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Lack of Access to HIV/AIDS Drugs in Developing Countries: Is There a Violation of the International Human Right to Health?

by Barbara Cochrane Alexander*

The Joint United Nations Programme on HIV/AIDS (UNAIDS) reported an estimated 36 million people worldwide are afflicted with HIV/AIDS in its December 2000 AIDS epidemic update, of which 25.3 million live in sub-Saharan Africa. In response to the spread of the HIV/AIDS epidemic over the past decade, pharmaceutical corporations have tested their HIV/AIDS drugs in developing countries. Unfortunately, these countries often cannot afford to purchase the drugs pharmaceutical corporations test on their citizens. The issue of affordable HIV/AIDS drugs is a primary obstacle to access. While not the only obstacle—others include underdeveloped healthcare infrastructure, and a lack of HIV testing, education, and prevention programs—making HIV/AIDS drugs affordable for developing countries is a necessary part of successful efforts to fight the AIDS epidemic. Over the past 12 to 15 months, affordability as a primary obstacle impeding access to HIV/AIDS drugs in developing countries has received increased attention from the international community and mass media.

On February 20, 2001, UN Secretary General Kofi Annan released a 29-page report in which he highlighted the important role pharmaceutical corporations have in providing affordable access to HIV/AIDS drugs in developing countries. Following this report, in March 2001, a number of pharmaceutical corporations, including Bristol Myers Squibb, Merck, and GlaxoSmithKline, agreed to provide their drugs at lower costs for developing countries. On April 5, 2001, Annan met with chief executives of six of the world's largest pharmaceutical corporations and urged them to lower the costs of HIV/AIDS drugs even further for certain African countries. The prices remain too high, and poor persons in developing countries most likely still will be unable to afford the drugs without the help of charities and government agencies. Furthermore, a number of pharmaceutical corporations appear opposed to governments' independent attempts to improve their countries' access to HIV/AIDS drugs. According to the *Washington Post*, Annan acknowledged the importance of patent protections but said he expected the companies to become "partners in the fight against AIDS."

In a case just recently dropped by the plaintiffs, 39 pharmaceutical corporations sued the South African government for its effort to import and produce cheaper generic HIV/AIDS drugs, which corporations allege violates their patent rights under

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international trade law. Specifically, *Pharmaceuticals Manufacturers Association v. the President of South Africa*, Case No. 4183/98, contested South Africa's 1997 Medicines and Related Substances Control Amendment Act, which allows South Africa to import and produce less expensive, generic versions of HIV/AIDS drugs. The lawsuit has delayed the implementation of this law. By extension, the lawsuit challenges South Africa's efforts to protect and promote the international human right to health. As a signatory to the International Covenant on Economic, Social and Cultural Rights (ICESCR), South Africa is taking steps to fulfill the ICESCR's international health



AP Photo/Denis Farrell

Placing a box containing the ashes of a baby who died from HIV/AIDS into a wall of remembrance in Johannesburg, South Africa.

obligations, even though until ratification it is not legally required to do so. Under General Comment 14's interpretation of Article 12 of the ICESCR, the international human right to health includes access to "facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health."

In the context of this right to health, several relevant questions arise. First, do developing countries violate this right when they fail to provide access to HIV/AIDS drugs for their citizens? The ICESCR takes into account developing countries' limited resources while mandating their progressive realization of the right to health over time. This progressive realization requires developing countries, if party to the ICESCR, to take steps toward full realization.

Related to this first question is the issue of the responsibility of developed countries for violations of the international human right to health under the ICESCR. Developed countries, in which most pharmaceutical corporations manufacturing and marketing HIV/AIDS drugs are located, may also have international health obligations to developing countries. If a developed country is a State Party to the ICESCR, it may violate the right to health by failing to influence pharmaceutical corporations' actions that restrict access to HIV/AIDS drugs in developing countries.

Finally, do pharmaceutical corporations' actions that block access to HIV/AIDS drugs violate the right to health? Although, generally, corporate responsibility in public international law currently is an underdeveloped and untested theory, there is growing support that public international law can apply to private actors. Pharmaceutical corporations eagerly enter

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developing countries to test their drugs with fewer restrictions than in developed countries. Although there are internationally accepted ethical guidelines governing clinical trials in developing countries, even these ethical guidelines are not always followed. Controversies surrounding aspects of study design and continued drug access post-clinical trials highlight how pharmaceutical corporations fail to follow ethical guidelines. For these reasons, among others, even though the legal argument for corporate responsibilities toward developing countries' right to health is not strong, it is worth improving. In practice, corporations and individual States' acts or omissions significantly impact the international human right to health in developing countries.

Lack of Access to HIV/AIDS Drugs as a Violation of the International Human Right to Health

There are a number of international legal instruments relevant to the international human right to health. The international human rights community's ongoing attempts to define the scope of a right to health have evolved through the UN Charter, the Universal Declaration of Human Rights (UDHR), the Constitution of the World Health Organization, and the ICESCR, among others. Article 12 of the ICESCR creates legal obligations for State Parties to take steps toward realizing that the right to health, including those States Parties currently unable to fully realize the right to health because of limited resources. Most recently, the UN Committee on Economic, Social, and Cultural Rights (Committee) further explained ICESCR Article 12's international human right to health in General Comment No. 14: "The Right to the Highest Attainable Standard of Health" (General Comment).

ICESCR and General Comment No. 14

A number of provisions in Article 12 of the ICESCR are relevant to the HIV/AIDS epidemic and the issue of access to HIV/AIDS drugs. First, Article 12(1) requires "State Parties to the present Covenant recognize the rights of everyone to the enjoyment of the highest attainable standard of physical and mental health . . ." Further, Article 12(2) (c) requires States Parties to take steps for "[t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases." Additionally, State Parties must create "conditions which would assure to all medical service and medical attention in the event of sickness" (Article 12(2) (d)). In order to better explain the right to health, the Committee promulgated the General Comment.

According to the General Comment, the scope of Article 12's right to health includes the right to the highest attainable standard of health; the right to affordable, quality healthcare; and the right to equality of access to health services. The "highest attainable standard of health" considers "the individual's biological and socio-economic preconditions and a State's available resources." This standard suggests developing countries have different "highest attainable standards" than developed countries. Nevertheless, it does not preclude developing countries from raising their highest available standards in efforts to realize more fully the right to health. Access to HIV/AIDS drugs is significant for improving quality of life, protecting the ability to exercise other human rights and, in certain cases, helping to stop the transmission of the disease. Therefore, it is necessary to close the gap between developing and developed countries' highest attainable standards. Additionally, within the context of HIV/AIDS research, Article 15(1) (b) of the ICESCR is also relevant. It states everyone has the right "to enjoy the benefits of scientific progress and its applications." While the General Comment recognizes a State cannot ensure the good health of

its citizens, it explains that State Parties must take the necessary steps for the realization of the highest attainable standard of health. Regarding HIV/AIDS drugs, these steps, under the ICESCR, also include an obligation by States Parties to assist their citizens in gaining access to HIV/AIDS drugs, which exist as a benefit of scientific progress.

Pharmaceutical corporations eagerly enter developing countries to test their drugs with fewer restrictions than in developed countries. Although there are internationally accepted ethical guidelines governing clinical trials in developing countries, even these ethical guidelines are not always followed.

As the Committee explains in the General Comment, "[t]he right to health, like all human rights, imposes three types or levels of obligations on States Parties: the obligation to respect, protect and fulfil." These obligations require States Parties "to refrain from interfering directly or indirectly with the enjoyment of the right to health" (respect); "to take measures that prevent third parties from interfering with Article 12 guarantees" (protect); and "to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures toward the full realization of the right to health" (fulfil). These rights and obligations suggest developing countries must provide access, or at least attempt to provide access, to HIV/AIDS drugs for their citizens as part of the right to health.

Currently, South Africa is only a signatory to the ICESCR. Although it is not legally bound until it ratifies the ICESCR, South Africa is still a useful example: it shows how developing countries progressively can realize and fulfil their legal obligations to protect the right to health of their citizens. First, by seeking to limit pharmaceutical corporations' patent rights, as the 1997 Medicines and Related Substances Control Amendment Act does, South Africa is taking measures to prevent interference by third-party pharmaceutical corporations and to protect the right to health. Second, by legislating for the importation and production of cheaper generic HIV/AIDS drugs, South Africa arguably is attempting to improve access to HIV/AIDS drugs for its citizens. According to the General Comment, acts or omissions of State Parties unable to comply with Article 12 obligations due to resource constraints, but making "every effort . . . to use all available resources at its disposal in order to satisfy, as a matter of priority, the obligations of [Article 12 of the ICESCR]," are not in violation of the right to health. Other ICESCR State Parties, developed countries in particular, however, do not benefit from the limited resources exception and arguably have additional responsibilities.

States Parties as Violators for Failing to Control Third Parties

In addition to direct violations of the international human right to health by ICESCR State Parties, the General Comment suggests State Parties also might be responsible for violations of the international human right to health caused by third parties in their jurisdictions. In the General Comment, the Committee provides that "State parties 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” (emphasis added). Within this understanding of the scope of State Parties’ legal obligations, pharmaceutical corporations can be characterized as third parties. Since States can regulate or attempt to regulate pharmaceutical corporations and their research and marketing, they should do so to prevent violations of the right to health. For example, States can choose not to fund pharmaceutical research if the pharmaceutical corporation does not follow fundamental biomedical research guidelines. Additionally, States can promote freedom of speech and expression to allow individuals and interest groups to apply pressure to pharmaceutical corporations to lower their costs or provide drugs at no cost. If the United States were a State Party to the ICESCR, its failure to prevent its pharmaceutical corporations from blocking South Africa’s access to HIV/AIDS drugs could violate the right to health.

Moreover, in its General Comment, the Committee proceeds even further to include an affirmative obligation for State Parties to protect the right to health. The General Comment provides that “[d]epending on the availability of resources, States should facilitate access to essential health facilities, goods and services in other countries wherever possible and provide the necessary aid when required.” This interpretation of State Parties’ international obligations serves as a call to resource-rich, developed countries to assist developing countries unable to comply with Article 12 obligations. It includes the possibility of working more closely with pharmaceutical corporations to provide HIV/AIDS drugs at low or no cost to persons living in developing countries.

Third-Party Pharmaceutical Corporations as Violators of the International Human Right to Health

The legal argument for corporate human rights liability for violations of the right to health resulting from lack of access to HIV/AIDS drugs is not strong. Public international law traditionally applies to public, State actors rather than private, individual actors. There is, however, some legal precedent upon which to build a stronger legal argument for corporate human rights liability. At least two international legal instruments set forth the possibility of corporate responsibility for human rights violations.

First, the UDHR, which has the force of customary international law, states in its Preamble that “every organ of society . . . shall strive . . . to promote respect for these rights and freedoms and . . . to secure their universal and effective recognition.” A pharmaceutical corporation arguably is an “organ of society.” Further, if the drafters of the UDHR intended to limit the scope of who should promote and recognize human rights to public, state actors, they could have used the phrase “every State” rather than “every organ of society.” Second, there is the UN Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms (Human Rights Defenders Declaration). This Declaration is aspirational and reaffirms the UDHR. It states in Article 18, Paragraph 2, that “[i]ndividuals, groups, institutions and non-governmental organizations have an important role to play and a responsibility in safeguarding democracy, promoting human rights and fundamental freedoms and contributing to the promotion and advancement of democratic societies, institutions and processes.” Unfortunately, pharmaceutical corporations are unlikely to agree that they have any legal responsibility regarding an international human right to health.

Additionally, pharmaceutical corporations testing their HIV/AIDS drugs in developing countries often disagree over their ethical responsibilities. Ideally, the international human

rights community should be able to use biomedical research ethics and human rights as complementary tools to strengthen the international human right to health. Unfortunately, these ethical disagreements do not provide a solid foundation from which to strengthen the legal responsibilities of pharmaceutical corporations. In the context of what type of access clinical trial participants should have to any available standard therapies, for example, two differing opinions predominate. One opinion is that study participants should have access to the best-proven standard therapies available anywhere in the world. Persons who hold this opinion argue against placebo/treatment research. A recent trial highlighting the controversy of placebo/treatment research was a perinatal HIV vertical transmission clinical trial. This trial was designed to test a less intensive and cheaper regimen of zidovudine, a drug that prevents the transfer of HIV to infants during birth. The trial contained a placebo arm, which meant some HIV-positive mothers participating in the study did not receive a known treatment to prevent HIV-transmission to their unborn children during birth. A second opinion asserts that study participants should have access to the highest attainable standard available based on resources (local standard). Pharmaceutical corporations argue that the economic realities of developing countries make it unrealistic for them to provide access to the best-proven standard therapies available elsewhere in the world. Certain ethical guidelines, however, suggest this point is not as relevant to the debate as pharmaceutical corporations claim.

In 1993, the Council for International Organizations of Medical Sciences (CIOMS) published *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, specifically citing as its impetus in its Background Note “the prospect of field trials of vaccines and drugs to control AIDS.” Guideline 8 addresses “Research involving subjects in underdeveloped communities.” In particular, it provides “[a]s a general rule, the sponsoring agency should ensure that, at the completion of successful testing, any product developed will be made reasonably available to inhabitants of the underdeveloped community in which the research was carried out” Additionally, paragraph 30 of the World Medical Association’s Declaration of Helsinki states, “[a]t the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.” These ethical research guidelines have relevance to developing a legal argument that third-party pharmaceutical corporations violate the right to health when they block access to HIV/AIDS drugs in developing countries. They establish ethical responsibility for pharmaceutical corporations to provide drug access at least to the countries in which they conducted their research. Furthermore, the term “sponsoring agency” could also apply to State actors financially sponsoring pharmaceutical corporations’ research in developing countries.

Conclusion

Although the international human rights community needs to strengthen its legal arguments, lack of access to HIV/AIDS drugs in developing countries does violate the international human right to health. It is particularly important to strengthen the legal arguments for non-state/third-party actors’ responsibilities. Pharmaceutical corporations feel vilified by criticisms that they value patents more than human lives, but perhaps they fail to realize that limited price reductions of drug treatments are not sufficient to address the scope of the HIV/AIDS epidemic. ☹

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