

Something to Be Done: Treating HIV/AIDS

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Largely because of disparities in access to drug treatment and care, AIDS morbidity and mortality have fallen in the developed world but continue to rise among developing countries. Achieving more equitable access to AIDS drugs is hindered by high drug prices, technical complexities related to the provision of health care, and conflict among stakeholders. Recognition that health is vital to the prospects of the emerging global society must be combined with new mechanisms to help all stakeholders work together cooperatively. Tiered drugs pricing should be coupled with investment in health services. An independent "Global Task Force," able to act as an "active think tank," could build consensus about the way forward.

Although prevention remains the first line of defense against HIV/AIDS, caring for the millions of people now living with AIDS is an essential element of our reaction to the epidemic. AIDS is increasingly a disease of the poor (1), and currently, as Ugandan AIDS doctor Peter Mugenyi has noted, "The medicines are where the problem is not, and the problem is where the medicines are not" (2).

Effective care programs have many features, but at their heart are interventions that make a substantial impact on the quality and length of people's lives (3). The U.S. Food and Drug Administration (FDA) now lists over 40 approved therapies that slow or disrupt viral replication or treat opportunistic infections (4), and as a result of these, the number of AIDS deaths has fallen dramatically across Europe and the United States. In the United States, for example, deaths fell from 49,895 in 1995 to 17,171 in 1998.

Although educated and relatively wealthy patients have been successful in marshaling the medical and social support necessary to mount an active and ongoing defense against the disease, the situation is much bleaker for most of those infected with HIV. Poor levels of education, economic development, and health not only encourage the disease's spread, they also inhibit effective care. First, medical interventions are expensive, with highly active antiretroviral therapy (HAART) costing up to \$20,000 per person per year. Second, health systems are inadequate, with as few as 10% of the population of the developing world having consistent access to health care and even highly developed health systems failing to deliver benefits to disadvantaged populations. Third, those with compromised immunity are weakened by poor nutrition and a lack of safe water. Fourth, the disease burden in developing countries is disproportionately high, heightening the dangers

from a disease that attacks the immune system. Tuberculosis (TB) and AIDS interact especially powerfully and have been dubbed the "dual epidemic." Fifth, the social structures that are the bulwarks of any care program are being overwhelmed by the severity of the epidemic.

This paper explores the major obstacles impeding a more effective response to the problem of AIDS care: the technical complexities that offer no easy "win-win" solutions and the friction between major stakeholders that have made this a controversial and often explosive subject. We call for a global response to a problem that is inextricably linked to globalization and warn that a failure to act now will not only be catastrophic for entire regions, but will further erode confidence in the capabilities of our emerging global society (5).

Technical Complexities

Ensuring access to more effective AIDS care is complex and has four distinct facets: affordability, finance, delivery, and rational selection.

The affordability of treatment has attracted much recent attention. Globally, antiretrovirals are only used by 1% of those with HIV, and drugs for treating opportunistic infections are also poorly distributed. Through patents, pharmaceutical companies receive monopolies on new drugs, offering companies the chance to earn a return on their investment in R&D, both for the patented drug and for other unsuccessful research. Critics identify pricing differentials between countries as evidence of unfairly exploiting a monopoly. Pfizer's Fluconazole is \$11.90 per 200-mg dose in the United States and \$13 in South Africa. In Thailand, where local companies compete with Pfizer, the price is \$0.69 (6). The unwillingness of pharmaceutical companies to reveal their investment and pricing policies leaves them poorly placed to refute charges of profiteering and increasingly vulnerable to activist pressure.

Expensive and complex treatments burden well-funded health services, and there is evidence of informal rationing of treatment, even

in developed countries (7). Financing in developing countries is currently extremely limited, despite growing evidence of the importance of health to development within the modern global economy (8). South Africa, for example, spends \$279 million on all drugs, compared to a defense expenditure of \$4.19 billion (9). Namibia spends a paltry \$42,000 on its AIDS program and receives \$126,000 from European Union and \$36,000 from the Joint United Nations Programme on HIV/AIDS (UNAIDS) (10).

Even when drugs are cheap or free, problems remain. Delivery systems are inadequate or nonexistent across much of the world, as shown by the failure to make progress against TB, despite the widespread availability of effective remedies. Similarly, major drug donations have not been immediately successful, with bitter arguments about responsibility for distribution and treatment protocols. Yet, there is unmet demand: The People's Health Organisation (India), for example, describes the new drugs as "promising heaven, but giving bankruptcy." The organization recommends HAART to patients on the basis of wealth, rather than disease stage, with patients advised to take the full combination, take a reduced combination, or avoid antiretrovirals, depending on income. As World Bank President James Wolfensohn argues, high prices offer governments little incentive to build health infrastructure (11).

AIDS is one of several serious diseases facing developing countries, and decisions on the allocation of limited funds remain controversial. Is it better to spend on nutrition or care, education for prevention, or sexually transmitted disease treatment, when all of these will have an impact on the AIDS epidemic? Further, the future consequences of interventions must be addressed. Plentiful access to cheap TB drugs in Russia fueled drug-resistant TB, an enormously expensive problem. Stepping up AIDS care requires selecting treatment interventions appropriate to delivery. It is quite conceivable that more virulent and even less treatable forms of HIV will emerge as the result of the inability to sustain complex courses of medication, itself often a result of the expense of treatment.

Conflict and Confrontation

Beyond the technicalities of widening access to treatment lie a series of political conflicts that continue to make it difficult to secure change. Access to drugs and treatments was fiercely contested throughout 1999, with acrimony among key stakeholders. The U.S. government, for example, threatened sanctions against South

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Africa in support of the pharmaceutical's legal action against the South African Medicines Act. This would have allowed compulsory licensing of AIDS drugs (where drugs are made locally and the intellectual property holder compensated at a rate set by the state) and parallel importing (cheaper drugs imported from other markets). Activists, however, mounted a vigorous campaign against the action. In 1999, for example, "307 public health experts and concerned persons" wrote to Vice-President Al Gore, accusing the United States government of protecting the pharmaceutical industry against global competition, ignoring the biggest public health crisis in recent history, and leaving people without access to pharmaceutical drugs to die (12).

In 2000, a more constructive approach emerged. In January, the United States completed a policy U-turn, by instigating an unprecedented UN Security Council debate that recognized AIDS as a threat to world security (13). On 10 May, President Clinton followed through with an executive order, intended to ensure that, within the scope of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, HIV/AIDS-related drugs and medical technologies become more accessible and affordable in sub-Saharan Africa (14). The next day, UNAIDS announced that five major drugs companies had agreed to ensure rational, affordable, safe, and effective drugs for HIV/AIDS-related illnesses, stressing the need for a new commitment to tackling AIDS from national governments and the global community and substantial investment in building efficient, reliable, and secure distribution systems. The French government, meanwhile, continues to press for an international fund for therapeutic solidarity, which would use public and private resources to promote access to AIDS drugs.

Reaction to these initiatives has not been wholly positive. Médecins Sans Frontières described the industry offer as minor, "much like an elephant giving birth to a mouse" (15). Nothemba Simelela, head of the South African HIV/AIDS directorate, was also suspicious: "There is little trust between pharmaceutical companies and this government, but obviously we will not kick them in the teeth if they are offering real assistance" (16). Alan Holmer, president of Pharmaceutical Research and Manufacturers of America, described the executive order as setting "an undesirable and inappropriate precedent [and] a discriminatory approach to intellectual property laws" (17). Debrework Zewdie, World Bank AIDS coordinator, noted that "even if the drugs were free, we would still have a horrendous problem getting this [offer] to work," and thinks that the drug companies may have opened a Pandora's box (18).

Tackling Complexity

Continued progress, therefore, relies on steering a path through technical complexity while

drawing stakeholders into more productive partnerships.

A major step on the affordability of treatments has been taken by the acceptance of tiered pricing for AIDS drugs. Consolidation, however, requires four steps. First, future R&D into HIV/AIDS remains an overriding priority. Activists must forgo using price reductions in developing countries in their arguments for lower prices in developed markets, and pharmaceutical companies must receive limited protection against parallel importing (19). Second, pharmaceutical companies should acknowledge through their actions that AIDS is a global emergency and there is natural public interest in both developed and developing market prices. Greater public oversight of the industry is required through access to information and "trust—but verify" mechanisms to scrutinize commercially sensitive information on profit levels and R&D expenditure.

Third, separate action is needed to address underinvestment in research into diseases that affect the poor (20). Tax incentives, schemes to guarantee markets, and direct public investment should all be considered, whereas the public and nonprofit sectors should explore ways of receiving a greater share of the ongoing returns on their 54% investment in health care R&D (21). Finally, the debate on price needs to extend beyond pharmaceutical manufacturers, with governments from developing countries addressing import tariffs, taxes, and distribution margins, which the pharmacy industry claims account for two-thirds of African drug prices (22).

As treatment prices fall, a strong case for increased investment in care arises. Donor countries, philanthropic foundations, and multilateral organizations should match greater investment from developing countries. Much of this money should be dedicated to delivery systems, along the lines suggested by Hans Binswanger elsewhere in this issue (23). It is possible to scale up existing, successful HIV programs.

Finally, rational selection of interventions needs consideration within a much broader context than cost-effectiveness, which calculates return on a limited and short-sighted basis. Globalization will be fatally undermined if it continues to act as a vehicle for greater inequality. Life expectancies are falling in a growing number of countries, reversing key development gains of the 20th century. Tackling AIDS—on all fronts—is a political imperative. Better health is a powerful tool for social inclusion, and at the heart of any vision of a fairer world.

Bringing Stakeholders Together

The signs that stakeholders are prepared to work more constructively together are encouraging, but more is needed. Further investment is required in techniques to extend

trust across stakeholders (itself a valuable form of international social capital) (24). Although peace has broken out publicly, tensions are still running high in private. External, unbiased mediators will help to focus minds on solutions; George Mitchell in the Irish peace process and Desmond Tutu in the South African Truth and Reconciliation Commission are good models. We also suggest exploring creative approaches to problem solving, like scenario planning, which has been successfully used to engage antagonistic stakeholders in Colombia, South Africa, and Japan (25). As the French government has argued, traditional conferences, with a succession of speeches and sterile debate, must be avoided at all cost.

Second, we think that broader and deeper partnerships should be developed, with parties committed to more open, transparent, and inclusive ways. Too many negotiations occur behind closed doors, inevitably raising suspicions among excluded parties. Those with AIDS need a stronger voice, and the wider business community must get involved. Pharmaceutical companies hold only part of the answer. Businesses have the scale, finance, channels, and motivation to significantly influence the course of the epidemic (26). Finally, it is essential that developing countries display ownership of the problem, with UNAIDS—relocated in Africa—acting as a facilitator for initiatives such as "regional pharmacies," where buying power and expertise are pooled transnationally to change market dynamics.

Third, we suggest a new, inclusive forum, with a global profile, to act as an "active think tank" and develop a consensus on ways forward. This "Global Task Force" on access to AIDS care should have a wide remit, a budget to call witnesses and operate a secretariat, and a guarantee that world leaders will pay serious attention to its findings. Members would have a high profile and experience in the issues, but they would act as individuals rather than as representatives of the constituencies from which they were drawn (27). The task force should be unequivocally free of ties to all existing stakeholders and aim to inform and catalyze (rather than duplicate) their efforts.

The Global Task Force would act decisively and quickly, reporting on the role of intellectual property in health, within the context of rapid changes in the concept of intellectual property in the knowledge economy, and outlining a clear framework for invoking World Trade Organization exemptions that allow for compulsory licensing and parallel imports. It would also provide an independent forum to explore pricing levels (discussed above) and set bold but achievable targets for improving access to treatment. It would explore incentives, delivery, and management issues, including care tailored for the poor and marginalized, where treatments are chosen to transcend, as far as possible, the

limitations of delivery systems (28). Finally, it would work to build global support for new investment in AIDS treatment. After all, the public will support spending more money—but only if convinced that something can indeed be done (29).

References and Notes

1. Ninety-five percent of HIV-positive people live in developing countries. Furthermore, our analysis shows a correlation of 0.49 across 51 countries with the requisite data between the absolute poverty rate in 1990 (the percentage of population living on less than \$1 per day) and the adult HIV prevalence in 1997.
2. M. Schoofs, "Part 8: Use What You Have," in the series "AIDS: The Agony of Africa," *Village Voice*, 29 December 1999 (available at <http://www.villagevoice.com/issues/9952/schoofs.shtml>).
3. Enhancing Care Initiative, "AIDS Care Framework" (available at <http://www.eci.harvard.edu/research/framework/index.html>).
4. For a complete list, see FDA, "Approved Drugs for HIV/AIDS or AIDS-Related Conditions," last updated 6 July 1999 (available at http://www.fda.gov/oashi/aids/stat_app.html); "Antiretroviral Drugs Approved by FDA for HIV," last updated 2 March 2000 (available at <http://www.fda.gov/oashi/aids/virals.html>).
5. See also D. E. Bloom and River Path Associates, "Social Capitalism and Human Diversity" (The Creative Society of the 21st Century, Organisation for Economic Co-operation and Development, Paris, in press).
6. Fluconazole is used to treat cryptococcal meningitis, which affects ~9% of people with AIDS and is otherwise fatal. Responding to criticism, Pfizer has now offered to develop a joint program with the South African Ministry of Health to deliver the drug "free of charge through appropriate medical specialists" (from letter from Pfizer to Mark Heywood of the Treatment Action Campaign on 31 March 2000; excerpts can be found at <http://report.kff.org/archive/aids/2000/04/kh000403.1.htm>).
7. J. Zuniga, *Int. Assoc. Physicians AIDS Care J.* 4, 23 (1998) (available at <http://www.aegis.com/pubs/iapac/1998/IA980401.html>).
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9. W. Hartley, "AIDS Hearings Turn Acrimonious," *Business Day* (Johannesburg), 10 May 2000 (available at http://www.africanews.org/health/stories/20000510/20000510_feat5.html).
10. Figures drawn from C. Maletsky, "Anti-AIDS Drugs 'Out of Question' for Nam," *The Namibian* (Windhoek), 11 May 2000 (available at http://www.africanews.org/health/stories/20000511/20000511_feat2.html).
11. M. Waldholz, "Makers of AIDS Drugs Agree to Slash Prices in Third World," *Wall Street Journal*, 11 May 2000.
12. J. Love (director, Consumer Project on Technology) and 306 other signatories, "Open Letter to Vice-President Al Gore," 1 August 1999 (available at <http://www.cptech.org/ip/health/sa/goresignon.html>).
13. For an overview of this U-turn, see B. Gellman, "A Conflict of Health and Profit," *Washington Post*, 21 May 2000, p. A01.
14. "Presidential Order on AIDS Drugs," 10 May 2000 (available by searching <http://usinfo.state.gov/products/pdq/wfarchive.htm>).
15. Médecins Sans Frontières, "MSF Reaction to UNAIDS proposal" (press release), 11 May 2000 (available at <http://www.msf.org/un/reports/2000/05/pr-unaid5/>).
16. P. Sidley, "South Africa: Skepticism Greets AIDS Treatment Plan," *Business Day* (Johannesburg), 15 May 2000 (available at http://www.africanews.org/health/stories/20000515/20000515_feat1.html).
17. Pharmaceutical Research and Manufacturers of America, news release, 10 May 2000 (available at <http://www.pfma.org/news/5-10-00a.html>).
18. D. Pilling, "Cheap Medicine Exposes Africa's Woes," *Financial Times*, 19 May 2000 (available by searching <http://www.globalarchive.ft.com>).
19. There is already resistance in the United States to cheaper prices abroad [see (28)].
20. Only ~1% of new medicines commercialized over the past 25 years, for example, were designed to treat tropical diseases [B. Pecoul, P. Chirac, P. Trouiller, J. Pinel, *JAMA* 281, 361 (1999)].
21. Ad Hoc Committee on Health Research Relating to Future Intervention Options, *Investing in Health Research and Development* (World Health Organization, Geneva, 1996); see also J. D. Sachs, "Helping the World's Poorest," *Economist* (14 August 1999) (also available at <http://www.cid.harvard.edu/cidsocialpolicy/>).
22. H. E. Bale Jr. (director-general, International Federation of Pharmaceutical Manufacturers Associations), "AIDS in Africa," testimony before the United States Committee on Foreign Relations Subcommittee on African Affairs (available at <http://www.ifpma.org/pdfifpma/Testimony-Feb24.pdf>).
23. H. P. Binswanger, *Science* 288, 2173 (2000).
24. For an overview, see M. R. Reich, *Nature Med.* 6, 3 (2000).
25. See, for example, the work of the Global Business Network in this area (available at <http://www.gbn.org/public/gbnstory/scenarios/>).
26. D. E. Bloom, A. Rosenfield, River Path Associates, "A Moment In Time: AIDS and Business" (American Foundation for AIDS Research, 30 November 1999) (available at <http://www.riverpath.com/library/library.html>); D. E. Bloom, L. Reddy Bloom, River Path Associates, in *The Africa Competitiveness Review*, World Economic Forum, Ed. (Oxford Univ. Press, New York, in press).
27. This approach has been used successfully in many contentious situations (for example, in the Low Page Commission, which set the UK minimum wage in 1998, with a minimum of controversy).
28. J. Laurence, *AIDS Reader*, in press.
29. River Path Associates, "You Made Africa Boring: Towards a New Vision for Development," 1998 (available at <http://www.riverpath.com/library/library.html>).
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VIEWPOINT

Scaling Up HIV/AIDS Programs to National Coverage

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The most important issue in the fight against HIV/AIDS is how to scale up existing programs that are only reaching small numbers of people to the national level. Here, I present suggestions on how to tackle the daunting challenge of building truly national HIV/AIDS programs, based on insights gained from participatory, decentralized rural development experiences and from HIV/AIDS programs.

In most of Africa, there are examples of excellent HIV/AIDS prevention, mitigation, and care projects. However, these projects reach only a small fraction of the population. Like expensive boutiques, they are only available to a lucky few.

A shocking example of limited reach is the Kagera Region of Tanzania, the first region hit by HIV/AIDS 16 years ago. The region has been studied by many scholars and experts. An estimated 200,000 of the region's 1.9 million

inhabitants are AIDS orphans. In addition to health posts and hospitals, some 10 nongovernmental organizations (NGOs) provide HIV/AIDS services. They are staffed by dedicated volunteers, but they are dramatically underfunded. The NGO leaders pointed out that they operate mainly in two out of five districts, leaving the other three with virtually no services. In the two districts on which they concentrate, they reach not more than 5% of the population with any of the HIV/AIDS services (counseling and testing, care of opportunistic infections, home-based care, support to orphans, etc.).

Extremely low coverage characterizes most of sub-Saharan Africa. In the Ivory Coast, only two out of eight regions have any programs in rural areas, and the services are confined to prevention; only a very small percentage of the estimated 6.3 million Ivorians living in rural areas are being served. In most other countries in Africa, HIV/AIDS services are only available in the largest cities, and even there the reach is limited. For example, in Mutare, the third largest city of Zimbabwe with a population of some 200,000, only 3% of patients classified as bed-bound or housebound (and who might qualify for inclusion in a home-care program) were being visited by any agency within the city (1).

African countries cannot afford a strategy of gradual expansion of the "boutiques"—which seems an appropriate way to characterize the existing AIDS projects and programs—to include more patients than just the lucky few and

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