

THE GLOBAL AIDS CRISIS: HUMAN RIGHTS, INTERNATIONAL PHARMACEUTICAL MARKETS AND INTELLECTUAL PROPERTY

Alan Berkman, MD*

Geneva, July 1998 (XII International AIDS Conference)

Fifteen thousand clinicians, scientists, AIDS activists and people living with HIV/AIDS (PLWHA) gathered on the shores of Lake Geneva under the slogan of "Bridging the Gap." Sessions addressing AIDS poor and developing countries were largely ignored by scientists and clinicians from the wealthy nations. None of the debates in the plenary sessions addressed how the global pandemic can be slowed. The pharmaceutical industry spent millions to entertain and influence doctors and researchers. The conference adjourned with no proposals on how to bridge the gap.

Durban, July 2000 (XIII International AIDS Conference)

Five thousand demonstrators, more than half of whom are African women, march through the streets of Durban wearing T-shirts that proclaim, "HIV Positive." They had just left a rally where international speakers and South African leaders, including Winnie Mandela and the Archbishop of Cape Town, demanded that international agencies and national governments mobilize to fight HIV and treat those with AIDS. A "Declaration of Durban" that outlined a plan of action against HIV/AIDS that combined treatment, care and prevention was presented by leaders of the demonstration on behalf of tens of thousands of signatories to the organizers of the conference and to the head of UNAIDS. The keynote speech the next morning by Judge Edward Cameron electrified the conference by echoing the demonstrators' demand for life-saving treatment. The realities of the global AIDS epidemic and, in particular, the need to expand treatment access dominate the conference.

I. INTRODUCTION

While not the proximate cause of the University of Connecticut School of Law symposium in December 2001, that demonstration in Durban can explain why a journal of international law considered it important to bring experts together to

* Alan Berkman has been a physician and a political activist for more than thirty years. He is an HIV medical specialist and has done a post-doctoral research fellowship in HIV prevention at the HIV Center for Clinical and Behavioral Studies at the New York State Psychiatric Institute. Under the auspices of the Mailman School of Public Health Fogarty program, he has served as a consultant to the South African Ministry of Mental Health and Substance Abuse. In 1998, he initiated the Health Global Access Project, a U.S.-based organization that has played a prominent role in the treatment access campaigns that have galvanized recent international efforts to confront the HIV pandemic.

discuss human rights and intellectual property rights in the context of the global AIDS crisis.

It is important to understand that context before addressing the issues of conflicting bodies of law. The global AIDS epidemic is a health catastrophe of unprecedented proportions. While AIDS in an individual is caused by a virus, the *epidemic* (its rapid spread, pattern of growth, catastrophic consequences) must be seen as much an economic, social and political phenomenon as a medical one. The fact that the epidemic is a *crisis* that is killing millions, reversing whatever economic gains have been made since decolonization in some of the most affected countries, and threatening the social fabric of those countries, is an indictment of the governments and international organizations (International Monetary Fund, World Bank, World Trade Organization, United Nations) that have controlled the direction of international development over the past two decades since HIV was recognized.

The deepening and expanding nature of this crisis points to the profound failure of these international organizations to generate a response designed to save lives and relieve suffering. For the first fifteen years of the epidemic this was masked by the absence of any treatment or vaccine. As long as HIV prevention was the only approach to the epidemic, the spread of the epidemic could be portrayed as a global tragedy caused primarily by individuals' sexual risk behaviors. The systemic factors (poverty, social discrimination, human rights abuses) that determine vulnerability to HIV infection were ignored or simply assumed to be as immutable as human behavior. The development of more effective treatment for HIV (antiretrovirals or ARVs) and opportunistic infections (OIs) had the potential to transform this seemingly irremediable tragedy into a public health opportunity for a comprehensive and effective program to stop the epidemic and ameliorate its impact. Rather than seize on that opportunity, the governments of wealthy nations, the international organizations they control and the multinational pharmaceutical corporations pointedly ignored these developments and continued with business as usual.

This profound failure and the moral indifference to human life and human rights that underlies it were clear by 1998 when the Geneva conference was held. People living with HIV/AIDS (PLWHA) in most of the world were confronted by the reality that their lives seemed to count for nothing in the global arena and that their own governments responded more to the demands of international trade and finance than to their suffering. Change, if it were to come, would be won as a result of social mobilization and political action.

That was the course engaged upon by PLWHA and AIDS activists from both the global South and their allies in the wealthy nations. Treatment was the issue that had the power and sparked the passion needed for social mobilization [see Csete for a succinct history]. The benefits of treatment in terms of extending life, reducing morbidity and preventing mother to child transmission of HIV were clear in the developed world and in Brazil, a middle-level country that had developed a model program that integrated treatment, care and prevention. Campaigns organized by organizations such as the Treatment Action Campaign (South Africa),

Health GAP (United States), Médecins Sans Frontières (international) and ACT-UP Paris (France) demanded expanded access to HIV and OI treatments. This demand, often articulated in human rights terminology [see Lazzarini], resonated among significant sectors of the most affected countries and mobilized a political constituency in the U.S.

The fundamental conflict, then, is about two radically different strategies for dealing with the global AIDS crisis. The dominant strategy, rooted in property rights and profit maximization, was not only responsible for the historical failure to contain the HIV epidemic but also had no new initiatives to suggest. The insurgent strategy, based on the human rights to life and health that reside in individuals, sees social mobilization as key to confronting the epidemic and demands that states (governments) and international organizations remove structural obstacles and supply the financial resources necessary for an integrated (treatment, care and prevention) response. This, then, is the context not only for the demonstration in Durban in July 2000 (see above), but also for the direct challenge to intellectual property rights posed by the demand for affordable and sustained access to pharmaceuticals needed to treat HIV and its related diseases.

II. INTELLECTUAL PROPERTY RIGHTS

The initial response of the dominant governments and international organizations to the demand for treatment was simply that it was unaffordable. The high prices for ARVs (US \$10-15,000/year) set by the large pharmaceutical companies were presented as the primary obstacle to expanded access. Treatment advocacy groups refused to accept this rationale, demanding to know the marginal cost of production of these drugs, exposing the inflated rate of profit earned by the multinational pharmaceutical companies and citing the potential for drastically lowered prices offered by generic manufacturers. Fair trade advocates working as part of treatment access campaigns pointed out that governments that had joined the World Trade Organization retained the right under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) to have their own country's pharmaceutical industry produce generic versions of essential medications (compulsory licensing) and/or to import the least expensive version of a branded drug that they could obtain from other countries (parallel importing).

The proprietary ("research-based") pharmaceutical companies aggressively opposed this interpretation of TRIPS and utilized their own substantial resources and those of the governments closely aligned with their interests (particularly the U.S. government) to attempt to block governments from utilizing their right to issue compulsory licenses or implement parallel importing. Joni (South Africa) and Viana (Brazil) discuss two crucial examples of governments exercising their right and responsibility to mediate between the demands of international trade law and the well-being of their citizens. In both instances, it should be noted that the building of an alliance between the government of the developing country and non-governmental organizations (NGOs) was a critical element in the each government's successful effort.

Adelstein warns against simplistic characterizations of the pharmaceutical companies as greedy monopolists. Basing his argument in classical economics, he points out that uncontrolled generic manufacturing of pharmaceuticals could undermine the profits that allow research-based companies to develop new drugs, including those for HIV/AIDS. Rather than a moral conflict of good and evil, he urges us to have a more nuanced understanding that society must balance today's need to treat fatal disease with the need to develop drugs for tomorrow's crises. He ends by calling for redistribution of substantial amounts of wealth from the wealthy countries to the people of poor ones. He does not directly address whether proposals for tiered pricing (with adequate policing mechanisms) combined with alternative incentives for pharmaceutical research (such as the substantial tax incentives that currently exist in the United States) might achieve the same ends and be more politically viable.

Viana, speaking as part of the government of a developing country, views the conflict between patents and public health by discussing Brazil's experience in producing generic versions of ARVs and by analyzing the negotiations that recently led to a clarification of TRIPS by the WTO. He strongly asserts that it is the role of the State, not that of international organizations, to balance the interest of the health of its people against the benefits gained by granting monopolies through patents. In the case of a national emergency, such as AIDS, the government must be free to adopt whatever measures are needed to protect the health of their people. In those circumstances, the assertion of patent rights and the insistence on high prices by pharmaceutical companies constitute an economic abuse, he explains, and must be opposed.

He points out that measures such as compulsory licensing and parallel importing have always been legal under TRIPS in cases of public interest and national emergency. The United States government has always asserted its right to use these mechanisms in cases of national security, and this exception to TRIPS is recognized by the WTO. At the WTO meeting at Doha in November 2001, an alliance of developing nations and non-governmental organizations succeeded in getting a Ministerial Declaration passed that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Viana's article in part answers the question posed by Adelstein about how conflicting interests are to be balanced [also see Lazzarini]. Traditionally, this has been done by governments, the grantor of patents and the party responsible for public health. To the extent that a government is democratic, the decisions that are made should be a reflection of the will of the people whose lives will be affected. This is admittedly a simplified and utopian view of governmental decision-making, but it contains some truth. In contrast, the rise of powerful international organizations that increasingly decide global macroeconomic policy threatens to totally isolate such decisions from any democratic process. The WTO, established by the G-8 countries to regulate global trade in an era dominated by multinational corporations, has been widely criticized for lacking transparency and any

semblance of democratic process. In this broader context, Brazil's actions in addressing the AIDS crisis gain even greater significance.

III. THE HUMAN RIGHTS PARADIGM

Lazzarini, while focusing on the specific issues raised by treatment access advocates, gives a more comprehensive view of the role of human rights in international law: "In this capacity, human rights serve as a body of international law, a set of norms for governmental behavior, and as a strategic tool for social change." She, like Viana, insists that intellectual property rights are not absolute and can be legitimately limited when significant public health threats exist. Extrapolating from this example, she proposes that the organizations and agreements that govern the regimes of international finance, trade and human rights coordinate their systems of monitoring and conflict resolution. Continued progress in confronting the AIDS crisis, she suggests, can only come if both state and non-state actors recognize divergent interests but find the will to negotiate solutions that will more effectively address critical global health issues.

Csete explores how broader access to treatment can strengthen other human rights related to HIV/AIDS and mitigate some of the human rights abuses suffered by PLWHA. She makes a particularly important contribution to the argument for treatment as a critical part of the response to the epidemic by reminding us of the impact of the epidemic on children: 13-15 million children orphaned by the epidemic and several times that number living in households with one or both parents ill with AIDS. Too often, debates about how to address the needs of these children have focused narrowly on such issues as whether governments should subsidize foster care arrangements or build public orphanages. Csete points out that life-extending treatment has the potential to keep families together and financially viable, and thus afford a longer period during which dependent children can be protected from abuses. This indirect benefit of HIV treatment may, in fact, be crucial to preserving the next generation in countries where the current generation of adults has been decimated by AIDS.

IV. THE ROLE OF NON-GOVERNMENTAL ORGANIZATIONS (NGOs)

Joni and Vieira focus on the shifting alliances between state and non-state actors that have resulted in significant victories for treatment access campaigns.

Joni first analyzes the role of the Treatment Action Campaign (TAC) in supporting the South African government against a legal challenge from the Pharmaceutical Manufacturers Association (PMA). The 1997 Medicines Act detailed various mechanisms, that the South African government could use to lower the cost of essential medications. The PMA challenged the constitutionality of the Act in 1998, asserting that such actions violated their intellectual property rights. TAC, formed in December 1998, did not initially join in the legal action but rather focused on building political understanding and support for the government's position in civil society, and particularly among PLWHA. This strategy served to isolate PMA, created an expectation that the government would utilize its powers

under the ACT, and mobilized important sectors of civil society. When out of court negotiations among the government, PMA and TAC failed to come to a settlement, TAC moved to join the case as an *amicus curiae*. TAC's brief not only clarified the legal issues but rooted the legal arguments in the reality of the AIDS epidemic in South Africa. Shortly after TAC entered the legal case, the PMA withdrew its action.

The alliance between the TAC and the South African government was temporary. The government has not only refused to use the powers granted under the Act but has actively opposed efforts to expand the use of ARVs in South Africa. As a result, TAC brought suit against the government, asking the Court to direct the government to supply nevirapine, a drug shown to reduce maternal to infant transmission of HIV, to pregnant women receiving care through the public health care system. In December, the Court ruled in TAC's favor.

Vieira comments on the role of NGOs in both domestic and international fora. He credits NGOs with playing a significant role in the debates leading up to the adoption of the Declaration on the TRIPS Agreement and Public Health by the WTO. He also points out that human rights groups and the lawyers associated with them are playing a major role in shaping national health care systems in several Latin American countries (see Lazzarini as well). Within this generally positive assessment he warns of the danger of health care policy responding to the most active NGO rather than to a more objective assessment of a nation's health needs.

V. CONCLUSION: FUTURE DIRECTIONS

The treatment access movement has won substantive victories over the past few years. The first, and perhaps most important, was building a consensus of world opinion that it was morally intolerable that scores of millions of people infected with HIV would die untreated despite the existence of drugs that could extend life. This consensus was given material form in campaigns that forced the pharmaceutical industry to lower their prices, in the clear establishment of a public health exception to TRIPS, and in the formation of a Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) in 2001. Plans to initiate and scale up treatment for HIV and integrate it into comprehensive programs to confront the epidemic are being developed both nationally and internationally.

This momentum is significant, but it is important to understand that each victory has been won only through active mobilization that forced changes in the dominant, market-oriented strategy. This will undoubtedly be true moving forward.

In the post-Doha period, the U.S. government has tried to narrow the interpretation of the Agreement announced there. It has opposed efforts to clarify the right of poor nations without a domestic pharmaceutical industry to import generics from other countries (correspondingly, countries must have the right to produce generics for export under compulsory licenses). The U.S. and the other G-8 countries have refused to fund the GFATM at levels that will enable it to finance comprehensive programs to fight the three diseases, and painful experience has shown that half-way measures that pit prevention and treatment will undoubtedly fail. The pharmaceutical industry has attached numerous conditions to their offers

to reduce the price of HIV-related drugs and is aggressively opposing plans for centralized bulk purchasing of pharmaceuticals. Addressing these obstacles will succeed only if the alliance between states and NGOs that succeeded at Doha continues to function together at the international level.

This alliance will be tested at the national level in many of the most affected countries as plans are developed for the introduction of ARV therapy. Most governments want total control over the funding streams and plan to use the funds only in the public healthcare system. NGOs which represent the interest of PLWHA and which are more directly tied to the most affected communities may find themselves marginalized and ignored by their own governments. Just as TAC in South Africa found itself in opposition to its government's policies, many other NGOs may find themselves in a similar position.

Treatment advocacy groups and their allies will need to build alliances with other sectors in civil society and strengthen their capacity for social mobilization. As Csete and Lazzarini point out, the links between the human right to health and other human rights can be the framework for such a broader mobilization.

Finally, there is another alliance that underlies the proposal put forward by Otunnu. This is the alliance between civil society in the wealthy countries and civil society in the global South. In addition to mobilizing additional resources for the most effective community-based programs in the most affected countries, the AIDS Fund for Africa would be a model of international cooperation. In a period of intensified geopolitical conflict, Otunnu proposes to build on direct people-to-people solidarity in the fight against this global catastrophe. Where others see hatred, he sees hope. Hope is the emotion that can empower the multi-level mobilization needed to successfully resolve the global AIDS crisis.

art
nt,
he
in
its

as
ler
ca.
he
nt
lth

ra.
he
he
ith
ral
ve
ost

of
le
ld
he
lic
S,
up
he

ch
he
d.
he
fy
ort
to
G-
ce
ias
lly
ers