

Amy Nunn

With foreword by Brazilian President Fernando Cardoso



The Politics and History of AIDS Treatment in Brazil

 Springer

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*To my parents, Gale Stewart and Walter
Nunn, to whom I owe everything, and who
taught me to ask lots of questions.*

“He who saves the life of one man, saves the world entire.”

-The Talmud

“Politics ought to be the part-time profession of every citizen who would protect the rights and privileges of free people and who would preserve what is good and fruitful in our national heritage.”

-Dwight Eisenhower

Foreword

Brazil's public policy response to the AIDS epidemic preceded those of many developing countries. During my tenure as President, in 1996, Brazil adopted a law guaranteeing free and universal access to AIDS treatment for all people living with HIV/AIDS. Brazil became the first developing country to provide publicly-financed AIDS treatment for all people living with HIV/AIDS. We now have one of the world's most successful AIDS programs that is considered a model for other developing countries. Today, 185,000 people receive life-saving AIDS cocktails in Brazil, and thousands of lives have been saved.

But this was not an easy battle.

There were many challenges along the way. Twenty years ago, Brazil's achievements today might have seemed impossible.

During the 1980s, in Brazil, as elsewhere, there was overwhelming stigma associated with AIDS; people living with HIV often lost their jobs and died quickly before the advent of life-saving antiretroviral drugs. Brazil's AIDS movement was extraordinarily important in promoting progressive AIDS policies; associations of people living with HIV were the first to denounce pervasive AIDS-related discrimination and called public attention to the importance of AIDS. Activists protested in the streets for over a decade, engaged the media, and framed AIDS as a human rights issue.

In the late 1980s, Brazil's government created a National AIDS Program. A lynchpin of our national strategy to fight HIV/AIDS were the long-term collaborations Brazil's federal government established with non-governmental organizations (NGOs). Since its inception, and at every step along the way, Brazil's AIDS Program has partnered with civil society. These long-term partnerships have been the most important factor influencing the success of the Brazilian AIDS treatment program.

In 1996, Congress approved national legislation ensuring the right of free and universal access to drugs for AIDS treatment. However, as we treated more people, costs rose quickly. To sustain our AIDS treatment policies, it became absolutely essential to lower the price of antiretroviral drugs. To contain costs, Brazil began publicly producing several generic antiretroviral drugs. When prices continued to climb, we requested that multinational drug companies lower their prices for AIDS medicines. When they refused, we considered producing generic versions of patented drugs locally.

This prompted the United States to issue a WTO trade dispute against Brazil. However, Brazil held its ground, as we believed that providing affordable access to AIDS treatment is part of the fundamental human right to health. The success of the Brazilian AIDS program provided us with the moral and political strength necessary to publicly counter the trade dispute.

Today, much has changed.

In partnership with local and global civil society organizations, Brazil helped promote global AIDS policies similar to those we adopted in Brazil. A strong global alliance of NGOs, scientists and organizations of people living with HIV/AIDS defended our policies to promote affordable access to life-saving AIDS treatment. These groups mobilized and helped sway global public opinion in our favor. United Nations Human Rights and World Health Assembly resolutions in 2001 also urged the WTO to find the proper balance between intellectual property rights and public health.

Under overwhelming public pressure, the United States dropped its WTO trade dispute, and pharmaceutical companies also dropped their prices. As recently as 2000, pharmaceutical companies charged exorbitant amounts for AIDS drugs in developing countries. The cost of an AIDS cocktail in 2000 in Brazil was five to ten times what Brazil pays for the same cocktail today. It wasn't until Brazil publicly challenged pharmaceutical companies about AIDS drug prices and threatened to produce drugs locally that companies lowered their drug prices.

As a result of negotiations with pharmaceutical companies, Brazil has saved over one billion dollars on AIDS drugs. Brazil's struggle has also brought attention to the global challenges associated with high drug costs, and has prompted decreases in global drug prices and more progressive treatment policies around the world.

The United States now finances AIDS treatment programs around the globe, as does the Global Fund to Fight AIDS, Tuberculosis and Malaria. The World Bank commends Brazil for its world-renowned AIDS program and finances AIDS treatment and care programs globally. Today, millions of people in developing countries around the world receive AIDS treatment, many who might not if Brazil hadn't challenged drug companies about prices and proved that AIDS treatment was possible in a developing country.

Brazil's feats in the field of HIV/AIDS are among the most important public policy achievements of my presidential administration. Thanks to broad partnerships with civil society, Brazil demonstrated that AIDS is not an intractable problem. Naturally, there were moments of intense disagreement among all the actors involved in implementing Brazil's HIV/AIDS policies. However, it is precisely those tensions, healthy public debates, calls for public accountability, and long-term partnerships with civil society that have been critical to our National AIDS Program's success.

With an interdisciplinary approach and painstaking attention to detail, Amy Nunn tells how and why Brazil developed its remarkable treatment programs, how they were related to democratization and globalization, and why they matter for global public health. With dozens of original interviews, thousands of news articles, historical analysis, and new economic analyses about the cost of AIDS treatment in

Brazil, Nunn has written a powerful book that tells the complex story of how and why Brazil, against all odds, turned the tide against HIV/AIDS in South America and revolutionized global AIDS treatment.

This book has been published at a critical moment in history, when the global health community is grappling with how to effectively respond to the AIDS crisis, a global scourge of unprecedented scope. Brazil's story, as told movingly in *The Politics and History of AIDS Treatment in Brazil*, serves as a testament to what is possible with effective leadership, a vibrant civil society, and global cooperation on the critical social issues of our time.

Fernando Henrique Cardoso
President of Brazil, 1995-2002

Foreword

Brazilian science has a centuries-long tradition of collaborating with international scientists. Brazil's tradition began with the "traveler-scientists", such as the German naturalist Alexander von Humboldt, who acquired a deep knowledge of Brazil's flora and fauna after his long excursions throughout the Brazilian Amazon. Another illustrious naturalist, the Danish Peter Wilhelm Lund, fell in love with Brazil's geology and climate and moved to Lagoa Santa in the state of Minas Gerais, where he made breakthrough discoveries in the field of archeology and paleontology.

Charles Darwin's diaries represent both a comprehensive inventory of our natural life, as well as interesting insights into Brazilian culture. Darwin wrote poignantly about 19th century Brazilian society, strongly criticizing the abuses of black slaves by Brazilian farmers and merchants. His papers and books on natural history, geology and evolution, inserted Brazil into a global system of ideas Evolutionary Biology for the first time. The illustrious German scientist Johann Friedrich Theodor Müller, Darwin's regular correspondent and provider of key specimens for his private collections, created the first institutions dedicated to the preservation and study of natural sciences in Brazil. This collaboration marked the beginnings of important centuries-long collaboration between Brazilian and foreign scientists.

This tradition of international collaboration continued into the 20th century, when American and French sociologists and anthropologists had strong influence on 20th century Brazilian thinking. German-American Franz Boas, the founding father of American anthropology, became the grandfather of Brazilian anthropology and cultural studies through the hands of his creative disciple Gilberto Freyre. In the 1920s and 1930s, renowned French scholars, such as the sociologist Roger Bastide and the anthropologist Claude Lévi-Strauss, in partnership with sociologist Florestan Fernandes and the literary critics Antonio Candido de Mello e Souza, established the first academic programs in anthropology and sociology in Brazil.

The early 20th century witnessed the birth of Brazil's modern public health and tropical medicine scholarship, led by Oswaldo Cruz, Carlos Chagas, and other notable founding fathers of the Oswaldo Cruz Foundation, which became Brazil's premier public health research institute.

However, during the 1960s, Brazil's dictatorship assumed power and ruled for 21 years. Unfortunately, the long dictatorship had strong adverse impacts on freedom

of speech and thinking, as well as Brazilian scholarship. The censorship imposed on access to documents and public information had detrimental impacts on long-term dialogue between Brazilian and international scholars. Nevertheless, during this time, the first departments in American and British Universities dedicated to studying Brazilian society and culture were established by the American historian Thomas Skidmore and the British literary critic John Gledson.

During the 1980s, Brazil began its long process of democratization, called *abertura*, which means “opening” in Portuguese. This period witnessed the return of expatriates and scholars, the reawakening of scholarship, as well as the modernization of Brazilian universities and research centers, including the Oswaldo Cruz Foundation. Among many other achievements by FIOCRUZ scientists, Bernardo Galvão-Castro isolated the HIV virus, only a few years after the original discovery by Gallo in the US and Montagnier in France. Since then, FIOCRUZ has maintained an enduring commitment with the national efforts to curb the AIDS epidemic and fosters collaboration with interdisciplinary research teams and activists around the globe.

During the 1980s, as the AIDS epidemic emerged as the most devastating pandemic in human history, the new Brazilian Constitution was promulgated, with its concept of health as a duty of the state and a right of citizens. This period witnessed the intense mobilization of the sanitary movement activists and scholars, and the key role of former expatriates, such as Herbert Daniel, sociologist and gay activist, and Herbert de Souza, known as Betinho, one of the most charismatic and influential sociologists and leader of numerous social movements in contemporary Brazil. These activists and a social movement for HIV/AIDS strongly influenced Brazil’s response to the AIDS epidemic, intrinsically linking the public policy response with the protection and promotion of human rights of people living with HIV/AIDS.

During the 1990s, and into the 21st century, Brazil’s tradition of international research collaboration has continued in the field of HIV/AIDS, with the important contributions of American anthropologist and AIDS activist Richard Parker, as well as the seminal work by the author of this book, Amy Nunn.

Amy Nunn first appeared in Rio de Janeiro as a promising PhD candidate from Harvard University, an institution with a long and successful collaboration with Brazil in all fields of science and the humanities. Equipped with a solid background in different areas of social sciences and public health, and with perfect command of Portuguese, Nunn resumed the enlightened scientific tradition of her illustrious predecessors, conducting exhaustive exploration of the civil society and public policy response to HIV/AIDS in Brazil. With deep understanding and appreciation for Brazilian culture, she traveled the country from top to bottom, interviewing dozens of politicians, activists, public servants, scholars, people living with HIV, pharmaceutical industry executives, and countless others. Only someone with her stamina, intrepid spirit, *joie-de-vivre* and painstaking attention to detail could have written this comprehensive volume about Brazil’s response to the AIDS epidemic.

Nunn’s book is situated at the complex crossroad of foreign affairs and domestic policy, exploring the AIDS epidemic as well as the broad social and biomedical

issues influencing the Brazilian public policy response to the AIDS epidemic. The social, political and economic conflicts related to HIV/AIDS, including Brazil's ongoing production of generic AIDS medicines and its heated price negotiations with drug companies, are all explored in detail in this powerful volume. By unpacking the complex historical development of Brazil's response to the AIDS epidemic, Nunn's book helps pave the way for other societies to learn from Brazil's example.

Brazil's response highlights the pressing need to fully integrate efforts to curb the epidemic with the respect for human rights in the context of a democratizing society. Her detailed chronicle of Brazil's decades-long fight and ultimate triumphs in the field of AIDS are a valuable resource for any society that wants to preserve and build its democratic institutions while mounting a successful response to the AIDS epidemic. Nunn explores the myriad themes influencing the Brazilian response to the AIDS epidemic, including Brazil's ongoing challenges with decentralization of prevention programs and health services delivery, state-sponsored versus grassroot-driven public policies, and the challenges of providing cutting edge scientific technology in emerging markets. These are among the many dilemmas Nunn explores in this extraordinarily researched and well-documented book.

Nunn's book is the latest seminal contribution to the multi-century tradition of collaboration between international and Brazilian scientists. As Richard Morse teaches in his classic "Prospero's Mirror," which provides insights into North American and Latin American relations, we must explore and develop deep understanding of other societies in order to better understand ourselves. By taking a deep look at Brazil's response to HIV/AIDS, Nunn's book helps scholars, activists and a general audience understand how Brazil both fought AIDS at home and defined the world's response to the AIDS epidemic. Brazil's response, as told poignantly by Amy Nunn, demonstrated that every person is a citizen of a globalized world, a world plagued by global dilemmas and challenges. Amy could repeat the old adagio coined by the Latin writer Terence: "I am a human being, so nothing human is strange to me."

Francisco Bastos
Senior Researcher, Oswaldo Cruz Foundation

Acknowledgments

The notion that a book is an independent project is a myth. I could never have completed this project without the gracious assistance of many special people.

One important lesson I learned while conducting research for this book is that one must *never* decline coffee in Brazil. When a Brazilian says, “*Vamos tomar um cafezinho?*” Portuguese for “Want to get some coffee?” what they really mean is, “Let’s talk. I’ve got something to tell you.” And boy, do Brazilians talk! I quickly learned to drink lots of coffee. Brazil must be the most social society on the planet, which makes it a qualitative researcher’s paradise. Never have I visited a country where people are so generous with their time or are so fun to talk to. No one ever declined an interview. Over hundreds of coffees, I had interviewed doctors, psychologists, policymakers, politicians, pharmaceutical industry executives, activists, public servants, and experts of all stripes, all of whom enthusiastically participated in this project. These people made this research possible and turned what would otherwise have been a lonely research project into a Brazilian adventure. I must also acknowledge how much these individuals inspired me: many of the 86 people I interviewed are trailblazers in diplomacy, global health, and public and private sector policymaking. The world is different today because of their hard work. By proving that AIDS treatment is possible in developing countries, and through their tireless advocacy, they have helped save millions of lives. I am truly awed by their accomplishments and honored by the time they spent with me while I conducted research for this book.

This book emerged out of my dissertation at the Harvard School of Public Health I’d be remiss not to formally thank my fantastic dissertation committee, including Michael Reich, Sofia Gruskin, and Joshua Salomon, all of whom have profoundly impacted my thinking and professional development. Working with three of the best scholars in global health was truly a gift. It was Michael Reich who first encouraged me to explore Brazil’s AIDS treatment program. His no-nonsense approach to using political analysis to explain health phenomena in developing countries impacted me in more positive ways than I could possibly squeeze into a paragraph. In the five years I worked under his supervision, his professional, fundraising, and academic support always went above and beyond the call of duty, often prompting me to wonder how he is able to simultaneously balance leadership, scholarship, and mentorship. Sofia Gruskin has been an exceptional role model

whose dedication to teaching students and advancing the field of health and human rights are unparalleled. Her passion and work ethic are contagious and set an exceptionally high standard for public health scholarship and practice. Joshua Salomon always made me think in new ways and forced me to challenge many of my assumptions. I remember numerous meetings in which Josh asked simple, yet profound, and often show-stopping questions that forced me to look at things in different, and always very useful, ways.

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This project would not have been possible without the generous support of several donors, including the US government, which financed my four years of Portuguese study and two years of fieldwork. I am also indebted to the Harvard Business School CASE program and the Harvard Center for Population and Development Studies, which supported my preliminary fieldwork. The Brown University Center for AIDS Research also supported me while I finished writing this manuscript.

I owe everything, including my curiosity and interest in political history, to my parents, Walter Nunn and Gale Stewart, the dynamic duo whose books on Arkansas politics and government inspired my own work. I thank them for their exceptional generosity and unconditional love, their thoughts on my ideas, and for always making learning fun. They have always pushed me to ask hard questions but tell me when I am wrong. My mother has frequently reminded me that “Southerners don’t think slow, we just talk slow.” I’d be remiss not to recognize my father’s important comments on countless grant proposals and dissertation chapters – is there a more sincere expression of love than to read and comment on someone’s entire dissertation?

Lastly, I acknowledge the important role my husband, Germán Velasco, has played in this process. Germán helped me in myriad ways, accompanying me to the most far-flung corners of Brazil, including the beautiful Northeast and spectacular Amazonia. Germán encouraged me in other moments from across the globe during my fieldwork, provided comments on my analyses, and answered many medical questions about AIDS. He supported me financially while I realized my dream of pursuing a doctoral degree at Harvard University. Most importantly, it was Germán’s optimism and sunny disposition that gave me the strength to persevere during the difficult moments of this ambitious project.

Amy Nunn

Contents

| | |
|--|----|
| Introduction | 1 |
| Ezio's Story..... | 1 |
| AIDS in Brazil..... | 2 |
| References..... | 8 |
| | |
| 1 The AIDS Crisis and Democratization in Brazil | 11 |
| Brazil..... | 11 |
| Building Democracy in Post-Authoritarian Brazil..... | 15 |
| The State and Public Health..... | 18 |
| AIDS in Brazil..... | 20 |
| Brazil's AIDS Program..... | 22 |
| References..... | 26 |
| | |
| 2 Democratization and Institutional Precursors to AIDS | |
| Treatment in Brazil | 31 |
| Sanitarista Health Reform Objectives..... | 31 |
| Reformers Working Within the State..... | 33 |
| Brazil's First Public and Civil Society Partnerships for AIDS..... | 34 |
| The Evolution of Sanitarista Strategies in Postauthoritarian Brazil..... | 36 |
| AIDS Activism in Rio de Janeiro State..... | 38 |
| The 1988 Constitution and the Right to Health..... | 40 |
| References..... | 43 |
| | |
| 3 Development of Brazil's First AIDS Treatment Institutions | |
| in a New Democracy | 45 |
| Social Movements Infiltrate the State..... | 45 |
| Early Federal AIDS Programs..... | 46 |
| The Genesis of the AIDS Movement..... | 49 |
| Committing to Treat AIDS..... | 54 |
| National AIDS Program Partnerships with the AIDS Movement..... | 61 |

| | |
|--|------------|
| Mounting Pressure for AIDS Treatment and Brazil's First World Bank Loans for AIDS | 64 |
| References..... | 70 |
| 4 Legislative Reforms and AIDS Treatment in the 1990s..... | 75 |
| Public/Private Partnerships to Develop AZT | 76 |
| Public Production of AZT..... | 78 |
| Industrial Property Law 9.279 | 80 |
| Fernando Henrique Cardoso's 1994 Presidential Victory..... | 80 |
| Brazil and the World Trade Organization | 82 |
| Law 9.279's Implications for AIDS Treatment..... | 84 |
| Political Action and Chronic Shortages in Drug Supplies for AIDS Treatment | 85 |
| Sarney's Law: Law 9.313..... | 87 |
| Cumulative Impacts of the Industrial Property Law and Sarney's Law | 91 |
| References..... | 91 |
| 5 Development of Brazil's Contemporary AIDS Treatment Institutions | 95 |
| Sanitarista Leadership in the National AIDS Program Bureaucracy..... | 95 |
| World Bank AIDS II Loans | 100 |
| AIDS II and the AIDS Movement | 102 |
| The Evolving Political Context of the Late 1990s..... | 104 |
| The 1998 Drug Policy Reforms | 108 |
| A Decisive Step: José Serra and the Domestic Production of ARVs..... | 109 |
| References..... | 115 |
| 6 Brazil's Contributions to Global Essential Medicines Institutions | 119 |
| Growing Political Momentum for Affordable Access to Medicines The Global AIDS Treatment Movement..... | 120 |
| Global Launch of Generic ARVs | 121 |
| The Global Fund to Fight AIDS, Tuberculosis and Malaria..... | 123 |
| José Serra's Essential Medicines Strategy | 123 |
| Brazil's Efforts to Change Global Essential Medicines Institutions in 2000 | 126 |
| Brazil's Contributions to Global Essential Medicines Institutions in 2001 | 127 |
| Intellectual Property and Human Rights Resolution | 131 |
| US Drops WTO Dispute | 134 |
| The UN General Assembly Special Session on HIV/AIDS | 135 |
| World Trade Organization..... | 136 |
| Price Declines for ARVs in Brazil | 139 |

| | |
|--|-----|
| The Symbiotic Relationship between José Serra and the AIDS Movement | 140 |
| Brazil's Contributions to Essential Medicines Institutions from 2002 to 2006 | 142 |
| Brazil's Enduring Legacies | 143 |
| References..... | 144 |
| 7 Conclusion | 149 |
| Building Brazil's AIDS Treatment Institutions | 150 |
| Costs and Compulsory Licenses | 152 |
| Looking Ahead..... | 156 |
| Global Impact..... | 158 |
| Implications for Other Countries | 160 |
| Study Strengths and Limitations..... | 163 |
| The Brazilian Model | 165 |
| References..... | 166 |
| Appendices | 171 |
| A Note on Sources | 179 |
| Index | 181 |

Introduction

Ezio's Story

Ezio has been living with HIV for 23 years. Every day, he wakes up and takes a handful of AIDS medicines that he gets at one of the Brazil's public health clinics in Rio de Janeiro. Twice a day, he injects himself with enfuvirtide, another AIDS drug. These drugs keep Ezio alive: although Ezio has twice survived tuberculosis, an infection common among people living with AIDS, today, he is healthy and is one of the Brazil's most well-known AIDS activists.

However, it was not always so easy to get AIDS medicines in Brazil. In fact, Ezio has outlived most of his friends who were diagnosed with HIV in the 1980s and 1990s, many of whom died before antiretroviral medicines were invented or became widely available in Brazil. Ezio was one of the lucky few who started taking AZT, the first AIDS drug brought to market, in 1990, immediately after its launch in Brazil. In the early 1990s, before AIDS drugs became readily available in Brazil, Ezio's family went to great lengths to gather enough money to pay for his treatment. Until 1996, his family paid nearly \$1,200 a month for his AIDS cocktails. In 1997, the year after Brazil adopted a law guaranteeing free and universal access to treatment, everything changed. AIDS drugs became available throughout clinics in Brazil, and Ezio, along with thousands of other people living with HIV, no longer had to pay for their medications out of pocket or forego treatment altogether. Since then, Brazil has managed to finance and provide AIDS treatment to over 185,000 people living with HIV/AIDS.

In 2008, financing treatment for his medicines is no longer Ezio's principal concern. The Brazilian government pays for the drugs for his treatment, even injectable enfuvirtide, a drug that costs over \$17,000 per year that is used as a "salvage therapy" to prolong the life of AIDS patients when other AIDS medications fail. Today, Ezio's principal concern is educating other people living with HIV about how to prevent tuberculosis and how to get people living with HIV and tuberculosis into long-term treatment. He's also engaged in AIDS programs beyond Brazil's borders, and has worked with the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria; the Open Society Institute on HIV/TB coinfection programs; and the Global Stop-TB partnership.

If Ezio had been born in almost any other developing country, he probably would not be alive today. More than 25 million people have died of HIV/AIDS worldwide since AIDS first surfaced as a mysterious fatal disease among gay men in 1981 in Los Angeles. Approximately 33 million people live with HIV/AIDS today, 2.5 million of whom are children. Although there is still no vaccine to prevent HIV infection and no cure exists for AIDS, the disease is now considered a chronic illness in developed countries because of the widespread availability of life-saving antiretroviral drugs (ARVs). However, millions of people living with HIV/AIDS in developing countries do not yet have access to highly active antiretroviral therapy (HAART) for AIDS treatment. Although the number of those living with AIDS receiving HAART in developing countries quintupled to 3 million from 2001 to 2008, less than a third of the ten million in need of HAART in developing countries receive it today. Moreover, many of the three million people who died of AIDS-related causes in recent years perished because they did not have access to HAART [2, 3], highlighting the grave consequences of poor global access to AIDS drugs.

Because Ezio was born in Brazil, which has long since provided treatment to all people living with HIV/AIDS, his life has been saved. In many ways, Ezio's experience is emblematic of the long history of the Brazilian AIDS program, and highlights many of the program's victories and current challenges. Today, hundreds of thousands of people in Brazil take AIDS medicines. AIDS-related deaths declined radically after 1996, when Brazil began providing free and universal access to AIDS treatment for all people living with HIV/AIDS. However, precisely because Brazil's AIDS patients are living longer, they require costly new, patented drugs to keep the HIV virus in check. Making the newest drugs available has caused the costs of treating the average AIDS patient to more than double in recent years.

In spite of the rising costs associated with treatment in Brazil, the country has miraculously saved the lives of hundreds of thousands of people like Ezio who live with HIV/AIDS. Brazil has also been enormously influential in shaping global AIDS policies, and in so doing, has revolutionized global AIDS treatment. *The Politics and History of AIDS Treatment in Brazil* tells Brazil's long and complex success story with AIDS treatment.

AIDS in Brazil

Approximately 12% of all people receiving HAART in developing countries reside in Brazil, home to the developing world's first and now largest public AIDS treatment program [4]. After Brazil began providing free and universal access to HAART in 1996, AIDS-related mortality and morbidity declined precipitously, the life expectancy of AIDS patients improved dramatically, and mother to child (vertical) transmission of HIV has been all but eliminated in Brazil [5–10]. Brazil's drastic improvements in population health outcomes stemming from AIDS treatment are remarkable and unprecedented in a developing-country setting.

The means by which Brazil has achieved these health outcomes is equally compelling. Rejecting donors' warnings that treating AIDS patients was not cost-effective

and should not be a public policy priority in a developing country, in 1996, during the Cardoso Administration, Brazil's Congress passed legislation guaranteeing free and universal access to HAART [11]. Brazil, which has the world's 10th largest pharmaceutical market and a long history of public drug production, began large-scale production of seven non-patented ARVs in the late 1990s. In 1997, also during the Cardoso Administration, Brazil began recognizing intellectual property protection for pharmaceutical products, much earlier than the World Trade Organization (WTO) deadlines of 2005 and 2016 for middle and low-income countries [12–14]. As a result, the remaining eleven ARVs in Brazil's AIDS treatment guidelines are under patent in Brazil and purchased from multinational pharmaceutical companies. Because of the high prices of several patented ARVs, since 2001 the Health Ministry has threatened to issue compulsory licenses to produce some ARVs locally. Under World Trade Organization rules, a compulsory license allows governments to produce or grant a third party authority to produce a drug without consent of the patent holder in cases of national public health emergency, among other limited circumstances [12–14]. Brazil's threats to issue compulsory licenses have attracted international media attention about ARV prices, prompted a trade dispute with the United States, and induced price negotiations with multinational pharmaceutical companies for five patented ARVs [15, 16]. In 2007, Brazil issued its first compulsory license for an ARV to import an antiretroviral drug from India, cutting the price for the drug by more than half. In 2008, Brazil announced it will produce efavirenz in public drug facilities. In attempt to justify its domestic AIDS institutions and fend off trade disputes, Brazil has also contributed to important changes in international health, human rights, and trade institutions governing essential medicines.¹

The importance of Brazil's AIDS treatment institutions extends far beyond the 185,000 Brazilians that received HAART for AIDS treatment in 2007; Brazil's domestic and international efforts have revolutionized AIDS treatment and global public health. By offering free and universal access to HAART and presenting a clinical and epidemiological evidence base that HAART could be scaled up in resource-limited settings, Brazil left an indelible imprint on global AIDS institutions, as did Brazil's challenges to multinational pharmaceutical drug prices. Brazil also spearheaded efforts to change international trade, health, and human rights institutions related to essential medicines (hereafter referred to as global essential medicines institutions), which had profound and lasting impact on global AIDS treatment institutions.

Brazil's AIDS treatment institutions are the result of several domestic and international political processes that unfolded slowly over time. Brazil's universal treatment policies developed as part of a complex 20-year process of democratization and were intricately related to two grassroots social movements that promoted greater access to health services. Additionally, Brazilian politicians' controversial decisions to produce ARVs locally and to challenge multinational pharmaceutical

¹“Essential medicines” is a term coined by the 1977 World Health Organization's first *Model List of Essential Medicines*, which established the first international guidelines for medicines that all governments should make available to their populations. The concept of essential medicines will be revisited in chapters 6 and 7.

companies on drug prices were strategic and deliberately highly politicized. Moreover, Brazil's efforts to change global essential medicines institutions were part of a global social movement for greater access to AIDS treatment. In spite of the remarkable achievements in health outcomes stemming from its AIDS treatment policies and the impact of the Brazil's AIDS treatment institutions on global AIDS treatment paradigms and ARV prices, little research has examined development of the Brazil's AIDS treatment institutions in these political contexts.

Complex political processes related to development of Brazil's AIDS treatment institutions from 1985 to 2008, including Brazil's evolving democratic institutions such as: new political parties, the 1988 Constitution, a freer press, social movements, and even Brazil's increased participation in international political institutions – ultimately influenced the public policy responses to the AIDS epidemic. Viewing development of AIDS treatment institutions through this lens elucidates the institutional openings that gave rise to the AIDS treatment institutions observed in Brazil today, explains how and why democratization and globalization gave rise to AIDS treatment institutions in Brazil, and demystifies Brazil's long-term political commitments to HIV/AIDS treatment. Understanding the institutional preconditions for scaling up AIDS treatment may also have important implications for AIDS interventions in other developing countries.

The Politics and History of AIDS Treatment in Brazil explores how several factors influenced Brazil's current AIDS treatment institutions. First, it examines how politicians responded to and operated within the confines of Brazil's fledgling democratic institutions, which evolved constantly after Brazil's 1988 Constitution and during the Cardoso Administration, until 2000. It also explains how political actors responded to and even worked with two vibrant social movements to improve population access to health services during the 1980s and 1990s. Third, the book explains the role of international political actors and institutions in the development of Brazil's domestic AIDS treatment institutions, including the United States government, the World Trade Organization, the multinational pharmaceutical industry and the World Bank. Finally, *The Politics and History of AIDS Treatment in Brazil* explains how and why Brazil helped shape international essential medicines institutions between 2000 and 2006.

Using a historical institutional approach, *The Politics and History of AIDS Treatment in Brazil* argues that AIDS treatment institutions – that is, laws, traditions, and public policies for AIDS treatment in Brazil – unfolded slowly over time between 1988 and 2006. Historical institutionalism explains how and why institutions develop over time, and holds that institutions shape political behavior and outcomes and vice versa [17–19]. *The Politics and History of AIDS Treatment in Brazil* explains how the long-term dynamic interaction of political actors, social movements and Brazil's fledgling democratic institutions produced Brazil's contemporary AIDS treatment institutions.

Institutions examined in this book include the development of: (1) Brazil's tradition of publicly financing and supplying drugs for AIDS treatment for AIDS patients since 1990; (2) a 1996 law approved by the Brazilian Congress in 1996 that guaranteed free and universal access to drugs for AIDS treatment; (3) Brazil's scale-up of public antiretroviral drug production in the late 1990s; (4) Brazil's

tradition of threatening to issue compulsory licenses as a means of inducing price negotiations from multinational pharmaceutical companies since 2001; and (5) Brazil's wide-ranging contributions to global essential medicines institutions from 2000 to 2006.

For the purposes of this book, institutions are not always laws or public policies. In some cases, institutions are organized or expected practices that are not legally codified. For example, Brazil's repeated threats to issue compulsory licenses are a tradition and not a law. However, this tradition represents a repeated, organized, and now expected practice that has been adopted by a variety of political actors in Brazil and is an institution whose development this book explains.

Although some of the Brazil's AIDS institutions developed slowly, others were quick decisions that were immediately reinforced by complex social processes, creating longer-term traditions. For example, Health Minister Alcení Guerra's 1990 decision to first publicly offer drugs for AIDS treatment was a spontaneous decision that occurred in the context of a new public health system that complex social processes later reinforced, creating long-term institutional tradition of providing free access to drugs for AIDS treatment. In contrast, Brazil's public production of ARVs began in several states in the early 1990s but was only scaled up at the federal level in 1998 when Cardoso Administration Health Minister José Serra began using an old institution to achieve new political goals. Whether institutions developed slowly or quickly, this analysis explains the factors influencing their development.

Each of the aforementioned institutions was important and had lasting impacts on public policy. However, *The Politics and History of AIDS Treatment in Brazil* argues that what matters most about these institutions is not their individual impact, but their *cumulative and long-term* effects on contemporary AIDS treatment institutions in Brazil. Development of these institutions was path dependent; each institution built on the previous institution and was influenced by other social processes.² This book explains how and why each of these institutions developed, how they relate to each other, and how other social, democratization, and globalization processes reinforced their development. Together, these AIDS treatment institutions have had important impacts on health and economic outcomes in Brazil as well as global AIDS treatment institutions.

The argument of the book is presented in five steps. The first step identifies the time frame and provides relevant background information for the second step, which explains the events and social processes that established the initial trajectory for AIDS institutions in Brazil. The third step identifies "critical junctures" in

²Path dependence is a political science theory that holds that once an institutional trajectory is established, it becomes increasingly more difficult for political actors or other forces to change the course of that institution's development, particularly as other social developments reinforce existing institutional arrangements over time. Because events that occur early in a chain of events often define the path of institutional development, they may be of greater significance than later events. Moreover, because the cost of switching from one alternative may vary at different points in time, *when* something happens may be as important as *what* happened [19, 20].

development of AIDS treatment institutions. A critical juncture refers to a turning point in institutional development.³ The fourth step explains the social mechanisms that generated positive feedback that reinforced commitments to AIDS treatment. The process of reinforcement often influenced political actors' decisions and led to political entrepreneurship; the fifth step, therefore, identifies and explains how political actors both reacted to and helped shape new institutional arrangements. The sequencing of events is particularly important to this entire analysis, as both the specific order of domestic and international events created a path-dependent process in which each institutional development often reinforced or built upon existing institutions.

Chapters 1 and 2 focus on the first and second methodological steps, situating the inquiry in time and context. These chapters provide essential background for the book's central theme: how and why Brazil's democratization process influenced development of Brazil's AIDS treatment institutions. Chapter 1 provides background on Brazil's slow process of democratization during the late 1970s and throughout the 1980s, explaining the relevance of several of Brazil's fledgling democratic institutions, including new legislative, judicial, and executive branch institutions, in shaping initial development of Brazil's AIDS institutions. Chapter 1 also examines how development of a new health system and an ongoing process of decentralizing public policy in Brazil set the stage for development of Brazil's AIDS institutions.

Chapter 2 also provides important background information for understanding the institutional arrangements discussed in the remainder of the book. It explains the development of political institutions and civic activity related to AIDS in the 1980s. Chapter 2 also explains the social processes influencing development of Article 196 in the 1988 constitution, which established health and health services as citizenship rights in Brazil. These developments gave rise to the critical junctures shaping development of AIDS treatment institutions in the 1990s.

Chapters 3–6 explain the development of Brazil's AIDS treatment institutions between 1988 and 2006. By identifying critical junctures in the process of institutional development, these chapters explore how and why democratization and globalization provided windows of opportunity for social change. These chapters then discuss how political actors' responses to those windows of opportunity and the events and social processes that either reinforced existing patterns of institutional development or changed the path of development of AIDS treatment institutions. Since critical junctures and reinforcing social mechanisms both depend on previous institutional developments and influence future institutional development, those relationships are identified and explained in each of chapters 3–6.

³In path dependency theory, critical junctures refer to turning points in which one path is chosen that has important implications for institutional outcomes. Critical junctures are events whose outcomes are *not* set in stone; a variety of alternatives that *did not occur* might have produced a different outcome. Critical junctures are frequently occurrences without concrete explanations whose outcome was not determined by the previous set of conditions or theories. However, analyzing the social phenomena leading up to the critical juncture often elucidates the social and institutional conditions that gave rise to the critical juncture [19, 21].

Chapter 3 explains the events that established the trajectory for AIDS treatment institutions in Brazil, focusing on the social processes influencing development of AIDS treatment institutions after the 1988 Constitution through 1995 in post-authoritarian Brazil. This chapter draws on social movement theory to explain how AIDS activists accommodated their political strategies to new democratic institutions in post-authoritarian Brazil. It explains the development of Brazil's social movement for AIDS and directly links Brazil's AIDS movement to the health minister's decision in 1990 to publicly finance AIDS treatment in Brazil, the first critical juncture and institution whose development this book analyzes. Chapter 4 explains how other factors such as political activism in the courts generated positive feedback,⁴ reinforcing development of Brazil's new commitment to publicly-financed AIDS treatment while simultaneously shaping the political landscape that would allow for the next critical juncture, National AIDS Program (NAP) Director Lair Guerra's⁵ decision to hire AIDS activists to write World Bank loans.

Chapter 4 also examines factors influencing the development of AIDS treatment institutions that were unrelated to the social movement, including the genesis of public production of generic AZT in the early 1990s and development of an Industrial Property Law approved by the Brazilian Congress in 1996. These events contributed to the institutional context preceding the third critical juncture, Senator José Sarney's decision to sponsor legislation to guarantee free and universal access to all people living with HIV/AIDS (PLWHA), commonly referred to as Sarney's Law. Chapter 4 also explains how the Industrial Property Law and Sarney's Law reinforced Brazil's commitment to AIDS treatment while changing the course of development of Brazil's future AIDS treatment institutions.

All these developments were prerequisites for major institutional change examined in detail in chapter 5, which examines how several factors changed the course of AIDS treatment institutions, including new NAP leadership, a growing AIDS movement, and new World Bank loans. These developments contributed to political momentum for AIDS treatment and provided windows of political opportunity that lead to the fourth critical juncture and institutional development in this analysis: Cardoso Administration Health Minister José Serra's decision to scale generic production of ARVs and threaten to issue compulsory licenses for patented ARVs.

Chapter 5 also explores the institutional conditions that gave rise to the fifth and final critical juncture of this analysis, José Serra's decisions to shape international health, human rights and trade institutions governing essential medicines. This chapter, situated in the context of a local and international AIDS treatment movement, explains Brazil's contributions to global essential medicines institutions from 2000 to 2006.

⁴In historical institutional theory, "positive feedback" refers to a social process that reinforces previous social outcomes.

⁵Guerra is alive today but was critically injured in a car accident in 1996. She has never fully recovered and was therefore unable to be interviewed for this research.

Chapter 6 explains these phenomena as the continuation of Brazil's domestic efforts to expand AIDS treatment. Though presented in this chapter as one institution to simplify initial discussion, each of Brazil's contributions to international health, human rights, and drug laws are examined separately in chapter 6. The chapter explains how the sequencing of international events shaped international policy, as each new international law or tradition built upon and reinforced Brazil's AIDS treatment institutions and contributed to evolving global AIDS treatment institutions.

Chapter 7 analyzes the collective impact of these international institutions on Brazilian AIDS treatment institutions and global essential medicines policy. This chapter also discusses Brazil's current AIDS institutions, presents quantitative analysis about the long-term costs of Brazil's treatment policies, reflects on Brazil's broader impact on global AIDS treatment paradigms, and discusses implications for other settings.

Brazil's AIDS treatment policies have led to remarkable improvements in health outcomes and have revolutionized global AIDS policy. *The Politics and History of AIDS Treatment in Brazil* unpacks the complex social processes and political phenomena that explain the historical development of Brazil's contemporary AIDS treatment institutions.

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Chapter 1

The AIDS Crisis and Democratization in Brazil

Brazil

Brazil is a federal republic of 188 million people, the world's fifth largest country in land area, the world's sixth most populous nation, and the economic engine of South America. The country is divided into five main geographic regions: the South, Southeast, Central-west, North (Amazonia), and Northeast (see [Figure 1.1](#)). Seventy percent of Brazil's population lives in urban areas [1].

Brazil is a middle-income country; per capita income is approximately US \$8,400. However, wealth distribution in Brazil is among the world's most inequitable. Ten percent of the population controls approximately 31% of the country's wealth and 22% of the population lives below the Brazilian federal poverty line of US \$160 per month [1]. Unequal distribution of income is widely viewed as Brazil's greatest social problem.

Brazil's regional differences also highlight Brazil's infamous health and income disparities. Although Brazil made tremendous improvements in health outcomes during the last 20 years, it still faces enormous challenges in reducing both health and socioeconomic disparities between regions, sociodemographic groups, and rural and urban areas. For example, illiteracy, infectious disease, fertility, sexually transmitted disease (STD), and maternal and mortality rates are much higher in the nine resource-poor northeastern states than in the wealthier southern states [2].

Average life expectancy in Brazil is 72 years and annual population growth is approximately 1.1%. During the last 35 years, Brazil has had one of the world's most rapid fertility declines. Total fertility rates dropped over 60% between 1970 and 2004, from 6.0 to 1.97 children per woman [2, 3]. Total AIDS prevalence is approximately 0.7% or about 660,000 HIV-infected individuals [4].

Eighty percent of the population is Roman Catholic and most of the remaining 20% is evangelical Christian [1].

Brazil's AIDS epidemic coincided with the country's transition to democracy and the country's integration into the post-Cold War global economy, both of which had had profound impacts on development of Brazil's AIDS treatment institutions. Like many other Latin American countries that experienced long periods of military rule after World War II, Brazil was governed by a military dictatorship from 1964



Figure 1.1 Map of Brazil by geographic region

to 1985. In 1964, the military regime dismantled the Brazilian party system, purged all members of Congress, and suppressed political activity for all executive positions such as mayors and state governors. The military government created two official parties: the National Renewal Alliance (ARENA), which supported the military government, and the left-leaning, catch-all opposition party, the Democratic Movement Party (MDB) [5, 6].

Because political parties had traditionally been weak and fragmentary in Brazil, and because the artificial party system created by the military further weakened that system, the military government did not deem most electoral activity as a threat to military power for the first 10 years of the dictatorship. To bolster the legitimacy of the military regime, elections were permitted but limited to federal senators and deputies, state deputies, and some local officials. It was these openings in electoral politics in the 1970s that allowed Brazil's democratic opposition to slowly chip away at military rule. In 1974, the opposition MDB made inroads in Congressional elections, capturing 45% of the chamber of Deputy seats and 72% of the Senate seats [5].

By the late 1970s, the Figueiredo military government realized that in order to hold on to any power, it would have to begin a slow transition to democracy. This began the slow process of *abertura*, the term used to refer to the gradual opening of political institutions to democratic practices in Brazil. This period witnessed unprecedented grassroots movements for democratization and party building in Brazil: intellectuals, students, labor unions, and artists began organizing in opposition to the military government.

In 1979, threatened by the MDB's continued legislative victories, the military government dissolved the two main political parties. However, because of widespread discontent with the dictatorship's monopoly on political power, the military regime permitted independent political parties to form in 1980. As a result of these electoral openings, several large opposition parties formed in 1980, including the Party of the Brazilian Democratic Movement (PMDB) and the Worker's Party (PT) [5]. The PMDB, the most heterogeneous of all the opposition parties, became the main opposition party. The PT was founded by union and labor leaders, liberation theology activists, and a variety of other leftists. The PT became the party for most of Brazil's contemporary social movements and has been Brazil's most enduring leftist party [7]¹.

These partisan developments and electoral openings are relevant to Brazil's AIDS institutions for several reasons. First, these democratic openings ultimately helped topple the dictatorship, which led to development of new democratic institutions in Brazil. Second, these democratic developments also provided the opportunity for a social movement for health called the Movimento para Reforma Sanitaria, or the Sanitary Health Reform Movement (SHRM), to organize in the late 1970s. Many members of these new left-leaning political parties became important members of the SHRM, and later, of the AIDS movement. *The Politics and History of AIDS Treatment*

¹Brazil's current President, Luis Inácio "Lula" da Silva is a founding member of the PT.

in Brazil explores how democratic electoral openings, partisan developments, and new vibrant civic activity influenced historical development of AIDS treatment institutions in Brazil.

In 1982, in response to more outspoken pressure of new political parties, the military government permitted democratic elections at the state and local levels for the first time since 1965. Because governors and local politicians could still not assume federal-level political positions in the executive branch of government, newly elected state and local officials quickly passed laws designed to decentralize governance, increase local decision-making authority, and circumvent strict military control over social and fiscal policy. For example, as a result of the decentralization movement, states and municipalities assumed greater roles in taxation, health, and social assistance programs [8, 9]. Most importantly for this book, the first public HIV/AIDS institutions (hereafter AIDS institutions) in Brazil stemmed from new decentralized democratic institutions before the end of the dictatorship.

Other electoral and partisan openings further whittled away at the military regime's political authority. In 1984, the center-right Liberal Front Party (PFL) and the center-left democratization party (PMDB) formed an electoral coalition called the Democratic Alliance. Though the military government tampered with the election results, the two-party coalition ultimately won the presidential election; Tancredo Neves of the PMDB was elected President and José Sarney of the PFL was elected Vice President. However, Neves died shortly before his inauguration and José Sarney became the first post-authoritarian president of Brazil in 1985. (Table 1.1 lists Brazil's post-authoritarian presidents). This election signaled the beginning of the demise of the military dictatorship and the transition to democratic rule. Though his presidency was riddled with problems, Sarney became an important political actor shaping AIDS institutions in Brazil.

Since the military government manipulated the 1985 presidential election results, the 1986 gubernatorial and congressional elections were the first truly democratic general elections in the new republic. Because the Congressional delegates also became the Constituent Assembly that wrote the 1988 Constitution that outlawed the dictatorship, these Congressional elections were, in retrospect, paramount to the future of Brazil's democracy. The PMDB won a majority of the congressional seats

Table 1.1 Post-military presidential administrations

| President | Elected | Inaugurated | Left office |
|--|-------------------|-------------------|-----------------------------------|
| Tancredo Neves | January 1985 | Never inaugurated | Died in April 21, 1985 |
| José Sarney | (Succeeds Neves) | April 1985 | March 1990 |
| Fernando Collor | November 1989 | March 1990 | Impeached 1992 |
| Itamar Franco | (Succeeds Collor) | October 1992 | December 1994 |
| Fernando Henrique Cardoso (first term) | October 1994 | January 1995 | Re-elected |
| Fernando Henrique Cardoso (second term) | October 1998 | January 1999 | December 2002 |
| Luiz Inácio "Lula" da Silva | October 2002 | January 2003 | Re-elected |
| Luiz Inácio "Lula" da Silva (second term) | October 2006 | January 2007 | Elections will be held in 2010 |

with the PFL placing a distant second. The two parties formed a democratic coalition united only by its efforts to overthrow the military dictatorship.

Because the catch-all democratic coalition had no clear-cut objectives other than to overthrow the military regime, the 1987 Constituent Assembly became a “free-for-all of parochial and sectoral demands and produced a document reflecting its chaotic politics and ad hoc procedures” [10]. With no broad-based objectives other than to overthrow the dictatorship, Constituent Assembly delegates were more concerned about short-term political interests than enduring democratic institutions. Rather than outline broad democratic rules of governance and delineate the role of local, state, and federal governments in the new federal republic, the Constitution that the Assembly drafted more closely resembles a lengthy piece of legislation catering to special interests than a new democratic charter. The 1988 Constitution outlawed the military regime, but its 250 articles include numerous, very specific issues generally not included in founding state charters. For example, the text includes highly specific articles related to regulating the blood supply, public drug production, sports, urban planning, and agricultural policy – issues usually reserved for specific laws and public policies. Also, the 1988 Constitution somewhat paradoxically established myriad highly specific citizenship rights to be guaranteed by Brazil’s decentralized federal republic but offered little clarity about how those rights should be guaranteed, particularly the role of local, state, and federal government in upholding new citizenship rights [8, 11, 12].

The Constitution nevertheless ushered in a new era of democratization, marking the beginning of a period of tremendous social and political transformation in Brazil. Brazil’s performance in building stable and enduring democratic institutions in the post-authoritarian era during the 1990s is mixed. As a result of Brazil’s poorly designed Constitution that did not clearly define state institutions and promised much to many interest groups, democratic institutions were under constant revision for the first 15 years of the democratic republic [11]. Constantly evolving, fragile, and poorly performing state institutions thus hampered the prospects for democratic institution building in Brazil. These new democratic legislative and executive arrangements nevertheless played an important role in the Brazilian response to the AIDS epidemic.

Building Democracy in Post-Authoritarian Brazil

Democratization in Brazil witnessed unprecedented decentralization of fiscal and social policies to state and local levels in the years after the end of military rule. Decentralization had begun in the early 1980s in an effort to weaken the military’s centralized authoritarian regime. To appease new democratic forces while maintaining power, the military government began transferring resources to subnational governments. However, in many states, these decentralized policies were implemented before federal, state, and locally elected officials had taken office. Devolving numerous areas of social and macroeconomic policies to Brazil’s 26 states did decrease the military’s control over public policies, but in many cases

devolution also enhanced clientelism, undermined economic and democratic stability, and magnified social and economic disparities between states.

During the 1980s, many states ran up enormous deficits and neglected to expand important social services, undermining economic and democratic stability. Although the 1988 Constitution calls for shared responsibilities between local, state, and federal government, many of these responsibilities were not clarified until many years later. Additionally, in the late 1980s, a number of responsibilities were devolved to the states without requisite federal financial transfers. In most cases, decentralization proceeded haphazardly without defining clearly the roles for each level of government. This weakened many institutions in Brazil; often, when the role of each level of government was unclear and requisite policy interventions were complex or expensive, each level of government deferred responsibility to a different level. As a result, many reforms were not implemented. Federal, state, and local governments frequently blamed each other for failure to implement duties and secure rights guaranteed by the new Constitution [8, 9].

Decentralization has therefore slowed or stymied important reforms in Brazil, including those related to the 1988 Constitution's goal of providing free decentralized health services to all Brazilians. Though the 1988 Constitution established health and health services as a right guaranteed by the state, the Constitution only vaguely assigned this duty as a shared responsibility of local, state, and federal governments. Many of the lofty health reform objectives detailed in the 1988 Constitution were not implemented until other health laws clarified the role of each level of government in providing health services [13]. This institutional challenge is paramount to the AIDS issues this book explores.

The 1988 Constitution also presented challenges for legislative and executive branch institutions. New electoral institutions in Brazil entrenched the patronage system in Brazil, which presents challenges that spill over into the legislative and executive branches of government [14]. Brazil's post-1988 open-list proportional representation electoral system arrangements with no national thresholds and multiple member districts deepened Brazil's tradition of personalistic-style governance [5]². Many individualistic politicians saw new, fragile democratic institutions as opportunities to promote their own interests [6, 11, 14]. Today, the patronage system undermines the party system, which weakens the federal legislature.

Additionally, because of the exceptionally strong presidential mandate Brazil's 1988 Constitution created, the federal legislature spends much of its time working on legislation the executive branch of government initiates rather than producing its own. As a result of Brazil's fragmented party system, Brazilian presidents have

²Most proportional representation legislative systems are closed lists in which the parties rank their candidates. Open-lists do not allow parties to rank their candidates, which discourages party loyalty and creates a system where constituents vote for individuals rather than for parties. Large, multiple member congressional districts create a system in which many legislators represent the same large districts, de-linking legislators from constituents. This institutional arrangement undermines accountability to voters and encourages individualistic, patronage-based politics.

generally lacked consistent party backing, resulting in high turnover in cabinets and legislative coalitions and frequent minority presidentialism, undermining broader institutional stability and necessary policy reforms [11, 15]. This also means that presidents in Brazil must rely heavily on patronage and payoffs to members of Congress, line-item vetoes, and executive decrees.

Institutional performance in the judicial branch of government in post-authoritarian Brazil faced similar challenges. In an attempt to expand access to the courts for ordinary citizens, the 1988 Constitution expanded the role of the Brazilian judiciary and gave judges tremendous independence. However, because the Constitution widely expanded the rights the state guarantees to Brazilian citizens without defining clearly the role of each level of government in securing those rights, the federal court system is flooded by over 100,000 annual public litigation cases that the Supreme Court must rule on, since the court is not permitted to decline to hear cases. This problem is compounded by a highly particularistic civil code system, which does not require and actually establishes few binding precedents. Therefore when an individual goes to court to secure his constitutional rights, widespread application of the judicial decision is not guaranteed; protection of individual rights are usually decided on an individual basis, with many options for appeal. The combination of all these factors results in an overburdened, slow-functioning federal judiciary with exceptionally high-operating costs and little ability to apply universally applicable binding policy decisions [16–18]. These judicial institutions have nevertheless been paramount to development of AIDS treatment institutions in Brazil today: since the early 1990s, thousands of individuals have secured medicines for AIDS treatment through the courts by citing the 1988 Constitutional right to health.

The challenges to democratic governance notwithstanding, each subsequent democratic administration in Brazil since 1988 has achieved moderate and incremental, if important, institutional changes. In several cases, Brazilian states and municipalities have used decentralization as an opportunity to improve local governance and social policies [8, 19]. The central government has also regained centralized control of fiscal policy, helping to stabilize the Brazilian economy. Economic and health reforms perhaps best exemplify Brazil's gradual progress in building stronger state institutions. Trade, fiscal, and market reforms began in early 1990s during the Collor administration and continued during the late 1990s with the Cardoso administration, ultimately leading to greater economic stability [12, 20]. Similarly, a series of health reforms helped define the role of the state in decentralized health delivery, expanding public health infrastructure with each presidential administration. Many population health indicators improved throughout the 1990s [13, 21].

The seemingly contradictory phenomena of weak state institutions and incremental institutional progress highlight the complex, dynamic process of democratization in Brazil. The effect of these constantly evolving, fragile, and often poorly performing institutions hampered many prospects for democratic institution building in Brazil. At the same time, new political parties, state institutions, and grassroots political and social movements provided opportunities for political entrepreneurship and innovative reforms. Development of institutions for AIDS treatment is Brazil's shining example of how new institutional arrangements also provided windows of opportunity

for progressive social change. *The Politics and History of AIDS Treatment in Brazil* explores how and why the institutional developments related to new political parties, decentralization and democratic institutions of the three branches of government, coupled with a freer media and social movements for more equitable access to health care, had profound and lasting impacts on the Brazilian response to the AIDS epidemic.

The State and Public Health

The 1988 Constitution established health care as a fundamental right of all Brazilian citizens. The Constitution also unified disparate government agencies established during the 1970s and 1980s into a single national health system called the Unified Health System, or *Sistema Único de Saúde* (hereafter SUS). The new Constitution ambiguously stated that responsibility for finance and delivery of health care was a shared responsibility of federal, state, and local governments. The Constitution, however, did not clarify what services the right to health entailed. Decentralized public health institutions only took shape after a series of federal health laws called the Basic Operational Laws, or *Normas Operacionais Básicas*, were approved by the Brazilian Congress in the 1990s [22]. This affected development of AIDS treatment institutions and will be revisited later in further detail.

Each of Brazil's 1990, 1993, and 1996 health laws as well as a 2000 Constitutional Amendment aimed to define more clearly the role of each level of government in healthcare finance and provision. The first 1990 health laws approved during the Collor administration echoed the vague language of the 1988 Constitution, claiming that access to health services should be free and established municipal health councils that would help inform decentralized local health policies [23, 24]. However, the 1990 law offered little clarification about how health reforms would be implemented and did not clearly define a package of health services to be guaranteed by the government.

The second health law, approved during the Franco administration in 1993, acknowledged the role of the government in primary, ambulatory, and tertiary health service provision³ and defined provision of primary health services as a municipal responsibility [25]. The law also permitted Brazil's more than 5,000 municipalities to choose the level of health services (primary, ambulatory, and tertiary care), they would provide to their populations. Those who implemented the policy chose to provide primary health care. However, by 1997, about 37% of all municipalities had not implemented any commitment to health service provision because the 1993 law did not guarantee automatic federal transfers to states and municipalities for healthcare provision [13].

³Primary care refers to the first point at which a patient seeks outpatient care in a health system, usually for common or simple illnesses. Ambulatory, or secondary care, refers to outpatient health care that requires a medical specialist or more complex case management. Tertiary care refers to in-patient hospitalization services.

The 1996 law approved during the Cardoso administration provided states and municipalities with direct, guaranteed federal transfers for health services [26]. States and municipalities would receive transfers in accordance with the services they provided. This provided financial incentives for states and municipalities to commit to health service provision, and by 2001, all municipalities had committed to providing some health services and began implementing health infrastructure toward that end [13].

To counter the problem of each level of government “passing the buck” of health-care provision to the other levels of government, Constitutional Amendment 29, approved in 2000, earmarked 7% of federal tax revenues for health care, increasing commitments to 12% and 15% in 2005. The amendment also mandated 5% annual federal health-spending increases through 2005 [27]. In summary, as a result of a long history of federalism, the 1988 Constitutional Mandate, and numerous health reforms, Brazil now has one of the world’s most decentralized public health systems [28–30].

According to the 2007 World Health Statistics report issued by the World Health Organization (WHO), health spending represents approximately 9% of total government expenditure in Brazil. Per capita health expenditure was approximately US \$381 in 2005. In spite of Brazil’s large public health infrastructure, access to high-quality health services remains fragmentary in many parts of Brazil, and many citizens use private healthcare providers. As a result, approximately half of all health spending takes place in the private sector [31]. Total public health expenditure increased from US \$10 billion in 2001 to \$16 billion in 2005 (Figure 1.2). Observed increases in expenditure from 2003 to 2005 are attributable to increased spending

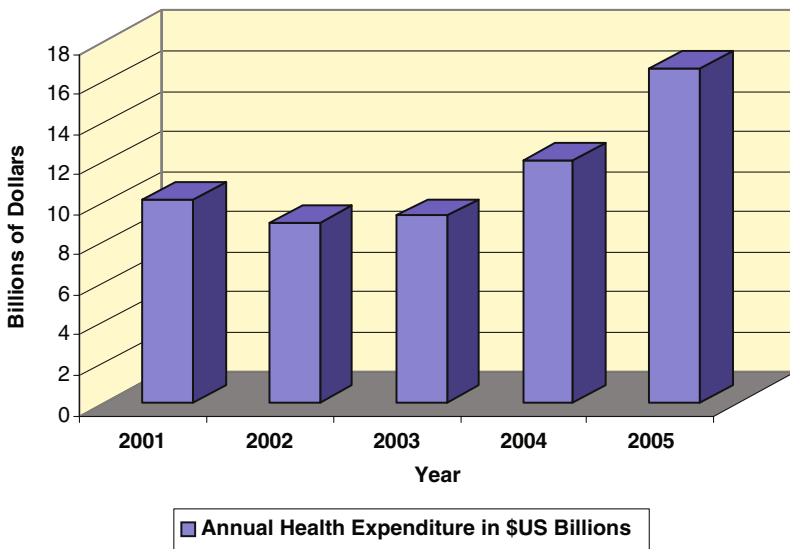


Figure 1.2 Federal public health expenditure in Brazil in US\$ Billions: 2001–2005. Data source: Planning Office, Brazilian Health Ministry, 2005.

Note: estimates are adjusted for inflation and presented in 2005 US dollars

on community health worker programs, hospital services and healthcare personnel (active and retired), and expansion of a variety of publicly financed drug programs [32]. Many of these new programs began under Health Minister José Serra's tenure, widely recognized as Brazil's most influential and effective Health Minister, who served from 1998 to 2002 [13]. Expenditure increases are also directly related to the 2000 Constitutional Amendment that expanded health expenditure.

AIDS in Brazil

AIDS epidemics, as well as each country's public policy response to the AIDS pandemic, vary widely across the globe. To elucidate how and why AIDS treatment institutions developed in Brazil, the remainder of the chapter provides background on the epidemiology of Brazil's AIDS epidemic as well as Brazil's contemporary AIDS policies.

Scientists now believe that Brazil's first AIDS cases surfaced in 1982, 6 years before Brazil adopted its democratic constitution. Historical expansion of the HIV epidemic in Brazil is usually separated into three phases. [Figure 1.3](#) displays diagnosed AIDS cases from 1983 to 2004.⁴ (Because of limited infrastructure for HIV surveillance early in the AIDS epidemic, case reporting is most accurate after 1992.)

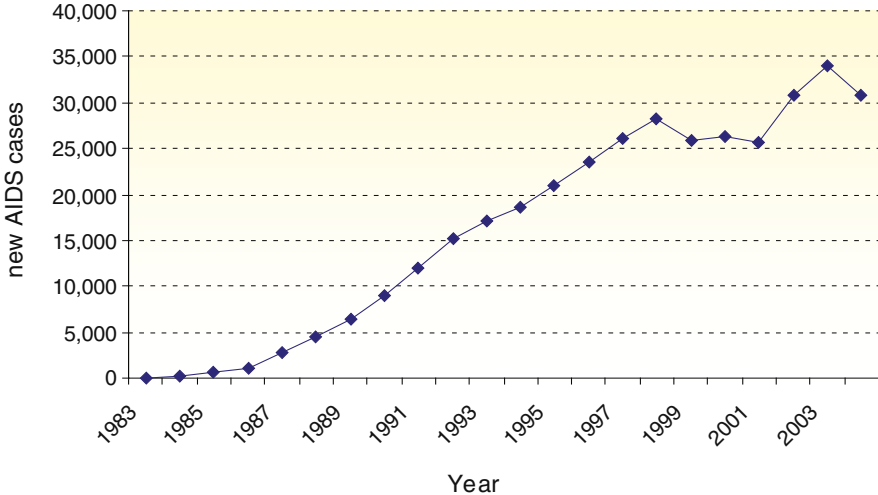


Figure 1.3 New AIDS cases in Brazil: 1983–2004. Data source: National STD & AIDS Program of Brazil, 2006

⁴There are two main strains of the HIV virus: HIV-1 and HIV-2. As in most countries in the Western Hemisphere, Brazil's epidemic consists mostly of HIV-1 cases. Within each HIV-1 strain, there are several subtypes; most of Brazil's cases are subtype B, although subtypes B, C and B/C and B/F have also been found in Brazil [33].

The first major expansion occurred between 1987 and 1989, when the total number of total diagnosed AIDS cases tripled from 3,000 to 9,000. Over 50% of newly diagnosed cases were among men who have sex with men (MSM) in the urban Southeast. The second major expansion of the HIV epidemic occurred in 1990–1992, when the majority of new AIDS cases were among intravenous drug users (IDUs). The epidemic was then largely confined to gay and bisexual men in the southeast and IDUs in the urban South [34]. Between 1990 and 1992, the cumulative number of diagnosed AIDS cases doubled from 38,100 to 76,000 [35]. The third phase of HIV expansion was between 1993 and 1996. By 1993, the majority of Brazil's over 5,000 municipalities had at least one reported AIDS case. The epidemic previously confined to the upper-middle and upper class gay communities in the urban Southeast began to spread to the general population during the early 1990s. By 1994, heterosexuals were becoming infected at higher rates than homosexuals for the first time [36]. The socioeconomic background of HIV-positive individuals also shifted during the early 1990s, when individuals of low socioeconomic status began to be infected at disproportionately higher rates than individuals from other socioeconomic strata [37].

In 1998, the Health Ministry used World Bank loans to conduct Brazil's first nationwide epidemiological surveillance studies in antenatal clinics. The study estimated that approximately 540,000 Brazilians of reproductive age were living with HIV, many of them undiagnosed [38]. This new finding surpassed previous Health Ministry HIV estimates. This same study was refined and expanded to more clinics in 2001. The authors concluded that 600,000 individuals were HIV-positive in Brazil and found overall prevalence rates had stabilized and that the epidemic had peaked in 1998 [39].

The most recent study on HIV prevalence and incidence in Brazil notes that in 2006, 660,000 Brazilians lived with HIV/AIDS; HIV prevalence among adults of reproductive age in Brazil is currently estimated to be 0.7% [4]. Brazil has the highest absolute number of HIV cases than any other country in Latin America but has lower prevalence than some other countries such as Guatemala, the Dominican Republic, Belize, Haiti, and Honduras. Brazil has a concentrated epidemic; less than 5% of women seen at prenatal clinics are HIV-positive [36]. However, these seemingly low prevalence rates may mask the gravity of the AIDS epidemic in Brazil, as the National STD and AIDS Program (hereafter NAP) estimates that prevalence rates are much higher in vulnerable populations such as commercial sex workers, the urban poor, women of low socioeconomic status, and men who have sex with men [40, 41]. Although data on mother-to-child transmission are scarce, one article estimates that transmission rates for a small cohort of HIV-positive pregnant women to be 4% [42]. A larger study in São Paulo state estimates maternal to child (vertical) transmission of HIV as 2.4% [43]. HIV prevalence among IDUs varies widely by region and is highest in port cities. It is highest in Southern Brazil; a recent study estimates 65% HIV prevalence among IDUs in Porto Alegre [44]. Less is known about HIV prevalence among other vulnerable populations, though the NAP is currently conducting research on these topics [45].

A 2006 study on AIDS incidence (or new AIDS cases) found that overall AIDS incidence has stabilized because the epidemic itself has stabilized in South and Southeastern Brazil, the regions with highest HIV prevalence. However, the study

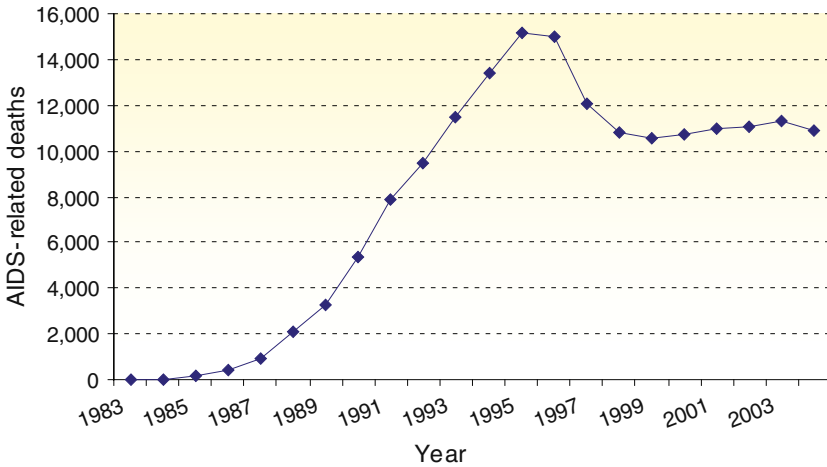


Figure 1.4 Annual AIDS-related deaths in Brazil 1984–2004. Data source: National STD & AIDS Program of Brazil, 2006

noted that AIDS incidence is still rising in the Central-West, North, and Northeast, as well as among women [4, 46]. Epidemiologists attribute the observed fluctuations in official AIDS incidence since 2001 (Figure 1.3) to improved reporting, increased notification associated with testing campaigns, and recent fluctuation in AIDS incidence among vulnerable populations such as MSM and IDUs rather than true increases in AIDS incidence [45, 47–49].⁵ Although AIDS incidence has been declining in Brazil since 2001, the latest (unpublished) analyses suggest that incidence declines are smaller than previously estimated [45]. In summary, it is difficult to draw concrete conclusions about AIDS incidence trends in Brazil since 2001.

It is clear, however, that AIDS deaths increased in Brazil from 1983 to 1996, declined from 1996 to 1999, and have remained fairly flat since 1999 (Figure 1.4). These health outcomes are directly attributable to Brazil’s AIDS treatment policies which are the focus of this book.

Brazil’s AIDS Program

Brazil’s public agency for AIDS, called the National STD and AIDS Program (NAP), began as a small two-employee office in the late 1980s, and mushroomed into a large Health Ministry Agency in the mid-1990s. This agency, which developed and expanded during Brazil’s democratic transition, has profoundly shaped AIDS treatment policy in Brazil. This section gives an overview of the four important program

⁵ A 2005 Health Ministry epidemiological bulletin also acknowledges a recent crash in the AIDS death database and the resulting AIDS incidence measurement challenges [47].

components of Brazil's NAP, including prevention, treatment, partnerships with civil society and human-rights based AIDS programs.⁶

The main tenets of Brazil's prevention program include nationwide condom and HIV testing campaigns and targeted prevention programs for vulnerable populations such as MSM, commercial sex workers (CSWs) and IDUs, the urban poor, women, and street children. Brazil offers free HIV testing in 320 clinics nationwide. However, the NAP estimates that only 28% of Brazil's sexually active population has had at least one HIV test; the remaining population does not know its HIV status [40]. Because of low testing rates and limited laboratory infrastructure in several states in Brazil, the NAP is now scaling up rapid HIV testing in several states.

Few official evaluations of Brazil's prevention campaigns have been conducted by the NAP. Also, HIV prevention is rarely discussed in detail in the peer-reviewed literature on Brazil's AIDS program, save for a handful of outdated statistics on the distribution of condoms, creation of a needle exchange program, and a 1986 law that requires HIV screening at all blood banks [34]. One 2005 article finds that Carnival condom campaigns influenced self-reported condom use among adolescent girls [50]. Another article finds that condom campaigns and counseling among 395 IDUs led to a decrease in sexual partners and an increase in condom use [51]. Because it is difficult to measure the impact of any prevention program, and this research focuses on treatment rather than prevention, this book does not offer a thorough evaluation of prevention campaigns. However, stabilization in AIDS incidence in the South and Southeast and declining prevalence and incidence among MSM and IDUs suggest that prevention programs have had positive effects on declining AIDS prevalence among certain subpopulations [48, 52].

The NAP is also well known for its historical partnerships with civil society organizations. Brazil's tradition of partnering with civil society can be traced to the first public policy responses to AIDS in São Paulo state in the early 1980s. In São Paulo, a small office within the state Health Ministry partnered with nongovernment organizations to try to reduce stigma and discrimination associated with AIDS. Since then, state and federal AIDS agencies have partnered with civil society for HIV/AIDS prevention and advocacy programs.

The NAP's commitment to human rights in HIV/AIDS programs is another important historical legacy of São Paulo's first AIDS program. Rights-based health programs often include nondiscrimination, civil society participation and accountability measures in program design [53]. The NAP program had many of these same ideas in mind when it developed its AIDS programs: the NAP supports nondiscrimination and antistigma campaigns and targets vulnerable populations for prevention and treatment programs. The NAP also includes civil society participation in prevention program implementation and development of NAP policy. Finally, the NAP also sponsors

⁶Later parts of this book explore historical NAP development in detail, including other program components such as epidemiological surveillance and NAP program monitoring and evaluation.

legal aid and other political measures through which nonstate actors can hold the government accountable for its legal responsibilities for AIDS [54].

Much has been written on the civil society contribution to AIDS programs, particularly to prevention programs. Brazilian AIDS experts agree that civil society participation and its focus on human rights have been important to the NAP's historical development [52, 55–59]. In addition, civil society participation and rights-based programs have also had important influences on AIDS treatment institutions. These topics are revisited in subsequent chapters of this book.

The Brazilian AIDS Program is best known for its treatment policies. Brazil was the first developing country to pledge free and universal access to highly active antiretroviral therapy (HAART) for PLWHA and has implemented health policies and health system infrastructure toward that end. Brazil began treating AIDS patients in the public sector in 1991 and began producing ARVs in public drug factories in 1993. Though Brazil's commitment to treat began in the early 1990s, access to HAART only stabilized in the late 1990s. Since 1997, Brazil has scaled up AIDS treatment each year; approximately 185,000 were receiving HAART in 2008 (Figure 1.5). HAART provision is a responsibility delegated to the federal government and treatment of opportunistic infections is a responsibility delegated to state governments. The book will return to this distinction and explain its development.

The Brazilian Health Ministry offers 20 ARVs in its 2008 AIDS treatment guidelines [60] (see Appendix A). The government has secured access to the most modern ARVs in several creative ways. In the mid-1990s, Brazil began producing seven nonpatented ARVs in Health Ministry factories and laboratories. However, this strategy of using local production to meet national ARV drug needs was limited

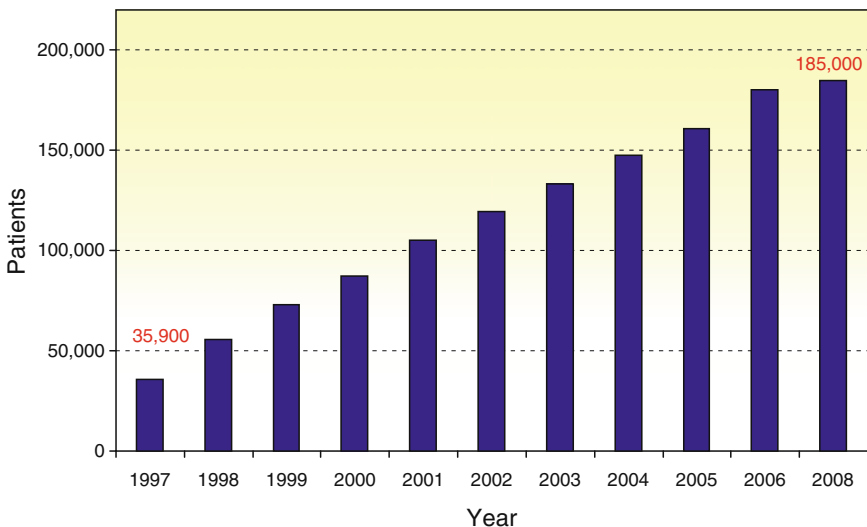


Figure 1.5 Patients receiving HAART in Brazil 1997–2008.
Source: National STD and AIDS Program of Brazil, 2008

by Brazil's 1996 Industrial Property Law, which required Brazil to recognize intellectual property rights for pharmaceutical products for the first time in over 20 years. The remaining 11 ARVs on Brazil's list are therefore patented and purchased from multinational pharmaceutical companies. To induce multinational pharmaceutical companies to lower their prices, the Health Ministry has threatened to issue compulsory licenses for drugs consuming the largest share of its AIDS drug budget. Under international trade rules, during cases of public emergency, a compulsory license provides governments the right to assign production to a local manufacturer without consent of patent-holding multinational pharmaceutical companies [61, 62]. This strategy proved highly controversial, prompting a World Trade Organization (WTO) trade dispute with the United States as well as heated price negotiations with several multinational pharmaceutical companies. Brazil's AIDS treatment policies unfolded slowly over 15 years in an effort to establish and preserve free and universal access to HAART to all PLWHA in Brazil and reflect Brazil's long-term political commitment to addressing the AIDS epidemic.

Drugs for AIDS treatment are financed and delivered by the federal government while drugs for treatment of opportunistic infections are financed and delivered by the states. (The roots of these differential policies are explored later in this book). In recent years, treatment services have been integrated into Brazil's health system, and several centers of excellence in major metropolitan areas have played important roles in shaping national treatment standards. Responsibility for delivery of AIDS treatment services is shared by the Brazilian local, state, and federal governments. Patients generally enter the health system at the municipal or state primary care level and are referred to state or federal secondary and tertiary care centers as the need for specialty services arises.

Brazil's improved health outcomes for HIV/AIDS are attributed to its AIDS treatment institutions. Sustained AIDS-related mortality decline (Figure 1.4) is often attributed to Brazil's policy of free and universal access to treatment [4, 34, 36, 63–66]. Another article also documents the impact of Brazil's national AIDS treatment program on AIDS-related morbidity [66].

However, a close look at epidemiological data shows that AIDS mortality peaked in Brazil in 1995, prior to Brazil's major nationwide scaleup of HAART (Figs. 1.4 and 1.5) [67]. The reasons for this early decline are unclear but may be attributed to early mortality decline in São Paulo state, where Brazil's early AIDS cases were concentrated, and AIDS-related mortality declines were reported as early as April 1992 and even more steeply in 1997 [68–70]. São Paulo, the epicenter of the AIDS epidemic, began treating large numbers of AIDS patients in the early 1990s, prior to the 1996 law guaranteeing free and universal access to treatment and Brazil's major treatment scaleup. This suggests that AIDS mortality decline in Brazil likely stems from AIDS treatment, but may have preceded the 1996 law guaranteeing nationwide free and universal access to treatment.

Brazil's universal access strategies proved highly effective in lowering the cost of AIDS treatment in Brazil [71]. The NAP estimates that by treating AIDS patients, it prevented 358,000 AIDS-related hospitalizations, as the average number of hospitalizations dropped from 1.65 to .28 per patient per year. The Health

Ministry estimates that this reduction saved the government over US \$1 billion in hospitalization and other health costs since 1996 [34, 72].

The Brazilian AIDS treatment model has won the praise of numerous global health institutions, including the World Health Organization; the Gates, Clinton, and Ford Foundations; and many developing country governments, among others. Moreover, Brazil's AIDS treatment institutions had direct effects on the global declines in the cost of drugs for AIDS treatment since 2001, influenced global AIDS treatment paradigms, and paved the way for massive scale up of AIDS treatment in dozens of other developing countries. *The Politics and History of AIDS Treatment in Brazil* explores development of these monumental achievements.

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Chapter 2

Democratization and Institutional Precursors to AIDS Treatment in Brazil

Sanitarista Health Reform Objectives

As discussed in chapter 1, during *abertura* – the gradual opening of political institutions to democratic practices in Brazil – a new social movement emerged in reaction to the military government’s failure to provide basic health care services to the Brazilian population. The *movimento para reforma sanitaria* – the sanitary health reform movement (hereafter SHRM) – was a social movement of middle-class health professionals that called for widespread, equitable access to medical care and preventive health services in Brazil, particularly for the poor. Though the SHRM was rooted in the preventive health care movement that began in Brazil in the 1940s, it evolved into an influential social movement in the late 1970s and 1980s that had a profound and lasting effect on health and AIDS institutions in Brazil [1].

The SHRM was part of a broader “social medicine” movement in Latin America that focused on the social and structural determinants of health, such as poverty, education, and poor access to health services. The SHRM also coincided with a global movement for provision of primary health care at the local level that traced its origins to the 1978 World Health Organization-sponsored Alma Ata Conference¹ [1–3].

Sanitaristas were both democratization and health activists. The SHRM argued that since the roots of poor health outcomes were rooted in socioeconomic inequality, improving population health required overwhelming social transformation and regime change. In the late 1970s, though the military dictatorship prohibited political party activity outside the two officially sanctioned parties, most members of the SHRM were members of the underground Communist Party, which promoted radical regime change.

Social movement theory helps explain the strategies of the SHRM. According to the sociologist Charles Tilly, a social movement is defined by three criteria: campaigns, social movement repertoire, and unifying actions. Campaigns consist of sustained, organized public efforts making collective claims on target audiences.

¹The Alma Ata Conference was a World Health Organization conference with 137 participating countries that called for all governments to provide access to primary health care services.

Campaigns are not one time occurrences, but sustained, repeated claims or requests directed toward another party, often governments. Social movement repertoire employs combinations of the following types of political action: creation of special-purpose associations and coalitions, public meetings, use of the media to shape public opinion, vigils, rallies, protests, petitions, and other types of political action. Unifying actions refer to slogans and actions that represent unity, commitment, and campaigns that members of the social movement are “worthy” of the claims they make of the parties (usually states) of whom they make their social demands [4]².

The SHRM publicly criticized the Brazilian military government’s health model, which focused on providing curative medical services for the civil servants and the urban middle class. In public campaigns, the SHRM denounced the military government’s health system, which excluded 70% of Brazilians from access to health services and also failed to address the basic health care needs of the poor, did not include preventive services, and relied heavily on the private sector for service delivery. Sanitaristas believed that these problems required mass mobilization of the disenfranchised poor, overthrow of the military regime, and creation of new, more democratic institutions for health. Sanitaristas also supported universal vaccination, improved sanitation measures, and a decentralized approach to health care delivery, as well as public provision of primary medical care near people’s homes [1, 5]. In their campaigns, sanitaristas promoted a greater government role in provision of health services, as most health care was delivered through the private sector during the military dictatorship.

Though the SHRM was not explicitly using the word “human rights” in the late 1970s, the sanitarista platform included components of what today would be considered as rights-based approach to health programs and reforms. These health and human rights concepts were first popularized in Brazil by sanitaristas in the late 1970s. Much of this book explores how these health and human rights concepts and unifying slogans were used by the SHRM and later by AIDS activists to promote social change for health, including AIDS treatment institutions.

To justify the sanitarista health reform campaign’s calls for decentralized health care delivery, sanitaristas used unifying slogans such as “participation,” “inclusion,” “equity,” and *integralidade* (“integral approach”), which refers to the concept of integrating preventive and curative services in a basic package of primary health care services. Participation and inclusion refer to health programs designed by and accessible to the general population.

The SHRM established several academic institutions to train health professionals in political action activities and sponsor its campaigns calling for nationwide health reforms. Several academic institutions were created in the 1970s in

²According to sociologists Tilly and Tarrow, social movements are necessarily “contentious” because they make controversial demands of states, elites, or political actors. Social movements use contentious political action to create political opportunities and mobilize large groups against more powerful opponents. Social movements can be distinguished from interest groups that lobby or solicit demands of the state because they usually challenge power holders, encourage popular participation in their movement, and have some deeper meaning or unifying characteristic.

Rio de Janeiro and São Paulo states, which became the outlet for political dialogue about greater access to health services. These included the Brazilian Center for Health Studies (CEBES) and the Brazilian Association for Study of Collective Health (ABRASCO) founded in 1979 [5, 6]. These groups were both academic and political. They campaigned for greater access to health services, trained health professionals, and made formal links between democratization and health reforms that would provide integrated health services to the entire population. Attaching the movement to universities gave the movement legitimacy, provided a fertile recruiting and training ground for sanitarista practitioners, and provided SHRM activists with fora to express controversial political dissent. Moreover, by linking health practice, research, and a social movement, these centers served as incubators for new ideas about health reform and political action.

The late 1970s also saw the SHRM attempt to develop broad-based support for health reforms at the grassroots level by working to mobilize the urban poor. However, this effort failed because of the interrelated problems of deep-rooted local clientelism and difficulties associated with mobilizing Brazil's urban poor. Sanitaristas, therefore, changed their strategies and began to try to penetrate state and federal health bureaucracies to promote health reforms [2].

Reformers Working Within the State

In the early 1980s, in the wake of corruption scandals, an economic crisis, and democratizing pressure from new opposition parties, the power of Brazil's military government was quickly eroding. In response to more outspoken pressure of new political parties, in 1982 the military government permitted democratic elections at the state and local levels for the first time since 1965. As a result, governors were democratically elected 3 years before Brazil's first democratic presidential election.

Unlike the officially sanctioned PMDB opposition party, other opposition parties were unable to make electoral advances because they were either silenced or strictly prohibited by the military government until 1988. The PMDB therefore attracted most of the political opposition throughout the 1980s, including the SHRM, many of whom were official members of the Communist Party that viewed the PMDB as the best option for advancing national SHRM health reform objectives during the 1980s [7, 8].

In these 1982 elections, the PMDB, Brazil's main opposition party, won 9 of 22 governor seats [9]. The PMDB electoral victories provided institutional openings for the SHRM to promote health reforms within new public institutions. Recognizing that the SHRM's efforts to create health reforms from within and outside the federal government had failed, and seizing on unique windows of political opportunity presented with regime changes, sanitaristas began trying to assume roles within state bureaucracies [2].

In 1982, Franco Montoro, a long-time democratization advocate and the new PMDB governor of São Paulo state, allowed sanitaristas to move into the São Paulo state Health Ministry machinery. In an interview, Dr. Richard Parker, sociologist

and expert on AIDS in Brazil, reflected on the SHRM and its strategy of moving into public bureaucracies:

The idea of “integrality” focused on integrating treatment and prevention. That all comes out of the sanitary reform movement, independent of AIDS. It’s a whole way of thinking how health should be constructed as a basic right of citizenship in Brazil. And that was percolating through the dictatorship period, when the sanitary reform movement was closely linked to the resistance of the dictatorship.

Most of the people of the sanitary reform movement were from the Communist Party, associated with leftist political parties, sort of underground at that time period. And when abertura starts at the state and local levels in 1982, they come into positions in the state health sector. In São Paulo state, for example, the cream of the SHRM becomes responsible for the Health Secretariat.

All of the leftists from the SHRM start taking over the machinery of the health programs, first at the state and local levels and later at the federal level. From about 1982 to 1987 when you have the Constitutional convention, there has been this kind of gradual infiltrating of progressive people from the sanitarista movement into various positions of power and influence [in the government] [10].

Because of the slow democratization process in Brazil, states opened to democratic electoral practices before the federal government. Once governors were democratically elected, they quickly implemented laws and reforms to solidify their powers and brought reformers into state governments [11]. This occurred in São Paulo state; after the SHRM secured its place in the São Paulo state health bureaucracy, it began implementing reforms that reflected its rights-based approach to health programs.

Shortly after sanitaristas assumed control of the São Paulo State Health Ministry in 1982, sanitarista Dr. Paulo Teixeira was appointed as the head of the “Dermatology and Sanitation” department. In accordance with sanitarista traditions, the department adopted a public health approach to health administration, often focusing on the social dimensions of disease, particularly leprosy. Activities included strategies to reduce discrimination, reintegrate leprosy patients into society, and help leprosy patients defend their labor rights. This type of social approach attracted Teixeira and other sanitaristas, many of whom had long worked with leprosy patients and other vulnerable populations.

The sequencing of this leadership change was important to the future of AIDS institutions in Brazil. The sanitaristas worked their way into São Paulo state health machinery just prior to the onset of the AIDS epidemic, of which São Paulo city was the epicenter. Shortly after Teixeira assumed leadership of the Dermatology and Sanitation department, the AIDS deaths of several homosexual men in 1983 set off a wave of panic in Brazil.

Brazil’s First Public and Civil Society Partnerships for AIDS

It was in 1983 that a small group of homosexual men from São Paulo city approached the state Health Secretariat for information about the causes of AIDS, demanding that the state address the looming crisis. Because of the heavy stigma associated with AIDS, the men who approached the Health Ministry were most

concerned about discrimination and human rights violations associated with AIDS. Many homosexual men were losing their jobs because their employers feared that they had AIDS. Newspapers reported on the “gay cancer,” and many public and private hospitals refused to accept AIDS patients. Public hospitals that did accept patients were completely full. Most patients who received private care paid out of pocket, because most private insurance companies refused to reimburse patients and hospitals for AIDS care [12, 13]. At that time, little was known about the science behind HIV or how to care and treat for AIDS patients. For these reasons, the social consequences of AIDS were considered equally as grave as the medical consequences [10, 14, 15].

Because of the stigma associated with the disease, and because AIDS was most prevalent among homosexual men facing discrimination, the São Paulo State Health Secretariat assigned AIDS tasks to the dermatology and sanitation department, experienced in working with diseases with strong stigmas associated with them. Paulo Teixeira, the first director of any AIDS program in Brazil, commented about initial partnerships between the sanitary health department and civil society groups:

My group worked with leprosy, so we already had experience that helped us a great deal; there are many things about working with leprosy patients that apply to HIV. First, both often affected marginalized populations; second, stigma was historically very strong; discrimination was also a serious problem. There was no social support; there were no rights for these patients. Leprosy was so complex, so difficult. And my team had experience with working with these kinds of issues with non-government organizations for leprosy.

We had also adopted some important strategies, like having an interdisciplinary support team, a program to fight discrimination, a program to promote policy change and legal action, a program for worker's rights.

I'd had five years of experience doing that kind of work, and I think it was really important when we began working with HIV because the situations were very similar. So both working with the community and engaging in antidiscrimination campaigns were very important from the beginning [14].

Teixeira recounted that he immediately invited the community members who approached the health secretariat about AIDS to work on AIDS education campaigns. São Paulo created a state AIDS program that began distributing pamphlets about the risks of AIDS in the homosexual community. After several informational meetings about the new epidemic, a group of individuals decided to start an independent organization to specifically address the AIDS crisis. They created Brazil's first non-government organization (NGO) for AIDS, the Support and Prevention Group for AIDS (GAPA), which worked closely with the São Paulo state AIDS program from that moment forward, as did many other NGOs [14]. This created a tradition of public and NGO partnerships that later influenced the path of institutional development for AIDS treatment in Brazil.

Brazil's first AIDS program at the São Paulo state secretariat thus grew out of the sanitaria model for leprosy programs. The rights-based program addressed the health and social needs of vulnerable populations, fought discrimination, and encouraged community participation in program development and implementation. The sanitaria rights-based approach to health policy, including campaigning for AIDS, is evident in the earliest strategies to combat AIDS in São Paulo. For example, in a 1985 magazine interview, Teixeira publicly addressed the then-controversial social dimensions of AIDS:

Social repression is the reason a large number of homosexuals opt for a heterosexual lifestyle. But many have a clandestine homosexual lifestyle. In the United States, there is far less social pressure on homosexuals [13].

The São Paulo AIDS program, grounded in sanitarista traditions, embraced political action and public campaigns from the earliest stages of the AIDS epidemic in Brazil. Teixeira's campaigns are documented in the Brazilian newspapers as early as 1985, when he publicly denounced six hospitals for discriminating against AIDS patients:

We are going to move mountains to get hospital beds for these AIDS patients—all these medical institutes are refusing to see them! When there is no profit, they just send them to the state health secretariat! [12].

Though sanitaristas failed to reform the federal health bureaucracy, sanitaristas were able to quickly and successfully implement AIDS programs in São Paulo. This success can be attributed to several factors. First, the first AIDS cases were among upper and middle-class homosexual men rather than the urban poor the sanitaristas had originally tried (and failed) to mobilize. Also, because nonstate activism for AIDS was percolating in São Paulo city, sanitaristas did not face the overwhelming task of mobilizing the entire local community; community groups had already mobilized.

Additionally, partnering with local community organizations for education and prevention campaigns did not require immediate mass mobilization of financial resources and lowered the cost of starting an AIDS program. In contrast with the institutional challenges, sanitaristas faced in reforming the federal system, and since AIDS was a new health problem, sanitaristas promoting AIDS programs were relatively unencumbered by entrenched interest groups. Finally, as sanitaristas controlled the São Paulo State Health Secretariat, they were not stymied by career bureaucrats; sanitaristas were able to freely create new health programs for AIDS.

São Paulo state AIDS programs established an enduring paradigm for Brazil's public policy response to the AIDS epidemic. Since development of São Paulo's first AIDS program, the AIDS response in Brazil has engaged civil society in program development and implementation, and had been highly vocal about social justice issues. These partnerships, coupled with other developments in Rio de Janeiro state examined later in this chapter, contributed to later development of a social movement for AIDS as well as the National AIDS Program's (NAP) health and human rights focus and strategic partnerships with civil society groups.

The Evolution of Sanitarista Strategies in Postauthoritarian Brazil

With democratic change in Brazil in the 1980s, many of Brazil's social movements' strategies evolved. In contrast to pre-1985 social movements, whose main objective was to topple the military dictatorship, social movements began engaging, lobbying, and working within the government increasingly more as public democratic institutions were established in Brazil. Many social movements called for cooperation with

the government and began defining their objectives as human rights associated with citizenship in the new Brazilian democracy, including public provision of land and social services such as health and education. Guaranteeing “citizenship rights” became the unifying slogan and strategy of many social movements at that time:

Many social movements in Brazil adopted “citizenship” as the main social and operational frame. Many of the social movements adopted citizenship language to reflect their goals of ‘participation’ and ‘inclusion’ in the democratic process defining ‘citizenship’ as a description of their own activities while seeking to extend those activities to marginalized social groups [16].

Post-1985 social movements also called for social inclusion and defined hunger, discrimination and violence as violation of citizenship rights of “social inclusion” [16, 17]. Though several social movements had used rights concepts and language for implementing their objectives, this change in language marked a change in strategy; many began using citizenship and rights language in campaigns, political action and tactics, and in their unifying slogans.

Brazilian social movements’ strategies of working with or within government bureaucracies have been common since the transition to democracy. This is because the federal government in Brazil has been historically very powerful as a result of both import substitution policies of the 1950s and 1960s and the highly centralized military dictatorship. Moreover, because the federal government was the major financier of social programs, and Brazil’s democratic institutions were quickly evolving, Brazil’s most successful social movements, such as the Landless Movement, the Women’s Movement, and several environmental movements, realized early that their greatest opportunities for promoting social change would be to work inside rather than outside the government [16].

After Brazil’s first democratic presidential election in 1985,³ the SHRM began working increasingly with the federal government to achieve reform objectives and also adopted citizenship and rights language to define the role of the new, more democratic government on health issues. Though the SHRM had adopted what is now considered a “rights-based approach” to health programs in the early 1980s in São Paulo state, around 1986 the SHRM began using more formal “citizenship” and “rights” language for campaigns, political action, and unifying slogans to promote health reforms. Sanitaristas used these social movement tactics to advocate for a strong role for the federal government in provision of primary health care services. The SHRM claimed that access to health care was a fundamental right of all Brazilian citizens and that the government should be the primary executor of that right [2].

As a result of the PMDB Presidential victory in 1985, many more PMDB sanitaristas made their way into the federal health bureaucracy [2, 18]. Several sanitaristas assumed control of the largest public health bureaucracies, namely the Institute for Health Care for the Social Security System (INAMPS), the Ministry of Social Security Welfare (MPAS) and the Health Ministry. Well-known sanitarista Hésio

³The 1985 presidential election is discussed in greater detail in chapter 1.

Cordeiro assumed the Presidency of INAMPS, the social security health care bureaucracy. Eulério Rodríguez Neto⁴ became head of the Health Ministry. José Saraiva Felipe⁵ became head of Medical Services of the social security administration, and Sérgio Arouca assumed the Presidency of Fundação Oswaldo Cruz (FIOCRUZ), Brazil's major health research institute [2, 8].

Though the sanitarias managed to move into federal health bureaucracies during Brazil's first democratic administration, their new positions prompted few immediate federal health policy changes. As in the late 1970s and early 1980s, the sanitarias' ambitious goals, the clientelistic nature of Brazilian bureaucracy, and the complexity of reforming Brazil's health sector stymied their reforms [2]. However, sanitaria leadership in federal bureaucracies did have significant impacts on the future of AIDS programs in Brazil. Connections to high-ranking bureaucrats became important for sanitarias working within state institutions as well as sanitarias and AIDS activists lobbying for continued health policy reforms. Additionally, by the mid-1980s, citizenship and rights language had become not only the ideological anchor of the SHRM; citizenship and rights became the centerpiece of SHRM political action tactics.

AIDS Activism in Rio de Janeiro State

Democratic practices were slower to take root in more traditionally clientelistic Rio de Janeiro state, where the populist and personalistic Democratic Labor Party (PDT) won the 1982 gubernatorial election. Sanitarias, therefore, did not enjoy the same success in penetrating the Rio de Janeiro state health bureaucracy they did in São Paulo state. As a result, despite Rio's high AIDS prevalence, the public policy response to AIDS was weaker in Rio de Janeiro than in São Paulo [19].

In spite of the slow public response to AIDS in Rio de Janeiro state, because of Rio's vibrant intellectual community and high AIDS prevalence rates, there has been a great deal of civic activity related to AIDS in Rio de Janeiro. Much of that civic activity began with Herbert da Souza – “Betinho” – an important figure who is remembered today as Brazil's most well-known democratization, citizenship, and AIDS activist. Betinho, trained as a sociologist, founded one of Brazil's first NGOs for AIDS and also launched several other social movements, including Brazil's land reform movement⁶ and anti-hunger campaigns. Betinho, who had many connections to high-profile political actors,

⁴Rodríguez' scholarship about the SHRM and the 1988 Constitution is also cited in this chapter.

⁵Brazil's Health Minister from 2005–2006.

⁶“O Movimento de Trabalhadores Rurais sem Terra” (MST), or Brazil's landless movement, began in 1984 and blossomed into a highly effective social movement in the 1990s. The MST holds that Brazil is long overdue for agrarian land reform to provide the rural poor with land to cultivate. This movement's slogan “Agrarian Reform by Law or Disorder” perhaps best summarizes the movement's objectives; the MST both tries to change laws to promote agrarian reform and also peacefully occupies government or private land in rural areas until government grants the occupants land titles.

sanitaristas in the Health Ministry and legislature, and members of the PMDB, shaped development of AIDS institutions in a variety of important ways before he died of AIDS in 1997.⁷ This chapter focuses on his contributions to civic activity related to AIDS in Rio de Janeiro and his contributions to the 1988 Constitution.

In light of the poor public policy response to AIDS in Rio de Janeiro, under Betinho's leadership AIDS activists solicited financial support from the federal government. In 1986, Betinho, a hemophiliac who contracted HIV through a blood transfusion, convinced his friend, sanitarista Hésio Cordeiro, then head of INAMPS, Brazil's federal social security bureaucracy, to provide him with seed money to start an NGO dedicated to AIDS in Rio de Janeiro [10]. Betinho's NGO, the Brazilian Interdisciplinary AIDS Association (ABIA), quickly became Rio de Janeiro state's foremost center of AIDS-related activity, fostering greater institutional dialogue about AIDS by publishing books, papers, and reports about AIDS. As the center of nongovernment AIDS activity in Rio de Janeiro, ABIA sparked other civic activity related to AIDS; ABIA began providing technical training to other smaller startup NGOs for AIDS and helped create several smaller offshoot NGOs such as *Pela VIDDA*⁸ and others [15, 20].

Betinho and ABIA helped shape strategies for public policy change related to AIDS. Like the SHRM, AIDS activists began using citizenship and rights language to guide activism and their demands of the state. In campaigns, ABIA publicly denounced human rights violations associated with discrimination and the stigma related to AIDS, labeling these as violations of citizenship rights. ABIA and other NGOs called upon the new, more democratic government to implement policies to protect the human rights of PLWHA. ABIA demanded that the federal government provide free and universal access to health services for PLWHA and publicly held the government accountable for treatment and care of AIDS patients. The AIDS activism of famous hemophiliacs like Betinho and his two brothers, one a famous cartoonist and the other a musician, lent great legitimacy to this new style of citizenship activism for AIDS. Moreover, their connections to insider policymakers were very important in the early stages of the democratic transition [10, 15, 20, 21].

In contrast with São Paulo, where there was early and consistent engagement between NGOs and the state Health Ministry, civic activity for AIDS in Rio de Janeiro remained largely independent of the state government, as sanitaristas had never penetrated the Rio state health bureaucracy. However, federal sanitarista bureaucrats helped create the momentum for Rio's AIDS activism by financing ABIA. This highlights the common informal, but nevertheless important, links between the SHRM and AIDS activists during the 1980s. These connections, as well as AIDS activist connections to high-profile policymakers, remained important over the years.

Civic activity in Rio de Janeiro is mentioned in detail in this section because the human rights and citizenship campaigns used by Betinho and several NGOs in Rio de

⁷Betinho is an important political actor in the AIDS movement and will be mentioned in several subsequent chapters.

⁸*Pela VIDDA*, an NGO, stands for *Pela Valorização, Integração e Dignidade do Doente de AIDS*, in English "For the Valorization, Integration and Dignity of People Living With AIDS."

Janeiro planted some of the initial seeds for what would later develop into a social movement for AIDS that vigorously promoted widespread access to AIDS treatment.

The 1988 Constitution and the Right to Health

SHRM penetration of state and federal-level health bureaucracies did lead to a few institutional victories related to AIDS in São Paulo and Rio de Janeiro states. However, the overall SHRM strategy of penetrating federal-level health bureaucracies to promote major federal health reforms did not bear fruit because of the overwhelming task of reforming a clientelistic bureaucracy and the complexity of developing nationwide health infrastructure. Sanitaristas therefore began developing a broad-based coalition to promote health reforms through the legislative branch of government [22].

Other opposition parties made minor inroads in the 1986 democratic elections, but the PMDB remained the main catch-all opposition party, holding 302 of 559 seats at the Constituent Assembly [18]. Although many sanitaristas considered themselves communists, the Communist Party had only become a legally sanctioned party in 1985 and had not yet gained the political momentum to be highly influential. To further their objectives in political fora, many sanitaristas instead joined the PMDB, which supported most sanitarista health reform objectives. Dozens of sanitaristas ran for office in Brazil's first free Congressional elections in 1986. Because the victors of the 1986 Congressional elections would also be members of the 1987 Constituent Assembly that wrote Brazil's new Constitution, the SHRM hoped to use Congressional victories to help enshrine the right to health in the new democratic charter [2, 8].

Sanitarista political action in the legislature began when Sergio Arouca, communist, sanitarista, and president of Fundação Oswaldo Cruz (FIOCRUZ, Brazil's premier health research institute), was appointed as the president of the 8th National Health Conference in 1986. The historically bureaucratic health conferences, which began in the Vargas presidential administration in the 1940s, aimed to foster dialogue between the states and federal governments about health administration and health care delivery. These conferences continued during the dictatorship, and the 8th conference ultimately became an outlet for SHRM and civil society dialogue about pending health sector reforms. Under Arouca's direction, the conference adopted an activist tone, highlighting strategies for the "movement for democratization of health" [23].

In an interview about the sanitarista legislative strategy, Sanitarista Ary Carvalho de Miranda, an organizer of the 1986 National Health Conference, (now vice-president of FIOCRUZ) commented on the SHRM's tactics for coalition building:

We convened a totally different Congress than those in the past. The fundamental difference was that we wanted to have a conference that mobilized all of Brazil that participated; not just people in the Health Ministry, not just in government positions, but all of civil society. So we had a conference in which half of the delegates were members of organized civil society. There were federal labor unions, all sorts of other different unions that identified with the left, even the more conservative unions. The organized groups of health professionals included doctors, nurses, psychologists, social workers, all the civil society groups that had anything whatsoever to do with health. For example, we had the social movement for

reintegrating leprosy patients into society, which were all people with leprosy who had organized civil society groups to fight discrimination and stigma. So over 4,000 people participated, and over half of those were from health unions, rural unions, political parties, and civil society organizations. The other half were official state representatives from the ministry of education, health, and local and state secretariats [8].

Participation of vulnerable populations and members of civil society exemplified the SHRM value of community participation in health reform. This tactic also helped create a broad-based coalition that endorsed the sanitarista platform. The 1986 health conference report that emerged out of this participatory conference became the blueprint for the sanitarista strategy to establish health as a right of all Brazilians at the 1987 Constitutional Convention. Sanitaristas believed this would require the new Brazilian government to take up the sanitarista agenda and would provide the SHRM with means to hold the government accountable for expanding access to health services [1].

In 1987, sanitaristas inside and outside federal and state government began lobbying Constituent Assembly delegates to include the right to health and the SHRM's other health reform objectives in the new Constitution. In an interview, de Miranda commented that the participatory nature of the 1986 health conference had given great legitimacy to the sanitarista cause; civil society endorsement of the 1986 conference prompted widespread support of the SHRM platform, and helped convince PMDB representatives to support the SHRM's health objectives during the 1987 Constitutional Convention. Other opposition parties that gained far fewer seats also supported the SHRM goals [2, 8].

Sanitaristas also sought to influence the Constituent Assembly from outside the Constituent Assembly. For example, sanitarista Sergio Arouca proposed a mechanism through which Brazilian citizens could introduce amendments that the Constitutional Convention was required to review. Sanitaristas proposed an amendment promoting universal access to health services. Though the sanitarista "plebiscitary" amendment ultimately failed, the amendment contributed to important debate about the right to health and access to health services. As a result of SHRM's persistent lobbying of Constituent Assembly delegates, sanitarista objectives including the right to health and health services were ultimately integrated to the 1988 Constitution [2, 7, 8, 22].

The final text of the 1988 Constitution represented an overwhelming victory for the SHRM. Articles 196–198 reflected most of the SHRM's major public policy goals. Article 196 of the Brazilian Constitution established health as a fundamental right guaranteed by the federal government:

Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection, and recovery.

Article 197 declared that the government must provide and regulate health services and reserves a role for the private sector:

Health actions and services are of public relevance, and it is incumbent upon the government to provide, pursuant to the law, for their regulation, supervision and control. Such actions

and services are to be carried out directly or through third parties and also by means of individuals or legal entities of private law.

Article 198 established a new public health system reflecting the SHRM's goals of decentralization, integrated health services, and community participation in health policy:

Health actions and public services integrate a regionalized and hierarchical network and constitute a single system, organized according to the following directives: 1) decentralization, with a single management in each sphere of government; 2) integrated health services, with priority given to preventive activities, without prejudice to assistance services; and 3) participation of the community [24].

After more than a decade of failed attempts to reform promote SHRM values in health reforms, these 1988 Constitutional amendments finally acknowledged the right to health and health services in Brazil and cemented the government's role in finance, regulation, and provision of health care. This would later have profound implications on development of Brazil's AIDS treatment institutions.

The 1988 Constitution also included articles on a number of very specific public policy issues that catered to special interest groups, including the SHRM and AIDS activists. At the time, prior to availability of antiretroviral medicines in Brazil, the issue of blood regulation was the single most important public policy issue discussed in the AIDS and public policy circles. Betinho testified before the Constituent Assembly about the importance of regulating commercial blood sales to prevent transmission of HIV [25]. He convinced the PMBD Constituent Assembly member Deputado Raimundo Bezerra to include an article banning commercial sale of blood products. Article 199.4 of the Constitution outlawed the commercial sale of blood products [7]:

The law establishes the conditions and requirements to allow the removal of human organs, tissues, and substances intended for transplantation, research, and treatment, as well as the collection, processing, and transfusion of blood and its byproducts, all kinds of sale being forbidden [24].

Article 199.4 called national attention to the AIDS epidemic and exemplifies the unofficial, yet very important role that Betinho played in using political action to link AIDS, democracy, and citizenship. This article also symbolizes the common informal links between Brazil's intellectual elite, the opposition PMDB and the SHRM; Betinho was the AIDS activist community's primary link to high-profile political actors. This is one of many examples in which Betinho's connections and credibility with high-profile policymakers helped advance the public policy response to AIDS. These connections were important for later development of Brazil's AIDS treatment institutions and will be discussed in greater detail in chapter three.

Article 200 outlined the government's role in drug production, epidemiological surveillance, and the role of the health system in providing other services that also influence population health:

It is incumbent upon the unified health system, in addition to other duties, as set forth by the law: 1) to supervise and control proceedings, products and substances of interest to

health and to participate in the production of drugs, equipment, immunobiological products, blood products, and other inputs; 2) to carry out actions of sanitary and epidemiological vigilance as well as those relating to the health of workers; 3) to organize the training of personnel in the area of health; and 4) to participate in the definition of the policy and in the implementation of basic sanitation actions; 5) to foster, within its scope of action, scientific and technological development; 6) to supervise and control foodstuffs, including their nutritional contents, as well as drinks and water for human consumption; 7) to participate in the supervision and control of the production, transportation, storage, and use of psychoactive, toxic, and radioactive substances and products; and 8) to cooperate in the preservation of the environment, including that of the workplace (Article 200) [24].

Another proposed article would have granted the federal government a monopoly in production of raw materials for drug production, but the amendment was not accepted in the Constitution's final text [7].

The 1988 Constitutional right to health exemplifies how the SHRM used health and human rights language in political action to promote public policy change. Adoption of the Constitution marks a turning point for health and AIDS policy in Brazil. The Constitution established the institutional conditions that gave rise to Brazil's future health institutions and reforms, including Brazil's institutions for AIDS treatment. As a result of the new Constitution, the SHRM and the AIDS activists finally could point to a Constitutional right to health for which to hold the government accountable for provision of a variety of different health services. This had dramatic impacts on the path of institutional development of AIDS policy: the 1988 Constitution and its declaration of the right to health later became the cornerstone of the AIDS treatment movement. As the next chapter discusses, the social movement for AIDS that developed in the early 1990s would also later draw upon the SHRM's citizenship framework, language, and strategy to start a social movement for AIDS, which ultimately helped mobilize the public sector response to AIDS in Brazil.

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Chapter 3

Development of Brazil's First AIDS Treatment Institutions in a New Democracy

Social Movements Infiltrate the State

Collaborating with the federal government became a common strategy for social movements in postauthoritarian Brazil. As chapter 2 explored, both AIDS activists and the sanitarista health reform movement (SHRM) endorsed this approach, employing partisan strategies and working both inside and outside the government to achieve reform objectives.

However, AIDS activists and the SHRM changed their political strategies after the 1988 Constitutional convention officially outlawed the military dictatorship and new political parties developed. In late 1988, many sanitarista and AIDS activists broke allegiance with Brazil's main prodemocracy political party, the PMDB. The PMDB lost much of its legitimacy because of its historical alliance with the Sarney government, whose dismal performance on economic policy sparked hyperinflation in Brazil [1].

In 1988, Fernando Cardoso,¹ along with several other founding members of the PMDB party, formed the Brazilian Social Democratic Party (PSDB) in 1988, which was ideologically further left of the PMDB but to the right of the Worker's Party (PT) [1]. The PT fared well in the 1988 municipal elections and placed a close second in the 1989 presidential election [2]. Disappointed with the PMDB's failure to implement major health reforms, thereafter, many sanitaristas and AIDS activists unofficially gravitated toward the PT party, which became known as the party of social movements [3–5]. Others gravitated toward the PSDB and some maintained connections to the PMDB.

Though both the SHRM and AIDS activists had used political parties to move their agendas forward before the 1988 Constitution, in postauthoritarian Brazil, neither group was officially affiliated with a specific political party. Both the

¹Fernando Henrique Cardoso (FHC), a world-renowned Brazilian sociologist exiled during the military dictatorship, returned to Brazil in the 1980s. He was first elected as Senator in Brazil in 1983 and served as both finance and foreign affairs minister during the Franco administration. FHC served as President of Brazil for two consecutive terms, from 1995 to 2003.

SHRM and AIDS activists maintained their allegiance to progressive health reforms and left-leaning political parties but relied less on political parties to influence public health policy. Instead, sanitarias began focusing on trying to infiltrate the Health Ministry bureaucracy to achieve their objectives. This nonpartisan strategy of social movements penetrating the state had profound impacts on historical development of Brazil's treatment institutions and is a key focus of *The Politics and History of AIDS Treatment in Brazil*. This chapter and future chapters explore the evolving nonpartisan political strategies of AIDS activists and highlight their influence on historical development of AIDS treatment institutions.

Early Federal AIDS Programs

In attempt to create progressive health infrastructure to achieve SHRM goals, many sanitarias had already moved into the upper echelons of federal and state health bureaucracies during the Sarney administration, even before the 1988 Constitutional convention [6]. In contrast, AIDS activists did not move into the federal bureaucracy until several years later.

It is difficult to pinpoint the exact date of creation of the National AIDS Program (NAP). The institutional responses to AIDS in Rio de Janeiro and São Paulo states highlighted in chapter 2 exemplify the decentralized nature of the first institutional responses to AIDS in Brazil. A small group had worked on AIDS issues within the Health Ministry since 1985, when Dr. Lair Guerra assumed leadership of AIDS initiatives. However, the National STD and AIDS Program did not develop as a separate administrative entity until after the 1988 Constitution was adopted. In newly decentralized Brazil, the National AIDS Program played only a small role in AIDS policy until the early 1990s [7].

Lair Guerra, the first NAP Director, was often referred to in inner circles as “a *Coronela*,” or “the little female colonel.” This title referred to her militaristic, centralized style of administration and her close ties to the former military government and the PFL party, which generally did not embrace sanitaria values or federal health reforms. Her support for AIDS programs was nevertheless unwavering. However, until the National AIDS Program had more federal financial support in the 1990s, the role of the federal government was somewhat obscured by state and NGO AIDS activity in São Paulo and Rio de Janeiro states.

Because there were still few federal health institutions and infrastructure to build AIDS reforms upon, even after the 1988 Constitution, leaders from AIDS NGOs in Rio de Janeiro continued to rely heavily upon personal connections to sanitarias in the federal health bureaucracy for support of small NGO prevention programs. In the absence of a strong federal AIDS programs, São Paulo state continued its decentralized AIDS programs.

With no reliable source of federal AIDS funding, AIDS activists began soliciting direct support from the executive branch of government for activities on a non-partisan, but still very personal, basis. This process of using informal channels, or

jeitinhos,² to garner support for important political reforms, is commonplace in postauthoritarian Brazilian politics [8]. In this political context, *jeitinhos* refers to using informal solutions to overcome institutional barriers. Using *jeitinhos* and personal connections to Lair Guerra, director of AIDS activities during President Sarney's administration, democratization activist Betinho was able to procure sporadic Health Ministry support for NGO prevention campaigns for several AIDS NGOs from 1988 to 1990.³

AIDS activists' attempts to influence public policy using personalistic political channels rather than by constructing stable democratic institutions symbolize the fragile state of Brazil's democracy and health institutions in the late 1980s. With few existing health institutions to build upon, soliciting direct, informal support from Health Ministry insiders was the only way for AIDS activists to receive direct federal support for their programs.

This proved problematic with the presidential administration change in 1989, which destroyed AIDS activists' inside connections to Health Ministry coffers. This may have ultimately contributed to development of the AIDS movement's more nonpartisan political action strategy throughout the 1990s, which allowed the AIDS movement to solicit public policy responses to the AIDS epidemic from politicians across the political spectrum.

The 1989 election marked Brazil's first completely free democratic presidential ballot. Fernando Collor of the new conservative National Reconstruction Party (*Partido de Reconstrução Nacional*, PRN) narrowly defeated PT candidate Luis Ignacio da Silva "Lula" in a runoff in Brazil's first free and democratic presidential election. In postauthoritarian Brazil, President Collor faced the task of privatizing several publicly-owned industries and implementing controversial macroeconomic and tax reforms. He also faced the daunting challenge of simultaneously building federal institutions to support important reforms while decentralizing the federal bureaucracy in accordance with requirements of the new Constitution [8]. One of the biggest challenges associated with democratization were the extensive health reforms required by the 1988 Constitution, including articles 196–200 of the 1988 Constitution, which required decentralized public provision of primary health care and established the right to health and health care.

Collor's presidential term was short-lived; after holding office only 2 years, he was impeached in 1992 after being charged with corruption for accepting bribes from business groups. The Collor administration is widely identified with corruption and with hyperinflation and pork-barrel politics. Collor's performance on health

²The literal translation for *jeitinho* is "little way." *Jeitinho* refers to a clever expedient, improvised solution, or way around a problem. This term is often used in everyday conversation in street slang but also appears in the literature on institutional development in Brazil, which holds that patronage and *jeitinhos* have been just as important to explaining development current institutional arrangements in Brazil as more formal democratic reform processes.

³Table 5 includes a list of NAP directors and health ministers in postmilitary Brazil.

reforms was lackluster: he vigorously promoted the role of private sector in publicly and privately-financed health care delivery, undermining efforts to expand universal primary health care. He also decreased federal health spending by nearly 50% during his short term in office and opposed the health system decentralization process required by the 1988 Constitution [9].

While the 1988 Constitution outlined numerous ambitious health reform goals, it did not elaborate on the specific health services included in the right to health and the role of each level of government in finance and provision of decentralized health services. In late 1990, the SHRM and local health authorities finally convinced a majority of Congress to adopt National Health Laws 8080/90, which would more clearly define how many of the 1988 Constitutional mandates would be implemented and regulated. However, Collor line-item vetoed many articles of the 1990 health laws in attempt to prevent decentralization of the health system and to allow for a greater private sector role in public health care provision. Congress ultimately approved two watered-down National Health Laws, which vaguely required that municipalities would manage local health care programs but maintained that the federal government would finance and coordinate health policy [9]. The laws offered little guidance about the specifics of how decentralized health reforms would be implemented, and are mentioned here because they later impacted development of AIDS treatment institutions.

Perhaps because of Collor's otherwise poor health record, no piece of scholarship has systematically examined important institutional developments related to AIDS during the Collor administration. However, the aforementioned laws that Collor sent to Congress had important impacts on AIDS treatment policies. Law 8080/90, adopted by Congress and signed by the President, states that "SUS⁴ include federal, state, and municipal public institutions for quality control, research and production of products, drugs, blood and blood products, and health equipment." However, Article 6.1 states that "SUS assumes responsibility for formulating policies for drugs, equipment, immunobiologics, and other inputs for health as well as in production of the aforementioned products" [10].

Law 8080/90 assigns the role of drug policy and provision to local, state, and federal governments, but offers little guidance on how drug policy should be implemented and which levels of government should assume responsibility for drug procurement and distribution [9, 11]. These health laws failed to interpret broad Constitutional health mandates, did not outline clear paths for implementing the Constitution's health reform goals and exemplify the general weakness of health institutions in the early 1990s. Even more importantly, this weak health law would ultimately lead to controversial debates about the role of each level of government in public provision of drugs for AIDS treatment.

In addition to new health reforms adopted by Congress during the Collor administration, several other important events occurred simultaneously that would have

⁴SUS stands for Sistema Único de Saúde, or Brazil's federal health system.

major impacts on AIDS treatment institutions: reported AIDS cases doubled from 1990 to 1992; and zidovudine (AZT), the first antiretroviral (ARV) drug to treat AIDS, was launched by the pharmaceutical company Wellcome in Brazil.⁵ AZT immediately became known as the miracle drug for AIDS patients. Though the \$8,000 annual cost of AZT was prohibitive for many Brazilians, the drug immediately sold well to Brazil's growing number of AIDS patients receiving care from private physicians.

Additionally, though AIDS activists solicited continued state support for its increasing number of prevention and advocacy activities during the Collor administration, because they had had no personal connections to National AIDS Program (NAP) bureaucrats in the Collor administration, financial support for nonstate AIDS activity was discontinued, straining relations between nonstate AIDS actors and the Health Ministry.

Strained relations between NGOs and the Collor Administration developed around the same time that NGOs formerly engaged in disparate civic activities related to AIDS began coordinating their efforts and jointly articulated their objectives for the first time, becoming a formal social movement. No longer relying exclusively on personal relationships or partisan connections to achieve its objectives, the AIDS movement began using political action tactics to encourage a public response to the AIDS epidemic in Brazil.

The confluence of new opportunities for political organization and outlets for democratic dialogue, federal health reforms, and new drugs for treatment transformed the institutional environment during the Collor administration in the early 1990s. These developments led to two critical junctures, or turning points, that resulted in enduring commitments to AIDS treatment in Brazil. The first was Brazil's initial federal commitment to providing drugs for AIDS treatment in 1990, and the second was NAP Director Lair Guerra's decision to hire activists to write World Bank loan proposals for AIDS programs.

The Genesis of the AIDS Movement

Civic activity for AIDS had been percolating since 1983 in São Paulo and the mid-1980s in Rio de Janeiro. However, prior to 1989, a few NGOs dedicated to AIDS such as ABIA, GIV, GAPA, and Pela VIDDA dominated nongovernment civic activity related to AIDS. As NGOs had actively fought stigma and discrimination and vigorously defended the rights of PLWHA since the beginning of the AIDS epidemic in Brazil, it is difficult to assess when AIDS-related NGO activity could officially be classified as a social movement in Brazil.

⁵ AZT was the first of many antiretroviral drugs invented to combat the retrovirus HIV, which causes AIDS. From 1987 to 2007, nearly 30 antiretroviral drugs were approved by the United States Food and Drug Administration.

New democratic political freedoms in postauthoritarian Brazil allowed AIDS activists to organize openly and officially express their political dissent. In 1989, after a major AIDS conference in Montreal,⁶ many NGOs and AIDS activists, including Betinho, Herbert Daniel, Paulo Teixeira, and many others, began organizing to exchange information and develop broad strategies to influence public policy related to AIDS in Brazil. This resulted in Brazil's first NGO network and first joint articulation of several NGOs' overarching human rights objectives, entitled the *Declaration of Rights for Individuals Living with AIDS*. The declaration outlined the movement's principles of nondiscrimination, social equity, democratic accountability, and participation of PLWHA in policy development [7].

The declaration, based on the 1988 Constitution's right to health and grounded in human rights principles, marked the beginning of the AIDS movement in Brazil. This delineates the moment when the AIDS movement formally articulated its objectives and began using organized campaigns, political action, and unifying slogans in sustained public efforts to demand a public policy response to the AIDS epidemic. Human rights became the umbrella framework for the AIDS movement's campaigns, political action strategies, and unifying slogans. The AIDS movement began using human rights language to unify the movement and to formally articulate the social "worthiness" of its demands of the government. Human rights language was useful for both nongovernment actors as well as public servants working on AIDS issues to articulate the social worthiness of the AIDS movement's demands.

Human and citizenship rights also became an effective means to legally justify the AIDS movement's demands of the government. The Declaration of Rights for Individuals Living with AIDS marks the moment when AIDS activists and a large coalition of NGOs began using social movement repertoire and political action, including coalitions, public meetings, rallies, protests, and the court system to hold the government accountable for treatment in the context of the right to health. These political action activities that emerged with new democratic political freedoms represent a departure from the movement's former near-exclusive reliance on the PMDB party, insider connections to politicians, and sanitarias in the Health Ministry.

Using a variety of political action tactics, the movement lobbied for direct support for civic activities and demanded that the federal government create health institutions to address the right to health in the context of AIDS.

Since the 1988 Constitution articulated a right to health, rights language was an effective way to hold the government accountable for responding to the AIDS epidemic. Rather than adopt strategies to promote legislative reforms for AIDS policy in a country with a weak and frequently unresponsive legislature, the AIDS movement

⁶In 1985, the International AIDS Society (IAS) began convening annual conferences to share scientific discoveries related to HIV/AIDS. In the early 1990s, in efforts to include people living with HIV/AIDS and civil society more broadly, the conferences became more participatory and are now unique fora for discussion of social, epidemiological, policy and scientific issues related to HIV/AIDS. IAS AIDS conferences are now held biannually.

began using the court system to file lawsuits to hold the government accountable for implementing the right to health and health services as described in Articles 196 and 198 of the 1988 Constitution. Attorney Miriam Ventura, former director of NGO Pela VIDDAs legal aid program, described the AIDS movement's political action strategy and links to the SHRM:

The strategy our legal aid department had two major fronts: First, to file lawsuits against the government, and second, to reinforce our legal claims with the Constitution that had been approved in 1988. This ideology and strategy was promoted by the sanitarista movement, many of whose leaders were on Pela VIDDAs and ABIA's board of directors, such as Sergio Arouca, Genia Kelson, and others. We had a commitment to fight so that this model, which was guaranteed by the Constitution, would be implemented.

So our lawsuits were always grounded in the rights-based approach, non-discrimination campaigns and were connected to the general Constitutional right to health, which guaranteed equity and the right to universal access to health services. Since the right to health was established in 1988, my job in 1989 was much easier than if I'd begun this campaign in before 1988, because in 1989 there was a Constitutional mandate....

We decided not to focus on AIDS itself as a public health objective. Instead we sought to connect AIDS to general public health concerns. We had two reasons for choosing this strategy: first, we wanted to really show that the general public health system needed to be regulated and perfected, since Brazil had so many public health problems. Second, we thought the strategy of working through the court system would be much faster, because if we had chosen the legislative strategy, particularly trying to move forward laws for treatment of people living with AIDS, we'd have a hopelessly endless legislative process, which has been the tendency of most of Brazil's social movements [14].

The AIDS movement believed that the judicial branch of government was the best option for hastening social change related to AIDS. Because the Brazilian legislature has been historically unresponsive to democratic lobbying efforts, the AIDS movement focused its efforts elsewhere. Moreover, many prior social movements in Brazil had focused on legislative action to achieve their objectives, including the sanitarista movement, whose objectives took over 20 years to accomplish at the federal legislative level, and even then, did not always succeed in developing strong public institutions to implement legislative mandates. However, the AIDS movement did effectively utilize and build upon the health rights the SHRM had helped enshrine in the Constitution, using the courts to hold the government accountable for those rights. When the AIDS movement brought lawsuits against the government, the courts often ordered government agencies to comply.

The AIDS movement, therefore, tailored its political action tactics accordingly. Rather than focus on developing new laws to cater specifically to the needs of AIDS patients, the AIDS movement used the courts to hold the federal government accountable for its duty to protect against discrimination, provide equal opportunities to PLWHA, and provide essential medicines as a basic right outlined in the 1988 Constitution. This approach also had another objective: by framing the AIDS discussion as a citizenship discussion, the movement abandoned any trace of an "AIDS victim" framework, (which often increases stigma). The AIDS movement instead directed the public policy discussion toward the role of government in providing health care to all citizens. Miriam Ventura commented:

Civil society groups used the judiciary not to ask for some sort of benefit from the state, but to force the state to comply with its legal obligations. You fortify people living with AIDS *not* by saying, “You’re a victim!”

There are no victims, there are only citizens seeking their rights and therefore the state must recognize them! This helped create an identity for people living with AIDS, identifying them as citizens with rights. At the time, that was one of our objectives, to identify that person not as a disease carrier, but someone with human rights. Our goal was not to allow someone die a “civic death,” as Herbert Daniel [a well-known Brazilian AIDS activist] often claimed....

That’s why we brought discrimination lawsuits against the state, forcing the state and the public to realize that people with AIDS weren’t victims or villains in this epidemic. The main objective of our lawsuits was to force the public to realize that individuals with HIV were people with rights, with specific health, work and social security needs. In a democracy, these needs had to be viewed as rights; we couldn’t let HIV-positive individuals be seen as victims! [14].

In Brazil, the court system was the first federal institution in which the right to health and health services were first interpreted in the context of AIDS. In April 1990, in the first of many lawsuits filed for violating the rights of PLWHA, a judge found an insurance company had discriminated against AIDS patients, violating article 5 of the Constitution that guarantees a “right to life” [15]. The judge called for the private health insurer to cover all diseases, including AIDS. A series of other subsequent important court decisions followed over the next few years, including decisions that the federal government was grossly negligent in regulating the blood supply [16]; prohibitions of discrimination against PLWHA; the right of PLWHA to serve in the military; the right of PLWHA to collect retirement and disability benefits [17]; the right of PLWHA to maintain their employment status [18]; the right of HIV-positive children to attend school [19], and most importantly for this discussion, the right to drugs for AIDS treatment [20–22].

Moving controversial issues through the courts and forcing the court to recognize the citizenship rights of PLWHA helped legitimize the AIDS movement and the rights and services it aimed to secure through the state. This type of strategy is common for special interest groups or social movements who want to use the courts for strategic social change or to legitimize their demands of governments [23, 24].

As mentioned in chapter 1, because Brazil’s poorly designed judicial branch of government does not permit binding precedents except under a set of very limited circumstances, these rulings were usually restricted to individual cases, limiting broader institutional change through the judicial branch of government. However, judicial interpretations are important for institutional development because they helped shape social norms for PLWHA; court decisions called attention to both public and private sector discrimination against PLWHA, prompting both public and private institutions to change many discriminatory practices against PLWHA. Additionally, high-profile, controversial trials brought against the government and major corporations prompted media coverage of important issues related to AIDS, including chronic shortages of drugs for AIDS treatment. These developments exemplify how the AIDS movement effectively borrowed and built upon sanitarista political action tactics, effectively using the 1988 Constitution, human rights, and the court system to influence social policy and hold the government accountable for citizenship rights related to AIDS.

The AIDS movement also used the media and public protests to pressure the executive branch of government to adopt and implement policies to address the AIDS epidemic. In contrast with most other infectious disease epidemics in Brazil, as in US, at that time, many of the first individuals to contract AIDS were well-educated, socially-engaged, upper-middle and upper-class homosexual men. Many were artists, journalists, and famous members of the Brazilian intelligentsia like Betinho and Herbert Daniel, who had direct ties to the democratization movement, the media, and who lent the AIDS movement great legitimacy. These connections helped increase media coverage of the AIDS epidemic.

Gaining momentum around the time of the Collor inauguration in March 1990, Brazil's civil society movement for AIDS began conducting more public protests, which generated press coverage for AIDS issues. Protests helped create local and national pressure for the executive branches of government at both national and state levels to respond to the AIDS crisis. News articles related to AIDS at this time reflect attempts to hold the government accountable for creating public institutions for treatment and care of PLWHA through public protests. For example, on the first day of Collor's presidency, numerous NGOs in Rio de Janeiro gathered for public protests about the federal government's poor response to the AIDS epidemic and the dramatic shortage of hospital beds for AIDS patients, attracting media attention to the Health Ministry's shortcomings in responding to the AIDS crisis [25].

AIDS also began to receive increased media coverage during the late 1980s and early 1990s, when new drugs became available for treatment. Moreover, in mid-1990, though AZT was not yet available in public sector hospitals and pharmacies in Brazil, newspapers reported that many people were buying AZT directly from British pharmaceutical company Wellcome for US \$6,000 to \$8,000 annually, an enormous sum by Brazilian income standards [26]. Several private hospitals were directly procuring the drug from Wellcome [27]. Media coverage of improvement in survival among AIDS patients taking AZT in the United States also highlighted the shortcomings of the Brazilian government in provision of medicines to its population.

The media was not only used by non-government actors; sanitaria reformers who were also members of the AIDS movement working *within* the São Paulo state Health Ministry began calling for free and universal access to AZT, then the drug of choice for AIDS treatment. Paulo Teixeira, director of São Paulo state's AIDS program, capitalized on media coverage of the high cost of AZT in Brazil, calling for free and universal access to drugs for AIDS treatment, claiming the only affordable way to treat AIDS patients would be for the federal government to finance treatment. Several of Brazil's foremost infectious disease doctors echoed Teixeira's calls for hospitalizing and treating AIDS patients in 1990 [28]. This type of political and media pressure from government and non-government actors helped create political incentives for the Health Ministry to begin to address the AIDS crisis. Partnership between non-government and public sector actors to pressure the federal government to develop AIDS institutions also became the hallmark of the AIDS movement in Brazil.

In summary, the AIDS movement used political action in the courts, public protests, and the media to hold the government accountable for developing institutions for AIDS. By influencing public opinion about the government's response to AIDS and securing citizens' rights to life, health, and health care for PLWHA in the court system, the AIDS movement helped change social norms and institutions for AIDS.

Committing to Treat AIDS

The Collor administration has been excoriated for its corruption scandals, failure to implement health reforms to comply with 1988 Constitutional mandates, and failure to collaborate with the civil society movement on AIDS programs. The few scholarly works that mention AIDS in Brazil during the Collor administration are highly critical of the Collor Administration for not partnering with civil society groups and implementing heavy-handed prevention campaigns that NGOs claim increased AIDS stigma [7, 29–32]. Collor was also criticized for poor implementation of AIDS treatment programs. Several individuals interviewed for this book also cited tensions between the AIDS movement and the NAP during the Collor administration [30–35]. However, analysis of numerous interviews, hundreds of news articles and historical documents from the time suggest that scholarly assessments of the Collor administration's performance on AIDS policy have been one-sided and neglect to document its important contributions to historical development of AIDS treatment institutions in Brazil.

Alceni Guerra, Health Minister during the Collor administration, made the first decision to provide publicly-financed drugs for AIDS treatment in 1990. His decision to provide drugs for AIDS treatment is the first critical juncture in this historical institutional analysis, a decision that established the institutional trajectory for AIDS treatment in Brazil. This decision created the first AIDS treatment institution examined in this book: Brazil's tradition of publicly-financing and delivering drugs for AIDS treatment. Surprisingly, this landmark decision has not been examined in any of the critiques of the Collor administration or the literature on AIDS in Brazil.

When Fernando Collor assumed the Presidency in 1990, he appointed Health Minister Alceni Guerra. Dr. Eduardo Cortes replaced Dr. Lair Guerra as NAP Director.⁷ Eduardo Cortes, MD, was asked to direct the AIDS Program because of his experience working with AIDS patients in the United States as well as his then-groundbreaking research on AIDS in Brazil [30, 36, 37].

This important change in Health Ministry leadership influenced development of Brazil's AIDS treatment institutions. Under Eduardo Cortes, the NAP first endorsed publicly financed AIDS treatment and procured expensive ARVs for public use. Also, Cortes began a dialogue with the World Bank about several loans for AIDS programs that later financed the epidemiological surveillance,

⁷See Appendix B for a complete list of Health Ministers and NAP directors.

health infrastructure development and civic activity for AIDS, all of which had enduring impacts on development of Brazil's AIDS treatment institutions.

Although *The Politics and History of AIDS Treatment in Brazil* does not attempt to review or resolve controversial disagreements between the civil society sector and the NAP during the Collor administration – other works examine those topics in greater detail [7, 30] – it does argue that understanding tensions between the AIDS movement and the Collor government is critical to explaining the development of Brazil's first AIDS treatment institutions. Tensions between the civil society movement and the NAP under Cortes stem from several factors: first, the AIDS movement aimed to move closer, and even collaborate with the federal government during the Collor administration. It failed, however, to attract federal financial support for its advocacy and prevention activities. Moreover, Cortes cut the previous administration's direct NGO support for HIV prevention programs to finance data collection for AIDS research [34, 37]. This also demonstrates the weakness of the previous relationship of the AIDS movement with the NAP, which had been based on personal connections between Betinho, Lair Guerra, and sanitarias in the Health Ministry rather than deep-rooted federal commitments to AIDS. Cortes' prevention campaigns also angered NGO groups, which claimed that his heavy-handed campaigns encouraged stigma and discrimination against PLWHA [7, 32]. Additionally, Cortes never embraced the AIDS movement's human rights approach to AIDS policy. Cortes certainly was not anti-human rights; rather, he approached the AIDS epidemic, and particularly AIDS treatment, with a more utilitarian, medical approach that was somewhat anathema to the values embraced by the AIDS movement. Finally, Cortes was criticized for poor NAP administration. Though Eduardo Cortes was certainly inexperienced as a program administrator and may have been a better doctor and scholar than national program administrator, many of his administrative problems stemmed from the historical institutional shortcomings of the Health Ministry and insufficient NAP budgets. In an interview, Cortes commented:

I began working for the AIDS program but there was no data [on AIDS prevalence]. The government wasn't willing to get involved with AIDS at the time. Provision of medical services for AIDS patients was chaos. There were no policies for AIDS care, there were lines, there were no drugs. When working as a doctor in an emergency room in Rio, I suffered each day taking care of AIDS patients, because the drugs I had in the USA I didn't have here. I'm not even talking about antiretroviral drugs. I'm talking about drugs for pneumocystis carinii, for opportunistic infections.

I saw hundreds of AIDS patients die, knowing there were drugs that could save them. It was overwhelmingly stressful. That's why I accepted directorship of the AIDS program. I went there, but there was no money for the AIDS programs. The Health Minister said that the AIDS program wasn't a priority, that Brazil's health priorities were maternal mortality, diarrhea, et cetera [37].

A Brazilian doctor who had trained in the United States and had experience working with AIDS patients, Eduardo Cortes was committed to providing AIDS treatment as program director. However, when he arrived at the Health Ministry, there were few existing institutions or programs for HIVAIDS, little funding and no protocols for AIDS treatment. Rather than focus on partnerships or direct support

with civil society groups, Cortes dedicated his limited resources to collecting AIDS surveillance data, which he believed to be the first essential step in responding to the AIDS crisis [34, 37]. This caused enormous tensions with NGOs who had previously received direct support from the federal government.

Ironically, the NAP's financial and institutional shortcomings and the tensions between the AIDS movement and the Collor administration forced the AIDS movement to increase political action to hold the federal government accountable for responding to the AIDS crisis. With no personal connections to NAP bureaucrats, the AIDS movement used political action tactics such as public protests and the media increasingly more to promote its causes, particularly for AIDS treatment. These new political action tools that had not been possible during the authoritarian regime helped create the social conditions that led to the first critical juncture in this analysis, Health Minister Alcení Guerra's decision to publicly finance AIDS treatment in Brazil.

Prior to 1990, most public policy discussions related to AIDS focused on increasing the number of public hospital beds for AIDS patients and regulating the national blood supply rather than providing drugs for AIDS treatment. Though interviews and newspaper articles confirm that there had been previous public discussions about AZT between 1987 and 1989, most were related to importation, government regulation of AZT, and pirated AZT rather than public provision of the drug [38–47]. At one point, sanitarista Hésio Cordeiro, then director of INAMPS, the social security administration, announced that he would distribute AZT through INAMPS [39]. However, that promise never materialized, perhaps because it, too, was based on personal connections between the AIDS movement, SHRM, and the Health Ministry rather than formal institutional commitments to AIDS treatment.

However, around 1989, when AZT and drugs for opportunistic infections became commercially available in the Brazilian marketplace, the AIDS movement helped shift public policy discussions about AIDS treatment [7, 25]. Media campaigns called attention to the government's failure to address the AIDS crisis, including drugs for AIDS treatment. Betinho and Paulo Teixeira called for public provision of AZT in 1989 and 1990 [28, 47]. One newspaper article from August 1990 quotes leaders at ABIA as criticizing Health Minister Guerra for his public statement that "AIDS was not a priority of the government" and also criticized the Collor administration for failing to provide treatment for PLWHA [48]. In summary the AIDS movement's public protests and media campaigns impacted the political environment in which politicians operated and ultimately influenced their political preferences and choices.

Protests, media campaigns, and court cases contributed to development of Brazil's first AIDS treatment institutions in 1990. In response to these criticisms, Health Minister Guerra spontaneously announced that the Health Ministry would provide drugs for AIDS treatment on 23 October 1990. This radical announcement was an impulsive decision made under media pressure rather than a formal public policy decision discussed with other important political actors and stakeholders. In recounting the historic day, Health Minister Alcení Guerra publicly announced that the Health Ministry would treat people with AIDS, Cortes remarked:

I was somewhat marginalized within the Health Ministry.... As AIDS director, I had *never* had a meeting with the Health Minister. One day, at the end of 1990, the Health Minister called me and said he wanted to talk to me. The press had requested a meeting with him, and he had a bunch of members of the press in the conference room adjacent to his office asking him about AIDS drugs. He had nothing to say. Why? Let me tell you. Just to give you an idea, in Brazil, no one challenges the Minister, no one tells him he's wrong, no one gives him bad news or makes him uncomfortable. Everyone flatters the minister. And he was a pediatrician, so he was much more sympathetic to causes like infant mortality, which really *is* a problem in Brazil. He had never paid any attention to AIDS in Brazil.

But since I wasn't a career bureaucrat, I had nothing to lose, I told him like it was. I said, "Of course children are important, but AIDS is also important. If you don't do anything you're going to go down in history as overseeing an enormous AIDS disaster." And the Minister said, "What's going on with AIDS medicines?" And I said, "Look we really don't provide AIDS medicines because we don't have any! They weren't appropriated by Congress." And the minister said, "*We don't have any drugs for AIDS patients?*" I replied "No." The minister retorted, "Which drugs?" and I replied, "Minister, there is a whole list!" The Minister was astounded. And he asked me if I'd done any forecasting for how much AIDS drugs would cost, and I told him I had and that it would cost US\$132 million but that it was cheaper than hospitalizing AIDS patients. The Minister gave a pained look, paused and thought for a moment, and said "We're going to have to provide those medicines, aren't we?" and I said, "Yes, we are." And the minister said "If we give any, we're going to give them all." And he walked out to talk to the press.

Fifteen minutes later, the press came to my door and said, 'The minister just announced he would buy [AIDS] drugs!' And then I made some comments to the media [37].

Articles in Brazilian newspapers also document this spontaneous announcement. On 24 October 1990, *O Globo*, Brazil's largest newspaper, reported that the Health Ministry would spend \$130 million for AZT and other drugs for AIDS treatment:

For the first time, the Brazilian government will invest significantly in drugs like AZT, pentadmine, ganciclovir and dozens of other drugs used for treating AIDS patients. AZT will be dispensed in public hospitals...

Eduardo Cortes, director of the AIDS program, commented that "the number of AIDS cases in Brazil doubles every 8 months," adding a surprising piece of information: "between 300,000 and 500,000 Brazilians have HIV" [49].

Guerra announced that the federal government would supply several drugs for AIDS treatment, including ARVs, among other drugs. At the time, many of the aforementioned drugs were not available or even registered in Brazil, had to be imported, and were quite expensive [34, 50]. It was unclear how the mandate would be implemented and what the role of the states and municipalities would be in distributing and providing drugs for treatment in Brazil's new, more decentralized health system. This challenge was particularly troublesome in light of Law 8080/90, adopted by the legislature 1 month prior to Guerra's announcement, which acknowledged the shared role of local, state, and federal governments in provision of drugs, but did not define a clear role for each level of government in public drug provision.

In an interview, Health Minister Guerra mentioned this spontaneous decision had not been discussed with other major ministries prior to his announcement. Minister Guerra commented that he later was harshly criticized by the Planning and Finance Ministers, but tried to justify that his decision was more cost-effective than not providing drugs for treatment:

The Planning Ministry, the Finance Ministry and even individuals within the Health Ministry....everyone told me it [AIDS drug expenditure] would be an infinite expenditure, that there'd be no end to what we were going to spend on AIDS drugs, that I was putting the government at a serious financial risk, that I was crazy. I had to stand before them and explain my decision from the Health Ministry, that this wasn't such a risky decision because we would have to finance hospitalizations if we didn't finance drugs for treatment [51].

Guerra's decision to provide drugs for AIDS treatment⁸ in the public sector is a critical juncture in this historical institutional analysis about AIDS treatment in Brazil.⁹ This decision was not inevitable; Health Minister Guerra could have announced any number of different policies related to drug provision or ignored the media altogether. For outsiders not privy to the political conversations precipitating these developments, it is impossible to know exactly how and why the radical, expensive decision was made to provide drugs for AIDS treatment. However, this is an example of a critical juncture in which a political actor adapted his preferences and strategies to accommodate to changes in the institutional environment. Political action by the AIDS movement, including media pressure and public protests, exacerbated by tensions between the civil society movement and the Collor administration, were almost certainly factors influencing the Health Minister's decision, as was Eduardo Cortes' expert recommendation. A different decision other than a public commitment to providing all drugs for treating PLWHA likely would have produced different institutional outcomes for AIDS treatment in Brazil. If the decision to provide drugs for PLWHA had been discussed with Congress and the Finance and Planning Ministers before it were announced, the decision to provide numerous drugs for treating AIDS patients likely would have been watered down or even rejected because of its enormous price tag.

Brazil's new commitment to AIDS treatment had lasting consequences. Though it was not clear what the role of the local, state, and federal governments would be in providing drugs, and widespread public availability of ARVs for PLWHA was not actually realized until several years later, this important decision to treat PLWHA established an important institutional trajectory for AIDS treatment in Brazil. This decision to provide drugs for treatment was sticky; once Guerra publicly announced his decision to offer drugs for AIDS treatment, a series of other events in 1990 and 1991 created a process of positive feedback that reinforced the federal commitment to treatment.

In addition to committing to treat AIDS patients, public recognition of the AIDS epidemic provided political momentum for a chain of important political events related to HIV treatment, many of which would have permanent impacts on public

⁸At the time, the federal Health Ministry assumed responsibility for providing both antiretroviral drugs and drugs for opportunistic infections (OIs) as part of federally-funded AIDS treatment. Responsibility for providing drugs for OIs was decentralized to the states in 1998.

⁹This meets the criteria for a critical juncture because this decision to treat AIDS patients is an event that is not easily explained by theory, and it is a decision for which a variety of other options that did not occur may have produced different institutional outcomes.

institutions for AIDS treatment in Brazil. This pattern of self-reinforcing events is documented in numerous newspaper articles from the time. Several interviews on this subject also confirm the findings detailed here. As a result of these developments, it became increasingly more difficult for political actors to deviate from the treatment commitment.

Thousands of people were tested for AIDS after the federal government announced widespread availability of AZT and other drugs [52]. Immediate widespread testing is a testament to the AIDS movement's success in de-stigmatizing AIDS; had the civil society movement not been so involved in antistigma campaigns since the early 1980s, and changing social policy toward that end, it is likely that fewer people would have come forward for testing and treatment.

However, the Health Ministry did not have the financial means to pay for a large supply of drugs because Congress had not appropriated funds for treatment. There was, therefore, a long delay in delivery of the first federally-funded HIV medicines to AIDS treatment clinics. Drug supply was woefully inadequate, particularly in light of all of the new HIV-positive patients who presented for testing after the minister's announcement. AZT, both the most expensive drug and the drug in highest demand, became the focal point of drug shortage discussions. Seven states received initial shipments of AZT in April 1991, and several state health secretariats and doctors commented that the shipment was only enough for a few patients [53].

After the AIDS movement publicly called attention to the AIDS treatment crisis and the Health Minister committed to providing AIDS drugs, in May 1991, AIDS Program Director Cortes more openly expressed his concerns about the urgency of treatment. In 1991, prodding the legislature to appropriate more funds for drugs, he announced to the press in June 1991 that insufficient federal funds had been appropriated to procure drugs for AIDS treatment [54, 55]. In an interview, NAP director Eduardo Cortes commented that the treatment challenge was further compounded by the thousands of new AIDS patients who had not been included in initial Health Ministry drug and cost forecasts [37].

Continued political action from the AIDS movement and press coverage of these new developments called greater attention to the AIDS treatment issue. For example, in July 1991, São Paulo state AIDS Program director Paulo Teixeira publicly lamented that only 2% of São Paulo's 4,251 AIDS patients would be able to receive AIDS treatment with the supply of AZT he received from the federal government [56].

Increased HIV testing and continuous press coverage of drug shortages helped create mounting pressure for the Health Ministry to take further steps to implement its mandate.

Other events at the time also contributed to the buildup of political pressure for the Health Ministry to address the AIDS crisis. For example, in August 1991, a WHO official visited Brazil and met with Health Minister Guerra. The WHO official then publicly announced that if nothing were done to address the Brazilian AIDS epidemic, then Brazil, with the third highest number of reported AIDS cases in the world after the USA and Uganda, would shortly have an epidemic of the same magnitude of Africa's [57]. This prompted an immediate response from President Collor, who announced his first national televised address about AIDS

[58]. As promised, in November 1991, President Collor made a nationally televised speech on the importance of AIDS just prior to World AIDS Day. Moreover, the government announced \$22 billion cruzeiros in new AIDS spending for 1992, a 16-fold increase in AIDS spending from 1991 [59]. At the time, the speech represented one of few official recognitions by any president in the world that AIDS was a major public health crisis. These events reinforced Guerra's commitment to providing drugs for AIDS treatment.

Also, in November 1991, the Health Ministry announced a \$7 million AZT purchase from British pharmaceutical company Wellcome [60, 61]. This announcement prompted even more people to come forth for AIDS testing [62, 63]. Reporting for AIDS cases increased 49% 1 month after Health Ministry decisions to offer treatment were announced [64]. However, due to the increasing number of AIDS cases, the small AIDS budget and the rising costs of drug procurement, the Health Ministry was unable to provide a steady supply of AZT to AIDS patients, and many clinics were forced to ration their drug supplies [63, 65–67].

In summary, the announcement about public provision of AIDS drugs prompted a series of path-dependent events that reinforced Health Minister Guerra's decision. As a result of the announcement, more patients presented for AIDS testing, and treatment and registered AIDS cases increased dramatically [64]. Because Health Minister Guerra had not secured financing for his announced treatment program, drug supply shortages became even more acute, triggering greater news coverage of the treatment crisis. This prompted the visit by the WHO official, which generated even more news coverage of the AIDS problem. This sequence of events, coupled with public protests from AIDS activists and NGOs, led to Collor's Presidential address about AIDS. This speech symbolizes how the confluence of all of the aforementioned events had shaped the political actors policy references, even creating the political incentives for major political actors to address the AIDS crisis. Collor's speech and the government's first large AZT purchases solidified the trajectory for public provision of drugs for AIDS treatment.

Several conclusions can be drawn about initial decisions to provide AIDS treatment in Brazil. First, the AIDS movement's political action tactics helped prompt the federal government's first steps in what proved to be an enduring institutional commitment to AIDS treatment. Second, the decision to provide drugs to treat PLWHA was not part of a long-term public dialogue about AIDS treatment and its costs, but a spontaneous decision made by a Health Minister under political and media pressure, in part generated by the AIDS movement. Once the decision to treat PLWHA was announced publicly, a chain of subsequent events created positive feedback that reinforced the Health Minister's decision to provide drugs for AIDS treatment. Though well-organized systems to procure and deliver drugs for AIDS treatment were not established until the late 1990s, as a result of new commitments to treatment, AIDS spending during the Collor administration increased from \$250 million cruzeiros in 1990 to \$144 billion cruzeiros in 1992, an increase from approximately US \$640,100 in 1990 to US \$37 million in 1992 [68]. These initial commitments provided the political inertia for ongoing institutional reforms related to AIDS. Eduardo Cortes perhaps best summarized the result of this chain of events:

After what we did [offer drugs for AIDS treatment], there was no turning back. How could we have stopped providing AIDS drugs? Who was going to say that AIDS was no longer important? Not us. After all that happened, we had to keep providing the drugs [37].

National AIDS Program Partnerships with the AIDS Movement

Corruption scandals overshadowed the Collor administration's contributions to AIDS institutions, including commitments to public provision of drugs for AIDS treatment. They also overshadowed the administration's preliminary discussions with the World Bank for major loans to address the AIDS crisis. These discussions with the World Bank and the resultant loans would become a second important component in the Brazilian response to AIDS. Understanding how these loans developed first requires an overview of the institutional context in 1992 and 1993.

Health Minister Guerra's and President Collor's public statements about the government's commitment to the AIDS crisis, which had formerly not been on the Health Ministry's list of strategic health priorities, opened up the possibility of including AIDS in Brazil's World Bank loan portfolio. In 1991, the World Bank was poised to loan Brazil several million dollars for AIDS programs. At the time, the bank was interested in investing in AIDS in Brazil, which had a growing but concentrated HIV epidemic; if the World Bank could intervene early and in an effective way, it was believed that the intervention might have a more positive effect than in countries with generalized epidemics [32, 69]. Moreover, if a large amount of money was not loaned to Brazil, the country would soon have a net negative transfer problem, which both the World Bank and governments prefer to avoid for political reasons¹⁰ [32, 37]. However, because the Collor administration was embroiled in an enormous corruption scandal, the World Bank held off on major loans until after President Franco's 1992 inauguration [32].

During the last 6 months of the Collor presidency, leadership changes at the NAP also had lasting impacts on World Bank loan for AIDS as well as Brazil's broader AIDS institutions. When Collor's Health Minister, Alcení Guerra, resigned in the midst of a scandal involving procurement of bicycles for community health workers, renowned cardiologist Adib Jatene was appointed as the Health Minister for the last 6 months of the Collor Presidency. Jatene subsequently resigned, but before doing so, he brought former AIDS Program director Lair Guerra back to head the AIDS program and Eduardo Cortes stepped down [30]. Though President Collor also resigned in December 1992 during Senate impeachment hearings, Lair Guerra continued as AIDS program director during the next two presidential administrations and only stepped down after chronic injuries from a serious car accident in 1996.

¹⁰Net negative transfer problems refer to situations in which developing country governments are paying back more in loans and interest than they receive in World Bank loan support. At the time, this was a common problem for many developing countries.

Lair Guerra originally was awarded the position as AIDS program director in the late 1980s because of family connections to President Sarney and the patronage-oriented PFL party. However, Health Minister Jatene brought her back to direct the NAP because of the AIDS expertise she cultivated while working in the Sarney administration. Though known for her militaristic, centralistic style of leadership, and her connections to influential legislators in the PFL party, Guerra made tremendous contributions to Brazil's AIDS institutions throughout the 1990s. In the absence of stable federal health and AIDS institutions, many of her contributions relied upon *jeitinhos* and family connections to powerful politicians. However, these connections were essential to developing some of Brazil's first formal AIDS institutions.

The first, albeit undocumented, contribution of Lair Guerra was to convince the Health Ministry to pay for AIDS' patients hospital bed-days in 1992 [70, 71]. Previously, public hospitals had not been reimbursed for bed-days, incentivizing hospitals not to accept AIDS patients, which often hastened AIDS patients' deaths.

Guerra's leadership endured several presidential administrations. During her tenure, she also hired dedicated *sanitaristas* and AIDS activists as her deputies, engaged the AIDS movement in developing policies for AIDS, and served as a power broker with clientelistic PFL party politicians in the legislature. Her accomplishments are symbolic of the broader institution building that took place during Brazil's democratic transition; though the AIDS movement had effectively used political action to force the federal government to respond to the AIDS crisis, even after Collor's resignation, *jeitinhos* based on personalistic politics were still necessary to jump-start large-scale reforms necessary for long-term institution building, particularly in the legislature.

It was Betinho, Brazil's foremost democratization and AIDS activist, who carried the civil society letter up the ramp of Congress to request impeachment proceedings of President Collor in 1991. That act symbolized the Collor administration's relationship with all of civil society, but particularly with the AIDS movement.

After Collor resigned, sweeping Health Ministry personnel changes influenced AIDS institutions in Brazil. When Itamar Franco of the PMDB party became President in October 1992, and *sanitarista* Jamil Haddad became Health Minister, many *sanitaristas* moved into the federal health bureaucracy, and the new federal health machinery began implementing progressive reforms that reflected SHRM values.

Around 1993, the Health Ministry slowly began creating health regulations and infrastructure to comply with the 1988 Constitution's lofty goal of free and universal access to health for all, which had advanced little during the Collor administration. Though health reforms to decentralize Brazil's health system and implement reforms aimed at achieving universal, decentralized access to health services took over 10 years to achieve, Health Ministry leadership since the Franco administration has generally embraced *sanitarista* ideology and has implemented progressive health reforms. This change in Health Ministry ideology and leadership has been fundamental to Brazil's incremental progress in developing its public health system and its AIDS institutions; after 1993, there were far fewer bureaucratic hurdles to implementing health and AIDS reforms [9, 32, 72]. Moreover, once *sanitaristas* controlled the Health Ministry, both movements engaged more directly with the

Health Ministry, and political parties became less important for both sanitariastas and the AIDS movement to achieve their objectives.

Around the same time, the sanitariasta Health Ministry reformers began implementing progressive health reforms, and the AIDS movement began closely engaging and working with the federal government both to develop and implement institutions for AIDS. “Government and civil society partnerships” are often touted as most important and enduring traditions of the Brazilian AIDS program [7, 73–75]. New, formalized federal institutional arrangements with civil society organizations began under Lair Guerra’s leadership, (which are now touted as the most important and enduring traditions of the Brazilian AIDS program [7, 73–75]), profoundly impacted development of AIDS treatment institutions in the 1990s.

For example, after Collor’s resignation, NAP director Lair Guerra created an office within the NAP dedicated to civil society activities for AIDS called the Department for NGO Engagement [7]. The NAP resumed financing nongovernment AIDS activity, and Guerra capitalized on the social movement’s AIDS expertise, hiring several leaders from the São Paulo Health Ministry and NGOs in Rio de Janeiro, many of whom were considered Brazil’s foremost AIDS experts, including Paulo Teixeira from the São Paulo AIDS Program and ABIA activists such as Richard Parker and Jane Galvão. Sanitariasta Pedro Chequer oversaw AIDS surveillance, and ultimately became Lair Guerra’s deputy.¹¹ These individuals, who had crafted the first decentralized public and civil society responses to AIDS in São Paulo and Rio de Janeiro states, helped strengthen the National AIDS Program.

In spite of some progress in developing new AIDS institutions within the federal Health Ministry, AIDS programs were under-funded until the mid-1990s because Congress had never appropriated sufficient funds for AIDS activities. However, conversations with the World Bank about major loans for AIDS resumed after President Collor resigned. The AIDS movement’s, and particularly Betinho’s, historical connections to inside policymakers like Lair Guerra had direct, tangible impacts on historical development of Brazil’s AIDS policies; three of the twelve people NAP Director Lair Guerra hired to write the World Bank loan proposal were activists from the NGO sector. Others were sanitariastas with a history in working on AIDS and reproductive health issues; all were (and still are) some of Brazil’s foremost experts on AIDS.

These individuals included a major role for nongovernment AIDS activity in the loan proposal. When interviewed, they were asked to comment on why NGOs played such a big role in the World Bank loan strategy and the motivations for Guerra’s decision to hire activists. All mentioned that they believed that civil society involvement in public policy was essential to development of public and private institutions for AIDS, and wrote the loan proposal accordingly. They all also mentioned that Guerra had a keen and sincere interest in improving the Brazilian public policy response to AIDS, and hired them for their expertise [31, 32, 34, 76–78].¹² Also,

¹¹ Sanitariasta Pedro Chequer became director of the NAP in 1996. Future chapters will explain his commitments to profound institutional changes at the NAP in the late 1990s.

¹² Lair Guerra was not interviewed for this project because she suffered permanent brain damage from a 1996 car accident.

because of hyperinflation in Brazil, AIDS-related NGOs in Brazil were in the throes of major financial crisis. In what today might be considered a conflict of interest, several of these individuals were also employed at institutions that would benefit directly from financial support of the civil society sector as detailed in the World Bank loan terms [69]. The proposal submitted to the World Bank carved out a large role for NGOs in AIDS programs, particularly prevention activities, which consumed the largest part of the proposal budget (Appendices E and F).

Lair Guerra's decision to include NGOs in the loan development process represents the second critical juncture in *The Politics and History of AIDS Treatment in Brazil*. It is not a decision that was inevitable: Guerra easily could have chosen other individuals from the Health Ministry to write the World Bank loan proposal. Had sanitaristas and NGO representatives hired by Lair Guerra not been among the principal authors of the initial major World Bank loan proposal for AIDS, this institutional outcome would likely have been different. This institutional development was sticky, formalizing NGO roles in federal AIDS program development. Guerra accommodated her preferences and strategies to changes in the institutional environment; with the new possibility of a World Bank loan, Guerra had the opportunity to shape new institutions for AIDS, and likely believed that AIDS activists would help her most effectively construct new AIDS institutions.

This was the first long-term, formal financial partnership between the federal government and the AIDS movement and marked an important change in the AIDS movement. From that moment forward, the AIDS movement was no longer lobbying for change exclusively outside the federal government; the movement was working within the federal government and receiving financial support to build institutions for AIDS.

Mounting Pressure for AIDS Treatment and Brazil's First World Bank Loans for AIDS

In 1993, the World Bank approved a \$160 million loan for Brazil's Sexually Transmitted Disease and AIDS Control Project, commonly known as AIDS I. The loan was distributed between 1995 and 1998. The Brazilian government supplemented this sum with another \$90 million, for a total of \$250 million for the 4-year project, which was approved in November 1993 [79].¹³ The project's objectives included (1) defining and implementing basic programs for HIV and sexually transmitted diseases (STDs) prevention; (2) establishing treatment services, including 300 AIDS and STD centers nationwide in existing health centers; (3) conducting epidemiological surveillance; and (4) developing institutional capacity to prevent

¹³This was only a small piece of Brazil's WB loan portfolio of \$1.2 billion in 1993, which included also education and infrastructure programs for northeastern Brazil, improving water quality in São Paulo, among other projects.

and treat HIV and STDs, including human resource training and laboratories for testing [69, 80]. Though \$84 million went to health infrastructure development for treatment services, and the World Bank financed drugs for treatment of STDs, World Bank policies strictly forbade expenditure on ARVs. At the time, World Bank policies held that HIV prevention was more cost-effective than AIDS treatment and treatment was too costly for developing countries with limited resources. In fact, the original 1993 World Bank program appraisal document explicitly states that “prevention is the only effective means to address AIDS, since once it is contracted, it is fatal.” In light of this policy, \$103 million of the \$250 million total was designated to prevention and media campaigns (Appendix E).

The timing of other political events delayed implementation and the important social impacts of World Bank loans: though the World Bank loan had been originally scheduled to disperse in January 1994, Planning Minister and future President Fernando Henrique Cardoso (FHC) only signed the World Bank loan agreement on 16 March 1994. World Bank funds were not disbursed until much later because Congress had again not yet appropriated the requisite matching funds for the World Bank loan program in 1994 [81, 82]. Weak legislative support for AIDS programs was complicated by Brazil’s hyperinflation crisis, which also stemmed from fiscal reforms long-postponed by the legislature. In short, though several social changes had prompted new commitments to addressing the AIDS epidemic, other important factors such as weak legislative institution building and poor Congressional response to the AIDS crisis stymied institution building for AIDS.

Institutions tend to continue on their path of development until some critical juncture prompts major social change. Such was the case with AIDS treatment. In spite of Health Ministry commitments to AIDS treatment, the legislature had not appropriated sufficient funds for AIDS treatment and World Bank loans for developing AIDS health infrastructure had not been dispersed. As a result, as increasing numbers of patients solicited treatment, the AIDS treatment crisis grew more acute from 1993 to 1995.

Though the WHO declared Brazil had the world’s second largest number of reported AIDS cases following the United States, Congress and the Health Ministry had not appropriated sufficient funds for drugs for AIDS treatment and numerous stockouts were reported throughout Southeastern Brazil from 1993 until 1995 [83–88]. In 1994, the Health Ministry estimated that only 16% of AIDS patients were receiving antiretroviral therapy. Because formal health infrastructure was lacking, many ARVs were never delivered or had expired by the time they reached patients [89]. Drug stockout challenges were further compounded when the Health Ministry had added two new ARVs, didanosine and stavudine,¹⁴ to the Health Ministry’s list of AIDS drugs before Congress appropriated sufficient funds (Appendix A) [90]. Even more importantly, no Health Ministry policy or federal legislation had clarified the inherent ambiguities in Health Law 8080/90; responsibilities

¹⁴These drugs were used in combination therapy with AZT.

of local, state, and federal governments in drug provision for AIDS treatment were still unclear. These vagaries influenced the path of institutional development of Brazil's AIDS treatment: with no institution clearly responsible for the expensive drugs required for AIDS treatment, neither local, state, nor the federal government prioritized drug provision for AIDS treatment.

It was within this context that members of the AIDS movement within and outside federal and state Health Ministries jointly pressured the federal government to correct stockout problems. Many news articles suggest direct collaborations for media campaigns between NGOs and officials at public hospitals, as NGOs frequently cited patient and drug data from public hospitals when publicly denouncing drug shortages [91–96]. Sanitaristas in the São Paulo state health secretariat publicly criticized the federal Health Ministry for stockout problems and Betinho and other NGO representatives often criticized the government's failure to commit financial resources for AIDS programs [97–99]. On World AIDS day in 1994 in Rio de Janeiro, protesters organized by the NGO *Pela VIDA* protested drug stockouts, claiming "Health is a right. I'm going to fight for more respect!" [82]. Other similar protests took place across Brazil [100].

As a result of political pressure from the AIDS movement and a variety of public servants from 1993 to 1995 poor availability of drugs related to AIDS treatment began getting increasing media coverage. Increasing numbers of officials at public hospitals began reporting drug stockouts directly to the media. Many openly claimed that drug stockouts contributed to chronic bed shortages for AIDS patients; with no drugs for treatment, patients stayed in the hospital for longer periods. Public hospitalization rates increased as a result. Insufficient supply of AIDS medicines compounded existing challenges with hospital beds shortages for AIDS patients; patients who could not be treated with drugs filled emergency rooms and hospital beds [101–105].

Public servants working within the federal health bureaucracies also pressured for change within the Health Ministry and worked informally with NGOs to help call attention to the AIDS treatment crisis. Dr. Rosanna del Bianco is the former director of both the AIDS program at Hospital Emilio Ribas in São Paulo as well as the NAP's federal AIDS treatment program. In an interview, she commented on collaborative political action efforts between NGOs and the NAP to expand access to medicines in the early 1990s:

NGOs did have a lot of influence [on access to treatment]. They always participated when we needed them to. When our technical advice wasn't enough to convince politicians to adopt certain policy positions, they helped. The newspapers helped too because NGOs had a lot of contacts in the media. When something needed to be presented to the public, or there was an AIDS battle to be had, NGOs are there for that. And I think that this partnership worked well for us, and it's a long partnership that still works today. For better or for worse, the NGOs are our partners. Since we had the same objectives, support from civil society helped. Sure, they threw eggs at us, and we also throw eggs at them. But these partnerships have been, and continue to be, very important [106].

As Del Bianco notes, these strategic, informal partnerships between a variety of government and nongovernment actors were well underway prior to the time that

World Bank loans were actually disbursed in 1995. Both NGOs and sanitarias working within state and federal health ministries and public hospitals held the federal government accountable for delivery of AIDS medicines, creating mounting pressure for federal politicians to implement policies for AIDS treatment.

It was in this institutional context that World Bank loans were finally distributed in 1995.

Since World Bank loans were delayed, so were the programs it financed and their social impacts. When the World Bank loans were disbursed in 1995, though AIDS treatment spending was forbidden, World Bank loans nevertheless strongly influenced the path of institutional development of AIDS treatment.

The loans had major impacts on institutions for AIDS treatment, infusing millions of dollars into the AIDS movement. The AIDS movement was already working both inside and outside the Brazilian government to promote development of institutions for AIDS treatment. This major World Bank loan financed and provided the initial institutional framework for a nationwide response to AIDS. The loan included a major role for NGOs in program implementation; 175 NGOs were to implement many of the more than 400 projects, particularly those related to the large prevention budget of \$103 million [79]. According to World Bank loan project assessment documents, AIDS I supported 564 prevention projects implemented by 181 NGOs (Appendices E and F).¹⁵

Although World Bank loans were geared largely to fund NGO prevention and surveillance, they impacted AIDS treatment institutions in several major ways. World Bank loans directly financed NGOs providing legal aid for PLWHA. This institutional design reinforced ongoing institutional reforms related to AIDS treatment in the executive and judicial branches of government that were beyond the scope of the National AIDS Program. For example, NGOs financed by World Bank loans were able to expand activities such as legal aid and public protests as a result of public support of NGO activity. NGOs continued to use human rights language to hold the government accountable for guaranteeing individuals the rights detailed in the 1988 Constitution. NGOs with legal aid services continued defending the rights of PLWHA for a variety of services, using the courts to secure the rights of PLWHA for equitable access to public schools, health care, drugs, and disability benefits. In describing this seemingly strange relationship between the NAP and the civil society sector in Brazil, Miriam Ventura, Brazil's foremost legal aid attorney for AIDS, commented:

¹⁵ Though disaggregated data on NGO expenditure was requested from both the World Bank and the NAP, neither organization was able to disaggregate precise historical expenditure data on civic activity the loans funded. The NAP's preferred method of measuring civic engagement in AIDS activities is the number of NGOs supported and the number of projects those NGOs implemented rather than total expenditure on NGO activity. This complicates analysis of historical spending trends for NGO activity related to AIDS. However, a later World Bank appraisal document indicates that a combined total of \$US 25 million was spent on civic activity for World Bank loans for Bank loan entitled AIDS II.

I still laugh about the strange relationship that civil society has with the National AIDS Program. Their program always had a very schizophrenic relationship with civil society. The National AIDS Program paid civil society groups and still finances civic activity today that is meant to criticize the National AIDS Program and Health Ministry activities. This strategy may seem a bit schizophrenic to an outsider. But actually, this is a very effective means of social control¹⁶ [14].

Though legal aid for PLWHA began several years before the World Bank loans, a steadier stream of revenue to NGOs providing legal aid was a catalyst that helped advance the legal dimensions of institutional change, including access to medicines. The NAP, with the support of World Bank loans finally disbursed in 1995, was funding the very NGOs groups that filed lawsuits against the government for violating citizenship rights. This was an early tactic NAP reformers employed to hold other government agencies such as local, state, and other branches of the federal government accountable for the health rights guaranteed by the 1988 Constitution. As mentioned before, as a result of a trial brought by several NGOs, several court cases ruled that the right to health included the right to medicines, particularly ARVs [20]. Though the 1992 trial did not set binding precedents, since then, a variety of local, state, and federal courts have always ruled that the government has a legal requirement to provide medicines to PLWHA, including ARVs and drugs for opportunistic infections [107].

As a result of the civil society movement's legal aid programs, since 1992, no AIDS patient seeking public provision of medicines has ever lost a case in the Brazilian court system [14, 108, 109]. Judicial victories about the right to AIDS treatment are perhaps one of the most tangible ways to measure the impacts of foreign aid on AIDS treatment institutions in Brazil; by filing lawsuits against the government for noncompliance with its duties to ensure rights and provide health services (including ARVs), NGOs helped shape AIDS treatment institutions. Though limited to individual cases with no binding precedents, this was a moderately effective means of enforcing federal commitments to AIDS treatment. Most importantly, court cases legitimized the AIDS movement's claims about the right to drugs for AIDS treatment and reinforced previous Health Ministry commitments to treatment.

The third, and perhaps most important, impact of World Bank loans was to foster AIDS treatment activism. World Bank loans provided prevention and media campaign funding for many NGOs engaged in treatment activism. Greater general financial support for NGOs had the indirect impact of fueling more political action and treatment activism in particular. Increased civic activity for AIDS put pressure on the executive branch of government to uphold its commitment to public provision of drugs for AIDS treatment. This pressure to provide drugs grew more acute as new ARVs became available in the Brazilian marketplace.

New and old NGOs continued protesting drug stockouts in the mid-1990s, and protests grew larger over time as organized coalitions of NGOs began protesting

¹⁶ AIDS activists in Brazil frequently use the term "social control" to refer to policies to hold the government accountable for implementing its public policy commitments.

drug stockouts [110, 111]. In 1995, 280 NGOs from all over the country joined forces to protest insufficient drug supplies for AIDS treatment in São Paulo city [112]. In another dramatic 1995 protest, AIDS activists threw fake blood onto the streets, wearing signs proclaiming their right to health and other phrases, such as “HIV-positive individuals demand dignity!” Paulo Teixeira, who had returned to São Paulo to direct the state AIDS program, also publicly denounced drug stockouts in 1995.

As a result of ongoing political action, CEME, the federal government’s drug procurement bureaucracy, announced acknowledging insufficient supply of ARVs [113]. Public recognition of the public policy failure contributed to the growing momentum for the AIDS treatment movement.

Additionally, World Bank loans influenced AIDS treatment institutions by formally institutionalizing the role of NGOs in the policy development process. World Bank loans infused large amounts of money into the nascent AIDS movement for the first time. New financial support strengthened existing NGOs such as Pela VIDDÁ, GAPA, GIV, ABIA, and others and created incentives for new NGOs to organize. For example, to receive NAP support, NGOs had to be registered with the Ministry of Health. In 1989, several dozen NGOs had participated in the conference that inaugurated the AIDS movement, but World Bank loans prompted mobilization and official registration of the NGO sector; in 1992, there were 120 registered NGOs dedicated to combating STDs and HIV. By 1998, more than 500 AIDS-related NGOs had registered with the Ministry of Health [114, 115]. This phenomenon will be explored more in the next chapter but is mentioned here to explain how NGOs guaranteed themselves a role in developing and implementing future AIDS policies, solidifying their role as permanent stakeholders in the institutional development process for AIDS treatment.

By deepening the social movement’s relationship with the government and providing funds for AIDS treatment activism, World Bank loans strongly influenced AIDS treatment institutions and the culture of the NAP. NGOs received (and still continue to receive) financial support from the NAP for their activities, which frequently include pressuring the government to finance AIDS treatment. With World Bank loan support for expansion of health infrastructure for HIV/AIDS treatment, the NAP also began heavily recruiting AIDS experts from NGOs to expand its infrastructure and bureaucracy. Because the NAP both recruited directly from the NGO sector and directly financed NGO activity, the lines between public and NGO activity became somewhat blurry in the mid-1990s; activist movement into the federal AIDS bureaucracy created a human rights and activist culture related to HIV/AIDS both within and outside the NAP. Moreover, government and civil society partnerships created positive feedback that reinforced the NAP’s human rights focus in AIDS programming and advocacy in the civil society sector. This advocacy culture within and outside the government reinforced federal commitments to AIDS treatment, had long-term impacts on institutions for HIV/AIDS treatment in Brazil, and is revisited throughout the book.

In spite of the social movement’s victories in eliciting a public commitment to providing drugs for AIDS treatment and securing federal financial support for its

advocacy and prevention activities, by the mid-1990s, the confluence of all of events explored in this chapter had not yet created the institutional conditions necessary to stabilize drug supply for AIDS treatment. Small numbers of patients were receiving ARVs through local and state health secretariats because of judicial victories. Others procured limited supplies of ARVs through NGOs. However, Congress had never appropriated sufficient funds for treatment, in part because of a poorly designed 1990 health law that did not clarify whether the legal responsibility to provide drugs fell upon the local, state, or federal government [14, 116, 117]. Similarly, the Health Ministry had never clearly defined which drugs were required for “AIDS treatment.” Because existing federal and state laws and judicial decisions never clarified which branch of government was legally obligated to provide both ARVs and drugs for opportunistic infections for AIDS, neither the federal Congress nor state and municipal governments had appropriated sufficient funds for AIDS treatment. Access to treatment was, therefore, sporadic through 1995.

Through political action, including public protests, social activism in the courts, media pressure, and by working within the NAP, the AIDS movement was able to strongly influence initial development of AIDS treatment institutions as well as help create an activist culture at the NAP. Political scientist Timothy Power’s characterization of many democratic institutions in postauthoritarian Brazil, which often “survive but don’t perform well or, alternatively, perform well for brief time periods and don’t survive” [118] is, nevertheless, an apropos description of Brazil’s first AIDS treatment institutions in the early to mid-1990s. Though World Bank loans and social activism in the courts had reinforced commitments to treatment, larger institutional weaknesses in the legislative, executive, and judicial government hampered implementation of policies to improve widespread access to drugs for AIDS treatment.

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Chapter 4

Legislative Reforms and AIDS Treatment in the 1990s

To meet growing demand for drugs for AIDS treatment, since the 1990s, the Brazilian government has produced some generic ARVs locally and imported other patented ARVs from multinational pharmaceutical companies. These traditions are the result of complex historical phenomena unrelated to social movements that are critical components of Brazil's AIDS treatment policies [1–4]. However, little has been written about how these policies originally developed, and research on Brazil's AIDS program has also overlooked the important role of the private sector in developing and producing Brazil's first generic ARVs. Chapter 4 examines these issues as well as important legislation in the mid-1990s that influenced historical development of Brazil's AIDS treatment institutions.

The history of Brazil's pharmaceutical industry influenced the social and institutional conditions leading to development of Brazil's 1996 Industrial Property Law. Because the Industrial Property Law ultimately had important impacts on Brazil's AIDS treatment institutions, the history of Brazil's pharmaceutical industry and intellectual property regulations is an important background and it is briefly reviewed here.

Brazil has a long history of protecting intellectual property rights. Brazil was one of the eleven countries to sign the 1883 Paris Convention and was one of the world's first intellectual property treaties. After World War II, Brazil began developing a national pharmaceutical industry as part of its Import Substitution Industrialization (ISI) economic development strategy. ISI promoted development of local industries by substituting imports with locally produced goods. Embraced by many Latin American countries from the 1940s to the 1970s, ISI first led to an economic boom in several countries but ultimately failed as a development strategy. However, as a result of Brazil's ISI strategy, Brazil developed a relatively strong state-owned generic pharmaceutical industry, some of which was ultimately privatized in the 1960s and 1970s [5, 6]. In an effort to grow several local industries, Brazil's Industrial Property Act of 1971 forbade patents for “food, chemical and pharmaceutical substances, materials and products and drugs of any kind, as well as the respective processes for obtaining and modifying them” [7]. Brazil recognized neither drug produce nor drug process patents from 1971 to 1996 [6, 8].

In 1974, the military government created the Central Medicines Agency (CEME) to develop a national drug policy to supply Brazil with a basic set of essential medicines. The government invested heavily in developing new public drug factories and fortifying existing factories. Drug purchases were centralized through CEME but drug production was highly decentralized; most factories were owned and operated by state governments, but several, such as Farmanguinhos (now Brazil's largest producer of ARVs), were run by the federal government [5, 9].

Several factors in the 1980s and 1990s led to tensions between both the US and Brazilian governments and the multinational pharmaceutical industry. During the 1980s, Brazil's generic drug industry mushroomed into a \$2 billion a year industry. With no product or process patents, the local industry could legally copy any drug without paying royalties to innovator companies. At the time, Brazil's federal government did not enforce rigid quality and safety control standards for generic products. Brazil was also exporting generic drugs to other countries in Latin America. As mentioned in chapter 3, the 1988 Constitution affirmed the continued role of the public sector in producing drugs in post-authoritarian Brazil [6, 10]. The pharmaceutical industry aggressively lobbied the US government, which in turn pressured the Brazilian government to recognize intellectual property rights of the pharmaceutical industry. These policies created tensions between the US and Brazilian governments, which ultimately influenced the path of development of Brazil's Industrial Property Law. The Industry Property Law, in turn, left indelible impacts on Brazil's AIDS treatment institutions.

Public/Private Partnerships to Develop AZT

The first generic ARV was produced in Brazil in 1992 by a private company called Microbiológica. The Health Ministry subsidized a private company to produce generic AZT in early 1990s, guaranteeing that the Health Ministry would then buy the products Microbiológica brought to market. Newspapers noted that a government agency called the Finance Agency for Studies and Projects (FINEP) financed portions of Microbiológica's research project, which would supply 60% of Brazil's demand for AZT [11–15]. Jaime Rabi, President of Microbiológica, explained how Microbiológica was founded and how subsidies helped develop AZT:

In the 1970s, Brazil began subsidizing classic biotechnology to produce the pharmaceutical products on the World Health Organization Essential Medicines List. Back then, the Health Ministry supported companies that were interested in developing technology manufactured in Brazil such as pharmaceutical products and pharmaceuticals. Microbiológica was born out of these policies. A group of us at the University decided to start a company that would develop drugs for public use for the Health Ministry...

I would say that Microbiológica would not exist as a fine chemicals company if it wasn't for the support we received from the Health Ministry. We first received a subsidy in 1984 to develop laboratory scale technologies for some essential drugs. We then received additional subsidies to scale up two of those technologies. We had to pay the loans back to the government but this was done with the results of our sales to the government. I consider this a form of subsidy.

In the case of the AZT Project, we had to take additional loans given the size and complexity of the project. We took a regular loan from the Ministry of Science and Technology, which was paid with high interest rates. We also went to the Health Ministry and obtained another loan. The most important support we received from the Health Ministry was the registration of our formulated AZT, which allowed us to participate in large tenders of that time [16].

Brazil's government subsidized development of generic AZT and then bought the drug in bulk from the private sector. Today, this type of model of subsidizing scientific research and also promising to buy drugs in bulk is often referred to as a push/pull model for drug development and is viewed by many experts as one of the most effective ways to incentivize companies to bring drugs to the market [17]. Ironically, though Brazil's public laboratories are often credited with first developing generic ARVs, generic AZT was first developed in the private sector, with subsidies from the Health and Technology Ministries. Jaime Rabi commented on how AZT was developed and Microbiológica's contributions to AIDS drug policy in Brazil:

At the end of the 1980s, when the AIDS epidemic began in Brazil, we believed that AIDS would really explode in Brazil because of the enormous inequality and social conditions our country faces. So we thought that AIDS and generic AZT represented an opportunity for Microbiológica, which had a history of working with nucleosides. AZT is a nucleoside. Nucleosides are fairly difficult to develop. However, Microbiológica had experience developing nucleosides. At that time, it was pretty difficult to produce AZT, because there were no raw materials. The most difficult part of making any drug is producing the raw materials, which we were able to do [16].

Producing generic drugs involves several important steps, and the details of all the steps are not discussed in this social science inquiry. However, it is important to note that the most technologically complex step in bringing generic drugs to market is the process of chemical synthesis of molecules used in active ingredients. In this process, generic drug makers replicate the production of chemical compounds used in the raw materials, which innovator companies use to make drugs. The chemical synthesis process is a highly complex technical process and requires highly trained scientists; only after this process takes place, raw materials can be formulated into drugs. In Brazil, Microbiológica was the first company to develop the chemical synthesis process for AZT and several other ARVs. Jaime Rabi explains his contribution to developing generic AZT in Brazil:

I think the most important thing Microbiológica did was to prove that producing AZT was possible in Brazil. For us, AZT meant we could create a company brand, but for the Brazilian government, it meant that Brazil could produce a high-quality drug at a lower price for people with AIDS. This contributed to the idea that other drugs could also be produced in Brazil that would extend the quality of life for people with AIDS. So, I'd say that Microbiológica's contribution to the Brazilian government was to prove that it was possible to produce generic antiretroviral drugs in Brazil without depending on multinational pharmaceutical companies. We demonstrated that it was possible to lower the prices. At the time, AZT from Wellcome was being produced for \$150 a box, and we reduced that price by about 50%. We were the pioneers that demonstrated it was possible to lower prices and to make high quality products...

...In terms of synthesis technology, we made a big contribution in the quality standards for active substances and the substances related to synthesis. We contributed by introducing analytic methods for quality control, and we did this for all the state labs, and most notably, FIOCRUZ and Farmanguinhos. This was very important for introducing lamivudine, which

is made with a very complex synthesis process. If not conducted exactly right, this process can generate toxic substances. Establishing the quality standard was another important contribution of Microbiológica [16].

In what would today be referred to as a “technology transfer,” Microbiológica shared its scientific methods for synthesis technology with state-owned laboratories in Brazil:

After we developed the synthesis technology, the analytic methods, the drug quality standards and the standards for related substances, we voluntarily gave over a lot of information, methods, and samples to the Health Ministry. Unfortunately, they used that technology as if they had developed it. They never gave credit to us for developing this technology. You could literally see how this great value we’d added enriched the state industries. They built new buildings, new laboratories, but they didn’t build a future... [16].

Rabi’s comments highlight several important facts about the production of generic AZT that have also been confirmed by other interviewees [9, 18]. The scientific processes required for developing raw materials for AZT and other antiretroviral drugs in Brazil were first and have historically been conducted in the private sector. When Dr. Rabi commented “they didn’t build a future,” he is referring to the fact that Brazilian public drug production facilities never developed the scientific capacity to synthesize the molecules for drugs’ active ingredients. (However, several laboratories did adopt some of Microbiológica’s quality control methods, and those are discussed in chapter 5). The scientific limitations of Brazil’s public factories and laboratories ultimately proved to be overwhelmingly important to the historical development of Brazil’s AIDS treatment institutions and will be revisited later in this book. In spite of Brazil’s technological shortcomings in producing raw materials, these developments influenced the path of historical development of AIDS treatment institutions: once Microbiológica brought generic AZT to market at reduced prices, other private and public drug laboratories began producing generic ARVs.

Public Production of AZT

In the 1980s, each of Brazil’s state and federal public drug production facilities “sold” drug products to CEME, Brazil’s centralized drug procurement facility, for public consumption. Eduardo Martins, expert on drug policy and former director of Farmanguinhos public drug laboratory, commented that when CEME closed in the 1990s, each state’s public laboratories adopted its own strategy for producing different drugs to sell to federal and state governments [9].

In 1993, a public drug laboratory in the small Northeastern state of Pernambuco called LAFEPE also began producing AZT. This was the first time that a public drug facility produced generic ARVs in Brazil. As early as 1993, newspapers reported that LAFEPE was supplying the federal government with 30% of its AZT supply [9, 19–21]. Several interviews for this research confirmed these facts [9, 22]. Gustavo Farias, then-director of LAFEPE, who was credited with bringing AZT to the public sector in Brazil, no longer works at LAFEPE and was unable to be

interviewed for this project. In interviews, Eduardo Martins, President of Farmanguinhos during the early 1990s, and Tiyoshi Nimonya, who runs FURP's¹ production line, commented that LAFEPE's decision to produce AZT was related to Brazil's then decentralized strategy of producing drugs for public consumption in federal and state factories. Both commented that LAFEPE began producing AZT to create a market niche for the products it would sell to the local, the state, and the federal governments [9, 22].

However, LAFEPE relied on raw materials from Microbiológica, (and later on imports), to produce AZT. Brazil's public sector drug laboratories have never developed the scientific capacity to make raw materials for pharmaceutical products; its public drug facilities only formulate pills. (Formulation refers to the last step in the drug production process in which raw materials are developed into pills). In an interview, Eduardo Martins former director of Farmanguinhos, which now produces most of Brazil's generic ARVs, commented that:

Brazil didn't have the capacity to develop raw materials [in the 1990s]. We never have had the scientific conditions to do so. Raw materials have always been imported from India or China or made by a couple of local companies like Jaime Rabi's Microbiológica. Scientists at LAFEPE tried to conduct the synthesis for AZT for a couple of years but were never able to do it. Rabi is special because he learned how to do chemical synthesis for making raw materials when he got his doctorate in the USA. Other than that and a couple of new companies in Brazil that make raw materials, the government has never been able to produce raw materials. People always say 'Brazil makes AIDS drugs.' That's not really true. Brazil *formulates* drugs. There is no technology involved, it's very simple. There is no science involved, there's no industrial secret. It's just formulating pills. That's not really *making drugs* [9].

In other words, Brazil's Health Ministry claims about producing ARVs are somewhat of a misnomer. Experts interviewed for this project all clearly stated that Brazil's public sector has never developed the scientific capacity to make the active ingredients used in pharmaceutical products; its public drug facilities only formulate drugs [9, 16, 18, 23, 24].

LAFEPE's public production of AZT set an important precedent for public production of ARVs. Though other public laboratories eventually followed suit, for a variety of reasons explored elsewhere in this book, there was not a centralized, public ARV production strategy until the late 1990s. Until 1998, the Health Ministry purchased drugs from a variety of sources, including Wellcome, LAFEPE, and Microbiológica [9, 18].

ISI played a critical role in developing Brazil's pharmaceutical industry and ultimately influenced the important role of the private sector in bringing generic AZT to market. These findings dispel the myth that ARV production in Brazil has historically been based on public sector efforts; generic ARVs were first produced in Brazil as a part of strategic public-private partnerships. Once Microbiológica proved AZT could be produced locally, public laboratories began purchasing raw

¹FURP is another state-owned drug laboratory in São Paulo.

materials from Microbiológica to formulate ARVs to be sold to local, state, and federal governments for public drug programs. However, Brazil's public laboratories have never been able to conduct much of the scientific process related to developing the raw materials necessary for producing ARVs, and have always relied on the private sector to supply raw materials.

Industrial Property Law 9.279

As mentioned in chapter 1, in Brazil, most significant public policy does not initiate in the legislative branch of government because of Brazil's very strong Presidential system. Moreover, the legislature is often used to dole out political pork and is generally not viewed as an important vehicle for social change [25]. These characteristics of legislative institutions in post-authoritarian Brazil help explain how and why Brazil adopted an Industrial Property Law in 1996 and why the AIDS movement did not engage in this important political process. The confluence of a presidential election, international pressure to adopt industrial property reforms, and Brazil's attempts to integrate into the global economy all influenced historical development of this law. The Industrial Property Law changed the institutional environment related to AIDS treatment in Brazil prior to the next critical juncture and later influenced how later political actors would respond to and implement Sarney's Law, which guaranteed treatment to all people living with HIV/AIDS (PLWHA).

Fernando Henrique Cardoso's 1994 Presidential Victory

Many of the important AIDS institutions whose development this book explores occurred during Fernando Henrique Cardoso's (FHC) two terms as President, from 1995 to 2002. FHC was a world-renowned Marxist sociologist who made important contributions to dependency theory, and whose books have large global circulation. In one of his most famous works, FHC endorsed ISI and advocated for southern hemisphere alliances to bolster economic development in developing countries, particularly in Latin America [26].

During Brazil's transition to democracy, FHC moderated his political stances; he was a member of the PMDB party and also founded the center-left PSDB political party in the late 1980s. In the early 1990s, Cardoso became most well known in Brazil not for his scholarship, but for his "Real Plan"² during his tenure as Planning Minister in the Franco administration. FHC's Real Plan stabilized Brazil's hyperinflation crisis by implementing neo-liberal economics policies and helped propel Cardoso to the Presidency in 1994. While campaigning for President in 1993, FHC

² Cardoso's Real Plan stabilized Brazil's hyperinflation crisis in the early 1990s by opening Brazil's markets to global trade, and implementing new monetary and fiscal reforms.

further moderated many of his formerly leftist stances related to economic development and globalization and controversially remarked, "Forget everything I wrote. The world has changed" [27]. This quote, perhaps more than any other, symbolizes FHC's moderated stances on economic policy, which are important in understanding development of Brazil's 1996 Industrial Property Law.

Intellectual Property Rights (IPRs) give a property owner exclusive rights to his or her creations. Intellectual property rights are usually divided into two categories: industrial property rights and copyrights (trademarks). Industrial property rights protect technologies or inventions and copyrights protect artistic or written materials [28]. Brazil has several intellectual property laws, but its Industrial Property Law is most relevant to this book.

In the late 1980s, both the multinational pharmaceutical and software industries were concerned about "pirated" software and drugs in Brazil. The multinational pharmaceutical industry strongly opposed generic drug production in Brazil (including ARVs), which was growing in the late 1980s and early 1990s without paying royalties to innovator companies for using their intellectual property. Both the software industry and the Pharmaceutical Manufacturers Association (PMA, now the Pharmaceutical Research and Manufacturers Association, PhRMA) directly lobbied the Brazilian Congress, the United States Trade Representative, and even the American Congress to take action against Brazil in the mid-to-late 1980s. The United States Trade Representative (USTR) and the American Embassy in Brasília began lobbying the Sarney Presidential Administration for more rigorous intellectual property standards. The Reagan administration imposed trade sanctions on Brazil in 1988, claiming that the Brazilian government permitted both industries to sell pirated copies of their products [6, 29].

Political pressure from the United States continued well into the Collor administration. President Collor, who embraced liberalizing Brazil's trade policies, sent an Industrial Property Bill to Congress in 1991. The United States subsequently rescinded its trade sanctions against Brazil. However, generic production of AZT prompted vigorous political responses from the multinational pharmaceutical companies. The multinational pharmaceutical industry strongly objected to generic production of antiretroviral medicines and its aggressively lobbied Congress in response to commercialization of generic AZT [30–32]. However, the Brazilian Congress neglected the industrial property reforms during Collor's impeachment proceedings, and the United States added Brazil to its list of priority countries to watch for intellectual property rights violations in 1993 [6].

The US request for more rigid intellectual property protection standards was not prioritized by President Franco,³ who was unsympathetic to the issue and known for strong opposition to the multinational pharmaceutical industry during his time in the Senate. Without Franco's support, Congress did not pass the law, and the intellectual property issue was not taken up again until the Cardoso administration [6, 10, 29].

However, it was during the Franco administration that the multinational pharmaceutical industry began lobbying then Foreign Minister Fernando Henrique

³Franco was President from 1992 to 1994 (see Table 1.1 for a list of Brazil's most recent Presidents).

Cardoso, who later became Planning Minister in 1994 and President of Brazil in 1995. When interviewed for this project, two pharmaceutical industry representatives who lobbied the Brazilian Congress for 8 years commented that Cardoso's early and enduring support for the Industrial Property Law was key to its ultimate adoption during the Cardoso administration [33, 34]. Cardoso's support for the Industrial Property Law was one of his many endorsements of globalization. Perhaps more than any other law approved during his tenure, the 1996 Industrial Property Law symbolizes FHC's ideological shift from the far left to the political middle.

Brazil and the World Trade Organization

Brazil's industrial property law reform proposals were directly related to Brazil's integration into the post-Cold War global economy. Though the discussion about the industrial property law was percolating in Brazil during the Franco administration, it gained momentum after FHC was inaugurated and Brazil joined the World Trade Organization (WTO).

The WTO was born on January 1, 1995, replacing the General Agreement on Tariffs and Trade (GATT) the same day as FHC's first presidential inauguration. The WTO, a global trade organization with approximately 150 member states, governs the rules of international commerce, including intellectual property issues. WTO country membership requires countries to adhere to GATT rules developed over the last 50 years, as well as the newer General Agreement on Tariffs and Services (GATS) and Trade-Related Aspects of Intellectual Property Laws (TRIPS). WTO member countries must also commit to transparency in trade policy and agree to WTO dispute settlement rules, which are conducted by an independent settlement panel.

TRIPS introduced rules governing intellectual property protection into the global trade agreements for the first time, established minimal levels of intellectual property protection for all countries, and outlined transition periods. Developed countries had 1 year to adopt domestic legislation to ensure TRIPS compliance. Middle-income countries like Brazil were required to implement TRIPS by 2005, and least-developed countries were required to implement TRIPS by 2016. However, for pharmaceutical and agricultural chemical products, developing countries had to accept patent applications beginning January 1, 1995. This is commonly referred to as establishing a "patent mailbox." Developing countries did not have to begin reviewing patents in their mailboxes until the end of their transition periods which were January 1, 2005 for middle-income countries and January 1, 2006 for least-developed countries.⁴ The 2005 deadline was later extended to 2016 for pharmaceutical products for least-developed countries [35, 36].

⁴ If a government allowed pharmaceutical or agricultural chemicals to be marketed, it was required to provide the shorter of 5-year exclusive marketing rights or exclusive marketing rights until the patent was granted.

Under WTO rules, Brazil was not required to adopt and enforce industrial property protections for pharmaceutical products until 2005. However, President Cardoso was under strong pressure from the United States to implement an Industrial Property Law much earlier. The pharmaceutical industry, the software industry, the US Trade Representative, the US Congress, the US media, Brazilian lobbyists, and the American embassy in Brazil were pressuring Cardoso to prioritize an industrial property bill. During Cardoso's 1995 visit to the US, the PMA launched an ad campaign in the *New York Times* and the *Wall Street Journal* calling Brazil the "country of pirated patents." During his visit, the Clinton Administration informed Cardoso that Brazil was once again on a priority watch list of countries that did not recognize intellectual property rights. President Cardoso, under strong pressure from the US government and PMA lobbyists in Brazil and the United States, promised to send an Industrial Property reform bill to Congress during his first year in office [6, 10].

When FHC launched his bill, he claimed that the bill was not an imposition of the United States, but Brazil's key to successful integration into the international economy [10, 37]. In an interview for this book, President Cardoso declined to comment about his motivations for proposing industrial property legislation so early [38]. However, it appears that FHC prioritized the bill because he recognized the importance of intellectual property regulations to attracting direct foreign investment and avoiding bilateral trade sanctions with the USA, Brazil's \$20 billion trade partner [39].

Law 9.279 allows for the patentability of food, chemical, pharmaceutical, and biotechnology products in Brazil. When Cardoso signed the bill into law on May 14, 1996,⁵ he declared

What we're doing, by signing this law, is doing away with the colonialist mentality of those who think that Brazil isn't competent, with those that think foreign countries know everything and will continue to dominate Brazil [40].

The bill's Congressional margin of victory could not be verified by examining Congressional vote records because there was no roll call vote in the final approval of the bill; legislators in both houses voted by raising their hands rather than voting electronically. It is therefore difficult to tell how each senator, deputy, and political party voted on the Industrial Property Bill. However, one pharmaceutical lobbyist commented that the legislation was approved by 85% of both houses [33]. Because this broader legal development is not the central focus of this book, the Congressional process related to development of this law was not explored in great detail.

Because of Brazil's strong presidential mandate, most legislation initiates in the executive branch of government. Because of Brazil's many political parties and low-party discipline, Presidents often move bills through Congress by exchanging

⁵ Two other important intellectual property laws, the Law on Computer Programs (Lei 9609:1998) and the Law on Rights of the Author 9610 (Lei 9610: 1998), were adopted on February 19, 1998. Since these laws are not related to pharmaceutical policy, they are not discussed in this book.

favors for political pork. The Industrial Property Bill failed in 1993 because President Franco did not support it. Cardoso's strong backing of the legislation was essential to moving the bill expeditiously through Congress. FHC is well known for exchanging political pork and favors for Congressional votes on important long-term reforms [41]. Though little is known about the specifics of how the Industrial Property Law was adopted, this may be how Cardoso moved this historically controversial legislation through both the houses of Congress in 1996. Regardless of how Cardoso was able to usher this bill through Congress, the law had important impacts on historical development of Brazil's AIDS treatment institutions.

Law 9.279's Implications for AIDS Treatment

Under WTO requirements, Brazil was required to adopt an industrial property law by 2005. However, Brazil's law became effective in 1997, much more quickly than it might have in the absence of international political pressure. The law recognized a variety of different types of property rights, but is important to AIDS treatment because it established intellectual property rights for pharmaceutical products and processes introduced in the Brazilian marketplace after May 15, 1997. Pharmaceutical processes and products produced in Brazil prior to 1997 would not enjoy patent protection; however, all new products would enjoy intellectual property protections, including AIDS medicines. This change in the institutional environment strongly influenced the AIDS treatment institutions in Brazil: public laboratories' generic ARV production would be restricted to older ARVs, and all new ARVs would enjoy patent protection. This would later have profound impacts on AIDS treatment in Brazil.

Several articles of the law became important to development of Brazil's future AIDS treatment institutions and Brazil's later international trade dispute with the United States. First, article 68 in Brazil's 1996 law requires that all foreign companies produce their patented products in Brazil within three years or else be subject to compulsory license. A compulsory license allows governments to use or grant a third party authority to use an individual or corporation's intellectual property without expressing permission. This clause was included in Brazil's IP law to encourage development of local industry and became the focus of a later 2001 WTO trade dispute between Brazil and US, which will be discussed in chapter 6. Second, article 71 establishes Brazil's right to issue a compulsory license in cases of national emergency or public interest. This clause will be revisited in chapter 5.

Surprisingly, at the time Law 9.279 was adopted, there was little public discussion about the effects of the new Industrial Property Law on public access to medicines. Though intellectual property laws got significant media coverage from 1988 to 1996 in Brazil and the United States, during the 5 years after Collor first introduced an industrial property bill to Congress and the time FHC signed the Industrial Property Bill into law in 1996, only one news article was found that discussed the potential impact of Law 9.279 on cost or access to medicines, and that article was

published in 1992 [32]. The impact of intellectual property regulations on access to AIDS medicines was largely unaddressed by the AIDS movement as well as sanitarians and activists working at the NAP and the Health Ministry. In interviews, when several leading AIDS activists were asked why they had not opposed the law, they stated that they had not recognized the importance of the law for access to treatment, and that there was very little public debate as the bill quickly moved through Congress. They also mentioned that the AIDS movement had focused more on moving into the federal AIDS bureaucracies and moving trials through the judiciary rather than working with Congress [42–44]. These activists' comments symbolize the AIDS movement's perception that Congress is a weak vehicle for promoting social change in Brazil.

However, neglecting political action in the legislature resulted in Congressional approval of a bill with enormous implications for the future of AIDS treatment. After May 1997, Brazil would recognize IPRs for all new ARVs, granting innovator drug companies' exclusive marketing rights for ARVs and permitting them to set monopoly prices for their products. This resulted in much higher ARV prices for drugs entering the marketplace after May 1997. Though this law had important impacts on development of AIDS treatment institutions, the full public policy impacts of this law on AIDS treatment, however, would not be recognized or publicly discussed until much later, after Congress approved a law guaranteeing free access to AIDS treatment in late 1996.

Political Action and Chronic Shortages in Drug Supplies for AIDS Treatment

Despite availability of generic ARVs and the federal government's commitment to improving access to drugs for AIDS treatment, for all of the complex reasons explained in chapter 3, AIDS drug stockouts persisted throughout 1996. NGOs continued political action activities, including protests, public denunciations of drug stockouts, and public lobbying of the Health Minister. Public officials continued to acknowledge drug stockouts in hopes that the Congress would appropriate greater funds for AIDS treatment. Health Minister Jatene publicly acknowledged federal budget shortfalls for AIDS drugs in February 1996 [45–47].

In spite of stockouts, the Health Ministry reiterated its commitment to AIDS treatment and became the first developing country to publicly distribute protease inhibitors [48]. As had happened when Brazil added other ARVs to its AIDS drug list, when Brazil added protease inhibitors⁶ to its list of available medicines in mid-1996, stockouts became more acute [49, 50]. In July 1996, although Brazil was spending over US \$100 million annually on drugs for AIDS treatment, there were still chronic shortages of hospital beds and drugs [51, 52].

⁶ In 1996, protease inhibitors crixivan, saquinavir, indinavir, and zidovudine were added to Brazil's AIDS drug list (see Appendix A).

In 1996, the AIDS movement continued its political action campaigns to pressure the executive branch of government to address chronic shortages of drug supply. After a widely publicized meeting with Health Minister Jatene, Betinho publicly criticized both Minister Jatene and President Cardoso, commenting that “Even Fernando Collor talked about AIDS! The President [Cardoso] isn’t prioritizing this issue!” [53]. The AIDS movement heavily criticized FHC for continuous drug stockouts and hospital bed shortages for AIDS patients, even organizing gay AIDS activists in France to demonstrate against FHC’s lack of commitment to AIDS 1996 during a Paris visit [54].

Two months later, in July 1996, the 11th International AIDS Conference took place in Vancouver. The Vancouver AIDS conference is perhaps best remembered as the International AIDS Conference in which scientists released evidence of the efficacy of triple therapy in AIDS patient survival [55]. Triple therapy consists of drugs from three antiretroviral drug classes, including a nucleoside reverse transcriptase inhibitor (NRTI), a non-nucleoside reverse transcriptase inhibitor (nNRTI), and a protease inhibitor (PI).⁷ This research had lasting impacts on global AIDS treatment protocols: after the Vancouver conference, triple therapy was considered the appropriate standard of care for treating people living with HIV/AIDS (PLWHA).

The Vancouver AIDS conference had a strong activist presence; activists organized to demand that drug companies lower their prices for antiretroviral medicines to improve global access to drugs [56]. In Vancouver, over 150 Brazilians protested high ARV prices, including representatives from 150 NGOs, NAP Director Lair Guerra, and several of Guerra’s deputies [57, 58].

Just after her return from the Vancouver AIDS conference, NAP Director Lair Guerra published an editorial in *Jornal do Brasil*, one of Brazil’s foremost newspapers. She outlined the Brazilian Health Ministry’s commitment to triple therapy, highlighting the new drugs Brazil had introduced into its treatment guidelines just prior to the Vancouver AIDS conference. Her editorial claimed that states and municipalities should share the financial burden of treatment and mentioned that the Brazilian political will to treat PLWHA was strong, but that there were insufficient federal funds available for drugs for treatment [59].

After the Vancouver AIDS conference, in August 1996, Brazil adopted its first official federal therapeutic guidelines for AIDS treatment, which called for protease inhibitors and required prescriptions for PLWHA to receive ARVs [60, 61].

Because the government had not yet stabilized federal drug supply, after the Vancouver conference, the São Paulo state Health Secretariat began procuring and distributing protease inhibitors independently of the federal Health Ministry. Several municipalities known for their progressive governments in São Paulo state also began independently procuring protease inhibitors for their patients and training doctors for new treatment protocols [62–64]. This exemplifies both the failure of the federal government to stabilize drug supply, and the importance of the decentralized public policies for AIDS through 1996, when a new law centralized federal AIDS drug policy.

⁷ In more colloquial terms, triple therapy is often referred to as “AIDS cocktails.”

By September 1996, the federal government had still not stabilized the drug supply, and many patients still had to purchase ARVs in the private sector. Betinho publicly encouraged PLWHA to go to file lawsuits against the government, announcing that

I've already pressured President Cardoso and Health Minister Jatene. That was three months ago and nothing has been done. I don't believe in the efficacy of our federal government. I'm directing PLWHA to file lawsuits against the government [to get their antiretroviral drugs] [65].

By mid-1996, the AIDS treatment crisis had gotten significant media coverage. It was in the context of ongoing drug stockouts, continuous political action by the AIDS movement, new international standards for treatment, and new treatment protocols that major legislative change related to AIDS treatment in Brazil finally took place.

Sarney's Law: Law 9.313

By mid-1996, Brazil had adopted triple therapy but still had not stabilized drug supply for AIDS treatment. In late 1996, with no public fanfare, former President and then President of the Senate, José Sarney introduced a bill that would require SUS, Brazil's federal public health system, to procure and distribute drugs for AIDS treatment. The law became known as "Sarney's Law" and is arguably the most important law related to AIDS treatment in Brazil. Sarney's decision to propose and push this bill through Congress is another critical juncture.

Nearly everyone interviewed for this book was asked why José Sarney suddenly sponsored an AIDS treatment bill. Many informants commented that this is the great unsolved mystery of AIDS policy in Brazil. As mentioned in chapter 4, because the AIDS movement believed it could accomplish more by pressuring the courts and the executive branch of government, it had not lobbied the legislature on treatment-related issues [43, 44]. This makes Sarney's Law all the more surprising.

Many individuals interviewed had a variety of different opinions about why Sarney sponsored the law. Former NAP Director Pedro Chequer, Senator Marcos Maciel (Vice President of Brazil when the bill was passed), and former Health Minister Adib Jatene (among other interviewees) all commented that NAP director Lair Guerra, a close friend of José Sarney and fellow PFL party member, "sensitized" Senator Sarney to the importance of addressing the AIDS epidemic and the importance of a federal law for gaining a Congressional appropriation [66–69].

Other experts had different opinions about Sarney's motivations. Under conditions of anonymity, one highly knowledgeable informant commented that Sarney knew he had overseen the greatest expansion of AIDS in Brazil and was clever enough to sponsor Brazil's most important AIDS treatment law in order to preserve his historical legacy. Brazilian AIDS expert Richard Parker commented that it was rumored that some of President Sarney's family members had AIDS and that Lair Guerra had served as a conduit between the AIDS movement, the NAP, and the Congress [68].

Under conditions of anonymity, a former NAP official responsible for drug distribution at the NAP commented that Sarney had family members living with HIV/AIDS:

President Sarney's wife had two nephews with AIDS. One died, and I believe the other one is still alive...since 1988, when Lair Guerra was buying only 50 boxes of AZT for the whole country...two of the boxes were always kept in her bathroom at the AIDS program. Back then, when I asked why she was hiding those boxes, she said 'Because one of those boxes goes to the Presidential Palace!' This is something that very few people know....

In an interview, in response to a direct question about why he sponsored the law, whether he had been lobbied by the AIDS movement, and whether he knew someone whose life had been affected by AIDS, Senator Sarney commented:

I had always been concerned about the AIDS problem. As an intellectual, I knew the disease was associated with life and death, and therefore would have devastating impacts on all of humanity if we didn't take some serious coordinated action worldwide to address the AIDS crisis. My initiative was motivated by humanitarianism rather than politics.

I never had any direct pressure from political groups; I just went with my instincts about the gravity of the AIDS epidemic. I followed what was going on at the Vancouver [AIDS] conference, and when I saw the announcement about protease inhibitors, I realized we could start distributing them to people living with AIDS in Brazil. I knew that people wouldn't be able to afford those drugs, so a few days after the Vancouver AIDS Conference, I presented a project saying that the government would provide antiretroviral drugs free to all people living with AIDS. I was the President of the Senate back then, so I was able to get the bill fast-tracked and approved in the Senate.

I immediately went to the House of Deputies and made sure it was quickly approved there as well. The [Cardoso] Administration resisted the bill, claiming it didn't have the requisite public resources to finance the project, and told me I shouldn't have sponsored the law because it was too expensive.

But I think being a former President of Brazil helped. I went directly to President Cardoso and told him that I absolutely would not accept a veto on the bill, because if the bill were vetoed, we'd override the veto in Congress. I told him that I'd successfully garnered support for the bill the first time around, and that I'd do it again if he vetoed the bill. The bill was the beginning of Brazil's program for free and universal access to treatment [70].

Sarney's comments suggest that all of the aforementioned institutional conditions, including the Vancouver AIDS conference, ongoing drug stockouts, and political dialog about AIDS treatment influenced his decision. Whatever the motivations for Sarney's sponsorship of the bill, he was able to use his leadership authority and existing institutions to achieve his new political goals of expanding access to drugs for AIDS treatment. Several individuals interviewed commented that Sarney was able to use his power as President of the Senate to move the bill quickly through Congress [66, 71, 72]. Both newspapers and Congressional records document that the legislation passed both houses of Congress unanimously without a roll-call vote [73, 74]. In an interview for this project, then Health Minister Adib Jatene asked who in the Senate had favored and opposed the bill, he commented that even he did not know: "Sarney's Law was a Senate discussion. It was not a public discussion" [69]. However, once Sarney had made the decision to sponsor the legislation, he used his political power to move the bill quickly through Congress.

Several amendments proposing means-tested treatment programs failed [74, 75]. President Cardoso preferred a means-tested program and initially threatened to veto the law because of its US \$200 million annual price tag. It is unclear why Cardoso

never vetoed the bill, but Sarney may have ultimately been able to garner Cardoso's support, because at the same time, Cardoso was seeking Congress' approval for a constitutional amendment that would allow him to run for re-election, and needed Sarney's (then President of Senate) support on that legislation [76]. Given the enormous cost of a law guaranteeing free access to HAART, unanimous support for this bill is surprising. Somehow, Sarney, perhaps best known for his personalistic, pork-barrel politics, somehow convinced Congress to support a very expensive bill. Sarney's Law exceptionalized public finance and delivery of medicines for AIDS; the bill did not address broader drug policy or supply, which has been historically equally as unreliable as AIDS drug supply.

On November 13, 1996, President Cardoso signed Law 9.319. The law has only four articles and includes the following substantive clauses:

Article 1: Individuals living with HIV/AIDS will receive, free of charge, from Unified System of Health [SUS], all medication necessary for treatment. The executive branch of government, through the Health Ministry, will standardize which drugs are to be used for each stage of the disease, and will procure drugs through SUS. Standardized therapeutic guidelines will be reviewed and published annually, or whenever necessary, in accordance with new scientific guidelines and availability of new drugs in the marketplace.

Article 2: The required expenditures will be financed with resources from federal taxpayer revenue, the states, the federal district, and the municipalities in accordance with SUS regulations [77].

The law placed no restrictions on the amount the federal government would spend on AIDS treatment. By deliberately excluding means-tests and regulatory clauses, and including the words "free of charge," and "all medication necessary for treatment," Congress signed a blank check for AIDS treatment.

Sarney's Law is another critical juncture in the path of historical development of Brazil's AIDS treatment institutions. A law that partially subsidized treatment, or used clinical or economic criteria to restrict AIDS treatment to select groups of patients could have been proposed and adopted. Alternatively, Sarney could have opted not to propose any AIDS treatment law. Those alternatives would have resulted in profoundly different AIDS treatment institutions in Brazil.

Law 9.319 has many of the qualities of traditional personalistic legislation in Brazil. There was no formal lobby of Congress by the AIDS movement, there was not an open and transparent political dialog about the bill, and the highly specific law exceptionalized drugs for AIDS treatment without addressing the government's role in improving access to other medicines, which has historically also been very sporadic. Moreover, most of the interviewees' comments suggest that Sarney's Law was a personal favor to Lair Guerra or even a bill to promote Sarney's family interests. Nevertheless, Sarney's decision to sponsor and usher this bill through Congress profoundly impacted historical development of Brazil's AIDS treatment institutions.

Though political action by the AIDS movement had resulted in Brazil's first commitment to AIDS treatment and ongoing political pressure to address the AIDS treatment crisis throughout the 1990s, the AIDS movement's political action efforts had not led to the important legislative reforms necessary to improve widespread access to AIDS treatment in Brazil. Rather, NAP Director Lair Guerra seems to

have played an important role in convincing Sarney to both sponsor this legislation and ensure that the policy was continually updated and guided by sound scientific evidence. Again, Lair Guerra served as an effective conduit between the AIDS movement, the NAP, the Health Ministry, and important politicians in Brazil's new democratic institutions. This exemplifies the importance of *jeitinhos* for early AIDS policy in post-authoritarian Brazil. Though personal connections were important to move forward a legislative agenda for AIDS, Sarney's high-profile sponsorship of controversial legislation also suggests that the social movement had effectively used the media and political action tactics to convince even the most high-profile politicians to respond to the AIDS epidemic for their own political gain.

Sarney's Law became an important vehicle for social change related to drugs for AIDS treatment, and is one of the five AIDS treatment institutions explained in this book. Sarney's public commitments to progressive AIDS policy added to important political momentum for AIDS treatment in several important ways. First, this law reinforced previous court decisions about the right to medicines, further legitimizing activists' claims about the right to treatment. Second, by specifically stating that SUS would provide medicines and that the Health Ministry would oversee antiretroviral drug policy, the law centralized formerly disparate drug policy related to AIDS treatment. Perhaps most importantly, though the law did not explicitly state that the federal government would finance all drugs for AIDS treatment, the law legitimized claims about the need for increased Congressional appropriation for AIDS drugs and created a legal obligation for further government action related to AIDS treatment. Miriam Ventura, who led the AIDS movement's efforts to move AIDS treatment issues through the courts, summarized the impacts of Sarney's Law on AIDS treatment institutions in Brazil:

Remember, there were already a series of court cases and a series of Health Ministry *portarias*⁸ that said patients had a right to AIDS treatment. So legally, Sarney's Law really wasn't necessary; however, Sarney's Law would prevent any other Health Minister from revoking previous *portarias*. Sarney's Law also helped get funding for AIDS in an era when treatment was controversial... Drugs were never paid for by international agencies in Brazil; Sarney's Law was important because back then, the development agencies thought that AIDS treatment would create super-viruses, and that it would be too expensive. Brazil had opted to provide treatment anyway, but hadn't gotten much support for its policies. Sarney's Law helped legitimize the treatment movement.

...I'm no fan of these highly-specific pieces of legislation; I think health should be regulated through the Health Ministry. If not, everyone has to wait on the legislature to act with highly specific legislation rather than interpreting existing laws, and that's not good for public health. But I will say that as a result of Sarney's Law, no one messes with the AIDS program, not Health Ministers, and not even our President [44].

Though Guerra's personal connections were important to jumpstart important legislative change, Sarney's Law had created a new legal mandate for providing drugs for AIDS treatment that helped formalize AIDS treatment institutions in

⁸Portarias are ministerial directives. They refer to executive orders or policies by members of Presidential cabinets. In this case, portarias refer to executive orders from the Health Minister.

Brazil. The law was sticky; as chapter 5 explores, once the formal institution was in place, with a vibrant AIDS movement to hold the government accountable for its new commitment, it became increasingly difficult for political actors to deviate from Brazil's commitment to AIDS treatment.

Cumulative Impacts of the Industrial Property Law and Sarney's Law

Though Laws 9.279 and 9.313 developed independently, their cumulative impact profoundly changed the trajectory of AIDS treatment institutions in Brazil. Sarney's Law reinforced AIDS patients' claims to the most modern drugs for treatment by clearly stating that all AIDS drugs would be publicly provided by SUS and updated annually. The law formalized and helped centralize ARV drug policy at the federal Health Ministry. However, starting in May 1997, less than 6 months after Cardoso signed Sarney's Law, Brazil began recognizing the intellectual property rights of multinational pharmaceutical companies for new drugs introduced in Brazil.

Brazil's 1996 Industrial Property Law, part of a complex domestic and international political process related to Brazil's integration into the post-Cold War global economy, and Sarney's Law, emblematic of Brazil's sometimes opaque, unpredictable, and personalistic legislative institutions, exceptionalized drug policy for AIDS. The two laws legally obligated the government to provide HAART to all PLWHA but limited political actors to what historical institutionalists refer to as "bounded change." Political actors had to operate within the confines of Laws 9.319 and 9.279, restricting the political options available to address the AIDS treatment crisis. The two laws, pointing in seemingly opposite directions, required the federal government to provide the most modern drugs for AIDS treatment but limited the government's former strategy of using locally produced generics to ARVs introduced in Brazil before 1997. All antiretroviral drugs introduced into treatment guidelines after May 1997 were patent protected (Appendix A). As a result, multinational pharmaceutical companies were given the sole rights to sell their products and dictated drug prices. The combination of these two laws led to a rapid spike in the cost of AIDS treatment and created a serious fiscal dilemma for Brazil that political actors in the executive branch of government would later have to resolve.

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Chapter 5

Development of Brazil's Contemporary AIDS Treatment Institutions

In October 1996, before Cardoso signed Sarney's Law, most individuals who had successfully procured drugs for AIDS treatment did so through AIDS NGOs and the court system rather than directly from government clinics [1]. Though stockouts continued through most of 1996, by December, after Sarney's Law had been signed by President Cardoso, antiretroviral (ARV) drug supply had stabilized to some degree. Several states were receiving enough of some classes of ARVs such as nucleoside reverse transcriptase inhibitors (NRTIs) and non-nucleoside reverse transcriptase inhibitors (nNRTIs) for 15 days, though protease inhibitors (PIs, the most expensive and new ARVs)¹ were still in short supply nationwide [2, 3].

In December 1996, after being roundly criticized for continuous drug stockouts in the media and by NGOs, in a radio address, President Cardoso ordered the Health Ministry to buy immediately more ARVs and announced, "the government has sufficient resources to supply treatment and prevention services for patients with AIDS. By the end of this week, all Brazilian states will have received AIDS cocktails [4]". Since that announcement, with few exceptions, ARV drug supply in Brazil has been very stable. Improved access to drugs for treatment is related to several complex social and political factors that chapter five explores.

Sanitarista Leadership in the National AIDS Program Bureaucracy

In late 1996, Dr. Lair Guerra, then director of the National STD and AIDS Program (NAP), had a car accident and suffered permanent brain damage. Lair Guerra began engaging the AIDS movement in the early 1990s and had a very important permanent impact on public policy related to AIDS. Because Brazil's legislative, executive, judicial, and civil society institutions were fragmentary and not always

¹Currently, there are four major classes of ARVs: nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), and fusion inhibitors. In 1996, NRTIs, nNRTIs, and PIs were the only ARVs available in Brazil.

well-functioning in the first 10 years after the dictatorship, the processes in which AIDS reforms took place had not always been transparent or participatory. Her personal connections to high-profile politicians like José Sarney had been equally as important as engaging the AIDS movement; her connections helped jumpstart important AIDS policy reforms in the first few years after Brazil's transition to democracy. However, after the first World Bank loans institutionalized the AIDS movement in the policy development process, and Sarney's Law helped further legitimize the AIDS movement's demands of the state, the process of developing AIDS treatment institutions became increasingly more transparent and publicly discussed.

Leadership changes at the NAP also contributed to changes in historical development of AIDS institutions. After Guerra's accident, sanitaria and Deputy NAP Director Pedro Chequer assumed directorship of the NAP from 1996 to 2000. Pedro Chequer was a sanitaria doctor and former Worker's Party (PT) activist who had organized rubber workers in the Amazon and who had spent much of his career in public service related to sexual and reproductive health. He had worked at the NAP since 1986 and as Lair Guerra's deputy for several years [5].

Rather than broker backroom deals with *jeitinhos* or personal connections, Chequer instead adopted a much more participatory approach emblematic of his sanitaria and activist background. As NAP director, he used the contentious tactics the AIDS and sanitaria movements previously used to pressure the state for health policy changes. Employing campaigns, political action tactics, and unifying slogans to promote the AIDS treatment, Chequer promoted AIDS treatment from within the state. For example, Chequer oversaw campaigns to demand that the Health Ministry provide funds for AIDS treatment. He consistently used social movement repertoire, including political action tactics such as speaking at rallies and protests and frequently engaging the media to raise public awareness about the importance of AIDS treatment. Moreover, in innumerable speeches, editorials, and public remarks, he used human rights language and unifying activist slogans to promote the AIDS treatment cause.

In addition to using social movement tactics from his NAP post, Pedro Chequer improved the NAP's human resource pool, quickly implemented health infrastructure for AIDS treatment, applied for another World Bank loan entitled AIDS II, and strengthened treatment activism by fortifying the AIDS movement inside and outside the NAP. This underscores the sanitaria and AIDS movement's strategies of working within the state of which they solicited demands.

Pedro Chequer's leadership marks the time that sanitarias assumed control of the NAP. One key impact of sanitaria leadership has been to build a strong human resource force at the NAP. Pedro Chequer inherited a NAP that already employed a highly dedicated cadre of activists and sanitarias. Chequer continued recruiting activists and sanitarias throughout his tenure, creating a cadre of public servants at the NAP very different from the traditional Health Ministry public servants. Many were activists with a long history working in the AIDS movement; others were AIDS providers or sanitarias looking for promising opportunities in public service. Most public servants in Brazil, including Health Ministry employees, have to pass a rigid civil service exam in Brazil. However, the NAP circumvented these regulations by hiring many activists and other AIDS experts as contractors. This is permitted under 1993 and 1995 civil service reforms designed to reduce clientelism in public

bureaucracies and to attract more highly qualified experts to public service [6, 7]. Moreover, the NAP was also able to attract the most qualified AIDS activists and experts in Brazil, as World Bank “consultancy” salaries offered by the NAP were often higher than NGO or public servant salaries at the Health Ministry. Though the NAP declined to provide data on salary rates, several interviewees commented on these salary discrepancies, citing the high NAP salaries as a frequent reason that many members of the AIDS movement began working for the NAP [8,–12].

Since 1996, all NAP directors have been self-proclaimed sanitariastas (Appendix D lists all NAP directors). Sanitarista leadership, particularly Pedro Chequer and his successor, Paulo Teixeira, helped create a dedicated cadre of public servants, including many sanitariastas and AIDS activists. Sanitarista control of the NAP is among the key reasons that the AIDS program was able to quickly develop health infrastructure to effectively scale delivery of ARVs and improve clinical infrastructure for treating patients. This dedication is difficult to measure empirically but is most tangible in the NAP’s remarkable accomplishments in scaling up health infrastructure for AIDS treatment and its success in creating the institutional conditions that encouraged political actors to take up the AIDS treatment cause. In an interview, an executive from the pharmaceutical industry best summarized this phenomenon in an interview: “AIDS drugs are delivered in Brazil because the people working at the National AIDS Program *want them delivered*. They are very dedicated. Other bureaucracies don’t work that way in Brazil” [13]. In other words, who was implementing the policy was just as important as what policies were implemented.

Moreover, hiring sanitariastas and activists helped create a semiautonomous NAP bureaucracy that has been relatively unencumbered by the clientelism and bureaucratic politics that historically plagued the Health Ministry and prevented sanitariastas from implementing important reforms. While most of Brazil’s health institutions were decentralizing in the late 1990s, under sanitarista leadership, the NAP became a vertical, centralized program insulated from traditional clientelistic politics. Though sanitariastas assumed control of the NAP much later than the Health Ministry, consistent sanitarista leadership has had remarkable and enduring impacts on AIDS treatment institutions in Brazil.

These results of Chequer’s leadership are tangible and had dramatic and immediate impacts on access to treatment. Perhaps the best way to measure the impact of Pedro Chequer’s leadership is to examine all the changes that took place shortly after he became NAP director. The most remarkable changes are related to his efforts to develop the health infrastructure and institutional resources to comply with Sarney’s Law establishing universal access to treatment for all people living with HIV/AIDS (PLWHA). In 1997, for example, committed to offering free and universal access, Chequer first began large-scale HAART distribution to PLWHA in the absence of laboratory infrastructure. By the end of 1997, newspapers reported that SUS had begun financing CD4 and viral load tests,² whose user fees had previously

²These clinical tests measure the level of HIV in a person’s blood and help evaluate the clinical progression of the HIV/AIDS. They are considered critical health infrastructure components for scaling up AIDS treatment.

been prohibitively expensive for many PLWHA. In 1997, the NAP also hired hundreds of laboratory technicians for viral CD4 count testing [14–18]. The NAP expanded HIV testing in public hospitals, trained doctors and dentists in treating AIDS patients and began pediatric treatment [16, 19–21]. These developments are confirmed by Brazil's program appraisal documents [22].

Moreover, in 1997, four new drugs were added to treatment guidelines including thalidomide, nelfinavir, delavirdine, and nevirapine (see Appendix A). By the end of 1997, approximately 37,000 people were receiving HAART from the NAP (see Figure 1.5). Precise data on the number of PLWHA receiving treatment prior to 1997 are not available because treatment had not been centralized or well-organized prior to Sarney's Law; however, this was a remarkable scaleup from the estimated few thousand people who had been receiving federally funded treatment 1 year earlier [23]. Additionally, in contrast to the dozens of articles from previous years that had reported stockouts, only one newspaper article reported a stockout in 1997. That challenge was quickly resolved when the NAP successfully juggled drugs between the states and improved its forecasting system in the second half of 1997 [24]. All of these phenomena exemplify the remarkable impacts of Pedro Chequer's leadership on health infrastructure development.

In addition to helping develop health infrastructure to improve access to HAART, sanitaria leadership reinforced and strengthened the existing activist tradition and culture within the NAP. Chequer served as the AIDS movement's de facto leader while directing the NAP. Using campaigns, social movement repertoire, and unifying slogans, he continued mobilizing the AIDS movement from within the NAP.

Like AIDS activists in the early 1990s, one of Chequer's political action tactics was to use the media to hold Congress and the Health Ministry accountable for its new legal commitments to financing drugs for all PLWHA under Sarney's Law. He used the media to publicly lobby the Health Ministry and Congress for increased funds for public treatment and care, publicly requesting increased spending for AIDS care [25]. As had happened when the Health Ministry first began AIDS treatment in 1992, after Sarney's Law, the promise of widespread availability of HAART prompted more people to present for testing. As a result, the \$150 million reais Congress had appropriated for ARVs was insufficient to meet demand for the number of patients presenting for treatment. By September 1997, perhaps because of rapid expansion of the number of patients throughout the year, ARV stock was again running low. One strategy Chequer used was to publicly announce low ARV drug stock *before* it depleted, which was most common for expensive protease inhibitors. Chequer immediately engaged the media and NGOs, announcing that he was waiting on an official government response.

The first time he employed this political action tactic was at an NGO conference in 1997 [26]. Two days later, Brazil's foremost AIDS infectious disease specialist, David Uip, described the serious medical implications of drug shortages to the media [27]. Two days after that, the Health Ministry announced another \$50 million reais for AIDS drug spending for the remainder of the year [28]. In the late October of 1997, Chequer

again publicly warned about potential stockouts in December or January, claiming that the September Congressional appropriation was insufficient to meet new demands for treatment [29]. He also publicly linked mortality decline to HAART and claimed that PLWHA would die if the Health Ministry did not address the issue, demanding that the Health Ministry commit another \$120 million reais for ARVs. He publicly reminded the Health Minister of his legal obligation to provide HAART to all PLWHA under Sarney's law [30, 31]. When asked about whether he had deliberately used the media to pressurize the government about AIDS treatment, Pedro Chequer commented

I remember, at the beginning of the AIDS epidemic, the media was uninformed about a lot of things, they didn't know which terminology to use...they used inappropriate language to refer to people living with HIV/AIDS. Since the beginning of the AIDS epidemic, we tried to engage the media, even with courses. First, we wanted to train them how to use the appropriate language that wasn't discriminatory. Second, we never wanted to hide any facts, *never, never, never*. Our premise is that citizens have the right to know things, even the bad things. So, I've always had frank discussions with the media [5].

In addition to developing a team of well-trained, technically oriented public servants that could implement AIDS treatment scaleup, Chequer had become Brazil's most vocal AIDS activist. Chequer was spearheading treatment activism from *within* the NAP, galvanizing the AIDS movement and even using activist and citizenship language in many public appearances. For example, in a lecture urging the Health Ministry to expand testing in September 1997, Chequer commented "Offering the possibility of HIV testing is important. We are exercising our citizenship rights. This is fundamental" [16].

In 1997, in what later became a turning point in AIDS policy, in response to Chequer's criticisms, Health Minister Albuquerque commented that he was concerned that 10% of Health Ministry expenditure was going to 0.1% of the population, adding that "it was unjust that the government was obligated to spend \$428 million reais on a disease that only affects 55,000 people." NGOs such as Pela VIDDA and ABIA denounced his comments [32]. NGOs such as Pela VIDDA, GAPA, and others nationwide threatened to flood the courts if the Health Ministry cut drug expenditure [33]. NGOs protested in the streets for a week, followed the Health Minister to each of his speaking events, protesting loudly each time Albuquerque spoke [34, 35]. Pedro Chequer continued his advocacy campaigns, and announced, "We have the political will to do this!" Buttressing his arguments with a new study on the cost effectiveness of treatment, Chequer announced that treating AIDS patients saved the Health Ministry US \$1 billion annually by reducing hospitalizations [36]. On November 12, Health Minister Albuquerque retracted his statements, announced he would not cut AIDS spending, and said the Health Ministry would cut other programs to pay for AIDS drugs [37, 38].

Even after Albuquerque's announcement, well-known infectious disease doctors and Pedro Chequer continued to speak publicly about the critical need to continue AIDS treatment [39]. On World AIDS day, even as the Health Ministry affirmed its commitment to AIDS treatment, NGOs marched to protest any potential future cuts in ARV drug spending [40, 41].

All of these phenomena highlight the importance of sanitarista leadership at the NAP. By working within the state, sanitaristas and AIDS activists were able to promote their causes more effectively. This catalog of important events symbolizes that Chequer effectively used public resources to successfully scale up health infrastructure in a remarkably short period of time. He orchestrated the AIDS movement from within the NAP, using the same campaigns, political action tactics, and unifying slogans the AIDS movement employed in the early 1990s. Given that Chequer reported to the Health Minister, his decisions to be vocal about access to drugs for AIDS treatment were very politically risky. However, by using political action tactics, engaging the media and the AIDS activist community, and delivering on all of his policy promises, he provided political cover for his actions. By engaging the media and treating the AIDS epidemic like a public health emergency, his actions prompted politicians to respond accordingly. Moreover, by protesting stockouts before they occurred rather than afterward, his strategies proved highly effective in stabilizing financial support for ARVs.

The cumulative impact of all of Chequer's campaigns, political action initiatives, unifying strategies, and health infrastructure and human resource improvements shaped the institutional environment in which political actors operated, which in turn influenced the path of institutional development of AIDS treatment. For example, Albuquerque's comment about the high opportunity costs of AIDS treatment was the last time that any Brazilian Health Minister or high-profile politician publicly opposed spending for any AIDS program, particularly AIDS treatment; the political costs of opposing AIDS programs had become too high. By working inside and outside government bureaucracies to achieve its objectives, the AIDS movement effectively held the legislative and executive branches of government accountable for appropriating AIDS funds for Sarney's Law. Another large World Bank loan reinforced these institutional arrangements.

World Bank AIDS II Loans

In 1998, Brazil was awarded another World Bank loan entitled AIDS II to fund AIDS programs from 1999 to 2002. The loan's main objective was to "promote more cost-effective approaches to health care, mainly by reducing overall health-care costs through disease prevention." The three specific objectives of the loan were to (1) prevent HIV and other sexually transmitted infections (STIs); (2) diagnose, treat, and care for people living with HIV and STIs; and (3) strengthen institutions and agencies responsible for AIDS and STD control, including physical infrastructure and human resources. Appendix I includes more information about the specific program components of this loan. The project appraisal document notes the first World Bank loan's impact on improved health infrastructure, increased NGO participation in prevention policies, and Brazil's political and nonstate commitments to addressing the AIDS epidemic as justification for AIDS II [42].

World Bank loans reinforced existing institutional arrangements for AIDS treatment by improving health infrastructure for AIDS treatment and fortifying the AIDS movement. These developments profoundly influenced the institutional environment in which political actors operated in the late 1990s, making it increasingly difficult for political actors to deviate from commitments to AIDS treatment in spite of the associated rising costs.

For the aforementioned reasons, by 1998, the NAP already benefited from a reasonable degree of political support for its costly AIDS treatment programs. AIDS II loans solidified the NAP as a centralized and largely independent Health Ministry agency.³ This independence has had some positive effects. For example, this is likely why health infrastructure was so quickly scaled up; experienced, well-paid technocrats at the NAP were unencumbered by traditional Health Ministry bureaucratic politics.

For example, according to a 2004 project appraisal report, the loan successfully financed human resource training for healthcare providers and NAP employees and developed needle exchange programs. The loan helped develop Brazil's laboratory capacity for CD4 and viral load testing, established 190 new AIDS treatment centers, and fortified 700 existing clinics for HIV and STD treatment and care. Not only did the NAP more than double its initial targets for developing treatment and care infrastructure; it improved the quality of outpatient services for AIDS patients [22].

World Bank loans financed infrastructure for developing a complex, centralized logistics system to deliver ARVs nationwide. Perhaps most importantly for this book, in contrast to other drug distribution systems which are run by decentralized state distribution centers, ARV distribution is managed at the well-financed and well-organized NAP. In a country with a highly decentralized health system, fragmentary health infrastructure in many remote areas, and large health budget disparities between the 26 states, centralized finance, and vertical control of ARV distribution programs facilitated rapid scaleup of the treatment program. From 1997 to 2000, newspapers did not report any ARV stockouts; even today, ARV distribution is highly reliable and stockouts are very rare. However, drugs for opportunistic infections, which are often decentralized, have been fraught with logistics problems and frequent drug stockouts [43–46]. This contrast best highlights the impact of centralized, NAP-controlled drug distribution.

³The financial and administrative differences between the NAP and the Health Ministry are tangible; there is a stark contrast between the state-of-the-art physical and technological infrastructure of the AIDS program and the dilapidated government buildings and outmoded technology at the Health Ministry. These differences symbolize how the NAP, with World Bank loan support, had developed a vertical and highly functional AIDS program that is financially and administratively separate from the Health Ministry.

AIDS II and the AIDS Movement

World Bank loans also solidified the role of the AIDS movement in AIDS program development and implementation through several mechanisms. As mentioned previously, in order to receive funds for civic activity from the NAP, NGOs had to register with the Health Ministry. The prospect of new support prompted more NGOs to register. By 1998, more than 500 AIDS-related NGOs had developed, a fivefold increase since 1992 [47]. NGOs also helped draft the AIDS II loan proposal. The larger, more experienced NGOs provided technical assistance to smaller NGOs for proposal development for AIDS II. Moreover, the World Bank hired a consultant from ABIA, one of Brazil's foremost AIDS NGOs, to select recipients of the AIDS II funds. "NGO consultants" had helped write AIDS I and NGOs wielded even more influence in drafting AIDS II [48]. By 1998, not only NGOs were receiving federal support for their activities; also they were shaping the type of support they would receive. Both the number of NGOs participating in government projects and the number of projects implemented in AIDS II more than quadrupled those for AIDS I (Appendix F).⁴ NGOs were receiving increased federal support for their activities, and then using financial support to lobby for expansion of AIDS treatment. As a result of the path-dependent process of World Bank loans and Pedro Chequer's leadership, the AIDS movement had guaranteed itself an even greater role in developing and implementing future AIDS policies. These developments contributed to the political momentum for AIDS treatment.

Though NGO participation in AIDS programs was officially intended to implement prevention campaigns and prevent new HIV infections, World Bank loans effectively subsidized treatment activism. Many NGOs financed by the NAP protested alongside Pedro Chequer during the late 1990s. By the end of the late 1990s, the program was conducting very strong advocacy campaigns. Though AIDS II outlined \$70 million for institutional development, much of which included sentinel surveillance, monitoring and evaluation of program and NGO activities, the NAP largely neglected this arm of the loan program. The NAP never developed a culture of monitoring and evaluation or using data to inform controversial decision making, particularly decisions related to drugs for AIDS treatment. The third World Bank loan (AIDS III) project information document notes that

Monitoring and evaluation system of the program needs to be implemented. Some advances have been made although they are still inadequate for a program of this magnitude and stature (and given the fact that this was to be an important focus of AIDS II). HIV/AIDS surveillance has improved but sexually transmitted disease surveillance continues to be inadequate. Although the project has developed numerous independent data sets developed for specific purposes (other than project monitoring and management), and has conducted some studies to assess project outcomes and impact, they have not been conducted systematically and

⁴Strangely, though NGOs have always played a key role in AIDS program implementation, neither the NAP nor the World Bank has documented historical NGO spending and NGO programs. It is unclear whether this omission is deliberate on the part of the NAP or this is an accounting oversight.

often fail to use comparable methodologies. Thus, as such, the project has studies and data but no evaluation strategy nor system, resulting in a lack of systematic information on project outcomes and impacts in various areas. They have never hired a monitoring and evaluation staff with the appropriate background and do not have a culture of using data for decision-making [49].

The NAP also failed to identify cost-effective interventions. The AIDS I and II project assessment document comments that “the project was successful in defining and supporting a core program for HIV and STD prevention, but fell short of the objective of assessing which interventions work best with a view to guiding future decisions regarding resource allocation.” The 2004 World Bank implementation report on Brazil’s first two loans (1994 and 1998) is critical of the AIDS’ program failure to implement nationwide HIV/AIDS surveillance system on monitoring and evaluation for its programs. Only 46% of budgeted expenditure for surveillance and monitoring and evaluation expenditure for AIDS I and 50% of expenditure for AIDS II was used for those purposes. In contrast, the program spent 128% of its original \$70 million program budget on prevention activities for AIDS II, much of which went to NGOs. Because of lack of baseline data and end-of-project epidemiological and behavioral data, it is impossible to assess the Brazilian AIDS Program’s performance in reducing incidence and transmission of HIV and STDs [22].

In summary, though the NAP spent disproportionate sums on prevention programs, there is no way to assess the program’s performance in preventing transmission of HIV. However, the NAP has performed well on the other goals of diagnosing and treating HIVs and STIs and training health professionals. The NAP used World Bank loans to subsidize political activism to the detriment of conducting epidemiological surveillance, monitoring and evaluation, and encouraging evidence-based health policies and interventions. This phenomenon is one consequence of activist-style leadership at the NAP.

By neglecting monitoring and evaluation on the NAP’s selected interventions, and focusing on NGO mobilization and political action, the NAP insulated itself from political and donor scrutiny about AIDS treatment, which the World Bank did not support. Avoiding monitoring and evaluation is common in development projects in which the ideological leanings of recipients of donor aid revolve around a single ideological issue or theme. Often, aid recipients choose not to conduct monitoring and evaluation when it might potentially undermine program support preferring that their programs not be held to public scrutiny by donors [50]. In the case of the NAP in Brazil, foregoing monitoring and evaluation allowed the NAP to continue to use its rights-focused programs, campaigns, and political actions rather than to conduct research on the cost effectiveness and efficacy of its chosen interventions, the objectives and frameworks the World Bank favored. Moreover, Chequer believed that advocacy was necessary to maintain political support and momentum of its costly treatment programs [5]. Focusing on advocacy campaigns and political actions rather than cost programs effective and program efficacy allowed the NAP to continue with its policies of promoting AIDS treatment and supporting a social movement from within the federal government.

Another important and related impact of World Bank loans was to heavily subsidize all non-treatment-related AIDS programs. This allowed domestic resources to flow toward drugs for AIDS treatment, which the World Bank would not support directly. Domestic funding shortfalls perhaps even prompted the second World Bank loan proposal, which was submitted right after Congress cut the overall AIDS budget by 70% in 1997. Though the AIDS movement (including Pedro Chequer) had convinced the President and the Health Minister to invest in AIDS, and no Congressmen publicly spoke out against AIDS, each time the Health Ministry submitted its budget to Congress, Congress trimmed AIDS appropriations considerably [51–53]. However, the World Bank loans did heavily subsidize other AIDS programs and health infrastructure for nearly a decade, allowing the NAP to work around a sometimes uncooperative Congress.

In conclusion, World Bank loans had several of their intended consequences as well as many unintended consequences. The intended consequences were to quickly implement health infrastructure for AIDS and STI treatment and to rapidly develop extensive facilities for treatment and care of PLWHA. The consequences unintended by the World Bank were the reinforcement of the NAP as an independent, centralized agency; and utilization of World Bank loans to work around an unreliable and often unsupportive Congress, whose support for AIDS budgets was often unpredictable in the late 1990s. Most remarkably, when Pedro Chequer became director of the NAP, World Bank loans were used to directly support the AIDS movement's treatment objectives, which sometimes directly conflicted with strategic objectives outlined in the World Bank loan terms. World Bank loans deepened the relationship of the AIDS movement with the NAP, subsidized treatment activism, and reinforced the activist culture within the NAP. Treatment activism helped encourage political actors to support AIDS treatment to the detriment of conducting important monitoring and evaluation research related to program performance in reducing HIV transmission and identifying cost-effective interventions. Ironically, the unintended consequences are the most enduring legacies of the NAP.

The Evolving Political Context of the Late 1990s

The late 1990s mark a turning point in development of AIDS treatment institutions. At FHC's urging, Health Minister Albuquerque resigned after his controversial statements about AIDS treatment budgets. In many ways, this is symbolic of the political sway the AIDS movement wielded by 1998. Though Congress did not appropriate sufficient funds for AIDS treatment until late 1998 [52, 53], never again did any high-profile politician speak publicly against funding AIDS treatment in Brazil. Political action by the AIDS movement, political action and campaigns from within the NAP, and Sarney's Law had established a path of institutional development for AIDS institutions in Brazil. Institutional commitments to deliver AIDS treatment were in place and health infrastructure was being implemented

toward that end with World Bank loan support. Moreover, the NAP had become a quasi-independent agency that developed a global reputation for its successful treatment program. All of these developments help explain why AIDS institutions in Brazil have been surprisingly robust; as a result of these phenomena, it became increasingly difficult for political actors to ignore the federal government's obligation to finance AIDS treatment. Political actors stood more to gain by endorsing the AIDS movement's causes. Rather than ignore the AIDS crisis or object to AIDS spending, political actors in the legislative and executive branch of government began endorsing the causes of the AIDS movement and using AIDS issues for strategic personal political gains.

By the late 1990s, politicians across the political spectrum began to support AIDS causes and began catering to AIDS movement for strategic political gains. For example, legislation was introduced by the right-leaning PFL party that would forbid insurance companies the right to deny AIDS patients coverage because of preexisting conditions. José Serra of the center-left PSDB party, who was appointed Health Minister in 1998 by President Cardoso, made a major push for adoption of the law (Law 9.656) in Congress and it was ultimately adopted in 1998 [54–56].

Also, a bill sponsored by sanitarista Deputy Sérgio Arouca outlawed commercial blood sales and implemented regulatory infrastructure toward that end [57]. Though the 1988 Constitution outlawed commercial blood sales, in the absence of any regulatory structure, commercial blood sales had continued illegally. Arouca's bill helped abolish those illegal practices.

Just two years after President Cardoso threatened to veto Sarney's Law, Brazilian First Lady Ruth Cardoso was defending the cost effectiveness of AIDS treatment in global political fora [58]. Also, Vice President Marcos Maciel had helped move appropriations for AIDS II through Congress. In an interview, Pedro Chequer commented:

Vice President Marcos Maciel was a very important figure for the AIDS program. He was the person who made the decision on [World Bank loan] AIDS II...Health Minister Albuquerque was opposed; it was Maciel who supported us. So we aligned ourselves with him and asked him to release the funds for AIDS medications. Another high-profile person who was really important was first lady Ruth Cardoso. She was the person who supported us in Geneva, launching our program successes globally in 1998. What I'm saying is, we had some very important political allies, politicians who were sympathetic to our cause, and who ensured that our programs were well-received [5].

These politicians had not supported AIDS causes in the early 1990s. This symbolizes how Pedro Chequer and the AIDS movement had helped create the institutional conditions in which it became politically advantageous for political actors to support AIDS treatment.

One of the AIDS movement's most important allies was Health Minister José Serra, who is widely recognized as the most influential and successful Health Minister in post-authoritarian Brazil. Serra served as Health Minister from 1998 to 2002. Serra was a former Planning Minister and the first economist to serve as Health Minister. As a member of the 1988 Constituent Assembly, a founding member of the PSDB party, and a politically active member of the Brazilian

intelligentsia who had lived in exile during the dictatorship, José Serra is also known as one of Brazil's most committed public servants and democratization advocates. A politician who used his Health Ministry post to launch his 2002 Presidential bid, Serra likely realized he would gain far more from working with the AIDS community than resisting the rising costs of AIDS treatment, which proved disastrous for the former Health Minister. Serra included generous sums for AIDS treatment in his Health Ministry budgets, allied with the NAP and the activist community in efforts to extract more funds for AIDS drugs from Congress, and used the media to accomplish his AIDS policy goals. Each year, the Health Ministry battled with Congress about appropriations for AIDS. In an interview, José Serra explained how he used the media to encourage Congress to appropriate more funds for AIDS:

Congress is often opposed to increasing spending or policy changes. I learned that my best strategy for getting what I wanted out of Congress was to take my issues public. Once you've got public opinion behind you, Congress doesn't want to oppose public opinion... that was important for all my political victories [59].

Serra used the media throughout his tenure as Health Minister to lobby for Congressional support for AIDS programs. In 1999, when Brazil had a major economic crisis and the value of the real plummeted 80%, Serra publicly declared that devaluing of the real would not affect access to AIDS drugs, linking HAART to sustained mortality decline [60, 61]. In April 1999, Serra promised that the Health Ministry supplement the AIDS drug budget and that "there will be no stockouts" [62]. In June, using activist-like rhetoric, Serra requested NGO help in mobilizing support for AIDS treatment and requested that the Minister of Education also help with prevention; Serra exclaimed in a rally, "We have to mobilize the entire country for this cause!" [63].

In September 1999, NAP director Pedro Chequer echoed Serra's calls for President Cardoso to decree an additional appropriation for AIDS drugs, linking poor Health Ministry finance to dramatic statements like "AIDS patients will die without drugs and Brazil will lose all it's gained." Activists from *Pela Vidda* protested forthcoming stockouts, directing their criticisms toward Cardoso rather than Serra, holding him responsible for potential deaths of 70,000 on treatment [64]. There were nationwide protests about budget cuts before stockouts ever happened; 70 NGOs gathered in São Paulo to protest budget cuts [65, 66]. On September 10, 1999, President Cardoso sent Congress an emergency appropriations bill for AIDS drugs, and Vice President Marcos Maciel publicly lobbied the Congress to approve the appropriation. The bill passed and AIDS drug stock remained stable [67].

When making budget cuts, Serra publicly pressured even President Cardoso to increase AIDS treatment spending. In August 2000, Serra announced that he had been forced to cut Health Ministry expenditure by \$1 billion reals because of the currency crisis, including \$100 million reals in AIDS spending.⁵ He declared that President Cardoso could decree another \$118 million reals for AIDS, but that the remaining \$100 million would have to be appropriated by Congress [68, 69]. By

⁵One billion reals was approximately US \$350 million at the time of the currency crisis.

aligning himself with the AIDS movement and publicly lobbying on its behalf, Serra insulated himself from political pressure related to financial challenges related to providing free and universal access to HAART.

All of these developments signal that the AIDS movement had finally won the support of a variety of high-profile politicians by the late 1990s. This process of political inertia is common in processes of path-dependent institutional development. Once there was a federal mandate for treatment, sanitarias and the AIDS movement controlled the NAP, and AIDS activists held the government accountable for its legal duty to provide drugs for AIDS treatment, it became increasingly difficult for political actors to deviate from the path of endorsing AIDS treatment. Once the primacy of AIDS issues had gained more widespread political support, politicians had more to gain by supporting than opposing the AIDS movement's causes. Increasing numbers of political actors were willing to support costly AIDS treatment programs, and many publicly allied themselves with the AIDS movement.

Though political actors' endorsement reinforced existing commitments to treatment, the cost of AIDS treatment was quickly rising as Brazil scaled up treatment and included new drugs in its guidelines (Figure 5.1). This fiscal dilemma posed a serious political challenge for political actors in the executive branch of government; the Health Ministry was legally obligated to provide free and universal access to treatment, a vibrant AIDS movement promised to hold the Health Ministry accountable for this commitment, yet the costs of treatment were rising much more quickly than Congressional appropriations. These institutional conditions gave rise to José Serra's political entrepreneurship related to AIDS. Rather than try to cut spending for the treatment, which had historically provoked strong political responses from the NAP and the AIDS movement, political actors, namely Health Minister José Serra, opted for a different tactic to lower the rapidly rising costs of AIDS treatment.

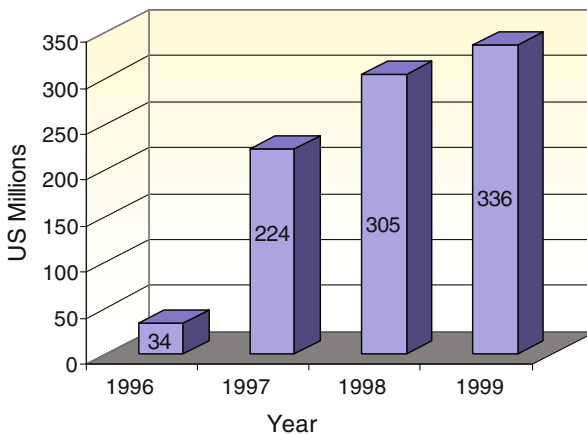


Figure 5.1 HAART expenditure from 1996 to 1999 in US\$ millions

The 1998 Drug Policy Reforms

A series of drug policy reforms in the late 1990s also influenced development of Brazil's AIDS treatment institutions. Previous health reforms had not clearly defined the role of the local, state, and federal governments in drug procurement, quality control, and regulatory policy. As part of the ongoing process of decentralization of Brazil's health system, CEME, Brazil's central drug agency, assumed less responsibility for drug policy throughout the 1990s and ultimately closed in 1997 [70, 71]. José Serra's National Drug Policy (Health Ministry Portaria 3.916) aimed to replace CEME by formally decentralizing drug policy in Brazil. The National Drug Policy also aimed to bring Brazil into compliance with World Health Organization (WHO) guidelines for rational medicines use [71].

The National Drug Policy defined Brazil's contemporary public drug policies and paved the way for a series of important regulatory reforms. The policy introduced a policy for rational use of medicines and a pharmacovigilance system in Brazil, required transparent public bidding for generic drugs purchased by the government, clearly defined the role of each level of government in provision of essential medicines, and reiterated the importance of public drug production to meet population drug needs. The National Drug Policy also paved the way for Brazil's 1999 law regulating generic pharmaceutical products and a new drug regulatory agency,⁶ raised quality standards for generic medicines and required bioequivalence tests for all generic medicines produced in Brazil [71, 72]. The National Drug Policy also delegated national drug and quality standards to the federal government and transferred funds to the states, which assumed responsibility for most drug procurement. States were required to dispense drugs to municipalities that administer them to the patients in local health care settings. Under the law, Brazil's 5,000+ municipalities are also responsible for purchasing drugs for primary health care.

These reforms are important for two reasons. First, they highlight Serra's commitment to much-needed general drug policy reforms in Brazil. Second, they had important impacts on ARV drug policy in Brazil. Though Sarney's Law had not explicitly outlined whether the state or federal government should supply and finance antiretroviral drugs in 1998, after the law was implemented, AIDS drug procurement and distribution were centralized, including ARVs and drugs for opportunistic infections (OIs). However, in 1998, a commission of experts on the National Drug Policy formally delegated ARV procurement and distribution to the federal government and drug procurement and distribution for opportunistic infections (OIs) to the states [73, 74]. Little information is available on this regulation and how it developed; no one interviewed for this book know much about this policy's development. The policy nevertheless had profound impacts on AIDS treatment institutions. Since 1998, ARVs have been financed by the Health Ministry

⁶Brazil's drug regulatory agency is called ANVISA and is similar to the US Food and Drug Administration (USFDA).

but distributed by the NAP with an entirely separate drug logistics system. In contrast, drugs for OIs are procured and distributed by the states.

This distinction is important for explaining differential access to drugs for OIs and ARVs after 1998. Though this book focuses on ARVs, these differences underscore many of the institutional arguments this book makes, namely, that exceptional, centralized policies for ARVs have led to stabilization of access to HAART, while access to other drugs, including OIs, has remained sporadic in Brazil. Though drugs for OIs are much cheaper than ARVs, drug supply has been notoriously unreliable. Differential access to ARVs and drugs for OIs have been cited in the news as well as in recent studies [45, 46, 75–77]. Had drugs for OIs remained in control of the well-functioning NAP bureaucracy, drug supply for OIs may not have been so problematic.

A Decisive Step: José Serra and the Domestic Production of ARVs

In 1998, José Serra decided to centralize and increase domestic production of generic antiretroviral drugs and threaten to issue compulsory licenses in order to produce patented ARVs locally. This decision is the next critical juncture in this analysis. Here, these issues are disaggregated for clarity, but are considered part of a unified decision by José Serra to lower the cost of AIDS treatment. These traditions shaped the AIDS institutions observed today in Brazil and have been the subject of international political controversy.

José Serra's policy choices were strongly influenced by the earlier path of development of Brazil's AIDS treatment institutions and drug policy reforms. Serra's menu of policy choices were constrained by a limited Health Ministry budget; an AIDS movement and a NAP that publicly demanded that the Health Ministry implement free and universal access to AIDS treatment; and Brazil's Industrial Property Law, which restricted the use of locally produced generic ARVs to those introduced in Brazil prior to May of 1997. All of these factors, coupled with new and important drugs integrated in Brazil's treatment guidelines (Appendix A), caused the cost treatment to rise rapidly after Sarney's Law. However, the political cost of cutting the HAART budget had also become very high. This institutional environment influenced Serra's political options and gave rise to his political entrepreneurship related to providing drugs for AIDS treatment.

At the previous political junctures discussed in this book, political actors made sudden and unexpected decisions that had long-term implications for AIDS treatment in Brazil. In contrast, the issue of how to fund costly AIDS treatment was publicly discussed and debated for several years prior to José Serra's decisions to scale up production of generic ARVs and threaten to issue compulsory licenses. With a legislative mandate for free and universal access to treatment, a vocal NAP director pressuring for continuity in treatment programs, a vibrant social movement to hold the government accountable for implementing its mandate, the incoming Health Minister was expected to address these issues. With the rising domestic and

international profile of the AIDS program, a Health Minister that could successfully tackle the rising costs of AIDS treatment would have much to gain politically. Given the institutional climate in which Serra was operating and his well-known presidential ambitions, a public policy response to the rising costs of AIDS treatment from the Health Minister was not surprising; fiscal tensions for addressing AIDS treatment had been percolating for nearly a decade and social pressure to effectively scale AIDS treatment had reached new heights. What is most compelling about this critical juncture is not Serra's decision to act in response to the rising cost of AIDS treatment, but the innovative way he chose to address the rising costs of AIDS treatment.

Serra addressed the rising cost of HAART immediately after he became Health Minister in 1998. He met with Eloan Pinheiro, then director of Farmanguinhos, a federal public drug laboratory and factory, to research whether Brazil might be able to produce more generic antiretroviral drugs in public factories. Previously, most publicly produced antiretroviral drugs had been produced at LAFEPE, a state-owned drug laboratory in the Northeastern state of Pernambuco. Eloan Pinheiro commented on José Serra's decision to begin producing generic ARVs at Farmanguinhos:

Because of Sarney's Law, in 1997, the government was really being pressured about providing antiretroviral drugs.... In 1998, when Health Minister Serra came in, we began preliminary discussions about producing antiretroviral drugs. José Serra decided to really take on this issue, at Pedro Chequer's urging, and with his support. And that is when Farmanguinhos really took up this issue and developed a strategic plan for producing AIDS drugs. The pressure from the AIDS patients was so strong by that time...we'd been discussing this issue of improving access to AIDS medicines since Lair Guerra's time, but it was Serra who really took up this issue.

Under Serra, the strategy was first to develop the drugs that weren't patented...and then develop the patented drugs. This wasn't just to break the patents; this was also to provide cheaper generics to AIDS patients [78].

It is important to note that Farmanguinhos' strategy did not include producing raw materials; rather, Farmanguinhos, like LAFEPE and other public laboratories in the early 1990s, purchased raw materials from other sources. The biggest challenge for scientists at Farmanguinhos was to develop technology to test the quality of raw materials purchased from other sources, mostly from India and China. Hilbert Ferreira, then Chief of Production at Farmanguinhos, described Farmanguinhos' technical strategy for developing ARVs in an interview:

The grand secret of the pharmaceutical industry is the synthesis of the molecules. That's the tricky part: producing a product that has tolerable levels of chemical impurities on an industrial level at a competitive cost...that was our big investment and the basis of our production strategy. We spent a whole year perfecting our analysis of the raw materials we bought from other producers. Then we bought a lot of equipment for the production area – computerized equipment, compression machines, the machines that stamped the powder into pills, the packaging machines. That brought us into compliance with Good Manufacturing Practices.

And that was how antiretroviral drugs were born at Farmanguinhos. We went in the order that drugs were brought to market. We started with the non-patented drugs, AZT, didanosine, stavudine, and lamivudine...*then* we started with the protease inhibitors and the patented drugs.

The strategy to scale up public ARV production began at Farmanguinhos. Other factories, including FURP in São Paulo, IQUEGO in Goiás, and LAFEPE in Pernambuco, also scaled up antiretroviral production in the late 1990s [79]. Ferreira also commented on this strategy:

Not all of the drugs were produced at Farmanguinhos. This was a deliberate strategy by the Health Ministry. To prevent stockouts, or in the event of an emergency at any of the factories, Farmanguinhos never produced more than 40% of Brazil's ARVs [80].

This was part of José Serra's centralized plan to ensure long-term stability of drug supply for AIDS. In an interview, Eduardo Martins, director of Farmanguinhos prior to Eloan Pinheiro, explained Serra's strategy of using Farmanguinhos:

Until the late 1990s, the government bought some ARVs from Wellcome, negotiated prices, bought some from LAFEPE, bought some from Microbiológica. It wasn't an organized policy. Then, when José Serra became Health Minister, he decided to fight with the industry. And by then, there were other drugs. It wasn't just AZT anymore – there were new antiretroviral drugs by 1997. José Serra decided to conduct an AIDS campaign, more for his own political propaganda for his later presidential campaign. You see, AIDS had become a high-profile issue in Brazil: it appears in the media, it's international, there are international conferences, et cetera. Serra highlighted that Brazil was the only country that provided free HAART, and it had to do so by law, and he made it an international issue.

Serra used Farmanguinhos first because it was a federal laboratory. Eloan Pinheiro, Director of Farmanguinhos, convinced him it was possible to make antiretroviral drugs. Serra invested a lot of money, and Farmanguinhos started making antiretroviral drugs – before the Health Ministry had always gotten its drugs from disparate sources. Serra centralized the policy. Farmanguinhos started buying raw materials from India and China. You see, it wasn't until José Serra entered the scene that Farmanguinhos began making antiretroviral drugs. When I was director, I never had the temerity to even suggest any such thing – we didn't have the technical capacity to produce antiretroviral drugs back then [81].

The process of technological development that Ferreira described took place during 1998 and 1999, before José Serra took this issue public in late 1999. The coordinated strategy did not appear in the press until the late 1990s, when Eloan Pinheiro announced that Farmanguinhos would manufacture protease inhibitors [82]. Even then, only one news article was found that mentioned the issue.

Other less well-known factors generated positive feedback that reinforced the government's public production of antiretroviral drugs. In 1998, when the Health Ministry began centralized procurement of raw materials for ARVs, it required that all firms participate in public bidding for pharmaceutical products. Microbiológica, which had up until then supplied the raw materials to the public factories producing ARVs and also produced ARVs for public consumption, could no longer compete with Asian companies' prices for raw materials. Nor could Microbiológica compete with the public sector for producing drugs, as the government removed what was formerly a hefty import tax on raw materials for government purchases, but continued taxing raw materials imported by the private sector. Together, these policies minimized the role of the Brazilian private pharmaceutical industry in production of generic ARVs and strengthened the role of the public drug factories [80, 81, 83–85].

As mentioned earlier, Brazil's strategy of scaling up public generic production had two objectives. The first objective was to develop a centralized public strategy

for supplying generic ARVs not under patent for the NAP's treatment program. The second, and most controversial, of Serra's goals was to develop generic versions of ARVs under patent protection in Brazil. If Brazil's public laboratories had the capacity to produce generic copies of patented ARVs, Serra could consider issuing a compulsory license either to produce generic versions of ARVs under patent or to use the threat of compulsory license as a tool to negotiate reduced prices for costly ARVs. Under TRIPS rules, a compulsory license allows governments to produce or grant a third party authority to produce a drug without consent of the patent holder in cases of national public health emergency, among other limited circumstances. Threatening to issue a compulsory license was part of Serra's plan to reduce the cost of treatment, either by producing drugs locally or by inducing price negotiations from multinational pharmaceutical companies.

Because of the increasing number of patients taking HAART, and the currency crisis which devalued the Brazilian real, Brazil's ARV drug stock was in peril by late 1999. Though Congress had passed an emergency appropriations bill for AIDS spending, on October 6, 1999, President Cardoso also issued a Presidential Decree that amended Article 71 of Brazil's Industrial Property Law, which governs the conditions under which compulsory licenses can be issued. (In an interview, Marcos Vaina, Brazilian diplomat to the WHO, commented that Serra had requested that Cardoso issue this decree [86]. However, neither Cardoso nor Serra commented on this in interviews [59, 87].)

Decree 3.201 expanded and more clearly defined the conditions under which Brazil could issue a compulsory license in cases of public interest or national emergency. Though the decree did not mention drugs specifically, it outlined public health reasons as a key justification for issuing a compulsory license [88, 89]. The decree was a strong signal that President Cardoso was considering issuing a compulsory license in order to suspend intellectual property rights for select ARVs. This coordinated effort by the Cardoso Administration to address the high costs of HAART is another sign of the political momentum for AIDS treatment that had developed in the late 1990s.

Though Farmanguinhos and other laboratories had been developing plans to roll out public production of antiretroviral drugs for some time, José Serra first took this issue public on World AIDS Day in December 1999. At a press conference, Serra condemned Brazil's costs of \$5,000 per patient per year for antiretroviral treatment and the exponential rise in cost as Brazil scaled up treatment while applauding the 37% mortality decline stemming from AIDS treatment [90, 91]. Serra announced increases in domestic ARV production, an increase in overall treatment spending, and declared:

There is a Presidential decree that allows for patents to be broken in the case of abusive prices, and two of our AIDS drugs are candidates for this clause. The laboratories will not be penalized if they lower their prices....The prevention campaigns cost ten times less than treatment. Not that our motivations are just economic...it's human, it's about solidarity. But we've got to take costs into consideration [91, 92].

This was the first public announcement by José Serra about producing ARVs locally and his first public announcement that Brazil would explore the possibility

of “breaking patents⁷” because of the high prices of nelfinavir and efavirenz, two patented antiretroviral drugs. At that time, efavirenz cost US \$2,540 per patient per year (PPPY) and nelfinavir cost \$5,585 PPPY, which dwarfed the then \$320 per capita health spending in Brazil. Since FHC had decreed the cases under which the government could issue a compulsory license, the Brazilian government could legally issue a compulsory license and produce generic ARVs in compliance with both domestic and international intellectual property regulations. A compulsory license would allow Brazil to either produce generic versions of patented ARVs or might induce multinational pharmaceutical companies to negotiate the ARV costs.

Brazil has a long tradition of negotiating ARV prices. Eduardo Cortes, NAP director from 1990 to 1992, negotiated prices for Brazil’s first AZT purchase from Wellcome and each subsequent purchase during his tenure [93]. Similarly, news articles in 1996 also document Lair Guerra’s successful negotiations for lamivudine, and Brazil’s first protease inhibitors, including saquinavir, zidovudine, and didanosine [94, 95]. Executives from multinational pharmaceutical companies confirmed that Brazil had negotiated prices in the 1990s before Serra began threatening to issue compulsory licenses [13, 96]. However, this was the first public announcement in which any Health Minister had threatened to issue a compulsory license if multinational pharmaceutical companies did not lower their prices. This was also the first time that price negotiations for ARVs were publicly discussed.

Serra’s high-profile public press conference signals that this was no longer a technical discussion taking place behind the scenes. With this deliberately highly politicized move, Serra was able to strategically use previously latent institutions such as price negotiations and disparate, decentralized production of ARVs in new ways to address the rising cost of AIDS treatment. In an interview, when asked why he chose to scale up domestic drug production and threatened to issue compulsory licenses to address the rising cost of AIDS treatment, rather than less geopolitically risky decisions, José Serra explained:

The thing is, I [as Health Minister] didn’t have enough money [for antiretroviral drugs]. The costs were rising at an unsustainable level. It’s that simple. That’s why we decided to increase generic production for everything that wasn’t patented and use the patent law’s exceptions. The patent law went into effect in 1997. The law favored American interests, but the patent law did allow exceptions for public interest and cases where the drugs weren’t produced in Brazil.

So I decided to use those local public interest exceptions. But always with caution. I first had to talk to the Indian drug laboratories to make sure I could get the raw materials from them. Because you can’t threaten to break a patent if you can’t actually produce the drugs – the problems aren’t only legal – there are also technological barriers.

The Ministry of Foreign Affairs was very concerned about what I was doing. That’s natural, because they have to deal with all the pressure from other countries. But the President, Fernando Henrique [Cardoso] gave me cover, he supported what I was doing [59].

⁷“Breaking patents” is a nontechnical, informal term often used to describe the process of issuing a compulsory license. However, since there are legal avenues for issuing compulsory licenses, “breaking patents” is somewhat of a misnomer.

President Cardoso confirmed in an interview that his Administration had endorsed Serra's decisions [87].

Serra's entrepreneurial decision took advantage of important legal loopholes related to generic drug production and international patent law. Serra's intended to import raw materials and then conduct the requisite scientific research to formulate the raw materials into drugs in Brazil. This is permitted under articles 42 and 43 of the 1996 Industrial Property Law, which permit importation and use of locally patented products from third parties without the consent of the patent holder under limited circumstances. These articles permit patented products and processes to be used for several limited purposes, including (1) scientific research purposes and (2) noncommercial uses that do not infringe on the economic interests of the patent owner [89].⁸ Under these exceptions to the industrial property regulations, Brazil's government was not legally required to issue a compulsory license to import generic raw materials for drugs under patent in Brazil. Serra's decisions would allow Brazil's public laboratories to legally import and conduct research on how to formulate the imported raw materials into drugs for "scientific and technological research purposes." Brazil could then threaten to issue a compulsory license in order to locally manufacture generic versions of patented ARVs if and when its public factories produced the drugs for public consumption.

This decision to scale up generic ARV production and threaten to issue compulsory licenses is a critical juncture in this analysis. It is impossible to know exactly why Serra made this decision. Given the political momentum behind the AIDS treatment movement, Serra likely could not have ignored the AIDS treatment crisis altogether. However, he might have opted to focus his efforts on greater Congressional appropriations, acknowledge the AIDS treatment crisis while continuing to muddle through its challenges (as previous Health Ministers did), or deflected Health Ministry criticisms back to Congress or the President. Serra might also have scaled up local generic drug production without threatening to issue compulsory licenses or could have limited the drugs in treatment guidelines to generics. He might also have instated strict drug price controls or continued private price negotiations with the multinational pharmaceutical industry. Since Serra's decision resulted in enduring AIDS treatment institutions, if Serra had chosen any of the aforementioned options, AIDS treatment institutions in Brazil would be different today.

Serra was able to use several previously latent institutions in new ways, accommodating his strategies to the institutional environment in which he operated.

⁸This type of article is not exclusive to Brazil; most countries include a similar clause in their intellectual property laws, particularly those related to medicines. For example, the 1984 US Drug Price Competition and Patent Term Restoration Act, (usually referred to as the Hatch-Waxman Act), a federal law designed to stimulate generic drug development in the United States, has a similar clause entitled the "Bolar Amendment." The Bolar Amendment allows biomedical research using patented compounds given that the findings are of important public use. This clause was included in the law to stimulate generic drug research so that generic drugs could be launched immediately after innovator drug companies' patent terms expire.

Though Serra's political options were constrained by Sarney's Law, political pressure from the AIDS movement inside and outside the state, and the Industrial Property Law, Brazil's public capacity to produce ARVs and traditions of negotiating drug prices provided Serra with options for changing the strategic direction of AIDS treatment in Brazil. Serra's choice may have been his best option for preserving free and universal access to treatment, lowering the costs of AIDS treatment, gaining political and media attention in preparation for his 2002 presidential bid, and accomplishing his well-known goal of making important public policy contributions while he was the Health Minister. Recognizing the political opportunities for progressive change with the AIDS program, Serra embraced what he recognized to be Brazil's health policy strengths and used political entrepreneurship to build upon them for his own political gain.

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Chapter 6

Brazil's Contributions to Global Essential Medicines Institutions

Growing Political Momentum for Affordable Access to Medicines

As Brazil discovered, the TRIPS agreement and new intellectual property regulations dramatically increased the costs of scaling up highly active antiretroviral therapy (HAART). Brazil was not the only country to realize that the TRIPS agreement might affect drug costs and population access to medicines. In 1997, the South African parliament passed the *Medicines and Related Substances Control Amendment Act*. This legislation was intended to facilitate access to generic medications in South Africa [1, 2]. The bill outlined the circumstances in which South Africa could issue compulsory licenses and use parallel importation to reduce the cost of pharmaceutical products.¹ The law prompted the South African Pharmaceutical Manufacturer's Association (PMA) to bring a lawsuit against the South African government in 1998. The PMA claimed that the law violated the TRIPS agreement, allowed generic companies to appropriate their intellectual property without compensation, and believed the law would flood the market with low-quality generics. Both the United States and the European Union threatened trade sanctions against South Africa. US trade sanction threats were announced by Vice-President Al Gore during the Clinton Administration [2–7].

In December 1999, Thailand, which also had a sizable public AIDS treatment program and also enjoyed the capacity to produce generic ARV medicines in public factories, was considering issuing a compulsory license to produce a generic version of the ARV didanosine, whose patent is held by Bristol Myers Squibb. In response, US also threatened trade sanctions against Thailand [3].

Though the Thai government eventually backed down and did not issue the compulsory license, the South African government countered the South African PMA's

¹Parallel importation refers to trade that takes place outside legally sanctioned distribution systems. In the context of pharmaceutical policy, parallel importation occurs when patented drugs are produced and sold in one market and then imported into a second market without authorization of the patent holder in the second market. Parallel trade usually occurs when drug prices differ across markets. The ability of the patent holder to legally exclude parallel imports depends on whether a country abides by rules of domestic or international exhaustion of international property rights. Countries with national exhaustion forbid parallel trade of pharmaceutical products and countries with international exhaustion permit parallel trade. Parallel trade is permitted in some markets; for example, the European Union permits parallel trade of pharmaceutical products [4].

lawsuit against the state in South African courts. Trade sanction threats prompted strong reactions from a growing global AIDS treatment movement that organized international protests to publicly denounce US trade sanction threats, global ARV prices, and the impact of free trade agreements on access to medicines. These developments, coupled with a global AIDS treatment movement, new availability of generic ARVs from India, and Brazil's global activism for AIDS treatment, helped fuel sea changes in global AIDS treatment policy.

The Global AIDS Treatment Movement

After the Vancouver AIDS conference, in the late 1990s, a variety of international advocacy organizations in several different countries became increasingly vocal about the global need to address global HIV/AIDS treatment challenges. Doctors Without Borders (Médecins Sans Frontières, MSF), an NGO that had historically focused on providing direct medical services to underserved populations in developing countries, began its *Campaign for Access to Essential Medicines*. MSF began the campaign after learning that many of its field offices could not provide adequate medical services to underserved populations because of prohibitive costs of many medicines, particularly ARVs. MSF's campaign promotes transparency about global drug prices and advocates affordable drug prices in developing countries [8]. Partners in Health, a Boston-based NGO with ties to Harvard University, vigorously promoted community-based approaches to treating infectious disease epidemics in developing countries, particularly AIDS and tuberculosis [9, 10]. ACT UP, an activist group that sponsored US treatment campaigns for over 10 years, began advocating global AIDS treatment. Oxfam International, an international poverty reduction organization, also became active in these AIDS treatment access discussions. In South Africa, the Treatment Action Campaign (TAC) was formed in 1998 to promote affordable treatment for people living with HIV/AIDS (PLWHA) [3].

In 1999, many of the aforementioned NGOs, as well as the Consumer Project on Technology, a consumer advocacy group funded by Ralph Nader (CPTech), Health Action International, and others formed a coalition called the Health Global Access Project Coalition (Health GAP) to promote greater access to AIDS treatment. Through campaigns and political action, these organizations demanded that multinational pharmaceutical companies lower ARV prices, which they claimed had detrimental impacts on access to medicines. Health GAP brought attention to public health implications of the TRIPS agreement as well as US and EU retaliation on developing countries that implemented policies to enhance population access to medicines. Seizing Al Gore's 2000 Presidential campaign as an opportunity to get media coverage for AIDS treatment issues, Health GAP followed Gore on the campaign trail, blaming him for the US stance on South Africa trade sanctions. Brook Baker, one of Health GAP's spokesmen, noted that

Health GAP, ACT UP and the Treatment Action Campaign were very active in the campaigns against Al Gore. He was the man who threatened the sanctions against South Africa for the Clinton Administration. They shamed him at every campaign stop, with banners,

chants, and signs about threatening trade sanctions on Africa at the same time that Africa was trying to respond to the AIDS crisis. That campaign against Gore was so successful that in December 1999, Clinton wrote a letter saying the US Trade Representative could no longer exert trade pressure on certain sub-Saharan countries [11].

Health GAP's campaign was very important to the global AIDS treatment movement because it prompted and provided momentum for a series of important policy changes during the Clinton Administration that paved the way for a series of global institutional changes. First, Clinton rescinded trade sanctions on South Africa. In January 2000, Gore testified before the UN Security Council, recommending that the AIDS epidemic be considered a global security threat and announced \$100 million in increased AIDS spending [12]. Gore's responses helped legitimize the global AIDS treatment movement and also signaled that the AIDS movement's campaigns and political action had been very effective in shaping US policy.

Additionally, between 1999 and 2001, TAC and MSF were able to mobilize global political action related to the South African PMA's lawsuit against the South African government. Protests against the PMA took place around the world and got significant media coverage, ultimately culminating in PMA withdrawal of the lawsuit against the South African government in April 2001 [2] (Figure 6.1).

As happened with many other social movements in the last 15 years, with the rise of the internet and global telecommunications improvements, the global AIDS treatment movement evolved quickly in the late 1990s and early part of the twenty-first century. The global AIDS movement used the internet increasingly more for its campaigns and political action tactics, vigorously defending developing country public health interests. Even more importantly, as public policy issues grew increasingly interdisciplinary and complex, a coalition of NGOs such as MSF, CPTech, Oxfam International, Health GAP, TAC, and others were no longer engaging solely in campaigns, political action, and international advocacy.

Moreover, as developing countries began serious efforts to resist US retaliation for their drug and trade policies and global essential medicines institutions, the coalition of advocacy organizations began providing *technical and legal* assistance to developing country governments to help change domestic and global essential medicines institutions, including, on occasion, the Brazilian Health Ministry and National AIDS Program [8, 11, 13–18]. The global AIDS movement's political action, campaign, and technical support became important to the historical developments this chapter explores.

Global Launch of Generic ARVs

Another important development occurred in early 2001, when Indian generic drug manufacturer Cipla launched a generic fixed-dose combination of three ARVs. Since India had not yet adopted an intellectual property law to comply with the TRIPS agreement and did not yet recognize intellectual property rights for drug products, Indian companies could legally produce and export generic ARVs. As a result of Cipla's new product offerings, the cost of AIDS treatment in many

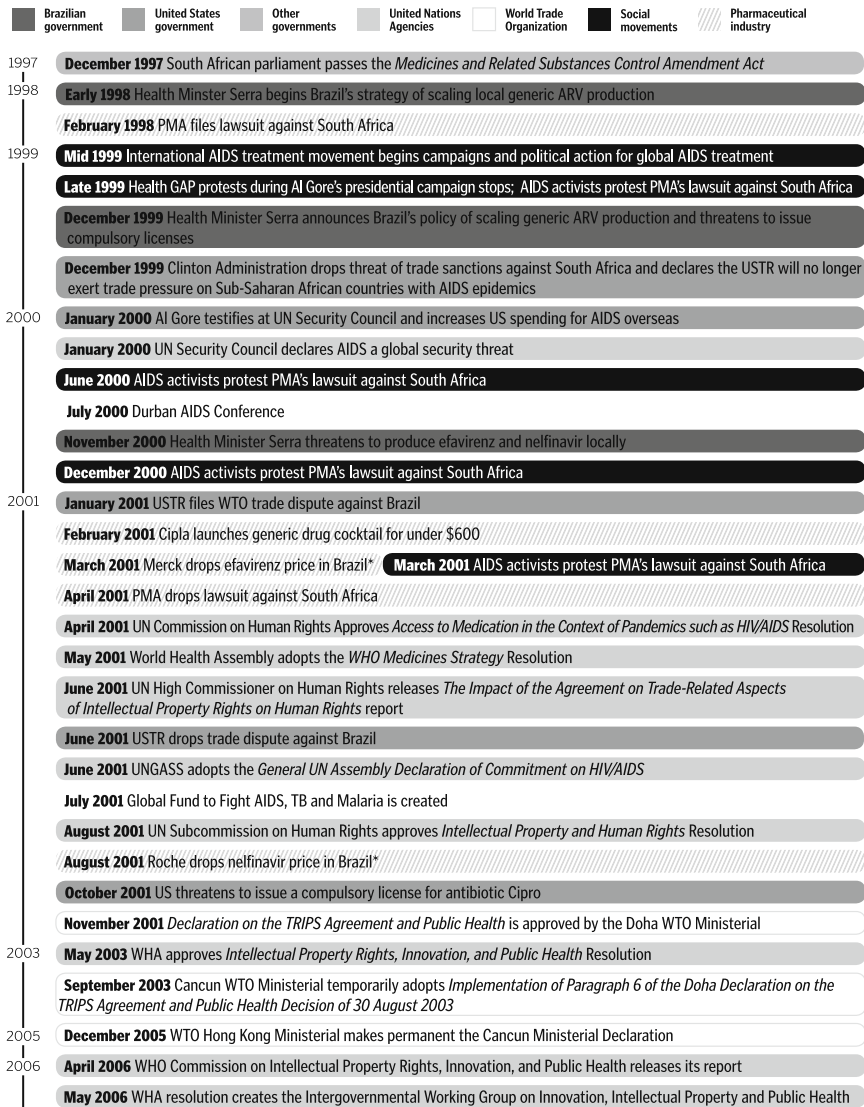


Figure 6.1 Timeline of important international events

developing countries dropped from approximately \$10,000 annually to below \$600 for a fixed-dose combination of three generic ARVs [19, 20]. This allowed for many developing countries to consider treating AIDS patients, which had previously been considered prohibitively expensive by multilateral development agencies and developing country governments. This dramatic decline in drug prices revolutionized global AIDS treatment institutions.

This new market for generic ARVs was directly tied to Brazil's AIDS treatment program. One reason Cipla had been able to undertake this project is that Brazil

helped create a market for raw materials for generic ARVs. By scaling up local production of ARVs, Brazil created demand for raw materials for generic ARVs. With economies of scale, the average cost of raw materials decreased steadily over time [14]. This process fed on itself: as the prices dropped, more countries began offering HAART to PLWHA. Cipla's success induced other generic drug firms in India and China to enter the ARV market, and increasing economies of scale and generic competition continued lowering ARV costs over time [21–26]. Declining generic drug costs also helped fuel the global AIDS treatment movement.

The Global Fund to Fight AIDS, Tuberculosis, and Malaria

In an effort to mobilize greater financial resources for AIDS, tuberculosis, and malaria, in July 2001, at the urging of United Nations (UN) Director General Kofi Annan, the G-8 financed creation of the Global Fund to fight AIDS, Tuberculosis, and Malaria. The Global Fund finances both state and nonstate activities related to prevention, treatment, and care for the three infectious diseases accounting for the largest percentage of total disease burden in developing countries. By financing and endorsing AIDS treatment and promoting use of generic drugs, The Global Fund helped legitimize the global AIDS movement's claims about the importance of AIDS treatment.

A series of important international events were thus occurring simultaneously with Brazil's efforts to lower AIDS treatment costs. This institutional environment both influenced Serra's decision to attempt to change global essential medicines institutions for essential medicines and also influenced the way he chose to implement his decision.

José Serra's Essential Medicines Strategy

Throughout 2000, José Serra continued announcing threats to issue compulsory licenses for nelfinavir and efavirenz,² claiming the two drugs accounted for 80% of AIDS treatment expenditure in 2000 [27]. In November 2000, at a press conference with a large activist presence, Serra announced, "If they [Merck and Roche] don't lower their prices, we're going to produce those drugs in generic form" [28]. In November, the Health Ministry first announced Brazil's \$472 million in official savings from producing generic drugs locally [29]. Also, in June and November 2000, NAP director Paulo Teixeira³ announced that the Health Ministry was considering transferring its generic ARV technology to Lusophone Africa [29–32].

² In Brazil, efavirenz is licensed to Merck and nelfinavir is licensed to Roche.

³ In March 2000, Pedro Chequer stepped down as National AIDS Program director to accept a position at UNAIDS. Sanitarista Paulo Teixeira, who had coordinated Brazil's first AIDS programs in São Paulo in 1983 and helped start the NAP, assumed directorship of the NAP. Equally vocal about maintaining Brazil's commitment to AIDS treatment, he played an instrumental role in Brazil's global essential medicines strategy.

The pharmaceutical industry had kept a close eye on what was happening in Brazil in the late 1990s and throughout 2000, but had not responded publicly to Brazil's threats. However, newspapers began reporting on the United States PMA's Washington lobbying efforts to encourage US trade sanctions in response to Brazil's announced policies [33]. Brazil's announcements in mid and late 2000 likely prompted the US Pharmaceutical Research and Manufacturer's Association (the United States PMA became the PhRMA in 2001) to begin pressuring the United States government to launch a trade dispute against Brazil at the WTO.

It was in this context, in early 2000, *before* the US government and pharmaceutical industries officially responded to his previous decision, that José Serra decided to attempt to influence global essential medicines institutions. Though this decision had to be approved by the President and implemented by the Ministry of Foreign Affairs, José Serra initiated and shepherded implementation of these policies. President Fernando Cardoso personally approved this decision [13, 15, 16, 34–37].

Serra's decision is the fifth and final critical juncture of this analysis and is hereafter referred to as Brazil's global essential medicines strategy. A decision to unilaterally challenge the multinational pharmaceutical industry and the US government would have resulted in very different local AIDS treatment institutions and global essential medicines institutions. A decision to resolve these issues privately with the pharmaceutical industry rather than to use the media and the international AIDS movement would also likely have resulted in different institutional and economic outcomes in Brazil and in international political fora. Since development of the global essential medicines strategy was path-dependent, and each new global institution reinforced previous global institutions and provided positive feedback for Brazil's AIDS treatment institutions, a decision not to change any one of these institutions might have changed the cumulative impact of Serra's global essential medicines strategy and the strategy's impact on Brazil's AIDS treatment institutions.⁴

José Serra and several diplomats interviewed for this project commented that Serra adopted the global essential medicines strategy because Brazil was anticipating a very vigorous response from the US government and the multinational pharmaceutical industry, particularly since the US had imposed trade sanctions on Brazil in the 1980s and 1990s. All commented that Brazil's strategy to change global institutions was a strategic means to counter potential US and pharmaceutical industry opposition to Brazil's AIDS treatment policies; Serra knew he could rely on the global AIDS movement to campaign on Brazil's behalf [13, 15, 16, 35, 38]. José Marcos Viana, a Brazilian diplomat who then represented the Health Ministry in foreign affairs (a position created by José Serra), explained Brazil's essential medicines strategy:

We had several pillars in our strategy. One pillar was to defend Brazil's stance on AIDS drugs in several of the UN agencies. We had to defend our position and change international

⁴Brazil's strategy to change essential medicines, discussed in a forthcoming article by Nunn, da Fonseca and Gruskin in *Global Public Health*, is discussed in greater detail in this chapter [39].

public opinion about these issues, with the press, with NGOs, in every way possible. The UN agencies were a vehicle for changing public opinion about Brazil's stance on AIDS issues and also for changing the legal frameworks to accomplish our objectives. Normally, all of these issues are reserved for the WTO. We decided our most effective line of defense would be to open the discussion to the Commission on Human Rights and the World Health Organization as well. The idea of moving our resolutions through the UN agencies was important for shaping global public opinion in our favor. So we developed a strategy at the World Health Assembly to introduce medicines resolutions. At the Commission on Human Rights, we pushed through that resolution that documented that access to medicines was a fundamental human right.

Our idea was that the Health Ministry, working with Itamaraty [Brazil's Foreign Affairs Ministry], was going to win over international public opinion. Our strategy was *not* to defeat the US government; the balance of power was not in our favor. The only way to win a trade dispute with the US, to convince the American government to change its policies, is to change the American public's opinion, and the opinion of the world. So that was our strategy, at the WHO, at the Human Rights Commission, at the WTO, with other NGOs, with the New York Times and other countries, to convince the American public to support us.... We bought ads in the New York Times, the Washington Post, the Los Angeles times, all the big papers in the US [16, 39].

The decision to challenge the pharmaceutical industry and the USTR carried significant geopolitical risk: at the time, Brazil had an annual US \$25 billion trade relationship with the United States [40]. As is common at critical junctures, it is impossible to fully understand Serra's personal motivations for making this decision. When asked directly why he chose this policy, he again simply remarked that the costs of the treatment had become prohibitively expensive and that pharmaceutical companies set unreasonable prices in developing countries [15].

Serra's decision was certainly influenced by the path-dependent process in which Brazil's AIDS treatment institutions developed. He had committed to continuing Brazil's policies of free and universal access to treatment and had threatened to issue compulsory licenses to lower the cost of AIDS treatment. Serra understood that his fiscal dilemma had expanded beyond Brazil's borders to become an international relations dilemma: given what had happened in South Africa, and Brazil's history of trade sanctions from the United States, Serra knew his previous choices would likely prompt retribution from the US government and the multinational pharmaceutical industry. However, Serra was also riding a wave of popularity for his previous decisions, which created political momentum for Serra to continue using political entrepreneurship to solve his fiscal dilemma. Moreover, he had the support of the President, the Foreign Ministry, the NAP, and both the local and global AIDS treatment movements, which had grown increasingly more vocal in the last year because of the South African lawsuit and trade dispute. Though the decision posed serious geopolitical risk, it was likely more politically advantageous for Serra to challenge the US government, the pharmaceutical industry, and to attempt to change global institutions than to back down on his political promises. In terms of Serra's personal political objectives, it may not have mattered if Brazil lost any international dispute; he'd still heighten his personal profile. The personal political benefits of his decision likely outweighed the

personal political risks; each time Serra Brazil's international efforts to support its AIDS treatment policies appeared in the media, he gained name recognition, which was useful for his 2002 presidential plans.⁵

Implementation of the global essential medicines strategy was a complex web of events that unfolded slowly over the next several years. To fully unpack its development and implications requires an explanation of each important institution to highlight the cumulative impacts these institutions had on global essential medicines institutions and Brazil's AIDS treatment institutions.

Brazil's Efforts to Change Global Essential Medicines Institutions in 2000

Brazil began its efforts to change global essential medicines institutions at the World Health Assembly (WHA)⁶ in May 2000, when Brazil first introduced WHA resolution 53.14 entitled *HIV/AIDS: Confronting the Epidemic*. The proposal solicited a WHO-sponsored international price index for essential medicines that would be continuously updated to provide developing country governments with access to information on global ARV prices. France, Zimbabwe, and South Africa also supported the resolution. The resolution prompted an aggressive response from the multinational pharmaceutical industry and the US delegation [41, 42]. Though the resolution ultimately failed, it signaled Brazil's plans to continue linking AIDS, drug and trade issues in the international arena.

At the July 2000 AIDS conference in Durban, South Africa, several developing country governments and advocacy organizations discussed strategies for lowering the cost of generic ARVs. This was one of the first times that Brazil began trying to mobilize other developing country governments to support its AIDS treatment policies. Sanitarista and then NAP Director Paulo Teixeira⁷ commented that this was the first time that Brazil began collaborating with other developing countries, NGOs, and the media to promote its own program and global access to AIDS treatment:

The discussion became international in 2000. The Durban AIDS Conference is when everything changed. Like I said, 95% of developing countries then didn't offer treatment. Brazil was in the minority, and there was a lot of criticism of our program. So we took the debate public and international in 2000. One of our goals then was to help expand the

⁵Serra's name and this topic appeared in over 400 Brazilian news articles used in this book research.

⁶The World Health Assembly is the World Health Organization's decision-making body and has 192 member delegates from each of the world's nation states.

⁷Paulo Teixeira, who had established Brazil's first public AIDS institutions in 1984, replaced Pedro Chequer in 2001. Teixeira continued Chequer's social movement repertoire, and even became vocal at the international level about Brazil's AIDS treatment initiatives.

number of countries offering treatment to reinforce our treatment policies and our strategy of local drug production....

And other countries started coming to us for help, so we started offering technology transfers, offering to teach them how to produce generics. The only way to sustain our program in the long term and confront rising costs was to break patents. The Health Minister authorized me to talk about that issue publicly. By the end of 2000, we knew that the USA was going to file a trade dispute about our patent law at the WTO, so we developed an international press strategy [31].

Teixeira's June 2000 announcements about technology transfers to other developing countries may have been what finally prompted the pharmaceutical industry to respond to Brazil's threats. Naturally, the industry was concerned about losing market share in Brazil. However, industry concerns became more acute when Brazil announced its intention to export its AIDS model to other countries. The pharmaceutical industry feared that Brazil's policies might be replicated elsewhere without providing the pharmaceutical industry with royalties, or that Brazil might begin exporting generic ARVs [43]. Under conditions of anonymity, another pharmaceutical executive offered his opinion, which reflects a common industry perspective about the perceived dangers of Brazil's AIDS treatment institutions:

Pharmaceutical companies have always, since the 1990s in Europe, been reluctant about deep-discounting in poor countries or emerging market countries, or countries on the periphery of the major markets, fearing that with all this chatter and drum-banging and even legislative openings for parallel importation that the lowest price would suddenly become everybody's price. You can cloak it all you want, but when a state steals a private company's intellectual property and awards it to a state-owned, state-run pharmaceutical company, is a clear conflict of interest. So I'm very harsh on this, very harsh... I think first of all, that the US government should retaliate.

In interviews, executives from the pharmaceutical industry all mentioned serious concerns that the Brazilian government was threatening to appropriate the industry's intellectual property without just compensation in accordance with international and local law [43–46]. At the urging of the multinational pharmaceutical industry, in January 2001, the United States government launched a trade dispute against Brazil.

Brazil's Contributions to Global Essential Medicines Institutions in 2001

The year 2001 was a global turning point for essential medicines institutions and AIDS treatment institutions; a number of interrelated and complex political events took place in 2001 (Figure 6.1). Many of the institutional changes can be attributed to Brazil's essential medicines strategy. However, the changes but are situated in the context of a WTO trade dispute against Brazil, Brazil's continuous threats to issue compulsory licenses for the ARVs, and the global AIDS treatment movement's support of Brazil's policies.

In 8 January 2001, at the great urging of PhRMA, the United States Trade Representative (USTR) launched a formal WTO trade dispute against Brazil [47]. The trade dispute cited article 68 of Brazil's 1996 Industrial Property Law, which requires that all foreign companies produce their patented products *in Brazil* within 3 years or else be subject to compulsory license. The United States claimed that the Brazilian Industrial Property Law was in direct violation of the TRIPS agreement, which is intended to guard against such protectionist measures. This controversial clause of the Brazilian law was included to encourage development of local industry. However, the Clinton Administration claimed that article 68 violated Article 27:1 of the TRIPS agreement, which states that

Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced [48].

The US trade dispute did not directly address Brazil's AIDS treatment program or its strategies to threaten to issue compulsory licenses to lower the cost of AIDS treatment. This may be attributed to the public relations disaster of the former USTR threats of trade sanctions against South Africa in 1999, as well as the fact that Brazil's strategy to lower the cost of HAART had not actually violated the TRIPS agreement. Since article 68 of Brazil's Industrial Property Law *did* potentially violate the TRIPS agreement, it was an indirect means of addressing Brazil's controversial AIDS treatment policies.

At José Serra's urging, Brazil countered the US trade dispute through legal means and immediately engaged the media. Diplomat Viana commented:

One pillar in our line of defense against the WTO dispute was to do to the Americans what they did to us. We looked at the American patent law and prepared a dossier in which we documented that articles 204, 205 and 209 violate the same code they were accusing us of violating. Between February and June of 2001 we launched our international battle of defense, which got the support of international NGOs and newspapers, including Tina Rosenberg's big New York Times article, *Look at Brazil*. The help of the media, NGOs, general public opinion, and even other governments was very important. We had several pillars to our defense: public opinion, the legal dimension, and the press. It was a very effective way to fend off the WTO dispute [16].

The US trade dispute did not prompt Brazil or Serra to back down; to the contrary. During the dispute, José Serra intensified his condemnations about drug prices and continued his threats to produce nelfinavir and efavirenz locally. President Cardoso announced that "Brazil is very firm about this. We will not cede one millimeter for something that is not in Brazil's public interest" [49, 50]. Several diplomats commented that they knew that Brazil could not win the WTO dispute through legal discussions alone, and that for that reason, diplomats began couching the trade dispute and Brazil's AIDS treatment program in life or death terms [13, 16, 35, 38]. Fred Meyer, Brazil's diplomatic representative to the UN Commission on Human Rights, perhaps best articulated the Brazilian position in an interview:

AIDS is not your typical commercial dispute. We're not talking about oranges or cotton or airplanes, which Brazil and the US have argued about. This is not just commerce; this was different. This was a question of human survival and that was how we framed it: *in life and death terms* [35].

Framing the issue in this manner helped the Brazilian government attract media attention and support from the global AIDS treatment movement.⁸ Though there were never any formal long-term partnerships between the international treatment movement and the Brazilian Health Ministry, by the year 2000, the global AIDS movement and José Serra had developed a symbiotic relationship: Serra depended on the global AIDS movement to promote his AIDS and essential medicines platform, and the social movement depended on Serra's political entrepreneurship to advance its goals related to AIDS treatment. As a result, when the WTO launched its dispute, the global AIDS treatment movement endorsed the Brazilian AIDS treatment cause and vigorously campaigned and engaged in political action tactics on behalf of the government [3, 8, 11, 14, 15, 17, 18, 54].

In addition to informally relying on the global AIDS treatment movement, Brazil also made concerted efforts to engage the media. Hundreds of news articles were printed in 2001 that raised the profile of the Brazilian AIDS treatment program, most notably a very favorable New York Times Magazine cover article entitled "Look at Brazil" by Tina Rosenberg [55]. Increasing media attention deliberately generated by the global AIDS movement and the Health Ministry buttressed the Brazilian stance in advance of its efforts to influence global essential medicines institutions.

In May 2001, building on the 2000 General Comment 14 of UN Committee on Economic, Social and Cultural Rights, which interprets the human right to health, Brazil introduced a resolution to the UN Commission on Human Rights⁹ entitled *Access to Medication in the Context of Pandemics such as HIV/AIDS*. Citing the General Comment's call for access to essential medicines, this resolution specifically called for nation-states to treat individuals with HIV/AIDS.

The United States strongly objected to the resolution. US ambassador Moose's floor speech best underscores the US government's strong reluctance to support any health rights, particularly those related to HIV/AIDS treatment and medications:

Simply put, this is bad public health policy. This resolution is, in essence, a flawed health document, not a human rights document. Complex health matters are best dealt with by the UN organization that has the technical competence in those matters – the World Health Organization. The 191 member states that comprise the World Health Assembly will be

⁸However, at the time, Brazil's local social movement was generally far less engaged about global treatment access discussions than domestic treatment access discussions. In interviews, several activists explained this was due to the complexity of the global treatment discussions [51–53]. Brazilian NGOs that had helped move Brazil to the frontier of AIDS treatment were interested in global access issues; however, international discussions required far more sophisticated policy dialogues and global engagement, and Brazilian NGOs did not develop the capacity to engage in policy dialogue on these issues until *after* Brazil's trade dispute with the United States.

⁹The UN Commission on Human Rights was the UN treaty body that drafts international human rights resolutions until 2006, when it was replaced by the Human Rights Council. The UN Commission on Human Rights' historical mandate has been to examine, monitor, and report on human rights situations and violations worldwide. The institution has historically been composed of 53 member states who are elected each year. The Subcommission on Human Rights is a subsidiary body of the Commission on Human Rights. It is composed of 26 experts representing the world's different regions. The Subcommission conducts reports and makes recommendations to the UN Commission on Human Rights.

meeting here in Geneva in three weeks time, and both HIV/AIDS and WHO's Revised Drug Strategy will be on the agenda. That is the most appropriate venue for health matters.

My government is also concerned by references which appear to be aimed at creating a new category of rights, such as the reference to the right to the highest attainable standard of physical and mental health. The United States does not support the creation of legally enforceable entitlements or the establishment of judicial or administrative remedies at the national or international levels to adjudicate such presumed rights [56].

The US abstained from the vote on this resolution, signaling its dissension to Brazil's controversial AIDS treatment policies. Nevertheless, the Commission overwhelmingly approved the resolution (52–0, with one abstention) in April 2001. *Access to Medication in the Context of Pandemics such as HIV/AIDS* was the first resolution adopted by the Commission on Human Rights that specifically addressed the human right to access to medicines. The resolution recognizes HIV/AIDS treatment as a fundamental component of the right to the highest attainable standard of physical and mental health. Article four of the agreement calls on states:

To facilitate, wherever possible, access in other countries to essential preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them, as well as to extend the necessary cooperation, wherever possible, especially in times of emergency;

To ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and that the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceuticals and medical technologies [57].

This resolution later proved to be overwhelmingly important to historical development of Brazil's AIDS treatment institutions and global essential medicines institutions. Once the right to AIDS medicines had been recognized as part of the human right to health, it became increasingly difficult for global political actors and institutions, including the pharmaceutical industry, governments and international agencies, to deny the importance of AIDS treatment. Moreover, substantive resolutions and reports cited and reinforced this resolution, and this resolution was renewed and updated every year through 2005.

In June 2001, the UN High Commissioner on Human Rights released a report entitled *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*. The report, though not exclusively linked to Brazil's campaign for access to medicines, identifies potential areas of conflict between intellectual property rights and human rights and identifies a normative human rights approach to interpreting the TRIPS agreement. This document highlights global disparities in access to medicines and the challenges poor countries face in paying market prices for drugs under patent. The report further describes disparities between developed and developing countries with respect to technology innovations, warning that TRIPS protections may deter state obligations to respect, protect, and fulfill the right to health. Finally, the report alludes to Brazil as an example of the dilemmas developing countries face in

promoting access to essential medicines at affordable prices [58]. Mary Robinson, then the UN High Commissioner, declined to be interviewed for this research. However, other experts commented that Brazil appeared in the report as a result of its world-renowned treatment policies and efforts to scale up AIDS treatment [59, 60]. The important document signaled that as a result of Brazil's vigorous campaigning, not only had it helped interpret the right to health in the context of HIV/AIDS, it had won the support and endorsement of the High Commissioner on Human Rights.

Intellectual Property and Human Rights Resolution

In August 2001, shortly after approval of *Access to Medication in the Context of Pandemics such as HIV/AIDS* and release of the High Commissioner's report, the Subcommission approved another resolution entitled *Intellectual Property and Human Rights* without a vote. It's unclear who introduced this resolution; however, it affirmed, for the second year in a row,¹⁰ the primacy of human rights laws over other rights, including economic rights:

...Reminds all governments of the primacy of human rights obligations under international law over economic policies and agreements, and requests them, in national, regional, and international forums, to take international human rights obligation and principles fully into account in international economic policy formation [61].

Other scholarship attributes this resolution to the UN Commission on Human Rights' interest and commitment to protecting the human rights of indigenous populations and its efforts to address potential conflicts between human rights and intellectual property rights related to medicines [62, 63]. Regardless of who introduced this latter resolution, the cumulative impact of all of these human rights resolutions helped reinforce Brazil's AIDS treatment institutions and underscored the primacy of international human rights law, which newly included access to medicines and drugs for AIDS treatment over trade agreements.

In May 2001, shortly after Brazil introduced its resolution at the UN Commission on Human Rights, to further advance Brazil's AIDS treatment agenda and counter the January WTO trade dispute, in May 2001, Brazil introduced another controversial resolution at the WHA. The resolution, entitled the *WHO Revised Drug Strategy* (WHA52.19), proposed to expand access to essential medicines and most controversially called for the WHO to pass measures to allow for developing countries to expand access to generic drugs. More specifically, the resolution called for member states to:

¹⁰A similar resolution had been approved in 2000 as part of a movement to protect the human rights of indigenous populations.

Cease and desist immediately from bilateral actions that effectively obstruct the efforts of other Member States to expand access and local production of generic drugs, where doing so has the potential to improve the health of millions of people, and particularly those in least developed countries; and

Provide the requisite international financial and technical assistance, as legally mandated in Article 12 of the International Covenant of Economic, Social and Cultural Rights, to enable measures undertaken by less developed Member States to expand access to essential drugs [64].

In 2000, the UN Committee on Economic, Social, and Cultural Rights issued *General Comment 14*, which interprets the human right to health guaranteed by Article 12 of the International Covenant on Economic, Social, and Cultural Rights. Article 12 reaffirms the provision of drugs for treating illnesses as fundamental components of infectious disease control programs [65]. In this proposed resolution, Brazil attempted to link human rights and essential medicines institutions, claiming that developing countries should be permitted to use locally-produced generics to uphold their commitments to fulfill the human right to health [35]. This strategy of linking human rights in WHA resolutions was highly unusual but had tremendous impacts on essential medicines policy.

The resolution also echoed Brazil's previous request for an international pricing database, calling for the WHO Director General to:

Facilitate Member States in urgently implementing, in partnership with non-governmental organizations, database systems for monitoring and reporting global drug prices and a consolidated worldwide database, in order to make it feasible, especially for least developed countries, to have reliable information and equity in access to essential drugs within their health systems [64].

In addition, Brazil, Zimbabwe, and other developing countries lobbied for the WHO to advise developing countries on IP issues related to health. Although José Serra campaigned vigorously for this resolution, even delivering a speech at the WHA to lobby for support of Brazil's position, the resolution was not adopted [66].

However, after a WHO report reiterated the concerns expressed in the Revised Drug Strategy resolution, a new 2001 WHA resolution entitled *WHO Medicines Strategy* (WHA54.11) was adopted during the 54th WHA. The new resolution superseded the former WHA *Revised Drug Strategy* and outlined a more comprehensive approach to promoting access and rational use of essential medicines. The new resolution preserved the link to the human right to medicines as detailed in the UNCHR resolution, *Access to Medication in the Context of Pandemics such as HIV/AIDS*. Although the strong language in the former Brazilian resolution was never adopted, it had a profound impact on the final themes of the 2001 *WHO Medicines Strategy* (WHA54.11), which encouraged states to implement policies that guarantee access to medicines, including medicines for HIV/AIDS. The final 2001 *WHO Medicines Strategy* resolution also responded to Brazil's 2000 request for development of a global drug pricing monitoring system, calling for the Director General to

Explore the feasibility and effectiveness of implementing, in collaboration with nongovernmental organizations and other concerned partners, systems of voluntary monitoring drug process and reporting global drug prices with a view to improving equity in access to essential drugs in health systems and to provide support to member states in that regard [67].

The *WHO Medicines Strategy* had important and lasting impacts on the historical institutional development of Brazil's AIDS treatment institutions. WHO acknowledgement of the human right to medicines, overwhelming global unmet need for AIDS treatment, and transparency about drug prices fueled local and global political momentum for Brazil's ongoing efforts to reduce patented drug prices. Global discussion about drug prices relative to per capita health expenditure in developing countries also lent further legitimacy to Brazil's controversial strategies.

The WHO Medicines Strategy resolution also had lasting impacts on global essential medicines institutions. As a result of the resolution and the new evidence base for treatment in developing countries, the WHO added ARVs to its Essential Medicines List in 2002 for the first time [68]. This established ARVs as part of the minimal standard of medicines for all health systems and represented official WHO endorsement of treating PLWHA. Once the WHO had endorsed treatment as a fundamental human right and classified ARVs as essential medicines, it became increasingly difficult for global political actors and institutions to deny the importance of treating infectious diseases in developing countries, particularly AIDS.

This resolution led to WHO policies to encourage greater transparency about drug prices. WHO began financing the Management Sciences for Health's (MSH) International Drug Price Indicator Guide, which is published once a year and provides electronic access to drug pricing information for many types of drugs [69]. Along with MSF's annual "Untangling the Web of Price Negotiations" the Drug price Indicator Guide reduced information asymmetries between manufacturers and purchasers of essential medicines, and price transparency helped foster important international dialogue about ARV prices.

Another result of this resolution was creation of the WHO-sponsored "prequalification system" for drug manufacturers considered for official WHO product endorsement. The prequalification process is a quality assessment and bioequivalence testing process designed to enhance access to high-quality drugs for AIDS, malaria, tuberculosis, and reproductive health. To gain official WHO prequalification status and to be used in any programs funded by UN agencies, both patented and generic drugs must meet bioequivalence, good manufacturing, laboratory, and clinical practices [70]. Raising the quality standards for generic drugs has been overwhelmingly important for essential medicines policy and scaleup of global AIDS treatment.

Additionally, in 2001, Brazil Sponsored *Scaling up the Response to HIV/AIDS* at the WHA. This resolution called on member states to promote and distribute generic drugs for HIV/AIDS treatment. Specifically, the resolution called for member states to establish health policies which promote access to drugs through:

Policy initiatives which embrace the right to use technical and intellectual capacity for the in-country production of AIDS drugs, under the auspices of the agreements reached within the bounds of international law, such as the TRIPS agreement;

Support for the establishment and financing of an International Fund for the promotion of access to antiretroviral and anti-opportunistic infection drugs, based upon the principle of equity;

Implantation of a policy to facilitate the supply of drugs, including the production and distribution of generic drugs and the negotiation of prices with pharmaceutical drugs companies, in accordance with the social and economic development profiles of each country [71].

After Brazil engaged in a long conference with the United States, South Africa, Sweden, and Thailand, the resolution was substantially watered down [72]. However, the final *Scaling up the Response to AIDS* resolution refers to the previous Human Rights Commission Resolution, *Access to Medication in the Context of HIV/AIDS*. The resolution encourages member states to:

In order to increase access to medicines, to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order to promote innovation and the development of domestic industries consistent with international law [73].

The resolution *Scaling up the Response to AIDS* officially endorsed use of locally-produced generics and represented tacit WHO endorsement of Brazil's AIDS treatment institutions. *Scaling up the Response to AIDS* also culminated in official WHO policy discussions about the impact of trade and intellectual property rights on access to medicines in developing countries. Perhaps most importantly, the resolution also called for creation of a global fund for HIV/AIDS and health by urging member states to "support the creation of a global HIV/AIDS and health fund." Official WHA endorsement of a global health fund fueled international political momentum for creation of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

US Drops WTO Dispute

During the entire first six months of 2001, the aforementioned coalition of organizations was campaigning and engaging in political action on the Brazilian government's behalf. Oxfam, MSF, CPTech, and others coordinated advocacy efforts to denounce the USTR response to Brazil's AIDS treatment program as well as abusive pricing on ARVs [11, 14, 17, 21, 54, 74]. Additionally, over 100 NGOs and intellectual property experts signed a petition requesting that the USTR drop the trade dispute against Brazil [3]. Brazil had used the media to lobby for its cause, sending press releases, taking out ads in major newspapers, and encouraging journalists to cover the trade dispute.

After much international protest from the global AIDS treatment movement and a strong response from the Brazilian government, on 25 June 2001, the first day of the United Nations General Assembly Special Session on AIDS (UNGASS), the USTR dropped the WTO trade dispute against Brazil. That day, USTR Robert Zoellick announced that

The Bush administration wants to resolve trade disputes by seeking constructive solutions to problems that arise...I stand four-square behind strong enforcement of the WTO rules on intellectual property. However, litigating this dispute before a WTO dispute panel has not been the most constructive way to address our differences, especially since Brazil has never actually used the provision at issue. The understanding reached with Brazil over the

issue represents another step forward in the Bush administration's "flexible approach" to health and intellectual property issues [74].

Alcides Prates, the Brazilian Diplomat who represented Brazil in the trade dispute with the USTR, commented:

I just read an interview with former President Bill Clinton in which he compliments our AIDS Program. But his government launched the trade dispute against Brazil! The good thing is, the US withdrew the dispute against the Brazil at the WTO. What was important from the beginning was the message that Brazil sent, which was "*We are not going to give up.*" There was this unexpected, helpful support from activists in the US. Remember, at the time, there were different versions of the same story going on with South Africa. The USTR realized it was a much more complex issue than they thought [38].

The USTR dropped its trade dispute against Brazil because of overwhelming international political pressure [14]. Since Brazil's policies had already gained legitimacy at the Commission on Human Rights and the WHA, there was overwhelming global pressure from the global AIDS movement and the media for the USTR to drop the trade dispute [75, 76]. The USTR's decision to drop the trade dispute against Brazil further legitimized Brazil's controversial AIDS treatment institutions on the first day of the UNGASS, where Brazil was promoting its AIDS treatment program.

The UN General Assembly Special Session on HIV/AIDS

In June 2001, shortly after the Human Rights Commission's approved *Access to Medication in the Context of HIV/AIDS* and the WHA approved the *WHO Medicines Strategy*, the United Nations General Assembly held a Special Session (UNGASS) on HIV/AIDS. Brazil promoted its AIDS program and campaigned for resolution text to encourage changes in essential medicines policy during the Special Session. For example, Brazil introduced resolution text that mentioned the public health challenges associated with intellectual property rights, drug prices, and access to essential medicines in developing countries. José Serra gave a speech in which he highlighted Brazil's dramatic decline in AIDS-related mortality, promoted Brazil's policy of producing generic drugs locally as an important option for developing countries with AIDS epidemics, and encouraged pharmaceutical companies to adopt differential pricing policies in developing countries. Serra also strongly urged the General Assembly to commit to providing treatment and affordable medicines to all PLWHA [77].

The final *Declaration of Commitment on HIV/AIDS* encourages heads of state and government representatives to:

By 2003, ensure that national strategies, supported by regional and international strategies, are developed in close collaboration with the international community, including governments and relevant intergovernmental organizations as well as with civil society and the business sector, to strengthen health care systems and address factors affecting the provision of HIV-related drugs, including anti-retroviral drugs, inter alia affordability and pricing, including differential pricing, and technical and health care systems capacity.

Also, in an urgent manner make every effort to: provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS, including the prevention and treatment of opportunistic infections, and effective use of quality-controlled anti-retroviral therapy in a careful and monitored manner to improve adherence and effectiveness and reduce the risk of developing resistance; to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order further to promote innovation and the development of domestic industries consistent with international law [78].

Citing the UNCHR resolution *Access to Medication in the Context of HIV/AIDS*, the Declaration of Commitment also reaffirmed access to medicines as a fundamental human right. Though it was ultimately impossible to tease out Brazil's precise contribution to the *text* of the final resolution, without Brazil's political pressure and evidence base for treatment, UNGASS may not have adopted strong commitments to AIDS treatment. The Declaration of Commitment bolstered the legitimacy of Brazil's treatment institutions, provided momentum for ongoing Brazil's ongoing price negotiations with multinational pharmaceutical companies, and bolstered Brazil's efforts to change global essential medicines institutions. Most importantly, this declaration was a formal universal acknowledgment by the United Nations that AIDS treatment and drug pricing were issues of global public health concern, which provided momentum for ongoing global reforms related to access to essential medicines.

World Trade Organization

Brazil's efforts to shape global trade institutions related to essential medicines began in April 2001, when developing countries began preparing for the November 2001 WTO round of trade discussions in Doha, Qatar. After the failed 1999 WTO Seattle Ministerial conference, which had generated international protests about developing country trade concerns, the Doha trade talks focused more on developing country trade interests.

In April 2001, Zimbabwe, which led a group of African countries in the TRIPS Council, requested that TRIPS council convene a special session related to access to essential medicines in Doha. The President of the TRIPS Council at the time was from Zimbabwe, which has one of the world's highest AIDS rates. After heated controversy about intellectual property rights and access to AIDS medicines in Brazil, South Africa, and Thailand, the TRIPS council met to outline a proposal to address conflicts related to trade and intellectual property for essential medicines [6, 13].

Even after the USTR dropped its trade dispute and Brazil had successfully negotiated enormous price reductions for the ARV efavirenz (discussed in detail in the next section), Brazil was particularly active in endorsing this movement for greater TRIPS flexibilities. The term "TRIPS flexibilities" is often used to refer to policies that permit more flexibility or leniency in enforcing the TRIPS agreement in developing countries, particularly regarding public health issues. Diplomat José Marcos Viana explained why Brazil became so vocal about TRIPS flexibilities in an interview:

Earlier in 2001, José Serra confronted me and said, “Now there is a World Trade Organization dispute against us. I want you to find some way that no one can ever file another trade dispute against Brazil, or against any other developing country related to essential medicines.” He was worried that it would happen again. So that was why Brazil got so active at the Doha round of the TRIPS meetings in November of 2001 [16, 39].

Concerned that Brazil would face another trade dispute or constantly have to defend its AIDS treatment program, Serra wanted to change global institutions to prevent further threats to Brazil’s domestic AIDS treatment model. There was also consensus among other developing countries, particularly those with AIDS epidemics, about a need for greater TRIPS flexibilities in cases of public health emergency.

Between June 2001 and November 2001, the United States, the European Union (EU), and a group of developing countries¹¹ were circulating and discussing different drafts of the *Doha Declaration on the TRIPS Agreement and Public Health*. Brazil, along with several other developing countries, played a key role in drafting the developing country position paper that called for greater flexibilities on essential medicines policy in trade regulations. The developing country coalition favored parallel importation of pharmaceutical products, differential pricing arrangements, and liberal compulsory licensing policies. The United States adopted a firm position in line with multinational pharmaceutical company interests, opposing parallel trade and supporting only very restricted use of compulsory licensing. The US, for example, opposed proposals to allow developing countries to define what constitutes a “national public health emergency” and TRIPS flexibilities that would permit developing countries to issue compulsory licenses in cases of national emergency. The US was also expected to apply strong pressure on other countries to adopt its position. The EU adopted a middle ground [6, 13, 15].

However, one completely unexpected event changed the political landscape. In September 2001, after the attack on the US World Trade Center in New York, when US was facing what was thought to be a bio-terror attack with anthrax bacteria, the United States Secretary of Health and Human Services threatened to issue a compulsory license for Bayer’s Ciprofloxacin, prompting drug company Bayer to lower its prices. The United States subsequently found itself in the awkward position of threatening to issue a compulsory license to induce Bayer to lower its drug prices while trying to restrict compulsory license use in developing countries fighting the AIDS epidemic. This prompted an outcry from consumer advocates and the AIDS treatment movement about the hypocrisy of the US position at Doha [6, 13, 14, 79, 80].

In response to strong political pressure about its hypocritical stance on compulsory licensing, the United States ultimately moderated its position on the Doha Ministerial [13, 81]. According to several diplomats and experts present in Doha, the final text of the Doha Declaration was negotiated behind closed doors between the US and the Brazilian delegation, and the United States ultimately accepted text

¹¹ Developing countries included a group of African nations which called itself the “Africa Group,” Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela.

that closely resembled the developing country coalition proposal [13, 81]. The final text of the Doha Declaration clarified some of the ambiguities in the 1995 TRIPS agreement, which recognized that compulsory licenses could be used in cases of public emergency but did not elaborate on the context in which states can declare public emergencies [48]. The Doha Agreement affirmed the right of each nation to declare and define what constitutes a public health emergency [82]. (Appendix H includes the text of the Doha Declaration). Diplomat Francisco Cannabrava, Brazil's TRIPS negotiator, commented on Brazil's efforts to shape the Doha Declaration:

Our objective was not to do away with TRIPS, but we wanted to preserve TRIPS flexibilities. So that was the very specific objective we pursued in Doha. We knew it wouldn't work to change the TRIPS agreement because that was something that would just take too long. The objective was to avoid very strict interpretation of the TRIPS agreement, to get the WTO to recognize publicly that developing countries had a right to issue compulsory licenses for public health needs.

Brazil was most interested in importing; our generic drug industry has never been able to make raw materials; we imported them from India and China. So importation is what we fought for at Doha. We promoted clauses to allow for importation of raw materials, which Brazil needed to make its generics. In contrast, India wanted to export generics. Africa just wanted to wait on the whole export issue. Since all the developing countries had different positions on importing and exporting, we didn't resolve the paragraph six issues. But we preserved the flexibilities that Brazil needed [13, 39].

Cannabrava's references to "Paragraph six" allude to the challenge developing countries with no domestic pharmaceutical industries would face in securing access to medicines. Paragraph six of the Doha Declaration says that

We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002 [82].

Developing countries with no domestic pharmaceutical industries would neither be able to produce generic drugs by issuing compulsory licenses, nor were they granted the right to engage in parallel trade to meet public health needs. Paragraph six reserved that discussion for future WTO trade rounds. However, the Doha Declaration extended least developing countries' deadline for TRIPS compliance to 2016.

The Doha Declaration proved overwhelmingly important for historical institutional development of Brazil's AIDS treatment institutions and global essential medicines institutions. By affirming the right of developing countries to define and declare national emergencies and issue compulsory licenses, the Doha Declaration allowed Brazil to preserve its AIDS treatment institutions. This further legitimized and reinforced Brazil's traditions of producing generics locally and threatening to issue compulsory licenses and had strong and lasting impacts on HAART costs in Brazil. WTO recognition of the important exceptions to the TRIPS agreement also legitimized the links and associated challenges between trade agreements and public health problems, which provided momentum for ongoing global institutional reforms related to essential medicines.

Price Declines for ARVs in Brazil

During the USTR WTO trade dispute with Brazil, in March 2001, Merck dropped its per-pill prices for indinavir by 59% to \$0.47 and efavirenz by 65% to \$0.84 [83, 84]. Brazil continued negotiating prices with Roche even after the UNGASS and several other changes in global essential medicines policy. After several months of heated price negotiations and Brazil's announcement that it would publicly produce nelfinavir, Roche finally ceded a 40% discount on nelfinavir, dropping its price from US\$ 1.07 to \$0.64 per pill. Serra announced that this program would save Brazil \$35 million annually [85].

After two years of controversy, José Serra's strategy of threatening to issue compulsory licenses finally resulted in major price declines for the two most expensive ARVs in Brazil's budget. Marcos Levy, then Director of Public Affairs at Merck Brazil, commented in an interview that

Merck had been conducting price negotiations with the Health Ministry since 1995, but it was done very quietly back then, and the government still got a good deal. It was José Serra who took this whole thing public when he was running for President [45].

Other pharmaceutical executives also commented about the Health Ministry's strategic use of the media to negotiate drug prices with the pharmaceutical industry. One informant even commented that she often read about Brazil's targeted ARV prices in the newspaper before negotiations even began [43–45]. One executive, who preferred his name not be mentioned, went so far as to say that the most important part of his job was to keep the Brazil ARV patents issue out of the media.

By generating national and international political and media attention to the issue, and by changing global essential medicines institutions, José Serra was able to negotiate unprecedented price reductions for ARVs. Moreover, José Serra gained international name recognition by challenging the multinational pharmaceutical industry and the USTR. Because Brazil saved millions of dollars in these negotiations and their legality had by then been upheld in several international fora, the institutional arrangements proved to be enduring; subsequent Health Ministers and NAP directors continued these policies. Merely *threatening* to issue a compulsory license may offer the greatest political return to these actors: threatening to issue a compulsory license satisfies the demands of the local and international AIDS movements to challenge the high costs of pharmaceutical companies and dramatically lowers treatment costs. Appeasing the social movements helps preserve the support of the social movements whose media campaigns and political actions make price negotiations possible. Additionally, threatening to issue a compulsory license rather than actually issuing a compulsory license likely helps Brazil preserve its now \$30 billion annual trade relationship with the United States. Since decisions to issue compulsory licenses or not negotiate drug prices might produce a different set of less desirable political or economic outcomes, threatening to issue a compulsory license may be the best option for Brazilian Health Ministers and Presidents. As a result of these first publicly debated ARV price

negotiations, Brazil has negotiated prices for several ARVs consuming the largest percentage of its drug budget, saving Brazil over US \$ 1 billion.

The Symbiotic Relationship between José Serra and the AIDS Movement

Once Serra had adopted the essential medicines strategy, the global AIDS treatment movement buttressed his controversial and entrepreneurial decision. The global AIDS treatment movement publicly defended Brazil's stance in every international forum, engaged in vigorous campaigns and political action, and provided technical assistance to other developing country governments supporting Brazil's position, particularly during the Doha negotiations [13, 14, 17, 59].

This exemplifies the common symbiotic relationship of social movements and political actors [86, 87]. Serra made his political decisions based on the institutional environments social movements had helped shape. However, the global AIDS movement also relied heavily on Serra's leadership to advance its goals of promoting global AIDS treatment: until Brazil began efforts to change international institutions, much of the dialogue and political activity related to changing AIDS treatment paradigms was spearheaded by transnational advocacy groups. José Serra and Brazil provided the personal and nation-state leadership that was necessary to propel these reforms forward in the World Health Assembly, the UN Commission and Subcommission on Human Rights, UNGASS, and the WTO. As a result of this symbiotic relationship and the path of institutional development, Brazil was able to preserve its AIDS treatment institutions, fend off a trade WTO dispute from the world's most powerful nation, and dramatically lower the prices of ARVs.

In the absence of Brazil's leadership, watershed developments related to essential medicines institutions may never have occurred. Serra was able to use global institutions and the new global AIDS treatment movement to achieve his domestic political goals of preserving Brazil's AIDS treatment institutions and promoting his own political profile. Seizing a window of political opportunity, Serra was able to harness the energy and technical abilities of Brazil's public drug facilities, the domestic AIDS and sanitaria movements, the Brazilian AIDS program's high-profile public image that Chequer had helped create, and an international movement for AIDS treatment to his advantage. Through concerted efforts to change global essential medicines institutions, Serra was able to shape and change the institutions that had formerly constrained his political options for preserving Brazil's AIDS treatment institutions. In so doing, he lowered Health Ministry HAART costs, enhanced his own political profile, and contributed to important changes in global essential medicines institutions. AIDS expert Richard Parker summarized this phenomenon:

I think there are lots of different reasons [Serra adopted these policies]. Certainly Serra had self-interest in that he very quickly perceived political opportunity. *He* could turn the success of the Brazilian program, which had already been created before he became Health Minister. *He* could ride that into the United Nations and the World Health Assembly, and he could *do politics* on that!

Serra was a very happy combination of a variety of opportunities, so that it was a brilliant thing to put an economist as opposed to a doctor at the National AIDS Program! It was the first time to put an economist in instead of a doctor. So he had a whole different kind of expertise – he could see windows of opportunity – who physicians, who come at this from a totally different viewpoint, just wouldn't see. He quickly saw the opportunities that AIDS presented for his own political career. I'm not saying that in a way that means in any way to demean him – Serra is a very serious man. His goals in life are not only to be a successful politician; he actually wants good things for Brazilian democracy.

And that, from my point of view, though I don't always agree with some of their policies....the thing that the PSDB politicians from that first era...Montero Franco, Cardoso, Serra, and others had in common....they had *um compromisso com a democracia* – strong commitments to democratization – that were very deeply felt. Like Betinho, most of them had been in exile, most of them had escaped out of the country – half of them escaped out of the country through Vera Paiva's basement!¹² And they had a commitment to democracy that was unwavering and unflinching. And almost anything else was secondary to that kind of commitment. Whatever one disagrees with their politics, that commitment never wavered. I don't think it was just political opportunism. I think Serra is recognized as an exceptional administrator. He is one of those people who sleeps three or four hours a day. He works! He's a workaholic. It isn't just his own career he's thinking about. I think when he became Health Minister he did it with the kind of quality that he has tried to do with everything in his life [88].

The importance of Serra's leadership and political entrepreneurship in changing essential medicines institutions to seek viable solutions to the rising cost of Brazil's AIDS treatment were echoed by several Brazilian diplomats [13, 35, 36]. Diplomat José Marcos Viana, who helped move Serra's essential medicines strategy through a variety of international political fora, commented on Serra's political entrepreneurship related to the essential medicines strategy:

This was a new strategy that had never been applied before. The Health Minister has never had this much public power in Brazil. Don't forget, José Serra was running for President. He was the mastermind behind this strategy, and he was Cardoso's preferred successor. If the Health Minister had been any other person, this strategy never would have existed. So for your research, you had better mention that some of this was due to chance, and circumstance. But having a Health Minister who was also running for President that addressed important issues proved to be very good for Brazil [16].

Serra's leadership and strategy and political entrepreneurship shaped Brazil's AIDS treatment institutions. Since 2001, Brazil has consistently engaged in price negotiations with multinational pharmaceutical companies for the ARVs consuming the largest share of its treatment budget and has steadily scaled up AIDS treatment, which had long term impacts on the costs of AIDS treatment. Moreover, if José Serra had not previously adopted the essential medicines strategy, global essential medicines institutions would likely be different today.

¹²Vera Paiva's was a well-known democratization activist and daughter of a famous opposition Congressman who was killed during the dictatorship.

Brazil's Contributions to Essential Medicines Institutions from 2002 to 2006

José Serra eventually lost the 2002 Presidential election¹³ to Luis Inácio da Silva “Lula.” However, Serra’s policies have endorsed subsequent presidential administrations. Brazil’s policies of changing global essential medicines institutions also continued to influence the development of global essential medicines institutions. Many of the changes Brazil moved forward have been reaffirmed. Furthermore, since 2002, Brazil has contributed to the ongoing evolution of global essential medicines institutions.

In 2002, the UN Subcommission on Human Rights renewed the commitments to AIDS treatment with another resolution entitled *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis, and Malaria*. From 2003–2005, resolutions entitled *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis, and Malaria* were approved by the UN Commission on Human Rights. These helped solidify and reinforce global human rights standards related to access to essential medicines.

However, Because many important trade issues were not resolved, the September 2003 Cancun round of WTO trade negotiations was viewed as a failure. Nevertheless, in Cancun, the WTO addressed the “Paragraph Six Problem” of the Doha Agreement. This was reaffirmed in the 2005 Hong Kong round of trade agreements [89]. The paragraph six decision, entitled *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003*, clarifies the parallel importation issue for countries with insufficient pharmaceutical production capacity. The decision sets rigid international standards for compulsory license use for essential medicines, requiring both the exporter and importer to issue a compulsory license, specify the name and quantity of the specific product for import, and label medicines accordingly [90]. Brazil was not active in this round of the WTO public health discussions, for reasons Diplomat Cannabrava explained: Brazil had achieved its primary objective of preserving its AIDS treatment institutions in Doha [13]. Many public health advocates and the AIDS treatment movement hoped that the WTO Ministerial would embrace less rigorous standards and endorse parallel importation. However, a few developing countries have used these TRIPS flexibilities for public health purposes, and these additional flexibilities may never have been possible in the absence of Brazil’s leadership in Doha.

In 2003, Brazil sponsored another important WHA resolution entitled *Intellectual Property Rights, Innovation, and Public Health*. Brazil led a delegation of countries who sought to give the WHO a strong mandate to address intellectual property rights issues that affect public health. The resolution, approved by the WHA, created an independent commission that investigated the public health implications of

¹³Serra later served as Mayor of São Paulo city and in October 2008 was governor of São Paulo state.

intellectual property protection for developing countries called the *Commission on Intellectual Property Rights, Innovation, and Public Health*. Previously, Brazil's efforts had focused largely on institutional changes that would enhance Brazil's AIDS treatment initiatives. By linking intellectual property rights, innovation, and access to a variety of medical technologies for developing countries, Brazil broadened the public policy discussion related to access to medicines [91].

In April 2006, the Commission released its report entitled *Intellectual Property Rights, Innovation, and Public Health*, which finds that intellectual property rights have not stimulated development of new technologies to meet public health needs in developing countries [92]. These findings also have been documented elsewhere [93–95]. The committee, however, was strongly divided about how to address insufficient affordable technologies for developing countries effectively with public policy. Nevertheless, official acknowledgement by the WHO that the global intellectual property system has not led to development of appropriate medical and diagnostic technologies for diseases accounting for the largest disease burdens in developing countries has further legitimized the global AIDS treatment movement and to continue reforms to promote more equitable access fostered global momentum to essential medicines.

The IPR report also contributed momentum to the ongoing debate about changing global research and development paradigms, particularly for diseases primarily affecting developing countries. In May 2006, Kenya and Brazil cosponsored a WHA resolution that called for another working group to develop ideas and report on public policies to address the concerns in the report of the Commission on Intellectual Property Rights, Innovation, and Public Health. The resolution, citing all of the aforementioned WHA resolutions sponsored by Brazil since 2001, calls on the new commission to develop policy recommendations for conducting the research and development necessary to bring drugs to market that address the health problems that disproportionately affect developing countries. The resolution created the *Intergovernmental Working Group on Innovation, Intellectual Property and Public Health (IGWG)*, which met in 2006 and 2007.

IGWG made its policy recommendations just prior to the 2008 WHA. The recommendations culminated in a 2008 WHA resolution, *Global strategy on Public Health, Innovations and Intellectual Property* that commits to exploring novel research and development paradigms to bring drugs and health products to market that address the health needs of developing countries. The WHA will appoint a working group to make policy recommendations for implementation of the strategy by 2010 [96].

Brazil's Enduring Legacies

Brazil's previous path of institutional development for AIDS treatment, along with an international AIDS treatment movement and potential political and economic retaliation for Brazil's AIDS treatment policies, gave rise to José Serra's decision

for Brazil to engage in concerted efforts to change global essential medicines institutions. Once Serra had chosen this political path, the global AIDS treatment movement and other developing countries buttressed Brazil's positions in international political fora. These political processes led to several important changes in essential medicines institutions that reinforced and legitimized Brazil's domestic AIDS treatment institutions. As a result of Brazil's essential medicines strategy, the associated publicity, and the support of the global AIDS movement and other developing countries, Brazil legally preserved its AIDS treatment institutions, continued price negotiations with the pharmaceutical industry, and warded off trade sanctions from the US.

Brazil's global essential medicines strategy, however, also had dramatic impacts on global essential medicines institutions. Brazil's reforms improved global transparency about drug prices, affirmed generic drug use to address public health needs, helped define access to medicines as a fundamental component of the human right to health, and promoted incorporation of ARVs into the WHO Essential Medicines List. Brazil's efforts have helped preserve TRIPS flexibilities for developing countries and may even prompt shifts in research and development paradigms for bringing new drugs and medical technologies to market. Many of these institutional changes helped pave the way for other countries to begin or expand their national AIDS treatment programs. These sweeping global policy reforms highlight the dramatic impacts and enduring legacies of Brazil's large-scale AIDS treatment program.

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Chapter 7

Conclusion

Brazil's rapid progress in procuring and distributing the most modern antiretroviral drugs (ARVs) to 185,000 AIDS patients is remarkable and unmatched by any other developing country. Since 1997, vertical transmission of HIV and AIDS-related hospitalizations, mortality, and morbidity have declined while the life expectancy of AIDS patients have more than tripled from 18 to 58 months [1–7]. Brazil also contributed to major global policy changes that revolutionized global AIDS treatment and global public health.

These health outcomes and global political victories stem from Brazil's AIDS treatment institutions, which developed as the result of the complex, dynamic, and evolving relationship between Brazil's institutions and political actors in post-authoritarian Brazil. Brazil's AIDS treatment institutions were a product of two social movements for health, broader institutional building during Brazil's transition to democracy, Brazil's integration into the post-Cold War global economy, and political actors' responses to these new institutional arrangements. Because Brazil's response to the AIDS epidemic was intricately intertwined with Brazil's democratic and economic development, *The Politics and History of AIDS Treatment in Brazil* used an interdisciplinary research approach to analyze the genesis and evolution of Brazil's AIDS treatment institutions. *The Politics and History of AIDS Treatment in Brazil* that explained the path-dependent development of Brazil's AIDS treatment institutions by elucidating the complex social mechanisms that reinforced and built upon Brazil's AIDS treatment institutions during the last 20 years.

The historical institutional frame helped unpack the complex social phenomena that gave rise to windows of opportunity for political actors to shape major institutional change related to AIDS treatment. Path dependency theory helped explain how the AIDS treatment institutions observed today in Brazil developed as a result of its complex process of democratization, the rise of two social movements, the ISI legacy, and Brazil's integration into the global economy.

Each individual AIDS treatment institution developed under a different set of circumstances. Some institutions, such as Health Minister Guerra's announcement to treat AIDS patients in 1990, and Sarney's Law, developed very quickly but had enduring impacts. Others, such as public production of generic antiretroviral drugs, threats to issue compulsory licenses, and contributions to global essential medicines institutions, most of which developed during the Cardoso Administration, were the result of

long-term strategic planning. Though some of these institutions often arose independently of the others, they all ultimately influenced development of Brazil's AIDS treatment institutions. *The Politics and History of AIDS Treatment in Brazil* explores the process of development of each of these institutions, the important critical junctures in the path of institutional development, the social mechanisms that reinforced development of each institution, and the cumulative impact of all of these social phenomena on the AIDS treatment institutions observed in Brazil today. It also discusses how new democratic institutions, including electoral competition; freedom of assembly, organization and freedom of the press; two social movements; a new judiciary system; and the local political response to globalization pressures influenced development of Brazil's AIDS treatment institutions, as well as global AIDS policy.

Building Brazil's AIDS Treatment Institutions

Each of the five critical junctures the book highlighted explored how the dynamic interaction between Brazil's evolving democratic institutions and political actors influenced historical development of Brazil's treatment institutions.

The institutional response to AIDS in Brazil began in the 1980s as a result of new democratic electoral openings in São Paulo state, which led to the PMDB party victory. The PMDB allowed sanitarias to penetrate the state Health Ministry and implement Brazil's first AIDS programs. The sanitaria movement helped integrate the right to health into the 1988 Constitution, which shaped the institutional and political environment in which political actors and the AIDS and sanitaria movements operated in the 1990s.

The rise of the AIDS movement in Brazil, which was facilitated by new democratic freedoms to organize, protest, and assemble, strongly influenced development of Brazil's first AIDS treatment institutions. As a result of the AIDS movement's lawsuits against local, state, and federal governments in the early 1990s, the judicial branch of government was forced to interpret the right to health in the context of AIDS. Political action through the courts resulted in judicial rulings that the 1988 Constitutional right to health included drugs for AIDS treatment. A variety of other rulings upheld the rights of people living with HIV/AIDS (PLWHA). Favorable court rulings helped shape social norms and prevent institutionalized discrimination against PLWHA. Court rulings also legitimized the AIDS movement's demands of the state. The AIDS movement also combined political action through the courts with political action through the media and public protests. The combination of these developments shaped the institutional conditions that gave rise to the first critical juncture: Health Minister Guerra's startling 1990 public commitment to AIDS treatment. Once the Health Ministry had committed to AIDS treatment, the AIDS movement held the Health Ministry accountable for upholding its commitment. This led to enduring executive branch commitments to AIDS treatment in Brazil.

At the second critical juncture, the AIDS movement found a toehold at the Health Ministry when National AIDS Program's (NAP's) director Lair Guerra invited Brazil's foremost AIDS activists to draft Brazil's World Bank loan proposal. By carving out a large role for civil society in AIDS program implementation, those activists helped create Brazil's first federal partnerships with AIDS NGOs. This institutional arrangement influenced the future path of development of AIDS treatment institutions: by using World Bank loans to create new institutional arrangements, sanitarias and AIDS activists gained financial support for their activities and eventually gained control of the NAP in the late 1990s.

Several of Brazil's AIDS treatment institutions stemmed from other policies that had nothing to do with either the AIDS or sanitaria social movements, including Brazil's Import Substitution Industrialization (ISI) policies, the decision to join the World Trade Organization (WTO) and legislative reforms related to AIDS treatment. Brazil's policies of producing generic ARVs developed in the early 1990s as the product of Brazil's previous import substitution policies (ISI) and new public-private partnerships to bring generic ARVs to market in Brazil. Two legislative reforms approved in 1996 forever changed the course of development of Brazil's AIDS treatment institutions. In 1996, in response to growing pressure to endorse globalization and protect American special interest groups, Brazil's Congress approved a new Industrial Property Law. Brazil became TRIPS-compliant nearly a decade before legal requirements for middle-income countries. The Industrial Property Law profoundly influenced the path of development of Brazil's AIDS treatment institutions by introducing intellectual property rights for drug processes and products after a 25-year hiatus.

By late 1996, Brazil's fragmentary democratic institutions had committed to treatment but had not yet clearly defined the role of each branch of government in providing drugs for AIDS treatment. As a result, Congress had not appropriated sufficient funds for AIDS treatment. These events led to the third critical juncture: Senator and former President Sarney's decision to sponsor a law guaranteeing free and universal access to AIDS treatment. Sarney quickly pushed a bill through the legislature that established free and universal access to AIDS treatment. The bill centralized formerly disparate treatment policy and provided a legal mandate for Congress to appropriate funds for AIDS treatment. Sarney's Law mandated treatment for all PLWHA, but the Industrial Property Law limited political actors' options for implementing the mandate by constraining the use of locally produced generics for AIDS treatment to those introduced in Brazil before May 1997. These two legislative reforms are emblematic of Brazil's newly democratic legislative institutions: the Industrial Property Law initiated in the executive branch of government, and Sarney's Law represents the opaque, patronage-oriented politics so common in post-authoritarian Brazil. Together, these two laws radically changed the course of institutional development for AIDS treatment and caused the cost of AIDS treatment to rise steadily as Brazil began scaling up treatment.

Several complex social processes led to José Serra's decision to scale up local production of generic ARVs and his threat to issue compulsory licenses. Although Sarney's Law created a legal mandate to treat PLWHA, alone, it was not enough to guarantee widespread access to AIDS treatment. Access to highly active antiretroviral

therapy (HAART) did not stabilize until the late 1990s, when both social movements took advantage of windows of political opportunity to move into the NAP federal bureaucracy to implement AIDS reforms, and most importantly, to promote AIDS treatment. Once members of both social movements had moved into positions of public authority, they continued AIDS treatment advocacy from their public posts. They also used World Bank loans to implement health infrastructure for AIDS treatment and Finance the AIDS movement's activities to hold the federal government accountable for its commitments in providing HAART to all PLWHA. As a result of these phenomena, ARV drug supply finally stabilized in 1997.

By the end of the 1990s, by moving into health bureaucracies, employing consistent campaigns and political action tactics to hold the government accountable for implementing Sarney's Law, and actually creating new health infrastructure to treat PLWHA, the AIDS movement had created the institutional openings and incentives for political actors to respond to its demands. Pressure from the AIDS movement, coupled with rising AIDS treatment costs, gave rise to the fourth critical juncture: José Serra's 1998 decision to address the rising costs of AIDS treatment by scaling local generic ARV production and threatening to issue compulsory licenses to produce patented ARVs locally.

José Serra's threat to issue compulsory licenses and produce patented ARVs locally led to the fifth and final critical juncture: Serra's 2000 decision to implement a strategy to change global essential medicines institutions. Serra's decision was a direct response to evolving local and international institutional conditions: faced with rising HAART costs, a trade WTO dispute from the USTR, but armed with the support of a highly effective global AIDS treatment movement and the Cardoso Administration, Serra directly challenged the USTR and the pharmaceutical industry about ARV prices while changing the very global institutions constraining Brazil's AIDS treatment institutions. Serra's essential medicines strategy ultimately helped preserve Brazil's AIDS treatment institutions while simultaneously enhancing his political profile. Serra's strategy, in turn, had profound and lasting impacts on Brazil's AIDS treatment institutions, global essential medicines institutions, and global AIDS treatment institutions.

Costs and Compulsory Licenses

Brazil's AIDS treatment institutions developed in part as a strategy to contain costs while expanding access to HAART. As a result of Brazil's policies of producing generic ARVs and engaging in price negotiations for patented ARVs, Brazil successfully lowered the cost of AIDS treatment. Brazil also has become internationally recognized for its price negotiations and has been touted as a model for political leadership in addressing the high costs of AIDS treatment. However, six years after Brazil first threatened to issue compulsory licenses, Brazil's AIDS treatment institutions face new challenges that threaten previous cost savings.

For the purposes of this discussion, the term costs refers to total public expenditures on one or more ARVs for all patients and the term price to refers to the annual

per-patient per year (PPPY) sale price of a drug to the Brazilian government. All prices and costs discussed in this chapter are presented in US dollars. The details on data and methods related to drug prices and cost trends presented here have been elaborated elsewhere [8].

One reason Brazil faces new cost challenges is the variety of patented drugs the country now offers in its treatment guidelines. For both social and clinical reasons, Brazil's treatment guidelines generally include more ARVs than most other developing countries. Clinical factors include the emergence and transmission of resistant HIV strains [9–11]; adverse events and side effects stemming from long-term AIDS treatment [12, 13]; complex case management of AIDS co-infections such as hepatitis C, tuberculosis, as well as complications related to drug dependence and psychiatric disorders [14–16]. Social factors cited include pressure from civil society groups and AIDS patients to provide the newest ARVs and judicial decisions that stipulate that a constitutional right to health care includes access to new ARVs [17]. For these reasons, and the clear therapeutic and practical benefits of the new ARVs available in the international marketplace, Brazil has replaced older ARVs with patented ARVs such as efavirenz, lopinavir/r, atazanavir, tenofovir, and enfuvirtide in its treatment guidelines. The variety of new-patented drugs available in Brazil is a key factor contributed to increasing HAART costs.

Since Brazil centralized its ARV drug production policies in 1999, it has produced eight generics locally. Brazil purchases the remaining 11 patented ARVs in its 2006 treatment guidelines from multinational pharmaceutical companies. As mentioned in chapter 6, since 2001, Brazil has engaged in price negotiations for five patented ARVs consuming the largest share of treatment costs. Price reductions have resulted in sustained reduced prices for several patented ARVs (Table 7.1). Brazil generally has limited power to threaten to issue compulsory licenses and negotiate prices for drugs for which no generics or active pharmaceutical ingredients (APIs) are available; often no generic competitors exist for several years after Brazil integrates the newest ARVs into treatment guidelines. Brazil's negotiations have therefore historically been most fruitful for ARVs for which generic competition is emerging, including nelfinavir, lopinavir/r, efavirenz, and tenofovir, and less so for atazanavir, whose generic equivalent was first approved by the FDA only in February 2008. Price negotiations for patented drugs resulted in a total of \$1.2 billion in cost savings over the period of 2001–2005 [8].

As a result of price negotiations and the associated cost savings of producing generic drugs locally, even as Brazil scaled up AIDS treatment from 2001 to 2003, average and total HAART costs declined. However, total and average costs more than doubled from 2003 to 2005 (Figs. 7.1 and 7.2). This trend is attributable to Brazil's increasing number of patients taking four patented drugs (lopinavir/r, atazanavir, tenofovir, and enfuvirtide) and the two most commonly prescribed generic ARVs, zidovudine (AZT) and a fixed-dose combination of zidovudine/lamivudine (AZT/3TC). Together, these six drugs accounted for the observed cost increases from 2003 to 2005 (Figure 7.1) [8].

Another cause of Brazil's rising treatment costs is the growing costs of its locally produced generic ARVs. Surprisingly, while the cost of generic ARVs produced in India declined significantly from 2001 to 2005, Brazil's per pill generic drug costs increased from 2003 to 2005.

Table 7.1 Per patient per year price declines from price negotiations

| Drug | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | Percent decline from launch price (%) | Percent decline from first purchase price (%) |
|---|-------|-------|-------|--------|-------|--------------------|-------|--------|-------|---------------------------------------|---|
| Atazanavir 150 mg | - | - | - | - | - | 10,074; | 2,373 | 2,190 | - | 78 | 8 |
| Atazanavir 200 mg | - | - | - | - | - | 10,074; | 2,373 | 2,285 | - | 77 | 4 |
| Efavirenz 200 mg | - | 2,540 | 2,540 | 920 | 920 | - | - | - | - | 77 ^b | 77 ^b |
| Efavirenz 600 mg ^b | - | - | - | - | - | 767; 577 | 577 | 577 | - | - | - |
| Nelfinavir 250 mg | 5,585 | 5,329 | 2,482 | 3,942; | 1,935 | 1,898 | 1,716 | - | - | 69 | 69 |
| | | | | 3,650 | | | | | | | |
| Lopinavir 133 mg + ritonavir 33 mg | - | - | - | 6,504; | 3,504 | 3,285 | 2,847 | 2,562; | - | 84 | 75 |
| | | | | 4,139 | | | | 1,380 | | | |
| Lopinavir 200 mg + ritonavir 50 mg ^c | - | - | - | - | - | - | - | - | 1,022 | - | - |
| Tenofovir 300 mg | - | - | - | - | - | 5,037; 3,296; | 2,803 | 2,657 | 1,387 | 72 | 58 |
| | | | | | | 2,905 ^d | | | | | |

Data source: Nunn, da Fonseca, Bastos, et al. (2007).

- denotes no negotiation that year because drug not in guidelines or price remained stable. Cells with two entries reflect two ARV purchase prices for that year

^a Reflects initial negotiation price and first purchase price

^b One daily dose of efavirenz 600 mg replaced thrice daily dose of efavirenz 200 mg

^c Heat stable version

^d Reflects initial negotiation price, first purchase price, second purchase price

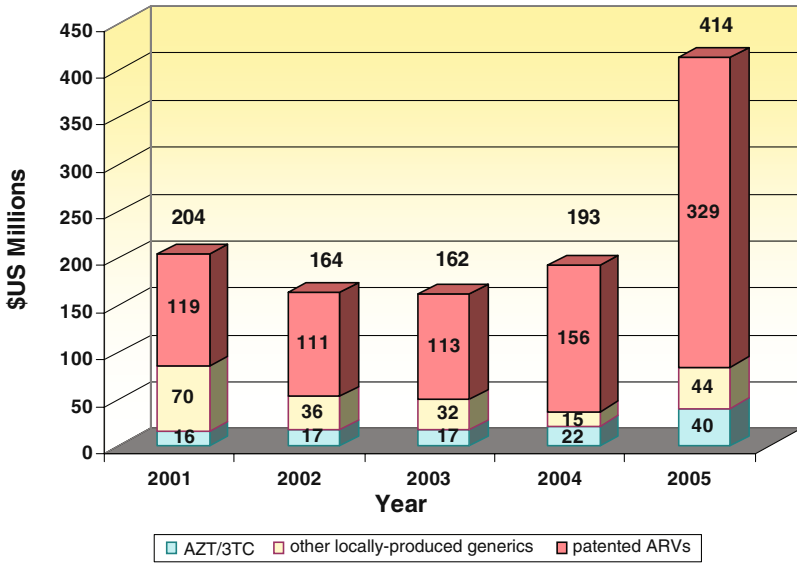


Figure 7.1 Total ARV cost from 2001 to 2005 in \$US dollars
 Source: Nunn, da Fonseca Bastos et al. (2007).

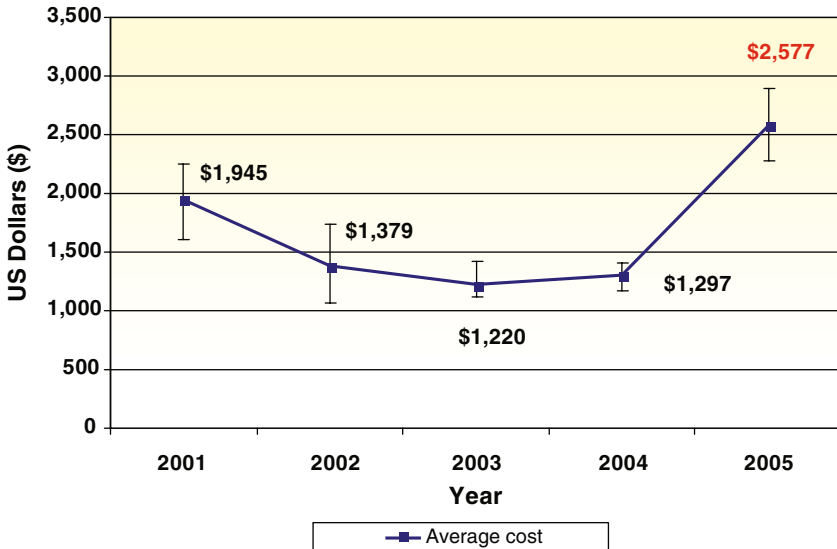


Figure 7.2 Average per patient cost of HAART by year in \$US dollars
 Source: Nunn, da Fonseca Bastos et al. (2007).

From available information and literature, it is unclear why Brazil’s prices are so much higher than drugs produced in India of comparable or superior quality. As the largest global producers of generic ARVs, Indian generic pharmaceutical companies may have benefited from economies of scale, and global competition

may have induced competing Indian firms to lower ARV prices. However, as a result of rising costs in Brazil, the Health Ministry spent a total of approximately \$200 million more than if it had bought ARVs at the lowest possible international generic price since 2001. Ironically, though Brazil initially helped stimulate the generic ARV industry, Brazil's government-run factories are no longer competitive with the private international generic drug industry [8,19–23]. The rising cost of generics represents one of the challenges Brazil's AIDS program faces [8].

However, when Brazil's broader AIDS treatment institutions are considered, accounting for the relatively more costly locally produced generics and Brazil's reduced costs from price negotiations, Brazil still saved nearly \$1 billion from 2001 to 2005. This is because the inefficiency in local generic production is dwarfed by Brazil's savings in price reductions for patented medicines [8]. Although Brazil's generic drug prices are no longer competitive with the international pharmaceutical marketplace, if Brazil stopped producing generic ARVs, it might lose its ability to negotiate steep price reductions for patented ARVs. However, in 2007, Brazil finally issued its first compulsory license for the antiretroviral drug efavirenz. However, rather than produce the drug locally, Brazil imports the drug from generic drug companies in India [24]. This suggests that Brazil's Health Ministry acknowledges that generic companies can now produce ARVs at prices much lower than Brazil's public drug facilities [8].

In summary, Brazil's AIDS treatment institutions initially lowered the population costs of AIDS treatment, but in recent years led to increases in population HAART costs. In spite of sustained price declines for four of the six drugs accounting for the largest share of drug expenditure, Brazil now faces rapidly rising population HAART costs. The rising costs are attributable in part to the rising costs of locally produced generics, but more importantly, reflect the economic consequences of extending new, patented medicines to an increasing number of PLWHA. Though the rising costs of locally produced generics might warrant policy intervention, other factors influencing rising costs should not be viewed as a public policy failure. Rather, rising costs should be viewed as the inevitable consequence of extending life-saving technologies to PLWHA and improving the life expectancy of AIDS patients. Nevertheless, even as Brazil continues to negotiate prices by threatening to issue compulsory licenses, Brazil will likely continue to grapple with the challenge of rising treatment costs as its scales up treatment, continues to improve its standard of care, and AIDS patients live longer [8].

Looking Ahead

The path-dependent development of Brazil's AIDS treatment institutions had important, positive impacts on health outcomes and reduced the cost of AIDS treatment in Brazil. However, the process of historical development of Brazil's AIDS treatment institutions may also present several challenges in the future.

One reason that Brazil's NAP has been able to implement effectively large-scale AIDS treatment is that it is developed as an independent, vertical program. This has historically isolated the NAP from the clientelistic and frequently dysfunctional

Health Ministry bureaucracy. The NAP is now under strong pressure from both the Health Ministry and the World Bank to integrate its programs into SUS, Brazil's decentralized health system [25, 26]. In contrast with other state-run drug programs, the NAP almost never experiences stockouts or delivery problems, which provides continuity in AIDS treatment programs. Integrating the NAP into SUS may present a variety of programmatic challenges, particularly with respect to AIDS treatment.

Another reason the NAP has been successful in scaling up AIDS treatment is the dedicated sanitarias and AIDS activists it employs. Today, according to the NAP, approximately 60% of NAP employees today have previously worked in AIDS NGOs [27]. Many sanitarias and activists work at the NAP precisely because it successfully implements high-impact programs and offers highly competitive World Bank consultancy salaries. Whether Brazil can preserve its dedicated cadre of public servants as the NAP integrates into SUS and World Bank loan programs end in 2007 may be an important factor influencing the future of Brazil's AIDS programs.

In campaigns calling for Brazil to issue compulsory licenses, AIDS activists and NAP officials often cite the rising costs of AIDS treatment as a threat to the sustainability of the treatment program. As discussed in the section "Costs and Compulsory Licenses," HAART costs are indeed rising rapidly. However, a close look at health expenditure trends finds that total public health expenditure rose in tandem with HAART costs; even as HAART costs doubled, ARVs accounted for a steady 3% of total public health expenditure each year from 2001 to 2005. Moreover, because overall public drug spending increased dramatically from 2001 to 2005 as a result of new public drug programs, HAART costs declined from 50% to 36% of total drug spending [28]. Because Health Ministry spending increases have more than offset HAART cost increases, to date, rising HAART costs seem not to have not directly imperiled other public health or drug spending. However, if HAART costs continue to increase rapidly as they did from 2004 to 2005, they may ultimately undermine other public health spending [8].

Though World Bank loan programs ended in 2007, since World Bank loans never financed AIDS drugs, and treatment programs have wide political support, the end of the World Bank loan programs will also likely not imperil continuity in AIDS treatment. However, since World Bank loans subsidize civic activity and other AIDS prevention programs, World Bank loan programs may influence the future of Brazil's AIDS programs in other important ways; the end of World Bank loan programs may lead to a decline in civic activity related to HIV/AIDS or declining expenditure on AIDS prevention.

As mentioned throughout this book, Brazil's courts never decline patients the right to ARVs for AIDS treatment. Consistent support of AIDS treatment helped legitimize the AIDS treatment movement and improve access to HAART during the 1990s. However, in recent years, many courts have ruled that patients have the right to ARVs beyond those included in Brazil's official treatment guidelines. For example, several courts ruled that the federal government was legally obligated to provide enfuvirtide, which costs \$17,000 PPPY. Because it was cheaper to buy drugs in bulk rather than on an individual patient basis, enfuvirtide was integrated into

patient guidelines in 2005. However, this stimulated increased patient demand for the drug [29, 30]. In 2005, Brazil spent \$20 million on enfuvirtide for 1,150 patients [8]. This trend reflects one challenge associated with implementing Sarney's Law, which declares, "Individuals living with HIV/AIDS will receive, free of charge, from Unified System of Health [SUS], all medication necessary for treatment." Unless the Brazilian legislature restricts Sarney's Law, which likely does not have broad political appeal, Brazil will likely continue to grapple with this challenge increasingly more as patients demand costly new, patented drugs and courts uphold patients' rights to secure drugs through the state. This may continue to contribute to the rising costs of AIDS treatment in Brazil.

To date, Brazil's controversial AIDS treatment institutions have proved surprisingly robust. Whether Brazil can integrate the NAP into SUS, survive in the absence of World Bank loans, and continue to provide costly patented ARVs to PLWHA may determine the sustainability of Brazil's AIDS treatment institutions.

Global Impact

The process of institutional development of Brazil's AIDS treatment program had important far-reaching and unprecedented impacts on global AIDS treatment institutions. First, Brazil provided evidence that AIDS treatment was possible and could reduce AIDS-related mortality in resource-limited settings. This, along with the Cardoso Administration's efforts to change global essential medicines institutions, and a global AIDS movement, led to significant contributions to international AIDS treatment institutions. When assessing the long-term impacts of Brazil's AIDS treatment program, these global impacts are equally important as the program's local impacts.

By establishing the right to medicines as part of the human right to health in resolutions at the UN Commission on Human Rights, Brazil was able to link AIDS treatment to universal human rights. Brazil then used human rights to justify changing other global essential medicines institutions. By promoting resolutions in the World Health Assembly (WHA) that improved generic drug quality standards and endorsed greater generic drug use to meet human rights obligations, Brazil helped build the global infrastructure necessary to scale up AIDS treatment. Shortly thereafter, the World Health Organization (WHO) endorsed AIDS treatment in resource-limited settings and added ARVs to its essential medicines list [31, 32]. By contributing text to the UNGASS Declaration of Commitment about AIDS treatment, Brazil helped legitimize the movement for AIDS treatment in developing countries. Brazil also played an important role in developing the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which affirmed the right of developing countries to exercise flexibilities in the TRIPS agreement to respond to public health concerns. Moreover, in part because of Brazil's early demand for raw materials, generic drug costs have fallen dramatically since 2001. These changes in global essential medicines institutions removed many of the institutional hurdles to scaling AIDS treatment in resource-limited settings, helped change global

thinking about AIDS treatment, and contributed to global political momentum for scaling up AIDS treatment.

As global AIDS treatment paradigms shifted, donors such as the World Bank, the US Department of State, and the Global Fund all began financing programs for global AIDS treatment from 2003 to 2005. The Global Fund funding treatment programs began in developing countries in 2003 [33]. In 2003, the WHO and UNAIDS began a campaign entitled *Three by Five* to promote AIDS treatment and provide technical assistance for developing countries to scale HAART to three million people by 2005. Though *Three by Five* did not accomplish its ambitious objective, it provided leadership and technical support necessary to jumpstart important reforms to implement AIDS treatment. In early 2003, US President George Bush launched a 5-year, \$15 billion plan to fund HIV prevention, AIDS treatment, and care of PLWHA in 15 countries [34]. In 2005, the World Bank changed its stance on AIDS treatment and began providing grants and loans to developing countries for AIDS treatment [35]. In December of 2005, the UN General Assembly endorsed universal access to AIDS treatment, care, and prevention by 2010, and UN agencies began financing and implementing policies toward that end [36].

As a result of all of these developments, AIDS treatment in resource-limited settings has become a reality. Global AIDS spending expanded from \$300 million to \$10 billion between 1996 and 2008 and US annual spending for overseas development assistance related to HIV/AIDS increased from \$121 million to \$3.2 billion from 1998 to 2008 [37–40]. In 2003, 50% of the people receiving HAART in developing countries resided in Brazil; by 2008, Brazilian represented less than 10% of all people in developing countries receiving treatment. In five calendar years, the number of people receiving HAART increased to 3 million people in developing countries [47]. If Brazil had not challenged the then conventional wisdom that developing countries could and should not treat AIDS patients, or implemented international institutional infrastructure to make treatment feasible in resource-limited settings, millions of people today might not have access to HAART. These global impacts of Brazil's AIDS treatment program are among the most important legacies of Brazil's AIDS treatment program and the Cardoso Presidential Administration.

However, progress made in tackling HIV/AIDS, tuberculosis and malaria is somewhat exceptional. Interventions to address many other important diseases that account for a large and preventable share of the global disease burden such as diarrheal disease, reproductive health ailments, chronic pain management, and a long list of neglected diseases, continue to be chronically under-funded at the global level. The challenge for global health practitioners will be to replicate the victories combating HIV/AIDS with successes combating other diseases.

Implications for Other Countries

Because Brazil's AIDS treatment institutions are the product of democratization, globalization, the legacies of Brazil's import substitution industrialization (ISI) policies, and two social movements for health, Brazil's institutions are unlikely to

be directly replicable in other developing countries. Some of the most important building blocks of Brazil's contemporary AIDS treatment institutions are unique to Brazil. For example, Brazil's AIDS institutions would never have developed in the absence of the two social movements that encouraged political entrepreneurship to address the AIDS epidemic. Members of two social movements effectively used the human right to health as an effective advocacy tool to advance incrementally AIDS policy in Brazil. Similarly, Brazil's AIDS treatment institutions would not have developed in the absence of Brazil's long tradition of producing drugs for public consumption in government-owned pharmaceutical factories. Only a few developing countries have state-run pharmaceutical industries, private generic drug industries capable of producing ARVs, or strong local social movements for AIDS. Moreover, though foreign assistance for AIDS has increased dramatically in recent years, foreign aid may have less impact in developing countries without strong social movements for AIDS and public servants committed in developing health infrastructure to respond to the AIDS epidemic. Moreover, few developing countries have the institutional conditions that would lead political leaders to challenge multinational pharmaceutical companies about drug prices.

However, some broader lessons may be useful for other settings, and some parts of Brazil's AIDS treatment institutions may be replicable elsewhere. The Brazilian experience suggests that progressive responses to the AIDS epidemic, particularly those related to AIDS treatment, may be most feasible in countries with an engaged civil society that helps destigmatize AIDS, promotes AIDS treatment, and holds governments accountable for commitments to PLWHA. Social movements cannot be imposed from above; they must develop locally. However, donors may be able to support and help expand civic activity for AIDS in other countries by financing nongovernment organizations.

Other developing countries may also consider issuing compulsory licenses to either import generic ARVs or produce generics locally in order to lower HAART costs. Some countries have already done so. For example, in December 2006 and January 2007, Thailand issued a compulsory license in order to import efavirenz and lopinavir/ritonavir [42]. Indonesia recently issued a compulsory license in order to produce lamivudine and nevirapine in public factories, and Zambia issued a compulsory license to a local company to produce stavudine and nevirapine. Developing countries without pharmaceutical industries might also issue compulsory licenses to import generic ARVs. To date, Ghana, Mozambique, Swaziland, Malaysia, Peru, Eritrea, and Guinea have issued compulsory licenses to import ARVs from generic producers in other developing countries [43]. These examples suggest that using compulsory licenses may be a useful option for many other developing countries that aim to reduce public HAART costs.

This is not to suggest that issuing compulsory licenses or producing drugs locally is the *only* solution for expanding access to treatment; many other countries have scaled AIDS treatment through other means. In some cases, the private sector has played an important role in scaling up AIDS treatment. Since 2000, Botswana has successfully scaled up treatment to over 90,000 PLWHA through a public-private partnership among Merck pharmaceutical company, the Bill and Melinda

Gates Foundation, and the National Health Ministry. In this model, Merck donated drugs for treatment and supported new health infrastructure development, the Gates Foundation helped finance the project, and the Health Ministry committed to long-term finance and delivery of the AIDS treatment and care services [44, 45]. Botswana's innovative programs underscore the fact that a variety of approaches can be useful in improving access to HAART in resource-limited settings.

Private sector initiatives have also been important to expanding treatment. Several major multinational corporations such as DeBeers, Heineken, British Petroleum, Anglo-American, Marathon Oil, Coca-Cola, Eskom, Volkswagen, BHP Billiton, and Shell Oil, among others, now offer comprehensive HIV/AIDS prevention, care, and treatment and care to all of their employees globally. These examples, among many others, highlight the important role the private sector can play in providing AIDS treatment and care to PLWHA, particularly in countries with poor public health infrastructure [46].

India's private generic ARV drug industry has reduced costs of generic ARVs dramatically since 2001, and innovator companies, in many cases, have matched lower prices [8]. Inexpensive generics have reduced many of the previous cost barriers in procuring first-line ARVs. New generic alternatives are now emerging for many patented second- and third-line ARVs. However, AIDS treatment remains expensive relative to most developing countries' health budgets. Several countries with large private pharmaceutical industries, including South Africa and India, have made recent progress in providing treatment to PLWHA, and have utilized local industry to provide HAART to their populations.

Somewhat surprisingly, though India has a large generic drug industry that supplies much of the developing world with inexpensive ARVs, the Indian government has been somewhat slow to implement AIDS treatment locally. However, dramatic progress has been made since 2006; in 2008, over 150,000 PLWHA receive publicly-financed HAART in India, most of whom take locally-produced generics [41]. South Africa's government, in contrast, has challenged drug companies about drug prices and has a strong social movement for AIDS, but has been slow to introduce evidence-based AIDS policies and implement health infrastructure for AIDS treatment. However, in late 2006, the South African government finally acknowledged the gravity of its AIDS epidemic and committed to providing HAART to PLWHA [47]. Today, more people receive HAART in South Africa than in any other country in the world [41]. Today, South Africa's local generic drug industry plays a key role in supplying the Health Ministry with generic ARVs. China, which also has the capacity to produce drugs locally, and even exports APIs, provides treatment to only 35,000 of its approximately 650,000 PLWHA [41].

In summary, India, China and South Africa enjoy some of the institutional conditions necessary to facilitate continued scaleup of AIDS treatment; however, there is still tremendous unmet need for treatment in each of these countries. Whether these countries are able to fulfill unmet need for treatment may ultimately depend on whether their political leaders adopt progressive policies for treatment, fully harness the power of their local drug industries, and implement the requisite health infrastructure to respond to the AIDS epidemic.

The generalizability of Brazil's HAART cost trends will ultimately depend upon several factors, including other low- and middle-income countries' treatment guidelines; the number of patients in low- and middle-income countries that take patented medicines; each country's epidemiological profile, intellectual property laws, and public policy response to the AIDS epidemic; and global generic drug prices. Most of the 3 million people receiving HAART in the developing world take older, first-line, generic ARVs. However, they too, and the millions of PLWHA who may soon start treatment will likely ultimately need patented medicines. If Brazil is considered a bell-weather because of its early and aggressive response to the AIDS epidemic, other countries will likely grapple with similar challenges as more people start treatment, AIDS patients live longer and move from first to second and third-line treatment, AIDS treatment becomes more complex, and newer patented drugs become available. Though the extent to which costs rise will vary by country, rising costs of AIDS treatment represent the inevitable consequence of extending life-prolonging technologies to the increasing numbers of PLWHA. If the global public health community is sincerely committed to increasing the numbers of people receiving HAART and sustaining commitments to those who already receive it, the Brazilian experience suggests that donors and developing country governments should anticipate and prepare for steady increases in AIDS treatment costs.

Another important lesson that can be gleaned from the Brazilian program is that cost effectiveness may not be the most important criteria for priority setting for AIDS interventions. By treating PLWHA, the Brazilian National AIDS Program, over the objections of the World Bank, adopted interventions that were not considered cost effective. However, the way Brazil chose to implement its treatment program has had remarkable impacts on health and economic outcomes. Merely examining the economic opportunity costs of Brazil's AIDS program might suggest that Brazil could have chosen other interventions and gotten far more "bang for its buck." However, it is dubious that, given the local institutional conditions such as Brazil's fragmentary health infrastructure and its decentralized and often clientelistic health bureaucracy, allocating the same financial resources to other more cost-effective health interventions would have the similar health, economic, and policy impacts as its AIDS treatment programs.

The Brazilian AIDS treatment experience therefore underscores the importance of considering what may be possible to implement given the local institutional conditions and the difficulties donors face in predicting the feasibility of interventions. Whether a public policy can be implemented is an equally, if not *more important*, criteria for priority setting as cost-effectiveness estimates. Foreign aid programs frequently overlook the importance of local institutional conditions in favor of sweeping universal goals across many countries with very different institutional contexts. However, if donor objectives are not buttressed by strong local support and tailored to local institutional conditions, AIDS programs are not likely to be well-implemented by aid recipients. This book's findings suggest that priority setting should not be restricted to cost-effectiveness criteria only; finite resources for AIDS programs might sometimes be best allocated to interventions

with strong local support that are less cost effective but have higher probabilities of being successfully implemented.

Study Strengths and Limitations

This book contributes to the public health and political science literature in several ways. In contrast with most of the research on Brazil's AIDS treatment program, which has focused on health and policy outcomes, this case study explains the *process* in which Brazil's AIDS treatment institutions developed. In so doing, the study helps demystify the AIDS treatment institutions observed today and how and why Brazil achieved desirable health and economic outcomes related to AIDS treatment. By providing an in-depth analysis of the complex social phenomena that influenced the AIDS treatment institutions observed today in Brazil, this book identified in which circumstances, and at what moments, social movements, institutions, and politicians influenced development of Brazil's AIDS treatment institutions. To date, no scholarship has examined Brazil's AIDS treatment institutions in this way. The historical institutional focus elucidated the genesis of AIDS treatment, the processes in which each AIDS treatment institution developed and was reinforced by complex social mechanisms, and the cumulative impacts of all of Brazil's AIDS treatment institutions on contemporary institutional arrangements. Finally, *The policies and History of AIDS Treatment in Brazil* explains how and why Brazil changed global thinking and global institutions related to essential medicines and AIDS treatment. Since many of these developments were interrelated and developed slowly, the historical institutional approach best elucidates how Brazil's contemporary AIDS treatment institutions developed over a long time period of time.

The few existing institutional analyses that examine AIDS institutions and have been written by members of the AIDS movement or NAP leaders [50–53]. Not participating in the reform process of institutional development may be a handicap of this research; “insiders” who participated and were present during any reform process are always privy to important information that is important to understanding how complex social change took place. Insiders also have a better grasp of the cultural and institutional context than “outsiders.” Living and working in Brazil and learning Portuguese to conduct this research helped me mitigate some of the major cultural and linguistic barriers to understanding social processes this book examined. Discussing interview interpretations and book findings with participants, a process called “member checks,” helped bolster my interpretation of each interview and the book's principle findings. Nevertheless, the perspective of a foreigner who never participated in the policy reform process or the AIDS movement could never substitute the deep understanding of any participant in the social processes that influenced development of Brazil's AIDS treatment institutions. This is a limitation of this research.

However, being an “outsider” also has important advantages. Since I was removed from much of the politics, I could move easily between informants and across sectors. The 91 in-depth interviews for this book were conducted with individuals

from many different backgrounds, and informed the book's findings. The research also incorporated the perspectives of the important stakeholders such as the pharmaceutical industry, leaders from the Collor administration, and a variety of international actors that other scholarship has overlooked. Speaking with a variety of experts and participants involved in the institutional development process and reviewing over 2,000 news articles helped inform a thorough, independent analysis of the way AIDS treatment institutions developed and also enhanced the validity of the book. Furthermore, the outside perspective of the book permitted new interpretations about the social phenomena this book examines, particularly about the role of two social movements and political actors in influencing historical development of Brazil's AIDS treatment institutions. These factors are strengths of this book.

Though negotiating access to informants was often time consuming, gaining access to informants was generally not a problem for this project. Only one person declined to be interviewed for the study, and the only important informant that could not be interviewed was Lair Guerra, because of poor health. However, because of the highly controversial nature of the study and the institutions each individual represented, some informants may not have been at liberty to freely discuss their opinions or answer all of the interview questions. For example, several executives from the pharmaceutical industry preferred not to discuss the process of price negotiations with the Brazilian government. Similarly, several NAP executives declined to discuss the root causes of rising HAART costs in Brazil. President Cardoso declined to discuss why he pushed the Industrial Property Law through Congress 10 years before TRIPS requirements. Many informants, including public officials and activists, preferred not to discuss the opportunity costs of Brazil's AIDS treatment program. In any qualitative study, and particularly in these interviews about controversial topics, the researcher grapples with the challenges of interpreting what is said as well as what is *not* said, both in the context of the interview and the broader social phenomenon in question. Interviewers can mitigate the impacts of this problem by interviewing a variety of different types of informants, and sometimes by increasing the number of interviewees, which I attempted to do. In the end, however, I became the filter for all information, and interpreted each interviewee's comments with my best judgment, which is ultimately colored by my worldview and theoretical framework. Despite painstaking efforts to enhance the project's validity and reliability, these qualitative research findings are ultimately subject to my biases and personal interpretation.

Though a qualitative case study can speculate about the implications of the case for other settings, it can only offer definitive conclusions about one case. This is another limitation of this study. Comparative qualitative case studies in other countries will be necessary to understand the institutional conditions giving rise to other successful AIDS treatment programs in developing countries. However, this book might be a starting point for comparative historical institutional analysis and theory related to developing country responses to pandemics.

One limitation of the study is that it did not actually measure population access to HAART or the efficacy of Brazil's chosen interventions. This study generally assumed that in recent years, most people in need of HAART in Brazil receive it. This

is a fairly safe assumption for Southeastern Brazil, where the AIDS epidemic is concentrated, hundreds of clinics offer treatment, and where AIDS incidence has declined. However, only one recent study has officially examined at the availability of ARVs in Brazil [54]. Though the study finds that access to HAART is generally stable in the clinics that offer treatment, the sample size was small. Only a very limited number of clinics in remote parts of Brazil offer HAART, and the distance between some clinics may be prohibitive in some parts of Brazil (see Appendix I). Access to HAART may therefore still remain a challenge in some parts of Brazil. This study also did not conduct any of the monitoring and evaluation that the World Bank reports cite as critical for assessing the efficacy of Brazil's program in reducing HIV transmission and the cost - a effectiveness of Brazil's AIDS interventions.

The interdisciplinary nature of this research is both a strength and weakness. Because research on access to medicines is inherently interdisciplinary, this book may appeal to a wide public health and public policy audience. However, because of its wide scope, some parts of the book might warrant further analysis by other experts. For example, Brazil's international efforts to shape global essential medicines institutions might be interpreted by a legal audience as an effort to change international law governing access to essential medicines. Analyzing the legal text of each international legal document might provide further insight into how Brazil has legally changed global essential medicines institutions. Similarly, experts on intellectual property rights and technology transfer might also offer more detailed insights or interpretations about the legal, scientific, and technical arguments the book presents.

The Brazilian Model

During the next 5 years, Brazil will integrate its historically vertical AIDS treatment program into its health system, and Brazil's AIDS treatment institutions will become increasingly more decentralized. A recent study finds that decentralization of administration and finance of harm reduction programs for intravenous drug users led to decreased access to needle exchange and declining expenditure on harm reduction programs [55]. This highlights one of the dangers of decentralizing AIDS programs in Brazil: when state and local actors assume control of AIDS programs they do not always prioritize AIDS programs over other competing health interventions or social spending. Future research might assess the impacts of integrating NAP programs into SUS and decentralizing ARV delivery systems on population access to HAART in Brazil.

To date, Brazil has not conducted intense monitoring and evaluation of its treatment or prevention programs. It is therefore difficult to systematically assess the program's impact on reducing HIV transmission and improving access to HAART. The decline of AIDS incidence in the South and Southeast suggests that access to treatment is reliable in the regions with the highest HIV prevalence. However, AIDS incidence continues to rise in the Central-west, North, and Northeast [6]. These regions

have far fewer clinics offering HAART. New research is needed to assess whether an unmet need for HAART exists, particularly outside southern and southeastern Brazil. Moreover, there is a large disparity between fairly stable access to HAART and frequently very limited access to drugs for opportunistic infections (OIs) in Brazil [54]. Further operational research is needed to understand how to improve access to drugs for OIs, particularly in the more remote regions of the country.

The AIDS pandemic is the gravest threat to public health in human history and demands immediate, aggressive, and effective public policy responses. Brazil's aggressive efforts to address the AIDS epidemic helped force the global public health community to finally embrace the notion that treatment is a necessary component of public policy responses to the AIDS epidemic. Billions of dollars are now flowing into the global fight against AIDS. However, global AIDS prevalence is increasing and only 30% of the ten million people who need HAART in developing countries receive it. Furthermore, little is known about countries that have successfully constructed and implemented effective AIDS treatment policies. Moreover, As the Brazilian example highlights, it is often difficult to assess *ex ante* what interventions may work in a variety of different settings. By using the constitutional right to health to advance AIDS treatment and rejecting donor's assertions that prevention should be prioritized over treatment, Brazil has built the largest and most successful AIDS treatment program in the developing world, and HIV prevalence in Brazil remains below 1% today. The Brazilian model suggests that home-grown programs, particularly those closely tied to grassroots democratization movements, are much more likely to succeed than donor programs imposed from the top-down. Given the success of Brazil's unconventional approach to AIDS treatment, an important goal of future research should be to explore the institutional conditions and political leadership that give rise to effective public policy responses to the AIDS epidemic in other resource-limited settings, particularly in emerging democracies.

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Appendices

Appendix A Antiretroviral drugs in Brazil's 2008 AIDS treatment guidelines

| Drug by class | Year introduced in treatment guidelines | Year public production began | Innovator company |
|---|--|-------------------------------------|---|
| Nucleoside reverse transcriptase inhibitors (NRTI) | | | |
| Lamuvudine 150 mg ^a | 1996 | 1998 | GlaxoSmithKline |
| Zidovudine 100 mg & 300 mg ^a | 1990 | 1992 | Wellcome/Glaxo |
| Stavudine 30 mg ^a | 1995 | 1998 | Bristol Myers Squibb |
| Stavudine 40 mg ^a | 1995 | 1998 | Bristol Myers Squibb |
| Didanosine 100 mg ^a | 1992 | 1998 | Bristol Myers Squibb |
| Didanosine 25 mg ^a | 1992 | 1998 | Bristol Myers Squibb |
| Didanosine enteric-coated capsules 250 mg | 2004 | n/a | Bristol Myers Squibb |
| Didanosine enteric coated capsules 400 mg | 2004 | n/a | Bristol Myers Squibb |
| Zidovudine 300 mg + lamuvidine 150 mg ^a | 1990 | 1999 | Wellcome/Glaxo |
| Nonnucleoside reverse transcriptase inhibitors (nNRTI) | | | |
| Abacavir 300 mg | 2001 | n/a | GlaxoSmithKline |
| Efavirenz 200 mg | 1999 | n/a | Bristol Myers Squibb ^b |
| Efavirenz 600 mg | 2003 | n/a | Bristol Myers Squibb ^b |
| Nevirapine 200 mg ^a | 1998 | 2000 | Bristol Myers Squibb |
| Tenofovir 300 mg | 2003 | n/a | Gilead Sciences |
| Protease Inhibitors (PI) | | | |
| Amprenavir 150 mg | 2001 | n/a | GlaxoSmithKline |
| Atazanavir 150 mg | 2003 | n/a | Bristol Myers Squibb |
| Atazanavir 200 mg | 2003 | n/a | Bristol Myers Squibb |
| Indinavir 400 mg ^a | 1996 | 2000 | Merck |
| Lopinavir 133 mg + ritonavir 33 mg | 2001 | n/a | Abbott Laboratories |
| Nelfinavir 250 mg | 1997 | n/a | Agouron Pharmaceuticals ^c |
| Ritonavir 100 mg | 1998 | n/a | Abbott Laboratories |
| Saquinavir 200 mg | 1996 | n/a | Hoffman-La Roche |
| Duranvir 300 mg | 2007 | n/a | Tibotec |
| Forsamprenavir 700 mg | 2007 | n/a | GlaxoSmithKline |
| Entry inhibitor (EI) | | | |
| Enfuvirtide 90 mg ml ⁻¹ | 2005 | n/a | Hoffman-La Roche & Trimeris |

Note Delavardine was included in AIDS treatment guidelines in 1998 and produced locally but is no longer clinically indicated

^aProduced in Brazil

^bLicensed to Merck in Brazil

^cLicensed to Roche in Brazil

Appendix B Interviewees

| Interviewee(s) | Professional title or relevance to research | Date(S) interviewed |
|---------------------------------|--|-------------------------------|
| Alexandre Amorim | Director, Communications, NAP | 12/19/06 |
| Araujo Almeida | Director of LAFEPE, 2005 | 12/22/05 |
| Michael Bailey | Director, <i>Make the Trade Fair Campaign</i> , Oxfam International | 1/4/06 |
| Brook Baker | Professor of Law, Northeastern University, and Spokesman, Health GAP NGO | 4/1/05 |
| Fernando Baptista | Director, Economics and Regulation, ANVISA (Brazil's drug regulatory agency) | 11/24/05 |
| Eduardo Barbosa and Rubens Duda | Director, Civil Society Programs, NAP Program Officer, Civil Society Programs, NAP | 11/23/05 |
| Jarbas Barbosa | Director, Health Surveillance, Health Ministry of Brazil | 11/23/05 |
| Mariastela Basso | Professor of Law, University of São Paulo | 12/8/05 |
| Ivo Brito | Director, Prevention Programs, NAP | 11/22/05 |
| Jorge Bermudez | Current Chief of Medicines, Vaccines, and Health Technologies Unit, former Brazilian representative to the World Health Assembly | 9/13/05 |
| Nubia Boechat, PhD | Former Director, Farmanguinhos public drug production laboratory, 2001–2005 | 12/6/05 |
| Marcia Martini Bueno | Director of Bioequivalence, ANVISA (Brazil's drug regulatory agency) | 12/8/05 |
| Otavio Brandelli | Brazilian Diplomat to the World Intellectual Property Organization | 11/24/05 |
| Francisco Cannabrava | Brazilian Diplomat, former TRIPS negotiator | 1/23/06 |
| Ingrid Carvalho | Director of Legal Aid, Pela VIDDA NGO | 9/1/05 |
| Abraham Lincoln Cardoso | Legislative Assessor, PMDB party of Brazil | 1/11/06 |
| Fernando Henrique Cardoso | Former President of Brazil, 1995–2003 | 12/22/05 |
| Pedro Chequer | Former Director, NAP, 1996–2000, 2004–2006 | 11/25/05 |
| Rachel Cohen | Former Director, Access to Essential Medicines Campaign, Doctors Without Borders USA | 2/20/06 |
| Eduardo Cortes, MD | Former director, NAP | 8/18/05 9/8/05 11/28/05 |
| Juliana Cruz | Director of Drug Logistics, NAP | 11/23/05 |
| Rosanna del Bianco | Infectious disease doctor and former Director of AIDS treatment programs, Brazilian NAP, 1992–1994 | 12/7/05 |
| Christina D'Almeida | Director of Intellectual Property Programs, NAP | 11/22/05 |
| Ary Carvalho de Miranda | Vice-President, Oswaldo Cruz Foundation, former health activist and sanitaria | 3/21/06 |
| Richard Elliot | Canadian Legal HIV/AIDS Network | 9/5/05 |
| Celeste Emerick | Director of Intellectual Property Programs, Oswaldo Cruz Foundation | 11/14/05 |
| Edjane Falcão | Director of Drug Logistics, São Paulo state AIDS program, 1991–2006 | 10/5/05 |
| Maria Goretti Fonseca | Director of Surveillance, NAP | 11/22/05 |
| Jane Galvão | Director of Western Hemisphere HIV/AIDS Programs, IPPF; Former Assistant Director, ABIA NGO | 9/15/05 |

(continued)

Appendix B (continued)

| Interviewee(s) | Professional title or relevance to research | Date(s) interviewed |
|-------------------------------|--|----------------------------|
| Hilbert Ferreira | Vice President, Farmanguinhos public drug production facility, former Chief of Production, Farmanguinhos | 9/6/05 |
| Elio Gaspari | Historian and Columnist, Folha de São Paulo newspaper | 4/11/05 |
| Clara Gaviani | Assistant Director, AIDS Program of São Paulo | 5/12/05 |
| Alceni Guerra | Former Minister of Health, 1990–91 | 3/22/06 |
| Alexandre Grangeiro | Independent Health Consultant, former NAP Director, 2003–04 | 5/12/05 |
| Paul Hunt | UN Special Rapporteur of the Commission on Human Rights on the Human Right to Health | 2/22/06 |
| Artur Kalichman, MD | Director, São Paulo State AIDS Program | 10/5/05 |
| Maurício Klai | Director of Public Relations, FURP public drug factory | 12/8/05 |
| Jeffrey Kempres | Director of Public Affairs for Latin America, Merck | 7/10/05 |
| Adib Jatene | Chief of Internal Medicine, Hospital das Clínicas; Former Minister of Health, 1992, 1995–1996 | 12/7/05 |
| Liane Lage | Director, Drug Patent Review Office, National Intellectual Property Institute | 10/4/05 |
| Marcos Levy | Private attorney and former Director of Public Affairs, Merck Brazil | 12/8/05 |
| Michel Lotrowska | Director, Doctors Without Borders Brazil | 9/13/05 |
| Jamie Love | Consumer Project on Technology | 4/10/05 |
| Marcos Maciel | Federal Senator and former Vice President of Brazil | 12/19/05 |
| Eduardo Martins | Former director, Farmanguinhos public drug factory | 8/23/05 |
| Alexandre Mesquita | Federal Judge, Rio de Janeiro | 11/11/05 |
| Frederico Duque Estrada Meyer | Brazilian Diplomat, Representative to the UN | 7/28/05 |
| Carlos Morel | Director, Center for Technological Development, Oswaldo Cruz Foundation; Former Director, Farmanguinhos drug factory; Former Director of Oswaldo Cruz Foundation; Former Director of Special Program for Research and Training in Tropical Diseases (TDR), WHO | 11/10/05 |
| Tiyoshi Nimoya | Director of Production, FURP public drug factory | 12/7/05 |
| Otávio Pacheco | President, Cristalia private pharmaceutical company | 11/17/05 |
| Vera Paiva | Director, Center for Prevention of AIDS Studies, University of São Paulo; former HIV/AIDS activist and sanitaria | 5/12/05 |
| Richard Parker | Chair of Department of Social Medicine, Columbia University, Former Director, ABIA NGO | 8/23/05 |
| Carlos Passarelli | Director, International Programs, NAP; Former Assistant Director, ABIA NGO | 5/2/05 |
| Eloan Pinheiro | Chemist and former Director, Farmanguinhos drug factory | 8/15/06 9/19/05 |
| Christina Possas | Director of Technology and Research, NAP | 11/22/05 |

(continued)

Appendix B (continued)

| Interviewee(s) | Professional title or relevance to research | Date(s) interviewed |
|------------------------------------|---|----------------------------|
| Marta Penna and Irapuan de Olivera | Commercial Director and Director of Institutional Relations, Abbott Brazil | 9/27/05 |
| Alcides Prates | Brazilian Diplomat, represented Brazil in WTO trade dispute with USTR | 1/23/06 |
| Jaime Rabi | President and Founder, Microbiológica, Incorporated | 9/6/2005 |
| José Serra | Governor of São Paulo, former Health Minister of Brazil 1998–2002 | 10/5/05 |
| Joe Steele | Vice President, Commercial Development, Gilead Sciences | 6/26/06 |
| Paulo Teixeira | Former director, São Paulo State AIDS Program, former Director, Brazilian NAP | 5/12/05 |
| José Teixeira | Director, Evandro Chagas Pharmacy, Oswaldo Cruz Foundation | 9/30/05 |
| Veriano Tertó | Director, ABIA NGO | 5/11/05, 3/10/06 |
| José Marcos Viana | Brazilian Diplomat and Brazilian Health Ministry Representative to the UN | 11/5/05 |
| Valdilea Veloso | Director, Evandro Chagas Hospital, Oswaldo Cruz Foundation | 9/20/05 |
| Miriam Ventura | Former director of Pela VIDDA NGO's legal aid programs | 9/12/05 |

Professional titles represent each individual's title on the date of his or her interview

Appendix C Brazilian Newspapers included in historical analysis

| Newspaper or magazine | City of issue |
|------------------------------|----------------------|
| Correio Braziliense | Brasília |
| Extra | Rio de Janeiro |
| Folha de São Paulo | São Paulo |
| Gazeta Mercantil | São Paulo |
| Jornal do Brasil | Rio de Janeiro |
| Jornal do Comércio | Rio de Janeiro |
| Jornal do Commercio | São Paulo |
| O Dia | Rio de Janeiro |
| O Estado de São Paulo | São Paulo |
| O Fluminense | Niterói |
| O Globo | Rio de Janeiro |
| O Povo | Rio de Janeiro |
| Revista Época | São Paulo |
| Revista Isto É | São Paulo |
| Revista Veja | São Paulo |
| Tribuna da Imprensa | Rio de Janeiro |
| Valor Econômico | São Paulo |
| Zero Hora | Porto Alegre |

Appendix D Presidents, Health Ministers and National AIDS Program Directors in postmilitary Brazil

| President | Health Minister(S) | National AIDS Program Director(S) |
|--|---|---|
| José Sarney (1985–1990) | Carlos Sant’Anna (1985–1986) Roberto Santos (1986–1987) Luis Carlos Silveira (1987–1989) Seigo Tsuzuki (1989–1990) | Lair Guerra (1985–1990) |
| Fernando Collor (1990–1992) | Alceni Guerra (1990–1992) | Eduardo Cortes (1990–1992) |
| Itamar Franco (1992–1995) | Adib Jatene (1992) Jamil Haddad (1992–1993) Henrique Santillo (1993–1995) | Lair Guerra (1992–1996) |
| Fernando Cardoso 1995–1999 (first term) | Adib Jatene (1995–1996) José Seixas (1996) Carlos Albuquerque (1996–1998) José Serra (1998–2002) | Pedro Chequer (1996–2000) |
| Fernando Cardoso (1993–2003) (second term) | José Serra (1998–2002) Barjas Negri (2002) | Paulo Teixeira (2000–2003) Alexandre Granjeiro (2003–2004) |
| Luiz Inácio da Silva “Lula” (2003–today) | Humberto Costa (2003–2005) Saraiva Felipe (2005–2006) Agenor Álvares (current) | Alexandre Granjeiro (2003–2004) Pedro Chequer (2004–2006) Mariângela Simão (2006–current) |

Appendix E World Bank AIDS I activities and budget

| Activity | Description | Budget in US Dollars | Percent of total loan expenditure |
|------------------------------|--|-----------------------------|--|
| Prevention | Implement mass media campaigns, targeted interventions, and conduct community outreach for high-risk populations. Conduct IV drug use studies. Develop counseling and testing programs. | \$102.7 | 41 |
| Treatment Services | Establish 300 STD centers in existing health centers nationwide. Develop clinical services and protocols for AIDS patients, including community support services for AIDS patients. Conduct program evaluation, including research on cost-effectiveness of treatment interventions. | \$84.6 | 34 |
| Epidemiological Surveillance | Conduct HIV sentinel surveillance, AIDS cases and deaths surveillance. Conduct surveillance training workshops for health professionals. | \$16.2 | 7 |
| Institutional Development | Strengthen reference laboratory infrastructure. Implement human resources training for the National AIDS Program. | \$46.4 | 18 |
| Total | | \$250 | 100 |

Appendix F History of World Bank loans and NGO activity

| Project | Total project amount ^a | Brazil contribution ^a | World Bank contribution ^a | NGO expenditure ^a | NGOs receiving World Bank support | Number of projects implemented by NGOs |
|--------------------|-----------------------------------|----------------------------------|--------------------------------------|------------------------------|-----------------------------------|--|
| AIDS I 1993–1997 | 250 | 90 | 160 | 25 total for | 181 | 564 |
| AIDS II 1999–2002 | 300 | 135 | 165 | AIDS I & II | 795 | 2,163 |
| AIDS III 2003–2006 | 200 | 100 | 100 | 21 | N/A | N/A |

Source: World Bank Loan Project Appraisal Documents

^a Reported in \$US millions

N/A = not available because states, rather than the federal government, defined project implementation

Appendix G World Bank AIDS II activities and budget

| Activity | Description | Budget in US \$ millions | % of total loan |
|---|--|--------------------------|-----------------|
| Prevention | Implement mass media campaigns, targeted interventions, and conduct community outreach for high-risk populations | \$128 | 43 |
| | Establish a National Human Rights Network to discourage discrimination against PLWHA | | |
| | Promote safer sex, condom distribution, and needle exchange | | |
| | Establish counseling services and AIDS hotline | | |
| Diagnosis, Treatment and Care for PLWHA | Improve operation, standardization and quality of existing care and treatment centers, including purchase of equipment and supplies for viral load | \$102 | 34 |
| | Establish 80 AIDS orphanages and group homes | | |
| | Strengthen STD Diagnosis and treatment through human resource capacity building | | |
| | Implement centralized control of drug logistics and condoms, a cost control system for HIV/AIDS care, and a reference system for gynecological care for HIV positive women | | |
| | Improve laboratory quality control for public laboratories, blood banks, and blood transfusions | | |
| | | | |
| Institutional Strengthening | Conduct HIV sentinel surveillance and epidemiological surveys among vulnerable populations, and develop a case notification system | \$70 | 23 |
| | Expand National Reference Laboratories for resistance studies and quality control in lab testing | | |
| | Sponsor training activities for health care professionals | | |

(continued)

Appendix G (continued)

| Activity | Description | Budget in US \$ millions | % of total loan |
|------------------------------|--|-------------------------------------|----------------------------|
| Institutional Development | Strengthen of reference laboratory infrastructure. Implement human resources training for the National AIDS Program Conduct research on cost and impact, survival studies, case notification delay, opportunistic infections, epidemiology, behavioral change, and others Conduct monitoring and evaluation activities for all state and municipal institutions implementing projects, evaluating NGO projects, including monitoring of 80 NGO projects, studies on preventive activities in the workplace, workshops for NGO participants on evaluation on monitoring and evaluation reports, project impact studies, and evaluation of interventions among specific populations | \$46.4 | 18 |
| Total | | \$300 | 100 |

Appendix H Text of the 2001 TRIPS Agreement and Public Health

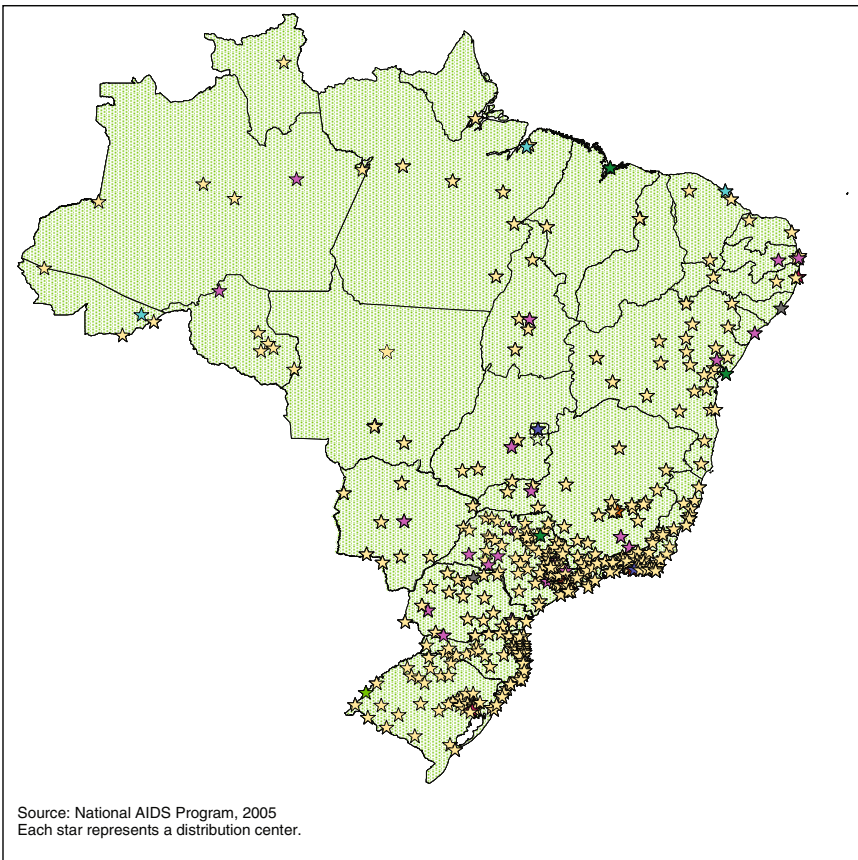
Adopted on November 14, 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and 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. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include the following:
 - a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
 - d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such

exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Appendix I Map of public HAART distribution centers in Brazil



A Note on Sources

Qualitative interviews, historical data, and quantitative data helped reconstruct the process of development of Brazil's AIDS treatment institutions this book explores. Though these three methods are separated here for clarity, more than one source of data was often used to justify choices of critical junctures or to explain social processes and final outcomes of interest. Each chapter relied upon qualitative and historical methods, but some chapters rely more on quantitative analysis or historical documents than others. Each of these methods helped identify critical junctures as well as the social mechanisms that reinforced development of AIDS treatment institutions in Brazil.

Original, semi-structured interviews are the primary source of original data for this inquiry. Qualitative data collection included purposeful sampling of important parties engaged in the process of developing national AIDS treatment institutions and global essential medicines institutions. Appendix B includes a list of 86 individuals interviewed for this book from April 2005 to March 2006.

The primary sources of historical information for this paper were news and research articles found at the Associação Brasileira Interdisciplinar de AIDS (ABIA), a non-profit organization and AIDS library in Rio de Janeiro. ABIA houses newspaper, magazine and research articles from 1985 to 2005. ABIA's library includes all of Brazil's major newspapers and news magazines as well as several smaller regional newspapers. ABIA subscribes to a "news clippings" service that selects all the articles related to AIDS in newspapers and news magazines with the widest circulation in Brazil. A list of these newspapers and news magazines included in this search is included in Appendix C. Although these are considered the most reputable newspapers in Brazil, it is important to note that nearly all of the major newspapers are from the Southern and Southeastern Brazil. Some regional AIDS news may be over and under-represented. (However, most AIDS cases and health infrastructure are located in the same regional areas as the newspapers used for this analysis).

Other documents found at the ABIA library such as protocols on AIDS treatment and AIDS law in Brazil also informed this analysis. Key informants also provided other historical documents related to this analysis, such as World Bank loan proposals and reports, documentation of state and civil society partnerships, among other documents.

Finally, this analysis relied on several formal and informal drafts of trade, health and human rights resolutions and international agreements governing essential medicines. Final resolutions from the World Health Assembly, World Trade Organization and UN Commission and Subcommission on Human Rights were downloaded from those institutions' websites. Because drafts of these materials may or may not have appeared in the final texts of resolutions and agreements, draft texts are often hard to come by. When available, draft texts are nevertheless a key part of examining the process of historical development of Brazil's AIDS treatment policies. Every effort was made to unearth important drafts of resolutions that were not adopted. In some cases, parties present at the resolution process provided draft texts from personal archives. Several diplomats commented on draft resolutions that were either never ultimately adopted or circulated publicly. Many news stories related to international institutions were downloaded from Lexis Nexis. Finally, events and former drafts of resolutions and resolutions that were not adopted were downloaded from the Consumer Project on Technology's (CPTech) website, which archives many international events related to intellectual property rights, health and access to essential medicines.

This research project relied on several official sources for secondary quantitative data related to health outcomes and health spending. Simple descriptive quantitative analyses are presented in several chapters of the book, and original analyses on the cost of ARVs for Brazil's treatment program are presented in the conclusion chapter.

Index

A

Abbott Laboratories, 171, 174
Abertura, 13, 31, 34
ABIA, 39, 49, 51, 57, 63, 69, 99, 102,
172–174, 179
ABRASCO, 33
Access to Medication in the Context of HIV/
AIDS, 133, 135
Active pharmaceutical ingredients (APIs),
153, 161
ACT UP, 120
AIDS. *See* HIV
activists, 1, 7, 32, 38, 39, 42, 43, 45–47,
49–51, 53, 60, 62, 64, 69, 85, 86, 97,
98, 100, 107, 122, 151, 157
cocktail, 1, 95
incidence, 21–23, 165, 166
prevalence, 11, 23, 38, 56, 166
prevention (*see* HIV prevention)
Albuquerque, C., 99, 100, 104, 105, 175
Alcides Prates, 134, 174
Almeida, A., 79, 172
Álvares, A., 175
Amorim, A., 172
Annan, K., 123
Anthrax, 137
ANVISA, 172
ARENA (political party), 13
Arouca, S., 38, 40, 41, 51, 105
Article 200 of 1988 Constitution, 42, 43
AZT, 1, 7, 49, 53, 54, 56, 57, 59, 60, 76–81,
88, 110, 111, 113, 153

B

Bailey, M., 172
Baker, B., 120, 172
Baptista, F., 172
Barbosa, E., 172

Barbosa, J., 172
Basso, M., 172
Bayer, 137
Bermudez, J., 172
Betinho, 38, 39, 42, 47, 50, 53, 55, 56, 62, 64,
66, 86, 87, 140
Bezerra, D.R., 42
Bill and Melinda Gates Foundation, 161
Boas, F., xiii
Boechat, N., 172
Bolar Amendment, 114
Botswana, 161
Brandelli, O., 172
Brazilian Congress, 3, 4, 7, 18, 51, 81, 82,
151, 158
Brazilian legislature, 51, 158
Bristol Myers Squibb, 119, 171
Brito, I., 172
Brown University, iv
Bueno, M.M., 172
Bush Administration, 134

C

Campaign for Access to Essential
Medicines, 120
Campaigns, 22, 23, 31–33, 35–39, 47, 50, 51,
54–57, 59, 63, 65, 66, 69, 80, 83, 86,
96, 98–100, 102–104, 111, 112,
120–122, 124, 129, 130, 132, 134,
135, 139, 140, 152, 157, 159, 172,
175, 176
Cannabrava, F., 137, 138, 142, 172
Cardoso Administration, 3–5, 7, 17, 19, 81,
82, 88, 112, 149, 152, 158
Cardoso, A.L., 172
Cardoso, Fernando Henrique, 14, 45, 65,
80–84, 86–89, 91, 95, 104, 106,
112–114, 124, 128, 140, 141, 172, 175

- Cardoso, R., 105
 Carvalho, Ary, 40, 172
 Carvalho, I., 172
 CEBES, 33
 CEME. *See* Central Medicines Agency
 Central Medicines Agency (CEME), 69, 76, 78, 108
 Chequer, P., 64, 87, 96–99, 102, 104–106, 110, 172, 175
 China, 79, 110, 111, 123, 138, 161, 162
 Cipla, 121–123
 Cipro, 122
 Citizenship rights, 6, 15, 37, 39, 51, 53, 68, 99
 Clinton Administration, 83, 119–122, 127
 Clinton Foundation, 26
 Cohen, R., 172
 Cold War, 11, 82, 91, 149
 Collor Administration, 17, 18, 47–49, 54–58, 61–63, 81, 164
 Collor, F., 14, 47, 55, 86, 175
 Commission on Human Rights, 122, 124, 125, 128–131, 135, 140, 142, 158, 173, 180
 Commission on Intellectual Property Rights, Innovation and Public Health, 122, 142, 143
 Communist party, 31, 33, 34, 40
 Compulsory license, 3, 5, 7, 25, 84, 109, 112–114, 119, 122, 123, 125, 127, 128, 137–139, 142, 149, 152–157, 160, 161
 1988 Constituent Assembly, 106
 1988 Constitution, 4, 6, 7, 14–19, 39–43, 45–48, 50–54, 63, 68, 76, 105, 150
 Constitutional convention, 34, 41, 45, 46
 Consumer Project on Technology (CPT), 120, 121, 134, 180
 Cortes, E., 54–59, 61, 62, 113, 172, 175
 Costa, H., 175
 Critical juncture, 5–7, 49, 54, 56, 58, 64, 66, 80, 87, 89, 109, 110, 114, 124, 125, 150–152, 179
 Cruz, J., 172
- D**
 D’Almeida, C., 172
 Daniel, H., 50, 52, 53
 Darwin, C., xiii
 da Silva, Luis Inácio, 141, 175
 Decentralization, 14–18, 42, 48, 108, 165
 Decision of 30 August 2003.
 See Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health
- Declaration of Commitment on HIV/AIDS, 122, 135
 Declaration of Rights for Individuals Living with AIDS, 50, 51
 del Bianco, R., 67, 172
 de Mello e Souza, Antonio Candido, xiii
 de Miranda, A.C., 40, 172
 Democratization, 3–6, 13–15, 17, 31, 33, 34, 38, 40, 47, 53, 62, 106, 140, 149, 160, 166
 de Oliveira, I., 174
 de Souza, H. *See* Betinho
 Doctors Without Borders (MSF), 120, 121, 133, 134, 172, 173
 Doha Declaration (on the TRIPS Agreement and Public Health), 122, 137, 142
 Duda, R., 172
 Durban AIDS Conference, 122, 126
- E**
 Efavirenz, 113, 122, 123, 128, 136, 138, 153, 156, 160, 171
 Eisenhower, D., vii
 Elliot, R., 172
 Emerick, C., 172
 Enfuvirtide, 1, 153, 158, 171
 Eritrea, 160
 Essential medicines, 3–5, 7, 8, 52, 76, 108, 120, 121, 123–144, 149, 152, 158, 159, 163, 165, 172, 179, 180
 European Union (EU), 120, 137
- F**
 Falcão, E., 172
 Farmanguinhos, 76–79, 110–112, 172, 173
 Federal transfers, 18, 19
 Felipe, J.S., 38, 175
 Fernandes, F., xiii
 Ferreira, H., 110, 173
 FIOCRUZ. *See* Fundação Oswaldo Cruz
 Fonseca, M.G., 172
 Ford Foundation, 26
 France, 86, 126
 Franco, I., 14, 63, 175
 Fundação Oswaldo Cruz (FIOCRUZ), 38, 40, 77
 FURP, 79, 111, 173
- G**
 G-8, 123
 Galvão, J., 64, 172
 GAPA, 35, 49, 69, 99

Gaspari, E., 173
 GATS. *See* General Agreement on Tariffs and Services
 Gaviani, C., 173
 General Agreement on Tariffs and Services (GATS), 82
 General UN Assembly Declaration of Commitment on HIV/AIDS, 122, 135
 Generic drug production, 81, 114
 Generics, 91, 110, 114, 119, 126, 132, 134, 138, 151, 153, 156, 160, 161
 Ghana, 160
 Gledson, J., xiv
 Gore, Al, 119, 120, 122
 Granjeiro, A., 173, 175
 Guerra, A., 5, 54–57, 62, 173, 175
 Guerra, L., 7, 46, 47, 49, 55, 62–64, 86–90, 95, 96, 110, 113, 151, 164, 175
 Guinea, 160
 Gustavo F., 78

H

HAART, 2, 3, 24, 25, 89, 91, 97–99, 106, 107, 109–112, 119, 123, 128, 138, 140, 152, 153, 155–157, 159–162, 164–166
 Haddad, J., 63, 175
 Harvard University, 120
 Hatch-Waxman Act, 114
 Health Action International, 120
 Health GAP, 120–122, 172
 Health Ministry, 3, 19, 21–25, 33, 34, 37–40, 46, 47, 49, 51, 53–70, 76–79, 85, 86, 89–91, 95–99, 101, 102, 104, 106–109, 111, 114, 121, 123–125, 129, 139, 140, 150, 151, 156, 157, 161, 172, 174
 Herbert de Souza. *See* Betinho
 HIV, 1, 2, 4, 7, 14, 21, 23–25, 70, 86, 88, 89, 97, 99, 102, 103, 120, 122, 126, 129–136, 142, 150, 157–159, 161, 172, 173, 176, 177
 prevalence, 21, 166
 prevention, 23, 55, 65, 157, 159, 161
 transmission, 104, 165, 166
 HIV/AIDS prevention, xv, 23, 24, 34, 36, 49, 54, 55, 64, 65, 67, 69, 70, 95, 100, 102, 103, 106, 112, 123, 135, 157, 159, 161, 166, 175, 176
 Human rights, 3, 7, 8, 23, 24, 32, 35–37, 39, 43, 50, 52, 53, 55, 63, 68, 70, 96, 122, 124, 125, 128–135, 140, 142, 144, 158, 160, 173, 176, 180
 Humboldt, A.V., xiii
 Hunt, P., 173

I

IGWG. *See* Intergovernmental Working Group on Innovation, Intellectual Property and Public Health
 Impeachment, 62, 81
 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: (Decision of 30 August 2003), 122, 142
 Import Substitution Industrialization (ISI), 75, 79, 149, 151, 160
 INAMPS, 37–39, 56
 India, 3, 79, 110, 111, 113, 120, 121, 123, 138, 155, 156, 161, 162
 Indinavir, 113, 138, 171
 Indonesia, 160
 Industrial Property Act of 1971, 75
 Industrial Property Law, 7, 25, 75, 76, 80–84, 91, 109, 112, 114, 115, 127, 128, 151, 164
 Injecting drug users (IDUs), 21–23
 Intellectual property rights (IPRs), x, 25, 75, 76, 81, 83–85, 91, 112, 121, 122, 130, 131, 134–136, 142, 143, 151, 165, 177, 180
 Intellectual Property Rights, Innovation and Public Health Resolution at the World Health Assembly, 122, 142, 143
 Intergovernmental Working Group on Innovation, Intellectual Property and Public Health (IGWG), 122, 143
 IQUEGO, 111

J

Jatene, A., 62, 86–88, 173, 175
 Jeitinho, 47, 62, 90, 96
 Judiciary, 17, 52, 85, 150

K

Kalichman, A., 173
 Kemprecos, J., 173
 Klai, M., 173

L

LAFEPE, 78, 79, 110, 111, 172
 Lage, L., 173
 Lamivudine, 77, 110, 113, 153, 160
 Landless movement (Movimento Sem Terra, MST), 37, 38
 Law 9.279. *See* Industrial Property Law
 Law 9.319. *See* Sarney's Law

Lawsuit, 51, 52, 68, 69, 87, 119, 121, 122, 125, 150
 Legislature (Brazilian). *See* Brazilian Legislature
 Legislature (US). *See* US Congress
 Lévi-Strauss, C., xiii
 Levy, M., 139, 173
 Lopinavir/ritonavir (kaletra), 160
 Lotrowska, M., 173
 Love, J., 173
 Lula. *See* da Silva, Luis Inácio
 Lund, P.W., xiii
 Lusophone Africa, 123

M

Maciel, S.M., 87, 105, 106, 173
 Malaysia, 160
 Martins, E., 78, 79, 111, 173
 MDB (political party), 13
 Media, 3, 18, 32, 50, 53, 54, 56–58, 61, 65–67, 69, 70, 83, 84, 87, 90, 95, 96, 98–100, 106, 111, 115, 120, 121, 124–126, 128, 129, 134, 135, 139, 150, 175, 176
 Medicines and Related Substances Control Amendment Act, 119, 122
 Men who have sex with men (MSM), 21–23
 Merck, 122, 123, 138, 139, 161, 171, 173
 Mesquita, A., 173
 Meyer, Fred Estrada, 173
 Microbiológica, 76–80, 111, 174
 Military dictatorship, 11, 14, 15, 31, 32, 36, 37, 45
 Morel, C., 173
 Movimento Sem Terra (MST). *See* Landless movement
 Mozambique, 160
 MPAS, 37
 Müller, T.J.F., xiii
 Multinational pharmaceutical industry, 4, 76, 81, 114, 124–127, 139
 Municipalities, 14, 17–19, 21, 48, 58, 86, 89, 108

N

Nader, R., 120
 NAP (National AIDS Program), 7, 21–25, 36, 46, 49, 54–56, 59, 62–64, 67–70, 85–90, 95–107, 109, 112, 113, 123, 125, 126, 139, 151, 152, 157, 158, 163, 164, 166, 172–174
 National Drug Policy, 76, 108

Negri, B., 175
 Nelfinavir, 98, 113, 122, 123, 128, 138, 153, 154, 171
 Neto, E.R., 38
 Nevirapine, 98, 160, 171
 Nimoya, T., 173
 Non-government organization (NGO), 35, 38, 39, 46, 47, 49–51, 53–56, 60, 63, 64, 66–70, 85, 86, 95, 97–100, 102, 103, 106, 120, 121, 124–126, 128, 134, 151, 157, 172–174, 176, 177
 Non-nucleoside reverse transcriptase inhibitor (nNRTI), 86, 95, 171
 Normas Operacionais Básicas, 18
 Nucleoside reverse transcriptase inhibitor (NRTI), 86, 95, 171

O

O Movimento de Trabalhadores Rurais sem Terra (MST), 38
 Oswaldo Cruz Foundation (FIOCRUZ), 38, 40, 77
 Oxfam International, 120, 121, 172

P

Pacheco, O., 173
 Paiva, V., 141, 173
 Paragraph six of the Doha Declaration, 138
 Parallel importation, 119, 127, 137, 142
 Parallel trade, 137, 138
 Parker, R., 33, 64, 87, 140, 173
 Partners in Health, 120
 Passarelli, C., 173
 Patent, 2, 3, 7, 25, 35, 75, 76, 82–84, 91, 109, 110, 112–114, 119, 126–128, 130, 132, 133, 139, 152, 153, 156, 158, 161, 162, 173
 Path dependency, 149, 150
 Patronage (system), 16, 17, 62, 151
 Paulo, S., 21, 23, 25, 33–40, 46, 49, 54, 60, 63, 64, 66, 67, 69, 86, 106, 111, 150, 172–174
 Pela VIDDA, 39, 49, 51, 66, 69, 99, 106, 172, 174
 Penna, M., 174
 People living with HIV/AIDS (PLWHA), 7, 25, 39, 49, 50, 52–55, 57–59, 61, 68, 69, 86, 87, 91, 97–99, 104, 120, 123, 133, 135, 150–152, 156, 158–162, 176
 Peru, 160
 PFL (political party), 14, 15, 46, 62, 87, 105

- Pharmaceutical Manufacturing Association (PMA), 81, 83, 119, 121–124
- Pharmaceutical Research and Manufacturing Association (PhRMA), 81, 124, 127
- Pinheiro, E., 110, 111, 173
- PMDB (political party), 13, 14, 33, 37, 39–42, 45, 51, 63, 80, 150, 172
- Political action, 32, 33, 36–38, 40, 42, 43, 47, 49–54, 56, 58–60, 62, 63, 67, 69, 70, 85–87, 89, 90, 96, 98, 100, 103, 104, 120–122, 129, 134, 139, 140, 150, 152
- Pork-barrel politics, 47
- Positive feedback, 6, 7, 59, 61, 70, 111, 124
- Possas, C., 173
- Prates, A., 134, 174
- Presidential Decree 3.201, 112
- Prevention, xv, 23, 24, 34, 36, 46, 47, 49, 54, 55, 64, 65, 67–70, 95, 100, 102, 103, 106, 112, 123, 135, 157, 159, 161, 166, 175, 176
- PRN (political party), 47
- Proportional representation, 16
- Protease inhibitors (PI), 86, 171
- Protectionism, 127
- PSDB (political party), 45, 80, 105, 106
- PT (political party), 13, 45, 47, 96
- Public-private partnerships, 79, 151, 161
- R**
- Rabi, J., 76–79, 174
- Raw materials, 43, 77–80, 110, 111, 113, 114, 122, 138, 159
- Reagan Administration, 81
- Revised Drug Strategy, 129, 131, 132
- Rio de Janeiro, 1, 36, 38–40, 46, 49, 53, 63, 64, 66, 173, 174, 179
- Rising cost of AIDS treatment, 110, 113
- Roche, 122, 123, 138, 171, 174
- S**
- Sanitarista, 31–41, 45, 46, 51–56, 62–64, 66, 67, 85, 95–100, 105, 107, 126, 140, 150, 151, 157, 172, 173
- Sanitary Health Reform movement, 13, 31
- Sant'Anna, C., 175
- Santillo, H., 63, 175
- Santos, E., 1–2Santos, R., 175
- Sarney Administration, 46, 62
- Sarney, J., 7, 14, 87, 96, 175
- Sarney's Law, 7, 80, 87–91, 95, 100, 104, 105, 108–110, 115, 149, 151, 152, 158
- Seixas, J., 175
- Serra, J., 5, 7, 20, 105–113, 123–126, 128, 129, 132, 135, 136, 139–141, 143, 152, 174, 175
- Silveira, L.C., 175
- Simão, M., 175
- Sistema Único de Saúde (SUS), 18, 48, 87, 89–91, 97, 157, 158, 166
- Skidmore, T., xiv
- Social movement, 3, 4, 7, 13, 17, 18, 31–33, 36–40, 43, 45, 46, 49–51, 53, 63, 70, 75, 90, 96, 98, 103, 109, 121, 122, 129, 139, 140, 149–152, 160, 161, 163, 164
- Social movement repertoire, 31, 32, 50, 51, 96, 98
- South Africa, 119–122, 125, 126, 128, 133, 134, 136, 161, 162
- Steele, J., 174
- Stop-TB Partnership, 1
- Sub-Commission on Human Rights, 122, 140, 142, 180
- SUS. *See* Sistema Único de Saúde
- Swaziland, 160
- Sweden, 133
- T**
- Talmud, vii
- Technology transfer, 78, 126, 165, 178
- Teixeira, J., 174
- Teixeira, P., 34, 35, 50, 54, 56, 60, 63, 69, 97, 123, 126, 174, 175
- Terto, V., 174
- Thailand, 119, 133, 136, 160
- The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, 1
- Threats to issue compulsory licenses, 3, 5, 123, 127, 149
- Three by Five, 159
- Trade-Related Aspects of Intellectual Property Rights (TRIPS), 82, 112, 119–122, 127, 128, 130, 133, 136–138, 142, 144, 151, 158, 159, 164, 172, 177, 178
- Trade sanctions, 81, 83, 119–122, 124, 125, 128, 143
- Treatment Action Campaign (TAC), 120, 121
- TRIPS. *See* Trade-Related Aspects of Intellectual Property Laws
- TRIPS flexibilities, 136–138, 142, 144
- Tsuzuki, S., 175
- U**
- UNAIDS, 159
- UN General Assembly Special Session (UNGASS), 122, 134–136, 138, 140, 158

Unifying slogans, 32, 37, 50, 96,
98, 100
 United Nations, 122, 134–136, 140
 United States, 3, 4, 25, 36, 53–56, 66, 76, 81,
83, 84, 119–129, 133–135, 137, 139,
143, 159
 United States (US) government, 4, 76, 83, 122,
124, 125, 127, 129
 United States Trade Representative (USTR),
81, 122, 125, 127, 128, 134–136, 138,
139, 152, 174
 UN Security Council, 121, 122
 US Congress, 83
 US Legislature. *See* US Congress

V

Vancouver AIDS Conference, 86,
88, 120
 Veloso, V., 174
 Ventura, M., 51, 52, 68,
90, 174
 Vertical (mother-to-child) transmission
of HIV, 2, 21
 Viana, J.M., 124, 136, 141, 174
 Vigneau, M., 174

W

Wellcome, 49, 53, 54, 60, 77, 79, 111, 113, 171
 WHO Medicines Strategy, 122, 132, 135
 World AIDS Day, 60, 66, 99, 112
 World Bank, 4, 7, 21, 49, 55, 61–71, 96, 97,
100–105, 151, 152, 157–159, 162, 165,
175, 176, 179
 World Bank Loan, 7, 21, 49, 61–71, 96,
100–105, 151, 152, 157, 158, 176, 179
 World Bank Loan AIDS I, 65, 68, 176
 World Bank Loan AIDS II, 100–101, 176
 World Bank Loan AIDS III, 102, 176
 World Health Assembly (WHA), 122, 126,
131–135, 142, 143, 158
 World Health Organization (WHO), 19, 60,
66, 108, 112, 122, 125, 126, 131–135,
142–144, 158, 159, 173
 World Trade Organization (WTO), 3, 25,
82–84, 122, 124–129, 131, 134–136,
138, 140, 142, 151, 152, 174, 177

Z

Zidovudine/lamivudine (AZT/3TC), 153
 Zimbabwe, 126, 132, 136
 Zoellick, R., 134