Antiretroviral therapy cannot be South Africa's first priority

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South Africa captured the world's headlines — and the developing world gave a sigh of relief — on Apr. 19, 2001, when the Pharmaceutical Association of South Africa (PMA), which represents some of the world's biggest drug manufacturers, withdrew its lawsuit against the government in the Pretoria High Court. The government's victory in this case was hailed as a precedent with important implications for all poor countries around the world that are confronting the HIV/AIDS epidemic.

Three years ago, the PMA went to court in order to forestall the implementation of a new law, the Medicines and Related Substances Control Amendment Act (Act 90 of 1997), which, *inter alia*, would have permitted the so-called "parallel importation" of cheaply priced generic HIV/AIDS drugs in direct competition with the brand-name products of the multinational pharmaceutical giants — such as GlaxoSmithKline and Merck Frosst — that are marketed in South Africa. The PMA argued that such importation would contravene international law and would violate the patent rights of its 39 member companies who do business in South Africa. In its defence, the government denied that the new law infringed patent rights and pleaded its moral obligation to ensure access to affordable HIV/AIDS drugs as one way to contain the pandemic, which has assumed the proportions of a national emergency.

Characterized as a case of greed versus morality, the lawsuit soon became an international *cause célèbre* and a growing source of embarrassment for the pharmaceutical industry, which was accused of putting profit before lives and being obscenely insensitive to the needs of the millions living with HIV and AIDS in South Africa and elsewhere. In a move seemingly contrived to blunt the criticism and obfuscate the implications of the lawsuit, some drug manufacturers announced large price reductions on HIV/AIDS drugs, and others offered outright donations of such drugs. All of these offers were given the cold shoulder by the government, for good reason. No government can be expected to develop a sustainable, national HIV/AIDS containment strategy on the basis of such charity. As Mark Heywood, general secretary of the AIDS activist group Treatment Action Campaign (which is pushing for universal access to HIV/AIDS medicines), told Reuters news agency, "The offers are conditional and only made under public pressure and could be just as easily taken away."[1]

The fact of the matter is that brand-name HIV/AIDS drugs are unconscionably expensive for developing nations, which is why countries such as India and Cambodia have taken it upon themselves to manufacture affordable generic substitutes, notwithstanding the chagrin of the manufacturers who hold the patents. "'We don't need to be apologetic about it,' says India's Health Minister Dr. Javid Chowdhury. 'Outside the Third World, there's very little realisation of how little money the poor live on. The per capita health expenditure in India is $10 a year.'"[2] A typical highly active antiretroviral therapy (HAART) cocktail costing US$10 000 per patient per year in the United States can be provided at the cost of US$300 using imported drugs from India. Fluconazole, which sells at a discounted price of US$8.25 per capsule in South Africa, sells for US$0.64 in India.[3]

As in other countries, HIV appears to have occurred in South Africa in the early 1980s mainly among gay men. However, later in the same decade, HIV was found among the heterosexual population. Fuelled by apartheid-inspired domestic migratory labour practices, rural and urban poverty and social disintegration, the heterosexual epidemic soon exploded to engulf the entire country. South Africa, therefore, currently has 2 independent epidemics — the lesser homosexual variety with viral subtypes consistent with those in North America and the rapidly spreading heterosexual variety with viral subtypes traceable to East and Central Africa.[4]

No one knows for certain how many South Africans carry the virus. Best estimates, extrapolated from the annual anonymous survey of cohorts of indigent women attending antenatal clinics, put the prevalence of HIV at between 4.7 and 5.4 million of a total population of 40 million.[5] There is no doubt, however, that South Africa is in the throes of a catastrophic pandemic, with the worst yet to come. Public hospitals across the country are overwhelmed with patients diagnosed with AIDS-related illnesses. The number of funerals in some jurisdictions has doubled over the last 5 years. It is estimated that by 2010, life expectancy and the economy will both shrink by 20%: over a million children will be orphaned, and poverty, homelessness and illiteracy will expand exponentially.[6]

The government is regularly castigated for lacking a coherent strategy to deal with the pandemic, and efforts at implementing a consistent AIDS policy have been hobbled by a breakdown of trust and cooperation both within government and between government and nongovernment organizations. Certainly, President Thabo Mbeki's flirtation with dissident views that deny the role of HIV in the causa-

tion of AIDS has only served to deepen the rift and to undermine the Minister of Health, whose policies and strategies are predicated on orthodox views of the syndrome.

Much of the criticism of the government has focused on its perceived ambivalence toward antiretroviral therapy (ART). AIDS activists, opposition politicians, academics and the press all continue to campaign for the availability of ART and treatment for opportunistic infections for all patients with AIDS. The government is particularly under pressure to devise a national program of prophylaxis against mother-to-child transmission (MTCT), using the modified, South African zidovudine regimen or, more recently, nevirapine, and for similar prophylaxis to be provided for women who have been raped.

The government's support for drugs to treat opportunistic infections has been unequivocal. However, it has quite correctly been cautious about committing itself to mass prophylaxis against MTCT, ART and other treatment programs, for a number of reasons.

First, it is not clear that South Africa can afford the cost of treatment for every patient with AIDS even at reduced prices, given that drugs alone are not sufficient for a successful ART program.

Second, much of South Africa's health care is provided by overworked nurse practitioners and basic physicians operating in sparsely equipped clinics and hospitals in far-flung rural areas. In these deprived areas, it is not feasible for the government to provide the prerequisite infrastructure for a successful treatment program, such as a sustained drug supply backed by effective regulatory mechanisms to ensure quality, as well as essential laboratory, clinical and social support networks to ensure proper testing and appropriate clinical monitoring.[5]

Third, South Africa lacks the capacity to counsel and test all pregnant women in order to identify those who are at risk for MTCT. It is well accepted that 75% of babies born to untreated mothers with AIDS will not be infected with HIV and that MTCT prophylaxis using the modified, South African single-drug regimen will have a salvage rate of 35% among those babies who would otherwise have been infected. Stated differently, of 100 mothers with HIV/AIDS treated for MTCT, 75 will have healthy babies with or without treatment, and 9 babies will benefit. Concern has been expressed about the unknown hazards of zidovudine for the unaffected babies and the real risk that the treated mothers will develop resistance to ART.

Finally, everyone agrees that whereas ART will help alleviate suffering, it will not help to contain the scourge. Yet, the oft-cantankerous debate about ART in our public media is beginning to detract from the campaign of prevention and lifestyle modification that is critical to the containment of the epidemic. The disproportionate emphasis on ART in public debates could result in complacency and a false perception that there is a panacea for HIV and AIDS. There is some evidence from San Francisco of increased risk-taking sexual behaviour and a greater likelihood of contracting sexually transmitted diseases among those taking ART who have become complacent.[7]

In summary, the landmark victory of the government against the PMA in the Pretoria High Court will almost certainly result in affordable HIV/AIDS drugs being more readily available in South Africa. Certainly, easier access to medicines for opportunistic infections will greatly benefit those afflicted with HIV and AIDS. However, in so far as ART is concerned, it may turn out to be a pyrrhic victory for the majority of AIDS sufferers in rural and periurban settlements who depend on public health facilities for their care, because the government is unlikely to be able to afford the infrastructure that is necessary for a successful universal ART program. The government is more likely to choose to devote its limited HIV/AIDS resources to programs that hold the promise of putting an end to the epidemic, which is indeed a wiser choice.

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