
NOT JUST A TRAGEDY: ACCESS TO MEDICATIONS AS A RIGHT UNDER INTERNATIONAL LAW*

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The author is grateful to Sean Flynn of the Consumer Project on Technology, for his insightful comments and guidance, and to Jaume Vidal Casanovas, for generously sharing materials, sources and ideas. Some of the arguments presented in this paper were submitted to the South Africa Competition Commission as part of a collection of expert reports compiled for the Commission by the Consumer Project on Technology in relation to the case of *Hazel Tau v. GlaxoSmithKline and Boehringer Ingelheim*. On October 16, 2003, the South African Competition Commission announced that it had found that the respondents abused their dominance in markets for AIDS medicines by denying competitors access to essential facilities, excessive pricing and engaging in exclusionary acts the anticompetitive effects of which outweigh procompetitive gains. Menzi Simelane, Commissioner at the Competition Commission, stated that the Commission “will request the [Competition] Tribunal to make an order authorizing any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty.” Press Release, Competition Commission, Competition Commission Finds Pharmaceutical Firms in Contravention of the Competition Act (Oct. 16, 2003) (on file with author).

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I. INTRODUCTION

*The miserable have no other medicine
But only hope.*¹

For millions around the world not much has changed since the Bard penned these famous lines; many do not even have hope. Nowhere is this more starkly true than in Sub-Saharan Africa where an estimated 29.4 million adults and children are living with HIV/AIDS. Many of these 29.4 million languish dying simply because they lack access to life-saving and sustaining medications.² Despite the fact that new combinations of antiretroviral (“ARV”) therapy and other medications have enabled HIV-positive people in much of the Western world to live productive lives for many years, HIV/AIDS is now the largest contributor to mortality in South Africa and in several other Sub-Saharan African countries.³ Similarly, tuberculosis and malaria are global killers that overwhelmingly affect the developing world where access to appropriate medications is not available.⁴ The recent establishment of the Global Fund to Fight AIDS, Tuberculosis and Malaria, together with countless other official and non-governmental initiatives, demonstrates that these diseases—especially the HIV/AIDS pandemic—have garnered attention due to their economic and social consequences, as well as because of the human

¹ WILLIAM SHAKESPEARE, *MEASURE FOR MEASURE* act 3, sc. 1.

² Joint United Nations Programme on HIV/AIDS & World Health Org., *AIDS Epidemic Update* at 6 (Dec. 2002), available at http://www.unaids.org/html/pub/Publications/IRC-pub03/epiupdate2002_en_pdf.pdf (last visited Sept. 25, 2003).

³ SOUTH AFRICAN MEDICAL RESEARCH COUNCIL, *THE IMPACT OF HIV/AIDS ON ADULT MORTALITY IN SOUTH AFRICA* (2001), in Charles Ngwena, *Access to Antiretroviral Therapy to Prevent Mother-to-Child Transmission of HIV as a Socio-economic Right: An Application of Article 27 of the Constitution* (May 2003) (unpublished manuscript, on file with the author).

⁴ See, e.g., The Global Fund to Fight AIDS, Tuberculosis & Malaria, at <http://www.globalfundatm.org/overview.html> (last visited Sept. 25, 2003).

tragedies they represent.⁵ However, what is frequently omitted in discussions regarding pharmaceutical policy, trade, and intellectual property issues—in the HIV/AIDS context and beyond—is that access to medications is also a matter of rights under international law. Human rights law not only offers an alternative paradigm for understanding issues relating to the availability and distribution of medications, it also provides a workable framework for influencing the way in which adjudicative and legislative bodies, as well as other actors, make decisions that affect access to medications.

From a public health perspective, access to essential drugs depends on: (1) rational selection and use of medicines; (2) sustainable adequate financing; (3) affordable prices; and (4) reliable health and supply systems.⁶ Understanding access to basic medications as a human rights issue means, first, that governments have not only moral or humanitarian responsibilities to undertake such measures to ensure access to essential drugs, but also have legal obligations. These legal obligations require access to medications to be reflected as a budgetary priority and taken into account in not only the organization of the health system, but also, *inter alia*, in competition, pricing, licensing, and other laws. Legal responsibilities, in turn, imply the need for accountability when obligations are not met by states.

Second, in a human rights framework, cost-effectiveness concerns are balanced with other priorities and the state has a critical role to play both in ensuring basic health care goods and services, and in regulating the inequities of the market. Indeed, the central question at issue from the human rights perspective is whether the government is taking steps by *all appropriate means* to make medications accessible, physically and economically, and to make information relating to medications accessible as well.⁷ Complying with the *all appropriate means* requirement may require the adoption of laws and policies as well as the effective implementation of programs, as universal access to medications cannot be achieved in isolation from a functioning health care system. However, treaties and

⁵ The Global Fund to Fight AIDS, Tuberculosis & Malaria (Global Fund) was created to “attract, manage, and disburse additional resources [to fight these three diseases] through a new public-private partnership.” *Id.* The reasoning behind the creation of the Global Fund, which supports the Millennium Development Goals, is that good health is fundamental to economic growth and poverty reduction and vice versa. “The health crisis faced by the developing world created by the unchecked spread of HIV/AIDS, TB, and malaria threatens to reverse the hard won development gains of the last 50 years.” *Id.*

⁶ *Technical Cooperation Activities: Information from Other Intergovernmental Organizations*, WHO Doc. IP/C/W/305/Add.3, at <http://www.who.int/medicines/organization/ood/techcoop.shtml> (last modified May 15, 2002).

⁷ *General Comment 14: The Right to the Highest Attainable Standard of Health*, U.N. Comm. on Econ., Soc. & Cultural Rts., 20th Sess., ¶ 12, U.N. Doc. E/C.12/2000/4 (2000).

statutes relating to trade, competition, intellectual property, or other factors bearing on access to medications can often be ambiguous; in such cases, a human rights framework imposes an obligation to interpret such treaties and legislation in the manner that most fully advances the public's health interests.⁸

Further, in accordance with human rights principles, access to medications—which in practice often accompanies access to health care facilities and trained personnel—must be realized on a non-discriminatory basis, without distinction of any kind based on race, ethnic group, color, sex, language, religion, political or any other opinion, national or social origin, property, birth, or other status. Discrimination based on any of the above that has the purpose or effect of nullifying or impairing the enjoyment or exercise of people's rights to life and to health constitutes a violation of international law.⁹

This article first sets out the principal norms under international human rights law that relate to access to medications. No issue more starkly illuminates the egregious inequalities that exist in the world today between and within countries and demands that we address such inequalities as urgent matters of social justice in accordance with international human rights law. At the same time, no issue more clearly demonstrates the indivisibility of civil/political and economic/social/cultural rights and challenges national courts and international human rights bodies to evolve in their definitions and approaches toward different rights categories. Part II discusses how the right to life has increasingly been expansively interpreted to include conditions that promote and sustain life with dignity, as well as both the minimum core content and progressive realization of the right to health. Part II also sets out the connections between access to medications and the rights to an adequate standard of living, to work, and to education, as well as between access to medications and the right to enjoy the benefits of scientific progress and the disproportionate effects on children and marginalized groups of failure to ensure access to medications.

In Part III, the article examines the obligations that flow from those human rights provisions, which could provide the practical basis for policy-making and legislation. Primarily focusing on the right to health, as defined by the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), the article analyzes governmental obligations according to the tripartite framework of duties that is now well-established.

⁸ See, e.g., *Human Rights and Intellectual Property*, U.N. Comm. on Econ., Soc. & Cultural Rts., 27th Sess., ¶ 12, U.N. Doc. E/C.12/2001/15 (2001) [hereinafter *Statement on Human Rights and Intellectual Property*].

⁹ E.g., U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶¶ 11-12.

lished under international law: to respect, to protect, and to fulfill.¹⁰ That is, first, states have obligations to respect the right to health by refraining from adopting laws or measures that directly infringe upon people's health. Second, states have obligations to adopt measures to protect the population from the effects of policies imposed upon states by pharmaceutical companies, third-party states, and international institutions, such as the World Trade Organization ("WTO").¹¹ Third, the normative framework of human rights requires adequate progress to fulfill universal access to essential medications. At a minimum in this regard, international human rights law requires a clear plan to be made and deliberate steps to be taken toward the progressive realization of the right to health and does not permit policies or acts, even under pressure from other actors, which would entail regression in terms of availability or affordability of medications.¹²

The article further considers the obligations of third-party states and international institutions. Discussions and examples relating to HIV/AIDS are intended as illustrative; other life-threatening diseases and conditions pose many of the same rights issues but, due to the unparalleled scale of the HIV/AIDS pandemic, these simply have not received the same attention from national courts or from international bodies.

The article concludes that transforming our understanding of access to medications into a human rights issue leads us to ask not *if* life-saving medications can be provided to the millions of destitute sick people around the world, but *how* governments, third-party states and international organizations can facilitate that process and ensure that they are. Further, human rights provides a set of principles according to which laws, policies and programs can be evaluated and reformed.

II. OVERVIEW OF NORMS RELATING TO ACCESS TO MEDICATIONS UNDER INTERNATIONAL HUMAN RIGHTS LAW

Discussions of "compassion fatigue" or debates about the cost-effectiveness of prevention versus treatment relating to the HIV/AIDS pandemic and other global scourges fail to take into account the central question of the human rights of those people who are already ill. As Paul Farmer writes, "The self-appointed guardians of international health cannot *ethically* erase the tens of millions already sick with HIV disease. . . .

¹⁰ *Id.* ¶¶ 34-36; *General Recommendation No. 24*, Comm. on the Elimination of Discrimination Against Women, 20th Sess., ¶¶ 14-17, U.N. Doc. CEDAW/C/1999/II/WG.II/WP.2/Rev.1 (1999) [hereinafter *CEDAW Gen. Recom. No. 24*].

¹¹ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 35.

¹² Victor Dankwa et al., *The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights*, 20 HUM. RTS. Q. 691, 694 (1998) [hereinafter *Maastricht Guidelines*]; U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 36.

The millions already dying during childbirth or from diseases such as HIV and drug-resistant malaria and tuberculosis face other challenges beyond prevention.”¹³ The fundamental premise underlying the notion of universal human rights is that people are not expendable; those people’s avoidable deaths are not just a tragic shame. Thus, adopting a human rights view of access to medications changes how we think about this crucial issue, and therefore what we do about it.

Although citing legal instruments will not by itself lead to changes in paradigms or policies, understanding how norms relating to access to medications have been interpreted at the international and national levels can lead us to think differently both about the issue itself as well as about the normative evolution of rights concepts. International and national jurisprudence has developed particularly rapidly in this area in recent years. The right to life—the classic, non-derogable, civil right—has increasingly been interpreted broadly and applied in cases involving access to medications. Further, a recent General Comment on the Right to the Highest Attainable Standard of Health and a General Statement on “Human Rights and Intellectual Property,” both of which were issued by the U.N. Committee on Economic Social and Cultural Rights (“ESCR Committee”), coupled with statements by other international and regional bodies and jurisprudence from national tribunals, have gone far in clarifying the normative content of the right to health and in eroding arguments that the right to health cannot be a fundamental, and enforceable, principle in law and policy making in this realm.¹⁴

This section analyzes how access to medications implicates the rights to life, to health, and to the benefits of scientific progress, and how it also affects the rights to education, to work, and to an adequate standard of living. A human rights framework also places great emphasis on the principles of non-discrimination and concern for vulnerable and marginalized groups, which have implications for policies and laws relating to access to medications.

A. *The Right to Life*

The right to life is the most basic of all rights; indeed, some international tribunals have pointed out that the right to life has attained *jus cogens* status under international law.¹⁵ Given that medications can be

¹³ PAUL FARMER, *PATHOLOGIES OF POWER: HEALTH, HUMAN RIGHTS, AND THE NEW WAR ON THE POOR* 206 (2003).

¹⁴ See generally U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7 (setting out, in General Comment No. 14, the scope of norms and obligations flowing therefrom with the aim of assisting states and other parties in compliance). See also James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLA J. INT’L L. 261, 271 (2002).

¹⁵ *Jus cogens* refers to a peremptory norm, which is defined under the Vienna Convention on the Law of Treaties as “a norm accepted and recognized by the

indispensable for life, it is foreseeable that state policies likely to lead directly to diminished physical accessibility and affordability of certain medications will, in effect, deprive people of life. Article 6(1) of the International Covenant on Civil and Political Rights (“ICCPR”) clearly sets forth a right to life and states that “this right shall be protected by law. No one shall be arbitrarily deprived of his life.”¹⁶ The right to life has generally been recognized to encompass more than not dying as a result of actions directly attributable to the state, to extend to conditions that permit, at a minimum, survival and, more broadly, to those that are conducive to dignity and well-being.

For example, the Human Rights Committee of the United Nations, which monitors implementation of the ICCPR, has articulated that “the expression ‘inherent right to life’ cannot properly be understood in a restrictive manner and the protection of this right requires that states adopt positive measures.”¹⁷ That is, even this most classic “individual” right cannot properly be understood (or enjoyed) as a liberty in a vacuum, which requires only restraint on the part of the state. On the contrary, guaranteeing a meaningful right to life entails ensuring that enabling conditions are in place in both the public and private spheres. Specifically, the Human Rights Committee has defined the role of the state in protecting human life to include obligations to reduce infant mortality, to increase life expectancy, and to eliminate malnutrition and epidemics.¹⁸ Further, in its reviews of states parties’ reports, the Human Rights Committee is increasingly finding that certain health and social policies, such as those relating to protections from domestic violence and to severe criminal penalties imposed on abortion, which have been shown to increase maternal mortality, implicate the right to life.¹⁹

The Inter-American Commission on Human Rights has commented on a general trend in international human rights bodies around the world to

international community of states as a whole 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.” Vienna Convention on the Law of Treaties, May 23, 1969, art. 53, 1155 U.N.T.S. 331, 340, 8 I.L.M. 679, 692 [hereinafter Vienna Convention]. For an example of the right to life being cited as *jus cogens*, see Street Children Case (*Morales v. Guatemala*), Judgment of Nov. 19, 1999 Inter-Am. Ct. H.R. (Ser. C) No. 63, ¶ 139, available at http://www.corteidh.or.cr/seriec/serie_c_63_ing.doc.

¹⁶ International Covenant on Civil and Political Rights, G.A. Res. 2200, U.N. GAOR, Supp. No. 16, at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, 174 (entered into force Mar. 23, 1976) [hereinafter ICCPR].

¹⁷ *The Right to Life*, U.N. GAOR Human Rights Comm., 37th Sess., Supp. No. 40, at Gen. Comment No. 6, ¶ 5, U.N. Doc. A/37/40 (1982).

¹⁸ *Id.* ¶ 5.

¹⁹ *E.g.* Concluding Observations of the Human Rights Committee: Peru, ¶¶ 13, 15, U.N. Doc. CCPR/C/79/Add.72 (1996).

recognize the underlying inputs necessary for sustaining life as part of the right itself:

There has been a tendency to move towards a broader and more comprehensive concept of the right to life which characterizes the right to life not only as the legal foundation for all other rights, but also as an integral part of all the rights that are essential to guarantee the access of every human being to all the goods . . . required for the development of his/her material, moral, and spiritual existence.²⁰

This trend is indeed observable with respect to interpretations of the right to life provided under a panoply of instruments across the globe. For example, article 6 of the Convention on the Rights of the Child (“Children’s Convention”) states: “States Parties recognize that every child has the inherent right to life” and “States Parties shall ensure to the maximum extent possible the survival and development of the child.”²¹ The Committee on the Rights of the Child (“CRC”) has spoken to the issue of HIV/AIDS in particular as it affects children being orphaned and, in turn, as it effects their very survival as well as their health and development.²²

On a regional level, article 4 of the African Charter on Human and Peoples’ Rights (“Banjul Charter”) establishes the right of every human being to “respect for life and integrity of his person” and states that “no one may be arbitrarily deprived of this right.”²³ In a recent decision, the African Commission on Human and Peoples’ Rights found the government of Nigeria responsible for violating article 4, because, among other things, pollution and environmental degradation that were attributable to the government had risen “to a level humanly unacceptable [and] has made living in Ogoniland a nightmare.”²⁴ The language of “humanly

²⁰ Status of Human Rights in Several Countries: Nicaragua, Annual report of the Inter-American Commission on Human Rights 1993, OEA/Ser.L/V/II.85, Doc. 9 Rev. (1994) at 465, available at www.cidh.org/annualrep/93span/cap.IVe.htm. (quoting *The Right of Everyone to Own Property Alone as well as in Association with Others*, U.N. Commission on Human Rights, 49th Sess., Provisional Agenda Item 7, at 25, U.N. Doc. E/CN.4/1993/15).

²¹ Convention on the Rights of the Child, Nov. 20, 1989 G.A. Res 44/25, U.N. GAOR, 44th Sess., Supp. No. 49, at 167, U.N. Doc. A/44/49 (1989) at art. 6(2) [hereinafter Children’s Convention].

²² *Concluding Observations of the Comm. on the Rights of the Child: Cote d’Ivoire*, U.N. Comm. on the Rights of the Child, 27th Sess., 721st mtg., ¶ 5, U.N. Doc. CRC/C/15/Add.155 (2001) (positive assessment of national plan).

²³ African [Banjul] Charter on Human and Peoples’ Rights, adopted June 27, 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force Oct. 21, 1986: [hereinafter Banjul Charter].

²⁴ *Social and Economic Rights Action Center v. Nigeria*, Communication 155/96 (African Commission on Human & Peoples’ Rights, Oct. 2001) ¶ 67, available at http://www.achpr.org/DECISIONS_30th_Session_-_Oct.2001_eng.pdf [hereinafter *Ogoniland Case*] (holding Nigerian government responsible for directly violating and failing to protect the rights to life, to health, and to housing of the Ogoni people).

unacceptable” and the notion of holding the government responsible for allowing oil exploitation to turn life into a “nightmare” suggest that given the appropriate case, similar reasoning could be applied in the realm of access to medications and to the government’s obligations with respect to the conduct of pharmaceutical companies.

For its part, the European Convention for the Protection of Human Rights and Fundamental Freedoms states in article 2(1): “Everyone’s right to life shall be protected by law.”²⁵ The European Commission on Human Rights has also underscored that this provision for the right to life requires states not only to prevent intentional killing but also to take steps against unintentional loss.²⁶

In the Inter-American System, the American Convention on Human Rights (“American Convention”) states: “Every person has the right to have his life respected. . . . No one shall be arbitrarily deprived of his life.”²⁷ The Inter-American Court of Human Rights (“Inter-American Court”) has interpreted article 4 in a broad sense. That Court has held: “The right to life must be examined in its relationship to the commitment of the State, established in article 1(1), to respect and guarantee the full exercise of every right recognized in the [American] Convention.”²⁸

Further, with respect to the language “arbitrary deprivation of life,” which some governments have argued is restrictive, two judges of the Inter-American Court have clarified that:

The right to life not only implies the negative obligation not to deprive anyone of life arbitrarily, but also the positive obligation to take all necessary measures to secure that that basic right is not violated. . . .

The arbitrary deprivation of life is not limited, thus, to the illicit act of homicide; it extends itself likewise to the deprivation of the right to live with dignity. This outlook conceptualizes the right to life as belonging at the same time to the domain of civil and political rights,

²⁵ *European Convention for the Protection of Human Rights and Fundamental Freedoms*, opened for signature Nov. 4, 1950, 213 U.N.T.S. 221, 224 (entered into force Sept. 3, 1953).

²⁶ *Tavares v. France*, Application No. 16593/90, Sept. 12, 1991 (European Comm’n of Hum. Rts.) (unreported), cited in Rebecca J. Cook & Bernard M. Dickens, *Human Rights Dynamics of Abortion Law Reform*, 25 HUM. RTS. Q. 1, 28 (2003).

²⁷ American Convention on Human Rights, Nov. 22, 1969, art. 4, O.A.S. T.S. No. 36, O.A.S. Off. Rec. OEA/Ser.LV/II.23 doc.21 rev.6 at 25 (1979) (entered into force July 18, 1978) [hereinafter American Convention].

²⁸ *Mendes v. Brazil*, Inter-Am. C.H.R. Report No. 59/99, Case 11.405, Apr. 13, 1999, ¶ 101, available at <http://www.cidh.oas.org/annualrep/98eng/Table%20of%20Contents.htm>.

as well as economic, social and cultural rights, thus illustrating the interrelation and indivisibility of all human rights.²⁹

This explication, which goes far toward putting to rest the tired distinctions between “positive” and “negative” rights, and between civil/political rights and ESCR, is not only significant with respect to cases brought in the Inter-American System, but for other human rights fora as well, as there is frequent cross-fertilization among regional human rights systems.³⁰

The concurring opinion in the Inter-American Court echoed reasoning in earlier reports by the Inter-American Commission on Human Rights (“IACHR”), including one relating to the violence in Guatemala, which stated that “the rights connected to life and integrity should be accompanied by parallel improvements in the standard of living of the population, in relation to economic, social and cultural rights, the implementation of which should be a priority for the state.”³¹ The duty to provide access to life-saving or life-sustaining medications would not only clearly seem to fall within these expanded notions of obligations deriving from the right to life, but has also explicitly challenged international human rights bodies to draw together conceptually the rights of life and health.

Indeed, the IACHR recently admitted a case relating to the failure of states to provide medications based on allegations of violations of article 4 of the American Convention.³² In the case of *Odir Miranda v. El Salvador*, the petitioners alleged that El Salvador’s refusal to purchase the triple therapy and other medications that prevent death and improve the quality of life of persons living with HIV/AIDS failed to guarantee them the rights to life and health.³³ The IACHR concluded that the case was admissible and stated explicitly that although it is not competent to determine violations of article 10 of the Protocol of San Salvador, the IACHR will take into account the provisions related to the right to health in its

²⁹ Street Children Case (Morales v. Guatemala), Joint Concurring Opinion of Judges A.A. Cancado Trindade & A. Abreu-Burelli, Inter-Am. Ct. H.R. (Ser. C) No. 63, ¶¶ 2-4, available at http://www.corteidh.or.cr/seriecieing/VotocancadoabreuSerie_c_63_ing.doc (street children had been subject to persecution, threats and were eventually murdered by state agents and the state had not provided protection or adequately investigated).

³⁰ This is explicitly provided for under some instruments. See, e.g., American Convention, *supra* note 27, at art. 27.

³¹ *Annual Report of the Inter-American Commission on Human Rights 1991*, Inter-Am. C.H.R., at ch. 4, OEA/Ser.L/V/II.81 (1992) available at www.cidh.org/annualrep/91span/cap.IVc.guatemala.htm.

³² *Odir Miranda v. El Salvador*, Case 12.249, Report No. 29/01, Inter-Am. C.H.R., Annual Report 2000, OEA/Ser.L/V/II.111, Doc. 20 Rev. (2001), available at <http://www.cidh.oas.org/annualrep/2000eng/ChapterIII/Admissible/ElSalvador12.249.htm>.

³³ *Id.* ¶¶ 2, 24.

analysis of the merits of the case, pursuant to the provisions of articles 26 and 29 of the American Convention.³⁴

In most countries, the constitution sets out the right to life as a fundamental right, in similar if not identical language to that found in international instruments. Moreover, domestic courts have increasingly interpreted the right to life in an expansive way, along the trends discussed above with respect to international tribunals and institutions. For example, in *Frances Mullen v. Union Territory of Delhi*, the Indian Supreme Court held that the right to life “includes the right to live with human dignity and all that goes along with it, namely, the bare necessities of life, such as adequate nutrition, clothing and shelter. . . . Every act which offends against or impairs human dignity would constitute deprivation pro tanto of this right to live.”³⁵ More specifically, in a series of cases dealing with the substantive content of the right to life, the Indian Supreme Court has found that the right to live with human dignity includes the right to good health.³⁶ In that context, a number of domestic courts have found that denial of access to certain medications can constitute a violation of the constitutional right to life.³⁷

The Constitutional Court of Colombia, which stands out among national tribunals for having developed an extensive jurisprudence on the right to treatment in cases of HIV/AIDS, has affirmed that the constitutional right to life should not be understood merely as biological existence, but rather as a right that permits the pursuit of a life of dignity:

[T]he fundamental constitutional right to life cannot be understood as referring to mere existence, but rather as dignified existence, with the conditions necessary to develop, to the extent possible, all the faculties that a human being can enjoy.³⁸

³⁴ *Id.* ¶ 36.

³⁵ *Mullen v. Union Territory of Delhi*, 2 S.C.R. 516 (1981), cited in Sheetal Shah, *Illuminating the Possible in the Developing World: Guaranteeing the Human Right to Health in India*, 32 VAND. J. TRANSNAT'L L. 435, 467 (1999).

³⁶ See *id.* at 453.

³⁷ *E.g.*, *Glenda Lopez v. Instituto Venezolano de Seguros Sociales*, 487-060401 (Supreme Court of Venezuela, Constitutional Chamber 1997), available at <http://www.tsj.gov.ve/decisiones/scon/Abril/487-060401-001343.htm> (violation of the right to life under article 58 of the Venezuelan Constitution, in that the failure of the social security institute to provide antiretroviral treatment on a regular schedule can provoke an inexorable destruction of the immune system, in addition to viral resistance, which leads to opportunistic infections and death).

³⁸ Protection Writ, Judgment of Fabio Moron Diaz, Magistrado Ponente, T-328/98 (Corte Constitucional de Colombia 1998), available at <http://bib.minjusticia.gov.co/jurisprudencia/CorteConstitucional/1998/Tutela/T-328-98.htm> (holding denial of costly antiretroviral treatment prescribed for plaintiff under social security system violates constitutional fundamental right to life) (author translation).

It should also be underscored that although HIV/AIDS presents the connection between health and life in urgent terms, national courts have also found the right to life implicated in access to medications involving other conditions and diseases as well. For instance, in Argentina, a successful protection writ action was brought to force the Ministry of Health to provide a particular anti-cancer drug necessary for the survival of a 63-year-old woman suffering from colon cancer.³⁹

B. *The Right to Health*

Access to medications of course constitutes an integral part of the right to health. The right to health, which is set out in fully as many treaties and instruments as the right to be free of torture or any other classic civil right, has undergone remarkable normative development and clarification in recent years.⁴⁰ There remain serious questions regarding conceptualizations of health, interpretation of specific language, and standards for monitoring progress. However, it can no longer be argued that the content of the right to health is unduly vague for implementing legislation or enforcement, or that it sets out merely political aspirations.⁴¹

The core provision on the right to health in international human rights law is set out in article 12 of the International Covenant on Economic, Social, and Cultural Rights (“ICESCR”), which recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”⁴² It further states that: “steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for . . . [t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases” and “[t]he creation of conditions which would assure to all medical service and medical attention in the event of sickness.”⁴³ Access to medications is a critical component of the right to health both as treatment for epidemic and endemic diseases and as part of medical attention in the event of any kind of sickness.

³⁹ Protection Writ, B., E. A. v. Ministerio de Salud, Banco Nacional de Drogas Antineoplásticas, Ley 16.986 (Supreme Court of Argentina 2002), cited in CENTRO DE ESTUDIOS LEGALES Y SOCIALES, DERECHOS HUMANOS EN ARGENTINA. INFORME 2002 ch. IX (2002). Note that the government has appealed in this case.

⁴⁰ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, supra note 7; see also *Maastricht Guidelines*, supra note 12 (establishing, inter alia, principle of obligations of conduct and result); *Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights*, U.N. Doc. E/CN.4/1987/17, Annex, reprinted in 9 HUM. RTS. Q. 122, 125 (1987).

⁴¹ See, e.g., Shah, supra note 35, at 442-50.

⁴² Int’l Covenant on Econ., Soc. & Cultural Rts., G.A. Res. 2200, U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc A/6316 (1966), 993 U.N.T.S. 3 (adopted Dec. 16, 1966) [hereinafter ICESCR].

⁴³ *Id.* at Art. 12(2)(c) and (d), respectively.

From time to time, treaty-monitoring bodies issue General Comments or General Recommendations, which are authoritative interpretations of aspects related to specific treaty provisions, that are intended to assist states in complying with their obligations. In its General Comment No. 14 on the “Right to the Highest Attainable Standard of Health,” the Economic, Social and Cultural Rights Committee (“ESCR Committee”) explained that all health care facilities, goods, and services—including medications and the provision thereof—should be: (1) available in sufficient quantity; (2) accessible to everyone without discrimination; (3) acceptable in the sense of respectful of medical ethics and customs; and (4) of good quality and scientifically appropriate.⁴⁴ Accessibility in particular includes: (1) physical accessibility (“health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS”);⁴⁵ (2) economic accessibility (“health facilities, goods and services must be affordable for all”);⁴⁶ and (3) information accessibility (“accessibility includes the right to seek, receive and impart information and ideas concerning health issues,” including pricing and treatments).⁴⁷

In the same General Comment No. 14, the ESCR Committee specifically recognized access to “essential drugs, as defined by the WHO Action Programme on Essential Drugs” as part of a state’s minimum core obligations under the ICESCR.⁴⁸ Thus, essential medications are part of each state party’s “core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant.”⁴⁹ Although ESCR Committee General Comment No. 14 recognizes that “[t]he precise nature of the facilities, goods and services [provided as part of the right to health] will vary depending on numerous factors,” core obligations are non-derogable and in many respects do not depend on a state’s development level.⁵⁰ The ESCR Committee has increasingly addressed specifically states’ failures with respect to providing essential drugs to halt epidemic disease, such as HIV/AIDS.⁵¹

⁴⁴ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 12.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.* ¶ 43.

⁴⁹ *Id.*

⁵⁰ *The Nature of States’ Parties Obligations*, U.N. Comm. on Econ., Soc. & Cultural Rts., 5th Sess., ¶ 10, U.N. doc. E/1991/23, Annex III; *see also* U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 47.

⁵¹ *See, e.g.*, Concluding Observations of the Comm. on Econ., Soc. & Cultural Rts.: Honduras, May 21, 2001, ¶ 26, U.N. Doc. E/C.12/1/Add.57 (2001).

The right to health is also set out in myriad other international treaties. For example, article 24 of the Children's Convention adopts a similar definitional approach as that of the ICESCR with respect to the rights of children.⁵² The International Convention on the Elimination of All Forms of Racial Discrimination of 1965 ("Race Convention") and the Convention on the Elimination of All Forms of Discrimination against Women of 1979 ("Women's Convention") set out obligations of states parties to eliminate race-based and gender-based discrimination in health services and in public health.⁵³ Again, access to medications cannot be provided in a vacuum; in practice, access to medications requires non-discrimination in access to health services, as well as in conditions that go beyond the health sector.

Further, the right to health is also included in a host of regional instruments, which generally set out both the right to adequate health care in the event of sickness and the obligations to undertake public health measures to prevent epidemic and endemic diseases. For example, article 16 of the Banjul Charter sets out the right of every individual to enjoy the "best attainable state of physical and mental health" and declares that states parties shall take "the necessary measures to protect the health of their people."⁵⁴ The European Social Charter states that contracting parties undertake "to take appropriate measures designed inter alia . . . to prevent as far as possible epidemic, endemic and other diseases."⁵⁵ Article 13(1) states further that contracting parties undertake "to ensure that any person who is without adequate resources and who is unable to secure such resources . . . be granted adequate assistance, and, in case of sickness, the care necessitated by his condition."⁵⁶

⁵² Article 24(1) of the Children's Convention states:

States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

Children's Convention, *supra* note 21, at art. 24(1). Needless to say, "health care services" include medications.

⁵³ International Convention on the Elimination of all Forms of Racial Discrimination, adopted by UNGA 21 Dec. 1965, U.N. GAOR Res. 2106 A(XX) (entered into force Jan. 4, 1969), reprinted in *Twenty-Five Human Rights Documents* (NY: Columbia University: 1994) at art. 5(e)(iv) [hereinafter *Race Convention*]; Convention on the Elimination of all Forms of Discrimination against Women, adopted 18 Dec. 1979, G.A. Res. 34/180, U.N. GAOR 34th Sess., Supp/ No. 44 at 193, U.N. Doc. A/34/36 91980) (entered into force Sept. 3, 1981) at art. 12. [hereinafter *Women's Convention*].

⁵⁴ Banjul Charter, *supra* note 23, at art. 17.

⁵⁵ European Social Charter, Oct. 18, 1961, art. 11(3), available at <http://www.conventions.coe.int/Treaty/en/treaties/html/035.htm>.

⁵⁶ *Id.*

The American Declaration of the Rights and Duties of Man states in article XI: "Every person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care, to the extent permitted by public and community resources."⁵⁷ Article XI was successfully invoked by petitioners in a case brought to the IACHR regarding the construction of a highway through lands belonging to the Yanomami Indians in Brazil. In that case, the IACHR found a violation of article XI, among other articles, and recommended to the Brazilian government, *inter alia*, that it: "take preventive and curative health measures to protect the lives and health of Indians exposed to infectious or contagious diseases" as a result of displacement stemming from the highway construction.⁵⁸ Although the case is limited in that it revolves around conditions proximately caused by the government, "preventive and curative health measures" must include access to the appropriate medications to treat infectious or contagious diseases.

Further, in recognition of the interdependence of ESCR and civil/political rights and the need to strengthen protections for ESCR in the region, an Additional Protocol to the American Convention on Matters of Economic, Social and Cultural Rights ("Protocol of San Salvador") entered into force in 1999, which includes the right to health.⁵⁹ In article 10, the Protocol of San Salvador specifically sets out two elements which bear on access to medications among the steps States parties should take to implement the right to health: the prevention and treatment of diseases, and the satisfaction of the health needs of the highest risk populations and those who, by virtue of poverty, are most vulnerable.⁶⁰

Even more important than the recognition of the right to health in international treaties or by international bodies is the possibility of asserting it in domestic courts, whether on the basis of international treaty provisions or national laws. On the domestic level, the right to health or a more limited right to health care is enshrined in over sixty national constitutions.⁶¹ Although some of those provisions refer to the right as a directive principle rather than as a fundamental right, courts at the

⁵⁷ American Declaration of the Rights and Duties of Man, art. 11, OEA/Ser.L.V/II.82 doc. 6 rev.1, at 17 (1948).

⁵⁸ Inter-Am. C.H.R., Annual Report 1984-1985, Resolution No. 12/85, Case No. 7615, (1985), at Resolutions ¶ 3(a), (c), *available at* <http://www.cidh.oas.org/annualrep/84.85eng/Brazil7615.htm>.

⁵⁹ Additional Protocol to the Am. Convention on Human Rights in the Area of Econ., Soc. & Cultural Rts., Nov. 17, 1988, OAS Treaty Series No. 69, *available at* <http://www.oas.org/juridico/english/Sigs/a-52.html> [hereinafter Protocol of San Salvador].

⁶⁰ *Id.* at arts. 10(d), (f).

⁶¹ See *The Right of Everyone to the Highest Attainable Standard of Physical and Mental Health: Report of the Special Rapporteur, Paul Hunt, submitted in accordance with Commission Resolution 2002/31*, U.N. ESCOR, 59th Sess., Agenda Item 23, ¶ 20, U.N. Doc. E/CN.4/2003/58 (2003) [hereinafter *Report of the Special Rapporteur*].

domestic level are increasingly finding specific state obligations to provide medication as part of the right to health, as well as part of the right to life. Costa Rica, India, Venezuela, Colombia, Argentina, and South Africa are among the many countries in which national courts have determined that the state has obligations to provide medications in HIV/AIDS cases and for other diseases.⁶²

It is important to acknowledge variation among countries both as to the status of international law in domestic legal systems and as to the extent to which national courts are willing to cite international treaty language as a basis for their decisions.⁶³ However, in a recent judgment unifying its own jurisprudence on the right to health, the Constitutional Court of Colombia set out an instructive four-point test as to when the right to health services becomes justiciable. First, the health issue must implicate other rights that are classified as “fundamental,” such as life, work or education. Second, there must be a “grave and imminent threat to human life or health” presented by the failure of the state to provide services. Third, the plaintiff must be in extreme need of services, i.e. financial need as well as physical need. Fourth, the possibility of providing services in the concrete case must lie within the resources of the state.⁶⁴ The court makes clear that what it sees as the generally programmatic, non-justiciable character of ESCR “tends to become transmuted

⁶² See, *Minister of Health v. Treatment Action Campaign*, CCT 8/02 (Constitutional Court of South Africa, July 2002), available at <http://www.tac.org.za/Documents>; *Ceballos v. Instituto de Seguros Sociales*, T-484 (Corte Constitucional de Colombia 1992), available at <http://bib.minjusticia.gov.co/jurisprudencia/CorteConstitucional/1992/Tutela/T-48492.htm> (social security institute obliged to provide ARV treatment under principles of non-discrimination and solidarity); *Alvarez v. Caja Costarricense de Seguro Social, Exp. 5778-V-97, No. 5934-97*, (Sala Constitucional de la Corte Suprema de Justicia de Costa Rica) (social security institute obliged to provide ARV treatment) (on file with author); *Lopez v. Instituto Venezolano de Seguros Sociales*, 487-060401 (Supreme Court of Venezuela, Constitutional Chamber 1997), available at <http://www.tsj.gov.ve/decisiones/scon/Abril/487-060401-001343.htm>; *B. E. A. v. Ministerio de Salud*, *supra* note 39; *C.E.S.C. Limited v. Subas Chandra Bose A.I.R. 1992 S.C. 572, 585* cited in *Shah*, *supra* note 35, at note 586.

⁶³ For example, in the recent case *Minister of Health v. Treatment Action Campaign*, the Constitutional Court explicitly looked to South Africa’s commitments under international treaties and interpreted the state’s obligations to adopt “reasonable measures”—as set forth in the ICESCR, for example—to implement the right to health as including an obligation to expand access to Nevirapine (to prevent mother-to-child transmission of HIV) from 18 pilot sites to all public health centers in the country. *Minister of Health v. Treatment Action Campaign*, CCT 8/02 (Constitutional Court of South Africa, July 2002), available at <http://www.tac.org.za/Documents>. For a discussion of the variation in the domestic effect of international treaties regarding the right to health, see BRIGIT TOEBES, *THE RIGHT TO HEALTH AS A HUMAN RIGHT IN INTERNATIONAL LAW* 191-93 (1999).

⁶⁴ *Alejandro Moreno Alvarez v. Estado Colombiano*, SU.819/99 (Corte Constitucional de Colombia 1999), available at <http://bib.minjusticia.gov.co/>

into individual rights to the extent that elements are in place that permit a person to demand that the State complies with a specific obligation, thereby consolidating the generalized duty of assistance with the concrete reality for a specific person.”⁶⁵ Thus, the court confirms that justiciability is a fluid notion, more aptly applied to dimensions of different rights than to certain categories of rights. Indeed, the trend among national tribunals to find justiciable dimensions to the right to health is increasingly common in—and at times in response to—cases relating to access to HIV/AIDS medications, where the connection to the right to life is direct and obvious, and the specificity of the normative obligation is generally high.⁶⁶

In the context of access to HIV/AIDS medications cases, in particular, several constitutional tribunals have emphasized the fundamental nature of the right to health, as a predicate to the right to life.⁶⁷ In the words of the Supreme Court of Costa Rica:

In a state of law, the right to life, *and in consequence the right to health*, receives particular protection. Any economic criterion that pretends to annul the exercise of such rights must cede in importance . . . because without the right to life all of the other rights are useless. . . . Of what use are all other rights and guarantees, the institutions and programs, the advantages and benefits of our system of liberties, if even one person cannot count on having the rights to health and life guaranteed?⁶⁸

C. *The Rights to an Adequate Standard of Living, to Social Security, to Education, and to Work*

Access to medications is indispensable for many people to be able to work and to attend school, and both reflects and has a direct bearing on the right to an adequate standard of living and to social security. The

jurisprudencia/Corte Constitucional/1999/Tutela/su819-99.htm (judgment to unify jurisprudence on right to health and social security services).

⁶⁵ *Id.*

⁶⁶ TOEBES, *supra* note 63, at 238-40.

⁶⁷ See, Alejandro Moreno Alvarez v. Estada Colombiano, SU.819/99 (Corte Constitucional de Colombia 1999), available at <http://bib.minjusticia.gov.co/jurisprudencia/CorteConstitucional/1999/Tutela/su819-99.htm>; Alvarez v. Caja Costarricense de Seguro Social, Exp. 5778-V-97, No. 5934-97 (Sala Constitucional de la Corte Suprema de Justicia de Costa Rica) (on file with author); Lopez v. Instituto Venezolano de Seguros Sociales, 487-060401 (Supreme Court of Venezuela, Constitutional Chamber 1997), available at <http://www.tsj.gov.ve/decisiones/scon/Abril/487-060401-001343.htm>.

⁶⁸ Alvarez v. Caja Costarricense de Seguro Social, Exp. 5778-V-97, No. 5934-97 (Sala Constitucional de la Corte Suprema de Justicia de Costa Rica) (author translation) (emphasis added).

Universal Declaration of Human Rights (“Universal Declaration”) states in article 25(1):

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.⁶⁹

The Universal Declaration further recognizes, as does the binding ICESCR, that “everyone, as a member of society, has the right to social security”⁷⁰ Particularly in Latin America, cases regarding access to medications have tended to arise in the context of affiliates of social security systems bringing suit when they have faced denial of treatment.⁷¹ For example, in the case of *Glenda Lopez v. the Venezuelan Institute of Social Security* (“IVSS”), a group of HIV positive plaintiffs alleged inter alia that their condition did not allow them to work and the IVSS had not paid them disability pensions to which they were entitled. They further argued that they were dependent upon the public health system, and the IVSS was not regularly distributing the antiretroviral drugs that they needed and which had been prescribed by IVSS doctors.⁷²

The facts of this particular case, as those of others, point to the need to consider access to medications in the broader context of people’s lives, which includes the needs (and rights) to earn a living or to receive some form of social support that provides a person and his or her family with security, and to obtain an education. For example, the ICESCR sets out obligations of states parties to work toward the achievement of full and productive employment and to provide not just compulsory primary education but to work toward accessible secondary and higher education for all.⁷³ Those rather abstract normative concepts reflect the reality that without access to medications, many patients simply cannot attend school or hold jobs. Any remaining possibility for individuals stricken with drug-resistant tuberculosis or malaria, HIV/AIDS, or severe mental illness to have choices and agency in their lives—which is both the underlying premise and promise of human rights—evaporates when access to medications is denied. The impossibility of “returning to a productive life”

⁶⁹ *Universal Declaration on Human Rights*, G.A. Res. 217 A(III), U.N. Doc. A/810, at 71 (1948).

⁷⁰ *Id.* at art. 22; ICESCR, *supra* note 42, at art. 9.

⁷¹ *E.g.*, *Lopez v. Instituto Venezolano de Seguros Sociales*, 487-060401 (Supreme Court of Venezuela, Constitutional Chamber 1997), available at <http://www.tsj.gov.ve/decisiones/scon/Abril/487-060401-001343.htm>

⁷² *Id.*

⁷³ ICESCR, *supra* note 42, at arts. (2)(a)(b)(c), 6(1), 13(1).

without access to medications has been specifically noted by courts taking up the issue of access to HIV/AIDS medications, for example.⁷⁴

D. *The Right to the Benefits of Scientific Progress*

As Paul Farmer writes, a few decades ago the impact of the gross inequities in access to medications between rich and poor countries and between rich and poor within certain countries “would have been significant, but not necessarily a matter of life and death.”⁷⁵ The better off have always fared better, but less than a hundred years ago, the wealthy were still dying of obstetric complications, pneumococcal pneumonia, tuberculosis and an array of other diseases. Farmer points out that:

Everything is different now, in large part because medicine is indeed becoming the ‘youngest science.’ . . . [B]iomedicine can at last offer the sick truly revolutionary new therapies. . . . Antibiotics and vaccines can, for the fortunate few, virtually erase the risk of mortality from polio, tetanus, measles, pneumonia, staphylococcal and other bacterial infections, diarrheal disease, malaria, tuberculosis. Even HIV disease, the latest rebuke to undue optimism, has been rendered, for those with access to therapy, a readily treatable disease. Then comes the obvious irony. In the [developing world] most of the premature deaths are caused by precisely these pathologies.⁷⁶

Such gross disparities in access to treatment, which stem from the same “pathologies of power”—to use Farmer’s term—that are at the root of so much suffering in the world, are starkly inconsistent with the notion of a universal right to benefit from scientific progress, which is established under a number of international instruments.

⁷⁴ See *Alvarez v. Caja Costarricense de Seguro Social*, Exp. 5778-V-97, No. 5934-97, (Sala Constitucional de la Corte Suprema de Justicia de Costa Rica) (on file with author); *Alejandro Moreno Alvarez v. Estado Colombiano*, SU.819/99 (Corte Constitucional de Colombia 1999), available at http://bib.minjusticia.gov.co/jurisprudencia/Corte_Constitucional/1999/Tutela/su819-99.htm (social security institute has obligations to provide essential medications and services to avoid the destruction of the population’s earning capacity). Cf. *Laverde v. Caprecom*, T-499 (Corte Constitucional de Colombia 1992), available at <http://bib.minjusticia.gov.co/jurisprudencia/CorteConstitucional/1992/Tutela/T-499-92.htm> (hip surgery ordered for postal worker who could not complete work tasks with her condition; court specifically noted that health treatments become fundamental rights when they implicate other rights, such as work); *Rivera v. Estado Colombiano*, T-533 (Corte Constitucional de Colombia 1992), available at <http://bib.minjusticia.gov.co/jurisprudencia/CorteConstitucional/1992/Tutela/T-533-92.htm> (eye surgery ordered for 63-year old man without family support who otherwise would not be able to work).

⁷⁵ FARMER, *supra* note 13, at 202-3.

⁷⁶ *Id.* at 203 (citations omitted).

For example, article 15 of the ICESCR sets out that states parties “recognize the right of everyone . . . [t]o enjoy the benefits of scientific progress and its applications,” which includes medications, and suggests a need to balance the public and private interests in knowledge when considering intellectual property systems.⁷⁷ In 2001, the ESCR Committee adopted a General Statement on “Human Rights and Intellectual Property.”⁷⁸ The second General Statement ever adopted by the ESCR Committee, this authoritative document seeks “to identify some of the key human rights principles that are required to be taken into account in the development, interpretation and implementation of contemporary intellectual property regimes.”⁷⁹

The General Statement underscores that “the realms of trade, finance and investment are in no way exempt from human rights principles” and that both national legislation and international rules and policies relating to intellectual property protection, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”), must abide by international human rights law.⁸⁰ The ESCR Committee affirms in this respect that “the end which intellectual property protection should serve is the objective of human well-being, to which international human rights instruments give legal expression.”⁸¹ Moreover, clearly alluding to the core obligation to provide essential medications, *inter alia*, the ESCR Committee goes on to “emphasize that any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or with any other right set out in the Covenant is inconsistent with the legally binding obligations of the state party.”⁸²

The right to enjoy the benefits of scientific progress is also mentioned in a number of regional instruments. For example, article 14 of the Protocol of San Salvador recognizes the right of everyone to enjoy the benefits of “scientific and technological progress” as part of the right to the benefits of culture.⁸³

E. *Disproportionate Effects on Children of Denial of Access to Medications*

Children are more affected by lack of access to medications than any other group, simply because they themselves are affected and their lives are also irreparably affected when their parents are denied access to life-saving or life-sustaining medications. There is perhaps nothing so heart-

⁷⁷ ICESCR, *supra* note 42, at art. 15.

⁷⁸ Statement on *Human Rights and Intellectual Property*, *supra* note 8.

⁷⁹ *Id.* ¶ 2.

⁸⁰ *Id.* ¶ 3.

⁸¹ *Id.* ¶ 4.

⁸² *Id.* ¶ 12.

⁸³ Protocol of San Salvador, *supra* note 59, at art. 14.

wrenching as the image of a desperately sick child or a child who has been orphaned by HIV/AIDS or some other deadly disease. Yet there are different ways to make sense of—and react to—that extreme misery.

These children can be objects of pity, their unquestionable “innocence”—in contrast to adults who may engage in risky sexual activities or somehow might have avoided their predicament—heightening the compassion that fellow human suffering elicits. Alternatively, when their numbers swell, orphaned and dying children create enormous drains on countries’ economies and threaten the future productivity of whole nations. Yet, a human rights framework offers a third way of understanding the effects of lack of access to medications on children which focuses on children as human beings who are being denied the possibility of fully developing their own capabilities, and in some cases of even surviving.⁸⁴ This applies to an epileptic child who lives perpetually locked in a cage-bed for lack of medication to control seizures, just as it applies to a child who is left weak and stunted from untreated diarrheal disease exacerbating malnutrition or a child who lives a short and painful life before succumbing to HIV/AIDS.

The Children’s Convention calls on states parties in implementing children’s right to health to take appropriate measures “to diminish infant and child mortality.”⁸⁵ The ICESCR also calls on states parties to reduce infant and child mortality, and to provide appropriate prenatal care.⁸⁶ But the issues entailed in lack of access to medications go beyond preventing mortality to the positive rights to life, survival and development, to information, to health, to social security, to special assistance from the state, and to rights of children with disabilities, among others.⁸⁷

When medication for parents directly affects the possibilities for survival and well-being of their children, as in the case of Nevirapine therapy to prevent mother-to-child transmission of HIV, state parties to the Children’s Convention have undertaken to have the rights of the child and his/her interests be a primary consideration.⁸⁸ This was the issue in the recent South African case, *Minister of Health v. Treatment Action Campaign*, mentioned above. In that case, the Constitutional Court specifically noted the effects of governmental policy on children’s rights:⁸⁹

[The children’s] needs are ‘most urgent’ and their inability to have access to Nevirapine profoundly affects their ability to enjoy all rights to which they are entitled. Their rights are ‘most in peril’ as a

⁸⁴ Children’s Convention, *supra* note 21, at art. 6.

⁸⁵ *Id.* at art. 24.

⁸⁶ ICESCR, *supra* note 42, at art. 12(2)(a).

⁸⁷ Children’s Convention, *supra* note 21, at arts. 9, 17, 20, 23, 24, 27.

⁸⁸ *Id.* at art. 3.

⁸⁹ *Minister of Health v. Treatment Action Campaign*, CCT 8/02, ¶ 79 (Constitutional Court of South Africa, July 2002), available at <http://www.tac.org.za/Documents>.

result of a policy that has been adopted and are most affected by a rigid and inflexible policy that excludes them from having access to Nevirapine.⁹⁰

In other cases, when an ill parent cannot function or work because of lack of access to medication, children's lives are also torn apart; they often assume greater household responsibilities and are forced to leave school to earn wages or to be caretakers. Article 28(e) of the Children's Convention requires states parties to take measures to encourage regular attendance at schools and to reduce drop-out rates, which invariably increase when families have to choose between buying essential medications to survive and sending their children to school.⁹¹ Again, the possibilities for children developing or becoming agents in their own lives are drastically reduced not merely by the fact of the disease, but by the absence of treatment to mitigate the necessarily social effects of the disease, whether it is tuberculosis, HIV/AIDS or malaria.

In a recent General Comment specifically relating to "HIV/AIDS and the Rights of the Child," the Committee on the Rights of the Child ("CRC") clarifies that protecting the rights of children under the Children's Convention requires treatment and care as well as prevention and support:

The obligations of States parties under the Convention extend to ensuring that children have sustained and equal access to comprehensive treatment and care, including necessary HIV-related drugs . . . It is now widely recognized that comprehensive treatment and care includes anti-retroviral and other drugs, diagnostics and related technologies for the care of HIV/AIDS, related opportunistic infections and other conditions . . .⁹²

The same "holistic child rights based approach" advocated in the General Comment with respect to HIV/AIDS might as easily apply to other diseases and conditions for which we are familiar with comprehensive treatments that have proven effective.⁹³

F. *The Principle of Non-discrimination and Protection for Vulnerable and Marginalized Groups*

Discrimination is both a cause and an effect of many life-threatening diseases. On the one hand, diseases such as HIV/AIDS and tuberculosis can be social X-rays, illuminating the most marginalized and excluded sectors of the overall society. Moreover, while there may be significant

⁹⁰ *Id.* ¶ 78.

⁹¹ Children's Convention, *supra* note 21, at art. 28.

⁹² *General Comment No. 3: HIV/AIDS and the Rights of the Child*, Committee on the Rights of the Child, 32nd Sess., U.N. Doc. CRC/GC/2003/1 (2003), ¶ 25 [hereinafter *CRC Gen. Comment No. 3*].

⁹³ *Id.* ¶¶ 2-3.

local variations in the ways in which discrimination affects people's lives and exposes them to different conditions, race, ethnicity, gender, sexual orientation, and poverty all tend to play a role.

On the other hand, once people have certain diseases, they are subject to tremendous stigma and discrimination, whether that disease is HIV/AIDS, schizophrenia, or leprosy. Even when the extent of a state's obligations to provide medications has not been well-defined, discrimination in the provision of access to medicine clearly constitutes a violation of international human rights law, as well as an actionable violation under many domestic legal systems. In his first report as Special Rapporteur on the Right to Health, Paul Hunt emphasized the importance of uncovering and remedying stigmas and discrimination, including those which affect people with certain health conditions.⁹⁴

In its recent General Comment, the CRC also highlights that "[d]iscrimination is responsible for heightening the vulnerability of children to HIV and AIDS, as well as seriously impacting the lives of children who are affected by HIV/AIDS, or are themselves HIV infected. Girls and boys of parents living with HIV/AIDS are often victims of stigma and discrimination as they too are often assumed to be infected."⁹⁵ Similarly, the HIV/AIDS pandemic has starkly illuminated gender dimensions of health policies and the susceptibility of women to infection due to their social position in the private as well as public sphere. In its General Recommendation on "Women and Health" the Committee to Eliminate Discrimination Against Women ("CEDAW") noted:

The issues of HIV/AIDS and other sexually transmitted diseases are central to the rights of women and adolescent girls to sexual health. Adolescent girls and women in many countries lack adequate access to information and services necessary to ensure sexual health. . . . States parties should ensure, without prejudice or discrimination, the right to sexual health information, education and services for all women and girls. . . .⁹⁶

Certain specific groups, such as women and girls who have been trafficked for prostitution, clearly require access to medications for HIV and other sexually transmitted diseases, regardless of their citizenship status. However, it should be clear that rights are not based on selecting categories of "innocent" victims of disease who merit treatment; rights-based notions demand treatment for individuals simply because they are human beings. Thus, for example, adolescents who engage in drug use and women who participate voluntarily in the sex industry are at particularly high risk for sexually transmitted diseases and require access to medications on a non-discriminatory basis through the health system.

⁹⁴ *Report of the Special Rapporteur, supra* note 61, ¶¶ 41, 56.

⁹⁵ *CRC Gen. Comment No. 3, supra* note 92, ¶ 5.

⁹⁶ *CEDAW Gen. Recom. No. 24, supra* note 10, ¶ 18.

In general, human rights law calls on states to pay particular attention to the inclusion and equitable treatment of vulnerable, marginalized, and previously disadvantaged groups.⁹⁷ The International Labor Organization Convention Concerning Indigenous and Tribal Peoples in Independent Countries (“ILO Convention 169”), for example, sets out the obligation of States parties to “ensure that adequate health services are made available to the [indigenous and tribal] peoples concerned” who often are marginalized, live in remote rural areas, and do not receive the same standard of care that urban dwellers do.⁹⁸

Prisoners can constitute another marginalized group, as demonstrated in the South African case of *B. and Others v. Minister of Correctional Services and Others*, in which petitioners successfully sued the federal Department of Corrections to pay for antiretroviral (“ARV”) treatment for four HIV-positive prisoners in a facility.⁹⁹ Tuberculosis (“TB”) also has an historic association with prisons. Paul Farmer writes:

In the mid-nineteenth century, for example, TB caused an estimated 80 percent of all U.S. prison deaths. . . . In our own post-antibiotic era, prisoners continue to endure TB risks well in excess of those faced by individuals not in prison. In most countries, TB prison rates five to ten times the national average are not uncommon, and outbreaks can lead rapidly to TB rates more than 100 times the national average.¹⁰⁰

Not only do prisoners face overcrowding and poor nutrition—the conditions that breed tuberculosis—but, as Farmer documents, in the prisons of the former Soviet Union and elsewhere, they are being systematically denied effective treatment.¹⁰¹

International law is, however, very clear with respect to the obligations of states to care for prisoners while in custody. The Standard Minimum Rules for the treatment of prisoners states in article 22(1):

Sick prisoners who require specialist treatment shall be transferred to specialized institutions or to civil hospitals. Where hospital facilities are provided in an institution, their equipment, furnishings and pharmaceutical supplies shall be proper for the medical care and

⁹⁷ See U.N. Comm. on Econ., Soc. & Cultural Rts., *The Nature of States' Parties Obligations*, *supra* note 50, ¶¶ 9-11.

⁹⁸ Convention (No. 169) Concerning Indigenous and Tribal Peoples in Independent Countries, at art. 7(2), ILO, June 27, 1989, *reprinted in* HUMAN RIGHTS: SIXTY MAJOR GLOBAL INSTRUMENTS 327, 330 (Winston E. Langley ed., McFarland & Co. 1992) [hereinafter ILO Convention 169].

⁹⁹ *B v. Minister of Correctional Services*, 1997 (6) BCLR 789 (C) (holding state has not demonstrated undue cost burden to provide ARVs to the two petitioners for whom they were prescribed).

¹⁰⁰ FARMER, *supra* note 13, at 179-80 (citation omitted).

¹⁰¹ *Id.* at 179-195.

treatment of sick prisoners, and there shall be a staff of suitably trained officers.¹⁰²

Similarly, patients in mental hospitals can suffer tremendous marginalization and discrimination. Although in their case, the over-administration of psychotropic medications can often constitute an abuse of their rights, mental patients may at the same time not be receiving appropriate medication for the treatment of physical conditions, including HIV/AIDS. In other cases, out-patient facilities or general hospitals may not be stocked with adequate psychotropic medications, which are only made available to in-patients. In still other cases, the most effective or appropriate psychotropic medications may not be available. The United Nations Principles for Protection of Persons with Mental Illness require a standard of care, including supplies of medication, equivalent to that of other sick individuals, and require the mental health system to promote community treatment and reintegration.¹⁰³

In practice, many issues relating to deprivation of access to medications can be characterized as questions of discrimination. Therefore, it is important to recall that in general, the principle of non-discrimination is a justiciable, procedural right in most domestic legal systems as well as under international law (i.e., equal protection), which applies equally to the right to health and other to ESCRs, as well as to civil and political rights. The Human Rights Committee, for example, has affirmed that the ICCPR's non-discrimination clause applies to legislation on social issues and the European Court of Human Rights has applied it to cases relating to pension benefits and other economic and social rights.¹⁰⁴ With respect to access to medications, proscriptions on discrimination demand both that certain marginalized individuals and populations are not treated differently or prevented from acceding to necessary medications, and that people are not discriminated against by health systems because of HIV-positive or other health status.

¹⁰² *Standard Minimum Rules for the Treatment of Prisoners*, art. 22(2), E.S.C. Res. 663 C (XXIV), U.N. ESCOR, 24th Sess., Supp. No. 1, U.N. Doc. E/3048 (1957) (amended 1977), reprinted in TWENTY-FIVE HUMAN RIGHTS DOCUMENTS 108. (Center for the Study of Human Rights, Columbia University 1994).

¹⁰³ *Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care*, princs. 8(1), 13(2)(d), G.A. Res. 46/119, U.N. GAOR, 46th Sess., Supp. No. 49, U.N. Doc. A/461/49 (1991).

¹⁰⁴ See *Zwaan-de Vries v. Netherlands*, Communication No. 182/1984, U.N. GAOR, Hum. Rts. Comm., 42d Sess., Supp. No. 40, ¶¶ 14-15, at 168, U.N. Doc A/42/40 (1987) (declaring discriminatory and unlawful Dutch Unemployment Act which required married women but not married men to prove that they were "breadwinners"); *Schuler-Zraggen v. Switzerland*, 16 Eur. H.R. Rep. 405, 423-24, 434 (1993) (declaring invalid the presumption of ineligibility of married women with children for unemployment benefits).

As a general matter, under international human rights law differential treatment must be related to a legitimate objective or purpose and the classifications that are created must be reasonably tailored to that purpose.¹⁰⁵ Differential treatment in access to medications or in any other matter will in practice almost certainly be invalid if: (1) members of two or more groups are similarly situated under the law (for example, citizens of the same country); (2) nevertheless, members of each group are treated differently (for example, some are not entitled to ARVs in their local public health center); and (3) the negative, differential treatment is based on a prohibited status such as race, color, sex, language, religion, political or other opinion, national or social origin, economic status, birth, or *any other social condition*, such as homosexuality.¹⁰⁶ In practice, geographic areas may closely overlap with religious, racial or ethnic identities and discrimination need not be intentional under international law, but merely needs to have the effect of nullifying or impairing the enjoyment of rights.¹⁰⁷

In short, there is a growing jurisprudence at both national and international levels that supports the notion that the provision of access to life-saving medications constitutes an integral part of the right to life, as well as the right to health. As the right to life is not subject to progressive realization under international law, it can be invoked to underscore the urgency of taking immediate measures with respect to providing access to medications in HIV/AIDS and other cases. Further, as domestic constitutions generally include the right to life as a fundamental right, while at times, the right to health can be a “directive principle,” it will be important to include arguments relating to the right to life when arguing, for example, that ARVs be made available.

Nevertheless, the right to health has increasingly been found to have justiciable dimensions and has been applied in access to medications cases. Although sometimes the mechanisms for protecting the right to health—e.g., protection writs in certain Latin American countries—cannot be applied to collective situations, the right to health is increasingly underpinning litigation to achieve access to medications for a variety of differently situated plaintiffs in a number of countries. Further, the rights to education, to work, to an adequate standard of living, to social security, and to enjoy the benefits of scientific progress are also implicated by issues arising around access to medications because people cannot be

¹⁰⁵ Note that affirmative action to promote an equal footing for marginalized groups is acceptable under human rights law. *See, e.g., The Main Types and Causes of Discrimination*, ¶¶ 6-7, U.N. Doc. E/CN.4/Sub.2/40/Rev.1 (1949).

¹⁰⁶ *See, e.g., TARA MELISH, PROTECTING ECONOMIC, SOCIAL AND CULTURAL RIGHTS IN THE INTER-AMERICAN HUMAN RIGHTS SYSTEM: A MANUAL FOR PRESENTING CLAIMS* 199 (2002).

¹⁰⁷ *E.g., U.N. Comm. on Econ., Soc. & Cultural Rts., General Comment 14, supra note 7, ¶¶ 11-12.*

examined in an abstract or fragmented manner. The narratives of people's lives are messy and tangled, involving themselves and their families and communities, and consequently multiple rights issues are implicated by the lack of access to life-saving or sustaining treatment. Moreover, the overarching concern for non-discrimination in a human rights framework can often be invoked as an enforceable right to ensure access to medications for marginalized populations or when discrimination on the basis of prohibited grounds is evident.

III. ANALYSIS OF ACTORS' OBLIGATIONS UNDER INTERNATIONAL HUMAN RIGHTS LAW

In order for human rights principles to be truly useful tools in guiding policy-making with respect to access to medications, it is necessary to understand what obligations flow from the various norms discussed above. States' actions in this area are in practice taken by commerce representatives negotiating trade agreements, legislatures passing relevant legislation, judicial and other tribunals deciding specific cases, and policy-makers responsible for health budgets and programming. Similarly, the paradigm of human rights must be made relevant to the issues relating to access to medications that decision-makers in international organizations confront on a daily basis. Tracing the contours of different actors' obligations under international law with respect to access to medications facilitates the efforts of policy-makers and adjudicative bodies seeking to create and execute policies in this field that are consistent with both a general human rights framework and with specific norms.

The following analysis of obligations relating to access to drugs focuses on the right to health and principally on the ICESCR, where the clarification of the normative content of the right to health has received most attention.¹⁰⁸ This section first analyzes three dimensions of governmental obligations with respect to the right to health under the ICESCR, and then turns to the obligations of third-party states. According to the ESCR

¹⁰⁸ However, the principles discussed here are applicable generally to other relevant rights—such as the enjoyment of the benefits of scientific progress—as well as in many other fora. For example, article 29 of the American Convention permits and even promotes the utilization of instruments and jurisprudence external to the Inter-American System to interpret the rights in that convention, and by implication, the Protocol of San Salvador. See *Proposed Amendments to the Naturalization Provisions of the Constitution of Costa Rica*, Advisory Op. OC-4/84, Inter-Am. Ct. H.R. (Ser. A) No.4 (1984), ¶ 67, available at http://www1.umn.edu/humanrts/iachr/b_11_4d.htm (last visited Sept. 28, 2003) (holding that proposed naturalization norms that provide a preference for married women but not for married men are discriminatory under the American Convention). See also Inter-Am. C.H. R., *Other Treaties: Object of the Consultative Function of the Court*, Advisory Op. OC-182, Sept. 1982, Ser. A No. 1 (1982), ¶ 43, available at http://www.umn.edu/humanrts/iachr/b_11_4a.htm (last visited Sept. 25, 2003).

Committee's General Comment No. 14, the right to health, like all human rights, imposes three types of obligations on States parties: the obligations to respect, to protect, and to fulfill. In turn, the obligation to fulfill entails obligations to facilitate, to provide, and to promote.¹⁰⁹ This tripartite framework is now widely accepted throughout the United Nations system.¹¹⁰ Regional human rights bodies have also explicitly adopted multi-dimensional frameworks of States' obligations relating to the right to health.¹¹¹ Further, within the parameters of domestic legal systems, the principles underlying the analysis in this section have relevance to policy-making and judicial decisions that relate to interpretation of local constitutional provisions of the right to health, as well as to provisions under other international treaties. Second, the section considers obligations of international organizations and third-party states to take measures to realize access to medications for people in developing countries.

A. Governmental Obligations

1. The Obligation to Respect

Under the ICESCR, as well as under other treaties, the obligation to respect requires that states parties refrain from "denying or limiting equal access for all persons, including prisoners or detainees, minorities, asylum seekers and illegal immigrants, to preventive, curative and palliative health services; [and] abstaining from enforcing discriminatory practices as a state policy."¹¹² Thus, any discriminatory allocation of medications or funding for medications would constitute a violation of the obligation to respect the right to health. Similarly, before any action is taken that could deny or limit the provision of basic medications, there must be a process

¹⁰⁹ U.N. Comm. on Hum., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7.

¹¹⁰ For one of the first elaborations of the tripartite obligations of states to respect, to protect and to fulfill rights, see *Report on the Right to Food as a Human Right*, U.N. ESCOR Comm'n. on H.R., 39th Sess., Agenda Item 11, U.N. Doc. E/CN.4/Sub.2/1987/23 (1987). With respect to the application of this scheme to women's rights, see *Respect, Protect, Fulfill, Women's Human Rights: State Responsibility for Abuses by Non-State Actors*, Amnesty International, Sept. 2000, available at <http://web.amnesty.org/library/Index/engIOR500012000>. See also CEDAW Gen. Recom. No. 24, *supra* note 10.

¹¹¹ For example, the African Commission classifies obligations as to respect, protect, promote and fulfill. *Ogoniland Case*, *supra* note 24, ¶¶ 43-47.

¹¹² U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 34.

of genuine consultation with the people who will be affected and an opportunity for recourse in the event that people's rights are violated.¹¹³

A violation of the obligation to respect the right to health occurs when a state "repeals or suspends legislation necessary for the continued enjoyment of the right or when it adopts legislation or policies that are manifestly incompatible with pre-existing domestic or international legal obligations relating to the right to health."¹¹⁴ For example, laws and regulations that would restrict access to medications by increasing prices—thereby decreasing access—would presumptively constitute a violation of the state party's obligations under the ICESCR.¹¹⁵ The ESCR Committee explicitly notes that examples of violations of the duty to respect the right to health include "the failure of the State to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations."¹¹⁶ Therefore, before entering into trade agreements that have the potential to force changes in government policy, governments have an obligation to consult with the public and to take measures to protect access to medications.¹¹⁷

In this vein, a 2002 resolution by the U.N. Commission on Human Rights stated: "[A]ccess to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."¹¹⁸ The resolution called upon states at the national level, on the basis of non-discrimination, "to refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them."¹¹⁹ This statement reaffirmed the principles agreed to by U.N. member states in the Declaration of Commitment on HIV/AIDS of the U.N. General

¹¹³ For a discussion of the critical importance of participation to the right to health, see Alicia Ely Yamin, *Challenges and Possibilities for Innovative Praxis in Health and Human Rights: Reflections from Peru*, 6 HEALTH & H. R. 35, 40 (2002).

¹¹⁴ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 48.

¹¹⁵ *Id.* ¶ 47.

¹¹⁶ *Id.* ¶ 50.

¹¹⁷ See Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The Fourth Wave of Corporate Human Rights Scrutiny*, 25 HUM. RTS. Q. 425 (2003).

¹¹⁸ *Access to Medication in the Context of Pandemics such as HIV/AIDS*, Hum. Rts. Comm. Res. 2002/32, U.N. ESCOR, 58th Sess., Annex, ¶ 3(a), at 145, U.N. Doc. E/CN/4/2002/200 (2002).

¹¹⁹ *Id.*

Assembly Special Session in 2001 (“U.N. Declaration of Commitment on HIV/AIDS”).¹²⁰

Similarly, in the Inter-American System, systematic pricing increases or other regressive measures constitute a *prima facie* violation of article 26 of the American Convention, and any such measure would be subject to a higher level of scrutiny by the IACHR or the Inter-American Court.¹²¹ Under such a higher scrutiny standard, a government would have the burden of proof of justifying actions, such as back-stepping on compulsory and government-use licensing or on parallel importation of medicines, as not only being determined by law, but also: (1) responding to a pressing public or social need; (2) being proportional to that aim; and (3) being objectively necessary to promote the general welfare in a democratic society.¹²² Further, there can be no less restrictive means available to promote such an objective and the restriction may not be imposed arbitrarily, i.e., in an unreasonable or discriminatory manner. A state imposing limitations on the right to health or any other economic and social right is responsible for putting into effect protections for the vulnerable and marginalized.¹²³

It is worth underscoring, with respect to international trade agreements and intellectual property protections themselves, that the TRIPS Agreement, developed during the Uruguay Round of the General Agreement on Tariffs and Trade (“GATT”), explicitly authorizes WTO Members “to adopt measures necessary to protect the public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development,” including the issuance of compulsory licenses as a remedy for anticompetitive practices.¹²⁴ Moreover, the Ministerial Conference of the WTO held in Doha in 2001 (“Doha Declaration”) explicitly instructed states to interpret the TRIPS Agreement “in a manner supportive of WTO members’ right to protect the public health and, in particular, to promote access to medicines for

¹²⁰ U.N. Declaration of Commitment on HIV/AIDS, June 25-27, 2001, U.N. GAOR, 26th Special Sess., Res. 33/2001 [hereinafter U.N. Declaration of Commitment on HIV/AIDS].

¹²¹ Annual Report of the Inter-American Commission on Human Rights 1993, Inter-Am. C.H.R., at ch. 5 pt. 1, OEA/Ser.L/V/II.85 (1994) available at <http://cidh.org/annualrep/93span/indice.htm>.

¹²² *The Limburg Principles on the Implementation of the International Covenant on Econ., Soc. and Cultural Rights*, U.N. ESCOR, Comm’n. on H.R., 43d Sess., Annex, ¶¶ 46-57, U.N. Doc. E/CN.4/1987/17 (1987), reprinted in 9 HUMAN RIGHTS Q. 122, 128-29 (1987).

¹²³ *Id.*

¹²⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, arts. 8, 31, Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 1, 33 I.L.M. 1125 (1994) [hereinafter TRIPS Agreement].

all.”¹²⁵ The Doha Declaration specifically recognizes that “[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”¹²⁶ Thus, even pursuant to the TRIPS Agreement, a government’s human rights obligations to respect the right to health ought not be subordinated to other commercial interests.¹²⁷

2. The Obligation to Protect

States parties to the ICESCR have an obligation under international law to *protect* the enjoyment of accessibility and affordability of basic medications from direct or indirect infringement by pharmaceutical companies and other third parties. In General Comment No. 14, the ESCR Committee clarified that obligations to protect include, *inter alia*:

ensur[ing] that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services; control[ing] the marketing of medical equipment and medicines by third parties; [and] States [ensuring] that third parties do not limit people’s access to health-related information and services.¹²⁸

Thus, controlling the marketing of medicines is explicitly addressed. Violations of the obligation to protect include “the failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others.”¹²⁹ Just as the state party would be expected to take action against a private corporation that was killing people through tainted medications, so too must the state party assume responsibility for protecting the public’s access to affordable medications on a non-discriminatory basis.

For example, the state is under an obligation to provide anti-competition remedies against patent abusers so that brand name drug producers are not permitted to price their medications at prices that exponentially exceed generic equivalents. As a general matter, access to lower priced generics would increase the number of previously disadvantaged persons that could access drugs needed to prolong their lives. Strong enforcement of anti-competition rules where patent holders refuse to grant licenses to

¹²⁵ Declaration on the TRIPS Agreement and Public Health, adopted on Nov. 14, 2001, ¶ 4, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].

¹²⁶ *Id.* ¶ 5(c).

¹²⁷ See Joseph, *supra* note 117, at 445; Patrick Wojahn, *A Conflict of Rights; Intellectual Property under TRIPS, the Right to Health and AIDS Drugs*, 6 UCLA J INT’L L. & FOREIGN AFF. 463, 491-96 (2001).

¹²⁸ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 35.

¹²⁹ *Id.* ¶ 51.

generic producers and excessively price their products is therefore a measure that can and should be taken “to reduce the inequitable distribution of health facilities, goods and services” in contemplation of the ESCR Committee’s General Comment No. 14. Moreover, such enforcement will also “promote . . . [t]he availability in sufficient quantities of pharmaceuticals and medical technologies used to treat pandemics such as HIV/AIDS” in accordance with the U.N. Declaration of Commitment on HIV/AIDS.¹³⁰

Without such enforcement and without a functioning regulatory system in general, the state party would fall short of its international legal obligations to protect the right to essential medications as part of the right to health. In this regard, it is also important to note that the Doha Declaration specifically recognizes that “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”¹³¹ In general, “although TRIPS requires increased intellectual property protection, a general purpose of requiring increased intellectual property protection is not inconsistent with allowing exceptions in the interest of public health,” including the issuance of compulsory licenses or other measures to “prevent the abuse of intellectual property rights by rights holders or the resort to practices which . . . adversely affect the international transfer of technology.”¹³²

In the event that private commercial pricing practices were shown to be probabilistically related to impaired or reduced access to medications, it would be reasonable to affirm that a failure to grant compulsory licenses or to adopt other protective measures would presumptively constitute a violation of the state’s obligations to protect the right to health. As set out by Sean Flynn in his access gap theory, evidence of abusive commercial practices would include, but would not be limited to, the following situations: (1) the number of people who need access to medicine to prolong their lives or to improve their health significantly exceeds those with access to the drug; (2) a substantial barrier to access is price; or (3) a patent holder has not promoted competitive pricing by issuing licenses to all qualified suppliers on reasonable terms.¹³³

3. The Obligation to Fulfill

Every state party to the ICESCR has an obligation to fulfill the right to health, including moving progressively toward universal accessibility of medications through legislation, policies, and programs that allocate

¹³⁰ U.N. Declaration of Commitment on HIV/AIDS, *supra* note 120, ¶ 14.

¹³¹ Doha Declaration, *supra* note 125, ¶ 5(b).

¹³² Wojahn, *supra* note 127, at 493; TRIPS Agreement, *supra* note 124, at art. 8.

¹³³ Sean Flynn, *Legal Strategies for Expanding Access to Medicines*, EMORY INT’L LAW REV. (forthcoming 2003); *see also* Sean Flynn, Memorandum on Compulsory Licensing Legal Assistance for Consumer Project on Technology (on file with author). *See also* www.cptech.org/ip/health/cl/.

resources and effect a sustained and equitable distribution.¹³⁴ The Children's Convention, the Banjul Charter, the Protocol of San Salvador (read in conjunction with article 26 of the American Convention), and a panoply of other international treaties similarly impose obligations on states parties to adopt measures by all appropriate means toward the progressive realization of the right to health, including the provision of medications.

Moreover, beyond the specific provisions of these treaties, the obligation to move toward universal access to pharmaceuticals has also been the subject of statements issued by charter-based organs of the United Nations. With respect to HIV/AIDS in particular, a U.N. Declaration of Commitment was adopted at the U.N. General Assembly Special Session held in June 2001. The U.N. Declaration of Commitment on HIV/AIDS, which includes a discussion of providing access to medications as a key action area, is not a legally binding treaty; nevertheless, it constitutes a clear statement by member states' governments concerning what they have agreed should be done to fight HIV/AIDS and what they have committed to do, with specific goals and targets. In accordance with the U.N. Declaration of Commitment, the U.N. General Assembly reviews a progress report on its implementation prepared by the Secretary-General.¹³⁵

Similarly, in 2000, the U.N. General Assembly adopted by resolution the Millennium Declaration, which established a series of Millennium Development Goals ("MDGs"), including the goal of combating HIV, malaria, and tuberculosis. Some of the indicators associated with that goal explicitly require access to medications, such as the "proportion of tuberculosis cases detected and cured under directly observed treatment short course."¹³⁶ The MDGs have been adopted and are to be put into practice by a consensus of experts from the United Nations, the International Monetary Fund, the Organization for Economic Cooperation and Development, and the World Bank.¹³⁷ All 191 U.N. member states have pledged to meet these goals by the year 2015, and they have assumed reporting obligations in the interim.

¹³⁴ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 36.

¹³⁵ U.N. Declaration of Commitment on HIV/AIDS, *supra* note 120.

¹³⁶ United Nations Millennium Development Goals, at <http://www.un.org/millenniumgoals/> [hereinafter Millennium Development Goals].

¹³⁷ Consequently, all of these institutions, as well as NGOs, are theoretically committed to policies that advance these goals. In brief, the MDGs set out the following eight goals: eradicate extreme poverty and hunger; achieve universal primary education; promote gender equality and empower women; reduce child mortality; improve maternal health; combat HIV/AIDS, malaria and other diseases; ensure environmental sustainability, and develop a global partnership for development. United Nations Millennium Declaration, G.A. Res. 55/22, U.N. GAOR, 55th Sess., Item 60(b), U.N. Doc. A/Res/55/2 (2000). Millennium Development Goals, *supra* note 136.

More recently, in Resolution 2002/32 the U.N. Commission on Human Rights reaffirmed the U.N. Declaration of Commitment on HIV/AIDS and called upon all U.N. member states to pursue policies, in accordance with applicable international law, including international agreements acceded to, which would promote:

The availability in sufficient quantities of pharmaceuticals and medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them;

The accessibility to all without discrimination, including the most vulnerable sectors of the population, of such pharmaceuticals or medical technologies and their affordability for all, including socially disadvantaged groups;

The assurance that pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them, irrespective of their sources and countries of origins, are scientifically and medically appropriate and of good quality.¹³⁸

This statement reaffirms the ESCR Committee's insistence on acceptability and quality of medications and other health services, as well as on their economic accessibility: "equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households."¹³⁹

The ESCR Committee, which has most closely examined the content of the obligation to fulfill the right to health, has explained that violations of this obligation include:

[the] failure to adopt or implement a national health policy designed to ensure the right to health for everyone; insufficient expenditure or misallocation of public resources which results in the non-enjoyment of the right to health by individuals or groups, particularly the vulnerable or marginalized;. . . [and] the failure to take measures to reduce the inequitable distribution of health facilities, goods and services.¹⁴⁰

For example, the absence of a national pharmaceutical policy or a national policy for the prevention and treatment of HIV/AIDS, tuberculosis, or malaria in relevant countries, or insufficient expenditure on medications could both constitute violations of the obligation to fulfill. In assessing the accessibility and affordability (i.e., economic accessibility) of medications under a country's pharmaceutical policy, it is interesting to note that the WHO considers, *inter alia*, the existence of generic policies,

¹³⁸ *Access to Medication in the Context of Pandemics such as HIV/AIDS*, *supra* note 118, ¶ 2(a-c).

¹³⁹ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 12(b).

¹⁴⁰ *Id.* ¶ 51.

therapeutic competition, price information, pricing policies, bulk procurement, differential pricing structures, and compulsory licensing, as well as whether access to essential drugs has been respected as part of health sector reform and drug reimbursement schemes in developing countries.¹⁴¹

Furthermore, although it would be absurd to assert, in reference to many countries, that everyone can have access to medications from one day to the next, under international law each State party does have immediate obligations to take deliberate steps toward the full realization of these rights and to provide interim solutions such as supporting purchasing power of indigent persons and groups in order that they might have access to essential medications.¹⁴² Moreover, the ESCR Committee has forcefully stated that violations of the ICESCR occur when a State fails to satisfy a “minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights” set forth under the ICESCR, which includes “essential drugs” as defined by the WHO.¹⁴³

That essential drugs are part of the minimum core content of the right to health under the ICESCR cannot constitute a simplistic litmus test of state compliance; however, it is widely agreed that it is a factor to be strongly weighed in considering the reasonableness of measures a state has adopted with respect to providing access to medications and the right to health in general.¹⁴⁴ The state thus has the burden to meet in justifying its non-compliance with core obligations, such as access to essential medications.¹⁴⁵ The ESCR Committee has explained: “In order for a State party to be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources it must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations.”¹⁴⁶ The Constitutional Court of South Africa, in the *Treatment Action Campaign* case, cited this language approvingly. In general, national courts that have examined the issue of core content have emphasized the obliga-

¹⁴¹ World Health Organization, *Essential Drugs and Medicines Policy: Access*, at <http://www.who.int/medicines/strategy/access/stacmain.shtml> (last updated July 5, 2002).

¹⁴² U.N. Comm. on Econ., Soc. & Cultural Rts., *The Nature of States' Parties Obligations*, *supra* note 50, ¶¶ 9-11.

¹⁴³ *Id.* ¶ 10.

¹⁴⁴ See *Minister of Health v. Treatment Action Campaign*, CCT 8/02, ¶ 34 (Constitutional Court of South Africa, July 2002), available at <http://www.tac.org.za/Documents>. Turk, Second Progress Report of the U.N. Special Rapporteur on Econ., Soc. & Cultural Rts., U.N. Doc. E/CN.4/Sub.2/1991/17, p. 18, ¶ 10; U.N. Comm. on Econ., Soc. & Cultural Rts., *The Nature of States' Parties Obligations*, *supra* note 50.

¹⁴⁵ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 47.

¹⁴⁶ U.N. Comm. on Econ., Soc. & Cultural Rts., *The Nature of States' Parties Obligations*, *supra* note 50, ¶ 10.

tions to develop national plans with measurable standards and to make core obligations budget priorities.¹⁴⁷

Of course, many medicines that are essential to the lives of many people are not included on the WHO's Essential Drugs List, and such exclusion should not be interpreted as meaning that the drugs are not needed and that the state should not work aggressively to promote their access. Contraceptives, for example, are not on the WHO's essential drugs list and yet are often "medications" which are crucial to women's health and well-being.¹⁴⁸ Regardless of medicines' inclusion on the WHO Essential Drugs List, a violation of the obligation to fulfill the right to health can occur "through the failure of States parties to take all necessary steps to ensure the realization of the right to health," including a "failure to take measures to reduce the inequitable distribution of health facilities, goods and services."¹⁴⁹

Moreover, beyond the essential drugs that are part of minimum core content, resource constraints cannot be used as a blanket excuse by governments not to take expeditious steps toward the progressive realization of the right to medications in general. The ESCR Committee has stated:

In determining which actions or omissions amount to a violation of the right to health, it is important to distinguish the inability from the unwillingness of a State party to comply with its obligations. . . . A State which is unwilling to use the maximum of its available resources for the realization of the right to health is in violation of its obligations . . . If resource constraints render it impossible for a State to comply fully with its Covenant obligations, it has the burden of justifying that every effort has nevertheless been made to use all available resources at its disposal in order to satisfy, as a matter of priority, the obligations outlined above.¹⁵⁰

It is also important to underscore that the provision of medications need not await the ideal conditions. For example, it has been argued too often that the necessary health care infrastructure does not exist in many of the developing countries where the HIV/AIDS pandemic rages and that, therefore, complicated ARV treatment regimens may be contra-

¹⁴⁷ See, e.g., *Minister of Health v. Treatment Action Campaign*, CCT 8/02, ¶ 26 (Constitutional Court of South Africa, July 2002), available at <http://www.tac.org.za/Documents>; *Rivera v. Estado Colombiano*, T-533 (Corte Constitucional de Colombia 1992), available at <http://bib.minjusticia.gov.co/jurisprudencia/CorteConstitucional/1992/Tutela/T-533-92.htm> ("a significant normative advance has been the introduction of criteria to look at unmet needs and priorities for social spending in the course of the elaboration of the national budget"). For a discussion of this requirement in the Inter-American System, see MELISH, *supra* note 106, at 176.

¹⁴⁸ See U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 34.

¹⁴⁹ *Id.* ¶ 52 (emphasis added).

¹⁵⁰ *Id.* ¶ 47.

indicated, as non-adherence to difficult regimens could result in drug resistance. However, studies have shown that such arguments are paternalistic and that HIV/AIDS and tuberculosis medications can, in fact, be effectively administered even in very resource-poor environments.¹⁵¹ In *Treatment Action Campaign*, mentioned above, the Constitutional Court of South Africa specifically addressed this issue and held that while it would be ideal if a comprehensive program were in place to provide counseling, bottle feed, and the like, it was *unreasonable* to establish those provisions as a precondition to distributing Nevirapine to pregnant HIV-positive women at public health clinics.¹⁵²

The Constitutional Court of South Africa is among many domestic courts that are beginning to look closely at whether governments are indeed meeting the burden of proof in showing they have adopted all *reasonable* measures to establish universal access to medications, given resource constraints. In *Treatment Action Campaign*, that court affirmed a lower court decision holding that the government could not reasonably limit the provision of Nevirapine to eighteen pilot sites in the public health system when such medication has been demonstrated to reduce mother-child transmission of HIV. In this landmark decision, the South African Constitutional Court generally accepted the lower court's broad inquiry into the basis for policy decisions by the Ministry of Health and also affirmed the authority of the judicial branch to oblige the Executive to undertake policies and to implement programs requiring specific social spending, despite the fact that in this case the Nevirapine had been donated.¹⁵³ The court stated that the courts' role was to "require the state to take measures to meet its constitutional obligations and to subject the reasonableness of these measures to evaluation. Such determinations of reasonableness may in fact have budgetary implications, but are not in themselves directed at rearranging budgets."¹⁵⁴ Further, the court affirmed that "[t]he formulation of a programme is only the first stage in meeting the State's obligations. The programme must also be reasonably implemented. An otherwise reasonable programme that is not implemented reasonably will not constitute compliance with the State's obligations."¹⁵⁵

Different domestic courts have evaluated the reasonableness of governmental measures to provide access to medications in a variety of ways.

¹⁵¹ See, e.g., Joseph, *supra* note 117, at 444-45.

¹⁵² Minister of Health v. Treatment Action Campaign, CCT 8/02, ¶ 50 (Constitutional Court of South Africa, July 2002), available at <http://www.tac.org.za/Documents>.

¹⁵³ *Id.* ¶ 38.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* ¶ 100, citing Government of the Republic of South Africa v. Grootboom, 2001 (1) SA 46 (CC); 2000 (11) BCLR 1169 (CC) (state housing policy failed to meet reasonable provision of services standard within available resources).

Although the order in *Treatment Action Campaign* was prescriptive, the Constitutional Court emphasized “flexibility” and stated that the government had discretion to adapt the order should equally appropriate or better methods for the prevention of mother to child transmission become available.¹⁵⁶ Other courts that have reviewed cases involving access to medications have chosen either (1) to convert stated political policies into legal obligations on the part of the executive, requiring as part of reasonableness that the government to implement what it already affirmed as being part of its political agenda,¹⁵⁷ or (2) to determine that a current failure to provide medications does not pass muster for reasonableness under constitutional or international standards, but allowing the executive to then go back and re-shape its own policy or program.¹⁵⁸ As a general matter, according to Craig Scott and Philip Alston, courts considering compliance by States in this regard should inquire as to whether the conduct in question is “consistent with, and faithful to, a full and sincere commitment” to realize this important aspect of the right to health.¹⁵⁹

With respect to the question of available resources, it is worth noting that drug treatment is often cost-effective as well as an essential part of the right to health, a point which has been taken into account by several national courts that have reviewed the question. For example, the Supreme Court of Justice of Costa Rica has argued in this regard:

[I]f it is necessary to put the problem in the cold light of financial imperatives, this Court believes that it would be no less appropriate to ask ourselves how many millions of *colones* [the national currency of Costa Rica] are wasted because ill persons have no possibility of

¹⁵⁶ *Id.* ¶ 135(4).

¹⁵⁷ This was the case in *Viceconte, Mariela Cecilia v. Argentine Ministry of Health & Social Welfare*, Case No 31.777/96 (1998) Poder Judicial de la Nación, in which a protection writ was granted to force the Argentine government to manufacture and distribute vaccines against Argentine Hemorrhagic Fever, which it had previously affirmed as a political priority.

¹⁵⁸ See, for example, two decisions of the Constitutional Court of Colombia in which the court held that failure to provide ARV treatment was unreasonable, but did not address how Social security Institute would have to provide such treatment. *Gomez v. Hospital Universitario del Valle*, T-505 (Corte Constitucional de Colombia 1992), available at <http://bib.minjusticia.gov.co/jurisprudencia/CorteConstitucional/1992/Tutela/T-505-92.htm> (infectious nature of HIV/AIDS is factor in reasonableness of state's actions to promote right to health); *Ceballos v. Instituto de Seguros Sociales*, T-484 (Corte Constitucional de Colombia 1992), available at <http://bib.minjusticia.gov.co/jurisprudencia/CorteConstitucional/1992/Tutela/T-484-92.htm> (fatal nature of AIDS is a factor to consider in the reasonableness of state's efforts to promote right to health).

¹⁵⁹ Craig Scott & Phillip Alston, *Adjudicating Constitutional Priorities in a Transnational Context: A Comment on Soobramoney's Legacy and Grootboom's Promise*, 16 S. AFR. J. H. R. 206, 242 (2000).

reintegrating themselves into the labor force and contributing, even if in a very small way, to the national wealth. If we did an accounting of these costs and all of those associated [with their care], it seems reasonable to postulate that the country loses more in direct and indirect costs due to the state of incapacity of those who are prostrated by a disease, which alternatively could be invested providing treatment that would permit them to return to a productive life.¹⁶⁰

The same reasoning applies to the prevention of mother-to-child transmission of HIV and the treatment of a series of other diseases. This is the case, for example, with schizophrenia, where out-patient provision of psychotropic medications can decrease or avoid expensive hospitalizations. Similarly, timely provision coupled with adequate monitoring of appropriate anti-tuberculosis drugs have been shown to be essential in reducing drug resistance as well as direct and indirect costs relating to the disease.¹⁶¹

Furthermore, not all measures require expenditure of resources. The obligations to respect, to protect, and to fulfill obviously overlap to some extent and indeed, the manner in which a state enforces and interprets its legislation, including competition, patent, and intellectual property legislation, in cases involving access to medicines involves important “administrative . . . and other measures” needed to fulfill the right to health. As noted above, strict interpretation and enforcement of competition legislation can greatly enhance access to affordable generic drugs. At the same time, interpretations of such national laws which favor the public’s health are permitted under the Doha Declaration.

Similarly, tax and tariff policies affect the pricing of medications in ways which do not call for direct state expenditures. For example, if imported medications are not subject to tariffs but inputs to produce medicines are subject to a 10% or 15% tariff or to high taxation, it may strongly discourage the production of generic drugs. On the other hand, the answer is not to increase tariffs on imported medicines, but to exempt the others or reduce their tax burden. Indeed, suspending tariffs on imported drugs can effectively reduce prices to the consumer, and

¹⁶⁰ Alvarez v. Caja Costarricense de Seguro Social, Exp. 5778-V-97, No. 5934-97, (Sala Constitucional de la Corte Suprema de Justicia de Costa Rica) (author translation) (on file with author).

¹⁶¹ See, e.g., P. Cowley and J. Wyatt, *Schizophrenia and Manic Depressive Illness*, in *DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES* 661-670 (D Jamison et al eds., 1993). See also *Minister of Health v. Treatment Action Campaign*, CCT 8/02, (Constitutional Court of South Africa, July 2002), available at <http://www.tac.org.za/Documents>; World Health Organization, *Treatment of Tuberculosis; Guidelines for National Programmes*. WHO/TB/97.220 (2d ed, 1997); World Health Organization, *Guidelines for the Management of Drug-Resistant Tuberculosis* WHO/TB/967.210 (1997). For a discussion of the cost-effectiveness of tuberculosis treatment and the costs of its resurgence in New York City, see FARMER, *supra* note 13, at 131.

thereby increase access. Thus, to be consistent with obligations under international law, these laws, policies, and regulations should be drafted and interpreted with the aim of realizing universal access to medications as part of the right to health.

B. *Obligations of Other Actors Under International Law*

In a recent panel discussion at the WTO's failed ministerial meeting in Cancún, Mexico, U.N. Special Rapporteur on the Right to Health Paul Hunt stated:

[R]ich states should not discourage a developing country from using the TRIPs flexibilities. On the contrary, they should actively facilitate the use of the flexibilities. They should help the [less developed country] deliver the essential drug to all at affordable prices. . . . Health-related [overseas development assistance] deserves the most sympathetic consideration . . ."¹⁶²

Indeed, both third-party states and international institutions have obligations to assist in the realization of rights relating to access to medications.¹⁶³ As a matter of fact, access to medications may usefully be considered within a broader context of development. For example, debt burdens have a direct bearing on access to medications because states with such burdens cannot allocate sufficient resources to confront epidemics such as HIV/AIDS. In 2001, for example, the government of Sierra Leone allocated 74.3% of exports of goods and services to service its debt.¹⁶⁴ In the same year, it spent 1.8% of its GDP on health expenditures (a fraction of which go toward medications) and the total of public and private health expenditure per capita was \$24, in purchasing power parity U.S. dollars.¹⁶⁵

In this regard, the United Nations Charter calls on members to take "joint and several action" to promote inter alia: "(a) a higher standard of living . . . and conditions of economic and social progress and development; (b) solutions of international economic, social health and related problems; . . . and (c) universal respect for, and observance of, human rights."¹⁶⁶ The ESCR Committee has emphasized that development assistance and cooperation are human rights issues: "[I]n accordance with articles 55 and 56 of the Charter of the United Nations, with well-established principles of international law, and with the provisions of the Covenant

¹⁶² Panel Presentation of Paul Hunt, U.N. Special Rapporteur on the Right to Health, *Towards Development: Human Rights and the WTO Agenda*, Panel Discussion, Cancun, Mexico 3 (Sept. 12, 2003) (on file with author).

¹⁶³ See generally Joseph, *supra* note 117.

¹⁶⁴ United Nations Development Programme, *Human Development Indicators 2003*, Sierra Leone, available at http://www.undp.org/hdr2003/indicator/cty_f_SLE.html.

¹⁶⁵ *Id.*

¹⁶⁶ U.N. CHARTER arts. 55-56.

itself, international cooperation for development and thus for the realization of economic, social and cultural rights is an obligation of all States.”¹⁶⁷

The ESCR Committee has noted that, among others, the World Bank, regional development banks, the International Monetary Fund (“IMF”), and the WTO

should cooperate effectively with States parties, building on their respective expertise, in relation to the implementation of the right to health at the national level, with due respect to their individual mandates. In particular, the international financial institutions, notably the World Bank and the International Monetary Fund, should pay greater attention to the protection of the right to health in their lending policies, credit agreements and structural adjustment programmes.¹⁶⁸

Further, in addition to calling on all states and international organizations to respect human rights in trade agreements, as noted above, in its General Statement on “Human Rights and Intellectual Property” the ESCR Committee observes that intellectual property rules should not necessarily be uniform and recommends the adoption and implementation of international mechanisms for intellectual property protection that offer special and differential treatment to developing countries.¹⁶⁹

Third-party states are also bound both specifically by the provisions of treaties to which they are parties and more generally to the resolutions of the United Nations and other regional human rights organizations, such as the Organization of African Unity, of which they are members. For example, the U.N. Declaration of Commitment adopted at a special session of the U.N. General assembly in 2001 recognized “that access to medication in the context of pandemics such as HIV/AIDS is one element fundamental to progressively achieving the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” The Declaration called upon states to:

pursue policies, in accordance with applicable international law, including international agreements acceded to, which would promote . . . [t]he availability in sufficient quantities of pharmaceuticals and medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them.¹⁷⁰

Further, as members of the WHO, third-party states have an obligation to support the mission and declarations of that organization. In 2002, the

¹⁶⁷ U.N. Comm. on Econ., Soc. & Cultural Rts., *The Nature of States’ Parties Obligations*, *supra* note 50.

¹⁶⁸ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 64.

¹⁶⁹ Statement on *Human Rights and Intellectual Property*, *supra* note 8, ¶ 15.

¹⁷⁰ U.N. Declaration of Commitment on HIV/AIDS, *supra* note 120.

World Health Assembly of the WHO issued a report by the Secretariat on the WHO medicines strategy: "expanding access to essential drugs." In that report the WHO stated as a commitment for 2003 to:

ensure that national strategies, supported by regional and international strategies, are developed in close collaboration with the international community, including Governments and relevant intergovernmental organizations, as well as with civil society and the business sector, to strengthen health care systems and address factors affecting the provision of HIV-related drugs, including anti-retroviral drugs, inter alia, affordability and pricing, including differential pricing, and technical and health-care system capacity. Also, in an urgent manner make every effort to provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS . . . and to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order further to promote innovation and the development of domestic industries consistent with international law.¹⁷¹

As members of the WHO, governments have an obligation to adopt measures consistent with these goals and not to contravene directly any of these commitments.

The ESCR Committee has explicitly stated with respect to the ICESCR: "States parties should refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment. Restrictions on such goods should never be used as an instrument of political and economic pressure."¹⁷² In its General Comment No. 3, the ESCR Committee noted the obligation of all States parties to "take steps, individually and through international assistance and cooperation, especially economic and technical, towards the full realization of the rights recognized in the Covenant," including the right to health.¹⁷³

In General Comment No. 14, the ESCR Committee went further, specifically calling on states parties to:

recognize the essential role of international cooperation and comply with their commitment to take joint and separate action to achieve the full realization of the right to health. In this regard, States parties are referred to the Alma-Ata Declaration which proclaims that the existing gross inequality in the health status of the people, particularly between developed and developing countries, as well as within

¹⁷¹ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 55.

¹⁷² *Id.* ¶ 41.

¹⁷³ U.N. Comm. on Econ., Soc. & Cultural Rts., *The Nature of States' Parties Obligations*, *supra* note 50, ¶¶ 13-14.

countries, is politically, socially and economically unacceptable and is, therefore, of common concern to all countries.¹⁷⁴

Although the extent of third-party states' obligation to underwrite the provision of pharmaceuticals in developing countries may be unclear, it is clear that to comply with their international obligations under the ICESCR, states parties at a minimum:

have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law.¹⁷⁵

Compliance would include "influence" over pricing policies established by their domestic pharmaceutical companies as well as by the WTO and other international institutions.

The ESCR Committee also affirms with respect to international agreements and institutions:

States parties should ensure that the right to health is given due attention in international agreements and, to that end, should consider the development of further legal instruments. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health. Similarly, States parties have an obligation to ensure that their actions as members of international organizations take due account of the right to health. Accordingly, States parties which are members of international financial institutions, notably the International Monetary Fund, the World Bank, and regional development banks, should pay greater attention to the protection of the right to health in influencing the lending policies, credit agreements and international measures of these institutions.¹⁷⁶

Thus, when their trade and finance ministries participate in the negotiation or interpretation of trade agreements, such as the TRIPS Agreement, and loan terms or debt-repayment schedules, third-party states parties to the ICESCR undertake responsibilities to consider and protect the right to medications, as part of the right to health. Third-party states that are signatories but not parties to the ICESCR assume obligations in accordance with the Vienna Convention on the Law of Treaties "to refrain from acts that would contravene the object and purpose" of the treaty, an obligation which remains in force until such time as the state makes clear its intention not to become a party to the ICESCR.¹⁷⁷ States

¹⁷⁴ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 38.

¹⁷⁵ *Id.* ¶ 39.

¹⁷⁶ *Id.*

¹⁷⁷ Vienna Convention, *supra* note 15, at art. 18.

that are neither parties nor signatories nevertheless assume general obligations not to contravene U.N. resolutions in this regard, as members of the United Nations.

Thus, proposed changes to Canada's Patent Act and Food and Drugs Act that would put into practice a recent WTO decision allowing countries producing generic copies of patented drugs under compulsory licenses to export them to countries with little or no manufacturing capacity should be applauded as being fully consistent with both Canada's human rights obligations and its obligations under the DOHA Declaration and the TRIPS Agreement.¹⁷⁸ On the other hand, it is reasonable to affirm that the efforts of the U.S. government, which is a signatory but not a party to the ICESCR, to deliberately block intellectual property reform in Thailand, Brazil, and South Africa constituted violations of the government's general obligation not to contravene the object and purpose of the treaty.¹⁷⁹

Obligations to respect the spirit of international law also apply to the use of third-party states' bilateral development aid. For example, a clear violation of human rights principles would occur were the U.S. government to expand its "global gag rule" to HIV funding, thereby disqualifying a large number of organizations—especially family planning programs—from delivering integrated HIV prevention services and medications. The "global gag rule" prevents any organization that offers abortion-related services or even counselling from receiving U.S. development assistance. In addition to the ICESCR, the United States is a signatory to the Children's Convention and to the Women's Convention, under which such actions would clearly be prohibited as they would foreseeably lead to more women's and children's morbidity and mortality.¹⁸⁰

In short, human rights law establishes some clear and reasonable parameters for governments, for third-party states, and for some international institutions to follow with respect to laws and policies affecting access to medications. As the U.N. Special Rapporteur on the Right to Health has stated:

Of course there are grey areas And there are good faith disputes and disagreements, just as there are in economics and trade. But the important point is that the right to health is not just a slogan—it is

¹⁷⁸ See, e.g., Press Release, United Nations, United Nations Human Rights Expert Welcomes Canadian Initiative on Access to Low-Cost Drugs in Developing Countries (Nov. 7, 2003), available at <http://www.un.org/News/Press/docs/2003/hr4702.doc.htm>.

¹⁷⁹ See, e.g., Rosemary Sweeney, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM L. & POL'Y J. 445 (2000).

¹⁸⁰ Being a signatory binds the state not to take actions that would contravene the general intent of the treaty. See generally Vienna Convention, *supra* note 15.

not a bumper sticker—it has normative depth and something constructive and concise to say to economics and trade.”¹⁸¹

Indeed, it cannot be underscored too frequently that human rights is a formal body of law in addition to a framework of principles; as such it binds developed as well as developing states that have voluntarily ratified treaties or joined international organizations. For example, the three-pronged governmental obligations flowing from the right to health impose some limitations on the untrammelled discretion of policy-makers, which can be made consistent with the TRIPS Agreement and other international trade obligations. In short, they require states: (1) to refrain from taking actions or enacting laws that would restrict the availability or accessibility of medications; (2) to protect the public's access to medications from threats imposed by third parties, including pharmaceutical companies; and (3) to take deliberate steps to move toward the progressive realization of access to medications on a non-discriminatory basis. Third-party states and international organizations have also assumed specific obligations under human rights law, which should, and can, guide their decision-making and legislative action.

IV. CONCLUSIONS

Compassion is a notoriously unstable emotion; as such, it ill-serves the interests of the millions who desperately need access to medications in order to survive.¹⁸² In Botswana, adult rates of HIV infection stood at 38.8% at the end of 2001; in Zimbabwe they were 33.7%.¹⁸³ Present projections for a fifteen year-old Southern African's chance of dying of HIV/AIDS vary between one in three and one in two.¹⁸⁴ These statistics are nothing short of scandalous in a world where effective therapy does exist. Similarly, tuberculosis deaths occur almost exclusively among the destitute, whether in the developing world or to a lesser extent in the inner cities of countries in the North.¹⁸⁵ As James Gathii writes, “The handouts that pharmaceutical companies have announced are laudable but the existence of such handouts does not address the question of affordability in the long-term.”¹⁸⁶ The Zapatista rebels in Southern Mexico, who suffered from a desperate lack of the most basic medications, health care,

¹⁸¹ Panel Presentation of Paul Hunt, *supra* note 162, at 2.

¹⁸² See SUSAN SONTAG, REGARDING THE PAIN OF OTHERS 101 (2003).

¹⁸³ UNAIDS, Table of Country-Specific HIV/AIDS estimates and Data, end 2002, in World Health Organization, report on the Global HIV/AIDS Epidemic, 2002, at <http://www.who.int/hiv/pub/epidemiology/pubepidemic2002/en> (last visited June 24, 2003).

¹⁸⁴ Joseph, *supra* note 117, at 427, n. 7.

¹⁸⁵ See FARMER, *supra* note 13, at 147.

¹⁸⁶ Gathii continues: “In addition, it is possible that these ad hoc responses and the infrequency with which AIDS drugs are consumed in Africa may contribute to the creation of drug-resistant strains of the virus.” Gathii, *supra* note 14, at 271.

and other social services, put the issue of charity more sharply in a communiqué explaining the causes of their rebellion: “these crumbs of charity solve our problems for no more than a moment, and then death returns to our houses. That is why we think, no, no more, enough of this dying useless deaths, it would be better to fight for change.”¹⁸⁷

Viewing access to medications as a matter of *fundamental human rights* forces us to face the momentous suffering and loss of life that is occurring in developing countries due to HIV/AIDS, tuberculosis, malaria, and other diseases as not just a tragedy; it forces us to recognize it as a horrific injustice. A human rights paradigm demands that we locate the suffering in the developing world on the same political and economic map as the privileges of many in the industrialized world, and to go beyond acknowledging or studying that suffering to protest and remedy it actively—to fight for change, as the Zapatistas assert.

Human rights sets out an alternative paradigm to models based entirely on charity or cost-effectiveness, which among other things, demands meaningful popular consultation and participation in decisions affecting access to medications, including the adoption of trade and intellectual property regimes that could affect accessibility.¹⁸⁸ In addition to underscoring principles of, *inter alia*, participation, non-discrimination, and concern for marginalized or vulnerable groups, a human rights framework with respect to access to medications is also grounded in specific norms under international law.

For example, access to medications has been recognized as implicating both the right to life and the right to health under international law. Both international adjudicatory bodies and domestic tribunals are finding enforceable dimensions to these rights in order to be consistent with local constitutions as well as international law. Further, a recent General Statement by the ESCR Committee makes it clear that the right to the benefits of scientific progress, including medications, must be respected in the realms of international trade and finance and provisions must be made for protecting the public health. The issue of access to medications, as it plays out in real people’s lives, also involves the rights to an adequate standard of living and to social security, and affects the rights to work and to education.

Although there are clearly challenges and numerous specific questions that have yet to be defined, applying a human rights framework is neither unrealistic nor premature in terms of the development of international norms. In particular, this article has discussed States’ specific obligations under the ICESCR and other international treaties to respect, to protect, and to fulfill the right to health, including ensuring access to basic medi-

¹⁸⁷ Communiqué from the CCRI-CG of the EZLN, January 6, 1994 *quoted in* FARMER, *supra* note 13, at 203.

¹⁸⁸ U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, *supra* note 7, ¶ 36.

cations, which are directly relevant to both policy-making and judicial interpretation. Indeed, increasingly, domestic courts are subjecting the reasonableness of such governmental measures to judicial scrutiny and mandating government programs to pay for such medications, especially in the case of HIV/AIDS. Moreover, international institutions and third-party States also incur the obligation under treaty-based and charter-based international law to respect international human rights, including the right to health, and intellectual property regimes, including the TRIPS Agreement, should be interpreted in light of those obligations.¹⁸⁹

¹⁸⁹ See generally Expert Declaration of James Packard Love, Director, Consumer Project for Technology at the Center for the Study of Responsive Law (Feb. 2003), available at www.cptech.org/ip/health/cl/cl-cases/rsa-tac/love02032003.doc.

