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# From the Bowels of an Epidemic: AIDS, Human Rights, and International Equity

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# **THE NEWEST SCOURGE**

# From the Bowels of an Epidemic: AIDS, Human Rights and International Equity

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Ronald Bayer

## I. Introduction

Epidemic diseases, we know, can be the source of profound disruption. In addition to the death and suffering they bring, they can serve as the occasion for great social conflict. Not unusually, those who have been socially marginal in a pre-epidemic era have become the targets of attack, depicted as the source of disease in the face of the threat posed by the outbreak of illness: Jews in medieval Europe, Asian and other immigrants to America in the 20th century, and, in the context of AIDS, gay men. But epidemic diseases, precisely because they so starkly reveal social fault lines and institutional inadequacies, can provide the occasion for progressive changes and ideas designed to address the limits of the pre-epidemic order.

I turn to the grave AIDS epidemic, which threatens the lives of millions of men, women, and children globally, and I examine the way in which a disease threat that first emerged on the world stage in 1981 has served to force a rethinking about the ethics of disease prevention, the conduct of research involving human subjects, the limits of the market, and moral obligations beyond our borders. In each instance, I will turn first to how the issue was addressed in the United States and other wealthy nations and then to how the impact of AIDS in the poorest nations has forced more radical rethinkings.

## II. The Two Worlds of AIDS

There was a time in the early days of the AIDS epidemic when a grim global equality defined the experience of all nations. In the richest

countries and in the poorest, medicine was all but impotent to meet the challenges of a disease that struck in the prime of life, and that rendered physicians helpless as their patients quickly succumbed to a succession of opportunistic diseases. In the industrialized nations, the onslaught was especially unsettling because in the post-antibiotic era, epidemics of infectious disease had all but been consigned to history. In the less developed nations, where the pattern of morbidity and mortality still reflected the impact of infectious diseases, AIDS threatened to reverse the hard won successes of public health, robbing years from life expectancy.

What made for a common pattern of misery in the epidemic's early years were the limits imposed by our shared medical ignorance. Slowly, however, that common bond began to yield to the developing understanding of how HIV rendered the immune system helpless, and a growing understanding of how to treat and even prevent the opportunistic diseases that took the lives of those who were infected. And at that juncture, the global inequalities that made infectious diseases treatable in the richest nations but untreatable in the poorest began to affect the experience of a common pathogenic threat. No longer did the limits of medicine define the situation. Rather, it was the inability to afford treatments because of resources. Just as diarrheal diseases were preventable and treatable when they occurred in wealthy nations but ravaged communities in the poorest nations, and just as tuberculosis was preventable and treatable when it occurred in the richest nations but took the lives of millions in the less developed nations, opportunistic diseases linked to HIV began to yield to successful treatments in the industrialized nations while they continued to take their toll in the poorest.

But the therapeutic and prophylactic advances that began to transform the world of AIDS in terms of opportunistic diseases was not so quick to affect experience with regard to the underlying threat caused by HIV itself. Men, women, and children across the economic divide continued to die in large numbers, albeit sooner in the poorest countries than in rich nations.

Hopes for assaulting HIV infection itself with antiretroviral drugs were repeatedly shattered. Research findings that suggested that AZT, the first antiretroviral, would radically improve life expectancy for those with the fully developed disease and even slow the onset of disease in asymptomatic HIV infected individuals were, all too soon, shown to be illusory.

But then in 1994, things began to change. With those changes came, once again, the roots of an inequality born of medical and scientific progress. First, there was the remarkable discovery in a clinical trial that AZT administered during pregnancy could reduce the rate of maternal-fetal transmission by two-thirds. A first antiviral success promised to make pediatric AIDS an increasingly uncommon tragedy, at least for those who could afford the cost of treatment. Then, in 1995–1996, even more remarkable discoveries about the power of combination therapies involving multiple retrovirals provided the basis for thinking that AIDS could be transformed from a rapidly fatal disease into a chronic illness, which, if still ultimately fatal, would no longer be marked by death so soon after diagnosis (at least in those countries that could afford the extraordinarily costly treatments).

Thus has the advance of science and medicine brought to an abrupt end the era of grim global equality. Two worlds of AIDS have therefore emerged—one where AIDS is treatable and those infected can live for years under careful, costly medical management, and another where AIDS equals death.

Let me now fill in this picture, turning to two sets of data that will underscore how different the worlds of AIDS have become. The first is based on the perspective of American physicians revealed in long in-depth interviews that are included in the recent book *AIDS Doctors: Voices from the Epidemic*, which I wrote with Gerald Oppenheimer. The second is drawn from a report published by the United Nations.

The encounter with AIDS in the early 1980s compelled many of the first AIDS doctors in America to rethink their therapeutic optimism and the assumptions that dominated the curative orientation, which reflected the achievements of medicine in economically advanced nations. Gerald Friedland, who treated impoverished drug users in New York, like others, needed to rethink the goals of medicine. Only such a transformation could permit him to endure the work to which he had committed himself.

I had lived in Nigeria for two years. It really helped me to know what the limits of medicine are. I never had the delusion that we were going to conquer this thing. It's the wrong thing to talk about. As long as we keep talking about cure, we'll always feel like failures. We're not failures. What do we cure? So we're limited, I've always felt limited as a physician.

In a nation where infants and children almost never fell victim to fatal disease, it was startling to encounter dying children, even among the poorest. Trained in El Salvador, Hermann Mendez was forced to remember his early medical experiences as he treated dying infants in Brooklyn, New York.

I became used to death (at home) I mean, from the autopsy room to the emergency room where we would receive very, very sick children all the time. I got re-educated in the United States. I came fresh, full of desire to practice differently, with a different population, and I allowed myself to be re-educated, so my losses were hard losses.

For virtually all doctors, it became all too apparent that only if they came to accept death as the inevitable fate of their AIDS patients could they provide the kind of care that was clinically relevant, that met their patient's needs. Constance Wofsy of San Francisco thus noted:

How long it took before it eventually became clear that we have to accept death in young people as something that did happen. We were moving from how we were going to resolve this? to how we can make this least painful, relieve suffering and achieve the longest, best life span possible? It will sound macabre, but I realized I was travel agent for death and that my role was to make the process as drawn out, as comfortable, and as full of interesting things as it was possible to do. I could not prevent the ultimate outcome but I could manage it.

Others expressed a despair that merged with disdain as they considered the undue optimism that informed the work of researchers whose careers were built on conducting expensive, but what they took to be futile, efforts to discover powerful antiretroviral agents. Donald Kotler remarked:

What it takes to not be a stupid fool is to accept the fact the first time you see the patient that the patient will die of the disease. I've helped a lot of people. I haven't cured anyone. The people who made their careers doing Phase 1 trials of one new antiretroviral after another have done very well for themselves but in some ways haven't done anything for their patients.

In sum, the first generation of AIDS doctors in America sought to reframe their understanding of what it meant to be a physician under

conditions that many equated to a kind of grim trench warfare. Many, overwhelmed by the experience, found themselves depleted and exhausted. So accustomed had they become to death and therapeutic limits that when the first good news of the mid-1990s presented itself, they responded with profound skepticism. Was this to be another AZT-like cycle of inflated premature hopes to be followed by shattered expectations? But as clinical experience began to reveal how truly remarkable the new combination therapies were, doctors began to recognize how radical a transformation was occurring. Richard Chaisson, whose clinic in Baltimore, Maryland, treated poor African Americans, had been skeptical in 1996. By 1998, his perspective had changed:

My initial response was more pessimistic than the events of the last two years would warrant. The new drugs are extraordinary. However, they are not having the effect of curing people; and so ultimately the question is how long will this last. But the fact that people who were months away from dying are robust and healthy and enjoying life now two, three years afterwards is wonderful. I haven't had a patient die for 10 or 11 months. So it's gone from constant death to infrequent death. Mortality in our clinic in the last three years has fallen by about 65 percent.

Wafaa El-Sadr, at Harlem Hospital in New York, had a similar experience:

I would walk into clinic several years ago and just look at the waiting room to see who's there. And there were a lot of sick people, leaning against the wall, very sick people. And now it's just amazing. I walk in, and it's like bubbling with energy and conversation, people hanging outside the door, smoking cigarettes; it's just filled with life and energy, I think it's wonderful. When I see a sick person today at that clinic it's unusual. The very sick people are in the hospital. It's almost like having a well-baby clinic.

Barbara Starrett, a physician who had treated gay men and who in desperation had been willing to provide access to many alternative therapies, captured the new optimism of many:

I think probably everybody that I take care of now is going to live for years. They all have the potential to die of something else. Like hypertension in the 50s. Many of those people on those imperfect drugs did live complete lives. So now we're going to have patients who live complete lives on these AIDS drugs.

Even those like Dan William, a longtime AIDS doctor in New York, who were more cautious, saw what they took to be a transformation of seismic implications:

I think we're entering into the disease as chronic illness rather than a terminal disease. That's my prediction. I think it's quite likely that AIDS wards are going to be emptying out, not unlike iron lung wards in the fifties, that people are going to be doing better, and they won't need to be in the hospital as much, and there will be fewer AIDS associated opportunistic infections.

Writing of the changes at the end of 1998, the *New England Journal of Medicine* captured epidemiologically what clinicians were seeing among their patients:

The good news continues in the battle against AIDS. In the United States, the age-adjusted death rate among young people with human immunodeficiency virus (HIV) in 1997 was less than 40 percent of what it was in 1995. The 16,685 deaths in 1997 represent the lowest annual total in nearly a decade.... Not only has mortality from AIDS decreased, but so has the incidence of AIDS among those who have HIV infection.... The dramatic declines in morbidity and mortality due to AIDS in Western nations are the result of the widespread use of potent combinations of antiretroviral drugs.

As the number of AIDS-related deaths declined, and as the deaths became less frequent, American doctors began to find that the hard won insights about how to practice medicine that emerged during the bleakest years began to lose their compelling force. No longer was caring as contrasted with curing viewed as a central mission of medicine. With new therapeutic tools, it was possible for the conventions of curative medicine, so denigrated in the epidemic's first years, to reassert themselves. Doctors began to see themselves as, once again, becoming *real* doctors, sometimes with a bittersweet nostalgia for the past. The observations of Gerald Friedland, who had in the early years comforted himself with the idea that doctors could not cure, were thus striking:

It's really been wonderful, so much so that it's almost hard to remember what it was like when everybody was dying. It's a magical moment. I reminisce about the good old days when you couldn't do anything. Isn't



that terrible? Because you had to focus on the caring part, and the love and interaction and the arrangements of a good death. Now we're more like doctors. We write prescriptions all the time; we wind up juggling medicines. With so much involved in the technical aspects of care that you don't have time for some of the human things; and so it has changed. On the scale of things, it's much better. People live longer, their quality of life is better, but something has been lost in the increasing complexity of AIDS care.

In the face of these dramatic events, a number of AIDS doctors began to describe changes that would have been unthinkable just a few years earlier. After years of devotion forged in the face of death and therapeutic limits, some began to speak of disengaging from the single-minded commitment to AIDS patient care. "It's not like war anymore," said one.

Donald Abrams in San Francisco, who had seen thousands of patients die, and who, like other gay physicians, had witnessed the death of countless friends, and lovers as well, captured the mood of some:

We were pioneers and were involved in a strange new frightening, challenging problem-solving endeavor. And it is now a bit like cancer in that research is sort of looking at three drugs compared to those four and which one gives you the marginal improvement in the surrogate marker benefit. You are not dealing with the intensities that we were dealing with previously, which were fear, contagion, death and disfigurement. A lot of the drama and the intensity of the early days of the epidemic are gone. Now you go to these AIDS conferences and there are just millions and hundreds of people doing what we used to do or what we do. I have worked in this now for 18 years and I probably have another 18 years left in my career. I would really prefer being on the front lines again doing something that is unique.

That, then, is the world of AIDS in America, where 40,000 people a year continue to become infected with HIV, where people continue to die of AIDS. But the carnage of the early years has ended. It is not too different in other wealthy nations. But very different is the picture in the poorest nations, those in Africa especially.

What is that other world of AIDS? In a careful analysis of both the epidemiological and clinical picture that makes the account of death and suffering all the more brutal, we are told by UNAIDS, the interna-

tional agency that seeks to coordinate AIDS efforts, that there are 24.5 million HIV infections in sub-Saharan Africa; 5.6 million in South and Southeast Asia; and 1.3 million in Latin America. Globally, 34 million are infected. In 1999, 4.7 million adults and 600,000 children younger than 15 were newly infected. There were 2.8 million deaths, 500,000 among children.

In an analysis based on modeling, UNAIDS has projected that any country where 15 percent or more of adults are currently infected with HIV, at least 35 percent of boys now aged 15 will die of AIDS—numbers that are both numbing and appalling. And the number of those infected has long exceeded 15 percent in some nations. In South Africa, Zambia, and Botswana, the deaths may exceed 60 percent unless radical changes in the incidence of infection occur or change in therapeutic options become possible. The notion of a plague, like the great Bubonic plague of the European Middle Ages, is no longer a metaphor. It is real and it is harsh.

It is against this backdrop that we are compelled to: rethink the value choices involved in preventing HIV transmission—a rethinking that entails a reconsideration of the relationship between public health and individual and human rights; reconceptualize the ethical challenges of conducting research with human subjects, especially concerning a disease characterized by profound social inequalities; and finally confront the question of the rights of the poorest in the world to have access to treatments available to those who live in the wealthiest nations.

### **III. Rights and AIDS Prevention: Toward a New Paradigm?**

In the early and mid-1980s, when democratic nations were forced to confront the public health challenge posed by the AIDS epidemic, it was necessary to face a set of fundamental questions. Did the history of responses to lethal infectious diseases provide lessons about how best to contain the spread of HIV infection? Should the policies developed to control sexually transmitted diseases or other communicable conditions be applied to AIDS? If AIDS were not to be so treated, what would justify such differential policies?

To understand the importance of these questions, it is necessary to recall that conventional approaches to public health threats were typically codified in the latter part of the 19th and early part of the 20th century. Even when public health laws were revised in subsequent

decades, they tended to reflect the imprint of their genesis. They provided a warrant for mandating compulsory examination and screening, breaching the confidentiality of the clinical relationship by reporting to public health registries the names of those with diagnoses of “dangerous diseases,” imposing treatment, and, in the most extreme cases, confining persons through the power of quarantine.

As the century progressed, the most coercive elements of this tradition were rarely brought to bear, because of changing patterns of morbidity and mortality and the development of effective clinical alternatives. Nevertheless, it was the specter of these elements that most concerned proponents of civil liberties and advocates of gay rights as they considered the potential direction of public health policy in the presence of AIDS. Would there be widespread compulsory testing? Would the names of the infected be recorded in central registries? Would such registries be used to restrict those with HIV infection? Would the power of quarantine be used, if not against all infected persons, then at least against those whose behavior could result in the further transmission of infection?

Although there were public health traditionalists in the United States and abroad who pressed to have AIDS and HIV infection brought under the broad statutory provisions established to control the spread of sexually transmitted and other communicable diseases, they were in the distinct minority. Often such opponents viewed the antagonism to traditional public health measures as a political distortion. One such critic in the United States wrote, “Plagues are not new, what is new are efforts by medically unsophisticated politicians and attorneys to dictate policy . . . AIDS isn’t a civil rights issue. It’s a genuine plague.” Typically, it was those identified with conservative political parties or movements who endorsed such efforts — although not all conservatives pursued such a course. Liberals and those identified with the democratic left tended to oppose such measures. There were striking exceptions, such as the Swedish Social Democrats, but in the end, it was those who called for “HIV exceptionalism” who came to dominate public discourse.

In the first decade of the AIDS epidemic, an alliance of gay leaders, civil libertarians, physicians, and public health officials began to shape a policy for dealing with AIDS that reflected the exceptionalist perspective. What accounted for the commitment to the exceptionalist idea that there was no true conflict between civil liberties and the public health, that the protection of the rights of the infected against

unwarranted discrimination was central to the task of AIDS prevention, and that persuasion and voluntarism were the core principles that should animate the public health response to the new challenge?

First, AIDS was not a threat like, for example, tuberculosis. Because it was transmitted largely in the context of acts between consenting adults in private, a behaviorally informed response was crucial, one that sought to understand why people acted in ways that placed themselves at risk, and that sought to craft interventions that could motivate behavioral change. Only the most intrusive forms of surveillance and the most drastic invasions of privacy could even theoretically serve the ends of prevention in lieu of efforts at persuasion. From an ethical perspective, the nature of HIV transmission dictated a new public health approach. "The disease's mode of contagion," said Richard Mohr, a philosopher, "assures that those at risk are those whose actions contribute to their risk of infection. . . . It is the general feature of such exposure that makes direct governmental coercive efforts to abate the disease particularly inappropriate."

Second, AIDS in the first epidemic years was seen largely as a disease of gay men. For those who had struggled against homophobia and the threats of a government that had criminalized their sexual lives, the prospect that AIDS would serve as a justification for the abrogation of privacy rights was anathema, and they used extraordinary political skill in pressing their case. At times the case was pressed through the conventional methods of constituency politics, at times with forceful advocacy, and on occasion demonstrative protests were crucial.

Third, those most affected by the epidemic, gay men and drug users, viewed the state as a threatening entity. Any measure that might further serve to alienate them and drive a wedge between public health officials and those with whom it was critical to establish relationships of cooperation was thought to be counterproductive. In the words of Surgeon General C. Everett Koop, coercive measures would "drive the epidemic underground."

Finally, in the absence of clinical interventions that could alter the course of disease in those who were infected or that could reduce their infectiousness, many of the conventional approaches to public health that were predicated on the efficacy of identifying the infected were simply irrelevant.

As the contours of the exceptionalist perspective were taking form, some saw the emergence of a new way of thinking about public health,

one that eschewed the authoritarianism of an earlier era. The lessons of AIDS would, it was thought, be applied in the face of other threats to communal well-being. AIDS would have thus served to provide the foundation of a new public health. But such optimism ultimately confronted a series of changes that undermined the foundations of exceptionalism in the United States and in other democratic nations as well.

Epidemiological changes began to transform the face of AIDS. From the late 1980s onward, the proportion of new infections associated with intravenous drug use increased, as did the proportion of those with HIV who were African-American and Latino. These transformations affected the extent to which white middle class men were interested in and could influence the course of public health prevention policy. Secondly, public health officials with years of experience began to consider the relevance of their own traditions of epidemic control. But most importantly, the transition from near therapeutic impotence to the era of effective clinical management of HIV disease has profoundly affected the understanding of how traditional public health approaches to screening could be brought to bear in the face of AIDS.

And so we have witnessed efforts to return AIDS to the clinical and public health mainstream. The era of HIV exceptionalism is drawing to a close. But lessons about the relationship between the protection of individual rights and public health have not been lost. They have become part of a new convention. Most significantly, there is a deeper appreciation of how restrictive measures, to the extent that they are ever needed, should be thought of as a last resort rather than as the first line of defense.

It is not surprising that the exceptionalist perspective that so informed policy in the advanced industrial nations, and especially the United States, would influence and shape the response of the World Health Organization (WHO) as it began to confront AIDS in the mid-1980s. It was in that context that the issues were framed in terms of human rights and within which a paradigmatic transformation occurred, propelled by the unique sense of vision, the almost missionary zeal of Jonathan Mann, who directed the WHO's AIDS efforts in its formative period.

In its first stage, the human rights-informed response to AIDS focused on the necessity of protecting people with HIV infection from discrimination in public life, and asserted the importance of privacy protections and the right to be free from compulsory measures. While human rights treaties always recognized that serious threats to the

public health could justify restrictions on some rights, the new perspective tended to minimize the extent to which rights and welfare might be in tension. "Public health interests do not conflict with human rights. On the contrary, it has been recognized that when human rights are protected, fewer people become infected and those living with HIV/AIDS and their families can better cope."

Most noteworthy was the way in which such a formulation instrumentally justified the centrality of human rights. It was not that human rights were of such importance that some risks to the communal health should be tolerated rather than endure rights-limiting interventions. Rather, rights-limiting interventions threatened the communal health.

The AIDS policies of the Cuban government were the specter that haunted this worldview. In that country, a decision had been made to apply the practice of compulsory screening to the entire adult population and to place in quarantine all those found to be infected. To the extent that such an approach worked effectively to reduce the rate of HIV transmission, it would compel an analysis of the way in which respect for individual rights and public health were, in fact, in tension. In the end, the Cuban example was simply denounced as involving a gross violation of human rights, which would eventually prove to be a failure from the perspective of public health.

While there was broad international consensus on the relationship between human rights and AIDS prevention, Jonathan Mann pressed the most uncompromising posture in the years after he left the World Health Organization. Writing from the vantage point as director of a human rights center at Harvard University in the journal *Health and Human Rights* (which he founded and edited), Mann declared, "All public health policies and programs should be considered discriminatory (or otherwise burdensome on rights) until proven otherwise." Mann, to be sure, understood that such a formulation was provocative, but it was a necessary provocation if rights were to be taken seriously.

More far-reaching than the link between health and civil and political rights — the individual rights of liberal democracy — was Mann's encounter with the question of how social inequality affected the vulnerability to disease. Targeting the analyses that alluded to the risk factors of individuals he wrote:

This view of disease as external, invading societies which would presumably otherwise enjoy good health, frames a problem such as cancer in the following terms: we have a cancer problem; what can we do about

it, within the given social system? Inevitably this framing and definition of the problem leads to a focus on individual behavior. Individual behavior is implicitly assumed to be largely a matter of choice.

The social conditions shaping the pattern of disease thus remained unaddressed. Such an approach, argued Mann, would have major benefits for a few, “some benefit for some, and little benefit to many or most.” By contrast, his new focus was on a social analysis that led to social action:

The new public health recognizes that the positive impact of traditional public health work will be inherently limited and inadequate without a commitment to changing societal conditions which constrain health and create vulnerability to prevent disease, disability and premature death.

The encounter with AIDS and the limits of the liberal conception of human rights had led Mann to forge a contemporary movement focused on the social roots of vulnerability: poverty, inequality, and marginalization. In so doing he had, without explicitly acknowledging those who came before him, joined the tradition that stretched back to Engels’ *Condition of the Working Class in England*, Virchow’s analyses of diseases and the social structure in the 19th century, and Thomas McKeown’s work in the 20th century. In short, he had rediscovered a social medicine. There was in this radical outlook a profoundly sobering warning: the meliorist efforts designed to limit the spread of HIV were all but useless. Only if the root causes of vulnerability were addressed could the epidemic’s toll be limited.

How Mann’s ideas might have evolved will never be known. His life was tragically cut short in an airplane crash a little more than two years ago. But his ideas have been instrumental in forging a broad constituency linking health and human rights, a movement that has sought to repackage the venerable ideas of social democracy in terms perhaps more palatable to a 21st century dominated by the hegemony of free market ideology.

As Mann and others focused on the challenges of prevention, others turned to issues of how best to conduct research to find therapeutic interventions that could have an impact on the life prospects of those who were already infected, research that would at the same time adhere to basic principles of ethics.

#### IV. Engaging the Ethics of Human Experimentation

The contemporary history of human experimentation is haunted by the specter of abuse. The work of the Nazi doctors exposed at Nuremberg, the Tuskegee syphilis study that exploited poor black men in the American South, and the catalogue of misdeeds made public by Henry Knowles Beecher in the *New England Journal of Medicine* all provide the backdrop to the effort to formulate ethical standards to guide the conduct of investigators who are dependent on the collaboration of women, men, and children as they seek to advance the scientific understanding of disease and its cures.

In the mid-1970s, the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research examined these issues and in its *Belmont Report* codified a set of ethical principles that sought to inform the work of researchers. Those norms provided the foundation for regulations subsequently enacted by the Department of Health and Human Services and the Food and Drug Administration. At the core of those guidelines was the principle of informed consent and the radical distinction between research designed to produce socially necessary, generalizable knowledge, and therapy designed to benefit individuals. Against the former, individuals, especially those who were socially vulnerable, needed protection against conscription.

AIDS forced a reconsideration of this formulation in the United States. There had been challenges to federal protections in the past, for example when prisoners at Jackson State Prison in Michigan demanded that they be permitted to serve as research subjects because participation provided them with *social* advantages. But the HIV epidemic provided the circumstances for the emergence of a broad and potent political movement that sought to radically reshape the conditions under which research was undertaken. The role of the randomized clinical trial, the importance of placebo controls, the centrality of academic research institutions, the dominance of scientists over subjects, the sharp distinction between research and therapy, and the protectionist ethos of the *Belmont Report* were all brought into question.

Scholars concerned with the methodological demands of sound research and ethicists committed to the protection of research subjects played a crucial role in the ensuing discussions, both as defenders of the received wisdom and as critics, but the debate was driven by the articulate demands of those most threatened by AIDS. Most prominent



were groups such as the People with AIDS Coalition and ACT-UP, organizations made up primarily of white, gay men. But advocates of women's, children's, and prisoners' rights also made their voices heard. What was stunning and disconcerting to some but exciting to others was the rhythm of challenge and response. Rather than the careful exchange of academic arguments, the mobilization of disruptive and effective political protest forced the process to change.

The threat of death hovered over the process. As Carol Levine noted in her essay, "Has AIDS Changed the Ethics of Human Subjects Research?:"

The shortage of proven therapeutic alternatives for AIDS and the belief that trials are, in and of themselves, beneficial have led to the claim that people have a *right to be* research subjects. This is the exact opposite of the tradition starting with Nuremberg that people *have a right not to be* research subjects.

That striking reversal resulted in a rejection of the model of research conducted at remote academic centers, with restrictive (protective) standards of access, and strict adherence to the "gold standard" of the randomized clinical trial. Blurring the distinction between research and treatment—"A Drug Trial is Health Care Too"—those insistent on radical reform sought to open wide the points of entry to new therapeutic agents both within and outside of clinical trials. They demanded that the paternalistic ethical warrant for the protection of the vulnerable from research be replaced by an ethical regime informed by respect for the autonomous choice of potential subjects who could weigh, for themselves, the potential risks and benefits of new treatments for HIV infection. Moreover, the revisionists demanded a basic reconceptualization of the relationship between researcher and subject. In place of protocols imposed from above, they proposed a more egalitarian and democratic model in which negotiation would replace scientific authority.

In the end, the shattering of the consensus that had governed human subjects protection in the United States made problematical what had been a bedrock assumption: that carefully controlled trials were necessary to protect the vulnerable from the wide scale use of drugs whose efficacy and safety had not been proven. In the intense struggles that had fostered this radical reconceptualization, an unusual alliance had emerged. Libertarians, antagonistic to the regulatory state

and partisans of the "Reagan Revolution," had joined with gay men and advocates of disenfranchised women to oppose the architects of a protective regime who had sought to protect the vulnerable from undue risk.

As antagonists confronted each other, they predicted very different consequences of the changes that were occurring, changes that had implications far beyond the case of AIDS. Martin Delaney, of the AIDS activist organization Project Inform, stated:

Regulatory practices contribute to the failure of science, demean the public good and tread heavily on our civil liberties. . . . Science and patients alike would be better served by a system that permits life threatened patients some form of access to the most promising experimental therapies, peacefully coexisting alongside a program of unencumbered clinical research.

Giving voice to those who saw in the liberalized regime not only the prospect for harming the desperate but a threat to the scientific enterprise upon which the future well-being of those infected with HIV depended was researcher-physician Jerome Groopman. He contended that "If the philosophy is that anyone can decide at any point what drug he or she wants to take then you will not be able to do a clinical trial."

Just as the protective regime surrounding research in the United States was a product of a history of abuse, efforts to enunciate ethical standards for the conduct of research in Third World nations was shaped by a history of exploitation, a history characterized by investigations of the poor, designed to serve the interests of the privileged. Central to those efforts was the belief that the ethical principles first encountered in industrialized nations, shaped by the liberal tradition, had a direct bearing on the norms that should govern research in very different settings. Such universalism took as a given that insights regarding cultural differences not serve as the basis for moral relativism.

Just as individual informed consent was the first principle of the ethics of research in advanced industrial nations, it was at the heart of the codes designed to guide research in the poorest nations. To preclude exploitation, international consensus also existed on the extent to which it was critical that research be responsive to the health needs and priorities of the community in which it was to be carried out. What

would remain a matter of uncertainty, however, was whether the needs of the poorest and the requirement of responsiveness could justify research that would be unacceptable in the richest nations, e.g., whether the principle of universalism could accommodate research in Burundi that would be prohibited in Brooklyn.

This is the issue that animated a furious international debate, when a therapeutic intervention, after many years of disappointing failures, was to prove remarkably effective in countering the transmission of HIV during pregnancy. Although superficially a conflict over a technical matter involving research design — the role of placebos — the dispute touched on the deepest questions of what ethical conduct means in a world characterized by great inequalities and profound inequities.

In 1997, an editorial appeared in the *New England Journal of Medicine* denouncing an international trial designed to determine if it was possible to develop an inexpensive clinical intervention that could provide something approaching what had been attained in wealthy nations in reducing the risk of mother-to-child HIV transmission. Those trials assumed that even if successful, the more affordable interventions would be less effective than was standard in Europe and America.

The standard of care in the United States and other advanced industrial nations to prevent maternal-fetal transmission of HIV entailed a great irony. The per-patient cost of prophylactic treatment (\$800 for the drug AZT alone) was affordable only in industrialized nations where such transmission, although tragic, represented a relatively limited problem. In developing countries, however, where maternal-fetal transmission represents an epidemiologically significant disaster — approximately half a million babies a year — the costs of prophylactic treatment (disregarding the absence of the infrastructure necessary for intravenous treatment during delivery) put the AZT regimen out of reach. For example, in Uganda, among the poorest of Third World nations, the cost of the AZT component of the standard regimen represents 400 times the yearly per capita expenditure on health care.

It was, therefore, a matter of some urgency that trials begin to determine whether radically cheaper alternatives to the regimen used in wealthy nations could achieve at least some measure of reduced maternal-fetal HIV transmission. In June 1994, a special consultation of the World Health Organization considered the challenge and called for the launching of studies to achieve that goal. The consultation made clear its conclusion that placebo-controlled trials (trials in which a comparison is made between an inert substance and the potentially

active agent) “offer the best option for obtaining rapid and scientifically valid results.”

There was no question that a placebo-controlled trial would have been considered unethical in the United States or any other advanced industrial nation. No trial that denied access to the effective standard, or to an intervention thought to hold the promise of being at least as effective as, if not more effective than, the prevailing standard of care, would have satisfied the requirements of ethical review. The question posed by the furious controversy that unfolded was whether it was ethical to conduct such a trial in a poor country, where no preventive intervention was available and where the standard regimen was out of reach as a potential therapy. *The New England Journal of Medicine* gave its answer unambiguously:

Only when there is no known effective treatment is it ethical to compare a potential new treatment with a placebo. When effective treatment exists, a placebo may not be used. Instead, subjects in the control group of the study must receive the best known treatment.

Given this premise, the *Journal* rejected as irrelevant the fact that health care available in most Third World countries provided nothing like health care available in industrialized countries. Citing the Declaration of Helsinki, the international code of research ethics adopted by the World Medical Association in 1964, the editorial noted that control groups had to be provided with the best current therapy, not simply that which was available locally.

The shift in wording between “best” and “local” may be slight, but the implications are profound. Acceptance of this ethical relativism could result in widespread exploitation of vulnerable Third World populations for research programs that could not be carried out in the sponsor country.

Then, with the obvious suggestion that racism was involved, the *Journal* compared the recent research undertakings with the infamous Tuskegee syphilis study in which poor, African-American men were studied for decades to learn the consequences of untreated venereal disease, even after effective, inexpensive therapy became available.

Women in the Third World would not receive antiretroviral treatment anyway, so the investigators are simply observing what would happen

to the subjects' infants if there were no study. And a placebo-controlled study is the fastest, most efficient way to obtain unambiguous information that will be of greatest value in the Third World.

Finally, the editorial suggested darkly that narrow financial interests might have decided the shape of the research. Clinical trials had become big business and, as in any business, work had to be done efficiently. The ethics of research, however, had to have a different logic, one that was not driven by considerations of efficiency above all else. To the extent that the logic of business had displaced the logic of research ethics, we had "not come very far from Tuskegee after all."

However sharp the tone of the editorial, it was constrained by the venue of the august *New England Journal of Medicine*. Its author, Marcia Angell, was even harsher when she denounced her antagonists in an op-ed piece in the *Wall Street Journal*.

All the rationalizations boil down to asserting that the end justifies the means — which it no more does in Africa than it did in Alabama. It is easy to see the failings of the Tuskegee study from a safe distance of 25 years. But those so offended by the comparison of the African research with Tuskegee have yet to show how these studies differ in their fundamental failure to protect the welfare of human subjects.

A formal public response to the challenge in the *New England Journal of Medicine* appeared two weeks later, signed by David Satcher, Director of the U.S. Centers for Disease Control and Prevention, and Harold Varmus, Director of the National Institutes of Health. Locating the criticized trials in the context of the profound poverty of many nations where mother-to-child transmission was so critical an issue, Satcher and Varmus made clear that placebo-controlled trials were dictated by the urgency of the situation. Only placebo-controlled trials, they argued, could provide "definitive," "clear," "firm" answers about which interventions worked, thus allowing governments to make "sound judgments about the appropriateness and financial feasibility of providing the intervention." The failure to employ a placebo would have made it difficult to clearly determine whether the affordable but less effective intervention was better than no intervention at all. In short, they concluded that placebos were crucial to policymakers required to make relatively costly decisions under conditions marked by profound poverty and scarce public health resources.

Thus was the issue joined. So critical were the stakes involved in the controversy that they ultimately provoked an international effort to reconsider ethical standards of research in the Third World. The World Medical Association undertook a series of consultations on the revision of the Declaration of Helsinki; the Council for International Organizations of Medical Sciences (CIOMS) did so as well. Finally, within the United States, which funded much of the international research that had been subject to scrutiny, the National Bioethics Advisory Committee took up the issue of studies in poor nations.

As the fury of the clash that occasioned the reconsideration would have predicted, the process of "rethinking" was anything but decorous. One account of the World Medical Association's efforts described three years of "wrangling," another spoke of "the ethics wars" and of "cynical maneuvering." What made the encounters so intense and furious is that they pitted against each other those who all saw themselves as deeply committed to the protection of the vulnerable. Some saw in any effort to craft "flexible" standards that reflected the uniquely pressing context of international poverty and inequality the treacherous embrace of moral relativism. Their opponents, however, persisted in arguing that a failure to consider the context of investigation was a failure of moral understanding. Principles could be universal; their application, however, could not be rigid.

It was against this backdrop, as the efforts were drawing to a close, that historian David Rothman published "The Shame of Medical Research" in *The New York Review of Books*. In his virtual *j'accuse*, Rothman, with a long and distinguished career of examining exploitation in the context of medicine, charged the international research community with violating the simple moral maxim, "Do unto others as we do unto ourselves." Rejecting the assertion that his human rights approach to medical research would hobble efforts to meet the needs of the poor and desperate, he asked rhetorically why the utilitarianism of those he opposed should be restricted to Third World AIDS. "If the threat of a disease is dire why not allow investigators more latitude wherever they are? With people living in pockets of poverty in the United States?"

The profoundly difficult issue of research in the context of global poverty is best demonstrated by conclusions reached by the World Medical Association, the CIOMS, and the National Bioethics Advisory Committee. Despite the fact that each body understood the considerable attention that was focused on their efforts, and the importance of

forging a common standard, consensus could not be attained. Only the World Medical Association, in its revision of the Declaration of Helsinki, adopted the position of those like Rothman who asserted that once an effective therapy was found, it became the standard against which all further interventions had to be measured. Regardless of the cost of the intervention, placebo-controlled trials were no longer tolerable. The still preliminary CIOMS recommendations, on the other hand, concluded that there might be sound scientific and ethical reasons to reject the "best current" method standard, if the failure to use a placebo would make the results inapplicable in the host country where the search for affordable alternatives was essential. That, too, was the position adopted by the U.S. National Bioethics Advisory Committee.

In the end, then, the AIDS-inspired debate over research ethics did not end in consensus. Rather, it opened wide the question of whether ethical principles could serve as a universal standard in a world characterized by gross inequality, or whether that very inequality made adherence to universal standards morally imperative.

### **V. Markets, Morality, and Mortality: Securing Access to Care**

If the conflict over the ethics of clinical trials was framed by the need to find affordable treatment for AIDS, it was the price of those same pharmaceuticals that became the occasion for a controversy with far broader implications. As I have noted, beginning in 1995, a new approach to treating AIDS and HIV infections in the advanced industrial world, involving a new class of drugs known as protease inhibitors, had transformed the AIDS epidemic. Multi-drug "cocktails" had radically slowed the disease in those who were infected and had dramatically changed the extent to which death defined AIDS. But the new regimens were complex, requiring many doses during the course of the day, sophisticated laboratory monitoring, and great skill in administration. And the drugs were very costly.

In nations with comprehensive national health programs, where health care was seen as a social good and access to care a social right, these new therapies became part of the treatment that those with HIV received. In the United States, which alone among advanced democratic nations did not recognize a social right to health care, and where millions were without health insurance, the advent of the era of effective antiretroviral therapy posed a challenge that was not new.

In the early 1970s, when kidney dialysis became available, the polity was compelled to address the question of whether access to lifesaving medicine should be limited by the ability to pay. In that dramatic instance, a determination was made to create a federal program that would pay the full cost of care for those with kidney failure. That gesture only served to highlight the extent to which medical care was rationed by the market in the United States.

It was within a system characterized by gross inequality that policy-makers, pressed by advocates for those with HIV, developed a federal program, the Ryan White CARE Act, that sought to assure access to treatment for those who had neither private health insurance nor Medicaid coverage. Access to care was dramatically broadened, although the progress was marred by continued inequality, revealed in the extent to which African Americans and the poor were less likely to receive optimal treatment.

On an international plane, the prospect of effective antiretroviral treatment would pose challenges vaster by many orders of magnitude. What justification was there for a system of pricing that put the cost of drugs beyond the reach of the desperate? Could markets ever respond to need where effective demand was nil? Could the monopoly confirmed by patent rights be compatible with a response dictated by claims of the dying? Was the treaty on intellectual property rights, incorporated into the World Trade Organization's international regime, a barrier to survival in the context of the AIDS epidemic? What moral obligation did the wealthiest nations have to the poorest to provide the resources necessary to purchase the new lifesaving agents and build the medical infrastructure necessary for their appropriate administration? Was there any reason to believe that a global community that permitted millions to die each year from treatable and preventable diseases such as tuberculosis and malaria would respond differently in the face of AIDS?

## **VI. Progress and Protest**

The first international AIDS conference to occur in the wake of studies demonstrating the power of protease inhibitors was held in Vancouver, Canada, in 1996. It was seized by a euphoria that was all the more striking given the utter despair that had characterized the prior international meeting, held in Berlin in 1994. When, in 1998, the conference again assembled under the banner "Bridging the Gap," there was an



increasing sense that the gulf was vast and growing between the countries where the new therapies were affordable and those where they were beyond reach.

AIDS activists ultimately seized on this issue—*Life Over Profits*—and began an international campaign to confront the pharmaceutical industry. What seemed like an utterly quixotic undertaking, however, ultimately took on worldwide dimensions linking protesters in the United States, France, and South Africa, institutional proponents of global health such as the World Health Organization, and a sympathetic public. Within less than three years, the pharmaceutical industry was placed on the defensive, perceived as protecting narrow self-interest when the lives of millions were at stake. Against the claims that high prices were necessary to fuel the engine of research, and that patent protections were crucial to spurring investments in drug investigations, those who sought to change the terms of the discourse asserted that urgency demanded that the barriers to drug access tumble. Mark Wainberg, a Canadian who had served as the president of the International AIDS Society, thus said in 2001, “This is a war, and when you are in a war as we are worldwide with HIV which will claim more lives than any other infectious disease in history, the rules of the game have got to change.”

The struggle against the pharmaceutical industry could not have occurred at a less propitious moment. The 1994 Trade Related Aspects of Intellectual Property Treaty (TRIPS) imposed exacting limits on what nations could do in imposing restrictions on free trade and the market. The World Trade Organization was founded in 1995 and incorporated the TRIPS accord into its regime. To be sure, the intellectual property accord included provisions for extraordinary action in the face of emergency situations. Nations faced with public health threats could engage in “parallel imports,” purchasing drugs at the lowest possible price, even from generic manufacturers who disregarded patents, or issue compulsory licenses to firms that could manufacture a potential product to meet a need that the market could not accommodate. But the hegemony of market ideology and the aggressive defense of the interests of industry by the U.S. Trade Representative meant that the advocates for radical adjustments would face formidable resistance.

The first encounters over drug prices actually occurred in the early 1990s, when therapeutic prospects for dealing with AIDS were very limited. The World Health Organization initiated discussions with

pharmaceutical manufacturers, with the hope that a certain flexibility in pricing would be available for developing countries. The response from the industry presaged what would become its stance over the next years. Their task was to discover therapeutic agents. It was the task of others to make them accessible. Indeed, a year after discussions began, the industry, which argued that AIDS drugs were simply too costly for poor nations, objected to language in a proposed draft statement that included terms such as "responsible prices," "commercially favorable terms," and "special prices."

With the failure of those initial discussions, it would not be until 1997 that another effort would be made to address the issue of drug prices. Then the Joint United Nations Program on AIDS (UNAIDS) began the HIV Drug Access Initiative, in which three pharmaceutical firms were to negotiate discounted prices with four nations. Two of the countries were in Africa, Uganda and Cote D'Ivoire. It was the dismal results of this effort that set the stage for mounting pressure by the year 2000. An evaluation found that in Uganda some 800 individuals were receiving drugs out of 930,000 who might benefit. The story in Cote D'Ivoire was not much better. The impact was "tiny."

Some indication of how outrage against the evolving situation, with increasingly effective care the standard in the wealthy nations standing in stark contrast to the absence of care for many millions in Africa and Asia, could begin to shape public discussion occurred in the United States. As Al Gore began his effort to win the presidential nomination of the Democratic Party he was confronted by protestors from ACT-UP, furious because the United States had threatened sanctions against South Africa, which had passed legislation that would have permitted parallel imports and compulsory licensing of drugs. "Gore's Greed Kills," "Blood Money," "Medical Apartheid" screamed the posters. It was such protest, and the potential impact on Gore's campaign, that led the Clinton administration to adjust its policies.

Those adjustments in prices that had occurred and those pilot programs that had been established seemed to pale in the face of what was increasingly viewed as a catastrophic situation. In January 2000, the French ambassador to the United Nations called for a meeting between the pharmaceutical industry, representatives of the industrialized nations, and the poor nations to address the issue of drug access. The Director General of the World Health Organization noted pointedly that "The drugs were in the North, the diseases were in the South."

With pressure mounting, five major pharmaceutical firms took the extraordinary step of announcing, in May 2000, that they were ready to negotiate steep cuts of up to 80 percent in the price of AIDS drugs for Africa and other poor regions. Hailed by many as a critical turning point, others saw it as a way for the pharmaceutical firms to maintain control over the issue of pricing while preserving their patent rights.

But despite such gestures on the part of the pharmaceutical industry, the public climate had begun to reflect an increasing sense of moral revulsion. An industry that had presented itself as serving the interest of health was clearly on the defensive. The mood was reflected in the press not only in editorial comments but in news stories as well. On July 9, 2000, *The New York Times* published a story about the drug fluconazole, used to treat cryptococcal meningitis, an opportunistic infection of those with HIV disease. A Kenyan doctor who could not prescribe the drug because of its price said, "They get no peace. With the intense pressure on the brain some go blind. Most just go into a coma and die and by then they are in such pain that it is really a blessing." The reporter then continued, "As soon as he diagnoses cryptococcal meningitis in a patient he says he dispenses advice he hates: If they want to be buried in their ancestral village as most Kenyans do they should board a bus. They have only two or three weeks to live and the cost of refrigerated trucks ruins many families." The doctor then said, "Can you imagine, as a doctor, having this conversation with your patient? I have it once a week." Without editorial comment, the "news" story had underscored a sense of moral outrage.

Responding to continuing criticism, drug companies argued that, at most, the price of drugs was a small part of the problem. The issue, they said, was the fundamental limits of the medical infrastructure of poor nations and the inability of the poorest to pay for even heavily discounted drugs. But such arguments, whatever their merits, carried little weight as long as prices remained high or as long as the offer to negotiate price reductions entailed protracted processes. In early 2001, the British medical journal *The Lancet* thus wrote, "The time has come for the pharmaceutical industry and the governments who represent them in trade disputes to acknowledge that the world is facing an extraordinary challenge."

Then, in February, an Indian generic pharmaceutical firm, Cipla, changed the terrain. It announced that it had reached an agreement with Doctors Without Borders to make a triple drug "cocktail" available for \$350 a year per patient. It would sell such regimens to govern-

ments for \$600, \$400 below the painstakingly negotiated price that Senegal had been able to obtain from the pharmaceutical companies. "This is," said the chairman of Cipla, "a way to break the stranglehold of multinationals." The firms that sought fiercely to protect their patent claims were outraged, describing Cipla and others that violated patent rights as "pirates."

Despite the furious response, Cipla's announcement produced a cascade of events. Merck cut the cost of one anti-AIDS drug by 92 percent. Bristol-Myers Squibb announced that it would sell its two AIDS medications below cost and would not oppose South Africa's efforts to bypass patents through compulsory licensing or parallel imports. In words that could not have been imagined a few months earlier, the company declared, "This is not about profits and patents, it is about poverty and a devastating disease. We seek no profits in AIDS drugs in Africa and we will not let our patents be an obstacle." When Abbott Laboratories followed suit, it declared, "AIDS has taken an unprecedented toll on the health, economic and social structure of Africa. Abbott has taken this action to give people most affected by this disease a better opportunity to access care." Finally, under threat from the government of Brazil to issue a compulsory license for two drugs, Merck agreed to slash the price of its products. Thus did the pressure of the market produce a series of events that moral suasion had failed to achieve over years of efforts.

In April 2001, a long-planned discussion was held, sponsored by the World Trade Organization and the World Health Organization. Despite fierce disagreements between AIDS activists and the pharmaceutical industry, and between the generic firms and the large pharmaceutical companies, broad agreement was reached on the importance of differential pricing designed to adjust the cost of drugs to reflect the purchasing capacity of poorer nations. The notion of "equity pricing" that had not so long ago been anathema had assumed the status of a common ground. It was within this context that yet another dramatic event occurred. On April 19, the 39 drug companies that had brought suit against the government of South Africa because of its legislation that would have permitted the circumvention of patent restrictions withdrew their case. "We don't exist in a vacuum," said the Chief Executive Officer of GlaxoSmithKline. "We're not insensitive to public opinion, that is a factor in our decisionmaking."

## VII. From Prices to Access

As drug prices began to fall, it became ever more apparent that the challenges posed by the international pharmaceutical industry as it resisted pressure by activists, generic manufacturers, and international public opinion, were not without foundation. Even if drugs were provided at cost, even if the principle of equity pricing guided sales, even if nations pursued the option of compulsory licensing and parallel imports, the cost of providing antiretroviral therapy was simply beyond the reach of the poorest and most HIV-burdened nations. And even if drugs could be paid for, the necessity of a medical infrastructure (that could offer and monitor the use of drugs in a way that was attentive to the needs of individual patients and to the risks to public health from drug resistance) would require huge investments. This was the context within which a remarkable movement to create a massive funding effort to respond to the threat of AIDS took shape. And while the effort demonstrated how wildly optimistic *The New York Times* was when it declared in a front page story, "Suddenly, the question is no longer whether Africans will get life-saving drug cocktails, but how," it also made clear how, in the face of impending catastrophe, it was possible to give credibility to ideas that under normal circumstances would have been viewed as nearly utopian.

In early 2001, U.N. Secretary-General (and Macalester College graduate) Kofi Annan issued a report in anticipation of a June General Assembly meeting devoted to the AIDS epidemic, which he described as "the most formidable development challenge of our time." But his call was conventional in its commitment to vaccine development and prevention efforts. With that emphasis, it continued to reflect a broadly shared view that treatment with the antiretroviral therapeutics available in the developed world could play a very limited role in resource-constrained nations. Annan's case mirrored a proposal from Jeffrey Sachs, a Harvard development economist who had, more than a year earlier, argued for a Millennium Vaccine Fund that would guarantee a market for pharmaceutical firms that developed malaria, tuberculosis, and AIDS vaccines. Such a fund would, he asserted, require a fundamental shift on the part of the world's powerful economies. "We need a serious discussion about long term finance for the international public goods necessary for the Highly Indebted Poor Countries to break through to prosperity. The rich countries are willing to talk about every aspect except money...."

By 2001, Sachs had taken on the challenge of AIDS in the poorest nations directly. In so doing, he embraced the vision of those who had asserted that it was morally unacceptable to stand by as millions of men, women, and children faced certain death. He said, "To me it's as though the Black Death were going on in Europe in the 14th century and China was sitting on a cure and saying, 'Why should we help?' We would consider it the crime of the Millennium, if that had happened, and yet we seem to be able to accommodate this without much trouble." Together with more than one hundred other Harvard faculty members, he rejected the claim that only prevention efforts were affordable for the poor. In an era of effective antiretroviral therapy, access to care was imperative.

We believe that on moral, health, social and economic grounds the international community should provide new scientific and financial leadership for a rapid scaling up of AIDS treatment in the poorest and hardest hit countries of the world.

The goal was to treat one million patients in Africa within three years. It was, according to Sachs and his colleagues, simply untrue that the infrastructural capacity of African health care systems precluded the provision of treatment. That there were limits was true, but they could be overcome with appropriate international assistance.

To those who had asserted that efforts to provide treatment would subvert already fragile prevention programs—a claim made by many of the humanitarian foundations that had funded such efforts—Sachs and his colleagues responded directly:

Treatment is necessary to optimize prevention efforts. When treatment is not available less incentive exists for an individual to take an HIV test since HIV positive status not only is associated with social stigmatization but is tantamount to a death sentence. Ultimately, treatment of infected individuals may become a major tool in AIDS prevention.

Finally, Sachs and his colleagues claimed that the provision of treatment was necessary to preserve the social fabric of societies affected with high levels of infection. "If the current lack of treatment continues a demographic shift is predicted...such that teenagers will outnumber their elders by 2020. Further, without treatment, millions of adults in the prime of their working lives will die of AIDS and with them skills

and knowledge that are necessary for human and economic development.”

In assessing the potential costs of such an effort, the Harvard group calculated that one million Africans could be treated for \$1.1 billion dollars a year. Were the program to expand to three million individuals—a goal achievable in five years—the cost would rise to \$3.3 billion a year. But even so vast an effort would not cover large numbers of people in need of care. To reach those millions could require significant investments in medical infrastructure that Sachs and his colleagues chose not to calculate. Finally, in addition to the costs of care, it was estimated that for prevention efforts for Africa alone, \$3 billion was needed annually. Thus, in all, the first year’s effort in Africa would require \$4 billion.

To meet this vast commitment it was proposed that an HIV/AIDS Prevention and Treatment Trust Fund be created. The sum involved, while very large, was not beyond the capacity of the wealthiest nations, totaling .01 percent of an aggregate GNP of \$23 trillion.

The Harvard call had an electrifying effect, most clearly demonstrated at a Rockefeller Foundation-sponsored meeting in Uganda in mid-April, 2001. Addressing the final session of the meeting, the foundation’s executive vice president declared that, “For the first time in this two-decade old epidemic, AIDS care appears not only feasible but also inevitable.” The North-South gap was described as “unpardonable,” since AIDS care was a “basic human right.”

Less than two weeks later, United Nations Secretary-General Kofi Annan appeared before the African Summit on HIV/AIDS, Tuberculosis and Other Infectious Diseases. He called for the creation of a global trust fund that would spend \$7–10 billion a year over “an extended period” to combat the threat to the world’s poorest people. Most striking was his assertion that the care, which had for so long eluded men, women, and children in the less developed nations, was a matter of rights. Speaking to Africa’s lenders he said:

Even a year ago few people thought that effective treatment could be brought within reach of poor people in developing countries. . . . There has been a worldwide revolt of public opinion. People no longer accept that the sick are dying simply because they are poor. Everyone who is infected should have access to medicine and medical care. Now we know that that is possible, it is surely an ethical imperative.

Like the Harvard group and the Rockefeller Foundation, Annan rejected claims that resources spent on care would imperil efforts at prevention: "We cannot and should not chose between prevention and treatment, we must do both."

Strikingly, the idea of a global trust fund not only won the support of editorialists identified with a liberal or social democratic posture, but by powerful institutions as well. Within days of Annan's speech, the Group of Seven, the International Monetary Fund, and the governing committee of the World Bank endorsed the fund, in principle. The Gates Foundation pledged \$100 million to the effort. Not unexpectedly, the Final Declaration of the June United Nations Special General Assembly session on AIDS asserted that \$7 – 10 billion should be in place by the year 2005. But between dramatic proposals based on moral principles of solidarity with the most vulnerable and willingness to provide the resources necessary to give life to such principles and commitments there is a vast distance. When the G-8 met in Genoa in July 2001, they committed \$1.2 billion to the global fund that Annan had called for. Declaring the gesture "laudable," the U.N. Secretary-General was quick to add, "It is not enough."

As the international community began to articulate a consensus regarding the need to rupture the economic barriers to antiretroviral therapy, cautionary voices were to be heard. But remarkably, these concerns centered on the need to do *more*, not less. In an editorial applauding efforts at creating a global trust fund, *The Lancet* noted that the successful provision of care to multitudes of those with HIV would require a different kind of commitment:

Far more crucial are the elements of a sustainable primary health care system. . . . Such fundamental services are not an eye-catching platform for politicians and policymakers. Yet they are desperately needed — for without them any effort to distribute medicines will fail. Such sums should be at the center of a strategy to combat AIDS and other diseases.

The gulf between conviction and action has become all the more stark as prevailing and pervasive international inequality has taken on moral significance. What was the unfortunate has become unfair; inequality has become inequity. In that translation, the possibility of human agency, of political action to effect change, has opened wide. It is far from certain how that opportunity will be apprehended.



### VIII. Envoi

At the conclusion of *Plagues and People*, William McNeill's magisterial history of epidemics and their impact on history, the enduring threat of biology is underscored:

Ingenuity, knowledge and organization alter but cannot cancel humanity's vulnerability to invasion by parasitic forms of life. Infectious disease, which antedates the emergence of humankind, will last as long as humanity itself, and will surely remain as it has been hitherto one of the fundamental parameters and determinants of human history.<sup>1</sup>

The AIDS epidemic has showed us with painful clarity how prescient McNeill's observation was. Never again will we have the security that hubris had provided in the era before HIV. But we have also learned another set of lessons. The course a pathogen takes is shaped by the social environment it seeks to invade. Epidemics are therefore both biological and social occurrences. While we may not be able to prevent the emergence of new biological threats, we do have it within our power to limit the points of social vulnerability. Whether we do so will be a reflection of the extent to which we are committed to limiting human suffering. How broadly we extend our commitments — whether we hold them close or are global in our efforts — will reveal the contours of our moral universe.

Secondly, we have learned the lesson again that scientific progress does not end or limit the necessity of confronting moral questions. The very opposite is the case. When nothing can be done to cure or treat the sick, the options we have are limited. It is only when we are empowered by scientific progress that we can answer the question: Who shall live? In responding to that question we again confront the extent to which our moral worldview is narrow or global.

From the depths of suffering imposed on us by the AIDS epidemic, we have had to confront these profound questions. How we answer them will be our legacy. And it will be the basis on which we will be judged by history. ●

### Notes

1. William McNeill, *Plagues and Peoples* (New York: Anchor Press, 1976), p. 291.

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