

EXPERT REPORT AY

HUMAN RIGHTS OBLIGATIONS REGARDING ACCESS TO MEDICATIONS

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28 August 2003

Introduction

Access to medications is not only an essential part of the right to health under international law, but it is also a precondition for the enjoyment of the right to life in many cases. Having access to appropriate medications also flows from the human right to enjoy the benefits of scientific progress. In a human rights framework, the question at issue is whether the government and other actors are taking steps by *all appropriate means* to make medications accessible—physically and economically—and to make information relating to medications accessible as well.¹ Such steps may require the adoption of laws, policies or programs. However, it is also the case that treaties and 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.²

Further, in accordance with a human rights framework, 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 such as 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 which has the purpose or effect of nullifying or impairing the enjoyment or exercise of people's rights constitutes a violation of international law.³ Indeed, discrimination by the public health system or the social security system on the basis of HIV-positive status is a common finding in cases where access to medications has been mandated by the courts.

From a public health perspective, we know that 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.⁴ Understanding access to basic

¹ United Nations Committee on Economic, Social and Cultural Rights General Comment Relating to the Right to the Highest Attainable Standard of Health, 20th Session .May 2000 (ESCR Committee General Comment No. 14), at para 12.

² See e.g. "Human Rights and Intellectual Property" Statement by the Committee on Economic, Social and Cultural Rights," Follow-up to the day of general discussion on article 15.1(c), 26 November 2001, E/C.12/2001/15, 14 Dec. 2001, para 12.(Statement on Human Rights and Intellectual Property).

³ E.g. ESCR Committee General Comment No. 14, *supra* note 1, at paras 11-12.

⁴ WHO, Information on Technical and Financial Cooperation Programmes carried out by the World Health Organization and that are relevant to TRIPS Implementation and Access to Drugs (2001) available at <http://www.who.int/medicines/organization/ood/techcoop.shtml>

medications as a human rights issue means that governments have not only moral or humanitarian responsibilities to undertake such measures, but also legal obligations, which 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, and licensing laws. Second, it also implies 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).⁵ 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 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.⁶

Moreover, as medications are not simply a market commodity --and health care in general is not a hand-out-- a human rights perspective demands meaningful popular consultation and participation in decisions affecting access to medications, including the adoption of intellectual property regimes. Consultation cannot be a mere formality, but must reflect the recognition that people have the right to control their well-being.⁷ Finally, a human rights framework requires that a system of accountability be put in place, which includes a functioning regulatory structure empowered to effectively police the health system and drug manufacturers, and provide remedies to victims in the event of violations.⁸

This concept paper first sets out the principal norms under international human rights law that relate to access to medications. Part I 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. It also sets out the connections between access to medications and rights to an adequate standard of living, work and education, as well as to 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 II, the paper then examines the obligations that flow from those provisions, primarily focusing on the right to health. Governmental obligations are analyzed according to the tripartite framework of duties that is now well-established under international law: to respect, to protect and to fulfill.⁹ The obligations of third-party States and international institutions are also considered. 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 AIDS pandemic, these simply have not received the same attention from national courts or international bodies.

⁵ ESCR Committee General Comment No. 14, *supra* note 1, at para 35.

⁶ Maastricht Guidelines on Violations of Economic, Social and Cultural rights, (Maastricht Guidelines), 20 Hum. Rts. Q 691,694 (1998) para 14 [“Maastricht Guidelines”]. ESCR Committee General Comment No. 14, *supra* note 1, at para 36.

⁷ ESCR Committee General Comment No. 14, *supra* note 1, at para 36.

⁸ See e.g. Statement by the Committee on Economic, Social and Cultural Rights, ‘Poverty and the International Covenant on Economic, Social and Cultural Rights,’ E/C.12/2001/10, 4 May 2001, para 11.

⁹ ESCR Committee General Comment No. 14, *supra* note 1, at paras 34-36. and General Recommendation No. 24. “Women and Health” (2 feb. 1999). 20th session of the Committee on the Elimination of Discrimination against Women. [CEDAW General Recommendation No. 24].Para. 14-17.

I. Overview of Norms Relating to Access to Medications under International Human Rights Law

The Right to Life

Given that medications can be indispensable for life, it is foreseeable that State policies that are likely to lead directly to diminished physical accessibility and affordability of certain medications in effect will 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.”¹⁰ 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 if not those that are conducive to dignity and well-being. For example, 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.”¹¹ Specifically, the Human Rights Committee has defined the role of the state in protecting human life to include obligations to reduce infant mortality, increase life expectancy, eliminate malnutrition and epidemics.¹² 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 severe criminal penalties imposed on abortion, which have been shown to increase maternal mortality, implicate the right to life.¹³

Similarly, the independent expert for the United Nations Commission on Human Rights, Luis Valencia Rodriguez, also recognized the underlying inputs necessary for sustaining life as part of the right itself: “A trend has been observed to consider the right to life as a more general concept, characterized not only by the fact of being the legal basis of all the rights, but also of forming an integral part of all the rights that are essential for guaranteeing access for all human beings to all goods... necessary for the development of their physical, moral and spiritual existence.”¹⁴

This trend is indeed observable with respect to interpretations of the right to life provided under a panoply of different instruments. 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. (art 6(1)) and “States Parties shall ensure to the maximum extent possible the survival and development of the child.”¹⁵ The Committee

¹⁰ International Covenant on Civil and Political Rights, G.A. Res 2200 (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966) 999 U.N.T.S. 171 (entered into force 23 Mar. 1976)[ICCPR], at art 6.

¹¹ United Nations Human Rights Committee, General Comment No. 6: The Right to Life” UN Doc A/37/40, CCPR 16th Sess. (1982), para 5.

¹² *Id.*, at para 5.

¹³ E.g.: Concluding Observations of the Human Rights Committee: Peru CCPR/C/79/Add.72 18 Nov. 96. Paras. 13, 15.

¹⁴ El derecho de toda persona a la propiedad individual y colectiva [The right of everyone to individual and collective property], final report submitted by Luis Valencia Rodriguez, E/CN.4/1993/15, 18.12.92, at 26-27.

¹⁵ Convention on the Rights of the Child (adopted 20 Nov. 1989) G.A. Res 44/25 U.N. GAOR, 44th Sess., Supp. No. 49 at 167, U.N. Doc. A/44/49 (1989) (entered into force 2 Sept. 1990) at art. 6(2)[Children’s Convention].

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, their very survival as well as their health and development.¹⁶

On a regional level, Article 4 of the African Charter on Human and Peoples' Rights (Banjul Charter) also 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."¹⁷ In a recent decision, the African Commission on Human and Peoples' Rights found the government of Nigeria responsible for violating article 4, among other things, because pollution and environmental degradation which were attributable to the government had risen "to a level humanly unacceptable [and] has made living in Ogoniland a nightmare."¹⁸ The language of "humanly unacceptable" and the notion of holding the government responsible for allowing oil exploitation to turn life into a "nightmare" suggest that similar reasoning might 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) that "Everyone's right to life shall be protected by law."¹⁹ 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 to take steps against unintentional loss.²⁰

In the Inter-American System, Inter-American Court of Human Rights has interpreted article 4 in a broad sense. The American Convention on Human Rights states that: "Every person has the right to have his life respected. ... No one shall be arbitrarily deprived of his life." (art. 4(1))²¹ The Court has held: "The right to life must be analyzed in relation to the commitment of the state established pursuant to article 1 to respect protect and fulfill the full enjoyment of the rights recognized in the [American] Convention."²²

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:

¹⁶ Concluding Observations of the Committee on the Rights of the Child: Cote d'Ivoire CRC/C/15/Add.155 9 July 2001 para 5 (positive assessment of national plan).

¹⁷ African Charter of Peoples and Human Rights, adopted by the OAU on 17 June 1981 (entered into force on 21 October 1986) reprinted in Twenty-five Human Rights Documents. Center for the Study of Human Rights, Columbia University [Banjul Charter]. at art 4.

¹⁸ Decision regarding Communication 155/96, The Social and Economic rights Action center and the Cenetr for Economic and Social Rights v. Nigeria. Para 67, African Comm'n Hum & Peoples' Rights, 30th Ordinary Sess. (2001)(Nigerian government responsible for directly violating and failing to protect the rights to life, health and housing of the Ogoni people).

¹⁹ European Convention for the Protection of Human Rights and Fundamental freedoms (opened for signature 4 November 1950), 213 U.N.T.S. 221.(entered into force on 3 Sept. 1953)[European Convention].

²⁰ Tavares v France, Application No. 16593/90, Decision 12 Sept., 1991 (European Comm'n of Hum. Rts.)(unreported) *cited in* R. Cook & B. Dickens, Human Rights Dynamics of Abortion Law Reform. 25 Hum. Rts. Q 1-59, 28 (2003).

²¹ American Convention on Human Rights, Signed 22 November 1969, 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 18 July 1978), reprinted in Basic documents pertaining to the Inter-American system (1992)[American Convention].

²² Inter-Am Court of H. Rts.. Annual report 1998. Report No. 59/99, Case 11.405. Newton Coutinho Medes and others, Brazil (13 April 1999).

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 rights 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, as well as economic, social and cultural rights, thus illustrating the interrelation and indivisibility of all human rights.²³

This explication is not only significant with respect to cases brought in the Inter-American System, but for the other systems of human rights as well, as there is frequent cross-fertilization and adoption of standards, which is explicitly provided for under some instruments.²⁴

For its part, in an earlier case, the Inter-American Commission on Human Rights (IACHR) 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.”²⁵ The failure to provide access to life-saving or life-sustaining medications would clearly seem to fall within these expanded notions of obligations deriving from the right to life.

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.²⁶ In the case of *Odir Miranda v El Salvador*, the petitioners alleged that the Salvadoran State’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 quality of life that allows them to achieve well being. 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 analysis of the merits of the case, pursuant to the provisions of Articles 26 and 29 of the American Convention.”²⁷

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

²³ Inter-Am. Ct. H. R. Villagrán Morales et al case (the “Street Children” Case) Judgement of Nov. 19, 1999 (Ser. C) No. 63, joint concurring opinion of Antonio Augusto Cancado Trindade and Alirio Abreu Burelli, paras 2-4.(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).

²⁴ See e.g. American Convention, *supra* note 21, at art. 27.

²⁵ Inter-Am Comm’n Hum. Rts. State of Human Rights in Various Countries: Guatemala. Annual report of the IACHR (1991). p. 225.

²⁶ Report N° 29/01. Case 12.249, Jorge Odir Miranda Cortez et al. v El Salvador, Mar. 7, 2001(Salvadoran State’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, guarantee them the quality of life that allows them to achieve well being).

²⁷ ESCR Committee General Comment No. 14, *supra* note 1, at para 47.

example, in a series of cases dealing with the substantive content of the right, the Indian Supreme Court has found that the right to live with human dignity includes the right to good health.²⁸ In that context, many domestic courts have found that denial of access to certain medications can constitute a violation of the constitutional right to life.²⁹

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:

The right to life in itself is not a restrictive concept, limited to the reduced idea of risk of death. Rather it is a concept that extends to the concrete possibility of recuperation and improvement --to the extent possible-- of health status when it is impaired, when such impairments affect the quality of life of individual persons or the conditions necessary to guarantee to every individual a life of dignity.³⁰

It should also be underscored that national courts have also found the right to life implicated in access to medications cases other than those involving HIV/AIDS. 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 man suffering from colon cancer.³¹

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. The right to life is not subject to progressive realization under international law and therefore can be invoked to underscore the urgency of taking immediate measures with respect to providing access to medications in HIV/AIDS and other cases. Some international tribunals have pointed out that the right to life has attained *jus cogens* status under international law.³² 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,” advocates should make full use of

²⁸ See S.Shah, *Illuminating the Possible in the Developing World; Guaranteeing the Human Right to Health in India*, 32 *Vand. J. Transnat'l L.* 453 (1999).

²⁹ E.g. *Mr Glenda Lopez v Instituto Venezolano de Seguros Sociales*, Supreme Court of Venezuela. Constitutional Chamber. Judgment 487-060401. Protection Writ. <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.)

³⁰ Constitutional Court of Colombia. Judgment of MP. Fabio Moron Diaz T-328/98 Protection Writ. (translation by Alicia Yamin)[antiretroviral treatment ordered for plaintiff under social security system].

³¹ *Campodonico de Beviacqua, Ana Carina et al c/Ministerio de Salud y Acción social—Secretaría de Programas de Salud y Banco de Drogas Neoplásicas*. Protection Writ. Supreme Court of Argentina. (2002)

³² *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 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 of the Law of Treaties, opened for signature 23 May, 1969, 1155 U.N.T.S. 331, 340, 8 I.L.M. 679, 692 (entered into force 17 Jan. 1980), art. 53[Vienna Convention]. For an example of the right to life being cited as *jus cogens*, see *Street Children Case*, *supra* note 23, para 139.

arguments relating to the right to life when arguing that courts have obligations to order that ARVs be made available, for example.

The Right to Health

Access to medications constitutes an integral part of the right to health. 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.”³³ 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.”³⁴ 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.

From time to time, treaty-monitoring bodies issue General Comments or General Recommendations that are authoritative interpretations of aspects related to specific treaty provisions, which 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:

- (a) available in sufficient quantity;
- (b) accessible to everyone without discrimination;
- (c) acceptable in the sense of respectful of medical ethics and customs; and
- (d) of good quality and scientifically appropriate.³⁵

Accessibility in particular includes:

- (i) 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;”³⁶
- (ii) economic accessibility: “health facilities, goods and services must be affordable for all;”³⁷ and
- (iii) information accessibility: “accessibility includes the right to seek, receive and impart information and ideas concerning health issues” including pricing and treatments.³⁸

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.³⁹ Thus,

³³ International Covenant on Economic, Social and Cultural Rights, adopted 16 Dec. 1966, G.A. Res 2200 (XXI), U.N. GAOR 21st Sess. Supp. No. 16, at 49, U.N. Doc A/6316 (1966), 993 U.N.T.S. 3 (entered into force 3 Jan 1976) at Art. 12(1). [ICESCR]

³⁴ *Id.*, at Art. 12(2)(c) and (d), respectively.

³⁵ ESCR Committee General Comment No. 14, *supra* note 1, at para. 12.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*, at para. 43.

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."⁴⁰ 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.⁴¹ The ESCR Committee has increasingly addressed specifically States' failures with respect to providing essential drugs to halt epidemic disease, such as HIV/AIDS.⁴²

The right to health is also set out in a number of 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. 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." Needless to say, "health care services" include medications.

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 discrimination in health services and public health. The Race Convention calls on States Parties to eliminate racial discrimination and "guarantee the right of everyone, without distinction of race, colour, or national or ethnic origin" to the enjoyment of, among other rights, "the right to public health, medical care, social security and social services."⁴³ Article 12 of the Women's Convention affirms: "States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning."⁴⁴ Again, access to medications cannot be provided in a vacuum; in practice, access to medications requires non-discrimination in access to health services.

The right to health is also included in a number of regional instruments. Article 16 of the Banjul Charter also 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..."⁴⁵ The European Social Charter states that Contracting Parties undertake "to take appropriate measures designed *inter alia*...to

⁴⁰ Id.

⁴¹ United Nations Committee on Economic Social and Cultural Rts, General Comment No. 3 "The Nature of States' Parties Obligations" (Fifth Session, 1990), UN doc. E/1991/23, Annex III.[ESCR Committee General Comment No. 3], at para 10. See also: ESCR Committee General Comment No. 14, *supra* note 1, at para 47.

⁴² See e.g. Concluding Observations of the Committee on Economic, Social and Cultural Rights : Honduras. 21/05/2001. E/C.12/1/Add.57. (Concluding Observations/Comments). at para 26

⁴³ International Convention on the Elimination of all Forms of Racial Discrimination, adopted by UNGA 21 Dec. 1965, UN GAOR Res. 2106 A(XX) (entered into force 4 Jan 1969), reprinted in Twenty-Five Human Rights Documents. (NY; Columbia University:1994) at art. 5(e) (iv) [Race Convention].

⁴⁴ 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 3 Sept. 1981) at art. 12.[Women's Convention].

⁴⁵ Banjul Charter, *supra* note 17, at art. 17.

prevent as far as possible epidemic, endemic and other diseases.”⁴⁶ 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.”⁴⁷

The American Declaration of the Rights and Duties of Man states in Article 11: “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.”⁴⁸ Further, 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.⁴⁹ 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: 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.⁵⁰

Further, the right to health or health care is enshrined in over 60 national constitutions.⁵¹ Although some of those provisions refer to the right as a directive principle rather than a fundamental right, increasingly courts at the domestic level are finding state obligations to provide medication as part of the right to health, as well as the right to life. Costa Rica, India, Venezuela, Colombia, Argentina, and South Africa are among many countries in which national courts have determined that the State has obligations to provide medications in HIV/AIDS cases and other diseases.⁵²

In a recent judgment unifying its own jurisprudence on the right to health, the Constitutional Court of Colombia set out a four-point test as to when the right to health services becomes justiciable, which is instructive. First, the health issue must implicate other fundamental rights, 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

⁴⁶ European Social Charter, signed 18 Oct. 1961. (entered into force 26 Feb. 1965) reprinted in *Twenty-Five Human Rights Documents*. (NY: Columbia University:1994) at art. 11(3).

⁴⁷ *Id.*

⁴⁸ American Declaration on the Rights and Duties of Man, signed 2 May 1948, OEA/Ser.L./V/II 71, at 71 (1988), at art. 11.

⁴⁹ Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights “Protocol of San Salvador,” OAS Treaty Series No. 69 (1998), entered into force 1998.[Protocol of San Salvador].

⁵⁰ *Id.*, at article 10(d) and (f).

⁵¹ 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. Comm’n on Hum Rts. E/CN.4/2003/58 13 Feb. 2003., at para 20.

⁵² *Minister of Health et al. v Treatment Action Campaign*. Constitutional Court of South Africa. 5 July 2002 available at www.tac.org.za/Documents. [Treatment Action Campaign]; *Mr. Alonso Munoz Ceballos vs. Instituto de Seguros Sociales*. Judgment No. T-484-92 Protection writ . Constitutional Court of Colombia (social security institute obliged to provide ARV treatment under principles of non-discrimination and solidarity); *William Garcia Alvarez v. Caja Costarricense de Seguro Social*. Sala Constitucional de la Corte Suprema de Justicia de Costa Rica. Exp. 5778-V-97, No. 5934-97[social security institute obliged to provide ARV treatment]; *Lopez v Instituto Venezolano de Seguros Sociales*, *supra* note 29; *Campodonico de Beviacqua*, *supra* note 31; *C.E.S.C. Limited v Subas Chandra Bose* A.I.R. 1992 S.C. 572, 585 cited in *Shah*, *supra* note 33 ,at note 186.

concrete case must lie within the resources of the state.⁵³ The court makes clear that the generally programmatic character of economic, social and cultural rights “tends to become transmuted 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.”⁵⁴ The trend among national tribunals to find justiciable dimensions to the right to health is common in—and a times in response to-- cases relating to access to HIV/AIDS medications, where the connection to the right to life is obvious and the specificity of the normative obligation is generally high.

For example, in South Africa, article 27 of the Constitution follows closely the language of article 12 of the ICESCR and in the recent *Minister of Health et al v Treatment Action Campaign et al* case, the Constitutional Court interpreted the state’s obligations to adopt “reasonable measures” 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.⁵⁵

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. 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, receive particular protection. Any economic criterion that pretends to annul the enjoyment of the right to life 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 benefits of our system of liberties and freedoms, if even one person cannot count on having the rights to health and life guaranteed?”⁵⁶

⁵³ Constitutional Court of Colombia, Sentencia SU.819/99 (1999). Sentencia de Unificación de Jurisprudencia.[Judgment to unify jurisprudence on right to health and social security services].

⁵⁴ Id.

⁵⁵ Treatment Action Campaign, *supra* note 52.

⁵⁶ Garcia Alvarez v. Caja Costarricense de Seguro Social, *supra* note 52 [Alicia Yamin translation].

The Rights to an Adequate Standard of Living, Education and Work

Access to medications is indispensable for many people to be able to work and attend school, and thus has a direct bearing on the right to an adequate standard of living. The 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.”⁵⁷ Although not a treaty, the Universal Declaration is generally considered to be an authoritative interpretation of human rights obligations of member States under Articles 55 and 56 of the United Nations Charter.

Moreover, it is now widely understood that rights are interdependent and indivisible and that the right to health, and in particular access to medications, must be understood in the broader context of people’s lives, which includes the need to earn a living and the right to 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.⁵⁸ Without access to medications, many patients simply cannot attend school or hold jobs. The impossibility of “returning to a productive life” without access to medications has been specifically noted by courts taking up the issue of access to HIV/AIDS medications, for example.⁵⁹

⁵⁷ Universal Declaration on Human Rights, adopted 10 Dec. 1948, UNGA Res. 217 A (III) reprinted in *Twenty-Five Human Rights Documents*. (NY: Columbia University:1994) at art. 25.

⁵⁸ ICESCR, *supra* note 27, at arts 6(1) art 13(1) and (2)(a)(b)(c), respectively.

⁵⁹ *Garcia Alvarez v. Caja Costarricense de Seguro Social*, *supra* note 52. Sentencia SU.819/99, *supra* note 53. [Social security institute has obligations to provide essential medications and services to avoid the destruction of the population’s earning capacity]. Cf. *Nery Chiquita Laverde v CAPRECOM*, Sentencia No. T-499/92, Constitutional Court of Colombia, (August 21, 1992), *Acción de Tutela*. [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]; *Eduardo Cifuentes Munoz*, Sentencia T-533/92, Constitutional Court of Colombia [eye surgery ordered for 63-year old man without family support who otherwise would not be able to work.]

The Right to the Benefits of Scientific Progress

Access to medications also implicates the right to benefit from scientific progress, which is established under a number of international instruments. For example, Article 15 of the ICESCR sets out that States Parties “recognize the right of everyone... To 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. In 2001, the ESCR Committee adopted a General Statement on “Human Rights and Intellectual Property.”⁶⁰ 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.”⁶¹

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 TRIPS agreement must abide by international human rights law.⁶² 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.”⁶³ 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.”⁶⁴

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.⁶⁵

⁶⁰ Statement on Human Rights and Intellectual Property, *supra* note 2.

⁶¹ *Id.*, at para 2.

⁶² *Id.*, at para 3.

⁶³ *Id.*, at para 4.

⁶⁴ *Id.*, at para 12.

⁶⁵ Protocol of San Salvador, *supra* note 49, at art. 14.

Disproportionate Effects on Children of Denial of Access to Medications

Individuals' lives are deeply embedded in their families and communities, and when an ill parent is denied medication, children are often irreparably affected. 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."⁶⁶ The ICESCR also calls on States parties to reduce infant and child mortality, and to provide appropriate prenatal care.⁶⁷

Sometimes, medication for parents very directly affects the possibilities for survival and well-being of the children, as in the case of Nevirapine therapy to prevent mother-to-child transmission of HIV. This was the issue in the recent South African case, *Minister of Health et al v Treatment Action Campaign et al*, mentioned above. In that case, the Constitutional Court specifically noted the effects of governmental policy on children's rights⁶⁸: "Their 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 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."⁶⁹

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 reduce drop-out rates, which invariably increase when families have to choose between buying essential medications to survive and sending their children to school.⁷⁰ Needless to say, the burdens of caring for sick and dying parents and siblings is in itself harmful to children's psychological health.

⁶⁶ Children's Convention, *supra* note 15, at art. 24,

⁶⁷ ICESCR, *supra* note 33, at art 12(2)(a).

⁶⁸ Treatment Action Campaign, *supra* note 52, para 79.

⁶⁹ *Id.*, at para 78.

⁷⁰ Children's Convention, *supra* note 15, at art 28.

Other Vulnerable Groups

Diseases such as HIV/AIDS and tuberculosis can be social X-rays, illuminating the most marginalized and excluded sectors of society. 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.

For example, 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 have been starkly illuminated by the HIV/AIDS pandemic. 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....⁷¹

Certain specific groups, such as women and girls who have been trafficked for prostitution, regardless of their citizenship status, clearly require access to medications for HIV and other sexually transmitted diseases. However, even 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.

In general, human right law calls on states to pay particular attention to the inclusion and equitable treatment of vulnerable, marginalized and previously disadvantaged groups.⁷² The International Labor Organization Convention concerning indigenous and tribal peoples in independent countries (ILO Convention 169), for example, also 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.⁷³

Prisoners can constitute another marginalized group, as demonstrated in the South African case of *B. and Others v. Minister of Correctional Services and Others*, where petitioners successfully sued the federal Department of Corrections to pay for antiretroviral (ARV) treatment for four HIV-positive prisoners in a facility.⁷⁴ 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

⁷¹ CEDAW General Recommendation No. 24, *supra* note 9, at para 18.

⁷² See ESCR Committee, General Comment No. 3, *supra* note 41, at paras. 9-11.

⁷³ The International Labor Organization Convention Concerning Indigenous and Tribal peoples in Independent Countries (Convention 169) adopted 27 June 1989, *reprinted in* Twenty-Five Human Rights Documents. (NY; Columbia University:1994) at art. 7(2)[ILO Convention 169].

⁷⁴ *B. et al v Minister of Correctional Services et al.* (6) BCLR 789 (C) (1997)(state has resources to provide ARVs to petitioners in the instant case).

equipment, furnishings and pharmaceutical supplies shall be proper for the medical care and treatment of sick prisoners, and there shall be a staff of suitably trained officers.”⁷⁵

Similarly, patients in mental hospitals can also 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 Principles for Protection of Persons with Mental Illness require a standard of care equivalent to that of other sick individuals, including supplies of medication, and requires the mental health system to promote community treatment and reintegration.⁷⁶

In general, the principle of non-discrimination is a justiciable procedural right (i.e., equal protection), which applies equally to the right to health and other economic, social and cultural rights, as well as 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 cases relating to pension benefits and other economic and social rights.⁷⁷ With respect to access to medications, proscriptions on discrimination demand both that certain marginalized individuals or 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.

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.⁷⁸ Differential treatment in practice will almost certainly be invalid if: (1) members of two or more groups are similarly situated under the law (e.g. citizens of the same country); (2) nevertheless, members of each group are treated differently (e.g. some are not entitled to ARVs in their local public health center); and (3) the negative, differential treatment is based on a prohibited status --i.e., race, color, sex, language, religion, political or other opinion, national or social origin, economic status, birth or *any other social condition* (e.g. homosexuality).⁷⁹ In practice,

⁷⁵ Standard Minimum Rules for the Protection of Prisoners. Adopted 30 Aug. 1955, ECOSOC Res. 663 C (XXIV) 31 Jul. 1957 and 2076 (LXII) of 13 May 1977 *reprinted in* Twenty-Five Human Rights Documents. (NY; Columbia University:1994)

⁷⁶ Principles for the Protection of Persons with Mental Illness. Adopted by the UN General Assembly Res. 46/119. 17 Dec. 1991.

⁷⁷ See *Zwan-de Vries v The Netherlands*, Comm. No. 182/1984, UN GAOR, Hum. Rts. Comm., 42d Sess, at 160, UN 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”); *Eur Ct. H. R. Schuler-Zraggen v. Switzerland*, Judgment of Jun. 24, 1993 (Ser. A) No. 263, *reprinted in* 16 Eur. H. R. Rep. 420 (1993)(declaring invalid the presumption of ineligibility of married women with children for unemployment benefits).

⁷⁸ Note that affirmative action to promote an equal footing for marginalized groups is acceptable under human rights law. See, e.g., UN Secretary General, *The Main Types and Causes of Discrimination*, U.N. Publ. 49.XIV.3, paras 6-7.

⁷⁹ See, e.g., discussion of standards under Article 24 of the American Convention in the Inter-American System in T. Melish, *Protecting Economic, Social and Cultural Rights in the Inter-American System : A*

geographic areas may closely overlap with religious, racial or ethnic identities and it is useful to recall that discrimination need not be intentional under international law, but merely needs to have the effect of nullifying or impairing the enjoyment of rights.⁸⁰

Manual for Presenting Claims, by Tara Melish (Orville H. Schell Jr. Center for International Human Rights, Yale Law School and Centro de Derechos Económicos y Sociales, Ecuador, 2002)p. 199.

⁸⁰ Eg. ESCR Committee General Comment No. 14, *supra* note 1, at paras 11-12.

II. Analysis of Actors' Obligations under International Human Rights Law

The following analysis of obligations with respect to the right to health focuses principally on the ICESCR, where the clarification of the normative content has received most attention. However, the principles discussed here are applicable generally to other relevant rights (e.g. the enjoyment of the benefits of scientific progress), as well as in many other fora. The content of the duties to respect, protect and fulfill the right to health under the ICESCR can be used to interpret the health provisions of other relevant human rights treaties, including both thematic and regional instruments. 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.⁸¹ Both the IACHR and the Inter-American Court have repeatedly invoked other treaties and relevant tendencies in the interpretation of human rights protections.⁸² Similarly, interpretations of the ICESCR are relevant in the Organization of African Unity (OAU) system. Indeed, the African Commission on Human Rights has explicitly adopted a multi-dimensional framework of States' obligations relating to the right to health.⁸³

Governmental Obligations

According to the ESCR Committee's General Comment No. 14, the right to health, like all human rights, imposes three types or levels of obligations on States parties: the obligations to respect, to protect and to fulfil. In turn, the obligation to fulfil contains obligations to facilitate, provide and promote. This tripartite framework is now widely accepted throughout the United Nations and regional systems of human rights.

The Obligation to Respect

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; abstaining from enforcing discriminatory practices as a State policy."⁸⁴ Before any action is taken that could limit the provision of basic medications, there must be a process of genuine consultation with the people who will be affected and an opportunity for recourse in the event that people's rights are violated.

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."⁸⁵ 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

⁸¹ See Inter-Am Court of Hum Rts. Enmiendas propuestas para las normas sobre naturalización de la constitución de Costa Rica. [Proposed amendments to the naturalization norms in the Constitution of Costa Rica] Consultative Opinion. OC-4/84 (19 Feb. 1984) para 20 (proposed naturalization norms that provide a preference for married women but not for married men is discriminatory under the American Convention).

⁸² See Inter-Am Court, "Other Treaties: Object of the Consultative Function of the Court" (Art 64 of the American Convention on Human Rights) Consultative Opinion OC-1/82 (24 Sept. 1982) para 43.

⁸³ Ogoniland Case, *supra* note 18. Note that the African Commission classifies obligations as to respect, protect, promote and fulfill.

⁸⁴ ESCR Committee General Comment No. 14, *supra* note 1, at para 34.

⁸⁵ *Id.*, at para 48.

obligations under the ICESCR.⁸⁶ Similarly, such regressive measures constitute a *prima facie* violation of Article 26 of the American Convention, and any such measure would be subject to “strict scrutiny” by the IACHR or the Inter-American Court.⁸⁷

Under such a “strict scrutiny” standard, a government would have the burden of proof of justifying actions such as back-stepping on compulsory and government-use licensing or 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 necessary (based on objective considerations) to promote the general welfare in a democratic society.⁸⁸ 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.⁸⁹

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.”⁹⁰ 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 take measures to protect access to medications. In this vein, a 2002 resolution by the UN Commission on Human Rights stated: “access 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” and called upon states at the national level, on a non-discriminatory basis “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.”⁹¹ This statement reaffirmed the principles agreed to by UN member states in the Declaration of Commitment on HIV/AIDS of the UN General Assembly Special Session in 2001 (UN Declaration of Commitment on HIV/AIDS).⁹²

It is worth underscoring with respect to international trade agreements and intellectual property protections themselves, that the Agreement on Trade-Related Aspects of Intellectual Property Rights (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

⁸⁶ *Id.*, at para 47.

⁸⁷ Inter-Am. Comm’n Hum Rts. Annual Report (1993).

⁸⁸ 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), at paras 46-57.

⁸⁹ *Id.*

⁹⁰ ESCR Committee General Comment No. 14, *supra* note 1, at para 50.

⁹¹ Access to medication in the context of pandemics such as HIV/AIDS. UN Comm’n on Hum. Rts Res. 2002/32, E.CN.4.RES.2002.32, at para 3(a)

⁹² United Nations Declaration of Commitment on HIV/AIDS. UN General Assembly 26th Special Sess. Res. 33/2001. 25-27 June 2001.[UN Declaration of Commitment on HIV/AIDS]

technological development,” including the issuance of compulsory licenses as a remedy for anticompetitive practices.⁹³ 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 all.”⁹⁴ The Doha Declaration specifically recognized 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.”⁹⁵ Thus, even pursuant to TRIPS, a government’s human rights obligations to respect the right to health ought not be subordinated to other commercial interests.

The Obligation to Protect

Second, 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*, “to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services; to control the marketing of medical equipment and medicines by third parties; [and] States should also ensure that third parties do not limit people’s access to health-related information and services.”⁹⁶ Goods and services include the provision of medications. 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”⁹⁷ 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 special anti-competition rules where patent holders refuse to grant licenses to 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 UN Declaration of Commitment on HIV/AIDS.⁹⁸

⁹³ Agreement on Trade-related Aspects of Intellectual property Rights, Apr. 15, 1994, Annex 1C, Legal Instruments—Results of the Uruguay Round vol 1, 33 I.L.M. 1125 (1994), arts. 8, 31. [TRIPS Agreement].

⁹⁴ Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health adopted at the Fourth World Trade organization Ministerial Conference (November 2001), para 4.[Doha Declaration].

⁹⁵ Id, at para 5 (c).

⁹⁶ ESCR Committee General Comment No. 14, *supra* note 1, at para 35.

⁹⁷ Id, at para 51.

⁹⁸ UN Declaration of Commitment on HIV/AIDS, *supra* note 92, at para 14.

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.”⁹⁹ 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.”¹⁰⁰

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 adopt other protective measures would constitute a violation of the state’s obligations to protect the right to health. As set out by Flynn and Love in their access gap theory, evidence of abusive commercial practices would include, but not be limited to, the following situations: (1) the number of people who need access to medicine to prolong their lives or 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.¹⁰¹

The Obligation to Fulfill

Third, 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 resources and effect a sustained and equitable distribution.¹⁰² 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 obligations 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 UN Declaration of Commitment was adopted at the UN General Assembly Special Session, held in June 2001. The UN 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 doing, with specific goals and targets. In accordance with the UN Declaration of Commitment, the UN General Assembly reviews a progress report on its implementation which is prepared by the Secretary-General.

⁹⁹ Doha Declaration, *supra* note 94, at para 5(b).

¹⁰⁰ P. 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, 492; and TRIPS Agreement, *supra* note 80, at art. 8.

¹⁰¹ S. Flynn and J. Love, *Access Gap Theory for Compulsory Licenses in Africa*, *Emory Int’l L. Rev.* (forthcoming).

¹⁰² ESCR Committee General Comment No. 14, *supra* note 1, at para 36.

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

- (a) 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;
- (b) 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;
- (c) 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.¹⁰³

It is interesting to note that in assessing the accessibility of medications under a country's pharmaceutical policy, the WHO considers *inter alia* the percentage of a minimum wage salary that is required to pay for a basic course of treatment of a given HIV/AIDS (as well as other medications).¹⁰⁴

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.”¹⁰⁵ 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; insufficient expenditure on medications; or the discriminatory allocation of funds for medications could each constitute violations of the obligation to fulfill.

Furthermore, although it would be absurd in many countries to assert 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.¹⁰⁶ Moreover, the ESCR Committee has forcefully stated that violations of

¹⁰³ Access to medication in the context of pandemics such as HIV/AIDS

UN Comm'n on Human Rights Res. 2002/32, E.CN.4.RES.2002.32, at para 2(a-c)

¹⁰⁴ WHO. Manual on Pharmaceutical Policy (2002). Accessible at www.who.int/medicines/strategy/policy/indicators.

¹⁰⁵ ESCR Committee General Comment No. 14, *supra* note 1, at para 51. For its part, the IACHR has stated in general that it “will pay special attention to the equitable and efficient use of available resources and the allocation of public spending to address the living conditions of the most vulnerable sectors of society who have been historically excluded from political and economic processes.” Inter-Am Comm'n Hum. Rts., Annual Report (1993).

¹⁰⁶ ESCR Committee General Comment No. 3, *supra* note 41, at paras. 9-11.

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 Covenant, which includes “essential drugs” as defined by the WHO.¹⁰⁷

It is widely agreed that although the fact that essential drugs are part of the minimum core content of the right to health under the ICESCR does constitute a simplistic litmus test on state compliance, 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.¹⁰⁸ The state thus has the burden to meet in justifying its non-compliance with core obligations, such as access to essential medications.¹⁰⁹ 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 obligation 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.”¹¹⁰ 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 obligations to develop national plans with measurable standards and to make core obligations priorities in budgeting.¹¹¹

Of course, many medicines that are essential to the lives of many 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. Regardless of 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.” (emphasis added)¹¹²

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

¹⁰⁷ Id, at para. 10.

¹⁰⁸ See: *Treatment Action Campaign*, *supra* note 52, at para 34. Turk, Second Progress Report of the UN Special Rapporteur on Economic, Social and Cultural Rights, UN Doc. E/CN.4/Sub.2/1991/17, p. 18, para. 10; ESCR Committee General Comment 3, *supra* note 41.

¹⁰⁹ ESCR Committee General Comment No. 14, *supra* note 1, at para 47.

¹¹⁰ ESCR Committee General Comment 3, *supra* note 41, at para 10.

¹¹¹ See e.g. *Treatment Action Campaign*, *supra* note 52, at para 26; Cifuentes Munoz, Constitutional Court of Colombia, *supra* note 59 (“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.”).

¹¹² ESCR Committee General Comment No. 14, *supra* note 1, at para 52.

disposal in order to satisfy, as a matter of priority, the obligations outlined above.¹¹³

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 not be followed and are therefore contra-indicated. In practice, certain non-governmental organizations (NGOs) and others have shown that HIV/AIDS medications can in fact be effectively administered even in very resource-poor environments.¹¹⁴ In the case of *Minister of Health et al. v Treatment Action Campaign et al*, 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 that as a precondition to distributing Nevirapine to pregnant HIV-positive women at public health clinics.¹¹⁵

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 18 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, on the one hand, generally accepted the lower court's broad inquiry into the basis for policy decisions by the Ministry of Health and, second, affirmed the authority of the judicial branch to oblige the Executive to undertake policies and implement programs requiring specific social spending, despite the fact that in this case the Nevirapine had been donated.¹¹⁶ There the court stated that the role of the courts 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 may have budgetary implications, but they are not in themselves directed at rearranging budgets."¹¹⁷ Further, the Court affirmed that "the formulation of a program 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."¹¹⁸

Different domestic courts have evaluated the reasonableness of governmental measures to provide access to medications in a variety of ways. For example, other courts that have reviewed cases involving access to medications have chosen: (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

¹¹³ Id, at para 47.

¹¹⁴ See e.g. the experience of Partners in Health. P. Farmer, Pathologies of Power: Rethinking Health and Human Rights, 89 *Amer. J. Pub. Health*, 1486-1496 (1999).

¹¹⁵ Treatment Action Campaign, *supra* note 52, para 50.

¹¹⁶ Id, para 38

¹¹⁷ Id at para 38.

¹¹⁸ Id, at para 100. citing Government of the Republic of South Africa et al v Grootboom et al 2001 (1) SA 46 (CC); 2000(11)BCLR 1169(CC)(state housing policy failed to meet reasonable provision of services stanadrad within available resources).

of its political agenda;¹¹⁹ or (2) to determine that a current failure to provide medications does not pass muster for reasonableness under constitutional or international standards, but allowed the executive to then go back and re-shape its own policy or program.¹²⁰ As a general matter, according to Scott and Alston, courts considering the 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.¹²¹

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:

if 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 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 affirm 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.¹²²

The same reasoning applies to the prevention of mother-to-child transmission of HIV and the treatment of a series of other diseases.¹²³

¹¹⁹ This was the case in *Viceconte, Mariela Cecilia v Argentine Ministry of Health and Social Welfare*, Case No 31.777/96 (June 2, 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.

¹²⁰ See e.g. Constitutional Court of Colombia’s decisions in *Mr. Diego Serna Gomez v. Hospital Universidad del Valle*. Judgment No T-505-92. Protection Writ [infectious nature of HIV/AIDS is factor in reasonableness of state’s actions to promote right to health] and *Ceballos v. Instituto de Seguros Sociales* *supra* note 52 [fatal nature of AIDS is factor to consider in reasonableness of state’s efforts to promote right to health], in both of which the court held that failure to provide anti-retroviral treatment was unreasonable, but did not address how Social security Institute would have to provide such treatment.

¹²¹ Scott & Alston, “Adjudication of Constitutional Priorities in a Transnational Context; A Comment on *Soobramoney’s* Legacy and *Grootboom’s* Promise” 17 S. African J Hum Rts. 206-268 (2000).

¹²² *Garcia Alvarez v. Caja Costarricense de Seguro Social*, *supra* note 52.

¹²³ For example, this is the case 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 similarly have been shown to be essential in reducing drug resistance as well as direct and indirect costs relating to the disease. See e.g. Cowley P, Wyatt J. Schizophrenia and Manic Depressive Illness in Jamison D. et al ed. *Disease Control Priorities in Developing Countries*. (Oxford University Press, 1993) pp. 661-670. See also Treatment Action Campaign, *supra* note 52; 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). See also P Farmer, J Bayona, M Becerr, et al, *The Dilemma of MDR-TB in the Global Era*. *Intl J. Tuberculosis and Lung Disease*. 1998;2(11):1-8; P Farmer, J Bayona, S Shin, et al. preliminary results of community-based MDR-TB treatment in Lima, Peru. *Intl J Tuberculosis and Lung Disease*. 1998;2(11)S371

Furthermore, not all measures require expenditure of resources. The obligations to respect, protect and 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 involve 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 and, 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 also 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 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.

Obligations of Other Actors under International Law

Both third-party States and international institutions have obligations to assist in the realization of rights relating to access to medications. Indeed, access to medications usefully may be considered within a broader context of development. For example, debt burdens have a direct bearing on access to medications because States cannot allocate sufficient resources to confront epidemics such as HIV/AIDS. In 1999, for example, the government of Ecuador allocated 3.8% of its national budget to the health sector, a fraction of which was made available for medications, in contrast to 38% to debt repayment; in 2000, those figures changed to 2.8% and 54% respectively.¹²⁴

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.”¹²⁵ The ESCR Committee has emphasized that development assistance and cooperation are issues of human rights: “in 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 itself, international cooperation for development and thus for the realization of economic, social and cultural rights is an obligation of all States.”¹²⁶

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

¹²⁴ Ministry of Finance of Ecuador. Budget of the Central Government 2000 (April 2000) and Budget of the Central Government 1999 (April 1999).

¹²⁵ United Nations Charter, art 56, signed 26 June 1945, 59 stat. 1031, T.S. No. 993, 3 Bevans 1153 (entered into force 24 Oct. 1945).

¹²⁶ ESCR Committee General Comment No. 3, *supra* note 41 .

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.”¹²⁷ 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.¹²⁸

Third-party States are also bound both specifically by the provisions of treaties to which they are parties and more generally to abide by the resolutions of the United Nations and other regional human rights organizations, such as the OAU, in which they are members. For example, the UN Declaration of Commitment adopted at a special session of the UN General Assembly in 2001, recognized “that access 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” and 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”.¹²⁹

Further, as members of the WHO, third-party states have obligations to support the mission and declarations of that organization. In 2002, the 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.¹³⁰

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.

¹²⁷ ESCR Committee General Comment No. 14, *supra* note 1, at para 64

¹²⁸ ESCR Committee General Statement on Human Rights and Intellectual Property, *supra* note 52, at para 15.

¹²⁹ UN Declaration of Commitment on HIV/AIDS, *supra* note 91.

¹³⁰ ESCR Committee General Comment No. 14, *supra* note 1, at para 55.

The ESCR Committee has explicitly stated with respect to the ICESCR that: “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.”¹³¹ 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.¹³²

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 countries, is politically, socially and economically unacceptable and is, therefore, of common concern to all countries.”¹³³

Although the extent of third-party states’ obligations 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.”¹³⁴ Compliance would include “influence” over pricing policies established by their domestic pharmaceutical companies as well as 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.¹³⁵

Thus, when their trade and finance ministries participate in the negotiation or interpretation of trade agreements, such as TRIPS, and/or loan terms and debt-repayment

¹³¹ Id, at para 41.

¹³² ESCR Committee General Comment No. 3, *supra* note 41, at paras 13-14. .

¹³³ ESCR Committee General Comment No. 14, *supra* note 1, at para 38.

¹³⁴ Id, at para 39.

¹³⁵ Id.

schedules, respectively, third-party States that are parties to the ICESCR undertake responsibilities to take into account 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 obligation 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.¹³⁶ States that are neither parties nor signatories nevertheless assume general obligations not to contravene UN resolutions in this regard, as members of the United Nations. Thus, it is reasonable to affirm that the efforts of the United States 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 obligations not to contravene the object and purpose of the treaty.¹³⁷

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 United States 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 US development assistance. In addition to the ICESCR, the United States is a signatory to the Children’s Convention and the Women’s Convention, under which such actions would clearly be prohibited as they will foreseeably lead to more women’s and children’s morbidity and mortality.¹³⁸

IV. Conclusions

Access to medications has been recognized as implicating the right to life, the right to health and the right to the benefits of scientific progress under international law. Access to medications is also indirectly necessary for the enjoyment of the rights to work, education and to an adequate standard of living, in many cases. Denial of access to medications has disproportionate effects on children, women and vulnerable or marginalized groups and often infringes upon the right to non-discrimination on the basis of either health status or other social condition.

States have specific obligations under the ICESCR and other international treaties to respect, protect and fulfill the right to health, including ensuring access to basic medications. Indeed, access to essential medications, as defined by the WHO’s Programme on Essential Drugs, is considered to constitute part of the minimum core content of the right to health under the ICESCR. But states have obligations to take reasonable measures to promote universal access to all basic medications, even those that do not appear on the WHO list. 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. Finally, international institutions and third-party States also incur obligations under

¹³⁶ Vienna Convention, *supra* note 32, at art. 18.

¹³⁷ See e.g. *The US 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).

¹³⁸ 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 32.

treaty- and charter-based international law to respect the right to health, and intellectual property regimes, including the TRIPS Agreement, should be interpreted in light of those obligations.
