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Brazil's AIDS Program: A Costly Success

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Brazil has rolled out a successful and widely respected AIDS treatment program, which has relied in part on producing cheap generic versions of anti-retroviral therapy (ART) and in securing significant discounts for patented ART. This paper describes this program and the tactics favored by the Brazilian government to reduce ART prices. While the Brazilian AIDS treatment model has achieved many successes, Brazil's special circumstances mean that it is not replicable in other countries affected by HIV/AIDS. In addition, Brazil's threats to intellectual property (IP) rights have probably deterred some companies from researching new AIDS therapies. As the rise in drug resistance is inevitable—creating the need for new drug therapies—governments around the world should be encouraging as much research and development as possible. Future generations requiring ART, particularly those in the poorest countries, are likely to pay for Brazil's current actions.

Brazil's economy has grown impressively and key health indicators have improved markedly in recent years; the infant mortality rate, for example, has been reduced from 115 deaths per 1,000 live births in 1960 to thirty per 1,000 in 2002.[1] Although the country is large and some areas sparsely populated, more than three-quarters of the population had access to improved sanitation and 87 percent to a sustained water source by 2000.[2] In 2001, diseases of the circulatory system were the highest cause of death[3]—a profile akin to that of the developed world. Against this background Brazil developed an HIV treatment system, partly based on cheap generic drugs.

AIDS in Brazil and Early Responses to HIV

Much of the success of Brazil's AIDS treatment program can be traced to action by civil society groups, particularly gay rights organizations. In 1983, the São Paulo state health secretariat established the first AIDS program. Awareness campaigns were conducted among the sector most at risk—men who have sex with men (MSM)—and notifications of all AIDS cases were compulsory.[4]

By 1990 the government introduced a national health care service, the Sistema Unico de Saude (SUS). The federal government began procuring drugs for HIV/AIDS, while local authorities and states procure drugs for opportunistic infections (the diseases that thrive in the damaged immune system of HIV patients) and sexually transmitted diseases (STDs). Brazil's linkage of STDs and HIV is essential in poor settings where cost considerations are paramount, and is one aspect of their program that should be copied in impoverished locations.

The Brazilian government had a strong health sector upon which to build an AIDS treatment program. Brazil's 2001 *Human Development Report*[5] showed that the government spent 3.2 percent of GDP on its health sector. However this was more than matched by private spending in the health

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sector of 4.4 percent of GDP, representing 57.9 percent of total health spending. The United Nations estimates that at the time there were a healthy 206 physicians for every 100,000 inhabitants in Brazil.[6]

By 1991, the government began to offer Zidovudine to people living with HIV/AIDS, and during the 1990s, a many-layered program of care, prevention, counseling, and treatment was developed through collaboration with civil society groups and religious organizations. This development was greatly aided by the major loans from the World Bank.[7]

The program guarantees free access for the entire population to HIV prevention and care, including the diagnosis of HIV infection, the treatment of opportunistic infections, laboratory monitoring, and the antiretroviral medications (ARVs) necessary for the treatment of HIV infection itself. Brazil outlaws the selling of blood, which significantly reduces the use of infected blood during transfusions—a major problem that helps spread HIV in other poor countries. Brazilian policy for good medical practice with the use of syringe needles is followed in all of the country's health care settings.

Specific goals for 2006 include reducing the prevalence of HIV to:

- 0.6 percent among men aged seventeen to nineteen and women aged fifteen to twenty-six;
- 20 percent among intravenous drug users (IDU), from 36.5 percent in 2003;
- 4.5 percent among commercial sex workers (CSW) aged twenty to twenty-four, from 6.1 percent in 2002; and
- 10 percent among MSM aged twenty to twenty-four, from 14 percent in 2002.[8]

These are modest and feasible targets, which attest to the integrity of the program. The program has the monitoring and surveying capability to make the targets meaningful.

A highly publicized and central role of the National STD/AIDS Program is the federal government's legally guaranteed provision of highly active antiretroviral therapy (HAART) and laboratory monitoring through the public health system to all Brazilians who meet the clinical criteria for treatment (i.e., all HIV-infected patients with CD4 counts below 200/mm^3 and asymptomatic patients with CD4 counts between 200 and 350/mm^3).[9] This commitment was made on the presumption of keeping drug costs low through the local production of generic ARVs.

The federal government is also committed to increasing the national health budget in general as well as to continuing to improve the STD/AIDS program. Further specific goals for 2006 are to reduce AIDS mortality to 6 percent, from 6.3 percent in 2000; and to reduce the incidence of AIDS to ten cases per 100,000, from 14.2 per 100,000 in 2000.[10]

TRIPS, Brazil, the Doha Process, and Domestic Brazilian IP Regulations

Brazil's domestic generic drug manufacturers received a significant boost in December 1971 when the Brazilian government passed Law No. 5772 on Industrial Policy, which gave generic drug producers the right to produce on-patent drugs.[11] Globally, the Brazilian pharmaceutical industry is ranked tenth in terms of expenditure and has over 500 companies and 47,000 employees, manufacturing its own supply of BCG, tetanus toxoid, yellow fever, human and canine rabies, and DPT/pertussis vaccines.[12] Brazilian law did not recognize patents for pharmaceutical products or processes until 1996 when legislation was introduced protecting the rights of innovators.[13] The patent protection, which was only granted to products registered after 1996, is considered to be "quite strong since it provides for a 20-year product patent term, pipeline protection for products in the approval process, and basic biotechnology protections in accordance with [Trade Related Aspects of Intellectual Property Rights (TRIPS)]."[14]

Several ART drugs were registered prior to 1996 and therefore have been legally copied in Brazil.[15] Of the seventeen ART drugs used in Brazil, local manufacturers produce seven, satisfying approximately 18 percent of the total demand.[16]

Legislation was introduced in Brazil in compliance with the TRIPS Agreement of the World Trade Organization (WTO).[17] The TRIPS regulations allowed developing countries a period of five years (to January 2000) in which to introduce the regulations, and least developed countries a period of eleven years (to January 2006). Brazil introduced TRIPS regulations in advance of its five-year grace period.

An objective for introducing the TRIPS regulation was to protect the rights of innovators and promote the dissemination of technology while at the same time balancing these rights with the needs of the consumers of that technology.[18]

Because TRIPS seeks to harmonize patent regulations, many public health experts and activists feared that the agreement would halt the use of and trade in cheap generic versions of medicines that were ordinarily patented elsewhere—putting "profits before patients."

After considerable opposition from some WTO members and from activist groups to TRIPS, a *Declaration on the TRIPS Agreement and Public Health* was agreed to at the WTO Doha ministerial meeting in 2001. Among other things, the declaration noted that the TRIPS Agreement "should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and in particular, to promote access to medicines for all."[19]

Assuring that poor countries could import generic versions of patented drugs or issue compulsory licenses to ensure that those drugs could be produced locally was seen as a vital element in improving public health. In reality, the Doha Declaration is largely irrelevant, as the main reason that people in poor countries lack access to medicines has little do with drug patents and much more to do with poverty.[20] As some commentators pointed out at the time, "The power to import generics and issue compulsory licenses is of little use if the basic health infrastructure is unable to distribute the drugs and ensure good compliance with the drug regimens."[21]

Long before the Doha ministerial meeting of the WTO however, Brazil and the United States were engaged in their own intellectual property trade dispute. Although Brazil introduced TRIPS regulation more than three years before the January 2000 deadline, the patent regulation contained the provision that a patent would only be granted on products manufactured in Brazil. Article 68 of Law No 9.279/96 would allow the Brazilian government to issue a compulsory license for the local generic production of a medicine should the patented product not be manufactured within Brazilian territory within three years of the issuance of the patent.

In the opinion of the Office of the U.S. Trade Representative (USTR), the provisions in Article 68 conflicted with Articles 27.1 and 28.1 of the TRIPS Agreement, which ensure non-discrimination in the protection of patents and exclusive rights of patent holders. In February 2001, the United States therefore filed a complaint against Brazil through the WTO, but decided to drop the case in June of that year. Instead of seeking to resolve the issue through the WTO, both Brazil and the United States decided to use the newly created U.S.-Brazil Consultative Mechanism in order to seek, in the words of then–U.S. trade representative Robert Zoellick, "creative solutions."[22]

In a statement by the U.S. government at the time, the USTR remained adamant that the provisions in Brazilian law that required local manufacturing as a precondition to patent protection were "inimical to the principles of free trade and inconsistent with various WTO rules, including the TRIPS Agreement. The U.S. Government will aggressively engage other countries that impose or maintain such requirements and, if appropriate, pursue WTO dispute settlement."[23]

The Brazilian ambassador to the WTO, Celso Amormim, had previously warned that the U.S. opposition to Article 68 of Law 9.279/96 was "not only legally unfounded. It may also prove politically disastrous."[24] The political pressure against the United States and in favor of Brazil was indeed significant. Numerous AIDS activist and leftist pressure groups strongly supported the Brazilian approach. The U.S. government was widely portrayed as attempting to undermine Brazil's free AIDS treatment approach, and the United States withdrew from the WTO case. Paul Davis of Health Gap Coalition noted, "I think this is a tremendous victory for the Brazilian people and for people with AIDS worldwide."[25]

The tension between the Brazilian and U.S. governments has remained, if not escalated in the interim. In August 2001, the Brazilian minister of health announced his intention to issue a compulsory license for Roche's patented AIDS drug, Nelfinavir. Roche is a Swiss-based company and therefore this action did not directly concern USTR. However, it was indicative of the way in which the Brazilian government was going to secure lower drug prices.

In July 2003, an administrative rule issued by the Brazilian minister of health began proceedings to issue a compulsory license for the production of three ARVs: Lopinavir/Ritonavir, Efavirenz, and Nelfinavir, patented by Abbott, Merck, and Roche Laboratories, respectively. The compulsory license was to be issued to state-run manufacturer Instituto Far-Manguinhos.

The July 2003 decision to issue a compulsory license against Abbott's, Merck's, and Roche's drugs was the first occasion that Brazil utilized the flexibilities of the TRIPS regime and Article 68 of Law 9.279/96.

On December 1, 2004, in the face of rising costs of drug treatment, Pedro Chequer, the head of the Brazilian

AIDS program, announced that the country would break patents in 2005 in order to contain costs. On March 14, 2005, the government of Brazil asked three research-based companies—Merck, Abbott Laboratories, and Gilead—to grant to it voluntary licenses for specified drugs produced by these companies.[26] Furthermore, the Brazilian Ministry of Health gave these U.S.-based companies only until April 4, 2005, to agree to transfer technology to Brazilian drug producers so that they could commence production.[27]

In July 2005, Abbott reportedly reached an agreement with then–Brazilian minister of health Humberto Costa on price reductions on their AIDS drugs. This deal however was not recognized by Costa's replacement, Jose Saraiva Felipe, who took over Costa's position shortly after the agreement was reached. In October 2005, Felipe announced that a new agreement had been reached with Abbott, and on November 30 the CEO of Abbott editorialized in the *Financial Times* confirming an agreement but stressing that continued attacks on patents would weaken future research and development.[28]

The Brazilian government is reported to be continuing its negotiations with both Merck and Gilead. Pedro Chequer characterized the current pricing as "absolutely abusive."[29]

Given the pattern of threats followed by conciliatory negotiations, followed by further threats, it is clear that other drug manufacturers will also be subjected to similar price reduction tactics. These interactions raise several questions: Will other countries follow Brazil's approach? Will Brazil's approach on HIV/AIDS be extended to other diseases? How are Brazil's actions against the research-based industry affecting investment in research for new therapies?

Drug Quality and Resistance

Despite the vibrancy and success of Brazil's drug industry, there were, and are, concerns about the quality of Brazil's domestically produced drugs. A 2000 World Bank study of the Brazilian pharmaceutical industry notes the following weaknesses:

> (1) the insufficient implementation and enforcement of drug regulations which can assure that quality standards are in place (such as Good Manufacturing Practices (GMP)); (2) insufficient and sometimes inappropriate supplies of publicly funded basic medicines; (3) weak human and institutional capacity for drug procurement at the federal, state and local levels; (4) self-medication which can lead to drug resistant viruses if only a partial course of treatment is consumed; and, (5) an absence of bioequivalence and bioavailability testing for generic drugs.[30]

The World Bank study went on to note that between 5 and 7 percent of all medicines sold in Brazil are counterfeit.[31] It is not clear whether the Brazilian government has taken concrete steps to improve quality assurance and the drug registration process. Ordinarily, medicines are subjected to a ninety-day review period for a new application, but the entire process of registration can take up to a year. The exception to this process is AIDS drugs, which, according to the World Bank, are registered in less than a month.

In November 2000, concerns regarding the quality of ART were expressed by the vice president of an organization known as Pela VIDDA/RJ (Group for Assessment, Integration, and Dignity of AIDS Sufferers), Ezio Távora dos Santos Filho. At the tenth meeting of People Living with HIV/AIDS, Mr. dos Santos asked:

> What's in this medication we're taking? We're fighting to break the patents, but we have to have good quality control. One month the drugs come from one company, one month they come from another. This is a serious problem. We swallow this, we accept this. We have to be concerned about the quality. Even with generics, the market [Brazil pays the lowest price it can get] still determines what we swallow. Sometimes we don't even know the capacity of the labs making the drugs. Some lack quality control. It's vital that the Brazilian government works on quality assurance. I want to know that what I'm taking is good for me. Even if the government doesn't consider this a priority, we do. We must not export low quality drugs.[32]

In the five years since Mr. dos Santos Filho expressed his concerns, drug quality remains a real and troubling issue in Brazil. In October 2005, the Brazilian medicines regulator, ANVISA, was forced to suspend the sale of generic versions of the non-nucleoside reverse transcriptase inhibitor, Nevirapine, because of a failure to comply with good manufacturing processes.[33] While ANVISA should be commended for ordering the withdrawal of the drug, it had already been distributed through the public

health system and presumably had been administered to patients on HAART.

Given these concerns it is perhaps better to call Brazil's domestically produced drugs "similars" rather than "generics"—since the latter must have passed bioequivalence and bioavailability studies.

A serious concern, which is directly related to the quality of ART, is the development of drug resistance. Although a 2004 review of primary HIV-1 drug resistance in Brazil found that "rates of primary drug resistance are still low when compared with those of developed nations," Brazil began widespread provision of ART several years after developed nations had.[34] It would therefore stand to reason that resistance levels would be lower than those reached in developed countries. That said, recent studies have found worrying and growing levels of drug resistance in several parts of Brazil. For instance, a study of virologic failure in HIV-1 infected patients starting HAART in Porto Alegre, Brazil, recorded a failure rate of 28 percent—indicating that patients had already developed resistance to treatment they had received.[35]

A 2005 report notes that far higher levels of resistance have been recorded in Brazil. According to the study, in a cross-sectional nonrandomized study:

> 88 percent had TAMs (Thymidine analogue (e.g. ZDV) mutations); 54 percent had resistance to NNRTIs; 58 percent had resistance to PI (protease inhibitors); 42.9 percent and 47.5 percent had resistance to two and three drug classes, respectively, with clade B/F (prior presentations suggest more 215 mutations with clade B virus).[36]

Problems down the Road

The government of Brazil has been widely praised for successfully rolling out its AIDS treatment program. Indeed many of those who require ART receive it, and years of investment in the public health system have ensured that the Brazilian government is able to manage ART patients well.

However, Brazil's national program may become a victim of its own success. By attracting more patients to the program and providing them with good quality treatment for both opportunistic infections and HIV, their lives will be extended and their progression to actual AIDS will be delayed. These are very good things, but they also mean more patients on ART indefinitely. And the longer a patient is treated, the greater the risk that the virus will develop resistance to the drugs he is taking. This risk increases if his treatment is discontinuous or if the drugs are of variable potency. Hence the federal budget for ARVs per person will inevitably increase.

In 1998 Brazil's federal AIDS budget was $426 million, of which 81 percent ($352 million) was spent on treatment; 10 percent ($42 million) on prevention; 9 percent ($41 million) on institutional development; and 0.2 percent ($1 million) on surveillance. In 2000, purchase of ARVs represented 69 percent of total costs, even though the cost per patient had been reduced between 1998 and 2001 by 54 percent, from $4,860 to $2,233.[37] By 2003 the budget for HIV/AIDS was essentially the same as in 1998 ($427 million), despite increased access and care, so this would suggest that the program is probably stable and sustainable. In 2004 the Brazilian government estimated that 154,000 patients were receiving ART treatment at the various health centers. In July 2005, the government announced that it expected the number of people on ART to have increased to 180,000 by the end of 2005.[38]

Indeed, the number of newly reported cases of AIDS stabilized recently to about 20,000 per year, but imperfect reporting and surveillance means there is a two-year lag in data. Studies of viral load in patients show worryingly high incidence of resistance to several drugs in different classes, and already two drugs are no longer recommended for therapy (Zalcitabine, a generic nucleoside reverse transcriptase inhibitor manufactured in Brazil; and Delavirdine, a non-nucleoside reverse transcriptase inhibitor).[39]

It is also a problem that, while AIDS itself is a notifiable disease, HIV infection is not, so there is little evidence of a reduction in new infections. Pregnant women are presenting themselves for testing at antenatal clinics with greater frequency, although prevalence among heterosexual women who are not partners of injecting drug users is very low. A survey of injecting drug users did detect a decrease in HIV prevalence, but this was thought to be due to a switch in habit away from injecting cocaine to smoking crack cocaine.[40] Unless HIV infection can be reduced, the number of patients on ARVs may become unsustainable.

Because of growing resistance to first-line therapy,[41] more expensive newer drugs must be used. Based on figures published by the health charity Médecins Sans Frontières, the average annual price of first-line ART ranges from between approximately $38 and $531. The price of second-line ART ranges between $252 and $1,515.[42] Currently there are far more producers of the first-line

treatments, which would in part account for the lower prices, and perhaps in time more producers of the second-line treatments will emerge. The fact remains, however, that second-line treatments are considerably more expensive than those of first-line; not only is the price of drugs more expensive, but hospitalization and other highly technical inputs may also be required, which vastly increases costs.

Despite Brazil's long experience in manufacturing drugs, shelter from patent requirements has meant little research and development capacity. This will inevitably change, but in the transitional period, Brazil is reliant on private research-based pharmaceutical companies for new drugs.

Here Brazil and almost every other country providing ART now and intending to maintain treatment programs in the future face a significant problem. While the tactic of threatening to issue compulsory licenses seems to have paid off in the short run in Brazil with lower drug prices, the long-run effect in terms of reduced investment in research and development will probably be extremely harmful to existing and future generations of patients on ART. Since 1997, the number of drug companies worldwide engaged in research on HIV/AIDS is down by around 23 percent and the number of new molecules in development for antiretroviral drugs is down by around 30 percent.[43] Research released by the Pharmaceutical Research and Manufacturers of America (PhRMA) confirms that the number of companies engaged in AIDS research has recently increased by about 10 percent.[44] While this increase is good news, it surely is a lot less than would be expected given the significant treatment funding being provided in the past year by the U.S. government, the Gates Foundation, the Global Fund, and others. At a time when people living with HIV/AIDS require renewed research efforts and an increased commitment to develop new therapies, the decline and limited recent uptick of firms investing in HIV/AIDS drugs should be cause for concern.

Without the aggressive stance taken by the Brazilian government on drug pricing, research-based drug companies would be able to price-discriminate more effectively. As it stands, most research-based drug producers have significantly cut the prices at which they sell ART drugs to sub-Saharan countries. The Doha Declaration was designed to assist poor countries with high HIV prevalence secure low drug prices and use the flexibilities inherent in the TRIPS Agreement. Brazil nonetheless threatened compulsory licensing, without ever declaring a health emergency over HIV/AIDS. Unlike most sub-Saharan African countries, Brazil is one of the world's largest economies, with an annual GDP of over US$600 billion. The pressure to reduce drug prices in Brazil probably reduces profitability in an important market for the research-based industry and in effect makes a "poverty disease" out of HIV/AIDS. While the greatest burden of HIV/AIDS is undoubtedly in poor countries, there are several countries (other than Japan, the United States, and those in the European Union) where research-based drug companies can and should make significant profits from their investments.

With reduced profit from markets like Brazil, the incentive to engage in research is reduced; how much it is reduced is uncertain. Improved information is required on this topic and the research-based pharmaceutical industry should be more forthright about the impact of Brazil's pricing. After all, the key issue is not the absolute level of profit that can be generated through research into HIV/AIDS, but the comparative profit that can be made through investment in other disease classes, such as research into cardiovascular drugs. The reality is that HIV/AIDS has to compete for research funding with other diseases, many of which do not carry the political stigma that HIV/AIDS does, and which are less likely to lead to threats against the intellectual property rights that in part stimulated the research in the first place. If Brazil's hostile approach is copied in other middle income countries, then expected returns from future investment will decline further.

Lastly, it is not clear that the Brazilian model of AIDS treatment can be replicated elsewhere in the world. HIV prevalence in Brazil is far lower than it is in sub-Saharan Africa, where HIV prevalence is frequently greater than 20 percent. The profile of HIV infection in Brazil is similar to that of western countries, with higher HIV prevalence among men who have sex with men, commercial sex workers, and intravenous drug users. In addition the Brazilian government has a far higher per capita health care budget.

Tables 1 and 2 detail some of the important differences between Brazil and some key sub-Saharan African countries. A crucial element in any successful ART program is ensuring there are enough sufficiently trained medical staff to treat patients. As mentioned above, Brazil has 206 physicians for every 100,000 inhabitants. The ratio is far worse in sub-Saharan Africa, which has far higher HIV prevalence. South Africa, the most

TABLE 1
LIFE EXPECTANCY AND HIV PREVALENCE IN SELECTED COUNTRIES

	Brazil	Kenya	Mozambique	Nigeria	South Africa	Uganda	Zambia
Life Expectancy (Years, 2003)	68.7	45.4	40.7	44.9	43.27	43.2	36.5
Prevalence of HIV (% of Population Aged 15–49, 2003)	0.7	6.7	12.2	5.4	15.6	4.1	15.6

SOURCE: World Bank, *World Development Indicators Database* (Washington, D.C.: August 2005).

TABLE 2
COMPARISON OF SELECTED HUMAN DEVELOPMENT INDICATORS

	Brazil	Kenya	Mozambique	Nigeria	South Africa	Uganda	Zambia
Population without Sustainable Access to an Improved Water Source (% of Population, 2002)	11	26.4	58	40	13	44	45
Public Health Expenditure (% of GDP, 2002)	3.6	2.2	4.1	1.2	3.5	2.1	3.1
Private Health Expenditure (% of GDP, 2002)	4.3	2.7	1.7	3.5	5.2	5.3	2.7
Health Expenditure per Capita (PPP US$, 2002)	611	70	50	43	689	77	51
Physicians per 100,000 people (1990–2004)	206	13	2	27	69	5	7

Source: United Nations Development Programme, *Human Development Report*, 2005, available at http://hdr.undp.org/reports/global/2005/pdf/HDR05_HDI.pdf.

advanced country in Africa, has only sixty-nine physicians per 100,000 people. Zambia and Mozambique have twenty-seven and two physicians per 100,000 inhabitants, respectively. The superior health infrastructure in Brazil as compared with that in sub-Saharan Africa would in part account for the fact that life expectancy in that country is between twenty-three and thirty-two years higher than it is in some sub-Saharan African countries.

The per capita annual health care spending in Brazil, both public and private, is approximately US$611, while it is only $70 in Kenya, $51 in Zambia, $50 in Mozambique, and $43 in Nigeria.

The fact that Brazil's health care system, health care spending, and rate of HIV prevalence are so dramatically different from those in sub-Saharan Africa makes any comparison of Brazil with this region largely meaningless. To promote the Brazilian model as workable and appropriate in sub-Saharan Africa is not only disingenuous, it is also mischievous and ignores the far more basic infrastructural problems that these countries face as well as their developmental realities, and may, moreover, lead to putting people on unsustainable HAART regimes.

Conclusion

Although Brazil's AIDS treatment program has recorded many notable successes, the aggressive stance that the country has taken in threatening drug patents and forcing down drug prices could weaken incentives for long-run development of new drugs. The government of Brazil has abused the spirit of international agreements such as the Doha Declaration to secure lower drug prices, even though these agreements were intended to secure lower prices for the poorest nations dealing with health problems like HIV/AIDS.

Brazil's almost unique circumstances among countries attempting to deliver increased amounts of ART—with its large and growing economy and relatively minor HIV prevalence—mean that it is not a model that can or

should be replicated elsewhere.[45] Poor nations attempting to save lives through an ART program and by preventing the spread of HIV should reject the aggressive anti-intellectual property and anti-pharmaceutical company stance that, in a resource-poor setting, is unlikely to be helpful in either the short or long term.

Notes

1. O. Bacon et al., "HIV/AIDS in Brazil Country" (report, AIDS Policy Analysis Project, University of California– San Francisco, 2004).

2. Ibid.

3. Ibid.

4. Notifying AIDS patients was extremely useful in planning the treatment response and ensuring that adequate care facilities were in place, but it did not help in measuring the spread of HIV. With lags of over ten years between HIV infection and the presentation of AIDS symptoms, the system of AIDS notification did not assist in monitoring the spread of HIV. The spread of HIV had to be inferred from the number of patients presenting with the symptoms of AIDS.

5. United Nations Development Programme, *Human Development Report*, 2001.

6. Ibid.

7. The World Bank lent $160 million in 1994–1998 and a further $165 million in 1998–2002. In June 2003, a further $200 million project was approved by the World Bank.

8. Brazilian Ministry of Health, *Recommendations for Antiretroviral Therapy in HIV-Infected Adults and Adolescents*, pamphlet, 2002–2003.

9. CD4 T-cells are white blood cells that play a vital role in the body's immune system. CD4 T-cell counts essentially measure the ability of an individual to fight infection and if the CD4 count falls below 200/mm3 an individual is considered eligible for ART.

10. World Bank, *Brazil, Project Appraisal Document: Third AIDS and STD Control Project*, World Bank Report no. 25750-BR, 2003.

11. Jillian Clare Cohen and Kristina M. Lybecker, "AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health," *The World Economy* 28, no. 2 (2005): 211.

12. It should be noted however that with respect to antiretroviral therapy, Brazil's generic producers only manufacture about 18 percent of the required domestic demand.

13. Brazilian Law No. 9.279/96 was passed on May 14, 1996.

14. Opinion expressed by Interfarma (the Brazilian Research-based Pharmaceutical Manufacturers Association) in a report listed on the Industry Canada website, September 9, 2003, available at http://strategis.ic.gc.ca/epic/internet/inimr-ri.nsf/en/gr119569e.html (accessed on October 19, 2005.)

15. The first ART to be produced in Brazil was AZT, patented by GlaxoSmithKline. Currently seven ARTs are produced in Brazil: zidovudine (AZT), didanosine (ddI), zalcitabine (ddC), lamivudine (3TC), stavudine (d4T), indinavir, and nevirapine. The combination drug, zidovudine plus lamivudine (AZT + 3TC) is also produced.

16. PhRMA, "Brazil—Myths and Facts," website write-up, undated, available at http://world.phrma.org/brazil.myths.facts.html.html (accessed on October 12, 2005).

17. The TRIPS Agreement is described by the WTO as "an integral part of the Agreement Establishing the World Trade Organization." The TRIPS Agreement covers "not only patents but other areas of intellectual property" and "lays down not only the minimum substantive standards of protection that should be provided for in each of these areas of intellectual property, but also the procedures and remedies that should be available so that rights holders can enforce their rights effectively." World Trade Organization, "Pharmaceutical Patents and the TRIPS Agreement," website note, July 11, 2000, available at http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm (accessed October 20, 2005).

18. Article 7 of the TRIPS Agreement states that "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to the social and economic welfare, and to a balance of rights and obligations."

19. World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)DEC/2, November 14, 2001, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

20. A. Attaran and L. Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa," *Journal of the American Medical Association* 286, no. 15 (2001).

21. Morris et al., *Ideal Matter: Globalisation and the Intellectual Property Debate* (Brussels: Centre for the New Europe, 2002), 72. The global debate about how the TRIPS Agreement undermines public health continued, despite the Doha Declaration. A further complaint concerned Article 31(f) of the TRIPS Agreement. The contention was that, while countries were granted flexibility to issue compulsory licenses in response to medical emergencies, countries without domestic generic drug production capacity would be unable to take advantage of the flexibility in

the TRIPS Agreement. Negotiations continued until an agreement was reached on August 30, 2003, which secured the rights of least-developed countries to take advantages of the built-in flexibility of the TRIPS Agreement and extended the deadline by which they had to grant patent protection to 2016 (for more information, visit http://www.wto.org/english/news_e/pres03_e/pr350_e.htm).

22. Robert Zoellick, quoted in Gavin G. Yerkey and Daniel Pruzin, "United States Drops WTO Case against Brazil over HIV/AIDS Patent Law," *WTO Reporter*, June 26, 2001.

23. Ibid.

24. Ibid.

25. Susan Warner, "U.S. Drops Case against Brazil over Generic Copies of Medicines," *Philadelphia Inquirer,* June 26, 2001.

26. These drugs were Merck's Efavirenz, Abbott Laboratory's Lopinavir and Ritonavir, and Gilead's Tenofovir.

27. This requirement is based on Presidential Decree No. 4,830 of September 4, 2003, which amends Law 9,279/96 to include conditions under which a compulsory license shall be granted. Specifically, the decree states: "The act whereby a compulsory license is granted may also establish that the patent holder is obliged to provide sufficient information needed to the effective reproduction of the protected subject matter, and the other technical aspects applied to the specific case, otherwise, Article 24 and Title I, Chapter VI of the Law 9,279 of 1996 shall be applied."

28. Miles White, "Drug Patents Are Good for Our Health," *Financial Times*, November 30, 2005.

29. Reuters, "Brazil Close to Deal on AIDS Drugs," October 3, 2005.

30. Jillian Clare Cohen, "Public Policies in the Pharmaceutical Sector: A Case Study of Brazil," *LCSHD Paper Series*, (Washington, D.C.: World Bank, January 2000), 14.

31. Ibid., 18.

32. Mark Harrington, "Brazil: What Went Right? The Global Challenge of Access to Treatment and the Issue of Compulsory Licensing" (*Accesso a tratamento e licenciamento compulsório: desafios em escala mundial*) (presentation, Tenth National Meeting of People Living with HIV and AIDS, Rio de Janeiro, Brazil, November 3, 2000), available at http://www.aidsinfonyc.org/tag/activism/brazil.html.

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45. The extent to which the Brazilian government subsidizes the HIV/AIDS program is unclear. Attempts to discover the level of subsidy failed to unearth any useful data. Without the subsidy level being revealed, it is also possible that the program is even harder to replicate than we argue because of actual costs being far higher than the amount announced.