medicines*, 12(1) HEALTH & HUM. RTS. 73, 74 (2010).

<sup>256</sup> According to paragraph 43 of the CESCR General Comment No. 14, “States parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential primary health care,” and “these core



immediately.<sup>257</sup> Therefore, it is misleading to assume that heterogeneous contents of the right to access medicines require only progressive realizations, and to conclude that TNPCs' human rights responsibilities in relation to access to medicine (in different disease conditions), are located only in the "can" dimension. For example, it is unreasonable to argue that TNPCs have the same human rights responsibilities to provide treatment access for chronic diseases and conditions as they do to provide treatment access for life-threatening diseases that reflect critical public health needs. In effect, imposing only moral responsibilities categorized in the "can" dimension on TNPCs for pharmaceutical accessibility regardless of whether individuals' healthcare needs for those medicines are related to their "minimal health" (minimum essential level of the right to health), could in some cases (e.g. HIV/AIDS) immediately diminish an individual's fair opportunity to pursue the good ends of life, or arbitrarily deprive him or her of life.<sup>258</sup>

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obligations include at least the following obligations: (a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups; (b) To ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone; (c) To ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water; (d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs; (e) To ensure equitable distribution of all health facilities, goods and services; (f) To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population."

<sup>257</sup> In another example, the *Soobramoney v. Minister of Health* Court argued that, according to section 27(3) of South Africa Final Constitution, citizens' right to access emergency medical treatment should be addressed differently from the general right to health care. The Court purposed that the right "not to be refused emergency medical treatment" was clearly "to ensure that in a situation of sudden and unexpected catastrophe or emergency, remedial treatment which [is] necessary and available would be given immediately," and "an injured person should not be refused available ambulance or emergency services or be turned away from a hospital which was able to provide the necessary treatment." Thus, the characteristics of emergency medical treatment, including strong life-relevance and urgent health care needs, render the state obligated to implement such healthcare services via immediate realization rather than progressive realization. In *South Africa vs. Grootboom*, the Constitutional Court also recognized that, even though the right to health should be realized progressively, certain contents of the right to health (e.g., children's right to adequate healthcare) were intended for immediate rather than progressive realizations and that the state was bound to fulfill these rights irrespective of resource availability. *Soobramoney v. Minister of Health, KwaZulu-Natal*, 1997 SACLR LEXIS 41, 42-43, 47 (S. Afr. 1997). *Government of the Republic of South Africa vs. Grootboom*, 2000 SACLR LEXIS 6, 19 (2000).

<sup>258</sup> In addition, indifferently applying the progressive realization principle to TNPCs' responsibilities for access to various medicines also means that TNPCs can use progressive realization as a shield to refuse to adopt necessary measures (e.g., differential pricing, foregoing patent protections on medications in primary need, and promoting increased information disclosure) to protect the minimum essential levels of the right to access medicines, and to justify their harsh, repressive measures (e.g., lobbying against compulsory licensing and parallel importing) against the right. For example, the legal argument for TNPCs' human rights responsibilities for right-to-health violations resulting from the lack of access to AIDS drugs (especially with regards to intellectual property rights) is weak because no TNPCs would have enough resources to provide life-saving drugs for all AIDS patients. In accordance with the progressive realization principle (i.e., the obligation to provide AIDS drugs is subject to resource availability), TNPCs then can claim

## *B. A Change of Strategy*

Since the right to access medicines contains heterogeneous elements with different functions and priorities, society then must closely inspect the details and priorities of TNPCs' human rights responsibilities for pharmaceutical accessibility based on diverse contents of the right to access medicines. In other words, TNPCs' human rights responsibilities for (diverse contents of) the right to access medicines should not all be treated as progressive realizations and classified in the "can" dimension only, but should be identified, differentiated, and prioritized based on the trade-off between the needs of sick people for access to effective medicines at reasonable cost and the importance of TNPCs' property rights. Numerous definitions and frameworks have attempted to explore the contents of the right to health and to set priorities among these contents.<sup>259</sup> Here I apply the biomedical health model and Norman Daniels' theory of just health care,<sup>260</sup> in which "function" and "opportunity" hold a precise meaning and thus are readily measurable, to delineate TNPCs' responsibilities to provide access to affordable medicines.

According to Daniel, access to medicines is equitable "if and only if there are no . . . financial barriers . . . that prevent access to a 'reasonable' or 'decent basic minimum' of health-care services,"<sup>261</sup> and decent minimum level of healthcare should include medicines that maintain and restore normal functioning — that is basic capabilities to achieve an individual's specific chosen goals.<sup>262</sup> Therefore, I propose that (see Figure 2):

- (1) TNPCs "ought to" fulfill the right to access medicines (soft-law human rights responsibilities) when and only when these medicines are necessary for restoring or maintaining "minimal health" (including life-saving), without which an

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scarcity of resources as a reason for not fulfilling the right to access medicines and that their only responsibility is not to impede (rather than to enhance or facilitate) access to AIDS drugs. However, the lack of AIDS drugs (as life-saving drugs) would deeply diminish an individuals' minimal health and significantly shrink his or her fundamental interests (fair opportunity range) to pursue his or her good ends. It seems unreasonable, therefore, to impose only moral responsibilities categorized in the "can" dimension TNPCs to cover individuals' healthcare needs regardless of their relevance (or correlation) to minimal health needs and basic capabilities.

<sup>259</sup> See e.g. TOEBES, *supra* note 96, at 243-59. Wu, *supra* note 9, at 168-84. Audrey R. Chapman, *Conceptualizing the Right to Health Care: A Violation Approach*, 65 TENN. L. REV. 389, 390 (1998).

<sup>260</sup> Daniels, *supra* note 97, at 59-85.

<sup>261</sup> *Id.* at 73. NORMAN DANIELS, JUSTICE AND JUSTIFICATION 214-15 (1996).

<sup>262</sup> More specifically, "impairments of normal species functioning reduce the range of opportunity open to the individual in which he may construct his or her plan of life" or 'conception of the good.'" Daniels, *supra* note 97, at 27.

individual cannot be a free or an equal member of society<sup>263</sup> and thus the right loses its significance. Minimal health can be further divided into two domains: (i) physical and mental functions directly related to life-saving (or life-maintaining), and (ii) physical and mental functions, which if substantially restricted, preclude an individual from being a free, equal, and fully cooperating member of society.

- (2) TNPCs “can” voluntarily fulfill the right to access medicine (moral human rights responsibilities) for common or insignificant physical and mental dysfunctions or for pain-killing that go beyond the level of “minimal health”.

Before further discussing TNPCs’ responsibilities, I must clarify that, in this framework, TNPCs’ soft-law human rights responsibility (in the “ought to” dimension) is not as strict as legal responsibility (in the “must” dimension) because the soft-law standards lack formal judicial mechanism, under which, to prosecute TNPCs for their violations of the right to access minimal-health-maintaining medicines.<sup>264</sup> However, unlike moral responsibility in the “can” dimension (as well as corporate philanthropy), the lack of direct judicial enforcement does not make TNPCs’ soft-law responsibility to protect the right to access minimal-health-maintaining medicines any less compelling because public pressure has proven effective in forcing TNPCs to realize the right to access medicines<sup>265</sup> (e.g., by lowering drug prices or by stopping challenging developing countries’ effort to make medicines cheaper). In addition, in the “must” dimension, TNPCs’ primary legal responsibilities remain limited to the context of normal business activities, such as complying with national and international laws and regulations, conducting research and development, bringing innovative and effective products to market, and providing goods and services that meet customers’ needs at competitive prices. I am not proposing to require TNPCs to expand their activities to improve the realization of the right to access medicines in general, in the same way that states are required to do so as part of their obligations to fulfill this right. With respect to the right to access medicines, by simply extending states’ human rights responsibilities to TNPCs would fail to recognize the differences between the nature and functions of states and corporations.<sup>266</sup>

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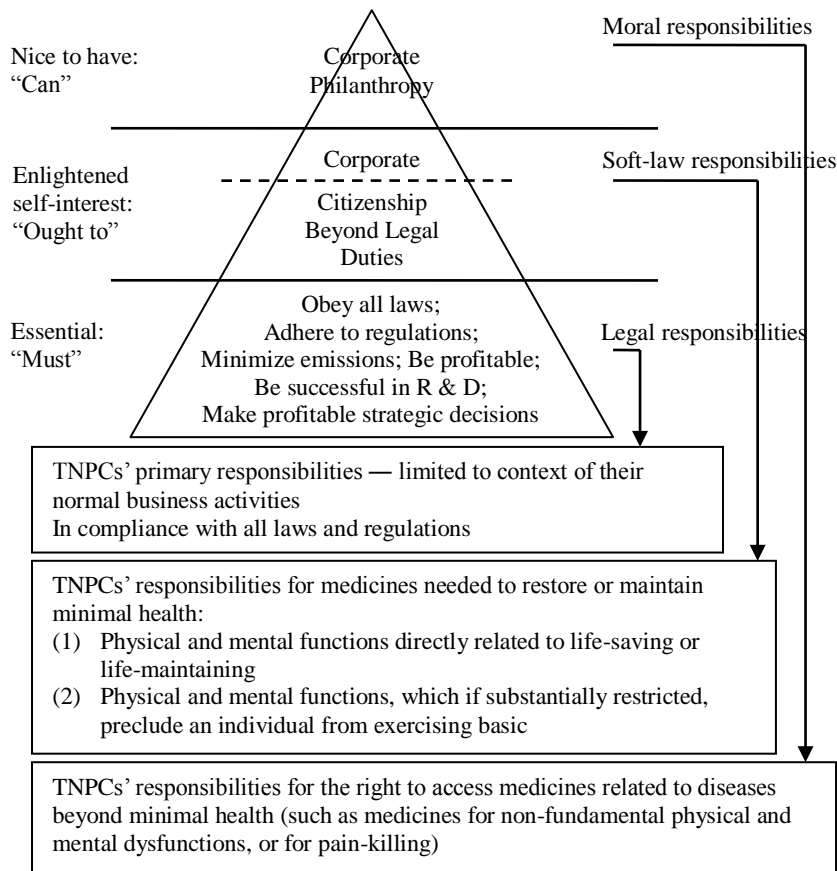
<sup>263</sup> *Id.* at 28.

<sup>264</sup> Ferreira, *supra* note 28, at 1172-73.

<sup>265</sup> *Id.*

<sup>266</sup> David Kinley, *From Talk to Walk: The Emergence of Human Rights Responsibilities for Corporations at International Law*, 44 VA. J. INT’L L. 931, 961 (2004).

FIGURE 2: Modified Hierarchy of Pharmaceutical Corporations' Responsibilities



**First**, TNPCs' human rights responsibilities to provide affordable medicines for minimal health should be categorized in the "ought to" dimension. That is, if medicines directly relate to life-saving or to an individual's substantial physical and mental functioning (especially daily living activities), TNPCs "ought to" correct shortages and inaccessibility of these medicines in the spirit of good corporate citizenship, especially in light of the inability of public sector to protect the right to access medicines in developing countries.<sup>267</sup> These medicines are necessary because their

<sup>267</sup> Klaus M. Leisinger, *The Corporate Social Responsibility of the Pharmaceutical Industry: Idealism without Illusion and Realism without Resignation*, 15(4) J. BUS. ETHICS 577, 586-87 (2005)

inaccessibility would hinder individuals from fully exercising their basic capabilities to develop more advanced capabilities<sup>268</sup> or to achieve an individual's specific chosen ends.<sup>269</sup> According to Amartya Sen<sup>270</sup> and Martha Nussbaum,<sup>271</sup> minimal health (especially certain physical and mental functions, such as life, being able to achieve/maintain good health, and being able to use one's primary senses)<sup>272</sup> is an essential capability, that an individual needs to enhance his or her substantial freedoms to choose and to lead the kind of lives they value, in terms of accessibility, affordability, appropriateness, and quality of healthcare (including life-saving and maintenance of substantial physical and mental functions)

*Second*, TNPCs' human rights responsibilities to provide non-essential medicines (e.g, for common non-life-threatening physical and mental dysfunctions, or for pain management) should be categorized in the "can" dimension, which corporate philanthropy dominates, as this constitutes an important aspect of corporate responsibility excellence, but remains discretionary.<sup>273</sup> In effect, TNPCs "can" voluntarily act to improve individuals' access to medicines for healthcare needs beyond minimal health.

Leisinger seems to agree with my proposal. Even though Leisinger states that within "moral free-space"<sup>274</sup> TNPCs "can" respect, protect, and fulfill the right to access medicines as a consequence of their personal value premises,<sup>275</sup> he also seems to agree that not all contents of the right to access medicines can be categorized in the "can" dimension (as proposed in this paper). Regarding life-saving drugs and vaccines, Leisinger argues that responsible TNPCs "ought to" adjust the price on a case-by-case basis for

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<sup>268</sup> For example, Nussbaum proposed the list of basic capabilities by asking an Aristotelian question: What activities characteristically performed by human beings are so central that they seem definitive of the life that is truly human? Two more precise questions are then formulated: (1) Which changes or transitions are compatible with the continued existence of a being as a member of the human kind and which are not? (2) What kinds of activity must be there if we are going to acknowledge that a given life is human? MARTHA C. NUSSBAUM, *SEX AND SOCIAL JUSTICE* 39-40 (1999).

<sup>269</sup> *Id.* at 44.

<sup>270</sup> See generally AMARTYA SEN, *DEVELOPMENT AS FREEDOM* (1999). See also Amartya Sen, *Human Rights and Development*, in *DEVELOPMENT AS A HUMAN RIGHT: LEGAL, POLITICAL, AND ECONOMIC DIMENSIONS* 1, 1-8 (Bard A. Andreassen & Stephen P. Marks eds., 2006).

<sup>271</sup> See generally Martha C. Nussbaum, *Capabilities and Human Rights*, in *THE PHILOSOPHY OF HUMAN RIGHTS* 212-40 (Patrick Hayden ed. 2001). Martha C. Nussbaum, *Capabilities, Human Rights, and the Universal Declaration*, in *THE FUTURE OF INTERNATIONAL HUMAN RIGHTS* 25, 34-60 (Burns Weston & Stephen Marks eds., 1999).

<sup>272</sup> Martha C. Nussbaum, *Capabilities, Human Rights, and the Universal Declaration*, in *THE FUTURE OF INTERNATIONAL HUMAN RIGHTS* 25, 44-45 (Burns Weston & Stephen Marks eds., 1999).

<sup>273</sup> Carroll, *supra* note 190 at 32; see also Buchholtz et al., *supra* note 190, at 167.

<sup>274</sup> Leisinger, *supra* note 45, at 14.

<sup>275</sup> *Id.*

patients living in individual or collective poverty.<sup>276</sup> The difference between Linsinger's and my proposals is that, in my proposal TNPCs "ought to" enhance not only the accessibility of life-saving drugs, but also the accessibility of minimal-health-maintaining drugs.

We now return our attention to the basic capabilities, or minimal health standard, that TNPCs "ought to" aim to protect. In this proposal, minimal health is defined on the basis of a functional definition — minimal health means an individual must have basic capabilities "to effectively exercise the required functions in a given environment."<sup>277</sup> Nussbaum further argues that basic capabilities include<sup>278</sup> (1) life (being able to live to the end of a normal life span, or until one's life is so reduced as to be not worth living), (2) bodily health (being able to enjoy a good health, including reproductive health, adequate nourishment, and adequate shelter), (3) bodily integrity (being able to move freely from place to place, and have opportunities for sexual satisfaction and for choice in matters of reproduction), and (4) senses, imagination, and thought (being able to use the senses to imagine, to think, and to reason, and being able to use one's imagination and thoughts in connection with experiencing and producing expressive works and events of one's choice). But Nussbaum's approach is still too broad because it implies an ideal and perfect health condition.<sup>279</sup>

Here, based upon the biomedical health model,<sup>280</sup> I modify Nussbaum's framework and propose that minimal health comprise only two domains: (1) physical and mental functions are directly related to life-saving, and (2) physical and mental functions, which if substantially restricted, preclude individuals from being a free, equal, and fully cooperating member of the society.

1. *Physical and Mental Functions Directly Related to Life-Saving or Life-Maintaining Needs.* — Maintaining life is the basic requirement for individuals to fully exercise their basic capabilities, which are necessary for individuals to enhance substantial freedoms to choose and to lead the kind of lives they value, because it is impossible to declare a person a cooperating member of society if he or she suffers from life-threatening diseases or is facing death.<sup>281</sup> It is also impossible to expect people with life-threatening diseases to maintain the basic capabilities to support

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<sup>276</sup> *Id.* at 13.

<sup>277</sup> TOEBES, *supra* note 96, at 282-83.

<sup>278</sup> *Id.* at 44-45.

<sup>279</sup> Wu, *supra* note 9, at 176.

<sup>280</sup> The biomedical health model includes four categories of biomedical functions: (1) carrying out physical and mental activities, (2) carrying out social functions and roles, (3) being free from pain, and (4) maintaining reasonably good spirits. DONALD PATRICK & PENNIFER ERICKSON, HEALTH STATUS AND HEALTH POLICY: QUALITY OF LIFE IN HEALTH CARE EVALUATION AND RESOURCE ALLOCATION 76-112 (1993). NORMAN DANIELS, DONALD LIGHT & RONALD CAPLAN, BENCHMARKS OF FAIRNESS FOR HEALTH CARE REFORM 25-26 (1996).

<sup>281</sup> *Id.* at 176.

themselves in dignity. Therefore, premature mortality is defined as a deprivation of basic capabilities and a threat to human rights. Nussbaum also agrees that life — “not dying prematurely or before one’s life is so reduced as to be not worth living”<sup>282</sup> — is the central capability. Since without these life-maintaining physical and mental functions, individuals are unable to form, to revise, or to fulfill their conceptions of good and sense of justice, the right to access medicines for life-threatening diseases should receive priority over other medicines. TNPCs’ human rights responsibilities for access to life-threatening medicines should not have the same priority status (in the “can” dimension) as access to other medicines.

In addition, categorizing physical and mental functions, directly related to life-saving in the minimal health, also corresponds to the right to life proclaimed in UDHR and ICESCR.<sup>283</sup> Because the right to life is not only non-derogable<sup>284</sup> under ICCPR Article 4.2<sup>285</sup>, but also holds *jus cogens*<sup>286</sup> status,<sup>287</sup> the right to access life-saving medicines (closely related to the

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<sup>282</sup> Nussbaum, *supra* note 272, at 42-47.

<sup>283</sup> For example, Duxbury and Avila agree that life should be protected as the ultimate human right. Alison Duxbury, *Saving Lives in the International Court of Justice: The Use of Provisional Measures to Protect Human Rights*, 31 CAL. W. INT’L L.J. 141, 143 (2000); Daniel Avila, *Assisted Suicide and the Inalienable Right to Life*, 16 ISSUES L. & MED. 111, 113 (2000); James Nickel, *Rethinking Rawls’ Theory of Liberty and Rights*, 69 CHI.-KENT L. REV. 763, 776 (1994); *Universal Declaration of Human Rights* art. 3 (1948). *International Covenant on Economic, Social, and Cultural Rights* art. 6 (1966).

<sup>284</sup> MARC J. BOSSUYT, GUIDE TO THE “TRAVAUX PRÉPARATOIRES” OF THE INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS 115 (1987).

<sup>285</sup> Article 4.1 of the ICCPR states that “[i]n time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, colour, sex, language, religion or social origin.” But according to Article 4.2, “[n]o derogation from articles 6, 7, 8 (paragraphs I and 2), 11, 15, 16 and 18 may be made under this provision.”

<sup>286</sup> Article 53 of the Vienna Convention on the Law of Treaties [VCLT] defines a peremptory norm (aka *jus cogens*) of international law as a “norm accepted and recognized by the international community of states as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.” To achieve peremptory status a norm must, therefore, have four elements. It must be a norm: (1) of general international law; (2) accepted by the international community of States as a whole; (3) incapable of derogation; and (4) incapable of being modified except by a peremptory norm of the same status. See Eva M. Kornicker Uhlmann, *State Community Interests, Jus Cogens, and the Protection of the Global Environment: Developing Criteria for Preemptory Norms*, 11 GEO. INT’L ENVTL. L. REV. 101, 112 (1998) for a discussion of identifying a norm as *jus cogens*. “Identifying a norm as *jus cogens* does not require recognition by each and every member of the international community, but only the consent of a very large majority of states reflecting the essential components of the international community. The prevailing doctrine extends the binding effect of peremptory norms even to those states that from the very beginning have objected to such a norm (‘persistent objectors’).” Vienna Convention, arts. 53 & 64.

<sup>287</sup> W. Paul Gormley, *The Right to Life and the Rule of Non-Derogability: Preemptory Norms of Jus Cogens*, in THE RIGHT TO LIFE IN INTERNATIONAL LAW 120-59 (B. G. Ramcharan ed., 1985); Dapo Akande, *The International Court of Justice and the Security Council: Is there Room for*

right to life) then should be identified as a major priority for human rights protection. Thus, even though no consensus exists on whether the right to access medicine is a binding norm of customary law, and further, whether it has reached the status of *jus cogens*, given the fact that certain contents of the right to access medicines (especially life-saving medicine) is “inextricably interwoven” with the right to life and its express inclusion in many of the major human rights instruments, it is quite likely that the right to access medicines also arises from customary international law and that at least some elements of the right (e.g., the right to access life-saving medicines) have achieved the status of *jus cogens*.<sup>288</sup>

Furthermore, because “international precedent and practice reveals that corporate liability, at least for *jus cogens* violations, is contemplated under international law,”<sup>289</sup> it is then unreasonable to impose only moral responsibilities, categorized in the “can” dimension on TNPCs, when their business conduct directly violates individuals’ right to access life-saving medicines. Take the South Africa case for example. When facing the HIV/AIDS crisis in the 1990s, South Africa adopted the Medicines Act Amendment, which explicitly sought to increase the availability and the accessibility of HIV/AIDS drugs through generic competition. However, by lobbying the U.S. government for threatening to sanction South Africa for enacting the act and bringing a lawsuit on the grounds of TRIPS violations, TNPCs effectively delayed the implementation of the Act and prevented a great number of HIV/AIDS patients from gaining access to affordable HIV/AIDS drugs that could have significantly maintained or prolonged their lives.<sup>290</sup> Since TNPCs’ behaviors in this case resulted in the direct loss of millions of lives that could have been saved through the availability of generic drugs,<sup>291</sup> and since the right to life has been recognized as non-derogable and of a *jus cogens* status, it is then reasonable for society to enforce stronger and more effective human rights enforcement in response to TNPCs’ violations of the right to access (life-saving) HIV/AIDS medicines.

2. *Physical and Mental Functions, Which If Substantially Restricted, Preclude an Individual from Exercising Basic Capabilities.* — Since there are different levels of illness (severity of illness), diseases and disabilities may not have the same effects on individuals’ physical and/or mental functions. For example, sleep and sexual disorders do not interfere with

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*Judicial Control of Decisions of Political Organs of the United Nations?*, 46 INT’L & COMP. L. Q. 309, 322 (1997).

<sup>288</sup> Beth Gammie, *Human Rights Implications of the Export of Banned Pesticides*, 25 Seton Hall L. Rev. 558, 590 (1994).

<sup>289</sup> *Talisman I*, 244 F. Supp. 2d 289, 308 (S.D.N.Y. 2003).

<sup>290</sup> See Gathii, *supra* note 198, at 733-34. Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 NW. J. INT’L L. & BUS. 379, 379 (2001).

<sup>291</sup> Ferreira, *supra* note 28, at 1177.



individuals' exercise of basic capabilities because they do not prevent individuals from thinking, reasoning, and understanding information and choices that they require to fully develop a conception of good and a sense of justice.<sup>292</sup> On the contrary, certain physical and mental functions, if substantially restricted, might preclude an individual from being a free, equal, and fully cooperating member of the society.<sup>293</sup> For example, delusional disorders can diminish an individual's capacity to form, revise, and pursue the conception of good and restrict his or her fair opportunity because an individual with delusional disorders can have abnormal subjective experiences (e.g., delusions of control or grandeur, or delusions with bizarre and culturally inappropriate content) and accompanying behaviors (e.g., incoherence or poverty of speech).<sup>294</sup> We can then claim, that such individuals should be guaranteed the necessary physical and mental functions to be capable to think and to reason in connection with experiencing and producing expressive works and events of their choice, religious, and so forth.<sup>295</sup>

Therefore, these vital (minimum essential) physical and mental functions are individually necessary and collectively sufficient for an adequate quality of human life. Because these vital physical and mental functions, which if substantially restricted, would preclude an individual from being a free, equal, and fully cooperating member of the society, they should be regarded as minimal health (minimum essential levels of the right to health) of comparable priority. TNPCs' human rights responsibilities for access to medicines which can restore or maintain vital physical and mental functions then should be itemized in the "ought to" dimension (rather than the "can" dimension) because of the moral importance of these functions (see Figure 2).

However, minimal health (vital physical and mental functions) is difficult to define. In this paper I do not thoroughly explore this issue due to the focus of this paper, and due to the massive literature review and analysis required.<sup>296</sup> Nevertheless, identifying the state's core obligation "to ensure the satisfaction of, at the very least, minimum essential levels [of

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<sup>292</sup> Wu, *supra* note 9, at 176.

<sup>293</sup> *Id.*

<sup>294</sup> ANDREW STEVENS ET AL., 2 HEALTH CARE NEEDS ASSESSMENT: THE EPIDEMIOLOGICALLY BASED NEEDS ASSESSMENT REVIEWS 168 (2nd ed., 2004).

<sup>295</sup> Meaning individuals should also be guaranteed to be capable to imagine, to think, and to reason things in a "truly human" way (species-typical functioning). Nussbaum, *supra* note 272, at 45.

<sup>296</sup> See, e.g., RICHARD GLENN ABRAMSON, DISTRIBUTIVE JUSTICE AND HEALTH CARE: BALANCING INDIVIDUAL CLAIMS WITH SOCIAL INTERESTS THROUGH AN EXTENSION OF RAWLS'S THEORY OF JUSTICE (1994) (unpublished A.B. thesis, Harvard University, on file with the Harvard University Library); see generally CHUAN-FENG WU, THE RIGHT TO HEALTH CARE AND HEALTH CARE DISTRIBUTIVE JUSTICE (2007) (unpublished J.S.D. dissertation, University of California Berkeley School of Law, on file with the University of California Berkeley School of Law Library).

the right to health]”<sup>297</sup> provides some basic concepts about minimal health and offers some guidance for TNPCs when realizing their human rights responsibilities. For example, the list-of-services approach adopted by the CESCR General Comment No. 14 to prioritize states’ core obligations to fulfill certain rights to health — including rights to access: essential drugs; reproductive, maternal (pre-natal and post-natal) and child health care; immunizations against major infectious diseases in the community<sup>298</sup> — can be used as a criterion to interpret the contents of minimal health under the framework of the right to access medicines. Namely, (1) essential drugs and (2) immunizations against major infectious diseases could be recognized as necessary medicines for restoring or maintaining minimum essential physical and mental functions that directly relate to life-saving or life-maintaining; and (3) reproductive, maternal (pre-natal and post-natal) and child health care could be recognized as necessary medicines for restoring or maintaining physical and mental functions that strongly relate to individuals’ free exercise of basic capabilities. In the third case, the state’s responsibility to ensure infants and children adequate healthcare has a special corollary: “an intrinsic part of ensuring their well-being involves ensuring that they have adequate conditions to develop their basic capabilities [for self-government].”<sup>299</sup>

Since the right-to-health priority is given to healthcare services that will most likely increase basic capabilities among individuals least able to exercise them without outside help, TNPCs’ human rights responsibilities for providing access to these medicines, then should be stronger than responsibilities for providing access to non-essential medicines. In effect, TNPCs’ responsibilities for access to medicines should be classified in the “ought to” dimension, rather than the “can” dimension. Imposing stringent responsibilities on TNPCs to provide access to life-saving/minimal-health-maintaining medicines is also consistent with Paragraph 47 of the CESCR General Comment No. 14, which confirms that the right to access essential drugs, pre-natal and post-natal healthcare, child

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<sup>297</sup> See Paragraphs 43-45 of the CESCR General Comment No. 14 and more discussions in Section (IV)(B).

<sup>298</sup> According to CESCR General Comment No. 14 articles 43 and 44, state parties have the following core obligations (which directly relate to health care services): (1) to ensure access to the minimum essential food which is nutritionally adequate and safe; (2) to ensure access to basic shelter, housing and sanitation; (3) to ensure access to adequate supply of safe and potable water; (4) to provide essential drugs; to ensure reproductive, maternal (pre-natal as well as post-natal) and child health care; (5) to provide immunization against the major infectious diseases occurring in the community; (6) to take measures to prevent, treat and control epidemic and endemic diseases. Committee on Economic, Social, and Cultural Rights, CESCR General Comment No. 14, ¶¶ 43-44 (E/C 12/2000/4) (2000).

<sup>299</sup> Maxine Eichner, *Dependency and the Liberal Polity: On Martha Fineman’s The Autonomy Myth*, 93 CAL. L. REV. 1285, 1316 (2005). Naomi Cahn, *The New Kinship*, 100 GEO. L.J. 367, 422-23 (2012). LINDA C. McCLAIN, *THE PLACE OF FAMILIES: FOSTERING CAPACITY, EQUALITY* 88 (2005).

healthcare, and immunizations are non-derogable and that the state cannot, under any circumstances, justify its non-compliance with its obligations to fulfill these rights. Thus, concerning life-saving/minimal-health-maintaining drugs, vaccines (immunization), obstetrics and pediatric drugs, responsible TNPCs “ought to” make substantial contributions (e.g., adjusting drug prices or foregoing patent protections on medications in primary need) to enhance accessibility of these medicines.

## VI. CONCLUSION

International human rights institutions generally focus on enhancing member states (not TNPCs) access to medicines, by restricting free trade or interfering with private market mechanisms, if and only if these actions are “necessary to protect human . . . life or health” (see Articles 27(2) of the TRIPS Agreement)<sup>300</sup>. For example, international trade laws, such as 31(b) (compulsory licensing) of the TRIPS Agreement,<sup>301</sup> the Doha Declaration and the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement, and Public Health (2003 Decision), afford member states the opportunity to impose restrictions on international trade in order to protect the right to health. However, these documents (including international human rights laws, such as ICESCR and CESCR General Comment No. 14) do not recognize TNPCs as legal subjects with human rights responsibilities and they require member states only to fulfill the right to access medicines (e.g., the TRIPS-exemptions). The role of TNPCs in a global economy is “to research, develop, and produce innovative medicines that make a difference to sick people’s quality of life, and it is

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<sup>300</sup> Article 27(2) of TRIPS, “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

<sup>301</sup> Article 31(b) of TRIPS, “Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: . . . (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.”

their duty to do so in a profitable way in the healthcare market.”<sup>302</sup>

However, the domain of the right to access medicines reflects problems that neither governments, nor the market itself can readily solve. The state cannot fulfill its obligations to protect the right to access medicines within its jurisdiction, without requiring businesses to conduct their activities in a manner consistent with enjoyment of such a right. Therefore, enhancing access to medicines solely through governments’ regulations or actions seems impossible, especially when TNPCs are one of the most powerful economic and political entities in the world today. Since globalization has contributed to, and in part has been driven by increasingly central role of TNPCs in both domestic and international healthcare policies, the continued ignorance of their power and their human rights responsibilities cannot only distort the processes through which the norms of the right to access medicines are elaborated upon and enforced, but also can destabilize the balance between the right to access medicines and other rights (e.g., intellectual property rights)<sup>303</sup>. Therefore, for certain contents of the right to access medicines, TNPCs should play a crucial role and share the state’s human rights responsibility to fulfill these rights. A new framework that considers not only TNPCs’ philanthropic activities (moral human rights responsibilities in the “can” dimension), but also their legal (at least soft-law) human rights responsibilities (in the “ought to” dimension) to enhance access to medicines then should be developed in accordance with the development of this modern world.

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<sup>302</sup> Leisinger, *supra* note 45, at 2.

<sup>303</sup> For example, when meeting U.N. Secretary General Kofi Annan in 2001 to discuss affordable access to HIV/AIDS medicines in developing countries, a number of pharmaceutical corporations appear opposed to governments’ independent attempts to improve their countries’ access to live-saving medicines. Alexander, *supra* note 16, at 12.

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