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Brazil's AIDS Model: A Global Blueprint?

Not as easy as it looks.

By Anne-christine d'Adesky

SEPTEMBER 4, 2003. In June 2003, an historic agreement took place in Washington between two odd allies: United States President George W. Bush and Brazil's charismatic, radical former labor leader "Lula," as Brazil's President Luiz Ignacio Lula da Silva is called at home. The duo agreed to assist in rolling out a national AIDS treatment program in two Lusophone (Portuguese-speaking) African countries, first in Mozambique, then Angola. The effort will rely on new partnerships among US, Brazilian and Lusophone African groups and institutions.

Because of Brazil's success pioneering AIDS treatment at home, it will oversee many details of these programs. That includes a transfer of technical knowledge in manufacturing generic antiretrovirals and overseeing their use in countries whose populace lacks adequate health care. The programs are part of Bush's effort to spearhead AIDS treatment to the hardest-hit nations of Africa and the Caribbean through his recently approved five-year, \$15 billion Emergency Plan for AIDS Relief.

David against the Goliath

For Brazilians, the joint agreement is the sweetest victory to date in the ongoing global effort to provide universal access to AIDS care and antiretrovirals to some 30 million people living in Africa and other developing regions.



Adriana Oliveira selects anti-AIDS drugs in a pharmaceutical laboratory in Rio de Janeiro. Julio Guimaraes

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AIDS - Latin America:
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Until now, the US has been strongly allied with multinational drug companies in a tooth-and-nail fight with Brazilian officials to prevent generic competition in the AIDS drug arena. After failing to negotiate drug discounts from multinational patent holders, Brazil, Thailand and Cuba opted to manufacture generics.

What was at stake for big pharmaceutical companies wasn't really the tiny AIDS market in Africa, which represents only 1 percent of the billion-dollar AIDS market, but the larger patent system. Makers of new products or processes are now guaranteed a 20-year market monopoly under a World Trade Organization Agreement on Trade Related Aspects of Intellectual Property and Public Health, or TRIPs. US trade officials feared that softening TRIPs' rules for lifesaving HIV medicines in a pandemic would usher in generic competition for other products.

Undeterred, Brazil fought back, arguing that Article 68 of Brazil's 1997 patent law allowed it to make generics to address its national emergency. These drugs, made only for its national AIDS program, not for export, do not break patents. In 1990, Brazil, the second-most populous country in the Western Hemisphere, had an exploding AIDS epidemic: average survival time was less than six months after a clinical diagnosis. Most citizens lacked access to HIV tests and drugs. In 1993, the private Brazilian company Microbiologics began making generic AZT, and in 1994, the state did the same, providing AZT free through its public health system. AZT prices fell dramatically. By 1997, the government was making ddC and d4T and, within two years, other nucleosides were available. In 2000, indinavir was added, then nevirapine.

Brazil's estimated savings on these last two drugs was \$80 million, or 30 percent of total drug costs for the year. By the time of the US WTO challenge in 2001, AIDS drug prices had fallen domestically by 70 percent. So had AIDS deaths. The health system had saved \$677 million, and freed up hospital beds. Armed with such positive, cost-effective results, Brazil was cast as a fiery David against the Goliath of greedy "big pharma."

Four months after filing the complaint, the US dropped it. Brazil continued to up the ante, threatening compulsory licensing to negotiate sharp 40 percent and 65 percent discounts on patented antiretrovirals from Switzerland's Roche and US-based Merck. Then in November, Brazil helped broker a victory for developing countries at the 142-nation WTO Ministerial Conference in Doha, Qatar. A new ruling guaranteed poorer nations facing national emergencies the right to practice parallel importing or issue compulsory licenses to import or make generic drugs.

But the Doha agreement was only a partial victory, due to a clause banning exports and requiring countries to develop the capacity to manufacture their own generics, something they all lack. In 2002, WTO members again failed to resolve this hurdle. Although 31 countries have implemented Brazil's treatment and prevention

guidelines, only Guyana has adopted its generics model. The Doha clause has effectively prevented the world from following Brazil's lead on generics.

"Why has no country adopted this? We need the agreement of countries," said Paolo Teixeira, the outspoken, outgoing head of the Brazilian Ministry of Health's AIDS program. "We can only say that some countries have tried to consider this and stopped with fear of pressure from the United States." For very poor countries, threatening to withhold foreign aid is an effective weapon.

The Pressure to Export

US opposition isn't the only reason for the global reluctance to produce generics. In reality, making quality antiretrovirals is neither cheap nor easy, even for richer countries. It requires a substantial investment, an industrial manufacturing base and technical manpower. Aside from Brazil, Thailand and Cuba's state programs, only a half-dozen private companies in India and China meet that criteria for making pills. Globally, not many can even produce the necessary raw materials. Analysts predict a few developing countries will be able to make generic antiretrovirals based on their current industrial capacity and experience. Generics are also a tough business, especially when the local market for AIDS drugs is not well established. Even when companies succeed, generic drug prices may not be cheaper than imported drugs.

In the face of these realities, there has been a growing international demand that Brazil export not just its technical know-how, but also its high quality drugs. But even with possible approval from the WTO, that won't be easy. Brazil still imports 80% of its raw materials from India, which is costly. "Many drugs could be produced in Brazil and a large number are not under patents," said Dr. Norberto Rech, head of the government technology division. Current domestic antiretroviral production, he said, "is insufficient to meet national needs."

Six of 17 public laboratories produce 15 AIDS drugs, and Brazil hopes to add four more by 2005, including two new "fixed-dose" combinations and soon, new fixed-dose drugs for tuberculosis and malaria. But it must buy 13 other antiretrovirals from private companies, nine of which are imported. A single imported brand-name drug, Viracept (nelfinavir), eats up 27 percent of the current AIDS drug budget.

Brazil's own regulatory drug agency has approved the quality of its state-produced antiretrovirals. But the WHO has not conducted any quality-control inspections of the state factories or laboratories, a critical step for a drug to be included on its list of approved drugs. A WHO inspection is planned for later this year at Far Manguinhos, the state-run generics plant. Although Rech and Teixeira dismiss talk of pill exports, to an outsider it looks like Brazil is getting ready should the global call come.

Technology, Not Drugs

"We will not break patents," insisted Teixeira. "We are focusing on the

transfer of technology. Our question now is concentrated on how to solve the Doha resolution for developing countries without capacity or production. We are trying to get the WTO to adopt one resolution, for example, where Paraguay can adopt compulsory licensing and ask Brazil to produce, as a way of overcoming these barriers."

With Bush pushing his new international AIDS agenda, Teixeira said, there are hints of the US accepting such a ruling. But critics say even that revision won't do the trick, since countries would still lack political muscle to issue compulsory licenses for generic imports. In September the WTO meets again in Cancun, where a showdown is expected, along with some resolution.

While awaiting the WTO's decision, Brazil has invested \$1 million to set up 10 pilot national antiretroviral production plants, five in Latin America and the Caribbean and five in Africa. It is working closely with the WHO to develop these "proof-of-concept" projects. Teixeira, a tough negotiator, has also been tapped to assist the WHO's new director, Dr. Jong-Wook Lee, in the agency's goal of treating 3 million people by 2005. Teixeira began developing a global scale-up plan for AIDS prevention and care based on Brazil's model in May. In July, Lee appointed him as AIDS Program Director at WHO to implement this plan. By then Brazil was starting to transfer technology and send teams from Far Manguinhos to train technicians in Guyana and Mozambique. The new Bush-Lula agreement is part of this new era of cooperation.

"We will use this as a kind of approval of the Brazilian policy," said Teixeira of the joint US-Brazil venture. "We are putting this out publicly as a sign from the WHO, the new administration and officially the American government, after some hesitation, that they have presented their support to me. We are going to use it, because we understand it is not easy to spend this money [\$15 billion]. They will need help from WHO, from Brazil, from the NGOs (non-governmental organizations)."

Mobilizing Civil Society

With the spotlight on Brazil, the question remains: how useful is its much-vaunted AIDS model for poorer countries? After all, generics are only part of its success. Brazil's AIDS program was built upon a decentralized, unified health system that offers free drugs and care to all. It links prevention to care and treatment, and favors innovative campaigns and strategies.

The government not only distributes condoms widely, but helped finance a condom factory in the Amazon rainforest using latex harvested from live rubber trees. It backs explicit safer sex campaigns in the media and has extended AIDS education to primary public schools, within a general health and sex education curriculum.

Although Brazil has tough laws against illegal drug use, the government supports harm reduction and rehabilitation programs for addicts. Such progressive policies reflect a general openness in Brazilian society to subjects like sexuality and hard drug use that are

more taboo elsewhere. Across Brazil today, AIDS awareness is high.

According to Teixeira, the national program reflects the mobilization of a broad sector of civil society and NGOs who, from early on, viewed the AIDS battle through a civil and human rights lens. These rights are important to a society that has recently undergone re-democratization. In 1988, Brazilians ousted a 20-year military dictatorship and drafted a new constitution, then adopted their universal health care system. In 1991, universal access to antiretrovirals began. A year later, Brazilians got rid of another president accused of dipping into the national coffers. This political engagement by gay activists and civil society spilled over to AIDS. Today, a handful of early activists, including Teixeira, hold key positions in the government AIDS programs.

"The AIDS program as a whole works very well, and I'm very supportive of that, but I always like to repeat, it is so because we were there first," explained Ezio Tavora dos Santos Filho, director of Grupo Pela Vidda (For Life), an AIDS NGO in Rio de Janeiro. An openly gay, HIV-positive activist, he can testify to a rough battle: "The community activists were there before to push the government to do something. People were dying like flies. We just hated the government. If I went to any hospital to say I had AIDS, they would put me out the door." Homophobia, activists assert, was behind Brazil's initially slow response to the epidemic, and drove them to seek legal means to address discrimination.

The role played by the church is also a bit different in Brazil than elsewhere in Latin America. Around 75 percent of citizens are Catholics, and many belong to a progressive wing of the church that includes radical liberation theologians dedicated to helping the poor. These religious groups have supported the government's AIDS prevention efforts, countering the opposition of a minority of conservative Catholics and evangelical Protestant groups.

An Encouraging Picture

Today, there are 600,000 Brazilians with HIV, half the number predicted a decade ago. Two hundred and fifty thousand people are under care, and 130,000 get antiretrovirals, most of them three-drug regimens. Nationally, 70 diagnostic laboratories measure viral loads and T cells three times a year for those on therapy. Officially, anyone who tests positive and registers with the public health system qualifies for free drugs and care. The program also provides prophylactic antiretrovirals for pregnant women and health workers in case of accidental exposure to HIV.

The latest national results remain very positive, showing Brazilians with AIDS continue to benefit from therapy with quickly restored health and a return to productivity. Most patients on therapy are now treated on an outpatient basis. This has boosted their quality of life and saved the health system money.

Most also adhere well to their regimens. An April survey reported a 6.6 percent rate of drug resistance among newly diagnosed HIV cases

in Brazil, far lower than similar figures for resistance in the US (15-26 percent), Britain (14 percent), Spain (23-26 percent) or neighboring Argentina (15.4 percent). Some resistance was expected in Brazil, since suboptimal AZT monotherapy and dual-nucleoside regimens were used before 1995 and 1996, when protease inhibitors were introduced. But it's good news because it shows that poverty or lack of infrastructure does not automatically spell drug resistance, something critics still cite as reasons to withhold therapy from poor countries.

On the downside, drug side effects such as lipodystrophy, a metabolic disorder that causes a disfiguring redistribution of body fat, are a growing problem. The rates are not as high as in the US or Western Europe, but still a cause for concern, said Teixeira. Yet again, Brazil has shown its humane side, helping those with severe lipodystrophy regain an appearance of health by covering the costs of facial cosmetic surgery or liposuction.

Unfinished Business

The generally rosy picture in Brazil tends to obscure the gaps. But they exist, and reflect serious hurdles. Brazil's poverty, say health officials, still limits overall health delivery, especially in rural areas. "It's very important to remember that we made a lot of progress but we didn't solve the situation absolutely," stated Teixeira. "We have some major problems concerning access and prevention. I fear they will not be solved in five years, particularly those dependent on the economic situation of the country."

Another challenge is testing. About 20 percent of Brazil's population has now been tested for HIV, impressive for a country of 170 million. But that still leaves four of five citizens who don't know their serostatus. The government is now pushing to increase voluntary testing rates, particularly in pregnant women; half now get tested. "That's unacceptable," admitted Teixeira.

Prisons are another problem. An estimated 15 percent to 20 percent of the total prisoner population of 200,000 is HIV positive. Conditions inside are terrible, said Teixeira, with severe overcrowding and inadequate facilities to provide care or drugs for inmates with HIV or AIDS.

Meanwhile, activists contend that universal access to care exists on paper, but reality may be different. "Officially, what the government says is that everybody who needs medicine is on therapy; it's not true," said dos Santos Filho. "If you are sick and you are not in Rio or São Paulo or a major city, it will take a while to get your drugs. There is no medicine on the shelf of the pharmacy of the public health center; there is medicine for a number of people who are registered. For new cases, it can take months."

For rural residents, Brazil's vast size is a hurdle. "The only AIDS reference hospital in the state of Amazon is Manaus," stated dos Santos Filho. "We saw cases of people who had to travel 10 days to go to Manaus to get their treatment."

Finally, the health system's decentralized funding structure has its

limits. It has become easier to get antiretrovirals, but not other state-funded drugs for opportunistic infections, malaria or hepatitis. "It's very inconsistent, because the majority of the 27 states don't put a penny in," claimed dos Santos Filho. "Malaria in this country is horrible. I met people who had malaria 12 times in Manaus, a city of 4 million people in the middle of the Amazon jungle. In February, there were 40,000 cases in an urban area."

The Bigger Picture

AIDS NGOs are now beginning to work with groups fighting TB and other diseases to fill this gap. "For a long time, AIDS was seen as the rich cousin among diseases," said Ana Paola Prado of Arco Iris (Rainbow), an AIDS NGO in Brasilia. "Today, we are beginning the opposite movement, a true movement for social control of health as a whole."

Though imperfect, then, Brazil's model is a useful compass for others. Its core tenets are available to all societies: a commitment to health as a civil right, and to upholding or passing laws that protect the most vulnerable citizens from discrimination. Pro-democracy and AIDS activists, progressive church groups, bold congressional leaders and talented health officials also played important roles. "The success of the Brazilian experience is because it was built by many hands," emphasized Prado. "We do not have the best model in the world, but our model answers the demands from Brazil."

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