Some Thoughts on the Right to Health in International Law: An American Perspective

By John S. Gardner*

"Property is surely a right of mankind as real as liberty."

Classic and Modern Conceptions of International Law

At least three of the Millennium Development Goals adopted in 2000 by the United Nations General Assembly² are related to health: Goal 4 ("Reduce child mortality"), Goal 5 ("Improve maternal health"), and Goal 6 ("Combat HIV/ AIDS, malaria and other diseases").³ Many would argue that Goal 7 ("Ensure environmental sustainability") has a health component as well, as poor environmental conditions often lead to deleterious effects on human health and a safe environment is a precondition to good health.

Yet, while this shows the deep concern of the international community to improve health worldwide, a discussion of whether there is a "right to health" in international law, and, if so, the contours of that right, the definition of to whom the right appertains and against whom it may be enforced, and the implementation of the right, is far more complex. To answer this question, one must first examine the classic and modern conceptions of international law.

In the classic conception of international law, the subject concerns the rights and obligations of sovereigns rather than private actors. "[I]nternational law is regarded as [a] set of objectively valid norms that regulate the mutual behavior of *states*."⁴ Similarly, the Restatement (Revised) of International Law \$102(1), affirms that "[a] rule of international law is one that has been accepted as such by the international community of states (a) in the form of customary law, (b) by international agreement, or (c) by derivation from general principles common to the major legal systems of the world."⁵

The crucial idea here is the acceptance by the community of *states*, rather than private actors or even international organizations, that a particular doctrine is part of international law. States may themselves decide to incorporate private actors into a scheme of international law, but this requires the affirmative action of States.⁶

This conception of international law is equally applicable to international human rights law. Human rights law has traditionally concerned obligations of and rights against governments, not private actors. Consequently, "human rights" were thought to include basic civil and political rights—for instance, guarantees against slavery, torture, arbitrary detention, extrajudicial killing, and governments acting with impunity against their citizens. Whether governments could be subject as a matter of international law to any kind of enforcement of these principles was, however, a very different question. The traditional answer is that they could not be, except through a treaty which bound the subject government and, for many States, including the United States, which also either was executable by its own terms under domestic law or had been incorporated by express enactment into domestic law. Certainly if governments took actions against the citizens of *another* country, international law principles could be invoked and the government of the affected country could seek to take action, but international law as such had no real enforcement mechanisms against governments for violations of their own citizens' rights, save war.

After the Second World War, the adoption of the United Nations Charter, the Universal Declaration of Human Rights,⁷ and other documents as discussed below opened the way to a new dimension of human rights as a subject of international law. Increasingly, on the basis of these documents, the proposition has been advanced and accepted by many states that international law, particularly in the form of international human rights law, broadly encompasses socioeconomic rights such as the right to work, the right to housing, the right to education, and the right to health care.⁸

So far, this is relatively uncontroversial. Yet recently some in the international legal community have been pressing for even further expansions of international law in the area of socioeconomic rights. In one notable recent exposition of this view, Louise Arbour, the United Nations High Commissioner for Human Rights, declared at the opening of the 61st session of the UN Commission on Human Rights this past Spring that: "Socioeconomic rights have the status of binding law. . .bringing them from the realm of charity to the realm of justice, and developing a body of ever growing jurisprudence by which we can be guided in bringing these vital rights to the reality of people's lives."⁹

Recognizing the evident difficulty of domestic enforcement of socioeconomic rights, however, Commissioner Arbour further hoped that "agreement can soon be reached to allow the entry into force of an Optional Protocol to the International Covenant on Economic, Social and Cultural Rights giving rise to a legal process that would allow individuals to bring their claims before an international forum in those situations where national recourse has been found wanting."¹⁰

While it would surely be some time before any such Optional Protocol could come into force and in any event would apply only to those states which ratified it, this statement is as audacious as it is open-ended. How could an appropriate level of socioeconomic rights justifying intervention by an international legal forum be defined? Moreover, how could these rights, or even the decisions of such a tribunal, be enforced? Are national officials to come to trial, as indicted war criminals do to the Hague or Arusha? Would such an indictment or a conviction end the national officials' responsibility for conduct of their own government? More basically, when states seek to assure a high standard of living for their own people, is that merely "charity," or is it rather the working of representative government and market-oriented economics—systems designed to ensure that governments keep the welfare of their citizens as the highest priority? And what does the implicit criticism of "charity" here mean for private industry, which has responded generously by providing programs to bring humanitarian goods, including pharmaceuticals, to needy people in their own countries and around the world?

States may of course establish whatever rights they wish for their own citizens and enforce those rights through appropriate domestic mechanisms. Indeed, legal scholar Paul Hunt of the Human Rights Centre at Essex University in the United Kingdom has noted that over 60 countries have enshrined a "right to health care" in their own constitutions.¹¹ But that in no way proves that the "right to health" is of itself a proper subject of *international* law, strictly considered under the traditional definition. Rather, the right derives from the affirmative acceptance by States that certain rules are binding on them, either as rules of general law or from their accession to treaties and conventions to which they have become parties. It is from this process that the right to health in international law exists.

Indeed, an analysis of special situations proves the point that the traditional standard of international law, such rights as the right to health care are strictly limited: States have an obligation to provide a certain level of health care for prisoners of war under the relevant Geneva Convention,¹² for instance, but this merely shows that the obligation runs to States rather than being simply a specific socioeconomic right pertaining to all individuals.

In any event, if a right to health is violated, other, more basic political and civil rights have likely been violated. If (for example) Tibetans, Darfurians, or Karen Christians are denied equal access to health care by virtue of government action, it is probably not their right to health as such that is being violated—though that is a result—but their clear right to equal treatment and non-discrimination based on their race, religion, or ethnicity. Furthermore, it is a fair bet that the discrimination does not stop at health care but most likely includes other concerns such as equal access to employment and housing and the rights of freedom of religion and freedom of speech, and, in extreme cases such as Darfur, even the right to life.

Sources of the "Right to Health" in International Law

The World Health Organization (WHO) was founded in 1948, and its Constitution came into force at that time.¹³ Its establishment, however, was prefigured in the United Nations (UN) Charter, which evidences an interest in human health as among the goals of the organization. For instance, Article I.3 of the Charter speaks of the need "[t]o achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character" (Article 13.1(b) gives this power to the General Assembly).

Similarly, Article 55 states that the United Nations shall promote "solutions of international economic, social, health, and related problems [.]" Under Article 56, Members "pledge themselves to take joint and separate action in co-operation with [the UN]" to achieve the purposes of Article 55. However, compliance with this provision is surely achieved by a UN member state's membership of and active involvement in the WHO. The provision is not selfexecuting; WHO cannot simply order a member state to take specific actions such as approving or banning pharmaceutical products. There is an elaborate governance system in the WHO, but the organization's actions and effectiveness in practice depend on the cooperation and affirmative decisions taken by the member states.

Finally, Article 62 of the United Nations Charter grants to the Economic and Social Council (ECOSOC) powers to prepare reports on the subject of health, prepare draft conventions, and call international conferences. Again, it is worth remembering that all of these are statements of positive law, or derived from the treaties themselves. There is no requirement that States must attend these conferences or ratify the conventions as a part of their membership of the United Nations, ECOSOC, or the WHO.

Next, the Universal Declaration of Human Rights,¹⁴ adopted in 1948, while not stating a "right to health" as such, provided that:

Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international cooperation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.¹⁵

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.¹⁶

Also in that year, the Constitution of the World Health Organization was adopted. The Preamble to the Constitution declares that "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. . . . The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic, or social condition." In Article 1 of the Constitution, the achievement of "the highest attainable standard of health" is called the objective of the WHO.¹⁷

Similarly, Article 12 of the International Covenant on Economic, Social, and Cultural Rights sets forth the principle of the "highest attainable standard of physical and mental health."¹⁸ Among more modern treaties comprising what is commonly referred to as international human rights law, the right to health is addressed in Article 24 of the Convention on the Rights of the Child (CRC),¹⁹ in Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW),²⁰ and in Article 5 (e)(iv) of the International Convention on the Elimination of All Forms of Racial Discrimination (CERD).²¹

Perhaps the most comprehensive and direct example of a right to health is in the proposed Constitution for Europe, which states in Article II-95 that "[e]veryone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."²²

With the exception of the Constitution for Europe (which would in any event be limited in application to the Member States of the European Union), the covenants discussed above were signed and ratified by (among the major industrialized nations) Italy, France, Germany, Canada, Switzerland, and Japan, and none of these states entered reservations to the conventions with respect to the application of the right to health of all the peoples under their jurisdiction. The states' parties to the conventions are also obliged to make periodic reports to the Committees that oversee these covenants and justify their approach or inaction before a panel. On the other hand, the United States, which is a signatory to all the aforementioned covenants, has chosen to ratify only the CERD but has entered a reservation on the relevant article concerning the right to health (among other reservations to the Convention).²³ In so doing, it has extricated itself from this obligation. With respect to the other conventions, the United States' signature does not complete the ratification process and is of political significance only. The conventions would come into force for the United States only upon ratification by the Senate,²⁴ subject to any reservations the Senate adopts.

Whereas the United States and the United Kingdom have "pledged" to cooperate with the UN in order to achieve the "observance of human rights" contained in the Universal Declaration of Human Rights, the latter is not legally binding but was rather intended for launching the pivotal International Convention on Economic, Social, and Cultural Rights and the International Covenant on Civil and Political Rights. Notwithstanding this, the other covenants of relevance to this synopsis, the ICESCR, CRC, CEDAW and CERD, are legally binding on States Parties to those conventions.

A fundamental principle of international law is that States that bring treaties and conventions into force for their jurisdictions are bound by their provisions-the crucial doctrine, formed by Grotius, of pacta sunt servanda. As the various reservations adopted by the United States to the CERD indicate, the different nature of the U.S. legal system, including its federal system, is one important reason why the United States has declined to ratify the Convention on the Rights of the Child,25 the Convention to End Discrimination Against Women,26 and other proposals that have served to dramatically expand the reach of international human rights law. In brief, the United States' position seems to be that international human rights law-indeed, international law more generally-should be well-defined rather than a fluid document, and treaty-based rather than flexible and evolving.

Scholars such as Paul Hunt, who is the UN Rapporteur on the right to health, and activists in many nongovernmental organizations have, however, sought to read these texts expansively to establish socioeconomic rights more broadly in international law. This is in despite of the evident lack of consensus that they in fact form customary law (as discussed below) and the numerous difficulties that would in any event accompany actual enforcement of these provisions, either against states parties to the conventions or, even more broadly, to private actors who are not subject to the conventions.

Based on the various provisions of international human rights law that address the right to health,²⁷ Hunt has summarized his definition of the right to health as follows:

The right to health includes the right to health care-but it goes beyond health care to encompass adequate sanitation, healthy conditions at work, and access to health-related information, including on sexual and reproductive health. It includes freedoms, such as the right to be free from forced sterilization and discrimination, as well as entitlements such as the right to a system of health protection. The right to health has numerous elements, sort of sub-rights, including maternal, child, and reproductive health. Like other human rights, the right to health has a particular preoccupation with the disadvantaged, vulnerable, and those living in poverty. Although subject to progressive realization, the right imposes some obligations of immediate effect, such as the obligations of equal treatment and nondiscrimination. It demands indicators and benchmarks to monitor the progressive realization of the right. . . [D]eveloped states have some responsibilities towards the realization of the right to health in poor countries -we learn this from the Millennium Declaration, including MDG 8, as well as the provisions of international human rights law on international assistance and cooperation.²⁸

One wonders whether many delegates to the UN Commission on Human Rights would as enthusiastically agree that developed countries have a responsibility towards the realization of the right to life in Sudan or Baathist Iraq, the right to peaceable assembly in Uzbekistan, the right to religious freedom in Saudi Arabia, or the right to freedom of the press in any number of countries around the world. Still, the quotation shows that at least with respect to the area of socioeconomic rights, the burden falls on developed countries to assist in ensuring implementation—though not enforcement as such—of these rights.

One example of a broad reading of socioeconomic rights in practice appears in paragraph 13 of the General Comment to Article 12 of CEDAW, which notes, "The duty of States parties to ensure, on a basis of equality of men and women, access to health-care services, information and education implies an obligation to respect, protect and fulfill women's rights to health care. States' parties have the responsibility to ensure that legislation and executive action and policy comply with these three obligations. They must also put in place a system that ensures effective judicial action. Failure to do so will constitute a violation of article 12." While the principle here is one of equal access to health care, rather than equality of delivery or still less equality of results (which in any event is surely impossible), nevertheless the General Comment shows that the scope of the article is broad and expansive. No one questions the goals; ensuring the health of women is crucial for development. But, as discussed below, unless it is clear that the obligations established by these treaties fall only on states, this can raise particular dangers in implementation and practice, not least for the private sector.

Hunt himself admits that

General Comments are not binding documents. But, based on the Committee's long experience, they are intended to shed light on the contours and contexts of the right in question. Many economic, social, and cultural rights are worded vaguely. How can one reasonably expect a state to honor its obligations in relation to economic, social and cultural rights when the rights are so imprecise that it is not clear what they mean? So the Committee's General Comments are designed to help states, *and other actors*, by clarifying the Committee's understanding of what the rights means [sic].²⁹

Americans should understand that much of international human rights law derives from a framework far more similar to civil law principles than to the Anglo-American common law tradition. While it is clear and uncontested that *travaux préparatoires* form an integral part of the interpretation of international treaties, the different principles underlying the UN system helps one to understand the higher position that documents such as General Comments and continuing actions of Committees established by various treaties compromising international human rights law have in the UN system in interpreting the treaties themselves and show how the interpretation of the treaties can change over time.

In short, some scholars and activists working in this area have sought to distort and not so subtly broaden the nature of the right to health agreed to by states which have ratified the various conventions comprising international human rights law. In the classic conception, the issue is not about the entitlement to health care per se but rather to equal *access* to health care. Fortunately, some references in the treaties comprising international human rights law themselves speak of equal access. However, with the new conception of international law, there is a clear danger that the subject could be beginning to encompass not only the question of citizens' rights relating to their own sovereign but also supposed obligations towards the international community.³⁰

There is as well a danger that international human rights law could be moving in the direction of attempts to elevate multinational companies to the rank only held by states in international law and to usurp the role to the state³¹ by, for instance, using a committee to review the policies and practices of pharmaceutical companies under the rubric of enforcement of the right to health. This is a radical departure from the traditional understanding of international law and is unwarranted by the texts of international human rights treaties themselves.

The Obligation to Provide the Right to Health Rests with Sovereigns

Let us be clear: the right to health in international law exists for those States which have chosen to ratify these pacts but does not, indeed cannot exist, for those States which have not, still less for private actors such as the pharmaceutical industry. It is ironic indeed that some States which focus on socioeconomic rights to the exclusion of political rights are also those which might prove singularly unwilling to permit challenges to their authority based on the conventions themselves.

The right to health, as with other socioeconomic rights, is based on treaties. In no way are these rights part of customary international law, both because important nations such as the United States have declined to ratify many of the conventions concerned and because state practice among many of the states which have ratified the conventions shows that they are in far too many instances practically unenforced.

One common UN definition of human rights also states that the obligations established by international human rights treaties belong to governments: Human Rights are universal legal guarantees protecting individuals and groups against actions which interfere with fundamental freedoms and human dignity. Some of the most important characteristics of human rights are that they are:

- · guaranteed by international standards;
- · legally protected;
- · focus on the dignity of the human being;
- · oblige states and state actors;
- · cannot be waived or taken away;
- · interdependent and interrelated; and
- universal.32

Obviously one crucial question concerns the achievement of the right in everyday life. Who, then, is responsible for providing the right to health? As the definition given above indicates, the answer is simple: sovereign governments. This is reaffirmed by the Preamble of the WHO Constitution: "Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures."³³

General Comment No. 14 (2000) to the ICESCR on "The right to the highest attainable standard of health" is useful for defining the role of states and the obligations of actors other than the state. This interpretive guidance rightly takes the view that apart from the state, the "other actors" mentioned in Articles 22 and 23 of the ICESCR refer to the other UN agencies and organizations³⁴ and not to the private sector. The obligations here pertain solely to sovereigns.

Countries also *enforce* the right to the degree they are willing or able to do so. Private sector actors such as the pharmaceutical industry can and certainly do undertake measures to help governments and other parties attain the aims of the right to health, as discussed below, but the responsibility for attaining this goal (and thus compliance with the treaties) rests with governments. Still less do the treaties require any particular form or method of attaining the goal; governments remain free to act in the way they choose.

Consequences of the Focus on Socioeconomic Rights

From the traditional perspective of international law, the new focus on socioeconomic rights, as well as the interpretation of these rights as encompassing obligations towards the international community, has several important consequences: First, in the international context, it (perhaps conveniently) can deflect attention away from gross human rights abuses in the traditional areas of focus, political and civil rights, including the right to life and to security of the person. Second, it can weaken the structure of international law by proposing to elevate to the structure of binding law rights which by their very nature are not readily susceptible of enforcement. Third, particularly with respect to the right to health, there is a danger that the new focus on socioeconomic rights can permits states asserting this right on behalf of their own citizens or the international community to criticize private actors, such as pharmaceutical manufacturers, for supposedly violating this right by not giving up their proprietary research, information, and products—even though doing so would have the deeply ironic and deleterious effect of retarding innovation and thus weakening the ability of the private sector to advance the health of millions of people around the world.

Fourth, the corollary of this last point is an increasing belief that private actors, no less than states, are proper subjects of international law. As noted above, states are free to make this shift through international agreement. They have not yet done so. It is a much further and more intrusive step, however, to seek to enforce socioeconomic rights on other states which have not signed these treaties and still more intrusive to extend their reach to encompass enforcement against private actors.

Specifically with regard to the pharmaceutical industry and similarly affected industries, a broad reading of the right to health may have additional consequences. First is the increasingly common view that the pharmaceutical industry has an obligation to ensure the availability and accessibility of, at a minimum, essential medicines³⁵ as defined by national governments or (from another perspective) some portion of the international community. Second, there is a view, following from this, that patent protection itself is impinging on the right to health in the developing world (or even the developed world). Hence the position that intellectual property rights should be limited and perhaps eliminated in certain cases and that companies do not have an absolute right to price their products at a cost which recoups their investment and permits a reasonable profit, some of which is reinvested in additional research and development activities. Third, if one accepts that the right to health is held by the public (or, more usually, by national governments in trust for the public), transnational companies have a wide variety of disclosure and self-reporting obligations respecting R&D, their expenditures, and their clinical trial practices. The right to privacy of their scientific research can thus be severely circumscribed. In this regard, at the 2005 session of the UNCHR, there was a sharp debate over whether a resolution on transnational corporations should even acknowledge their positive contributions at all.

A few examples will illustrate the dangers:

To end litigation in Thailand, the U.S. company Bristol-Myers Squibb surrendered its right to produce the drug didanosine (sold as Videx®), making a decision to "dedicate the product to the people and government of Thailand." This had been the case even though the Thai government had already refused a request for compulsory licensing. Director of the Foundation for Consumers Saree Ongsomwang, stated that "[t]his case can be an example for other consumer organizations in other parts of the world if people cannot access pharmaceutical products, they can use their rights to basic needs as a consumer."³⁶ While the litigation specifically concerned the scope of the patent, it is easy to see how activists and other parties could attempt to use the new international treaties granting a right to health to argue for compulsory licensing and other remedies on the grounds of the "rights to basic needs as a consumer." For the countries concerned, however, the danger, of course, is that foreign companies could decide to exit the market. But, a government could respond to this rational step by escalating the stakes: actually breaking the internationally valid patent held by the pharmaceutical company.

Worse, there could easily be specific consequences for human health with regard to use of generic drugs which have not gone through typical testing by a stringent regulatory authority such as the United States Food and Drug Administration, the European Medicines Evaluation Agency, the Swiss Federal Office of Public Health, or the Japanese Ministry of Health. For instance, there is a danger that use of unapproved drugs could lead to under dosage of patients, possibly resulting in mutations of a virus—an exceptionally serious consequences for a virus like HIV, possibly jeopardizing the remarkable progress made to date in the fight against HIV.³⁷

Responding to concerns that a new type of drug combining three drugs had not undergone separate testing and evaluation, one physician noted,

Many health experts are rightly skeptical of a one-size-fits-all approach to a complex disease that doctors in the West routinely treat with a flexible armament of drugs, adjusted to each patient according to that individual's needs. . . . In rural Africa, where sophisticated medical care is lacking, a calculable percentage of patients will become very sick or even die from the nevirapine component of this three-in-one drug. Thus the dilemma: the need to balance drug-related deaths and illness from using Triomene against the numbers of people who would go untreated altogether if aid agencies adopted a flexible but more expensive strategy."³⁸

No one expects clinical practice in the developing world to have the same standard as in the developed world; regrettably, the resources in many cases are simply not present. However, one can and should expect that Western governments at least recognize the medical dilemmas here before adopting a particular policy.

While efforts to use the new human rights treaties as grounds for action against transnational companies have heretofore focused primarily on suggestions that pharmaceutical companies either make their products available at low or no cost (thus denying them the ability even to recoup the costs of developing the products), the views of some are considerably more extreme. Referring to the unavailability of antiretroviral therapy for all HIV sufferers who need it, Stephen Lewis, the special representative for AIDS for UN Secretary General Kofi Annan, stated on January 8, 2003 that "There may yet come a day when we have peacetime tribunals with this particular version of crimes against humanity."³⁹ Commissioner Arbour's view of simple enforcement through international tribunals, radical enough itself, is taken to another level by the implication of invoking criminal proceedings.

On the positive side, however, some governments have shown a willingness to address this issue in the international context. in spite of the numerous international treaties between states and other voluntary codes of conduct drawn by corporations, 38 states, including the United Kingdom, Germany, France, Italy, and Switzerland (all of whose pharmaceutical companies are well represented in the global market) have successfully lobbied for the appointment of a special UN representative on the issue of human rights and transnational corporations who will not only identify and clarify corporate responsibility and accountability but also monitor sphere of influence and complicity in human rights violations.⁴⁰ These states, however, are already states parties to the ICESCR and thus already have obligations to monitor companies that violate those provisions. Further, a number of governments have previously opposed the adoption of the optional protocol to the ICESCR discussed above because they did not want reports from individuals on state abuses of human rights to come under scrutiny of the committee.

Using the New Treaties: An Alternative Strategy

How can those who favor a more traditional interpretation of international law, including international human rights law, respond to the attempt to read international human rights treaties more broadly than their plain terms would allow?

Given that international law works to a large degree on consensus, a radical shift is not inevitable, so long as some states resist its transformation. An alternative strategy is simply to shift the terms of debate. Accepting the treaties discussed above as binding on the states which signed them, there is nothing to indicate what, if anything, in those treaties privileges certain socioeconomic rights above others. Rather, a strategy of using the new treaties to reaffirm the fundamental principles of free inquiry into and free ownership of the results of scientific research would focus upon and accentuate different provisions of human rights instruments which should be given equal weight with other provisions in the same treaties. This approach has the virtue of viewing the treaties concerned as unified documents and treating socioeconomic rights as a whole, not privileging some over others.

For instance, the Universal Declaration of Human Rights states that "[e]veryone has the right to own property" and "no one shall be arbitrarily deprived of his property."⁴¹ With respect to intellectual property, such as research into pharmaceutical products, Article 27 declares that "[e]veryone

has the right to the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author.³⁴² It follows naturally that the author or inventor of such writings or discoveries has the right, through freedom of contract, to alienate these interests to another person, a corporation, or an organization such as a non-governmental organization.

Similarly, the Convention on Economic, Social, and Cultural Rights recognizes "the right to work" and says that states should adopt policies and techniques to achieve steady economic. . .development. . .under conditions safeguarding fundamental economic freedoms to the individual."⁴³ States Parties to the Convention also "undertake to respect the freedom indispensable for scientific research and creative activity."⁴⁴ This freedom is limited indeed if states are able to take away the fruits of that research at will.

In a remarkable parallel which may almost be read as a corrective commentary on the clause in the Preamble of the WHO Constitution that "[u]nequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger,"45 the Vienna Declaration and Programme of Action of the World Conference on Human Rights stated in contrast that "[w]hile development facilitates the enjoyment of all human rights, the lack of development may not be invoked to justify the abridgement of internationally recognized human rights."46 This clearly encompasses the rights of intellectual freedom and of ownership of property, including intellectual property. Under the scheme of the Universal Declaration and the ICESCR which grew from it, States cannot arbitrarily deprive researchers or owners of their intellectual property. One can perhaps even take this a step further to argue that if particular provisions of a treaty are to be interpreted by reference to the treaty as a whole, then provisions relating to health and private property would interact to support the proposition that there is an international principle favoring the use of market-oriented mechanisms to develop and distribute new drugs.

In short, international human rights law both recognizes property interests—which clearly includes property interests held by corporations as well as private individuals—and protects against their unreasonable alienation to or expropriation by governments. Moving beyond the strictly legal sphere, one may also easily make the argument that market-oriented economic policies focusing on economic growth and protection for internationally recognized intellectual property rights actually promote economic and social development, thus achieving the goals of the treaties themselves and, more practically, making more national resources available which may be used by both governments and the private sector to provide better access to health care and a better quality health care.

Industry Responses

Despite the real toll in human suffering and the tragedy of diseases such as AIDS, the situation is not as gloomy as Stephen Lewis' comment quoted above would suggest. As noted earlier, the right to health in international law gives obligations and responsibilities to governments. However, progress in achieving more comprehensive health care is best advanced when governments work cooperatively with the domestic private sector, all types of civil society organizations, and international companies.

There are, fortunately, numerous examples of industry working with governments to assist in improving health care for their people. Of the many possible examples from which to choose, this paper will highlight a few early interventions in response to the AIDS crisis, to show that the response of transnational corporations is not simply a reaction to WHO Director General J.W. Lee's declaration of AIDS as a "global emergency" in 2003 or to the discussions of intellectual property rights in the context of the Doha Round of the World Trade Organization.

To take but a few examples:

In December 2000, the U.S. company Pfizer, Inc. and South Africa agreed on Pfizer's donation of US \$50,000,000 of its drug Diflucan® for two-types of AIDS-related concomitant infections affecting about 40% of AIDS patients.⁴⁷ Crucially, the donation is targeted to those who cannot afford to pay for the drug. The company can still market it to private patients approximately four times above the rate for government purchases. Thus, under the scheme there are effectively three levels of price in South Africa: the private rate, a sharply lower rate for government purchases (which surely reflects not only compassion and targeted marketing to a lower-income group but also economies of scale and the strong, near monophony power of many national health ministries), and the donated drugs.

In April 2003, Gilead Sciences, Inc. announced that it would sell tenofovir disoproxil fumarate (Viread®), its HIV/ AIDS drug, to 68 developing countries at cost. The company has also worked with the AIDS Healthcare Foundation to support a clinic's expansion to 1,000 patients on ARV therapy through donations of its proprietary drugs, including the then-recently approved emtricitabine (Emtriva®).⁴⁸

Private foundations have also played a role. The William J. Clinton Foundation, founded by the former U.S President, negotiated an agreement with Indian and South African makers of generic drugs "to sell the drugs for \$140 per patient per year if large orders were guaranteed, payment was in cash and the drug maker did not have to pay the legal and lobbying costs of getting each drug licensed in country."⁴⁹ Yet this did not mean an endorsement of compulsory licensing or an abandonment of international intellectual property rights. Rather, a joint announcement on April 6, 2004 of the William J. Clinton Foundation, the Global Fund to Fight AIDS, Tuberculosis and Malaria,

UNICEF, and the World Bank noted that "[a]ll four organizations support strong protection of intellectual property" and further noted that "[s]ome compounds can be purchased most cheaply through procurements from patent-holding manufacturers."⁵⁰

The overall environment with respect to AIDS drugs has been one of declining prices generally, including from use of generics that do meet international standards.⁵¹ As of 2003, GlaxoSmithKline had agreements to make Combivir® antiretroviral therapy able to non-profit organizations for as little as 65 US cents per day. In that year, the company shipped 10,000,000 tablets of preferentially-priced ARV medication, including 165 agreements in 56 countries, of which 17 agreements were with private companies who provide treatment to their uninsured employees.⁵²

Perhaps the best known industry initiative is the Accelerating Access Initiative (AAI). The AAI brings together states, international organizations, and pharmaceutical companies with the aim of increasing access to medication for HIV/AIDS in developing countries by making the drugs more affordable. Forty-nine countries have already reached an agreement on reduced prices for HIV treatment with the companies concerned. AAI has increased the number of people taking triple ARV therapy ten-fold in Africa since May 2000.⁵³

Quite simply, the pharmaceutical market today is global. As GlaxoSmithKline PLC executive Jean Stephenne stated in commenting on the test of a vaccine against rotavirus, "Our business model is to supply vaccines to the world, not just the U.S. and Europe."⁵⁴ The company also responded to an urgent WHO request for a vaccine against a new strain of meningitis and sold 6,000,000 doses for just US \$1.00 per dose. However, in this instance, donors had to help cover the costs.⁵⁵

These examples all help to show that "[i]n combined donations, the pharmaceutical companies are giving more money to AIDS charity in Africa than many European/OECD *governments* are giving in annual aid for AIDS to Africa!"⁵⁶

Yet the opposition to these efforts by some has been equally strong. One prominent U.S. activist organization greeted Boehringer-Ingleheim GmbH's early announcement of donations of Viramune® for HIV-infected pregnant women with the view that it was "completely unethical" to provide these drugs; instead, "[t]he only acceptable program must provide a clear plan for treatment to women and other infected family members, as well as assurance of medical follow up and treatment for mothers and babies." The release further stated that donations "must not be allowed to obscure efforts to increase access through means such as compulsory licensing and parallel importing. Any country doing generic production or importation of nevirapine must not be excluded from this offer.⁵⁷ In other words, only if a pharmaceutical company agreed to essentially underwrite the health care system of a family or village for a lifetime and also agreed to eliminate its market share even among patients who can afford the drugs through compulsory licensing and parallel importation is the donation acceptable. Not only would there be no donors under such a system, but even if sound could be found, they would have little to donate in the future. As British Prime Minister Tony Blair reminded the World Economic Forum in Davos in February 2005, the first responsibility of business is to "make a profit."⁵⁸ Without that, there would be no corporation and hence no ability even to discuss the idea of corporate social responsibility.

Further, within the implementation of the right to health itself, what grounds are there to privilege one part of that right-the alleged need to invoke compulsory licensing of pharmaceutical products with the implicit or explicit threat of breaking patents—over the failure of domestic governments to strengthen their own health delivery systems⁵⁹ or to pursue policies that lead to economic growth and increasing national wealth which could lead to greater resources, both public and private, available for health care ?⁶⁰ An expropriated (or donated) vaccine can do nothing to help a child if proper refrigeration is not maintained in the delivery system. Taxes,⁶¹ tariffs, and other government policies can also weaken the ability of ordinary citizens to purchase health care for themselves or to have access to health care products paid for by private, bilateral, or multilateral donors.

Rather than simply criticizing industry, a better approach to the right to health would be to reaffirm the original intent of the various international human rights treaties and focus instead on national governments' own actions with respect to their own health care priorities. As WHO Director General J. W. Lee said on September 23, 2003, "Today, we have medicines to treat AIDS patients for a dollar a day or less but these medicines are not getting to the people who need them. . .Investing in treatment for AIDS also means strengthening health systems. This will benefit all those who require health care, for AIDS, for TB and for any other health needs."62 As the obligation to fulfill the right to health pertains in the final analysis solely to governments, ensuring that the responsibilities remain there as well would also be more consistent with a traditional approach to international law readily accepted by all in the international community.

* John S. Gardner is the former General Counsel of the United States Agency for International Development. The author would like to thank Mr. Leonard Leo of the Federalist Society, Washington, D.C., for the use of his notes from the 61st Session of the United Nations Commission on Human Rights.

Footnotes

¹ John Adams, Dissertation on the Canon and the Feudal Law (1765).

² G.A. Res. 55/2, UN Doc. A/RES/55/2 (Sept. 18, 2000).

³ The Millennium Declaration may be found at http://www.un.org/ millennium/declaration/ares552e.pdf (last visited Sept. 9, 2005).

⁴ HANS KELSEN, PURE THEORY OF LAW, 215 (Knight trans. 1967) (emphasis added).

⁵ RESTATEMENT (SECOND) OF INTERNATIONAL LAW, § 102; *see also* (RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES). *See also* Article 38 of the Statute of the International Court of Justice: 1. The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:

a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;

b. international custom, as evidence of a general practice accepted as law;

c. the general principles of law recognized by civilized nations;

d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

⁶ Perhaps the best example of this is the International Federation of Red Cross and Red Crescent Societies, which has international personality even though the most of the national societies are not themselves state actors. The Global Fund to Fight AIDS, Tuberculosis and Malaria has also signed a headquarters agreement with the Swiss Confederation which confers similar rights on it.

⁷ Universal Declaration of Human Rights, G.A. Res. 217A (III) at 71, U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc. A/810 (Dec. 12, 1948). (The Universal Declaration was actually adopted by the General Assembly on December 10, 1948.).

⁸ *Charter of Economic Rights and Duties of States*, G.A. Res. 3281, U.N. GAOR, 29th Sess. (Dec. 12, 1974).

⁹ The speech may be found at http://www.unhchr.ch/huricane/ huricane.nsf/view01/527ED2F6E7DD06ADC1256FC400406C8D? opendocument?.

¹⁰ Id.

¹¹ As have several states in the United States, *see, e.g.* N.Y. CONST. art. XVII, § 3: "The protection and promotion of the health of the inhabitants of the state are matters of public concern and provision therefore shall be made by the state and by such of its subdivisions and in such manner, and by such means as the legislature shall from time to time determine." This provision was adopted in 1938.

¹² Geneva Convention relative to the Treatment of Prisoners of War, (Aug. 12, 1949, entry into force Oct. 21, 1950) arts 2, 13, and 15. Article 15 states the principle most directly: "The Power detaining prisoners of war shall be bound to provide free of charge for their maintenance and for the medical attention required by their ¹³ According to the official statement of the WHO, "[t]he Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (*Off. Rec. Wld Hlth Org.*, 2, 100), and entered into force on 7 April 1948."

¹⁴ Universal Declaration of Human Rights, G.A. Res. 217A (III) at 71, U.N. GAOR, 3d Sess., 1st plen. Mtg., U.N. Doc. A/810 (Dec. 12, 1948). (The Universal Declaration was actually adopted by the General Assembly on December 10, 1948.).

- ¹⁵ Id., art. 22.
- ¹⁶ *Id.*, art. 25(1).
- ¹⁷ WHO CONST., art. 1.
- ¹⁸ The complete text of the article states:

1. State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2. The 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:

a. The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

b. The improvement of all aspects of environmental and industrial hygiene;

c. The prevention, treatment and control of epidemic, endemic, occupational and other diseases,

d. The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

¹⁹ Convention on the Rights of the Child, GA Res 44/25 (Nov. 20, 1989).

²⁰ Convention on the Elimination of All Forms of Discrimination Against Women, GA Res. 34/180 (1979). Article 12 reads: "1. 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. 2. Notwithstanding the provisions of paragraph I of this article, States Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation."

²¹ International Convention on the Elimination of All Forms of Racial Discrimination, GA Res. 20/2106 (Dec. 21, 1965).

²² EUR. CONST., art. II-95.

²³ The reservation may be found at http://www.unhchr.ch/html/menu3/ b/treaty2_asp.htm.

²⁴ U.S. CONST., art. II, § 2.

²⁵ Convention on the Rights of the Child, GA Res 44/25 (Nov. 20, 1989).

²⁶ Convention on the Elimination of All Forms of Discrimination Against Women, GA Res 34/280 (Dec. 18, 1979).

²⁷ Right to health care (Art. 12.2.d ICESCR); sanitation (Art. 24.2.e); healthy conditions at work (Art. 7.b and 12.2.b ICESCR); access to health-related information, including sexual and reproductive health (Articles 10.h., 14.2.b. and 16.e. CEDAW, Art. 24.2.f CRC);maternal health (Art. 10.2 ICESCR and Art. 12 CEDAW); child health (Art.12.2.a ICESCR and Art.24 CRC); sterilisation (Art. 16.e. CEDAW); non-discrimination (Art. 2.2 ICESCR); responsibility of developed states vis-à-vis developing states (only in Art. 24.4 CRC); disadvantaged, vulnerable and poor (Preamble ICESCR).

²⁸ Paul Hunt, Presentation at the panel discussion on the Rights to Sexual and Reproductive Health, 10th Canadian Conference on International Health (Oct. 28, 2003) *available at* http://www.acpd.ca/ acpd.cfm/en/section/csih/articleid/223.

²⁹ Paul Hunt, The Right to Health: New Opportunities and Challenges, Speech at the Plenary Session, 10th Canadian Conference on International Health, (Oct. 28, 2003), *available at* http:// www.acpd.ca/acpd.cfm/en/section/csih/articleid/221 (last visited Aug. 9, 2005) (emphasis added). To American ears, Hunt's phrase "contours and contexts" has a remarkably similar sound to the Warren Court's discovery of "penumbras, formed by emendations" of enumerated Constitutional rights. *See* Griswold v. Connecticut, 381 U.S. 479, at 484 (Douglas, J).

³⁰ It is notable how much discussion of the right to health has focused on issues regarding sexual and reproductive rights. *See, e.g.*, Paul Hunt, Presentation at the panel discussion on the Rights to Sexual and Reproductive Health, 10th Canadian Conference on International Health (Oct. 28, 2003) *at* http://www.acpd.ca/acpd.cfm/en/section/ csih/articleid/223 (last visited Aug. 9, 2005)("as [UN] Special Rapporteur on the right to health I have to submit a report to the UN General Assembly and also one to the UN Commission on Human Rights. Next month I submit by [*sic*] report to the Commission and I have decided that a significant section of this report—perhaps some three to four pages—will be on the rights to sexual and reproductive health."). Later in the same presentation, Hunt noted that "It is a source of regret that the [Millennium Development Goals] do not refer to sexual and reproductive health." *Id*.

³¹ See General Comment No. 14 (2000) to the ICESCR, "The right to the highest attainable standard of health." General Comment 14 clearly defines the role of the states parties to the Convention in the implementation of the right to health in their own jurisdictions and in monitoring that third parties do not violate this right.

³² CONSULTATIVE COMMITTEE ON PROGRAMME AND OPERATIONAL QUESTIONS, ADMINISTRATIVE COMMITTEE ON COORDINATION, THE UNITED NATIONS SYSTEM AND HUMAN RIGHTS GUIDELINES AND INFORMATION FOR THE RESIDENT COORDINATOR SYSTEM, 16th Sess. (2000) (emphasis added).

³³ WHO CONST., preamble.

³⁴ See also the Vienna Convention on the Law of Treaties, Articles 2.1.i and 5.

³⁵ For the WHO's definition of "essential medicines," *see* http:// www.who.int/topics/essential_medicines/en/: "Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; *exactly which medicines are regarded as essential remains a national responsibility*" (emphasis added).

³⁶ Amy Kazmin, *Thai Victory on Aids drug patent paves way*, FIN. TIMES, Feb. 20, 2004.

³⁷ In any event, the use of generic pharmaceuticals, some of which have not been subject to approval by a "stringent regulatory authority" (as defined by the WHO) or to continual review of Good Manufacturing Practices (GMP), can raise concerns over safety, as the withdrawal in 2004 of three Indian-made drugs from the WHO's approved list shows. See Dagi Kimani, Key Aids Drugs Dropped from WHO List, THE EAST AFRICAN, Aug. 9, 2004, available at http:// /www.nationmedia.com/eastafrican/09082004/Regional/ RegionalMain09082004.html. Of course, the company concerned should be commended for its prompt action in withdrawing its drugs from the international market once it discovered the quality concerns. Similarly, "[U.S. State Department Official Mark Dybul] added that if anything bad happened because the Bush program [the President's Emergency Plan for AIDS Relief. see 39 WKLY, COMP. PRES. DOC. No. 5, at 112 (Feb. 3, 2003)] used substandard drugs, 'you would crucify us for not have the due diligence of looking at the data ourselves - and rightly so." David Brown, AIDS Program Balks at Foreign Generics, WASH. POST, Mar. 27, 2004, at A3. See also Roger Bate & Richard Tren, The Cost of a Cure, NATIONAL REVIEW ONLINE, Jun. 15, 2004, found at http://www.nationalreview.com/comment/ bate tren200406150851.asp, reporting on a visit to Zambia: "At one of the best pharmacies we visited. . .the pharmacist said she encourages people to buy the patented version of GSK's [GlaxoSmithKline's] drug first, and then perhaps the generic alternative. Why? Because GSK drugs are better and of more reliable quality, and it is more likely that the GSK drugs are genuine, rather than the increasingly prevalent counterfeit copies. If a patient starts on the GSK drug and then switches to a generic, the pharmacist can note whether the generic is effective. If it's not, the patient can switch back to GSK's drug." The two researchers also noted that wholesalers sell generic drugs "at a significant premium to the announced price," id., thus reducing the price differential between generic and patented drugs.

³⁸ Sally Satel, *WHO's Dubious Bag of HIV Medicines*, LA TIMES, Jul. 1, 2004.

³⁹ Notes for Press Briefing, Jan. 8, 2003, *available at*: http:// stephenlewisfoundation.org/docs/20030108-UNPressBriefing.html.

⁴⁰ E/CN.4/2005/L.87.

⁴¹ Universal Declaration of Human Rights, art. 17.

⁴² Id., art. 27.

⁴³ ICESCR, art. 6.

⁴⁴ *Id.*, art. 15. *See also* Universal Declaration on Human Genome, 29th Gen Conf. of UNESCO, art. 14 (Nov. 11, 1997): "States should take appropriate measures to foster intellectual conditions favourable to freedom in the conduct of research."

⁴⁵ WHO CONST., pmbl.

⁴⁶ World Conference on Human Rights, Vienna Declaration and Programme of Action, (June 14-25, 1993) ¶ 10, U.N. Doc. A/ CONF.157/23 (July 12, 1993).

⁴⁷ Michael Waldholz, *Pfizer, South Africa Agree on Plan for Donations of AIDS Medicine*, WALL ST. J., Dec. 4, 2000.

⁴⁸ Available at http://www.aidshealth.org/newsroom/press/ press_archive/PR070203a.htm.

⁴⁹ Donald McNeil, *Plan to Fight AIDS Overseas is Foundering*, N.Y. TIMES, Mar. 27, 2004.

⁵⁰ See "Global Fund, World Bank, UNICEF Agreement" available at http://www.clintonfoundation.org/040604-nr-cf-hs-ai-pr-coalition-aims-to-provide-low-cost-aids-drugs.htm.

⁵¹ "Q. And what is the average price for a year of treatment? A. Now less than \$25 per month, but it's come down. It used to be \$1,000 per month." John Zarocastas, "Uganda leads in fight against AIDS," WASH. TIMES, Jun. 3, 2004, at A17. The response to the question was given by Brigadier General Jim K Muhwezi, Minister of Health of Uganda. *See also* comments of Richard G.A. Feachem, Executive Director of the Global Fund to Fight AIDS, TB, and Malaria, *in id., Global Fund optimistic about AIDS Battle*, WASH. TIMES, May 17, 2004, at A15:

> A few years ago, antiretroviral therapy cost something on the order of \$25,000 a year in the [United States] and might have involved taking 20 to 30 tablets per day. Today, antiretroviral therapy can cost as little as \$150 per year as a result of agreements between the Global Fund and the Clinton Foundation. It involves taking only two pills per day, and they are the same pills. You take one pill twice a day. Now, that is a revolution in cost and practicality of a kind that we have not seen in medical history. It's a most remarkable change in only three or four years.

⁵² Press Release, GSK (Jan. 19, 2004).

⁵³ See material on the AAI at http://www.ifpma.org/Health/hiv/ health_aai_hiv.aspx.

⁵⁴ [Anon.], Vaccinating the World's Poor, BUSINESS WEEK, Apr. 26, 2004.

⁵⁵ Id.

⁵⁶ Dave Kopel, Carlo Stagnaro, Alberto Mingardi, *Articles of Faith*, TECHCENTRALSTATION, Jul. 23, 2004, found at http://www.techcentra lstation.com/072304D.html.

⁵⁷ Press Release, ACT UP, found at http://www.actupny.org/reports/ durban-Boehringer.html (last visited Sept. 5, 2005). ⁵⁸ Alan Murray, When CEOs Have Tea With Tony Blair, WALL ST. J., Feb. 2, 2005, found at http://online.wsj.com/article/0,,SB11072967 4209542849,00.html.

⁵⁹ Governments' own priorities in health care are sometimes shocking, as outside evaluations have shown. For instance, one group of studies on neonatal health reached the conclusion that "Each year four million babies around the world die in the first month of life. More than half the deaths could be avoided with simple measures such as cutting umbilical cords with sterile blades, prescribing antibiotics for pneumonia and keeping newborns warm." David Brown, *Many Newborns Could Easily Be Saved, Researchers say*, WASH. POST, Mar. 4, 2005, at A16. *See also* [Anon.], *Women and children first*, THE ECONOMIST, Apr. 9, 2005, at 68:

While a complex set of factors, from AIDS to poor educational and economic opportunities for women, contribute to the problem [of newborn deaths], the technical solutions are well-known and relatively cheap —for example, immunisation to protect infants, and simple drugs such as magnesium sulphate for preeclampsia to deal with some of the complications of childbirth. But the key to solving the problem is not so much technology as organisation. The biggest challenge. . . is to find the political will—and the resources—to create primary-health care systems that bring together the public, private and informal sectors [.]

⁶⁰ "Africans are ill, unable to receive medical treatment and short of food because most African governments have kept people poor, frustrated trade and interfered with markets. By increasing economic freedom and enabling the private sector to thrive, Africa will be able to create the wealth that can build health infrastructure." Richard Tren, quoted in Kopel, et. al.; *supra* note 55.

⁶¹ See Kopel, et. al; supra note 55.

⁶² "Press Conference on AIDS treatment global health emergency, Sept. 22, 2003, found at: http://www.who.int/dg/lee/speeches/2003/ AIDS_treatment_pressconference/en/_committee/en/index.html.