PRIVATE AUTHORITY AND GLOBAL HEALTH GOVERNANCE

PRIVATE AUTHORITY AND GLOBAL HEALTH GOVERNANCE: PUBLIC-PRIVATE PARTNERSHIPS AND ACCESS TO HIV AND AIDS MEDICINES IN THE GLOBAL SOUTH

By SHERRI A. BROWN, B.A., M.A.

A Thesis Submitted to the School of Graduate Studies in Partial Fulfilment of the

Requirements for

the Degree of Doctor of Philosophy

McMaster University DOCTOR OF PHILOSOPHY (2011) Hamilton, Ontario (Political Science)

TITLE: Private authority and global health governance: Public-private partnerships and access to HIV and AIDS medicines in the global South

AUTHOR: Sherri Brown, M.A.

SUPERVISOR: Professor Stephen McBride

NUMBER OF PAGES: xiii, 305

Abstract

The global HIV/AIDS pandemic has emerged alongside a changing world order marked by the growing power and authority of business, new constraints on public authority and policy autonomy, and new global hierarchies, inequalities, and contradictory tendencies. These conditions have helped midwife new configurations of public and private power, authority, and relations and shaped normative and operating environments for global health governance. In these contexts, public-private partnerships emerged as an institutional experiment, ostensibly to address health governance gaps and failures, including access to HIV and AIDS medicines in the global South.

This study investigates the growth and roles of private authority in health governance through the lens of four case studies of public-private partnerships intended to enhance access to HIV and AIDS medicines in the global South. The study reveals that public-private partnerships in health emerged from this history as institutional experiments, yet not convincingly as functionalist responses to governance gaps and failures. The history demonstrates that private business actors opted to engage in partnerships in the contexts of a convergence of social, political, and commercial pressures, and normative and structural transformations in the world order. The case study partnerships emerged as accommodation or *trasformismo* strategies which offered concessions in an attempt to neutralise and co-opt social contestation around treatment access, without succumbing to demands for deeper structural and legislative reforms. These strategies offer bilateral, narrow, and tactical contributions in a framework of poor design, governance, accountability, and equity considerations and obligations, and are

ultimately unconvincing in their commitment or capacity to expand access to HIV and AIDS medicines. Ultimately, public-private partnerships in health present practical, strategic, and normative consequences that necessitate new approaches to reform and/or serious reconsideration of their role and prospects in global health governance.

Acknowledgments

Research for this dissertation took me to six countries, three of which are in the throes of major HIV/AIDS epidemics. I have witnessed extraordinary acts of courage and generosity, and have had the great privilege of meeting several contemporary heroes. This dissertation is but a tiny contribution, but I type every word and recount every finding remembering and hoping to honour these places, stories, and peoples. Thank you to the people of Lesotho, Malawi, and South Africa. There would be no dissertation had it not been for the openness and willingness of strangers to let me into their world, if even for just a brief period.

I owe many thanks to an exceptional group of individuals who have offered tremendous patience, guidance, and mentorship over the last five years. My Senior Supervisor, Professor Stephen McBride, is what every graduate student hopes for in a supervisor, offering a combination of kindness, brilliance, patience, and commitment. He championed and shepherded my research and academic development from the first day of my PhD to the last. Saying thank you seems insufficient, but thank you, nonetheless. I am also deeply indebted to my supervisory committee, including Professors Tony Porter, John Lavis, and Sandra MacLean. It has been a tremendous privilege to work with all of you. Each of you offered extraordinary support, and this dissertation is imprinted with your unique insights and contributions. I am also very grateful to the Trudeau Foundation and the Social Sciences and Humanities Research Council of Canada for generous financial support.

I am thankful to friends and colleagues who lent sympathetic ears, helpful advice and support, and abundant kindness. In particular, I would like to thank Cam Sylvester, Cathy & Howie Attfield, Elizabeth Blackwood, Joanne & Dave Barker, Manuela Dozzi, Melissa Finn, Robin Adams, and the 2010 PhD cohort at McMaster.

Thank you to my parents, Rob and Bette Ann, who have always been generous with their love, understanding, and encouragement. Although I am grateful for the many years of support, I thank them for allowing me to draw heavily on it over the past year, and for their incredible devotion as grandparents. Many thanks to my sisters, Lauren and Lindsay, who have been the greatest friends, the safest places to land, and the most loving aunties. And, thank you to my late grandmother, Dorothy, whose feisty and unrelenting spirit and commitment to her family, friends, community, and politics inspired me, pushed me forward, and kept me on my toes.

Finally, my deepest gratitude goes to my partner, Warren, and my son, Quinn. Warren, you, more than anybody, made this dissertation possible. You provided all manner of love and support, and cared for Quinn so that I could have the time and the peace of mind to complete this dissertation. Quinn, you came along about two-thirds of the way through the PhD, and in many ways, helped me complete this dissertation. You make me stronger, more patient, and more dedicated than I have ever been. This is a beautiful, peculiar, and complex world, and completing this dissertation means that we can move on and show it to you.

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List of Acronyms and Abbreviations

3TC	Lamivudine (ARV medicine)
ABC	Abacavir (ARV medicine)
ACT-UP	AIDS Coalition to Unleash Power
AAI	Accelerating Access Initiative
ACHAP	African Comprehensive HIV/AIDS Partnership
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral therapy/treatment
ARV	Antiretroviral
ATV	Atazanavir (ARV medicine)
AZT	Zidovudine (ARV medicine)
BI	Boehringer Ingelheim
BMS	Bristol-Myers Squibb Company
CCM	Country coordinating mechanism
CDC	Centers for Disease Control and Prevention (USA)
CEO	Chief Executive Officer
CHAI	Clinton HIV/AIDS Initiative
CSR	Corporate social responsibility
DAI	Drug Access Initiative
d4T	Stavudine (ARV medicine)
ddl	Didanosine (ARV medicine)
DPP	Diflucan Partnership Programme
DRV	Darunavir (ARV medicine)
EFV	Efavirenz (ARV medicine)
ETV	Ertravirine (ARV medicine)
FPV	Fosamprenavir (ARV medicine)
FTC	Emtricitabine (ARV medicine)
GATT	General Agreement on Tariffs and Trade
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GHG	Global Health Governance
GHI	Global Health Initiative
GHP	Global Health Partnership
GPPP	Global Public-Private Partnership
GSK	GlaxoSmithKline, Inc.
HAART	Highly active antiretroviral treatment
HDI	Human Development Index
HIPC	Heavily Indebted Poor Country
HIV	Human Immunodeficiency Virus
IAVI	International AIDS Vaccine Initiative
IDV	Indinavir (ARV medicine)
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IMF	International Monetary Fund

IPPPH	Initiative for Public-Private Partnerships in Health
IPM	International Partnership for Microbicides
IPR	Intellectual property rights
LDC	Least developed country
LIC	Low-income country
LMIC	Lower-middle income country
LPV	Lopinavir (ARV medicine)
MAP	Multi-country HIV/AIDS Program
MIC	Middle-income country
MMV	Medicines for Malaria Venture
MSF	Médecins sans Frontières
NAFTA	North America Free Trade Agreement
NFV	Nelfinavir (ARV medicine)
NGO	Nongovernmental organisation
NVP	Nevirapine (ARV medicine)
OECD	Organisation for Economic Co-operation and Development
PEPFAR	President's Emergency Plan for AIDS Relief
PMA	South African Pharmaceutical Manufacturers Association
P^3Hs	Public-Private Partnerships in Health
PPP	Public-Private Partnership
PPY	Per patient, yearly
PRSP	Poverty Reduction Strategy Papers
RBM	Roll Back Malaria
RTV	Ritonavir (ARV medicine)
SAP	Structural Adjustment Programmes
SQV	Saquinavir (ARV medicine)
SSA	Sub-Saharan Africa
STF	Secure the Future Partnership
TAC	Treatment Action Campaign
TDF	Tenofovir Disoproxil Fumarate (ARV medicine)
TPV	Tipranavir (ARV medicine)
TRIPs	Agreement on Trade-Related Aspects of Intellectual Property
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGA	United Nations General Assembly
UNGASS	United Nations General Assembly Special Session
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNITAID	United Nations International Drug Purchasing Facility
US	United States of America
USTR	United States Trade Representative
WHO	World Health Organisation
WTO	World Trade Organisation

Chapter 1: Introduction and Methodology

In 1981, five men in Los Angeles visited their physicians complaining of symptoms of coughs and shortness of breath and were subsequently diagnosed with a rare pneumocystis pneumonia (CDC, 1981). Increasing numbers of patients presenting with similar sets of illnesses and infections, including pneumonias, skin lesions, and opportunistic infections, prompted a series of investigations at the US Centers for Disease Control and Prevention (ibid.). These investigations culminated in a newly designated virus, the human immunodeficiency virus or HIV, and syndrome, Acquired Immune Deficiency Syndrome or AIDS, which represents the last stage of HIV infection when an individual has progressed through asymptomatic and symptomatic stages following initial infection (CDC, 2007).

By 1985, HIV/AIDS had been identified in every region of the world (Bertozzi, Martz, & Piot, 2009) and less than 10 years later, in 1993, the World Health Organisation (WHO) estimated that over 2.5 million people were living with HIV (WHO, 1995). What began with five cases had quickly accelerated into a global pandemic. As the global pandemic unfolded, a globalising world was also emerging. Characterised by growing privatisation, deregulation, and trade and financial liberalisation, globalisation dismantled many of the barriers to global flows of people, culture, goods and services, finance, and capital. The velocity and volume of these and other flows multiplied under globalisation and the new world order became progressively more interconnected and interdependent.

These global transformations intersected with health and with the HIV/AIDS pandemic and ushered in new risks, constraints, and opportunities in domestic and global health governance (GHG). Increasing population mobility created new risks for the trans-border spread of disease while global trade rules and flows facilitated *and* obstructed the distribution of products, including medicines,[1] pollutants, waste, tobacco, and foods. It has also been argued that globalisation, through new global trade and finance arrangements, sustains or exacerbates economic inequalities and poverty in and among states (Dodgson, Lee, & Drager, 2002) and thus drives health and disease epidemics such as HIV/AIDS, malaria, and tuberculosis. Lee (1999) argues that globalisation is contributing to greater inequities in health, where poor and marginalised states and populations share an expanding proportion of the global disease and poor health burden.

The global HIV/AIDS pandemic reflected and exposed structural and global health inequalities. Although HIV/AIDS could be found in every region of the world, it quickly became obvious that the global disease burden was disproportionately shouldered by countries in the global South, and particularly in Sub-Saharan Africa. Of the 34 million people currently living with HIV/AIDS, 96% live in a low or middle-income country, and 68% live in countries in Sub-Saharan Africa (see Figure 1-1) (WHO & UNAIDS, 2011), while 2.5% and 3.9% live in Western and Central Europe and North America, respectively (ibid.).[2]

[1] The terms drugs and medicines are used interchangeably, although medicine refers to a range of health products and technologies, including, but not limited to, drug and chemical entities.

[2] These proportions have held steady since the mid-1990s.

The development of antiretroviral therapy (ART)[3] to suppress the human immunodeficiency virus (Hogg et al., 1998) was a scientific and historical achievement which transformed HIV from a fatal to a potentially chronic condition by suppressing the virus and therefore preventing the onset of AIDS-defining illnesses. [4] Despite exponentially greater needs, however, there was gross delay and inequity in access to ART and other medicines for treating AIDS-defining illnesses throughout much of the global South. At the end of 2003, ART coverage[5] was 2% in Sub-Saharan Africa, and 7% for all low and middle income countries, yet approximately 84% in North America and Western Europe (WHO, 2004; WHO & UNAIDS, 2006). These conditions generated massive AIDS morbidity and mortality and created new domestic and international governance challenges. Private actors, including civil society and business actors, took up many of these challenges through modes of public-private interaction, including advocacy, activism, research, and partnerships.

The new terminology around health reflects these changes in growing public-private interaction in health governance. The shift towards 'global health' from 'international health' underscores its transnational, polycentric, and mixed actor character

[3] The terms triple therapy, HAART, and antiretroviral treatment (ART) are commonly used interchangeably and refer to standard three-drug protocols for first and second line treatment for HIV-positive children, adolescents, and adults.

[4] The US Centers for Disease Control and Prevention recognise 21 AIDS-defining illnesses in adults. For the complete list, see: http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm.

[5] Treatment coverage rates refers to the percentage of people eligible to receive treatment who are currently accessing treatment (WHO, UNICEF, & UNAIDS, 2010). As of 2010, WHO guidelines recommend that adolescents and adults (including pregnant women) should be placed on antiretroviral therapy when they have a CD4 cell count that is < 350 cells/mm^3.

and imputes responsibility for its management on a multi-layer authority structure. This structure, now widely conceptualised as global health governance, connotes that authoritative functions in health governance are shared among state and nonstate actors and institutions that are based inside and outside the traditional interstate fora of international health, specifically the WHO and United Nations organisations. Nonstate actors include civil society actors, private business actors, nongovernmental organisations (NGOs), faith-based organisations, and mixed-actor coalitions. These actors participate in, inter alia, advocacy coalitions, public-private partnerships, global health initiatives, financing, health service delivery, and product development and access initiatives.

The delegation of governance functions to private actors, though, is not an innovative practice. Domestic health governance has frequently consisted of mixed actors, including public actors (states, bureaucracies, etc.) and private actors (community and faith-based organisations, private firms, private practitioners, industry associations, etc.). States have also been delegating governance functions to private actors via privatisation, deregulation, and transformations in the public service (e.g. use of private consultants). Although these governance arrangements are not new at the domestic level, they are relatively new at the international level (Börzel & Risse, 2005; Witte & Reinicke, 2005). These types of public-private partnerships involve state and/or interstate institutions and transnational private business actors.

A public-private partnership in health (P^3H)[6] is a collaborative relationship consisting of at least two parties: 1) nonstate transnational business actor(s), such as a private business firm, industry association, or private foundation,[7] and 2) public actors, such as state and interstate institutions. Partnerships supply practical contributions, including access to health products, and human, financial, and technical resources. They also provide strategic contributions in coordinating and implementing programmes and services to address health governance needs, including financing coordination, policy development, research and development, health systems strengthening, and advocacy and education. Finally, partnerships exercise normative functions in governance through pursuit and/or creation of particular values, ideas, and ideological approaches.

From the mid-to-late 1990s, there has been a significant increase in authoritative activity by private business actors ("private authority") in global health, particularly in communicable diseases such as HIV/AIDS, tuberculosis, malaria, and other tropical diseases. Over 200 new P^3Hs formed from 1986 to 2006, with half emerging over a five-year period from 1998 to 2003.[8] Originator (branded) pharmaceutical firms, particularly, have been at the forefront of these activities. In 2010, the International Federation of

[6] I conceived this umbrella term to cover the scope of public-private partnerships in health, including public-private partnerships (PPP), global health partnerships (GHPs) and global health initiatives (GHIs). In Chapter Four, I distinguish between P^3H subtypes.

[7] Private foundations are included given that for many foundations (but not all) the bulk of their funding originates from private business activity.

[8] Author calculation based on data retrieved September 15, 2006 from the Initiative for Public-Private Partnerships in Health database.

Pharmaceutical Manufacturers and Associations (IFPMA)[9] Developing World Health Partnerships Directory listed 213 active partnerships, a 491% increase from 36 partnerships in 2003 (IFPMA, 2010a).[10] These partnerships operate in 153 countries with participation from 35 pharmaceutical firms and 106 state and interstate organisations , including 8 United Nations organisations.[11] Of the 213 partnerships, 60 (28.2%) have an explicit HIV/AIDS disease focus, of which 87% include an access to medicines orientation with programmes addressing patent and/or pricing flexibilities, health system capacity building, health system resources, and health delivery services.

The growing popularity of P^3Hs provoked a range of studies, the earliest ones primarily located in public health literatures with a slightly more delayed engagement from scholars in the social sciences, including political science and international relations. The earliest works (2000-2003) cautiously regarded these configurations as experimental (Buse & Waxman, 2001; Buse & Walt, 2002; Widdus, 2001) arrangements in global health policy and practice. Scholars emphasised partnerships' functional[12] and problem-solving (Kettler & White, 2003; Reich, 2000; Wheeler & Berkley, 2001)

[9] The IFPMA represents the bulk of the global originator pharmaceutical industry. Its members include national and regional pharmaceutical industry associations and individual firms. For more information, see: http://www.ifpma.org/about-ifpma/welcome.html..

[10] Author calculations based on data extracted from 2010 IFPMA developing world health partnerships directory. The directory lists partnerships with public authorities, non-governmental organisations, faith-based organisations, and academic institution

[11] This includes the Joint United Nations Programme on HIV/AIDS, the World Health Organisation, UN Women, United Nations Refugee Agency, United Nations Development Programme, United Nations Children's Fund, United Nations Population Fund, and the World Bank.

[12] The terms functional or functionalist appear throughout this dissertation and refer strictly to analytical frameworks which emphasise utility, function, and purpose, and does not refer to any particular sociological, psychological or international relations theories on functionalism.

contributions, underscoring their necessity for global health problems that cannot be solved by the public sector alone (Buse & Walt, 2000a). Public-private partnerships in health, moreover, potentially offered a medium for reconciliation of public and private sector needs(Buse & Walt, 2000b; Reich, 2000; Ridley et al., 2001), and integration of their respective skills and resources (Buse, 2003; Buse & Walt, 2002; Reinicke et al., 2000; Widdus, 2001). These early works were highly optimistic about P^3Hs, but not entirely insensitive to the challenges of public-private cooperation. In particular, these works referenced issues with P^3H governance, including problematic membership selection (Buse, 2003; K. Buse & A. Waxman, 2001), partner representation (Buse & Walt, 2000b), potential conflicts of interest (Buse, 2003), and poor transparency (Buse, 2003). Indeed, Buse (2003) submitted that "the most radical aspect of these initiatives might lie in their governance" (p. 225). Many of these works, however, reiterated a similar functionalist and reformist proposition: partnerships offer significant problem-solving potential in global health governance, but would need to attend to governance and other issues that undermined their effectiveness.

Studies also discussed questions of reconciliation of public and private interests (Richter, 2003, 2004a), accountability (Bartsch, 2008), legitimacy (ibid.), representation and participation of Southern partners (Bartsch, 2006, 2009; Buse & Harmer, 2004), policy alignment with national health governance (Buse & Harmer, 2007), effectiveness (Aginam, 2007; J. F. Naimoli, 2009; Y. Nair & Campbell, 2008; Walker, 2009), and human rights (Hallgath & Tarantola, 2008). Studies, though, maintained the functionalist, reformist position with few exceptions. The exceptions (B. Bull, 2010; B. Bull &

McNeill, 2006; Richter, 2003, 2004a, 2004b), moreover, tended to come from critiques of public-private partnerships as a global governance phenomenon, and not studies specifically investigating public-private partnerships in health.[13] Scholars investigating public-private partnerships in health continued to stress their problem-solving and value-added possibilities, and in consideration of "considerable shortfalls in the quality of their governance" (Buse & Lee, 2005, p. 36) and other issues, emphasised good governance reforms (Aginam, 2007; Buse & Tanaka, 2011; J. F. Naimoli, 2009), strengthened evaluation efforts (Walker, 2009) and new forms of incentives and sanctions (Buse & Harmer, 2007; Y. Nair & Campbell, 2008). In other words, the predominant research orientation on P^3Hs has been concerned with evaluating and advancing partnership *functionality* and *effectiveness.*

This type of approach, Fuchs (2007) argues, expresses a "presumption of desirability" (p. 39) and consequently insufficient engagement with considerations of history and power underlying governance arrangements. The literature on public-private partnerships in health[14] has not entirely neglected the role of history and power in these arrangements. However, there is typically very minor engagement; the majority of studies

[13] Richter's (2004a, 2004b) works are a notable exception, although there were no subsequent publications by Richter on P^3Hs after 2004. Bartsch's (2006, 2008, 2009, 2011) works also draw attention to the role of power and interests in P^3Hs, although in more recent work (2011) she stresses that partnerships should be evaluated in terms of their intended functions in governance.

[14] Again, this refers to studies on P^3Hs. The global governance and private authority literature contains a more significant representation of critical investigations of public-private partnerships and public-private interaction. This literature will be explored in more detail in Chapter Two.

do not attempt systematic and critical interrogation.[15] Given the dominant functionalist and reformist bias, few studies have sufficiently considered the critical historical and social origins and significance of public-private partnerships as a new policy paradigm, governance arrangement, and as this study will argue, an emergent accommodation strategy for private business power and authority. In Gramscian conceptual terms, an accommodation or *trasformismo* strategy refers to cooptation of resistance and opposition, typically achieved through compromises and concessions from ruling elites (Gill, 2000; Gramsci, 1971; 58-59).

Furthermore, even fewer conduct this form of analysis across case studies of partnerships; therefore, the bulk of what we know about P^3Hs in a health issue or disease area emerges from single case studies, evaluation and performance reviews, and often thin partnership documentation. The objectives of this study are to both address some of these deficits and to bridge the gap between deficits in critical approaches in the P^3H literature and relative neglect of P^3Hs in the critical political economy literature, through a cross-case and critical investigation of four HIV and AIDS access-oriented partnerships operating in the global South.

Statement of Problem and Purpose of the Study

The purpose of this study is, broadly, to investigate the quantitative and qualitative growth and transformations in private authority in health governance, and, specifically, to examine such authority through the lens of public-private partnerships

[15] Several chapters in Rushton & Williams' (2011) edited volume on 'Partnerships and Foundations in Global Health Governance' provide contributions that begin to address this deficit.

intended to enhance access to HIV and AIDS medicines, particularly in Sub-Saharan Africa, but also throughout the global South.[16] These include antiretroviral (ARV) medicines and one antifungal medicine (fluconazole); the former suppresses the human immunodeficiency virus and the latter treats cryptococcal meningitis and candidiasis, two common[17] and fatal[18] AIDS-defining illnesses. Access partnerships involve various strategies, including patent flexibilities (voluntary licensing, technology transfer, patent pools), pricing strategies (differential pricing, donations), capacity building, health system resources and services to help overcome barriers to treatment.[19]

In the age of a global HIV/AIDS pandemic, the issue of access to medicines has profound public health and human rights dimensions. Antiretroviral treatment has been shown to not only enhance and extend life (Hogg et al., 1999; Low-Beer et al., 2000), but multiple studies confirm that treatment also acts as a prevention mechanism. With appropriate administration, ART has proven efficacy in substantially reducing the probability of HIV transmission from pregnant mother to child (UNAIDS & WHO, 2010). Furthermore, large randomised controlled studies have established that ART in an

[16] As a major epicentre of the global HIV/AIDS pandemic, a key regional focus for new public-private partnership activity and home to multiple operational locations for the four case studies, Sub-Saharan Africa is highlighted in this study. All four case studies operate in countries in Sub-Saharan Africa, although two (AAI and DPP) operate elsewhere in the global South, including countries in Central and Latin America and Asia.

[17] Cryptococcal meningitis affects, on average 9% of people living with HIV. In developing countries, however, prevalence can be as high as 25% (Perez-Casas, Herranz, & Ford, 2001).

[18] Without treatment, the average life expectancy following diagnosis is approximately one month (ibid.).

[19] See also Table 1-1.

HIV-positive, heterosexual partner significantly[20] reduces the chance of transmission to the uninfected partner (Donnell et al., 2010; HPTN, 2011). Treatment, therefore, has the potential to help curb the spread of the pandemic and allow millions of people living with HIV to live longer and healthier lives.

The advent of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) in 1995 secured broad intellectual property rights, and effectively monopolistic protection, for medicines patent owners, thus driving up prices and limiting the number of producers. The implications this rule system were that in the years following the discovery of ART, access was largely limited to wealthy states and classes. Growing civil society movements contested the power and privilege of pharmaceutical firms and advanced capitalist states in denying treatment access to millions of people living with HIV and AIDS. Civil society demanded pricing and patent reforms and new governmental and intergovernmental funding and normative commitments. Many new P^3Hs, including the cases in this study, emerged during this period of intense social contestation and increasing political awareness around HIV/AIDS and treatment access and positioned themselves as institutional experiments to help overcome access barriers in the global South. This study, through a cross-case analysis of four access-oriented P^3Hs, problematises the emergence of these new hybrid governance arrangements and the issues, challenges, and prospects for their role in the global health governance of access to HIV and AIDS medicines.

[20] In May 2011, findings from the HIV Prevention Trials Network Study 052 showed that ARV treatment in an HIV infected partner reduces transmission to an uninfected partner by up to 96% (HPTN, 2011).

Public-private partnerships with originator pharmaceutical firms serve as an excellent lens to examine private authority in health. These firms are representative of the growing class of large transnational firms headquartered in advanced capitalist states that are becoming increasingly authoritative in national and global governance. These partnerships are also representative of new modes of public-private interaction in health governance. The issue selection of access to HIV and AIDS medicines is timely and critical as a study of a multi-faceted governance issue and an evolving governance challenge given the chronic nature of HIV treatment and the scale of the problem. The issue selection is also relevant to other emerging health crises, including other communicable and non-communicable diseases, and real and potential contestations around the competing rights of pharmaceutical firms to retain and exercise their intellectual property rights and the human rights of individuals to access life-saving pharmaceutical interventions and to achieve the highest attainable standard of health.[21]

Conceptual and Theoretical Framework

This study accepts the premise that globalisation reconfigures the traditional state-centric system of health governance, both in terms of the health challenges that transcend traditional territorial boundaries, and the responses which are multi-actor in nature (Brown & MacLean, 2009). One of the most important contributions of critical political economy is its ability to inquire into the development of the political system rather than

[21] As stipulated in multiple international and domestic human rights instruments, including, inter alia, the United Nations Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the Convention on the Rights of the Child, and the Convention on the Elimination of All Forms of Discrimination against Women. See Chapter Three for specific health references in these instruments.

using the current system as the starting point for inquiry. Critical political economy draws attention to the interests served by theory and to the historical and social frameworks and interests that have contributed to the development of theory (Cox, 1981; Cox & Sinclair, 1996). The unit or focus of inquiry is not the state but rather the social and political forces and processes of change in the world. Critical political economy understands globalisation as an historical process shaped by social relations, and therefore locates private authority and P^3Hs within these processes.

The development of this study's analytical framework is constructed by combining conceptual and theoretical precepts from two bodies of literature. A growing body of literature on private authority provides conceptual and analytical frameworks and propositions for problematising the historical and social origins, forms, processes, and transformations in private business power and authority in global governance. In particular, Cutler, Haufler & Porter's (1999b) frameworks for explaining the emergence of private authority in global governance, Börzel and Risse's (2005) typology on private authority forms and structures, and Hall & Bierksteker's (2002b) inventory of authoritative action, , inform the analysis of the growth and transformations in private authority and P^3Hs in health governance.

Second, the development of a critical historical and power-based analysis of private authority and P^3Hs draws from Gramscian-inspired frameworks, particularly in relation to works by Robert W. Cox, Stephen Gill, and David Levy. Specifically, use is made of analyses of transformations in the postwar world order (Cox, 1983, 1987; Cox &

Sinclair, 1996), and forms of structural[22] and behavioural power which Gill characterises as disciplinary neoliberalism and new constitutionalism, and which generate enabling and disabling conditions for capital, states, and civil society, in a globalising market civilisation (Gill, 1995, 1998, 2003). Attention is paid to the distributional and ideational consequences of these transformations, notably the creation of new global and social hierarchies, social contestation (Gill, 2003; M. Rupert, 1997, 2003a, 2003b, 2005a, 2005b; M. Rupert & Solomon, 2005), accommodation from transnational elites facing threats to their hegemonic position (Levy & Egan, 1998, 2000; Levy & Newell, 2002; Levy & Prakash, 2003), and discursive[23] and normative transformations in global health governance.

These Gramscian inspired analytical tools problematise social phenomena and change through attention to disequilibrium and struggle, and therefore offer an important alternative to mainstream international relations theorising and its preoccupation with problem-solving and stability within the international system. By focusing on inherent tensions and contradictions within the historical and social relations underlying governance phenomena, as well as possibilities for transformation within these relations (Soederberg, 2007), Gramscian analysis offers the potential to reveal important insights into processes of contestation, accommodation, and transformation (Cox, 1999; M.

[22] Structural power allows private business actors to shape policy and political agendas without having to resort to direct lobbying or other pressure tactics (referred to as 'instrumental' or 'direct' power) by virtue of their "material position within states and the global economy" (Fuchs, 2007; pp. 8-9).

[23] Fuchs (2007) refers to discursive power to the ability of corporations to pursue or create interests through production and reproduction of ideas and concepts in social and political relations. Discourse is therefore fundamental to norm production, reproduction, and contestation.

Rupert, 2000, 2005a). The approach adopted here, therefore, significantly widens the analytical net on P^3Hs from a predominantly problem-solving and effectiveness orientation, to problematising their historical and social origins and significance, ideational and distributional consequences, and possibilities for social transformation.

Research Questions

The investigation of the study problem proceeds through two central research questions and several within and cross-case subresearch questions. The within-case subresearch questions direct investigations and analyses of the individual case studies, while the central and cross-case research questions help to extract empirical and theoretical findings, including concepts, constructs, and themes.

Central research questions.

1. What explains the growth of private authority in health, particularly in the form of public-private partnerships in health?
2. What are the intended and unintended consequences of private authority in health, as evidenced through the lens of public-private access partnerships, for national and global health governance?

Within-case subresearch questions.

1. What are the history and origins of the partnership?
2. What is the rationale for partner participation? What do partners perceive as their contributions and competencies?
3. What are partnership goals, objectives, and strategies? How does the partnership operate? (governance, resources, partner roles and responsibilities)
4. What challenges have partners(hips) faced in design or implementation of partnership goals?

Cross-case subresearch questions.

1. Where and how do private authority and partnerships interact with national and global health governance actors and institutions?

2. What are the implications/consequences of partnerships and public-private interfaces in terms of public authority, normative environments in global health governance, and global health priorities, strategies, and outcomes?

3. What barriers to global treatment access remain? What role for private authority and/or partnerships?

This study proceeds with a theoretical and historical analysis of the rise of private authority (Chapter Two) and, subsequently, an examination of the political economy and social relations of HIV/AIDS and treatment access from 1987 to 2011 (Chapter Three). These chapters contain analyses on the evolution of social relations under globalisation and intersections with private authority, health, HIV/AIDS, and access to medicines. In Chapter Four, a review of the literature on private authority and P^3Hs draws out partnership histories, modes, contributions, and consequences. Chapters Five and Six present findings from investigations of four case studies of access partnerships relevant to central, within, and cross-case research questions. Chapter Seven concludes the study with discussions on key findings and arguments, and practical, policy, theoretical, and research implications and recommendations.

Study Methodology

In conducting this study, I employed a qualitative research approach and a collective case study research design. Hancock (1998) defines a case study as "an in-

depth study of a single or small number of units. The unit may be individual people, groups or organisations" (21). Yin (1994) elaborates:

> A case study is an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident. (13)

Case studies, therefore, help us to understand social phenomena through detailed investigations of social phenomena (Creswell, 1998). According to Creswell's (1998) typology, an instrumental case is used to explore issues around particular phenomena, whereas an intrinsic case undertakes an investigation of a person, group, or organisation. I employed a collective case study approach, combining instrumental and intrinsic elements. Accordingly, I selected multiple cases, conducted an investigation of each (referred to as a within-case analysis), and surveyed empirical and theoretical themes and findings in cross-case analyses (Berg, 1998; Creswell, 1998).

Case selection.

Given the objective of this study to conduct a collective case study investigation of access-oriented public-private partnerships, I employed information-oriented[24] case selection techniques (Flyvbjerg, 2006) to select among a small (22) sample of P^3Hs, and achieve maximum variation in the sample. Case selection utilised the 2007 IFPMA Health Partnerships Directory which contains information on the population of health partnerships with originator pharmaceutical firms. The directory supplies information on

[24] Instead of random or stratified sampling techniques, information-oriented techniques collect information on a list of potential cases from a typically smaller sample. After gathering information on potential cases, the researcher performs criteria-based case selection. Criteria may include a search for extreme or deviant cases, critical cases with respect to the specific phenomena being investigated, maximum variation in cases, and/or paradigmatic or prototypical cases (Flyvbjerg, 2006).

date of establishment, participants and beneficiaries, disease or health issue focus, objectives, operations, resource contributions, and other relevant information. Literature and web searches confirmed that the IFPMA directory supplied a current and complete list of the population of P^3Hs with originator pharmaceutical firms.

I filtered directory information for the following criteria: 1) one or more state or interstate partners, 2) HIV/AIDS focus, and 3) programmes to support access to medicines, which yielded 22 cases. Analyses of these cases produced five major categories of access support (see Table 1-1). These included patent flexibilities, pharmaceutical pricing, capacity building, health system resources, and service delivery.

Table 1-1: Categories of Access P^3H Support

Access Strategies	Sub-strategies	Relevant case studies
Patent flexibilities	Voluntary licensing	AAI
	Nonassert/ nonenforcement declarations	AAI
	Technology transfer	AAI
	Contracting with generic manufacturers	AAI
Pharmaceutical pricing	Differential pricing	AAI
	Nonprofit pricing	AAI
	Donation	DPP; ACHAP
Capacity-Building	Health worker training/education	STF; ACHAP; DPP
	Technical and policy capacity building	ACHAP
Health system human and capital resources	Salaries for health professionals	STF, ACHAP
	Capital costs; lab equipment and buildings	STF, ACHAP
	Health products and related supplies	ACHAP
Health care services	Treatment programmes and services	STF, ACHAP
	Prevention programmes and services	ACHAP, STF
	Psychosocial programmes and services	ACHAP, STF
	Socioeconomic programmes and services	ACHAP, STF

To achieve maximum variation in the sample, I selected the final four cases that offered variation in organisational forms (independently hosted partnerships –DPP,

ACHAP, STF- and public sector hosted partnership- AAI), functions (a cross-section of the major access categories and subcategories), and integrative approaches (operational, on-the-ground partnerships – ACHAP and STF- and negotiation and administrative partnerships – AAI and DPP) (See Tables 1-1 and 1-2). Furthermore, the AAI comprises originator firms who represent the key patent holders of existing antiretroviral medicines[25] which constitutes the preponderance of global activity on pricing and patent flexibilities for originator ARV medicines. The AAI, therefore, supports maximum variation and critical case sampling techniques. These case selection techniques yielded a large, rich dataset from which to build histories, explore themes, and facilitate comparisons within a manageable research design.

Table 1-2: P^{3}H Cases and Actor Composition

No.	Case Study	Private business actor(s)	State and/or interstate actors
1	**Accelerating Access Initiative (AAI)**	Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, F. Hoffman-La Roche, Gilead Sciences, GlaxoSmithKline, Merck, Tibotec, ViiV HealthCare	WHO, UNICEF, UNFPA, World Bank, UNAIDS Secretariat and governments of least developed, low and middle-income countries
2	**African Comprehensive HIV/AIDS Partnership (ACHAP)**	Merck & Co, Inc.	Government of Botswana
3	**Secure the Future™ Partnership (STF)**	Bristol-Myers Squibb	Governments of Botswana, Burkina Faso, Côte d'Ivoire, Lesotho, Namibia, Mali, South Africa, Swaziland, Tanzania, and Uganda
4	**Diflucan Partnership Program (DPP)**	Pfizer, Inc.	63 governments

[25] This selection, however, excludes more minor ARV patent holders, including the US National Institutes of Health and Sequoia Pharmaceuticals. For more information see MSF (2010).

Data collection, management, and manipulation.

I conducted 75 semi-structured interviews[26] with respondents across five groups, including representatives from pharmaceutical firms and business associations, public authorities,[27] nongovernmental and civil society organisations, knowledgeable observers, and other P^{3}H representatives (See Table 1-3). Internet and documentation searches and snowball techniques identified potential respondents.

Table 1-3: Interview Respondent Groups

Group	Respondent group	Selected examples of respondent organisational affiliations
1	Pharmaceutical firms and business associations	Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Pfizer, Merck, Roche, Tibotec, ViiV HealthCare, IFPMA.
2	Public authorities	National AIDS Commission, bureaucrats and political leadership from Ministries of Health (Lesotho/Malawi), UNICEF, WHO.
3	Nongovernmental and civil society organisations	Médecins Sans Frontières (field: Lesotho/Malawi, and policy: Geneva), Partners in Health, Treatment Action Campaign, AIDS Law Project, Health GAP (policy).
4	Knowledgeable observers	Professors in global and public health, law, and political science; medical doctors; epidemiologists; authors; research scientists in HIV/AIDS Centres of Excellence.
5	Other partnership representatives	Partnership Secretariats, implementing partners, representatives from partnership Board of Directors, partnership country directors or senior staff.

Interviews were conducted via telephone or in-person with the modes approximately equal. The decision to conduct interviews over the telephone was a function of limited time and financial resources. Whenever possible, the preferred mode

[26] Ethics clearance was granted by Simon Fraser University Office of Research Ethics and subsequently transferred to the McMaster University Research Ethics Board.

[27] This includes public sector and political officials from state and interstate institutions. Wherever possible in the text I identify the specific public authority that is referenced as a respondent.

was an in-person interview. In-person interviews were conducted in Canada, USA, and the UK, and during extended field site visits to three partner countries. The purpose of field site visits was to collect multiple data sources, including documentation and interviews for two research components, 1) historical and contemporary trends and issues in HIV treatment access, and 2) P^3H and private authority histories and operations. The criteria for field site selection were that partner countries must have: 1) experience with at least three of the four case studies, 2) extended histories (at least three years) with the cases, and 3) English as an official language.[28] The final selections were South Africa, Lesotho, and Malawi.[29] Field sites included P^3H Secretariat offices, field offices, affiliated health and treatment clinics, implementing partners, beneficiaries (e.g. recipients of donated products), state and interstate institutions, nongovernmental and civil society organisations, private business organisations, and universities.

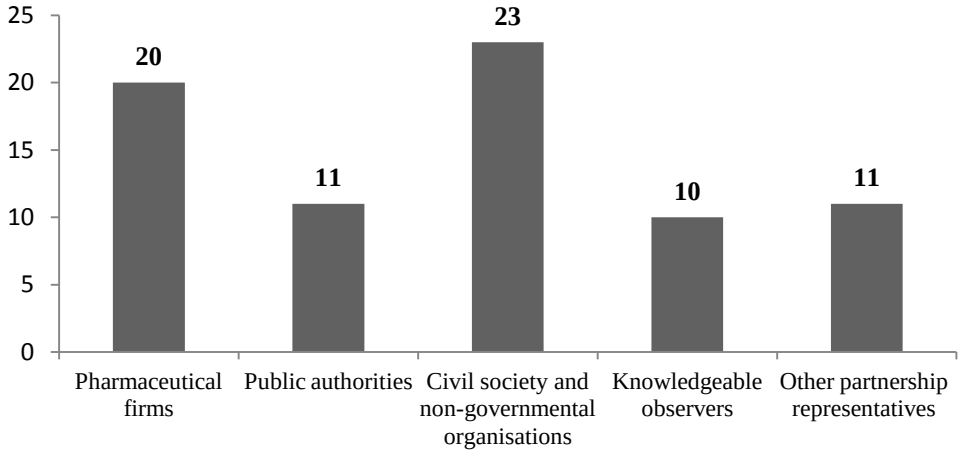
I developed an interview guide (see Appendix B) containing lists of core (all groups) and supplemental questions targeted to each group of respondents. The guide, although developed prior to the interviews, was refined throughout the data collection phase, particularly for non-core questions. This semi-structured, organic approach ensured flexibility to deviate from the guide, pose follow-up questions, or new questions as the interview or study warranted (Berg, 1998).

[28] While this created bias in case selection, I opted for expedience and comfort in unfamiliar field settings with a contentious research topic and elite groups of respondents.

[29] This selection invariably excluded field visits to ACHAP (Botswana). Given time and resource constraints I opted for telephone interviews with respondents from this partnership.

I obtained satisfactory representation from each respondent group (see Figure 1-2) and case study partnerships. I obtained data from a minimum of 20 respondents for each case study, which was accomplished, in part, because many respondents were able to discuss at least two cases (e.g. a public sector official responded to questions on the AAI, DPP, and STF). Rolling data collection took place from November 2007 to May 2011, although the majority of interviews (67%) were conducted over a 20-month period from October 2007 to May 2009. This included trips to South Africa (October-December 2007), Lesotho (October-December 2008), and Malawi (May-June 2009).

Figure 1-1: Interview Respondents by Group



The large majority (89%) were elite interviews, or interviews with respondents who have participated in the case (or related phenomena) and who hold social and/or political positions that allow them special access to information and programmes (Elwell et al., 1987; Kezar, 2003). Respondents therefore tended to be professionals with several years of service at their organisations. The elite interview approach offered several advantages as a purposive recruitment sampling technique. Elite respondents furnished

critical information and offered technical, legal, scientific, and other expertise for specialised health and access issues. Elite respondents also often shared unpublished documentation, including manuscripts and internal reporting. Elite respondents were also frequently willing to facilitate connections with colleagues, which fostered respondent recruitment and acquisition of new data.

Where respondents consented to the identification of their name, role, and/or organisational affiliation, these details are noted in the text; otherwise respondents are represented by an identification number. The identification number is a randomly sorted number ranging from 1 to 75, followed by a respondent group identification number. For example, respondent 1 is from group 5, and is identified in the text as respondent 1-5. This identification method protects respondent anonymity while clarifying respondent group affiliation. A list of respondent identification numbers, corresponding respondent group, and affiliations, is available in Appendix A.

Interviews and field notes were transcribed by hand or type and filed by interview identification number. Although this method inevitably failed to capture some of the respondent's comments, this approach was selected given the sensitivity of the subject material, potential concerns around audio taping, and the interview medium (telephone).

I used NVivo8 qualitative research software to analyse interview transcripts and field notes. I developed a coding system adapted from Aberbach and Rockman's (2002) elite interview coding approach. I initially performed manifest coding, or coded responses based on core and subgroup questions. Secondly, I developed a latent coding system that identified specific categories and themes emerging from the data. I refined

latent coding categories to capture patterns and themes and revisited the data and re-coded where necessary. This coding system produced a framework of coherent categories relevant to the research questions, allowing for unambiguous data extraction and analysis.

Study limitations and design controls.

Study limitations and controls require discussion, specifically issues with the case study method, case and respondent selection, elite interviewing, research environment(s), and researcher bias. First, case study research design has been criticised as unscientific for failing to produce causal inferences or findings that serve as a basis for scientific generalisation (Bennett & Elman, 2006; Campbell & Stanley, 1966; Yin, 1981). Other concerns relate to standards of rigorousness and systematic data collection. Because case study researchers often modify data collection instruments and/or hypotheses throughout the study, critics have claimed that these methods are insufficiently scientific (Yin, 1981).

Qualitative inquiry does not claim to reveal universal truths or scientific laws around human or social behaviour or phenomena. Rather, these methods explore phenomena, constructs, and patterns and relate these to assumptions, hypotheses and theories. Case studies provide insights, through detailed investigation of single or collective cases, to the larger population of similar cases (Gerring, 2004; Yin, 1994) or what Creswell (1998) terms naturalistic generalisations. They also yield findings which may be generalisable to theory and policy (Yin, 1994).

Case study research designs may employ one or more methods for verification, or procedures to evaluate data and research results for reliability. The issue of reliability in qualitative research relates more to concepts of dependability and trustworthiness than to

reproducibility standards in positivist research (Golafshani, 2003). Creswell (1998) discusses verification procedures (see Table 1-4) and advises researchers to employ a minimum of two techniques. I employed four verification procedures and adhered to respected techniques for data collection and analysis.

Table 1-4: Qualitative Research Verification Procedures

Procedure	Function	Used in study?
Negative case analysis	Removal of case outliers until all cases conform to central hypotheses or arguments	
Clarifying researcher bias	Declaration of all known biases that may impact study results	✓
Member checks	Return of data, analytical categories, and/or interpretations to respondents for commentary and/or critique	✓[30]
Peer review	Assistance from peers or colleagues in evaluating data and findings to assess if the researcher has achieved a goodness of fit between the two	
Triangulation	Use of multiple sources and methods, including direct observation, interviews, participant observation, physical artefacts, archival records, document analysis, multi-media, etc. (Yin, 1994)	✓
Thick description	In conjunction with the triangulation technique, the provision of a richly detailed account of the case and its subunits	✓
External audits	Similar to peer review but with the use of an external consultant	

Adapted from Creswell (1998).

For example, Yin (1994) suggests that a case study design benefits from the triangulation of sources of evidence. Examples of evidence include documents, archival records, interviews, and direct observation. Yin argues that by collecting multiple sources of evidence, the researcher acquires a greater breadth and depth of data, which

[30] I returned interview transcripts and/or field notes to multiple respondents over the course of data collection. These data were returned to respondents in cases where respondents indicated that they wished to review data, or where I sought clarification or elaboration of respondents' views. Respondents were asked to return the notes and transcripts with their comments, which were then integrated into the respondent's master file.

strengthens the reliability of the results. In addition to interviews, I conducted document reviews for each of the cases and many of the respondents. These reviews analysed academic and grey literature as well as industry and civil society website data and blog posts. I also obtained access to and utilised financial[31] and tax[32] archival records from pharmaceutical firms and their private foundations for purposes of analysing published and unpublished firm and P^3H data. These triangulation techniques, coupled with the four verification procedures listed in Table 1-4, yielded a rich and reliable dataset.

Limitations in case and respondent selection, elite interviewing, the research environment, and researcher bias.

The use of information-oriented techniques, maximum variation, and a critical case selection offered the most appropriate fit to the study's objectives; however, they also contain some important limitations. Although maximum variation techniques offer enhanced representativeness in sampling (Seawright & Gerring, 2008), the study's focus on access-oriented partnerships precludes examination of P^3Hs with different disease or health issue orientations and thus limits representativeness to access-oriented partnerships. The broad historical origins around P^3Hs, however, are largely universal, although within and/or cross-case analyses of other partnership functional orientations might yield other insights into the formative interests, conflicts, and strategies. This case

[31] I compiled and analysed pharmaceutical firm and P^3H (where available) annual financial reports from 2000-2010.

[32] I obtained researcher permission from www.guidestar.org on March 14, 2011 to access tax 501(c)(3) filings for pharmaceutical firms' private foundations. With the exception of the AAI, all partnership financial activity is channeled through firms' private foundations. In the case of the ACHAP, funds are channeled through the Merck Foundation and the Bill and Melinda Gates Foundation.

selection, however, does not unduly restrict generation of naturalistic generalisations to the larger population of P^3Hs, nor negate the potential for theoretical and policy implications arising from analyses. On the contrary, it offers potential for intrinsic and instrumental insights into the phenomena of growing private authority in health, P^3Hs, and the governance of access to medicines in the global South.

On a more technical level, there are a few concerns with the case selection tool, the IFPMA directory. First, although I attempted to case select among the population of P^3Hs with pharmaceutical firms, it is possible that the directory was not exhaustive. Furthermore, because the directory was developed by the IFPMA, there are potential concerns with information accuracy and bias. It is conceivable that the directory contained inaccurate information, overstated partnership roles and contributions, or misrepresented philanthropic activities as partnerships. As well, although the directory listed public authorities as partners, it was not always sufficiently clear if these actors had substantive roles in the partnership—a considerable problem given the focus on public-private partnerships. I addressed these issues through triangulation and with discussions in Chapters Two, Four, and Seven on the complexities of partnership typologies.

Respondent identification and selection was challenging, particularly for respondent groups 1 and 2. Pharmaceutical firms and state and interstate institutions rarely post names, titles, and contact information for their staff; complicated Internet-based sleuthing exercises were critical to compiling a respondent recruitment list. The study achieved a 30% response rate (out of 200 identified potential respondents); however, this was distributed unevenly across respondent groups. I experienced difficulty

accessing public authorities as they frequently did not respond to communications, were travelling, or refused requests. In part, this was a result of overextended, over-requested state and interstate officials. Although I interviewed 11 public authorities, the study would have benefited from a higher response rate from this group.

Another caveat of elite interviewing pertains to respondent bias. Berry (2002) cautions that respondents approach an interview with their own objectives and motivations. Elite respondents, particularly, are in a position where they may be defending their role and their organisation (ibid.) and may therefore present biased interpretations of events or tend towards obstruction or falsification (Richards, 1996). Otherwise, respondents were sometimes unable to respond to questions given the passage of time or organisational confidentiality. These issues, to a significant extent, were mitigated through triangulation and verification procedures.

Executing a study that deals with contentious and affective topics such as HIV and AIDS treatment access presents certain challenges. First, conducting interviews and site visits in countries that are experiencing generalised HIV epidemics and other social and economic crises can be physically and emotionally demanding (Devereux & Hoddinott, 1992), and when interviews take place over a period of approximately four to eight weeks per site, familiarization with field sites needs to occur more quickly. Extensive pre-departure preparation, including literature reviews and email communications with respondents afforded logistical and research supports which significantly alleviated challenges with field site acclimatisation.

Researcher bias also inevitably flows from the study's controversial and affective subject matter. I empathised with civil society and NGO respondents who detailed their struggles with treatment access and had respect for the efforts of many public authorities. I was also cognisant of a bias towards pharmaceutical firms or governments that had been criticised for undermining access to treatment. As a researcher, though, my objective was to professionally execute the interview guide, triangulation techniques, and verification procedures. Ultimately, the study has benefited from rigorous efforts to acknowledge, manage, and mediate respondent and researcher bias.

Definition of Key Terms and Concepts

This section reviews selected terms and concepts in the study, specifically: *developing country*, *global South*, *governance* and *global health governance*, *originator and generic pharmaceutical firms, public authority, private authority*,[33] and *public-private partnerships in health.*[34] The section concludes with a short conceptual and literature review of *access to medicines*.

Developing country and global South.

The concepts *developing country* and *global South* are not covered by formal classification and are therefore subject to interpretation. The global South describes a large group of states—the Center for the Global South cites 157 ("Center for the Global South," undated)—in Africa, Central and Latin America, and parts of Asia, which face often acute human security and governance challenges, including poverty, disease,

[33] See Chapter Two for a conceptual and literature review of private authority.

[34] See Chapter Four for a conceptual and literature review on public-private partnerships in health.

conflict, environmental degradation, resource depletion, and political instability (Odeh, 2010). The concept of the global South has evolved with a largely critical character, frequently relating these challenges to conditions of inequality, exploitation, and dependency in relations with the global North; understood as wealthy and politically powerful states (ibid.). The term developing countries/states (used interchangeably) is used to capture least developed countries (LDCS)[35] and countries in the global South.

Governance and global health governance.

The concept of *governance* disentangles government from the totality of authoritative activity organised in pursuit of social goals (Börzel & Risse, 2005; Dodgson, et al., 2002; Rosenau & Czempiel, 1992). Governance activities, according to conventional definitions are pursued amongst a plurality of actors, of which government represents the most formal component, in steering (rule-setting and decision-making) and driving (rule implementation and service delivery) towards shared or collective social goals (Doyle & Patel, 2008; Fidler, 2007; Rosenau & Czempiel, 1992). This definition has provided the conceptual foundation for global health governance, which implies sharing of responsibilities with nonstate actors, new institutional forms and networks, and transcendence of state boundaries in managing global health issues (Fidler, 2005, 2010b; Hein & Kohlmorgen, 2008; Kay & Williams, 2009; Smith, 2010; Sridhar & Batniji, 2008). As Fuchs (2007) observes, these concepts describe governance (and, by implication, global health governance) as functional problem-solving tools with enlarged

[35] As classified by United Nations (UN-OHRLLS, undated) criteria for the identification of LDCs. See:http://www.un.org/special-rep/ohrlls/ldc/ldc%20criteria.htm.

and mixed actor participation. She warns that this conceptualisation proceeds from potentially misleading logics around shared or objective social goals, and pays insufficient attention to questions of "power, control, participation, and distributional implications" (p. 32) of authoritative activities. My study, aligned with Fuchs' approach, proposes that global health governance describes not only constitutive, methodological, and integrative transformations in authoritative activities in global health, it also includes historical and social relations underpinning governance definitions, deliberations, action and inaction, as well as the consequences arising from these processes.

Originator and generic pharmaceutical firms.

This study uses the term *originator* to describe pharmaceutical firms with large research and development capacities that market originator (on patent) or generic medicines. *Generic* pharmaceutical firms, generally, do not engage in original research and produce on- and off-patent medicines. Partner firms in the P^3H case studies are exclusively originator firms.

Private authority and public-private partnerships in health.

Public authority describes authority retained by states and interstate institutions (Hall & Biersteker, 2002b) to exercise decision-making and responsibility functions within jurisdictional boundaries (Pandya, 2006). *Private authority* is defined as authority that is "neither states, state-based, nor state-created" (Hall & Biersteker, 2002b, p. 5), although accounts of state delegated authority to private actors (discussed in Chapter Two) suggest that while states may not 'create' private authority, delegation can 'translate' business power into authority. Hall & Biersteker (2002b) identify four

categories of private authority based on their sources of power: market, moral, religious, and illicit (ibid.). Market or business authority refers to power derived from participation in markets, particularly commercial activity, and includes firms, corporations, and business associations. Moral authority denotes actors who wield moral power, specifically humanitarian, civil society, and nongovernmental actors. Illicit authority refers to criminal and underground activity, or authority derived through illegal means. In this study, private authority indicates private business authority.

Public-private partnerships in health are commonly defined as "voluntary and collaborative arrangements" (Nelson, 2002, p. 47) in which public and private actors "share risks, responsibilities, resources, and benefits" (ibid.). While most scholars[36] agree that P^3Hs entail shared goals around a health issue area, there is otherwise considerable confusion surrounding their parameters (Ridley, 2001; WHO, undated-c). These and other issues around the conceptualisation of P^3Hs are discussed in Chapter Four.

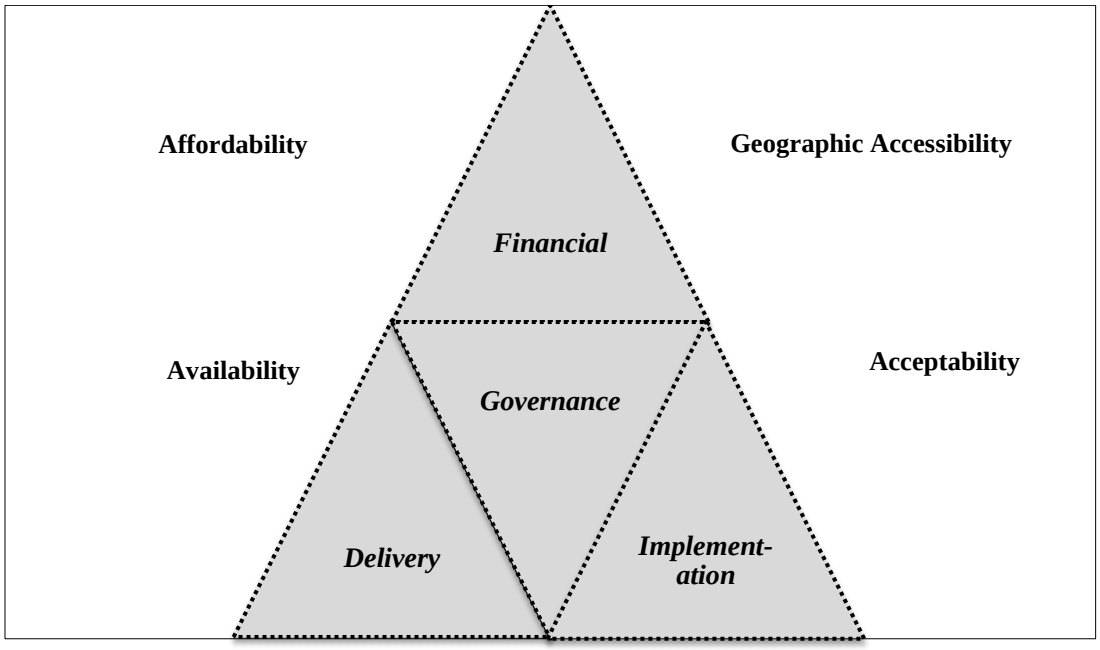
Access to medicines.

Access to medicines is often depicted through reference to coverage rates, while the political concept of treatment for all, or universal treatment coverage, refers to the UNAIDS national standard of 80% ART coverage for people eligible to receive treatment (Rowden, 2009). The Centre for Pharmaceutical Management (2003) conceptualises access as comprising four major components: 1) affordability, 2) physical availability, 3)

[36] This criterion appears almost universally in the literature. For a cross-section, see Buse and Walt (2000a, 2000b), Dodgson, Lee, and Drager (2002), Richter (2004b), and Ridley (2001).

geographic accessibility, and 4) acceptability. Affordability refers to supply and demand factors related to pricing, as well as the purchaser's ability to pay for the product. Physical availability requires the product to be available to the end users. Products may be available; however, geographic accessibility requires that they be at a reasonable distance from the end user. The acceptability dimension relates to the end users' perceptions of the products. This apolitical conceptualisation of access fails to appreciate access as a set of interconnected economic, political, and social relations. However, it heuristically identifies key factors that can be integrated into a schematic (Figure 1-3) to broaden the conceptualisation of access to a multifaceted relationship of governance, financial, delivery and implementation dimensions interacting with affordability, availability, acceptability, and geographic accessibility factors.

Figure 1-2: Access Dimensions and Interactions Schematic



Note: Access schematic developed by author and adapted from the Centre for Pharmaceutical Management (2003) and from the categories and subcategories listed at the Health Systems Evidence website, www.healthsystemsevidence.org.

The financial dimension includes all funding, financing, and financial resource activity around medicines access. This includes public, private, and mixed actor fundraising, distributive strategies, compensation strategies, official development assistance, health budgeting, grants, loans, philanthropy, and other financial measures to support medicines access. Research in this component might focus, for example, on global health funding (See: McCoy, Chand, & Sridhar, 2009), private foundations' (See: McCoy, Kembhavi, Patel, & Luintel, 2009), financing strategies (See: Beauliere, Le Maux, Trehin, & Perez, 2010), insurance schemes (See: Adamski et al., 2010), etc.

Delivery arrangements in medicines access include health care delivery systems, its targets and populations, human resources, and quality assurance. Research on access to medicines and the delivery dimension examines institutional capacity and delivery arrangements for treatment programmes and health care services. This research has revealed how many states in the global South experience delivery challenges including: lack of primary care, specialised, and diagnostic facilities (Barker et al., 2007; Druce & Dickinson, 2008; Lange, Schellekens, Lindner, & van der Gaag, 2008), human resource shortages (Anyangwe & Mtonga, 2007; Ishengoma et al., 2009; Ruud, Toverud, Radloff, & Srinivas, 2010), lack of training for health professionals (Fomundam, 2008), and attrition of the health workforce through HIV,[37] migration, or other factors.

[37] Between 18% and 41% of health workforces in Sub-Saharan Africa are living with HIV (Anyangwe & Mtonga, 2007).

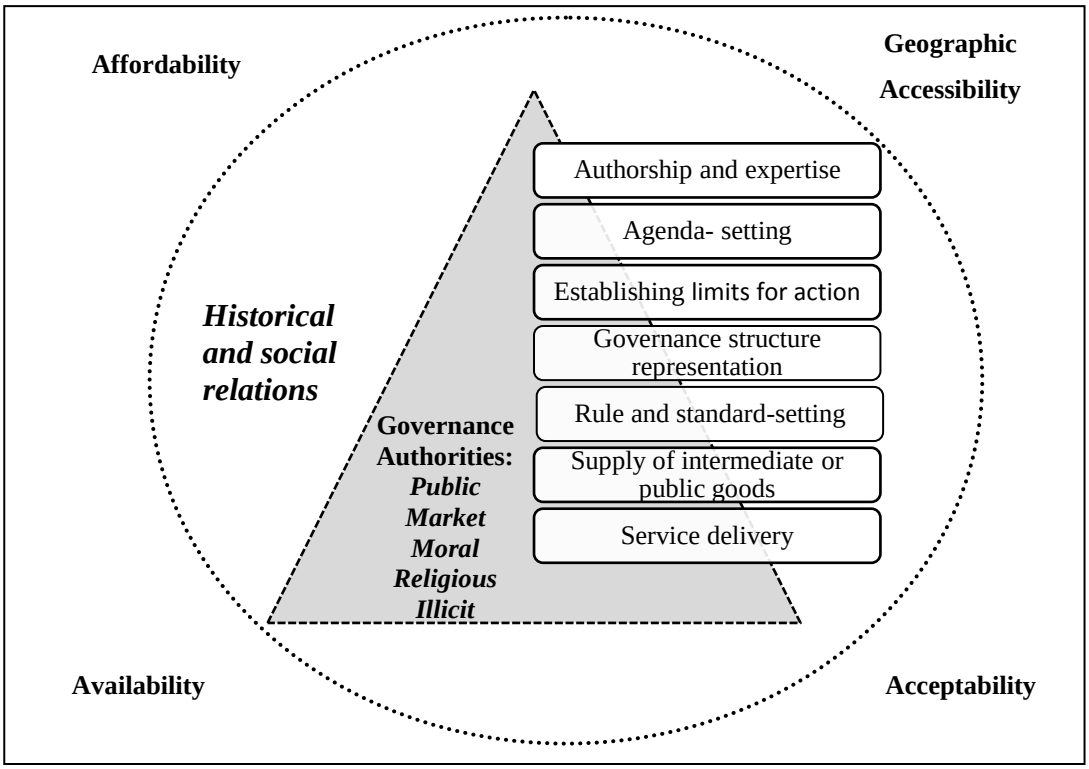
Access implementation arrangements refer to strategies designed translate and enhance delivery arrangements for health care consumers and providers. Strategies involve personal and professional supports, behavioural change, skills development, and evaluation mechanisms. Specific strategies include training, education, adequate salaries, and professional supports to ensure essential training, tools, and information to deliver medicines and related health care services. [38] Research investigates these strategies as well as socioeconomic and sociocultural factors, including poverty[39], malnutrition, and lack of transport to health facilities (Tuller et al., 2010), and the role of stigma (Agnarson et al., 2010; Biadgilign, Deribew, Amberbir, & Deribe, 2009), domestic violence (Young, Washington, Jerman, & Tak, 2007) and cultural beliefs and practices (Owen-Smith, Diclemente, & Wingood, 2007) as access determinants.

The governance dimension refers to configurations of authorities, authoritative action and inaction around medicines access, and the historical and social relations shaping governance action and inaction (see Figure 1-4). This study employs Hall & Biersteker's (2002b) inventory of authoritative action, including authorship and expertise, rule- and standard-setting, agenda-setting, establishment of boundaries and limits for action, representation on governance, supply of public goods, and service delivery.

[38] These implementation strategies were gleaned from the Health Systems Evidence website, www.healthsystemsevidence.org, a project of the McMaster University Health Forum.

[39] A large body of research confirms correlations between socioeconomic status and health care seeking behaviours. These correlation appear across age groups (Abdulraheem, 2007); countries in the global South and North (Kristiansson et al., 2009; Taffa & Chepngeno, 2005) and communicable and noncommunicable diseases (Woods, Rachet, & Coleman, 2006).

Figure 1-3: Governance Authorities and Authoritative Action around Access



Research in the governance dimension may investigate specific institutional forms and authoritative processes around access to medicines. For example, research has shown that developing states face diverse governance challenges in planning and implementing large-scale ARV treatment programmes. In addition to acute challenges around medicine affordability and availability in developing states (discussed in Chapters Two and Three), political and bureaucratic research, technical, and logistical capacities are often underdeveloped (Kirigia & Wambebe, 2006; Zewdie, Cahn, McClure, & Bataringaya, 2008), overextended (Harman, 2009), or deficient (King & Fomundam, 2010; Wang, 2008). Furthermore, bureaucratic red tape (Parkhurst & Lush, 2004), confusion, incoherence, and/or tension in institutional mandates and responsibilities (Biesma et al.,

2009; Hongoro, Mturi, & Kembo, 2008), and coordination challenges undermine the quality, coherence, and scale of ARV treatment programmes.

The governance dimension may also explore, *inter alia*, historical, structural, and ideational variables, including historical contexts and evolution in policymaking, economic and political structural constraints and opportunities, the role of ideas and ideology in governance, and agenda-setting behaviours and contestations. Research therefore, explores not only specific institutional forms and processes around access to medicines, but also the historical and ideological foundations, constraints, and contestations within these processes that shape governance action and inaction.

This short literature review and conceptual schematic illustrate that access operates as a multifaceted relationship between governance, financial, delivery, and implementation dimensions. This study focuses on the governance dimension of access; specifically examining P^3Hs within their wider historical and social contexts and with respect to their significance and prospects as a governance mechanism for enhancing access to HIV and AIDS medicines.

Central Arguments

The global HIV/AIDS pandemic emerged alongside a changing world order marked by the growing power and authority of business, new constraints on public authority and policy autonomy, and new global hierarchies, inequalities, and contradictory tendencies. These conditions have helped midwife new configurations of public and private power, authority, and relations, and shaped operating and normative environments for global health governance. Public-private partnerships in health emerged

from this history as institutional experiments, yet not convincingly as functionalist responses to governance gaps and failures. The history demonstrates that private business actors opted to engage in partnerships in the contexts of a convergence of social, public, political, and commercial pressures, and normative and structural transformations in the world order. The case study partnerships emerged as accommodation or *trasformismo* strategies which offered concessions in an attempt to neutralise and co-opt social contestation around treatment access, without succumbing to demands for deeper structural and legislative reforms. These strategies offer bilateral, narrow, and tactical contributions in a framework of poor design, governance, accountability, and equity considerations and obligations, and are unconvincing in their commitment or their capacity to expand access to older and newer HIV medicines. Ultimately, public-private partnerships in health present practical, strategic, and normative consequences that necessitate new approaches to reform and/or serious reconsideration of their role and prospects in global health governance.

Practical and strategic consequences of public-private partnerships in health.

The study argues that while P^3Hs with originator pharmaceutical firms offer some value-added and limited strategic contributions, they largely reflect bilateral, narrow (breadth of coverage and contribution), and private actor tactical approaches to global health. The cases also corroborate many of the concerns around partnership design, governance, accountability, and outcome orientations. Finally, partnerships confront and generate challenges and consequences in health governance around health policy and

system alignment, coordination, absorptive capacity, transaction costs, distortions, duplications and redundancies, and geographic and population disparities and inequities.

Normative and transformative effects of private authority in health.

This study argues that growing private authority in health is helping to transform and consolidate normative agendas and consequently shape health governance action and inaction through several critical ways. First, public authority is increasingly shared with actors who possess different interests and accountability obligations. Second, expanding private authority in global health governance supports a business transformation of statehood and promotes the neoliberal project by advancing private interests in global health. Third, growing private authority in health reflects and advances agendas in philanthrocapitalism, pharmaceuticalisation, and the depoliticisation of health. Finally, a functionalist partnership narrative obfuscates relations of power and inequality. In so doing, it legitimises private authority without sufficient consideration and evaluation of the intended and unintended consequences of private authoritative action in health governance. These agendas push global health governance towards expanded hybridisation, commodification, and technological agendas, which ultimately obfuscate critical questions—and potential transformations—in the historical and structural roots of inequality, ill health, and disease.

Contribution to Knowledge and Conclusion

International relations and international political economy scholars have been weighing in on issues around global health, particularly around interfaces with international law (Aginam, 2005), diplomacy (Aginam, 2010; Fidler, 2010a), and

institutions such as the WHO (Lipson, 2001), the World Bank (Bienan & Shelton, 2001; Haddad & Mohindra, 2001), the Global Fund to Fight AIDS, Tuberculosis, and Malaria ("the Global Fund") (Bartsch, 2009; Poku, 2002b), the Joint United Nations Programme on HIV/AIDS (UNAIDS) (Poku, 2002a), and the World Trade Organisation (WTO) trade agreements (Bettcher, Yach, & Guindon, 2000; Birdsall & Lawrence, 1999; Labonte, 2004). Scholars have also been investigating the roles of civil society (Blas et al., 2008; Doyle & Patel, 2008; Ford, Wilson, Bunjumnong, & von Schoen Angerer, 2004), NGOs (Seckinelgin, 2005), and private foundations (Fox, 2006; McCoy, Kembhavi, et al., 2009; Moran, 2008, 2009) in health governance.

Although this literature contains an array of studies examining the structures, functions, and contributions of old and new actors and institutions in global health governance, few analyse private business actor participation (other than private foundations) and even fewer have investigated pharmaceutical firms, despite their prominent role in global health governance. There are also no academic studies (that I am aware of) that focus exclusively on pharmaceutical firms and access to HIV and AIDS medicines in P^3Hs. This study addresses these gaps and supplies new data on private business actors and hybrid governance arrangements in global health governance.

Furthermore, there are few studies that have examined practical, strategic, and normative impacts of private authority in global health governance and the global South. The bulk of studies on private authority focus on OECD states and around issues related to economic and financial governance (Dingwerth, 2008). This study examines private

authority arrangements in health governance around a critical health and development issue in the global South.

This study makes a specific contribution to the understanding of this particular institutional experiment in supplying new empirical data on P^3Hs and their intended and unintended consequences on national and global health governance. Also, as discussed earlier in the chapter, it addresses important empirical and theoretical deficits in an emergent political science, international relations, and international political economy literature in global health and in public-private partnership scholarship in public health disciplines.

Finally, understanding what an appropriate institutional response would look like is a pressing practical challenge given the severity and complexity of global health issues. These partnerships do not appear to be a temporary phenomenon and therefore, as an institutional experiment, warrant measured academic investigation to evaluate their practical, strategic, and normative implications for national and global health governance.

Chapter 2: Theoretical Considerations

Private business authority in global health has rapidly expanded since the mid-1990s. Private business actors, including firms, foundations, and business associations, increasingly perform authoritative functions in global health under the auspices of partnerships. Public health literature has cautiously regarded these configurations as experimental arrangements between the international health complex and private business actors. Political studies and international relations scholars nearly ignored them altogether until a few years ago when they became a subject of marginal (although growing) interest. Scholars have turned their attention to emerging forms of private authority, yet a focus on private authority in global health governance remains sidelined.

Private business actors supply funds, health care goods and services, expertise, and representation on health governance structures and participate in rule, standard, and agenda-setting. Originator pharmaceutical firms and private foundations have been at the forefront of many of these activities. In many ways, there is a useful fit between the financial and scientific largesse of these actors and seemingly expanding gaps in global health governance resources and capabilities.

Narratives of private business efficiencies, competencies, and added resources, however, fail to interrogate the basis for apparent weaknesses or failures in public authority. They assume that emerging gaps or institutional weaknesses necessitate coupling private power to public authority to create greater effectiveness and legitimacy in governance. This approach neglects a critical treatment of the determinants of power

and authority and the historical and social relations that shape the distribution of power, resources, and rewards. And while the literature on public-private partnerships in health has considered questions of accountability, legitimacy, and transparency, this literature, as well as global health practices and leadership appeared to have settled on a functionalist and reformist narrative of P^3Hs.

In this chapter I analyse historical and systemic trends in global political economy and argue that governance gaps and failures are not natural givens but consequences of a globalising neoliberal market civilisation. This changing world order produces 1) growing power and authority of private business, 2) constraints on public authority and policy autonomy, 3) new social and global hierarchies and inequalities, and 4) contradictory tendencies generating exploitations, displacements, democratic deficits, and social resistance. These conditions reconfigure public and private power, authority, and relations and shape operating and normative environments for global health governance.

The chapter proceeds in four sections. The first section provides an overview of the conceptual vocabulary in the study of private authority and situates it within the larger context of the study of international politics. This section also reviews conceptual frameworks of private authority in global governance. The second section provides an intersecting historical, power-based, and functional analysis of the rise of private business authority. The third section relates these developments to contemporary operating and normative environments of global health governance. The concluding section summarises arguments and presents preliminary implications of the issues raised in the chapter.

Conceptualisation and Operationalisation of [Private] Authority

Weber (1978) understood political authority as a fusion of coercive power with legitimacy, or what he termed *Herrschaft*. Weber (1978) argued that legitimacy would produce broad compliance without the need to resort to coercive power. Authority is therefore now widely understood as legitimised power (Biersteker & Hall, 2002; Blau, 1963; Hurd, 1999; Porter, 2008). The right to exercise authority originates from legitimation processes, suggesting that legitimacy functions as a social relationship between subjects and authorities. Publics comply (most of the time) based on shared perceptions of the appropriateness of authority (Franck, 1990).

Political legitimation processes provide support for actions of public authorities and for public authority in general (Underhill & Zhang, 2008). Hall and Biersteker (2002b) suggest that authority derives not only from political legitimation processes such as elections, but also through social processes. Normative practices and institutionalisation and habituation of social practices help to shape the structure of expectations or criteria for participation and process in governance (McDougal, 1959). While the structure of expectations determines criteria for participation and processes in decision-making, the structure of obligation defines the hierarchical structure of authority. Authority implies that participants perceive rules and practices to be obligatory (Cutler, 2002), regardless of whether they choose to comply (Bernstein, 2004). Participants submit to authority because they accept, filtered through the structure of expectations, criteria for governance participation and processes. Participants accept, under a structure of obligation, that a rule, process, or body is authoritative. Participants

may choose to ignore or resist their obligations to authority; however, there are formal or informal consequences to these in/actions. Authority, therefore, is defined as legitimised power that is normally capable of extracting obligation.

The authority afforded to private actors is socially constructed but not derived from law or democratic practices, nor is it exclusively granted by states. Private actors acquire and exercise authority as a result of perceived sociopolitical, economic, or technological expertise (Hall & Biersteker, 2002b; Porter, 2008), implicit or explicit delegation by states (Hall & Biersteker, 2002b; Kobrin, 2007), or through repeated historical practices (Kobrin, 1997). Explicit delegation of authority implies formal bestowal by political authorities. Implicit delegation refers to the failure of political authorities to occupy a governance space that becomes assumed by private authorities, or the existence of informal practices that allow private actors to exercise authority in governance. Private actors, therefore, may be invited into public authority structures, may penetrate them over time, or may occupy spaces that have been vacated or not taken up by public authorities. Private actors, however, frequently rely upon public authorities to translate power into authority. While private actors may possess authority within their own constituencies, devolution, privatisation, and hybridisation often requires that public authorities implicitly or explicitly endorse the legitimacy claims of private authority.

Situating authority in global governance.

Emergent literature grapples with the challenge of positioning private global authority in the stubbornly state-centric discipline of international relations. According to mainstream IR theories, specifically realist and liberal approaches, private global

authority is an ontological non sequitur (Cutler, 2002). The Westphalian modern political system exclusively endows states with legitimate political authority to prescribe and proscribe behaviour over a territorial domain (Cutler, 2002; Krasner, 1999). For realists, the absence of legitimate collective coercive power in the international system makes it impossible to speak of international political authority, let alone private authority. The supposedly anarchic international system of states implies a system of self-interested states who submit only to international agreements when it aligns with their interests. Therefore, without a world government can we even begin to speak of international political authority, let alone private global authority?

A groundswell of approaches and literature has confronted this question through studies of transnational corporations,[40] international regimes,[41] activist coalitions and networks,[42] civil society and nongovernmental organisations,[43] and private firms and associations.[44] The literature came to regard private actors as important participants in the exercise of authority. These studies also revealed that in the absence of a world

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[40] Earliest works include studies by Nye and Keohane (1971), Keohane and Nye (1972), Huntington (1973), and Gilpin (1975).

[41] See works by Krasner (1983), Kratochwil and Ruggie (1986), and Ruggie (1982) for a useful introduction to the study of regimes.

[42] Keck and Sikkink's (1998) *Activists beyond borders: Aadvocacy networks in international politics* is a seminal work in this area.

[43] This is an understudied, yet emerging research area in political studies and international relations. See works by MacDonald (1994), Cox (1999), and Amoore and Langley (2004) for key concepts and issues in global civil society.

[44] This area of study took off in the late 1990s. Seminal works include Cutler, et al. (1999b) and Hall and Biersteker's (2002a) edited volumes.

government, international authority exists across multiple issue areas; while not legally binding, this authority creates consequences whether or not states choose to comply. For example, international environmental and economic regimes create consequences for states even if they choose not to comply (Koppell, 2008).

More recent literature has begun challenging the idea that the authority of private actors can only be filtered through the authority of the Westphalian state. Emerging literature on private authority analyses how private actors exercise authority *for* (substitution), *with* (hybridisation), and *alongside* (parallel) the state and interstate system. In essence, the literature over the last forty years has destabilised realist claims that states are the only legitimate and authoritative actors in the international system. Further, they lend strong support to Ruggie's (2004) caution that to discount or underestimate the role that private actors play would be a theoretical and practical miscalculation. Private actors matter in international politics across multiple issue areas.

The literature has identified governance functions performed by private authorities, including service delivery,[45] rule- and standard-setting,[46] private international regimes,[47] representation on governance structures,[48] supply of merit, intermediate, or

[45] See Börzel and Risse (2005).

[46] Works by Salter (1999), Sell (1999), Sinclair (1999), and Lipschutz and Fogel (2002) describe private authority roles in rule- and standard-setting in global governance.

[47] See Cutler (1999c, 2002; 1999a).

[48] See Bull, et al. (2004), Bull and McNeill (2007), and Biersteker and Hall (2002).

public goods,[49] authorship and expertise,[50] agenda-setting,[51] order and security, establishment of boundaries and limits for action, and offers of salvation. Private authorities perform these functions across a range of global issues, including communication and information technologies,[52] commodities regulation and trade,[53] international law,[54] economic, financial, and trade governance,[55] environmental governance,[56] humanitarian intervention and human rights,[57] and global health. Private authorities perform many governance functions that are traditionally associated with the state and interstate system, and frequently operate in high-profile areas.

Private authority forms, structures, and processes in governance

Private authority structures or arrangements have been broadly categorised into two groups: private cooperative arrangements and public-private partnerships (Cutler, et al., 1999b). The former covers a broad spectrum of activity, including private

[49] See Biersteker and Hall (2002a) and Porter (2005).

[50] See works by Kobrin (2002, 2007) and Porter (2005).

[51] Sell's (1999) study on the role of multinational pharmaceutical firms in the development of the TRIPs Agreement highlights critical agenda-setting roles and modalities of private authority.

[52] See case studies by Salter (1999) and Spar (1999).

[53] Bernstein and Cashore(2007), Porter(1999), and Webb (1999) overview private authority roles across resource-based and commodities industries.

[54] This study by Cutler (1999c) looks at private international trade law.

[55] See selected works by Cutler (1999b, 2002; 1999a), Kobrin (2002), and Büthe (2004).

[56] Green (2009, 2010) and Pattberg (2004; 2008) offer excellent analyses of emerging private authority roles in global environmental governance.

[57] This is an underdeveloped research area in private authority. See Pandya (2006) and Brysk (2005).

international regimes, coordination service firms, epistemic communities, private networks and alliances, subcontractor relationships, dispute resolution processes, private arbitration of trade and commercial disputes, harmonisation of private law, and an augmented role for private authority in international negotiations and standard-setting (Cutler, 1999a; Kobrin, 2007; Porter, 2009). The second grouping, public-private partnerships, refers to:

> Institutionalised cooperative relationships between public actors (both governments and international organisations) and private actors beyond the nation-state for… the making and implementation of norms and rules for the provision of goods and services that are considered to be binding by members. (Börzel & Risse, 2005, p. 198)

Börzel and Risse describe four subtypes of public-private partnerships: 1) co-optation, in which public and private business partners regularly consult with one another, 2) delegation of governance functions to private business actors, 3) co-regulation, in which public and private actors share joint authority in decision-making, and 4) self-regulation of authoritative action by private authorities.

Upon inspection of terminology and typologies, it becomes challenging to conceptually differentiate public-private partnerships from the first category of private cooperative arrangements. The groupings identify specific and overlapping roles for private authority. The second category introduces public authorities as partners with shared goals in arrangements; however, this distinction does not alleviate much of the ambiguity. It is unclear whether there is a substantive difference between partnership and cooperation or if public and private partners share the same incentives and goals for cooperation. The ambiguity is not resolved solely by relying on a single measure of the degree of publicness in the arrangements. The challenges of employing the degree of

publicness criteria is that private cooperative arrangements are not exclusive to private business actors. Private cooperative arrangements do have a lesser degree of publicness than public-private partnerships; in some cases, particularly self-regulation arrangements, public authorities are largely absent from these configurations. Public authorities, however, participate, either formally or informally, in many of these arrangements, although the nature of their participation is not always transparent or well understood.

Public-private *linkages* and *leakages* create further challenges in delimiting boundaries around actor identity and interests. Linkages refer to relationships between supposedly bounded actors (public/private) that exist for the purpose of carrying out specific tasks, agendas, or responsibilities. Leakages refer to the potential escape, entry, or passage of public or private business interests into the other, usually through current or former social relations, including employment, representation on governance structures, funding/financial relationships, and so forth. For example, public authorities may be lobbied, invited, or authorised to participate in private cooperative arrangements.

In terms of leakages, public and private authorities may be interchangeable in the sense that public and private authorities oscillate between public and private roles. For example, an individual from a private business firm may take up a state and/or interstate institutional role, serve on a board, committee, or other representative forum, or bid for tenders with public authorities. A recent study by Stuckler, Basu, and McKee (2011) analysed linkage and leakage patterns in private foundations and identified how actors move between private corporations and private foundations (such as the Bill and Melinda Gates Foundation, etc.) and may sit on multiple boards of directors. Their study draws

attention to the critical dearth of research on mapping institutional linkages and leakages between private business actors and public authorities.

The typology framework for this study applies Börzel and Risse (2005) partnership subtypes to a larger framework for assessing the constitutive, methodological, and integrative dimensions of public-private interaction (See Table 4-2 in Chapter Four). This framework could also conceivably be employed as an analytical tool for private cooperative arrangements for the purposes of classification and comparison across and within various types of arrangements.

Private authority and global governance.

At a macrogovernance level, Rosenau (2006) conceptualises emerging global governance arrangements as collectivities of authority (Rosenau, 2006), or groups of private actors that exercise authority in a world consisting of multicentric spheres of authority (Rosenau, 1997). His earlier work (1997) conceptualised two distinct worlds of authority: a state-centric sphere consisting of public authorities and another sphere consisting of nonstate actors. His framework treats these two worlds as separate and delimited, whereas work on private authority by other scholars (See: Cutler, 1999c, 2002; Cutler, et al., 1999b; Kobrin, 2002; McBride, 2006; Porter, 2008, 2009; Sassen, 2002) explores interfaces, relations, and dialectics between state and nonstate actors.

Porter (2008, 2009), borrowing from Slaughter's (2004) conceptual framework, describes nonstate actor authority arrangements as a disaggregation of authority or assemblages. Porter conceptualises authority as being distributed, delegated, or decentralised *away* from its original source. A disaggregated authority structure

resembles a web of networks in which sources of authority are discrete, but boundaries intersect in carrying out governance functions and responsibilities. The state may retain an important role in this structure, but disaggregation implies that distance between state and nonstate actors can vary significantly.

Jessop (1997) advances concepts of denationalisation and destatisation to describe processes by which disaggregation occurs. Denationalisation refers to the transfer of central state authority to other levels, particularly through privatisation of public entities. The state becomes hollowed out as its responsibilities are relocated (Jessop, 1997). The process of destatisation entails reconfiguring the state's role in governance activities, particularly vis-à-vis partnerships and collaborative governance with nonstate actors.

Ruggie (2004), however, questions these and other conceptualisations of public-private arrangements that emphasise delegation and privatisation criteria. Ruggie suggests that the new global public domain does not so much represent a shift or devolution of public authority, but rather that private authority has managed to carve out new spaces and arrangements to exist alongside public authority. Ruggie describes the global public domain as an "arena of discourse, contestation and action concerning the production of global public goods" (p. 8) involving both public and private actors.

Koenig-Archibugi (2002) supplies other criteria, including the degree of publicness and inclusiveness. Koenig-Archibugi suggests that these new governance arrangements can be understood through an assessment of the scope of public authority involvement and the extent to which actors are able to access decision-making structures and processes, respectively. These criteria supply Ruggie's and other frameworks with

analytical tools for exploring the imprecision of global public domain, spheres of authority, partnerships, cooperative arrangements, and other criteria. These frameworks, however, risk collapsing into functionalist exercises in the absence of macrohistorical and power analyses. In and of themselves, conceptual and functionalist analyses of private authority provide analytical tools in the study of private authority. However, they frequently discount questions of historicity, power, and discourse. These questions are addressed through intersecting functionalist, power, and historical investigations in the study of private authority, which are described in the next section.

Explaining the Growth of Private Authority in Global Governance

Cutler, et al. (1999b) list three approaches for explaining the rise in private authority in international politics: efficiency, power, and historical. The efficiency approach relies on functionalist analyses of efficiencies incurred through private authority. For example, private actors may supply important financial, human, or informational resources and therefore reduce transaction costs in governance (ibid.). The power approach examines more critically the calculus of social and political power in investigating how private actors acquire and exercise legitimised power in international politics. Power approaches, therefore, investigate power relations in social institutions to assess distributions of power, resources, and rewards. Historical approaches take a longer view of trends in international politics and global political economy, linking systemic events and transformations to the rise of private authority. This approach pays specific attention to changes in international institutions, global political economy, technology, and so forth (Cutler, 1999a). Historical explanations situate private authority in a wider

systemic analysis, linking individual case studies within a broad macrohistorical framework of social, political, and economic crisis and change. The following section intersects these three approaches and provides a critical historical analysis of the rise of private business authority, generally, and subsequently, in global health governance, specifically.

Private authority: Intersections in function, power, and history.

Some argue that the growing role of private authority in governance yields positive, value-added effects on global governance. These functional narratives emphasise potential problem-solving and efficiency advantages of private authority. Private authority purportedly helps to fill governance gaps (Börzel & Risse, 2005; Kantz, 2007; Ngoasong, 2009; Sturchio, 2008a, 2008b), improve regulatory efficiencies (Büthe, 2010; Green, 2010), address government failure in the provision of rules, standards, goods, or services (Börzel & Risse, 2005), provide additional resources (Buse & Walt, 2000a, 2000b; Knill & Lehmkuhl, 2002; Lo, 2008; Ngoasong, 2010), and lend visibility to global problems (Conway, Gupta, & Prakash, 2006). Private authority, therefore, may enhance governance effectiveness by supplying technical, technological, financial, commercial, and political resources and capabilities. These new arrangements may also help strengthen democracy by bolstering institutional capacity and expanding democratic participation in governance structures (Börzel & Risse, 2005; Porter, 2009).

The assumption driving functional narratives in global health governance is that public authorities are not solely capable, effective, and/or legitimate problem-solvers. Whether this assumption is a function of failure to provide rules, standards, goods, or

services, the assumption is the qualitative and/or quantitative insufficiency of public authority, and by implication, the superiority of private business efficiencies and competencies. The rise of private authority in global health governance draws heavily on these narratives. The discourse also strongly expresses urgency and legitimacy for public-private collaboration for global health issues.

Beginning in 1999, the United Nations and the WHO formally invited the participation of private business actors in health governance through UN and World Health Assembly Resolutions and invitations from top leadership. UN General Assembly Resolutions 55/215 (UNGA, 2000), 56/76 (UNGA, 2001), and 58/129 (UNGA, 2003) were key Resolutions to promote the development of partnerships with private business actors. The Resolutions stated that partnerships would involve "financial resources, access to technology, management expertise, and support for programmes, including through the reduced pricing of drugs, where appropriate, for the prevention, care and treatment of HIV/AIDS and other diseases" (UNGA, 2001, p. 2). Further, the United Nations General Assembly called upon private business actors to "engage as reliable and consistent partners in the development process" (UNGA, 2003).

Top leadership, including former Secretary-General Kofi Annan, promoted greater integration of private business actors in addressing global health needs. In 1999 during the inaugural Princess of Wales Memorial Lecture, Secretary-General Kofi Annan called for a "new approach to public health" involving new private business resources (Annan, 1999). The Secretary-General stressed that, "no company and no government can take on the challenge of AIDS alone" (ibid.). Echoing the Secretary-General, former

WHO Director-General, Dr. Gro Harlem Brundtland, in her address at Davos, invited private business actor participation in global health:

> We are facing major health challenges. There is a real scope for meeting them. It is within our grasp to drastically reduce the global burden of disease. WHO is determined to do its part. And I am happy to welcome other stakeholders - and that includes industry - to join us - because investing in health yields high returns. (Brundtland, 1999a)

In an earlier speech, Dr. Brundtland stated that "influential partnerships" with the private sector were critical to solving global health problems because the issues are "too big for WHO alone" (Brundtland, 1999b). This normative and procedural turn within the UN and the WHO was significant; it not only heralded an influx of private business actors into global health governance through various disease or problem-specific entry points, it distinguished them as essential and legitimate actors in health governance. These invitations were often replicated at the state level; many states sponsored the development of public-private partnerships and devolved authority for health, particularly for health services and infrastructures, to private business actors (Rao, 2009). This era marked a significant turning point in public-private relations in state and interstate institutions. The late 1990s and early 2000s saw an unprecedented increase in private authority in global health governance through representation on governance structures,[58] public-private partnerships,[59] global health initiatives,[60] and new funding arrangements.[61]

[58] Private business actors sit on Boards of Directors and governance structures of numerous global health partnerships, including the Medicines for Malaria Venture, International Partnership for Microbicides, International HIV/AIDS Vaccine Initiative, the Roll Back Malaria Partnership, the Stop TB Partnership, etc. Private business actors also participate on Boards of Directors at country-level public-private partnerships.

[59] Public-private partnerships in health expanded exponentially in this period. Brugha (2008) estimates that 12 new global health partnerships were added every year between 1998 and 2002. This estimate does not include country-level public-private partnerships in health, which evolved even more rapidly.

Private authority, from a functionalist perspective, provides answers to the question of how to generate more resources for global health. However, the questions that such an analysis obfuscates include: What explains governance gaps and failures that seem to necessitate the inclusion of private actors in governance? What motivates private actor involvement in governance? And, what are the intended and unintended consequences of private authority in global health governance? The next section considers the first question through a critical and macrohistorical analysis of the emergence of private authority in global governance, tracing its evolution from the postwar emerging neoliberal world order to contemporary processes of globalisation.

Critical historical developments in private authority and global governance.

In the post-war world order (Cox, 1987), advanced capitalist states, including the United States, Canada, Britain, and other Northwestern European states, developed welfare benefits, wage and worker protections, and social insurance programmes, including public pensions, health care, and employment insurance. This set of social and economic policies became known as the Keynesian welfare state (Jessop, 1996) and entailed a significant interventionist role for the state in its commitment to full employment and social protection measures. This social contract (Cox, 1987) was breached with the introduction of the neoliberal project in the 1970s and 1980s. This period was marked by global oil, currency, and debt-servicing crises (Gill, 2003; Morton,

[60]This includes the Global Fund for HIV/AIDS, TB, established in 2002, and the President's Emergency Plan for AIDS Relief in 2003 (Bertozzi, et al., 2009).

[61] For example, private business actors have formal representation on governance structures at the Global Fund for HIV/AIDS, Tuberculosis and Malaria.

2003), culminating in a global economic recession in the 1980s. Crises were framed as failures of the welfare state (Sheppard & Leitner, 2010) and assigned market-oriented solutions. Neoliberal governance norms of privatisation, deregulation, and competitiveness (Gill, 2003) began displacing Keynesian and developmentalist governance frameworks. The turn towards neoliberalism in the 1980s gained traction with endorsements from political leadership in the United States and Britain, and progressively became the preferred global economic framework.

A globalising world emerged; privatisation, deregulation, and trade and financial liberalisation dismantled many of the barriers to global flows of people, culture, goods and services, and capital. However, narrowly conceptualising globalisation as an increase in global flows and interconnections depoliticises its normative and coercive elements. Cox (1987) and Gill (1993) argue that the new world order is characterised by globalising, regionalising, and disintegrating economic, political, and social forces. Gill (1995) summarises this new world order as a globalised market civilisation.

Disciplinary neoliberalism and the new constitutionalism.

The key features of a globalised market civilisation are disciplinary neoliberalism, new constitutionalism (Gill, 1993, 1995, 1998, 2003), and growing material and structural power of capital. Disciplinary neoliberalism, which Gill (1995) refers to as a form of structural and behavioural power, refers to the tendency of markets to discipline and compel obedience from states, parties, organisations, and other economic agents. In a highly competitive, interdependent global economy, markets discipline parties who fail to align their policies with the expansionist goals of private capital. States, therefore, align

domestic policies to the demands of the global economy, the rules and authority of interstate institutions, and private cooperative arrangements. States also cede autonomy vis-à-vis their participation in constitutional, quasi-constitutional, or regulatory agreements and frameworks. Gill (1995, 1998) describes this phenomenon as the "new constitutionalism," a relatively new (1990s) feature of disciplinary neoliberalism expressed through policies, proposals, and agreements that exert constraining and disciplining effects on domestic policy making. These include International Monetary Fund (IMF) and World Bank conditionality, bilateral and multilateral trade agreements (e.g. NAFTA, GATT), and multilateral regulatory frameworks (e.g. WTO) (Gill, 1998).

Disciplinary neoliberalism and new constitutionalism reconfigure public and private power and authority by elevating the role of private business actors in government and governance and by placing new constraints on the autonomy of public authorities. The shift away from state interventionist roles in social and economic management under neoliberalism and its contemporary form, disciplinary neoliberalism, entailed significant restructuring in the redistributive priorities of states. Many states performed selective retrenchment, privatisation, and/or devolution of public programmes in health, education, family support, employment, labour and skills, etc.[62] States also engaged in deregulation in the 1990s, when they began a process of reducing or eliminating regulatory standards on private business (Cafaggi & Janczuk, 2010). States have also been ceding much of their management role over the economy to interstate institutions and private cooperative

[62] There is a large body of literature investigating retrenchment of public programmes and the public service. Swank (2005) provides a useful comparative analysis of 18 advanced capitalist states, while Adésin (2009) examines the impact of neoliberalism in selected countries in Sub-Saharan Africa.

arrangements (Cutler, 2002). States are adopting policies emphasising public fiscal austerity, low inflation, flexible labour markets, and trade and financial liberalisation (M. Rupert, 1997). Interstate institutions, including the WHO, engaged in similar policy paths. Major cuts for health and development programming within UN institutions took place throughout the 1990s. These cuts created a situation in which many organisations, including the WHO, encounter perpetual financial crises (Börzel & Risse, 2005; B. Bull, et al., 2004).

While states and interstate institutions are complicit, often active participants in the construction of a globalising market civilisation (Bieling, 2007; Gritsch, 2005; Helleiner, 1994; Panitch, 1996; Pauly, 2002; Sassen, 1996, 2002), it is critical to acknowledge that their complicity has different origins and meanings. States in the global South or peripheral states (Cox, 1987; Gill, 2003) face extraordinary pressures toward denationalisation and destatisation. Compounding these pressures is the fact these states often exist in contexts of debilitating disease and other social, economic, and political exigencies. Further, many states, vis-à-vis Structural Adjustment Programmes (SAPs) or multilateral trade agreements (e.g. TRIPs), found themselves ill-equipped to respond to the impacts of rapidly changing internationalised rule structures and obligations.

Structural Adjustment Programmes were policy manifestations of the World Bank and IMF's commitment to the principles of the Washington Consensus. The Washington Consensus, coined by John Williamson (1990), refers to a set of neoliberal policy

prescriptions for public institutional reform.[63] Structural Adjustment incorporated these principles and directed World Bank and IMF recipient states to implement a number of reforms in order to secure loans. States were required to significantly reduce social spending and direct spending towards debt repayment, privatise public and social services and infrastructures (Smith, 2010), and liberalise their economies by removing import and export restrictions (Gill, 1995).

The effects of SAPs, for many states, were nothing short of catastrophic. Health and education systems were dismantled and poverty, food insecurity, social polarisation, and disease burden multiplied disease burden multiplied (Bienan & Shelton, 2001; Cheru, 2002; Navarro, 2004; SAPRIN, 2002; Useche, 2008). Despite growing resistance to SAP reforms, recipient states had little bargaining power with their lenders. World Bank and IMF conditionality also insulated specific subsets of social and economic policy from democratic and domestic interference and locked in neoliberal reforms.

In 1987, the World Bank published a report on health and health care delivery in developing countries (*Financing health services in developing countries: An agenda for reform*). This report signalled that the Bank did not view health care as a human right and that universal and free access to health services was implausible in many least developed and developing countries. In fact, the Bank endorsed reductions in public spending on health care and privatisation of health care services, fundamentally transforming public

[63] This term includes policy prescriptions for fiscal policy discipline and deficit avoidance, reductions in public spending, changes to promote competitive tax, interest, and exchange rates, guarantees for private property rights, broad trade and foreign direct investment liberalisation, privatisation of state-owned enterprise, and deregulation of private business enterprise (Williamson, 1990).

health systems that were often functioning well and reaching large portions of populations (Navarro, 2008).

These and other World Bank and IMF proposals and conditionalities undermined domestic policy autonomy, discredited the state as the principal legitimate arbiter of domestic policy preferences and reforms, and elevated private business interests in economic and social development. They also undermined the very basis of effective public health responses to growing disease epidemics. SAPs compelled states to reduce public spending on health and education during a period in which strong responses to rapidly expanding disease epidemics such as HIV/AIDS and tuberculosis were critical.

Furthermore, international and bilateral trade agreements help bolster the position and power of private business actors, not only through the expansion of markets, but also through the elevation of private property rights over human rights and environmental claims. The WTO has refused to evaluate membership applications based on any form of human rights or labour standards principles (M. Rupert, 2003b); the overriding membership requirement is recognition of national treatment and most-favoured nation trade principles. The WTO has also been reluctant to incorporate any form of environmental, health, or social clauses into trade agreements. The TRIPs Agreement, for example, was initially devoid of any clauses pertaining to the effect of the agreement on public health, despite the fact that the agreement itself was, for the most part, an initiative of Pfizer, Inc. ("Pfizer") (Sell, 1999; Sell & Prakash, 2004), a large American pharmaceutical firm that sought to entrench and extend its intellectual property rights. Sell (1999) describes how Pfizer's CEO joined with 11 other CEOs to form the

Intellectual Property Committee. This Committee was instrumental in securing enhanced IPR protections in the TRIPs Agreement by crafting proposals and successfully lobbying for their inclusion (ibid.).

Another example of the elevated power and position of private business actors can be found in Chapter 11 of the North American Free Trade Agreement (NAFTA). This provision furnishes private firms with the right to pursue legal action against signatory states when firms perceive that state actions or policies have adversely impacted their investments (McBride, 2006). McBride (2006) argues that Chapter 11 confers significant authority on private business actors and facilitates a "diminishing national state and public authority" (p. 771). The NAFTA also insulates domestic policymaking from democratic pressures by locking in neoliberal economic policy provisions and relocating policymaking and dispute resolution functions outside traditional domestic processes. These and other effects of new constitutionalism and disciplinary neoliberalism reconfigure public and private power and authority in a globalised market civilisation. While risks and rewards in this changing world order are distributed unevenly, private business has been a major beneficiary of change. Elevation of private interests in policymaking, new sets of investor rights and defence of rights, and the ability to discipline retractors significantly bolsters private power and interests.

Accordingly, private material and structural power over the last 30 years has grown extensively. In terms of material power alone, the world's largest 200 transnational corporations have revenues greater than 182 of the world's states, or 80% of the world's population (Smith, 2010). Specifically, pharmaceutical firms' revenues have

grown substantially since the early 1990s with an average annual growth rate of 10 per cent (Applbaum, 2009). Strange (1996) argues that corporate structural power has increased significantly since the 1980s and as a result corporations possess significant power to displace and/or influence public authority in governance.

Rewards, risks, and resistance in the new world order.

Not surprisingly, extensive social risk and inequality flow from these conditions. Between 1968 and 1994, social inequality increased dramatically in the United States and globally (Coburn, 2000; Gill, 2003; Rupert, 2002). The distribution of risks and benefits shifts in a globalised market civilisation and creates new social and global hierarchies. Cox (2000) suggests that a three-part social hierarchy has emerged consisting of top, middle, and excluded components. The top level is comprised of those who are included and protected in the global economy. The middle section contains groups acting as the engine of the global economy, supplying their labour, resources, and land. The excluded sections are those who exist on the margins of the global economy; primarily found in developing countries or in low income quintiles in states. Social hierarchies thus develop both within and between states, and middle and excluded populations absorb the greatest burden of social risk, including poverty, disease, displacement, and exploitation while top levels generate and retain extensive material and structural power.

A globalised market civilisation is therefore inherently contradictory and establishes the foundation for struggle and resistance. Widespread and growing poverty, disease, and alienation provoked grassroots and activist movements across the world in the late 1980s and early 21st century. Resistance has taken many forms and cut across

multiple issue areas, including anti-globalisation,[64] anti-war,[65] anti-poverty, access to medicines,[66] environmental, [67] trade, and investment agreements.[68] Contestation can be issue-specific, grassroots, and state-based, such as the Karnataka State Farmers' Movement in India or the Reclaim the Streets movement in the UK (M. Rupert & Solomon, 2005), or may result in the development of global resistance networks such as the Global Justice Movement and the Direct Action Network (ibid.).

Resistance has also been at the level of states where states have challenged the globalising market civilisation by resisting new constitutionalist rules or prescriptions. For example, Section 3(d) of the Indian Patents Act only grants patents to highly innovative products to discourage patent evergreening[69] and abuses (t'Hoen, 2009). In 2006, Swiss pharmaceutical firm Novartis sued the Indian government, charging that this provision contravened intellectual property protections under the TRIPs Agreement (Swamy, 2007). In August 2007, the Indian High Court in Chennai dismissed the complaint on the grounds that the Indian government has a constitutional obligation "to provid[e] good health care to its citizens" (Ecks, 2008, p. 165).[70] Governments in

[64] See Rupert and Solomon (2005).

[65] See works by Rupert (1997, 2000, 2003a, 2003b, 2005a).

[66] See works by Robins (2004) and t'Hoen (2009).

[67] See Rajagopal (2000).

[68] See Kobrin (1998)and Tielman (2000) on resistance and the Multilateral Agreement on Investment.

[69] Refers to minor modifications to patented innovations that extend the patent term (Swamy, 2007).

[70] Novartis subsequently filed an appeal, which is due to be heard by the Indian Supreme Court in September 2011 (Jebaraj, 2011).

Thailand, South Africa, and Brazil have also resisted pressures, including threats of legal action and sanction, from transnational pharmaceutical firms and the United States government in application of national patent law and the TRIPs Agreement.[71] Backed by large civil society networks, these governments successfully implemented patent law and policy positions that were favourable to domestic industry and public health objectives. Very few states, though, have successfully applied legal flexibilities in the TRIPs Agreement that provide expanded scope for compulsory licensing.[72] Markets and states discipline potential retractors and warn states, through action or threat of action, of the economic and political costs of resistance.

Public and private authority reactions to resistance.

Growing global resistance prompted various responses from multilateral institutions, states, and private business in the late 1990s and early 2000s. The UN system responded to social contestation with the introduction of two key normative and governance reforms. First, UN orgnaisations began to incorporate discourse around poverty reduction into policies and programmes; and second, they moved from a conditionality to a post-conditionality governance framework (Harrison, 2004), which expanded the range and scope of private authority.

[71] These states faced sanction or legal action from pharmaceutical firms when they attempted to produce or procure generic antiretroviral drugs. They also faced threat of sanction from the United States Trade Representative (Abbott & Reichman, 2007). The United States also filed (and eventually dropped) a dispute with the WTO, claiming that Brazil's industrial policy violated the TRIPs Agreement and American private firms' intellectual property rights (Shaffer,2004)

[72] Under TRIPs, governments have the right to issue compulsory license to a patent owner to produce the patented product (or process) for their own use. In situations of public health crises or emergencies, the TRIPs Agreement specifies that the government may bypass negotiations with the patent owner and proceed with issuing the license. See: http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

A focus on poverty reduction took the form of two new IMF and World Bank programmes: the Heavily Indebted Poor Country (HIPC) Initiative and the Poverty Reduction Strategy Papers (PRSP) (Sheppard & Leitner, 2010). The HIPC Initiative was designed to support the cancellation of debt for 40 of the world's most heavily indebted poor countries (Schrecker, 2009). However, continuation of neoliberal-inspired eligibility criteria, including privatisation, tax reform, and balanced budgets (Sheppard & Leitner, 2010), frequently translated to weak outcomes for debt cancellation (Schrecker, 2009; Sheppard & Leitner, 2010). The PRSP Initiative, which replaced SAPs in 1999, focuses on alleviating poverty by providing an enhanced role for governments and local NGOs in designing country -specific policies. Similar to the HIPC Initiative, the PRSP contains many of the same eligibility requirements and prescriptions as its predecessor (Sheppard & Leitner, 2010). Changes therefore, are more discursive than structural; employing the language of poverty reduction, country ownership, and local consultation belied many of the enduring neoliberal principles in these initiatives.

The second key strategy involved a movement towards a post-conditionality governance framework. Organisations within the UN system began to incorporate the language of governance, which referred to both processes of decision-making and configurations of actors authorised to participate in these processes. The WHO[73], the

[73] In 2011, there were 189 organisations in official relations with the WHO, including the IFPMA and the International Pharmaceutical Federation; organisations that represent the bulk of the global originator pharmaceutical industry (WHO, 2011).

World Bank[74], and the WTO[75], authorised nongovernmental organisations and private business actors to serve as experts and/or observers in once exclusively interstate deliberative and policymaking processes. In 2006, the World Health Assembly passed Resolution 59.24 which authorised the participation of selected private actors in WHO working groups (WHO, 2006b). In 2009, 40 representatives from originator pharmaceutical firms attended the 62nd World Health Assembly, the largest showing among nonstate actor organisations.[76]

The UN system now has an official UN-Business office to oversee the development of public-private partnerships throughout the UN system.[77] The UN-Business office lists over 300 partnerships between one or more members of the UN system and private business actors. States are also adopting the public-private partnership model in several jurisdictional areas, including health (e.g. building and administrating hospitals[78]), transportation (roads), other infrastructure, and so forth.

Private business actors mirrored these discursive reforms; they adopted language of social responsibility and sustainability, and created and accepted opportunities to

[74] The World Bank designates a participatory role for civil society and non-governmental organisations in the poverty assessment component of PRSPs as well as in the Multi-Country AIDS Programme.

[75] The WTO permits nonstate actors to submit Amicus Curiae or friends of the Court briefs to panels in dispute settlement proceedings.

[76] For a complete list of participants, see: http://apps.who.int/gb/ebwha/pdf_files/A62/A62_DIV1Rev1.pdf

[77] For more information on the UN-Business office, see: http://business.un.org/en.

[78] Hundreds of studies explore PPP s in building and operating health infrastructure in developing and developed countries (McKee, Edwards, & Atun, 2006).

expand their authority in global governance. Private business actors increasingly developed socially responsible practices, including corporate social responsibility (CSR) initiatives, industry-based or international voluntary codes of conduct, self-regulation, and sustainability initiatives. During this period, private business actors exponentially expanded CSR initiatives. In 1993, fewer than 100 CSR reports were filed by transnational corporations; by 2003 that figure had escalated to over 1500 (Thompson, 2005). Corporate social responsibility and corporate citizenship are now mainstays of private business; many firms publish citizenship reports and have dedicated CSR business units and private foundations.[79]

Private business actors also signed on to a number of voluntary codes of conduct, including the United Nations Global Compact, an initiative which began in 2000 and now has over 8500 signatories ("Corporate sustainability in the world economy: The UN Global Compact," 2011). The Global Compact commits signatory firms to aligning their practices with 10 principles concerning human rights, labour, the environment, and anticorruption (ibid.). Private business actors also developed and adopted voluntary codes governing specific industry practices such as marketing. For example, in 1988 the IFPMA instructed member firms to align corporate policies and practices with the IFPMA Code of Marketing Practices (IFPMA, undated). Private self-regulation across a number of different industries has also increased dramatically beginning in the late 1990s (Bondy, Matten, & Moon, 2004; Cafaggi & Janczuk, 2010). While voluntary and self-

[79] All originator firms in this study have CSR business units and US-based 501(c) (3)-registered private foundations.

regulating behaviour may be celebrated as important achievements in private business actor social learning and responsibility (cf. Ruggie, 2002), they also represent the failure of states and interstate institutions to impose stringent oversight and legally binding restrictions on private business actor behaviour. Instead, public authorities have opted to author, permit, and/or vacate these governance arrangements.

Transformations in Global Health Governance

The phenomena of disciplinary neoliberalism and new constitutionalism suggest that growing private authority in global health governance cannot be attributed to a strictly functionalist rationale. An historical and power analysis demonstrates that the operating and normative environments for global health governance has been profoundly shaped by: 1) the growing power and authority of private business, 2) new constraints on public authority and policy autonomy, 3) social and global hierarchies and inequalities, and 4) contradictory tendencies in a globalising market civilisation. It is in this climate that states and interstate institutions have moved toward public-private collaboration, self-regulation, and other modes of implicit or explicit legitimisation of private authority.

Global health issue areas and interests have unquestionably become more numerous and complex. Communicable and noncommunicable disease epidemics, including HIV/AIDS, tuberculosis, heart and lung diseases, cancers, diabetes, etc., create serious challenges for states and international institutions and require vast human, technical, and financial resources. In a globalising world, emerging governance gaps in

health demand action as they become matters of international security[80], human rights, and humanitarian disaster. The challenge is that lean states and international institutions are, in many ways, normatively and authoritatively hamstrung by changes that they themselves authored (Panitch, 1996) or assumed.

As a result, there is a strong normative and functionalist orientation towards partnership for complex governance issues. Private business actors are invited to participate in governance because they are perceived as powerful and legitimate partners who can supply contributions or solutions for complex issues. States and interstate institutions have endorsed and/or authored many of these changes, but changes can also be traced to the conditioning effects of disciplinary neoliberalism, new constitutionalism, and the direct and structural power of capital. And, while it can be argued that states and interstate institutions still retain the ability to devolve authority to private actors or permit their inclusion in governance entities, it is equally difficult to argue that states may just as easily reverse arrangements, extract private business actors, or filter their authority from governance.

For developing countries, these challenges are significantly amplified. Domestic legal and regulatory frameworks governing private business investment and behaviour may be weak, absent, or subject to pressures arising from disciplinary neoliberalism and new constitutionalism. Public authorities in developing countries operate with limited financial, human, and technical resources and capacities, which drive necessity and

[80] In April 2000, the US declared the expanding HIV/AIDS pandemic a national security threat ("U.S. declares AIDS as national security threat," 2000).

partnership agendas. Furthermore, these are the places where communicable and noncommunicable diseases are most prevalent. For example, Sub-Saharan Africa contains two-thirds of the world's least developed countries.[81] It also contains 11% of the world's population, yet accounts for 24% of the global noncommunicable disease burden (King & Fomundam, 2010) and 44% of the global communicable disease burden (Lange, et al., 2008). Thus, these and other states in the global South have become targets and testing grounds of expanded public-private collaboration. However, there are few studies and minimal political or policy consideration afforded to public-private relations in developing states. For example, a study conducted by the Government of Kenya in six Sub-Saharan African states reported that while each government had integrated public-private partnerships into national policies, only one (Uganda) had a formal public-private partnership policy in place and none had legal frameworks (HENNET, 2008). Furthermore, although the UN has established guidelines for public-private collaboration in humanitarian action, [82] there is no attendant oversight or reporting body. These are issues for future research and reform initiatives inside and outside the UN system.

Conclusion

A functionalist rationale claims that problems have become so intractable that they cannot be solved alone, yet such explanations ignore history, power, and process.

[81] As of May 2011, 48 countries met LDC criteria. Sub-Saharan Africa is home to 32 of 48 LDCs (Author calculation) (UN-OHRLLS, undated).

[82] UN Guiding Principles for Public-Private Collaboration for Humanitarian Action: http://www.un.org/partnerships/Docs/Principles%20for%20Public-Private%20Collaboration%20for%20Humanitarian%20Action.pdf.

The supposedly unavoidable necessity of private authority has been largely driven by structural and normative transformations propelled by a globalising market civilisation. States and interstate institutions, however, remain important for a number of public goods, including health, environmental degradation, control of hazardous waste and materials, management of intellectual property and knowledge, and so on. However, disciplinary neoliberalism and the new constitutionalism limit and order government action around these issues. A globalising market civilisation places limits on autonomous state action while strengthening the material and structural power of capital, yet capital also depends on the policy, legitimation, and coercive agency of the state (Gill, 1995). These contradictions create complex relations between public and private authority and are the source of considerable social tension and resistance.

The history and political economy of HIV and AIDS treatment access reflects and exposes these transformations and contradictions in the world order, as well as the private business accommodation strategies used to co-opt and neutralise growing social contestation and reform pressures. The next chapter examines these transformations over the period from 1987 to 2011.

Chapter 3: The History and Political Economy of HIV/AIDS Treatment Access

Rapid escalation of global HIV/AIDS antiretroviral treatment coverage over a relatively short period and in states where it was initially considered impracticable has been described as a modern success story. At the end of 2009, approximately 5.2 million people were on ARV treatment, which represents a 13-fold increase from 2003 (WHO, et al., 2010). These statistics, while impressive, belie a more problematic picture of global inequality in HIV/AIDS prevalence, care, and treatment. In 2003, despite exponentially greater needs for ART in Sub-Saharan Africa and in other low and middle –income countries, coverage was only 2% and 7%, respectively, while in the Americas it was 84% (Bertozzi, et al., 2009). Therefore, although 2.9 million lives have been saved through access to treatment, over 30 million lives have been lost (UNGA, 2011); the vast majority of which were among people living in countries in the global South.

Denial and delay of treatment access throughout much of the global South produced not only mass morbidity and mortality but also a new generation of civil society organisations and activism. Contestation between civil society, governments, and pharmaceutical firms helped midwife new and modified rules, legislation, commitments, and governance arrangements. The history and politics of treatment access reveal an evolution from an international health governance model based primarily on state and UN intervention to a polycentric and mixed actor governance architecture. This architecture has been shaped by structural inequality, social contestation, and growing private authority in global health. And, while prospects for treatment for all are now within

reach, in the absence of structural reform—which has not been a feature of the history of treatment access—these prospects will continue to depend on civil society activism and social contestations. Therefore, despite gains in global treatment access, this success story is more fittingly characterised as a tragic drama that is still unfolding.

This chapter proceeds in four sections. The first section examines how political and policy manifestations of structural inequality shape global health and treatment access. The second section traces the historical evolution of social and political action and contestation around treatment access across two periods: 1987-1998 and 1999-2003, and situates these developments within a Gramscian conceptual framework. The third section explores the most recent period in treatment access, 2004-2011, and examines the contemporary global governance architecture, particularly growing private authority, around HIV/AIDS treatment. Finally, the chapter concludes with a discussion on the prospects for achieving treatment for all.

Structural Inequality and Access to Treatment

Access to ARV treatment and other medicines is profoundly affected by the structure of world order and social position relative to the centres of power (Cox, 1987; Grinspun & Kreklewich, 1994). The contemporary neoliberal world order promotes the goals of advanced capitalist states and the transnational capitalist class and generates a hierarchical social structure based on social position to core groups (Grinspun & Kreklewich, 1994). Social position is determined by the level of integration into the existing world order (Cox, 1987, 2000). Grinspun & Kreklewich (1994) classify these relations as core, semi-periphery, and periphery; forming a social structure of global

inequality. Divisions of labour, resources, and power reinforce global structural inequality and allow core advanced capitalist states to extract surplus capital (Cox, 1987) for the purposes of capital accumulation. Global structural inequality, in turn, shapes global health inequities in the distribution of disease, health resources, research and development priorities, and global power in policymaking and priority setting.

Access to health care and medicines is affected by conditioning frameworks (Grinspun & Kreklewich, 1994), including the Agreement on Trade-Related Intellectual Property or TRIPs (discussed later in the chapter) and IMF conditionality–specifically, Structural Adjustment Programmes. Grinspun & Kreklewich (1994) describe a conditioning framework as an "institutional mechanism that effectively restricts policy choices at the nation-state level" (p. 36). Conditioning frameworks, including the NAFTA, SAPs, and financial deregulation constrain domestic policymaking, transfer policymaking to international and transnational levels, impose penalties (or the threat of penalties) for noncompliance, and lock in neoliberal reforms (ibid.). Conditioning frameworks reflect the interests of the transnational capitalist class, particularly their interests in internationalising the state through the relocation of policy deliberation and enforcement to international and transnational arenas. Although frameworks may contain abrogation clauses, normative and governance path dependencies and structural constraints often inhibit states from exercising these options. Grinspun & Kreklewich (1994) argue that conditioning forces weigh more heavily on states that are farthest[83] from the centres of power, specifically developing states.

[83] As measured by social position in the world order, not distance (Grinspun & Kreklewich, 1994).

Grinspun & Kreklewich (1994) point to IMF conditionality and SAPs as formal conditioning frameworks. IMF conditionality refers to a set of neoliberal policy criteria that states were required to adopt in order to secure loans through the IMF Structural Adjustment Facility during the 1980s and 1990s. For example, states were required to significantly reduce social spending and direct spending towards debt repayment (Cheru, 2002; Cohn, 2006; Poku & Whiteside, 2004), privatise public services and infrastructures, and liberalise their economies (Gill, 1995). The logic of SAPs was that they would promote economic growth and development; however, a multi-country study by the Structural Adjustment Participatory Review showed that, for many states, impacts reversed development gains (SAPRIN, 2002). Health, education, and social services were dismantled, and poverty, food insecurity, social polarisation, environmental destruction, and disease multiplied under SAPs (Benatar, 2001; Bienan & Shelton, 2001; MacLean & MacLean, 2009; SAPRIN, 2002; Useche, 2008).

Many states affected by Structural Adjustment were also experiencing growing HIV/AIDS epidemics, and therefore the erosion of public and social services under SAPs would have undermined the very basis of a potential AIDS response. When governments were eventually provided with sufficient financial resources to roll out large-scale HIV/AIDS treatment responses, many departments and public health and education systems were often too fragile and ineffective to respond quickly and comprehensively. Structural Adjustment Programmes are, in many cases, largely responsible for eroding infrastructures necessary to expand HIV/AIDS prevention, care, and treatment.

Global biases and inequalities in health research, drug development priorities, health systems, and human resources also perpetuate structural inequality, creating vast global disparities in disease burden and access to care and treatment. Developing states are home to 80% of the world's population but only 20% of the global pharmaceutical market (King & Fomundam, 2010). Poverty accounts for much of this disparity; weak, small, or inefficient markets and poor political, research, and manufacturing capacity obstruct drug development, purchasing, and distribution. Only a handful of developing and middle-income countries possess sufficient technical capacity to manufacture a patented pharmaceutical product, specifically Argentina, Brazil, Mexico, India, China, and South Africa (Muzaka, 2009a). Patent terms of 20 or more years provided a small group of originator firms with monopolies on new ARV drugs, allowing them to price medicines at levels that were widely prohibitive. Small health budgets, coupled with competing health and social priorities meant that many states in the global South were unable to subsidise large-scale treatment programmes for expensive ARV treatment.

The global distribution of HIV/AIDS and inequalities in care and treatment access are not exceptional; the pandemic mirrors other inequities in health research and systems. For example, tropical and infectious diseases, endemic in developing countries, receive only a small fraction of drug research and development investment. Since 1975, less than 2% of new drug development has been geared towards tropical diseases and tuberculosis, despite the fact that these diseases comprise 12% of the total global disease burden Global trends of persistent structural inequalities in health research and treatment priorities are captured by the expression, "the 10/90 gap" (Kilama, 2009; MacLean,

2009), which describes how 90% of the world's research resources are directed to 10% of global health problems. These patterns of inequality and inequity are reproduced in distributions of disease, health resources, care and treatment access, and health spending.

Despite being home to 44% of the communicable disease burden, 68% of people living with HIV[84], 60% of malaria cases, and 30% of tuberculosis cases (Lange, et al., 2008; WHO & UNAIDS, 2011), the Commission for Africa estimates that Sub-Saharan Africa possesses only 3% of the global health workforce (Anyangwe & Mtonga, 2007). Conversely, the Americas contain 14% of the global population, 10% of the global disease burden, and 37% of the global health workforce (Anyangwe & Mtonga, 2007). Moreover, public health systems in Sub-Saharan Africa are underfunded, exacerbating efforts to recruit and retain health workers. In 2007, public health spending in Southern Africa, averaged, US$90 per capita[85], while in advanced capitalist states such as the United States, Canada, and the United Kingdom it averaged US$3,188 (WHO, 2007).

Underfunding of health systems creates governance and institutional deficits and weaknesses and places pressure on citizens to bear a greater proportion of health care costs. Significant out-of-pocket costs for health care and medicines, including user fees (Beauliere, et al., 2010) and private insurance (Gustafsson-Wright, Janssens, & van der Gaag, 2011) in Sub-Saharan Africa hinder large-scale access to health care, including HIV/AIDS care and medicines. Accordingly, there are poor health and development

[84] This figure was calculated by the author based on WHO/UNAIDS data from December, 2011.

[85] At average US$ exchange rate.

outcomes in Sub-Saharan Africa. Human Development Index rankings are particularly low in Southern Africa, reflecting low life expectancies, standards of living, and educational attainment.[86] There are also wide disparities in rankings between countries in Southern Africa and OECD countries.[87] In 2009,[88] the 10 countries in the Southern African region had an average[89] ranking of 146.6 whereas OECD countries had an average ranking of 21.6. Global structural inequality, therefore, functions as a perverse determinant of health and drives HIV/AIDS epidemics through multiple pathways- including historical and contemporary processes of marginalisation, exclusion, and exploitation- in Sub-Saharan Africa and elsewhere in the global South.

Why Africa?

There is a large and protracted scholarly debate around causal factors in development and underdevelopment in Africa. There is a wide spectrum of theories linking underdevelopment to factors such as unfavourable geography (Sachs & Warner, 1997), tropical environment and diseases (Bhattacharyya, 2009; Gallup & Sachs, 2001), agricultural production methods (Sachs, 2005), low population densities (Simensen, undated), domestic trade barriers (Sachs & Warner, 1997), political decision-making, and poor institutions (Luiz, 2006). These and other microlevel factors are in some cases

[86] For more information on HDI rankings, see: http://hdr.undp.org/en/statistics/hdi/.

[87] As of June 2011, the OECD had 33 member countries. For the full list, see: http://www.oecd.org/countrieslist/0,3351,en_33873108_33844430_1_1_1_1_1,00.html.

[88] See United Nations Development Programme: http://hdr.undp.org/en/statistics/.

[89] Author calculation. This figure is calculated by adding up and averaging the 2009 HDI rankings of the 33 OECD countries and 9 Southern African countries. Zimbabwe did not receive an HDI ranking in 2009.

empirically significant, but they ultimately intersect with historical and structural conditions of unequal social and economic relations. Three centuries of slavery (Inikori, 1992, 2000; N. Nunn, 2007, 2008) and 75 years of colonialism (Acemoglu, Johnson, & Robinson, 2001; Amin, 1972; Bertocchi & Canova, 2002) are key antecedents of African underdevelopment. Whiteside and Barnett (2002) argue that epidemics in Africa are the outcome of histories that have made many of the countries "unhealthy" (128). The social, economic, and political effects of imperialism and colonialism, including conflict, inequality, exploitation, and poverty, have had an enormous impact on creating risk environments for health. Underdevelopment is thus historically constructed and perpetuated through structural inequality; specifically through violent, exploitative, and inequitable flows and practices in trade and resources (Burnett & Manji, 2007), investment (Schneider, 2003), and finance (Bond, 2007; Cheru, 2002; Poku & Whiteside, 2004; Rowden, 2009; Toussaint, 1999) in the global economy. These practices depress development, undermine governance capacity, and sustain widespread poverty. Structural inequality is therefore not just an historical by-product or temporary market failure; it is an ordering principle of the world order, with critical consequences for global health.

History of the Global HIV/AIDS Pandemic and Treatment Access

The history of treatment access for HIV/AIDS can be separated into three periods: 1987-1998, 1999-2003, and 2004-2011. The first period, between 1987[90] and 1998, is

[90] This year marks three turning points in the HIV/AIDS pandemic. First, HIV/AIDS becomes the first disease to be debated in the United Nations General Assembly (Gottlieb et al., 1987). Second, the WHO launches the Special Programme on HIV/AIDS (Bertozzi, et al., 2009). Finally, AZT is approved as a treatment for HIV/AIDS (ibid.).

characterised by a state and interstate system, property-rights-based, exchange model for treatment, which resulted in extremely low treatment coverage. The principal actors were originator pharmaceutical firms, the UN system (particularly the WHO), and individual states. While HIV/AIDS received increased political attention during this period, prevention rather than treatment remained at the top of the global agenda. The next period, between 1999 and 2003, was a short but intense period of social and political activity. Key accommodation strategies were carved out during this period, including new P3Hs, price reductions, drug donations, and TRIPs flexibilities. Simultaneously, new bilateral, multilateral, and nonstate actor responses and commitments transformed the state-based model of access to a polycentric and mixed actor global governance architecture. Treatment access, however, did not exponentially expand during this period. This was a period of contestation, reaction, and response in which global recognition of ARV treatment and subsequent institutional developments outpaced treatment coverage.

The third timeframe, from 2004 to 2011, is a period in which treatment access becomes a global priority sponsored by three major funding programmes: the Global Fund, the President's Emergency Plan for AIDS Relief (PEPFAR), and the World Bank's Multi-Country AIDS Programme (MAP). From this focus come a plethora of new public and private actors, institutions, rules and policies, governance arrangements, and programmes operating in every HIV/AIDS-afflicted country in the world. Despite these remarkable transformations in treatment access, goals around universal access are still significantly out of reach. The final section of the chapter considers challenges and prospects for HIV/AIDS treatment access.

Health for some: Early experiences in global HIV treatment from 1987-1998.

Treatment to suppress the human immunodeficiency virus was first discovered in 1987 in the drug zidovudine (AZT) (Yarchoan & Broder, 1987). Treatment with AZT enhanced immune function and helped restore physical functioning (Yarchoan, Mitsuya, & Broder, 1988). AZT, however, did not significantly extend life expectancy, was expensive (Bertozzi, et al., 2009), and carried the risk of serious side effects (Yarchoan & Broder, 1987). The pandemic continued to grow with millions of new infections recorded each year.

In 1994, amidst a growing global pandemic, member states of the WTO signed the TRIPs Agreement,[91] which secured patent protections for new intellectual property for a minimum of 20 years. The Agreement required WTO member states to align or develop domestic legislation to reflect these standards. Prior to TRIPs, patent protection was a matter of domestic policy; over 40 states, for example, did not issue patents for intellectual property, including medicines (Forman, 2008; Klug, 2008). Some states, such as India, only patented processes, and many states issued patents for less than 20 years (Forman, 2008). Developing and least developed countries have until 2006 and 2016, respectively, to comply with their obligations under TRIPs (ibid.).

The Agreement, in effect, offered monopoly protection to originator pharmaceutical firms for new ARV medicines, several of which were already in the drug pipeline during TRIPs negotiations. The Agreement was sponsored by the USA, Switzerland, and the European Union (Muzaka, 2009b) and proposed by the

[91] For the full text of the TRIPs Agreement, see: www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

pharmaceutical lobby led primarily by Pfizer and the IFPMA (Klug, 2008; Sell, 1999). The pharmaceutical industry maintained that enhanced intellectual property protection was necessary to stimulate innovation and reward firms for investments in research and development processes (Muzaka, 2009b).

Shortly after the implementation of TRIPs, the world learned of the discovery of new combinations of medicines that would fundamentally transform the course of the pandemic. An announcement in 1996 at the International AIDS Conference in Vancouver, Canada, represented an historic turning point in the HIV/AIDS pandemic. Researchers announced that antiretroviral therapy had proven efficacy in reducing HIV viral load and improving the body's immune functioning (Montaner et al., 2006). Treatment, therefore, had the potential to reduce AIDS-related mortality and morbidity (Abaasa et al., 2008; Hogg, et al., 1999; Joseph, 2003; Mahy et al., 2010; Phillips, 2007) and transform HIV/AIDS from a fatal to a chronic condition. The cost of ARV medicines, however, ranging from $10,000 to $20,000 per patient per year, was far too expensive for millions of infected persons (Ford & Calmy, 2010; Joseph, 2003).

While several governments in North America and Europe began providing publicly subsidised treatment, few governments of developing countries expressed interest in developing national treatment programmes. At the time, there was limited political discussion of HIV/AIDS; indeed, many political leaders refused to acknowledge AIDS or admit that their countries were becoming severely afflicted (Altman, 2006; UNAIDS, 2008). Where political will did exist, in countries such as Uganda, Senegal,

and Thailand, prohibitive drug prices made it impossible to entertain seriously the prospect of providing free universal treatment.

During this period, the UN system, and in particular, UNAIDS[92] and the WHO, were chiefly responsible for coordinating the global response. Efforts centred on HIV prevention and treatment programmes were discouraged (Bertozzi, et al., 2009). There was considerable scepticism, or, as Basu (2009) argues, scepticism underpinned by racism, which stalled considerations of developing universal HIV treatment programmes in developing countries. The Director of the United States Agency for International Development, Andrew Natsios, told the Boston Globe that ARV treatment (which requires taking medicines at set time intervals) was not feasible in Africa because:

> Africans don't know what Western time is…many people in Africa have never seen a clock or a watch their entire lives. And if you say, one o'clock in the afternoon, they do not know what you are talking about. (Quoted in:Basu, 2009)

Other objections to providing treatment included concerns around health infrastructure in developing countries, costs of universal treatment, questionable commitment by African leaders, as well as concerns around how treatment efforts might distort funding from prevention programmes. Treatment coverage in developing countries, therefore, remained extremely low. During this period, the only non-OECD state to initiate a national and universal ART programme was Brazil in 1996 (A. S. Nunn, da Fonseca, Bastos, & Gruskin, 2009; t'Hoen, 2009).

Concerns around the feasibility of large-scale public treatment programmes in developing countries were ultimately dispelled by nongovernmental pilot programmes,

[92] In 1996, UNAIDS replaced the WHO Special Programme on AIDS (UNAIDS, 2008).

including Partners in Health and Médecins Sans Frontières (MSF). These organisations proved that it was possible to provide quality treatment services and achieve high rates of treatment adherence in resource-limited settings (Respondent 28-3; 55-3; 71-3, personal interview, October 30, 2008; July 31, 2008; and May 30, 2009). Furthermore, prominent groups such as the Harvard Consensus issued statements refuting reports that it was not possible to administer widespread HIV treatment in resource-limited settings.[93] In conjunction with growing global treatment activism, these initiatives challenged the political stasis within state and interstate institutions. Towards the ends of the 1990s, UNAIDS and the WHO began exploring possibilities to expand access to ART in developing countries.

The first multi-country pilot programme, the Drug Access Initiative (DAI), was developed in 1998 by UNAIDS to promote negotiations between originator pharmaceutical firms and four countries[94] (UNAIDS, 2008) with the objective of reducing drug prices. The DAI introduced the concept of differential pricing whereby firms tier prices based on disease and/or economic indicators.[95] Negotiations were successful in the sense that prices declined to $7,200 per patient per year (ibid.). However, these prices were still too high for many developing countries. Treatment

[93] For full text of the statement, see: www.hsph.harvard.edu/bioethics/pdf/consensus_aids_therapy.pdf.

[94] Chile, Cote d'Ivoire, Uganda, and Vietnam.

[95] Commonly, firms use any of the following indicators: World Bank income classifications, HDI rankings and/or HIV prevalence (see Chapter Five for more information).

access in Sub-Saharan Africa and in many other parts of the global South remained very low throughout this period (UNAIDS, 2008; WHO, et al., 2010).

Nongovernmental and civil society organisations documented and protested the devastating impacts of HIV/AIDS. Many of these organisations were at the heart of local responses, providing care and support to people living with HIV/AIDS and engaging in advocacy efforts. Several influential HIV/AIDS civil society organisations formed between 1986 and 1998, including the Treatment Action Campaign (TAC), the AIDS Support Organisation, the AIDS Coalition to Unleash Power (ACT UP), the Global Network of People Living with AIDS, the African Network of AIDS Service Organisations, and others (TAC, undated). Activist movements and networks of people living with HIV/AIDS contested the power and property rights of pharmaceutical firms and demanded recognition of their rights to health and medicines.

Founded by Zackie Achmat in 1998, the TAC has been vocal, influential, and successful in multiple treatment access campaigns. The TAC was formed initially to promote the rights of HIV-positive people and demand treatment for people living with HIV/AIDS in South Africa (Bertozzi, et al., 2009) and is now widely credited with advancing national and global treatment access. In one of its first campaigns, beginning in 1998, the TAC protested the South African government's withdrawal of programmes for HIV-positive pregnant women. The TAC eventually pursued legal action against the government and won its case in December 2001 (Heywood, 2009).

The TAC subsequently took on the US government after the United States Trade Representative (USTR) placed South Africa on its watch list. The US argued that South

Africa's 1997 Medicines and Related Substances Control Amendment Act was in violation of the TRIPs Agreement (TAC, undated). The Act contained measures for compulsory licensing, parallel importation, and generic substitution to make medicines more affordable and accessible (Heywood, 2009). The TAC campaign accused the US government of using intimidation tactics to advance the interests of pharmaceutical firms at the expense of human lives. The campaign was successful, and the Clinton Administration abandoned its position.[96]

Subsidiaries of the world's biggest pharmaceutical firms through the South African Pharmaceuticals Association (PMA), however, filed a lawsuit on February 18, 1998 against the Government of South Africa. They complained that the Act violated their rights to freedom from deprivation of property under the South African Bill of Rights (Heywood, 2001). The pharmaceutical industry signalled that it was willing to sue the government of Nelson Mandela to secure protection for its intellectual property rights. This case would become a matter of international interest and social contestation during the next period in the history of treatment access.

By the end of this first period, there were approximately 40 million people living with HIV/AIDS worldwide and three million new infections each year (UNAIDS & WHO, 2002). AIDS had already claimed over 20 million lives and had become the fourth largest killer worldwide (Dixon, McDonald, & Roberts, 2001; WHO, 1999). A massive body of literature emerged analysing and forecasting the social, economic, and political

[96] President Clinton issued Executive Order 13155 stating that countries in Sub-Saharan Africa would not be subject to trade retaliation should they enact measures such as compulsory licensing for the purposes of production and/or importation of generic ARV medicines (t'Hoen, 2009).

impacts of HIV/AIDS.[97] AIDS could no longer be conceptualised solely as a public health issue; it was clearly threatening to exact enormous social, economic, and political costs. Political and international communities began to awaken to these devastating impacts and responded with new normative and funding commitments.

Contestation, concession, and commitment: Developments in treatment access from 1999-2003.

Several critical developments mark this short, yet intense period in global HIV treatment access. New bilateral, multilateral, and private business actor commitments and compromises secured during the period from 1999-2003 galvanised political action towards treatment access. However, activism during this period from growing civil society movements underscored many political and industry developments. Yet, there was very little progress in the expansion of treatment access during this period. This was a period of contestation, reaction, and response in which global recognition of HIV treatment access and institutional developments outpaced treatment coverage.

International and domestically based civil society groups, including the TAC, MSF, ACT-UP, the AIDS Law Project, Health-Gap Coalition, and Oxfam engaged in large-scale access-to-medicines campaigns. Campaigns reframed treatment access as a human rights issue, particularly the rights to life, dignity, equality, and health. Originator pharmaceutical firms, however, struggled to position the issue as a matter of IPR protection and underlined the necessity of such protection in scientific innovation and

[97] For a cross section of literature, see Boutayeb (2009), de Waal (2010), Dixon, McDonald and Roberts (2001), Foster and Williamson (2000), Marlink, et al. (2008), and Poku and Whiteside (2004).

advancements. The TAC and other civil society organisations, however, were not opposed to patents per se, but rather to their abuse. Civil society activists argued that patent abuses, including monopolistic pricing and failure to reasonably share intellectual property through voluntary licenses, created significant barriers to treatment for all (TAC, undated). Social contestation around treatment access, therefore, became not a clash about rights (human vs. property), but rather about abuses of rights and the impacts of those abuses on human rights to life, equality, dignity, and health. From that point, civil society efforts generated extensive public and media attention and harnessed public support and sympathies. Governments, intergovernmental organisations, and pharmaceutical firms became subject to increasing public scrutiny and censure and were forced to respond to mounting civil society action.

One of the earliest cases of civil society action around HIV treatment access centred on Pfizer's drug, Diflucan (generic name: fluconazole). Diflucan is used in the treatment of fungal infections, including cryptococcal meningitis and candidiasis, two common AIDS-defining illnesses (Perez-Casas, Chirac, Berman, & Ford, 2000). Beginning in 1998 and later joined by ACT-UP and MSF, the TAC condemned Pfizer's excessive pricing of Diflucan and demanded that they immediately reduce their prices and issue voluntary licenses for generic production of the drug in South Africa.[98] Pfizer refused all such requests (ACT-UP, March 22, 2000; TAC, 2000). Civil society continued to pressure Pfizer through global protests, letter writing, and media engagement. It was

[98] Pfizer held a patent on Diflucan in South Africa, thus prohibiting production or importation of generic fluconazole.

only after the TAC and MSF initiated legal action against the firm that Pfizer publicly announced that it was willing to make concessions on Diflucan (Schoofs, 2000).

In March 2000, Pfizer announced that they intended to donate Diflucan to the South African government (Flouty, 2000). While the TAC and MSF supported this proposal, civil society respondents stressed that these and other organisations favoured patent flexibilities (voluntary and compulsory licensing) as more sustainable solutions to drug access (B. Baker; J. Berger, personal interview, September 23, 2008; November 30, 2007). Months later, after Pfizer failed to reach an agreement with the Government of South Africa on the terms for the donation, TAC founder Zackie Achmat returned from Thailand with 5,000 capsules of biozole, a generic form of Diflucan (Robins, 2004). The capsules were purchased for R1.78 per capsule, whereas Diflucan was being sold to the South African government at a cost of R28.57 (Perez-Casas, et al., 2000). The TAC issued a press release announcing the importation of biozole and Zackie Achmat was promptly arrested and charged with drug smuggling (TAC, 2000).

On October 17, 2000, the TAC formally announced the Christopher Moraka Defiance Campaign. In July 2000, Christopher Moraka, a member of the TAC, died from AIDS-related candidiasis (Robins, 2004). Following civil society campaigning, protests, and threats of legal action, Pfizer and the South African government finally settled on an agreement in December 2001 (TAC, undated). The programme became known as the Diflucan Partnership Programme (DPP). Again, while the donation was welcomed by civil society organisations, it failed to address either of their requests for patent flexibilities or deep price reductions. Zackie Achmat lamented that what was needed was

not pharmaceutical firm philanthropy but rather changes to policy and legal frameworks to prevent profiteering and patent abuses (Achmat, 2001).

Civil society organisations continued to observe the development of the Diflucan Partnership Programme, and also focused their attention on the South African Pharmaceutical Manufacturers Association lawsuit against the Government of South Africa. The TAC, supported by numerous global civil society organisations, including the Red Cross, Oxfam, and Médecins Sans Frontières, organised multiple protests at offices of pharmaceutical firm applicants involved in the lawsuit across South Africa. Civil society held vigils at applicant offices, at the Consulate of the United States in Johannesburg, and at the office of the PMA, and delivered letters and petitions requesting that applicants withdraw their case (Heywood, 2009). When these actions failed to elicit a case withdrawal, the TAC and other organisations coordinated global marches and events styled as "days of action" in South Africa and US and European countries. On July 9, 2000, the Global March for Access garnered support from over 250 civil society organisations worldwide, all broadcasting the message: drop the case against the South African government (Heywood, 2009).

In March and April 2001, civil society organisations secured several victories in the case. First, the global days of action received widespread coverage from local and international media (Heywood, 2001). Second, the WHO, the European Union Parliament, and other states condemned the lawsuit and supported the South African law (ibid). Third, the TAC was admitted as an amicus curiae (friend of the court) on March 6, 2001, allowing them to submit affidavits, including a founding affidavit which contained

accusations of patent abuses and drug profiteering, to which PMA firms were required to respond (Steele, February 16, 2001). The discourse surrounding this case pitted pharmaceutical firms in a "battle" or "war" [99] with civil society groups, people living with HIV/AIDS, and Nelson Mandela's government. When the court case began on March 5, 2001, civil society organisations maintained their vocal opposition and organised protests across 30 cities worldwide (Heywood, 2001). On April 19, 2001, the PMA withdrew their case.

Throughout this period, civil society organisations pursued social and legal action against a number of originator pharmaceutical firms in the US and Europe. For example, activism at two American universities prompted pharmaceutical firms to initiate concessions, including price reductions, on ARV medicines. Stavudine (d4T), an ARV medicine, is licensed to Bristol-Myers Squibb Company (BMS) for marketing and distribution, by Yale University, who retains patent rights (Martin, Hitchcock, De Clercq, & Prusoff, 2010). Civil society organisations and student activists protested the high price of d4T and criticised the University's role in blocking access to ARV medicines. As patent holder, Yale University received substantial royalties, nearly $40 million annually, from sales on d4T (Borger & Boseley, 2001), yet was unwilling to engage in pricing or licensing talks with BMS. Student activists and civil society organisations protested the firm and the University, accusing them of undermining drug affordability in developing countries. Within weeks of the start of the protests, BMS announced that they would not

[99] See: Daily Mail and Guardian (2001, March 16). "Drug giants prepare for war", and Swarns, R. (2001, March 8). "AIDS drug battle deepens in Africa", New York Times.

enforce their patent rights for d4T in South Africa and would offer significant price reductions (Demenet, 2002). Although these were important changes, they failed to produce new licensing that would allow for competition between multiple suppliers.

In a similar case at the University of Minnesota, student and civil society activists demanded that the University offer an open license for its patented medicine, abacavir (ABC), an ARV drug licensed to pharmaceutical firm GlaxoSmithKline, Inc. (GlaxoSmithKline or GSK). Abacavir was invented by researchers at the University of Minnesota with US government financial support (Ritter, 2001). The University holds patent rights for abacavir, and, following a 1999 court settlement, receives royalties from GSK on sales of the drug. In March 2001, student activists and the TAC, Health GAP, Oxfam, and the Agua Buena Human Rights Association protested GSK pricing and licensing policies and pressured the University to relinquish royalties and engage with GSK in pricing and licensing discussions (Borger, 2001). While the University eventually came out in support of price reductions, they did not meet any other activist demands.

In May of 2001, Bristol-Myers Squibb again found itself the subject of civil society action. Patients and civil society organisations in Thailand filed suit against the firm, questioning the validity of the its patent on didanosine (ddl) (Ford, Wilson, Costa Chaves, Lotrowska, & Kijtiwatchakul, 2007). The plaintiffs in the case prevailed, and the Thai court even went so far as to issue a statement on the potentially harmful effects of patents on essential medicines. The court argued that because patents may result in higher prices and thereby obstruct access to medicines, patients have the right to pursue legal

action in cases of alleged patent abuse or invalidity (Ford, et al., 2004). BMS filed an appeal in October 2004, which they eventually dropped (ibid.).

In October of 2002, civil society organisations (including the TAC) filed a complaint with the South African Competition Commission over the ARV pricing and licensing practices by GSK and Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer Ingelheim or BI) (Sidley, 2003).[100] The Commission ruled that the firms were charging excessive prices and failing to issue voluntary licenses, practices that were in contravention of the 1998 Competition Act of South Africa (ibid.). The Court ordered penalties against the firms if they failed to implement changes to their pricing and licensing practices ("Competition Commission finds pharmaceutical firms in contravention of the Competition Act," 2003). Additional settlements between the firms and the TAC resulted in seven new voluntary licenses for ARV drug production (Heywood, 2009). Further, on the day that the Commission made their ruling, GSK announced a new wave of price reductions on their ARV medicines (Sidley, 2003).

Amidst mounting civil society contestation, pharmaceutical firms began offering concessions on drug prices and patent enforcement. As previously mentioned, BMS indicated that it would reduce prices and not enforce its patent rights on d4T in South Africa. Several other firms adopted similar strategies to neutralise social contestation. In 2000, the DAI expanded into the Accelerating Access Initiative (AAI), a P^3H involving

[100] The complaint concerned GSK's ARVs zidovudine and lamivudine and the combination 3TC/AZT as well as Boehringer Ingelheim's ARV nevirapine (Sidley, 2003).

five UN organisations[101] and five pharmaceutical firms.[102] The AAI combines differential pricing, and patent flexibilities to enhance access to originator ARV medicines (Ngoasong, 2009). The AAI was one of the first major P^{3}Hs to target ARV treatment access for developing countries. The programme expanded slowly and, at first, did not significantly expand treatment coverage. Within 18 months, the AAI had provided medicines for 27,000 people (WHO/UNAIDS, 2002a), a small fraction of the millions requiring treatment.

Further announcements came in 2001, including offers from Merck & Co. ("Merck") to sell its ARV medicines, Crixivan and Stocrin, at nonprofit prices in least developed countries (Wertheimer, Santella, & Lauver, 2004). Abbott Laboratories, Inc. ("Abbott") announced that same month that Abbott would sell its ARV medicines, lopinavir and ritonavir, and its Determine HIV test at nonprofit prices in Africa and other least developed countries (Wertheimer, et al., 2004). In June of 2001, GSK agreed to sell many of its ARV and some infectious disease medicines at nonprofit prices to 63 of the world's least developed countries (ibid.). Further reductions came in 2002 when Merck announced that it would make a new formulation of Stocrin available at less than $1 per day. GSK also began providing deep discounts for ARV medicines and antimalarials to projects funded by the Global Fund (ibid.). While these discounts offered major reductions from earlier prices, originator medicines were still significantly more

[101] This includes two UN specialized agencies, WHO and the World Bank, two UN programmes, UNFPA and UNICEF (WHO, 2005), and one other UN entity, UNAIDS.

[102] Abbott, Boehringer Ingelheim, Bristol-Myers Squibb, F. Hoffman-La-Roche, Inc., GlaxoSmithKline, and Merck (WHO/UNAIDS, 2002a).

expensive than their generic counterparts (F. Orsi & D'Almeida, 2010). Around this time, Indian generic firms began offering ARV medicines at significantly reduced prices, allowing states in Sub-Saharan Africa to develop national treatment programmes. Very few states in Sub-Saharan Africa (with the exception of South Africa) patented ARV medicines and were therefore able to purchase generics for their treatment programmes. Generic competition significantly expanded treatment access and placed downward pressure on ARV prices (t'Hoen, 2009; Waning et al., 2010).

Over this short second period (and in the first period, as well), civil society organisations proved to be highly organised, credible, and powerful sources of resistance. Organisations employed multiple strategies, including protests, petitions, letter writing, sit-ins, press releases, litigation, and participation in political processes and events. Campaigns relied on social and legal action and threat of action in pursuit of their goals for expanded treatment access. Social and legal action employed rights-based language and argumentation, including the human rights to life, health, equality, and dignity. The right to health and equality as articulated in the United Nations Declaration of Human Rights,[103] the International Covenant on Economic, Social and Cultural Rights,[104] the

[103] Article 25 stipulates, "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control." For the full text, see: http://www.un.org/events/humanrights/2007/hrphotos/declaration%20_eng.pdf.

[104] Article 12 contains three sub-clauses pertaining to the right to health. Article 12 (c) specifically states that states must take steps to ensure the realisation of the right to health as it relates to "the prevention, treatment and control of epidemic, endemic, occupational and other diseases." For the full text, see: http://www2.ohchr.org/english/law/cescr.htm.

Convention on the Rights of the Child,[105] and the Convention on the Elimination of All Forms of Discrimination against Women,[106] as well as rights afforded by individual states in constitutional documents (for example, Section 27 of the South African Constitution)[107] permeated civil society claims made in defence of the right to treatment.

Campaigns used rights-based and emotionally compelling language to mobilise public and political sympathies and support. For instance, the TAC accused pharmaceutical firms of profiteering from the HIV/AIDS pandemic (TAC, undated) while ACT-UP argued that the inability to access treatment because of high drug prices constituted "murder" (ACT-UP, March 22, 2000) and "market-driven genocide" (Eric Sawyer quoted in:ACT-UP, April 3, 2000). In the South African medicines case, the TAC compiled affidavits from individual members who described personal, physical, financial, and emotional hardships of living with HIV/AIDS and lack of access to treatment (Steele, February 16, 2001). Profiteering, patent abuses, and political stasis were revealed to have dire consequences for human health, life, and dignity.

Accommodation and *trasformismo* in global HIV/AIDS treatment access.

It is therefore not coincidental that a wave of pharmaceutical firm concessions and TRIPs compromises arose in the midst of growing social contestation. What began with

[105] The Convention contains multiple references to health and the role of governments in providing health services for children. See: http://www2.ohchr.org/english/law/crc.htm.

[106] Article 12 sets out expectations for the promotion and protection of women's health. See: http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm#article12.

[107] Section 27 of the South African Constitution affirms the right of access to health care, food, water, and social security, and compels the state to implement measures to support the realisation of these rights. For the full text, see: http://www.info.gov.za/documents/constitution/1996/96cons2.htm#27.

civil society activism in various parts of the world had transformed into growing global networks of social contestation denouncing the exploitation of monopoly power at the enormous expense of human life and rights. The globally visible PMA case further galvanised civil society and some governments and international organisations in pushing forward demands for both the protection of South African legislation and more widespread deployment of TRIPs flexibilities to significantly expand global treatment access. The ensuing wave of public announcements may have been an indication of what Ruggie (2002) describes as corporate social learning around the need to integrate broader social interests into corporate conduct. This interpretation does not explain, though, years of neglect and dismissal of demands from then weaker social groups. It was at the convergence of escalating social contestation on the ideological, structural, and corporate behavioural foundations of global inequity in treatment access, and growing commercial threats from generic firms that pharmaceutical firms began to issue new compromises and concessions on drug pricing, and to a lesser extent, patent flexibilities.

These concessions represent a characteristic strategy of accommodation or what Gramsci referred to as *trasformismo.* Gramsci's concept of *trasformismo* is embedded within his larger theoretical framework on hegemony which Levy (1997) summarises as the "congruence of material and ideological forces that enables of a coalition of interests to maintain a dominant position in society" (p. 129). Gramsci argued that hegemony is achieved and maintained through broad adherence to universalised principles, or what he referred to as "popular common sense"(1971 ,330-331). Legitimation is therefore integral to the maintenance of hegemony; hegemonic orders will face decline if they are unable to

secure the consent of both allies and subordinate social groups. Because hegemons often confront legitimation and ideological struggles, hegemony involves continuous struggle and conflict over social, economic, and political ideologies and interests. Hegemony is therefore neither monolithic nor uncontested; social contestation, around intellectual property rights and treatment access for example, takes place in civil society, a social grouping distinct from the economic base of society and linked to the political society via the *historic bloc*. Gill (1993) defines the historic bloc as social groupings and alliances that are the sites of material, institutional, and ideological capacities, while Cox (1996) specifically identifies as transnational corporations, international banks, and international organizations in the contemporary world order. To maintain their dominant position in society, a hegemonic world order must be grounded in consensual power and respond to the interests of subordinate social groups with concessions, thus transcending their own narrow economic-corporate interests (Augelli & Murphy, 1993). These concessions represent accommodation strategies or what Gramsci termed *trasformismo* to "annihilate[e]" and/or absorb (co-opt) oppositional demands into the dominant ideology (Quoted in: Cutler, 2005, reference: Gramsci, 1971: 58-59) without fundamentally altering dominant economic and social re/production relations.

Inherent tensions and contradictions of a globalising market civilisation have generated new forms of social contestation and demands for radical change in labour and worker's rights, the environment, global poverty, trade justice, foreign policy, war, and conflict, and across many other issues. Dominant organisations and alliances have accommodated these challenges through *trasformismo* strategies, particularly through

self- and co-regulating voluntary arrangements, that offer both material and discursive concessions. David Levy's (1997; 1998, 2000; 2002; 2003) works examine environmental management and corporate social responsibility strategies as *trasformismo* strategies deployed by corporations to accommodate oppositional demands from environmentalists. These strategies involve modification ['greening'] of material production and ideational and discursive framings of responsible corporate environmental behaviour. Levy (1997; 2003) suggests that these changes neutralise and/or co-opt contestation by reducing their environmental impacts to socially tolerable levels, while leaving production relations fundamentally intact. These strategies also position corporations as new stewards over the environment, capable of self-regulating and monitoring their impacts consistent with broader social and environmental interests (Levy, 1997). The distributional consequences of this bargain, Levy suggests (ibid.) are that corporations frequently direct these strategies to stronger subordinate groups, while weaker groups[108] remain marginalised. Other examples of *trasformismo* include private voluntary codes of conduct and other non-binding soft law instruments (Cutler, 2005). The Global Compact, for example, argues Soederberg (2007)[109] represents a strategy for co-opting and depoliticizing social contestation through relocation to a "controlled

[108] Levy is referring broadly to politically weak groups such as, "the poor and unemployed, less developed countries, future generations, or radical environmentalists."

[109] Soederberg refers to Gramsci's theory of 'passive revolution' and its application to the Global Compact. Gramsci explained passive revolution as a way to understand the re-organisation of capitalism in contexts of struggle and crisis. In the theory of passive revolution, hegemony undergoes various shifts in alliances (i.e. *trasformismo)* and reconstitutes itself through new forms, while leaving intact the dominant accumulation strategy (Morton, 2003).

institutionalized space" (p. 503) that relies on voluntary corporate declarations of adherence to Compact principles.

Concessions by large pharmaceutical firms, including P^3H strategies, during this period of social contestation and crisis can be understood in Gramscian conceptual terms as *trasformismo*. Pharmaceutical pricing concessions and to a significantly lesser extent, some modest patent flexibilities, were initially directed at stronger subordinate groups (in South Africa) to co-opt and annihilate opposition. In the case of the Diflucan Partnership Programme, Pfizer invited representation from a civil society group (AIDS Law Project) into the South African Ministerial Working Group, and the AAI, ACHAP, and STF partnerships also sought representation from civil society in programming and governance.[110] The concessions accommodated some of the needs for expanded access to medicines through reduced pricing, but stopped short of transformative changes to pricing structures, patent flexibilities, and intellectual property and trade rules, thus preserving the dominant accumulation strategy of the originator pharmaceutical industry.

New funding and normative commitments in global treatment access between 1999 to 2003.

The period between 1999 and 2003 also witnessed the development of major bilateral, multilateral, and mixed actor funding and normative commitments integral to the global treatment access agenda. An historic Declaration in June 2001 at a special session of the United Nations General Assembly (UNGASS), pledged to support "treatment to all those infected" by mobilising billions of additional dollars for

[110] This will be discussed further in Chapters Five and Six.

HIV/AIDS care and treatment.[111] The UNGASS Declaration represented a critical departure from past political rhetoric and inaction. Kofi Annan extended the call for a global fundraising effort for HIV/AIDS care and treatment (Bertozzi, et al., 2009), and, by the end of the year, it was realised in the form of the Global Fund to Fight AIDS, Tuberculosis and Malaria (Caceres et al., 2010). Two additional major funding initiatives, PEPFAR and MAP, were launched during this period, providing billions of dollars of support for treatment access.

The Global Fund is a P^3H developed to support national care and treatment programmes for three diseases: HIV/AIDS, tuberculosis, and malaria. The Global Fund is based in Geneva and governed by a Board of Directors composed of donor and recipient governments, NGOs, private foundations, community representatives, and private business representatives (Aginam, 2007; Walker, 2009). The Global Fund provides grants to public, private, and nongovernmental organisations to implement proposals approved by Country Coordinating Mechanisms (CCM)[112] (Caceres, et al., 2010). With the financial support of the Global Fund and other donors, many developing countries began planning new national ARV treatment programmes. Botswana became the first African state to provide free universal ARV treatment in 2002, and many other states in Sub-Saharan Africa and throughout the global South followed suit shortly thereafter.

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[111] For more information on the Declaration, see: http://data.unaids.org/publications/irc-pub03/aidsdeclaration_en.pdf.

[112] CCMs are groups of state and nonstate actors who work collaboratively to develop and implement Global Fund grant proposals. For more information, see: http://www.theglobalfund.org/en/ccm/.

However, there was still the unresolved issue of navigating the complexities and barriers posed by the global patent rule system. Critics denounced the impact of the system on access to medicines, linking TRIPs to monopolistic pharmaceutical pricing (Aginam, 2008; Heywood, 2002; Meiners, 2008; Mirza, 1999; M. D. Nair, 2008; E. R. Shaffer & Brenner, 2004; t'Hoen, 1999, 2009), undersupply (Odermatt, 2009; Shadlen, 2007), and the suppression of trade and policy autonomy through restrictions on compulsory licensing and parallel importation (Atik & Lidgard, 2006; Saslow, 1999). Following years of activism and criticism against TRIPs and its impact on access to medicines, in 2001, the Fourth WTO Ministerial Conference adopted the Doha Declaration on TRIPs and Public Health (t'Hoen, 2009). The Doha Declaration clarified compulsory licensing and parallel importation clauses[113] which granted states the right to issue compulsory licenses or parallel import patented medicines (WTO, 2001) These provisions are known as TRIPs flexibilities (t'Hoen, 2009). The Declaration did not allow for generic importation of medicines or the suspension or removal of patent protection for medicines in emergency situations. It also failed to amend Article 31, Paragraph 6, which prohibits the export of medicines manufactured under a compulsory license (ibid.).

In 2003, following complex negotiations (Matthews, 2004), the WTO adopted what has become known as the August 30th decision, a set of rules and procedures governing the export of medicines produced under compulsory licenses (t'Hoen, 2009).

[113] These flexibilities existed in the original TRIPs Agreement; the Doha Declaration clarified countries' rights and obligations. There is no formal rule or requirement of a national emergency or health crises in the TRIPs agreement or Doha Declaration as grounds for deploying the flexibilities. See: http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

The decision attempted to address criticisms of Paragraph 6, yet is widely perceived as too cumbersome and complex (MSF, 2006; F. Orsi & D'Almeida, 2010; t'Hoen, 2009). In the seven years following the decision, TRIPs flexibilities have rarely been used (F. Orsi & D'Almeida, 2010). As Grinspun and Kreklewich predicted, the effects of the TRIPs Agreement have been more acute for countries that are distant from the centre status. Countries with ample manufacturing capacity and/or financial resources have been largely able to circumvent the impacts of the Agreement. Although TRIPs flexibilities offer expanded scope for compulsory licensing, threats and pressure from drug firms[114] and powerful states[115] deter states from making full use of them.

Although ARV treatment access expanded in developing countries following new pricing arrangements and the rise of generic competition, treatment for all remained an elusive goal. In 2003, only 100,000 out of an estimated 5.7 million people in Sub-Saharan Africa were on treatment, representing a coverage rate of 2% (WHO, 2004). On World AIDS Day, December 1, 2003, the WHO announced a major global treatment initiative- the 3 x 5 Initiative- which sought to place three million people in developing countries on treatment by the end of 2005, and called upon member states to provide additional

[114] In 2007, Thailand issued a compulsory license for Abbott's patented drug combination, lopinavir/ritonavir. Abbott responded by withdrawing several of their drugs from Thailand, and persuaded the USTR to investigate the matter and to take action on their behalf (I-MAK, 2010).

[115] The US has been particularly aggressive in pressuring countries through USTR watch lists, lobbying, and WTO disputes, against the use of practices perceived as unfavourable to American business interests, including compulsory licensing, generic substitution, and parallel importation. For an overview of US tactics in South Africa, see Forman (2008) and, in Brazil, see Nunn, Fonseca and Gruskin (2009) and Nunn, et al. (2009).

resources towards this goal (Bertozzi, et al., 2009). The US government responded with PEPFAR, the largest single disease-specific bilateral aid programme in history.

In 2003, President George W. Bush requested authorisation from Congress for US$15 billion over five years to go towards HIV/AIDS prevention, care, and treatment programmes in 15 focus countries and 123 additional countries (Bjerkreim-Hellevik, 2009; El-Sadr & Hoos, 2008). PEPFAR channels funds to recipient countries through implementing partners, including governments, NGOs, universities, and other organisations. Congress re-authorised PEPFAR in 2008, providing an additional $39 billion in funding for the period to 2013 (Bjerkreim-Hellevik, 2009). Despite several criticisms aimed at PEPFAR concerning its impacts on (and circumvention of) national health systems (Biesma, et al., 2009; Bradley-Springer, 2010; Dybul, 2009; Hanefeld, 2010; Walensky & Kuritzkes, 2010), its propensity to emphasise ideology over science (specifically, abstinence programmes) (Bradley-Springer, 2010; Brugha, 2008; 2005), and use of branded drugs over generics (Dietrich, 2007; Holmes et al., 2010), it has been hailed as a major achievement in the expansion of national treatment programmes (Dybul, 2009).[116] When the 3x5 2005 deadline arrived, the WHO had fallen far short of its goal with an estimated 1.3 million people receiving treatment, out of a total estimated population of 6.5 million requiring treatment (Bertozzi, et al., 2009), yet in combination with PEPFAR and the Global Fund, offered significant promise for the future scale-up.

[116] PEPFAR is the second largest contributor to the scale-up of global HIV/AIDS treatment access. As of September 2009, PEPFAR sponsored programmes provide treatment for 2.4 million people (PEPFAR, 2009) of the total 5.2 million people accessing treatment worldwide (WHO, et al., 2010).

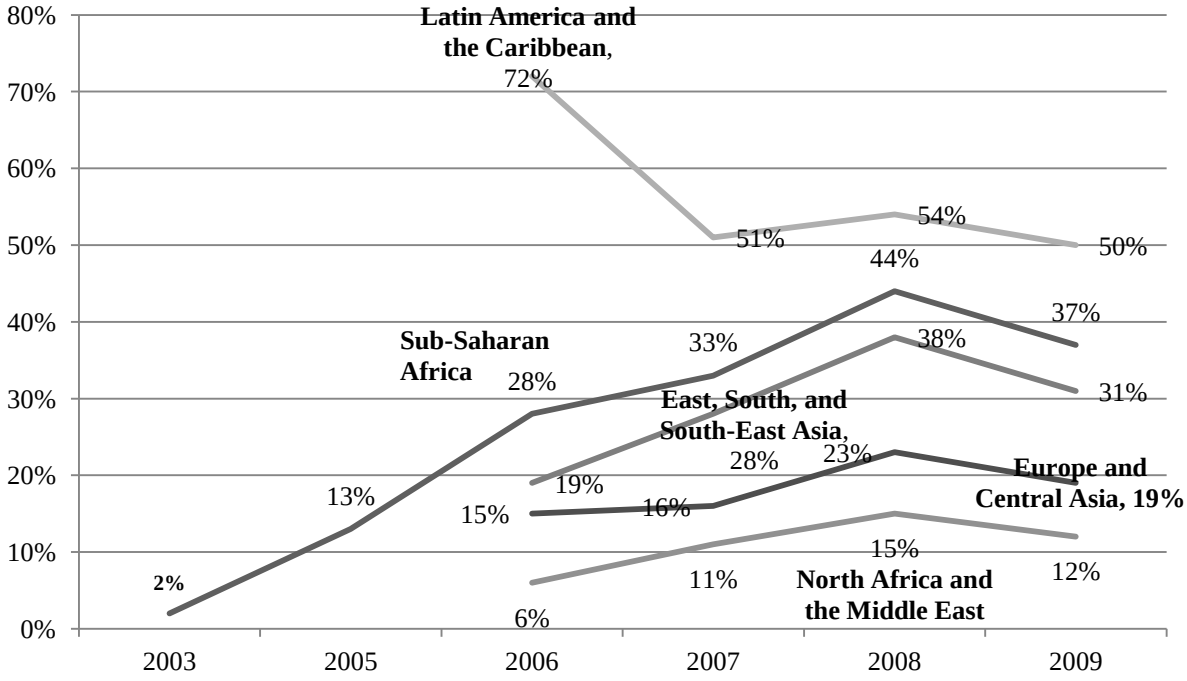
Global treatment access from 2004-2011.

The third timeframe, from 2004 to 2011, is a period in which ARV treatment access in the global South becomes a global priority (Bertozzi, et al., 2009) and is sponsored by three major funding programmes; the Global Fund, PEPFAR, and the World Bank's Multi-Country AIDS Programme. During this period, access to ARV treatment in the Sub-Saharan African region expands from 2% in 2003 to 37% at the end of 2009. Similarly, other low and middle-income countries in East and South-East Asia, Europe and Central Asia, and North Africa and the Middle East experience significant expansion in ARV treatment coverage over this period (See Figure 3-1). Although, by the end of 2009, only two low-income[117] and five lower-middle and upper middle-income countries[118] had achieved universal ARV coverage (80%+) (WHO, 2009).

[117] Cambodia and Rwanda (using World Bank Income classifications).

[118] Botswana, Croatia, Cuba, Guyana, and Romania (using World Bank Income classifications).

Figure 3-1: Antiretroviral Treatment Coverage in Low- and Middle-Income Countries According to Region



Sources: WHO, UNICEF, & UNAIDS (2007, 2008, 2009; 2010); WHO (2004).
Note: WHO treatment coverage data for 2003 and 2005 is only available for Sub-Saharan Africa.

From the growing momentum in ARV treatment access in the global South, come a plethora of new public and private actors, institutions, rules and policies, governance arrangements, and programmes operating in every HIV/AIDS afflicted country in the world. Accordingly, the global governance of HIV treatment access no longer reflects a UN system and state-based model and is now a polycentric, mixed-actor, and multilateral model. The mode of exchange remains a competitive market exchange model; however, it is has become a marketplace heavily managed by private and institutional actors. The marketplace managers are the Global Fund, the Clinton Foundation, PEPFAR, and UNITAID. These marketplace managers use bulk purchasing, financing, drug tenders,

and price negotiations to secure low prices on ARV medicines for developing countries from primarily generic producers. As of 2009, approximately 80% of all ARV medicines intended for use in developing countries are procured from generic manufacturers (Waning, Diedrichsen, & Moon, 2010).

Throughout this period, the marketplace managers have used their influence and spending power to leverage price reductions on ARV medicines. By 2010, the average price of the six most common ART regimens had fallen to US$137 per patient per year (WHO, et al., 2010) . Price decreases and significant infusions of resources enabled many countries in Sub-Saharan Africa (and elsewhere in the global South) to provide free public treatment programmes and rapidly expand treatment coverage, although only two have achieved universal coverage[119]. Gains in global treatment access, however, are tempered by the reality that there is still a long road ahead and by emerging questions surrounding the sustainability, accountability, and efficacy of new financing and governance arrangements.

Private Authority and the Global Governance of HIV/AIDS

Over the 15-year period between 1996 and 2011, but most remarkably during the last seven years, the global governance architecture around HIV/AIDS has become an agora occupied by private business actor participation. As the pandemic grew and treatment became a major priority, private business actors entered new governance spaces created at sub-national, national, international, and multilateral levels. An influx of new

[119] Botswana and Rwanda have achieved universal coverage (minimum 80%) (WHO, et al., 2010).

funds for ARV treatment created new incentives for pharmaceutical firms to offer further compromises and concessions on prices; certainly, pharmaceutical firms did not wish to be excluded from accessing these newly enlarged markets, and accommodation strategies offered key strategic entry points for new engagement with state and interstate health institutions and actors. Furthermore, developing country governments were often overextended by the magnitude of their challenges in health governance and reluctant to refuse help when it was offered. States and UN agencies, confronting challenges generated by a globalising market civilisation, including new risks and constraints in the transborder spread of disease, constraints on public authority and policy autonomy, growing private business power and authority, and budgetary shortfalls, increasingly relied on nonstate actors to fill health governance and resource gaps. These circumstances provided key entry points for private business actor participation in global health.

Private philanthropy for global health issues has grown exponentially over the past 100 years. Private foundations such as the Rockefeller Foundation, Milbank Memorial Fund, Commonwealth Fund, and Sage Foundation funded public and international health campaigns (Loughlin & Berridge, 2002).[120] Many private foundations have since been established which focus their philanthropic giving on domestic and global health issues. However, private foundations have also expanded their role beyond grant-making and public advocacy to supply authorship, expertise, agenda-setting, service delivery, and policymaking and coordination activities within health governance.

[120] The Rockefeller Foundation hookworm campaign, for example, is one of the earliest international health campaigns spearheaded by a private foundation (Fox, 2006).

Foundations, for example, engage in drug pricing and procurement negotiations, develop and/or support global health partnerships, and participate in the governance of global health initiatives involving HIV treatment components.

The Bill and Melinda Gates Foundation ("Gates Foundation") has provided $23.1 billion in grants since its inception in 1994 (BMGF, 2010); the majority (57%) of which have been allocated to global health.[121] The Foundation contributes more money to global health than any other public or private actor, including all governments, with only two exceptions: the US and the United Kingdom (McCoy, Chand, et al., 2009). Contributions from the Foundation to the Global Fund comprise 97% of all nonstate contributions (Hein & Kohlmorgen, 2008); the Foundation is also the third largest donor to the WHO (McCoy, Chand, et al., 2009). The Foundation contributes millions of dollars to P^3Hs, including the GAVI Alliance[122], the Medicines for Malaria Venture (MMV), and the PATH Malaria Vaccine Initiative, among others (BMGF, 2010). With an endowment of $36.4 billion and a total staff of over 800, the Gates Foundation is, by far, the world's largest grant-making foundation (ibid.).

Private business actors contribute to global health through philanthropic giving and corporate social responsibility programmes. The Global Fund, for example, solicits private business actor contributions; while such contributions form a small component of

[121] Author calculation- $13.8 billion in global health grants from a total of $23.1 billion in grants.

[122] In 1999, the Gates Foundation provided a seed grant of $750 million dollars to GAVI (Lancet, 2009).

total funding[123], they have been increasing steadily since 2006[124] (McCoy, Chand, et al., 2009). Corporate social responsibility programmes include product and equipment donations, product sales at cost, technical assistance (i.e. employee secondment and consulting), and training. The most prominent private business actors in global health are originator pharmaceutical firms, who, according to the IFPMA, contributed US$6.7 billion over the period from 2000 to 2006 towards global health (IFPMA, 2008) [125].

Corporate drug and equipment donations, particularly, have increased substantially between 1990 to 2007 (Ravishankar et al., 2009). Pharmaceutical firms donate their products towards several infectious diseases, including lymphatic filariasis, schistosomiasis, parasitic worms, trachoma, leprosy, Chagas disease, and HIV/AIDS (IFPMA, 2010a) . Abbott, for example, has committed to donating up to 20 million rapid HIV tests (Arnold, 2006; Wertheimer, et al., 2004) and Boehringer Ingelheim donated[126] nevirapine to prevent vertical transmission[127] of HIV (Arnold, 2006).

Pharmaceutical firms also provide HIV training interventions, capacity building supports, and funding for HIV/AIDS care and treatment. The Pfizer Global Health

[123] In 2008, private organisations and NGOs contributed a total of US$182 million, or 6.6% of total contributions to the Global Fund (GFATM, 2010b).

[124] Contributions have increased every year since 2002, although there was a decline in contributions in 2008 and 2009 (McCoy, Chand, et al., 2009).

[125] This figure represents product donations, sales of medicines at cost or discount, and supply of training, equipment, and labour (IFPMA, 2008).

[126] Boehringer Ingelheim is phasing out this programme (Respondent 51, personal interview, April 7, 2011).

[127] Formerly referred to as PMTCT – or prevention of mother-to-child.

Fellows Programme places employees in developing countries for brief periods in order to provide training and capacity-building support (Vian, Richards, McCoy, Connelly, & Feeley, 2007). Furthermore, Pfizer's Diflucan Partnership Programme trains health personnel in the treatment of opportunistic infections.

There has been significant growth in the scope and modes of private business actor participation in global health over the past 30 years. Many of these contributions provide practical and strategic supports to developing countries experiencing HIV/AIDS epidemics. An investigation of the growth in private authority and public-private partnerships, as detailed in this chapter and the preceding chapter, however, contextualises emerging private authority roles and contributions within a changing global architecture shaped through contradictions, contestation, and compromise.

Private business actors responded to civil society, political and commercial pressures with corporate social responsibility, philanthropic, and public-private partnership initiatives. These concessions, however, failed to address civil society demands for reasonable, equitable, and sustainable reforms to ensure enhanced affordability, availability, and accessibility to ARV medicines in the global South. Concessions were largely ad hoc, discretionary, and often time limited. Furthermore, they did not eliminate, reduce, or suspend intellectual property rights, nor compel firms to provide long-term price reductions. These initiatives are self-regulating, relying on the goodwill of firms instead of legitimate rule systems to regulate behaviour. Pharmaceutical firms had already demonstrated that they were capable of profiteering

from a global pandemic; these concessions offered nothing in the way of holding firms accountable for their behaviour.

The Doha Declaration and the August 30th decision offered similar compromises following years of contestation and negotiation. Both affirmed the need to provide greater policy flexibility to countries to expand access to medicines. However, neither provided for structural reform of the patent system or global trade rule systems. In fact, the only significant developments since the implementation of TRIPs have strengthened intellectual property rights. A growing number of regional and bilateral trade agreements[128] contain TRIPs+ provisions, or IPR protection that goes beyond TRIPs minimum requirements (Forman, 2008; Krikorian, 2006). The US has been particularly aggressive in negotiating bilateral trade agreements which include enhanced IPR provisions (Russell, Boyle, Flynn, & Baker, 2008). These agreements undermine generic competition (Forman, 2008) and may complicate efforts to produce affordable second- and third-line ARV medicines.[129] Therefore, there is a potentially precarious future for access to ARV treatment, and medicines and health care, more generally. Chapters Four through Seven explore prospects and challenges of public-private partnerships in health as mechanisms of global health governance for enhancing access to medicines.

[128] The number of agreements rose from 20 in 1990 to 159 in 2007 (K. Lee, Sridhar, & Patel, 2009).

[129] Individuals commencing ARV treatment are typically placed on first-line regimens. When individuals become treatment experienced and show signs of drug resistance, they may be switched to second and third-line treatments, which involve new classes of drugs (AVERT, undated).

Conclusion

It took 20 years[130] for the United Nations General Assembly to endorse the objective of universal access to treatment, and, as of 2011, that goal has not yet been realised. There is cynicism that global universal coverage will never be achieved (Fauci & Folkers, 2009); that the barriers are intractable and that the pandemic will outpace resources and capacities. Growing social contestation against hegemonic and monopoly power resulted in new concessions and compromises that provided relief, but not reform. In the absence of structural reform, therefore, social contestation may prove critical to ensuring that treatment for all remains a policy and normative focus.

[130] From 1981, when the first cases of HIV/AIDS were reported, to 2001, with the UNGASS Declaration.

Chapter 4: Private Authority and Public-Private Partnerships in Global Health Governance

The preceding chapters situated the growing popularity of public-private partnerships in health within macrohistorical and sociopolitical conditions of crisis, contestation, and change. This chapter takes a closer examination of this specific institutional experiment and the emergent roles of private pharmaceutical authority in global health governance. The latter undertaking identifies trends and modalities of private pharmaceutical authority in global health governance, suggesting that while P^3Hs provide a vehicle for private authority, they are also part of a larger landscape of growing and widespread private authority in health.

A closer examination of P^3Hs warrants attention to their conceptual and operational features, challenges, and prospects. Over 10 years of inquiry into P^3Hs and private authority in health has produced a range of heuristic categories, conceptual approaches, and practical, strategic, and normative insights and issues. The literature reveals considerable conceptual and operational disjunction and deliberation, which, is a function of its emergent status, its disparate linkages to public health, policy, and critical approaches, and blurred, flexible, and shifting boundaries around the subjects and objects of global health governance. Ultimately, this chapter argues that while P^3Hs generate multiple contributions in national and global health governance, their predominantly undemocratic, unaccountable, and underlying normative characters and agendas deserve serious re/consideration and at minimum, new approaches to reform.

This chapter contains four sections. The first section reviews private pharmaceutical authority in health and locates P^3Hs within these modalities. Secondly, the chapter surveys key typologies for conceptualising and classifying P^3H criteria and subtypes. The third section explores the narratives and debates surrounding contributions and controversies of P^3Hs. The concluding section presents a summary of major themes and preliminary argumentation based on the issued raised in the chapter.

Private Pharmaceutical Authority and Global Health Governance

Chapter One identified multiple forms of private authority, including authorship and expertise, representation on governance structures, rule- and standard-setting, agenda-setting, establishment of boundaries and limits for action, service delivery, supply of intermediate public goods, private international regimes, and order and security This section locates authoritative activities performed by pharmaceutical firms, inside and outside the confines of P^3Hs. In doing so, it reveals growing and widespread private pharmaceutical authority in global health governance.

Expertise and authorship functions.

Pharmaceutical firms provide authorship and expertise in health governance, through not only scientific competencies in research and development but also through deployment of technical and policy expertise and authorship. Pharmaceutical firms and their representatives exercise consultative roles on numerous state and interstate research, advisory, and regulatory bodies. At the WHO, representatives from pharmaceutical firms are invited to participate, for example, on the WHO Expert Committee on Biological

Standardisation,[131] WHO Expert Committee on Specifications for Pharmaceutical Preparations,[132] and the Consultative Expert Working Group on Research and Development: Financing and Research.[133] The appointment of Paul Herrling from Novartis Pharma to the latter group was greeted with civil society opposition (Love, 2010); critics charged that Herrling would be evaluating research proposals in which his firm had a direct stake. The WHO allowed his appointment to stand.

Pharmaceutical firm representatives also sit on P^3H scientific advisory committees, including the International Partnership for Microbicides (IPM),[134] the Drugs for Neglected Diseases Initiative,[135] and the Global Fund.[136] These committees seek out scientific and industry experts to fulfil advisory roles on specific issues in the partnerships. Accordingly, they afford opportunities for private business actor insight and participation in deliberative and decision-making processes in health governance.

Even when industry experts are not formally included on advisory panels or committee structures, the WHO continues to seek expert advice from pharmaceutical

[131] For more information, see: http://www.who.int/biologicals/expert_committee/en/.

[132] For a list of participants, see: http://www.who.int/medicines/publications/TRS957_2010.pdf.

[133] For a list of participants, see: http://www.who.int/phi/news/phi_cewg_members_2011_en.pdf.

[134] See Derek Newall: http://www.ipmglobal.org/about/ipm-governance/scientific-advisory-board/derek-newall.

[135] See Federico Gomez de las Heras and J. Carl Craft: http://www.dndi.org/our-people/sac.html?id=633.

[136] Ian Boulton of TropMed Consulting and formerly of GSK sits on the Market Dynamics and Commodities Ad Hoc Committee: http://www.theglobalfund.org/en/board/committees/contacts/?#mdc.

firms on a regular basis.[137] Pharmaceutical firm representatives have been invited to attend deliberative and consultative forums, including the WHO Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property. Chapter Two described how WHO Resolution 59.24 authorised private business actor participation for the purposes of providing advice and expertise.

Furthermore, vis-à-vis their official relations status with the WHO, pharmaceutical firms are entitled to participate in World Health Assembly forums. Forty representatives from the IFPMA, for instance, attended the Sixty-Second World Health Assembly in 2009, and another 16 attended from the International Pharmaceutical Federation. These two groups represented two of the four largest showings of nongovernmental groups.[138] Attendance entitles firm representatives to make a public statement, access confidential documents, and submit memoranda (WHO, undated-b). Therefore, while attendance does not entail formal participation, it provides informal opportunities for engagement with state and interstate delegates and access to issues and matters under discussion at the World Health Assembly.

Representation on governance structures.

Pharmaceutical firms are also formally represented on multiple P^3H governance structures. These P^3Hs conduct a wide range of health governance functions, including the provision of public goods such as research, vaccines, and medicines, as well as

[137] For example, the WHO invites firms to attend meetings on issues such as procurement and forecasting. For a list of participants at a 2010 meeting, see: http://www.who.int/hiv/amds/participants2010.pdf.

[138] Author calculation. The top four nongovernmental groups in attendance were the IFPMA, the CMC Churches' Action for Health, the Global Health Council, and the International Pharmaceutical Federation.

supplying expertise to governments and other stakeholders. Pharmaceutical firm representatives sit on boards of directors, coordinating boards, and other governance committees for the Roll Back Malaria Partnership (RBM),[139] IPM,[140] GAVI Alliance,[141] International AIDS Vaccine Initiative (IAVI),[142] MMV,[143] and the Global Fund.

The Global Fund invites private business actor participation in Country Coordinating Mechanisms. A study conducted by the Global Fund reported that private business actors participated in 76% of all CCMs (GFATM, 2010a), including 14 representatives from the pharmaceutical industry.[144] Furthermore, private business actor organisations may now serve as principal and sub-recipients on Global Fund grants. In 2009, a Ghanaian mining firm, AngloGold Ashanti, won a US$30 million grant to conduct malaria prevention activities (ibid.). Thus, private business actors, including pharmaceutical firms, not only enjoy widespread representation on P^3Hs, but may be poised to become direct beneficiaries.

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[139] Rebecca Stevens of Novartis International is one of two pharmaceutical firm representatives. Jon Pender, of GSK, is an alternate. For the full list of board members, see: http://www.rollbackmalaria.org/mechanisms/partnershipboard.html.

[140] Albert Profy of Ironwood Pharmaceuticals is a member of the Board of Directors. For a full list of board members, see: http://www.ipmglobal.org/about-ipm/ipm-governance/board-of-directors.

[141] Ronald Prus, of Crucell Pharmaceuticals, is on the Board of Directors at GAVI. For a full list of board members, see: http://www.gavialliance.org/about/governance/gavi-board/members/.

[142] Michel Greco (Aventis Pasteur), and Margaret G. McGlynn (Merck) are on the Board of Directors at IAVI. For a full list of board members, see: http://www.iavi.org/about-IAVI/Governance/Pages/board.aspx.

[143] Denis Schmatz (formerly with Merck-Banyu Research Laboratories) and Per Wold-Olsen, formerly of Merck, sit on the MMV Board. For a full list of board members, see: http://www.mmv.org/about-us/organisation-and-governance/board-directors.

[144] Author calculation on April 20, 2011, using CCM membership lists obtained from: http://www.theglobalfund.org/en/ccm/.

Rule-, standard-, and agenda-setting.

Pharmaceutical firms also exercise authoritative roles in standard-setting, agenda-setting, and establishment of limits for action. Sell (1999) describes how 12 representatives from pharmaceutical and technology firms advanced a new agenda for strengthened IPR during the WTO Uruguay Round, which subsequently became enshrined in international law. Sell (1999) argues that private authoritative action in a deliberative process supposedly exclusive to interstate actors had profound consequences for international intellectual property rules and hence access to medicines and other intermediate public goods.

Provision of public goods and services.

Intermediate public goods are goods that are nonexcludable, but rivalrous (Brando, 2004). Intermediate public goods are seen to "bring us partially to the goal of global public health" (Brando, 2004, p. 3). Pharmaceutical firms and P^3Hs provide intermediate public goods, including disease treatment, research, pharmacovigilance, disease control, and disease eradication. The supply of HIV and AIDS medicines, therefore, constitutes an intermediate public good.

Pharmaceutical firms supply these goods through commercial activities, P^3Hs, philanthropy, and corporate social responsibility programmes. Pharmaceutical firms generally do not directly deliver health care or related services (direct patient care, procurement services, etc.); however, they routinely fund HIV prevention and treatment services. They also support service delivery through philanthropic and CSR initiatives.

GlaxoSmithKline's Positive Action Programme, for example, supports HIV testing, prevention, and treatment literacy services to multiple sites (GSK, undated).

Case study partnerships and authoritative action in health governance.

Private pharmaceutical authority performs multiple authoritative functions in health governance under the auspices of P^3Hs (see Table 4-1). Although the partnerships rarely engage in rule and standard-setting, they each perform roles in agenda-setting, authorship and expertise, establishing limits for action, representation on governance structures (as established by the P^3H), and in the supply of public goods.[145] In the ACHAP, for example, Merck supplies intermediate public goods (pharmacovigilance, disease control, and disease treatment) and supports HIV and other health services. Merck also helped to set agendas around Botswana's plans to roll out a national ART programme (Respondent 42-1, personal interview, June 23, 2008). The Secure the Future partnership supplies intermediate public goods, expertise, and authorship, as well as supports for HIV prevention and treatment services. The AAI and the DPP supply intermediate public goods and also perform agenda-setting and boundary establishment functions in the global health governance of access to medicines. The partnerships established boundaries around problem definition (pricing of medicines) and action (differential pricing, donations, and country-by-country negotiations). These restrictions helped pre-empt alternative strategies, including broad patent flexibilities, reforms to domestic and global intellectual property rules, earlier uptake of generics, patent pools, etc.

[145] These roles will be discussed in more detail in the within-case investigations in Chapters Five and Six.

Table 4-1: Private Authoritative Action in P^3Hs

P^3H	Agenda-setting	Rule and standard-setting	Authorship and expertise	Establish limits for action	Supply of public	Representation on governance structures	Service Delivery
AAI	✓	✓	✓	✓	✓	✓	
ACHAP	✓		✓	✓	✓	✓	✓
DPP	✓		✓	✓	✓	✓	
STF	✓		✓	✓	✓	✓	✓

Pharmaceutical firms, therefore, through commercial and non-commercial modalities, exercise new and significant authoritative roles in health governance. Despite their emergent roles, very little is understood about their participation in health governance. While pharmaceutical firms have new roles as invited experts, observers, representatives on governance structures, and providers of goods and services, it is difficult to track the degree and implications of their authority in these forums. This topic is not only an area for future research, but also underscores the importance of applying a closer lens to private authority in global health governance. The next two sections of this chapter apply this lens to the conceptual and operational forms and functions of P^3Hs and subsequently explore debates on their practical, strategic, and normative contributions and controversies in global health governance.

Conceptualisation of Public-Private Partnerships in Health

The introductory chapter furnished the conventional definition of P^3Hs as arrangements of public and private actors collaboratively pursuing health governance objectives (Nishtar, 2004). However, the chapter also identified considerable diversity in identifying and classifying partnerships. The objectives of this section, therefore, are to survey conceptual typologies, and discuss issues and transformations in the constitutive,

methodological, and integrative landscape of public-private partnerships in health and its scholarship.

Constitutive typologies.

Scholarship on public-private partnerships employs multiple typologies and criteria for distinguishing between partnership subtypes. Table 4-2 integrates key constitutive, methodological, and integrative typologies on public-private partnerships. These typologies can be combined to further delineate partnership forms and functions.

Table 4-2: Constitutive, Methodological, and Integrative Typologies for P^3Hs

Typology Dimension	Criteria	Subtypes
Constitutive	*Source of authority*	Public (state and interstate) Private market (businesses, firms) Private moral actor (NGO, civil society)
	Hosting arrangements and legal status	Public host and independent legal status Private host and independent legal status Public or private host without independent legal status
	Governance level and complexities	Public-Private Partnership Global Health Partnership Global Health Initiative
Methodological	*Authoritative actions*	Rule and standard-setting, agenda-setting, authorship and expertise, establish limits for action, supply of public goods, service delivery, representation on governance structures
	Operations	Research-based Access-based Financing-based
Integrative	*Mode of public-private integration*	Cooptation Delegation Co- or self-regulation
	Degree of collaboration	Financial Transactional Integrative

Adapted from: Dogdson, Lee and Drager (2002), Hall & Biersteker (2002b); Evans & Chen (2005), Börzel and Risse (2005); and McRobbie and Kolbe (2009); Bartsch (2011).

The most rudimentary constitutive typology employs criteria around partners' sources of authority. Public-private partnerships involve a minimum of one public actor (state and/or interstate) and one private actor (market or moral) organisation. However, while partnerships between public and private moral actors are common in health governance (for example, an agreement between a government agency and a nongovernmental organisation to implement a health programme), conceptually, public-private partnerships refer to partnerships between public actors and private market actors.

Secondly, P^3Hs are often categorised into subtypes according to their hosting arrangements and legal status. Evans and Chen (2005) describe two broad groupings of public-private partnerships in health. The first subtype includes publicly hosted partnerships with separate legal status. These partnerships typically operate under the auspices of a UN agency, such as the WHO. The RBM and Stop TB partnerships are examples of this category of partnership. The other grouping includes partnerships that are privately hosted partnerships with separate legal status. This includes the DPP, ACHAP, Secure the Future, and many other P^3Hs. A third subtype that can be added to Evans and Chen's (2005) typology is a publicly or privately hosted partnership without separate legal status. The AAI is an example of a publicly hosted partnership without separate legal status. While partnerships are primarily formal legal entities, they may also operate as informal arrangements of public and private actors who have agreed to a partnership framework of health governance strategies and objectives. The unifying conceptual criteria for partnership (as opposed to a network or contract) relates to shared

goals and the pooling of resources and competencies (Dodgson, et al., 2002; Lo, 2008; McRobbie & Kolbe, 2009; Ridley, 2001).

Finally, P^3Hs are grouped into subtypes according to their governance level and complexity. Partnerships that exist outside the UN system are categorised as public-private partnerships in health. These partnerships may involve one or more state and/or interstate institutions and transnational private business actors. This feature is what distinguishes global from domestic public-private partnerships. Domestic private-partnerships involve domestic public and private actors, whereas P^3Hs involve state and/or interstate actors and transnational private business actors, including firms and industry associations. These subtypes frequently have independent legal status in one or more locales; for example, in the pharmaceutical firm headquarters location and in a partner country.

The terms Global Health Partnership (GHP) and Global Health Initiative (GHI) evolved from their predecessor, the Global Public-Private Partnership (GPPP) (Bartsch, 2011; Brugha, 2008; Walker, 2009). This term referred to partnerships operating in conjunction with one or more UN organisations and other state and nonstate actors around specific diseases and/or global health goals. The terminology has since shifted, generating some conceptual and identity confusion.

The WHO differentiates between GHIs and GHPs (Brugha, 2008) and recognises the RBM partnership, Stop TB, GAVI Alliance, and the Global Fund as GHIs (WHO, undated-a). However, McCoy, Chand, and Sridhar (2009) label the Global Fund and Stop TB as GHPs. Khoubesserian (2009) identifies eight major GHIs: the Global Fund,

Clinton Foundation HIV/AIDS Initiative, the Bill and Melinda Gates Foundation, the WHO 3 x 5 Initiative, IAVI, GAVI Alliance, Stop TB, and the WHO Smallpox Initiative. Zikusooka, Tumwine, and Tutembe (2009) list only four: the Global Fund, PEPFAR, MAP, and the U.S. President's Malaria Initiative.

The criterion that differentiates a GHP from a GHI appears to be the ability to raise and disburse large sums of money for a particular disease. Global Health Partnerships and Initiatives are multilevel partnerships that bring together large groups of actors working on global health goals (Buse & Harmer, 2007). Hanefeld (2009) and Biesma et al. (2009) describe GHIs as new forms of aid that perform disease coordination and control functions in multiple countries. Global Health Partnerships also mobilise significant financial, technical, and material resources to conduct research (e.g. MMV), develop new products (e.g. IAVI and IPM), donate products (e.g. Global Alliance to Eliminate Lymphatic Filariasis), strengthen health services (e.g. the Global Fund), and expand product access (e.g. GAVI Alliance and AAI), but rarely disburse funds to states or other beneficiaries. Global Health Initiatives raise and disburse funds from government and private donors and rely principally on the former. The Global Fund, PEPFAR, and MAP, for example, raise the majority of funds from government donors.

While public-private partnerships, GHPs, and GHIs vary in scale, scope, resources, and disease focus, they represent new forms of hybrid governance in global health. All three models draw extensively on private business authority in terms of expertise and authorship, intermediate public goods, service delivery, agenda-setting, and representation on governance structures. Furthermore, they each perform functions in

global health around product research and development, product access, health care service delivery, and health systems strengthening, advocacy, and Scholars have recognised this methodological and integrative pluralism and developed several approaches for typologising partnerships; Table 4-2 features commonly used approaches.

Methodological and integrative typologies.

Given the range of functions of public-private partnerships, Börzel and Risse (2005) and Bartsch (2011) have advanced two typologies for classifying partnerships into subtypes according to their methodological orientations. Börzel and Risse classify partnerships according to their authoritative functions using three main categories: 1) rule- and standard-setting, 2) rule implementation, and 3) service delivery. However, as this chapter has demonstrated, P^3Hs perform a much wider range of authoritative functions than is captured by this typology. Therefore, the framework in Table 4-2 makes use of Hall & Bierksteker's (2002) more comprehensive inventory of authoritative action.

Bartsch (2011) sorts P^3Hs according to their primary functions: research and development, access, financing, and advocacy and coordination. Although partnerships perform multiple functions, their primary activities generally fall within one or more of Bartsch's categories (see Figure 4-1 for a cross section of P^3Hs).

Figure 4-1: P3H Methodological Types and Selected Examples

Research-based	Access-based	Financing-based	Advocacy & coordination
• MMV • IP • IAVI	• AAI • ACHAP • DPP • STF • GAVI	• Global Fund	• RBM • Stop TB Partnership

The final method for typologising partnerships examines methods of public-private integration in partnerships. Börzel and Risse (2005) describe four predominant methods of integration: 1) cooptation of private business actors into hybrid or public authority structures, 2) delegation of authoritative functions to private actors by public authorities, and 3) co-regulation, and 4) self-regulation of private or hybrid governance structures. Börzel and Risse offer the example of the Global Compact as a form of self-regulating entity and the International Standardisation Organisation[146] as an example of a delegation entity. Again, despite Börzel and Risse's compartmentalisation of discrete forms, public-private integration evolves and transforms through overlapping delegation, co- and self-regulation, and cooptation modalities.

McRobbie and Kolbe (2009) depict public-private integration as operating along a collaboration continuum, ranging from financial integration (i.e. a grant or donation) to a transactional stage in which public and private partners agree to merge resources and competencies, and finally to an integrative stage that culminates in a new identity.

These integrative approaches can be combined to assess degrees and methods of partnership collaboration and integration. They can also be combined with constitutive and methodological approaches to clarify partnership forms and functions. Table 4-2, for example, notes that the ACHAP, DPP, and STF are privately hosted P^3Hs with independent legal status whereas the AAI is a publicly hosted Global Health Partnership with no independent legal status. All partnerships are classified as access-based, yet also

[146] This private organisation devises technical, industrial, and commercial standards (Börzel & Risse, 2005).

perform service delivery (ACHAP, DPP, STF), financing (ACHAP, STF), rule implementation (AAI, ACHAP, and DPP), and rule- and standard-setting functions (AAI, DPP). The AAI, ACHAP, and DPP partnerships are classified as rule-implementing as they operate under the auspices of the TRIPs Agreement and implement its rules through observance and defense of its rule system. The AAI and DPP, however, also perform rule- and standard-setting by effectively setting boundaries and limits for action around access to ARVs and fluconazole, respectively. And, as will be discussed in detail in Chapter Six and Seven, the ACHAP and STF are also financing-based partnerships that implement access strategies through extensive grant-making activity.

Table 4-3: Constitutive, Methodological, and Integrative Typologies of Case Studies

Case Study	Typology Dimensions		
	Constitutive	**Methodological**	**Integrative**
Accelerating Access Initiative	• Public host with no independent legal status • Global Health Partnership	• Rule- and standard-setting • Establish limits for action • Authorship and expertise • Agenda-setting • Supply of public goods • Access-based	• Co-regulating • Integrative
African Comprehensive HIV/AIDS Partnership	• Public-Private Partnership • Private host with independent legal status	• Agenda-setting • Establish limits for action • Authorship and expertise • Supply of public goods • Service delivery • Access-based • Financing-based	• Self-regulating • Integrative
Diflucan Partnership Program	• Public-Private Partnership • Private host with independent legal status	• Agenda-setting • Rule and standard-setting • Authorship and expertise • Establish limits for action • Supply of public goods • Service delivery • Access-based	• Self-regulating • Integrative

Secure the Future Partnership	• Public-Private Partnership • Private host with independent legal status	• Agenda-setting • Authorship and expertise • Establish limits for action • Service delivery • Access-based • Financing-based	• Self-regulating • Integrative

The heuristic categories furnished across constitutive, methodological, and integrative typologies provide analytical tools for exploring partnership forms, functions, and methods of integration, but clearly there is no universal conceptual framework. Scholars agree on the most basic constitutive and methodological arrangements, but have largely overlooked systematic typologising. This is in part attributable to the absence of systematic or detailed investigations of partnerships in the literature. It also relates to a more problematic issue around the lack of understanding about what it actually means to characterise an initiative or entity as a public-private partnership. The substantive and procedural boundaries are unclear and shifting. The most general interpretation of a partnership relates to mutual participation; however, extending the boundaries to all manner of public-private activity enlarges the field of public-private partnerships quite substantially. It is unclear what degree of public-private integration and/or institutionalisation is necessary to warrant the label of partnership.

Moreover, given that partnership connotes mutuality and commitment to the partnership and its broader goals, the term obfuscates relations of power and inequality and supports a functional narrative. Richter (2004b) suggests that the term partnership is "value-laden" (p. 47) because it assumes that the roles, responsibilities, and benefits of the partnership are equal. Thus, partnership may not be the most appropriate term to

characterise public-private governance arrangements as it may overstate the substantive and procedural qualities and/or underplay the normative implications.

Many of the ambiguities surrounding P^3Hs may be resolved as these entities mature as mechanisms of global health governance. Several P^3Hs have only just passed the ten-year mark,[147] and many others are in their first five years of operations. The partnership label is adhesive, however, and now firmly entrenched in the global health vernacular. It continues to be used to describe a broad spectrum of public-private activity.

Contributions, Challenges, and Consequences of Public-Private Partnerships

This section contains a review of academic and policy debates on the prospects and challenges of P^3Hs in national and global health governance. These debates address many of the intended and unintended effects of partnerships rather than questions around agreement with or abandonment of the model. As a result, much of the literature yields functional and operational insights to partnership governance and value-added contributions. Newer literature, predominantly emerging from political science, international relations, and political economy scholars, has taken a more critical perspective (cf. Rushton & Williams, 2011), yet has, hitherto, stopped short of calling for a moratorium or abandonment of public-private partnerships. The literature, however, has drawn out new evaluative criteria and contributions towards potential research agendas. The debates presented here discuss these findings, themes, and contributions.

[147] See a recent study by Buse and Tanaka (2011) summarising major lessons and best practices of Global Health Partnerships in their first 10 years of operations.

Practical, strategic, and normative contributions.

The dominant narrative in the public health literature and around policy practitioners' tables centres on P^3Hs as win-win scenarios (Bartsch, 2008; Buse & Harmer, 2004; McRobbie & Kolbe, 2009; Mgone, 2008) for health issues that have elements of market (Evans & Chen, 2005) or institutional failure (Börzel & Risse, 2005; Holm, 2001; Ngoasong, 2009) as well as global complexity (Aginam, 2007; Buse & Walt, 2000a). This narrative contains two implications: first, P^3Hs are a response to the deficiencies of market, state, and/or multilateral institutions' ability to supply health care goods and services in a globalising world. Proponents accept that growing complexity in global transactions coupled with weak or absent commercial incentives and overextended or incompetent governance necessitates the development of new hybrid forms of governance. Thus, P^3Hs complement or replace supposedly insufficient state activity in health governance. Secondly, the narrative implies that partnerships provide benefits to all partners and are therefore mutually satisfying problem-solving arrangements for global health. Private business actor partners provide needed resources to global health and, in return, can expect certain benefits.

The literature highlights numerous benefits to private business, including direct financial returns, whether through tax breaks or payment for services or products (for example, discounted drug pricing). Buse and Walt (2000a) note that many of the contributions made by private business partners are tax deductible. Partnerships, particularly financing- or research-based partnerships, may also provide assurances of advance market commitments for drug and product purchases (Baker & Ombaka, 2009).

Partnerships allow private business actors to penetrate a market that may have previously been inaccessible and promote their image and brand (Baker & Ombaka, 2009). This may help strengthen a product monopoly in that market (ibid.) through brand loyalty or reliance on product donations or differential pricing arrangements. Partnerships may also help to establish new policy and/or infrastructure mechanisms that facilitate market penetration for products (ibid.). Partnerships, therefore, promote favourable business strategies and environments for partner firms. Ahn, Herman, and Damonti (2000) refer to this phenomenon as "interdependent philanthropy," or the strategic impacts of philanthropic activity on business profitability and expansionist agendas.

Public-private partnerships borrow or acquire legitimacy that is filtered through the persona of political legitimacy, and thus enhance corporate legitimacy and authority with UN institutions (Buse & Walt, 2000a), internal and external corporate stakeholders, and other bodies. Furthermore, partnerships, offer opportunities for access to policymakers and policymaking processes, potentially around issues in which private business actors have specific stakes. Furthermore, in the wake of public scrutiny on many private business organisations, partnerships provide an important vehicle to recoup reputational losses. These legitimacy benefits generally come at low cost to private business actors. For example, Buse and Walt (2000a) note that Bristol-Myers Squibb's annual Secure the Future contribution of US$20 million represents 0.1% of the firm's US$18.3 billion in annual sales (ibid.). Private business actors may therefore instrumentalise partnerships to obtain practical, strategic, and normative benefits.

In exchange for these benefits, proponents of P^3Hs argue that these arrangements provide extensive benefits to states and interstate organisations, and broadly, to global health goals, processes, and outcomes. Proponents point to value-added effects of partnerships (Holm, 2001; Lo, 2008; Sturchio, 2008a, 2008b; Vian, et al., 2007; Widdus, 2001), specifically: additional funds, drugs, supplies, services, human resources, and expertise. These contributions provide resources within resource-poor settings and potentially expand access to health services (Buse & Harmer, 2007; Machuron, Bruneton, & Trénado, 2008; Mizwa, 2008) or attend to emergency health needs (Gustavsen & Hanson, 2009). Börzel and Risse (2005) suggest that value-added contributions of expertise can increase the knowledge base of public actors. Partnership contributions may also allow governments to divert resources to other priority areas (Gustavsen & Hanson, 2009; Sinanovic & Kumaranayake, 2009), thus broadening the base of health interventions. Ultimately, argues Sturchio (2008b), these efforts contribute to global health goals, particularly the Millennium Development Goals for HIV/AIDS, child health, and maternal health.

Partnerships may also help to build and strengthen health systems' capacity by addressing gaps in infrastructure (Distlerath & Khalil, 2004; Distlerath & Macdonald, 2004), research and development (Wheeler & Berkley, 2001; Williams & Rushton, 2011), services (Hanisch, 2008), and health human resources (Ramiah & Reich, 2006; S. Richards, 2006). Furthermore, Gustavsen (2009) claims that P^3Hs, such as the ACHAP partnership, can help strengthen local health systems' capacity by improving administrative and operational processes. Conway, Gupta, and Prakash's (2006) study of

multiple P^3Hs lends support to Gustavsen's assessment; results suggested that partnerships perform important coordination and capacity-building functions in national health governance. Accordingly, P^3Hs not only provide value-added effects, but may also strengthen local health systems.

Partnerships also purportedly support enhanced national and global health policy processes and content. Partnerships may help to prompt action in neglected policy or programme areas (Ngoasong, 2009) or around specific diseases (Sturchio, 2008b). In doing so, partnerships often draw upon capabilities from diverse groups of actors, from state and/or interstate institutions, and private business, nongovernmental, academic, faith-based, and community-based organisations. Accordingly, P^3Hs may empower "old and new actors" (Brugha, 2008, p. 72), which Börzel and Risse (2005) argue expands democratic participation and contributes to problem-solving capacity in governance.

Furthermore, proponents maintain that the inclusion of private business actors imparts unique competencies, efficiencies, and innovations to governance. Distlerath and Macdonald (2004) claim that Merck brought private business competencies, including business and financial acumen, to the ACHAP. Ramiah and Reich (2005) point to increased access to global managerial networks; for example, services donated to ACHAP by global consulting group, McKinsey & Company. Ultimately, Distlerath (2006) argues that private business actors supply innovative ideas and approaches, while Williams and Rushton (2011) emphasise their role in driving greater efficiencies in governance. Ruggie (2002), Huckel-Schneider (2009), and Sturchio (2008a) perceive the relationship between public and private actors as operating more bidirectionally. Huckel-

Schneider suggests that P^3Hs may promote better governance practices for both public and private partners. This supposedly takes place through socialisation (Ruggie, 2002) and collective learning (Sturchio, 2008a) as partners work towards common goals.

There are clear benefits to both public and private partners; therefore, the prevailing functional narrative around P^3Hs appears grounded in incontrovertibly win-win arrangements. However, this win-win logic obfuscates practical, strategic, and normative interrogations, both proximal and distal. Proximal interrogations include rigorous investigations of partnerships that go beyond functional, problem-solving, value-added accounting of public-private interaction. These types of interrogations examine partnership histories, governance, operations, interactions, and counterfactuals, posing questions about the rationales for partnership and examining alternatives. Distal level interrogations focus attention on broader governance questions, including how P^3Hs intersect with historical, strategic, and normative developments in health and political economy. This next section reviews themes and findings that have emerged in the literature from these kinds of interrogations of partnerships.

Practical, strategic, and normative challenges and consequences.

The literature presented in this section problematises P^3Hs first in terms of their intended functions, structures, and interfaces with national and global health governance. It draws attention to concerns with partnership governance arrangements, public-private relations, and local and national impacts of partnerships. Secondly, it considers the implications of P^3Hs as a governance mechanism and seeks to understand how partnerships intersect with global health governance agendas, capacities, and objectives.

Admittedly, the literature, particularly the critical literature addressing the latter analytical objectives, is in its adolescence, but it offers the potential to fulfil an important role in policy and academic debates.

Much of the criticism launched against P^3Hs pertains to their governing arrangements. There are concerns in terms of membership, representation, accountability, transparency, sustainability, and outcome orientations. In terms of membership, there have been reported problems with the selection and representation of partners. Richter (2004b) and Buse and Waxman (2001) claim that corporate partners are not adequately scrutinised by state and/or interstate institutional partners, both in terms of potential conflicts of interest (Richter 2004) and the typically in-house manner of performing evaluations (Buse and Waxman 2001). Buse and Harmer's (2004) study substantiates concerns around partner selection, noting that only four out of the 19 P^3Hs in their study performed formal assessments of private business partners. They suggest that while many international agencies have guidelines governing corporate selection, "they are not widely adhered to" (p. 238).

Furthermore, Buse and Harmer (2004) note that there is a "gross under representation of southern stakeholders" (p. 240) in the governing arrangements of P^3Hs. Sonja Bartsch's (2006, 2009) studies of Southern actors in P^3Hs, and specifically, the Global Fund, depict poor Southern actor representation as well as deficient participation mechanisms and protocols. Moreover, analysis of the 92 global P^3Hs listed in the IPPPH database revealed that all but four have secretariats in northern states (North America and Western Europe) and approximately 40% of the secretariats are located in the United

States, and 35% are in Switzerland.[148] Biasing the loci and procedures of decision-making to advanced capitalist states generates questions about the prospects for meaningful involvement of developing states in partnership governance.

Studies have also described absent or deficient monitoring and evaluation procedures among P^3Hs (Buse & Harmer, 2007; K. Buse & A. Waxman, 2001). Given that P^3Hs are primarily self-regulating arrangements, they typically report to themselves through a board of directors or other partnership leadership. Partnerships may enlist internal or external auditors, but they are generally not obliged to do so by national law, international law, or policy.

Deficient monitoring and evaluation systems are one aspect of a larger debate around accountability expectations and obligations in public-private partnerships. There is considerable discussion on the issue of accountability and partnerships in the literature (Buse & Harmer, 2004; Buse & Walt, 2000a; Evans & Chen, 2005; Nishtar, 2004). This literature reveals that partnerships have weak or absent internal (partnership stakeholders, Boards of Directors, employees, grantees, etc.) and external (affected groups and individuals, communities, etc.) accountability procedures and obligations. Accountability procedures include transparency, participatory, evaluative, and complaint and feedback mechanisms around organisational activities and decision-making processes (Brinkerhoff,

[148] Author calculation on October 20, 2006, using the IPPPH database. This database, an initiative of the Global Forum on Health Research (www.global forumhealth.org), compiled data on public-private partnerships between 2000 and 2005, although the database remained searchable until 2006. The database was located at www.ippph.org.

2001). Bartsch (2006, 2008, 2009, 2011) has conducted much of the work on accountability and P^3Hs. She identified issues in three main areas of accountability: giving an account, taking account, and holding to account. Bartsch argues that P^3Hs often fail to provide detailed and useful information on their operations (giving an account), are insufficiently participatory or representative (taking account), and lack procedures for sanction, dispute resolution, or otherwise holding partners to account for their behaviour and/or responsibilities.

Accountability relies on transparent governance processes to ensure that actors give, take, and are held to account. Not surprisingly, then, P^3Hs have poor transparency records. While they frequently make basic information (profile, programmes, partners, contacts, and public relations material) available on their websites,[149] few post annual budgets and expenditure reports, programme evaluation, and impact documentation. Buse and Harmer (2004) also found that none of the P^3Hs with independent legal status make available the minutes of their deliberations. They also note that while auditing practices are common in P^3Hs, they are not universally practiced. They conclude that regardless of whether the partnership is publicly or privately hosted, very little information is available on their governing arrangements. In order to become effective and legitimate mechanisms in global health governance, P^3Hs need to commit to enhanced transparency and adhere to rigorous accountability procedures to ensure that they do not risk becoming, as Aginam cautions, "accountable to no one" (p. 6).

[149] See www.achap.org, www.securethefuture.com, and http://directrelief.org/DiflucanPartnership/EN/DiflucanProgramOverview.aspx, for a cross section of partnership websites. Note: not all partnerships have websites.

There are also controversies with regard to outcome orientations of P^3Hs. Partnerships in general report effectiveness in terms of value-added contributions including the number of drug units distributed, the number of personnel trained, the total funds distributed, and other quantitative impacts. However, there is little information on whether the partnerships actually contribute to improvements in the quality and efficiency of drug donations, health services, research, public information and advocacy, and product development. There is also little information on how the partnerships interact with national health governance institutions, and even less consideration is afforded to potential problems or unintended side effects of partnerships. Holm (2001) notes that there is minimal baseline data upon which to conduct research on the effectiveness of partnerships in their specific contributions to health.

Barr (2007) has developed a research protocol to assess partnership effectiveness that employs a range of research questions and partnership criteria. The protocol involves questions regarding the relationship between public and private business actors, financial arrangements, indicators for improved delivery of products and services, policy and legislative frameworks for partnerships, use of longitudinal data, and intended and unintended outcomes. Furthermore, Barr supplies a new approach to partnership evaluation by incorporating equity criteria into evaluations. He recommends reporting on new indicators for marginalised groups and evaluating partnership effectiveness based on how partnership activities contribute to improvement in health inequities.

Currently, few P^3Hs include equity considerations in partnership design and evaluation and risk exacerbating existing global health inequities. For example,

partnerships (such as the AAI and ACHAP) often choose countries that have existing health infrastructure to administer and deliver their programmes and products, potentially excluding the poorest countries. Yamey (2001) makes similar conclusions in his study of the GAVI Alliance, revealing that the vaccines were being sent to countries that already had some basic immunisation coverage, while the poorest countries that lacked even basic immunisation coverage (tetanus, polio, diphtheria) were not covered under the GAVI Alliance. Moreover, it is difficult to measure how equitably products and services are distributed within the country under partnership arrangements. Equity evaluations have been a critical oversight in P^3H outcome and evaluation orientations. Focusing predominantly on governance arrangements and added-value problem-solving offers a narrow and biased representation of P^3H activities and impacts.

There are also concerns surrounding the sustainability of P^3Hs in global health governance. Some of the partnerships do not have stated timelines, some have guaranteed drug donation until there is evidence of disease eradication (e.g. Merck Mectizan donation) (Sturchio, 2008b), and others have between three- and six-year life spans, after which the partnership is either terminated or extended by agreement of the parties. Furthermore, there is a question of whether drug donations are sustainable models for the provision of medicines, particularly for chronic diseases such as cryptococcal meningitis (a targeted AIDS defining illness in the Diflucan Partnership Programme) (Baker & Ombaka, 2009; Machuron, Bruneton, & Trénado, 2008; Pinheiro, 2008).

Partnerships have responded to criticisms of sustainability, arguing that many state and/or interstate institutions often do not make programme commitments for longer

than five years. While these institutions could potentially be charged with many of the same governance deficiencies and controversies as the partnerships, there is, at minimum, accountability expectations and mechanisms in state and interstate institutions that do not normally exist in partnerships, particularly those that are independent nonprofit entities. Perhaps most important, though, is the partnership model's limitations as a long-term strategy in global health governance. Chronic and endemic diseases and structural conditions of global economic and health inequity demand long-term solutions to structural and social determinants of health. While P^3Hs help address gaps in health products and services, the model has serious shortcomings as a long-term solution for meeting global health challenges.

Public-private interfaces and impacts on national health governance.

Interfaces between partnerships and institutions of national health governance are rarely revealed by the partnerships themselves but are beginning to be considered in the literature. These studies have begun to investigate the obstacles and unintended side effects of integrating partnerships within health governance structures. The literature identifies several interfaces, including policy autonomy and country ownership, transaction and coordination costs, system distortions, and relational issues.

One of the most interesting emerging critiques of public-private partnerships calls attention to the interfaces between partnerships and state autonomy. Although developing countries are frequently targets of public-private partnership activity and involve governmental participation, Asante (2007) faults partnerships for a consistent lack of country ownership. For example, P^3Hs may not give financial or administrative control to

the state and/or interstate partner[150] (Conway, et al., 2006) and often create parallel administrative processes (Conway, et al., 2006; Fleming, 2005). Partnerships have also been criticised for failing to align with national health policies and systems (Brugha, 2008; Buse & Harmer, 2007) and creating system distortions (Baker & Ombaka, 2009). Studies demonstrate that P^3Hs can affect policy choices and regulatory environments (Baker & Ombaka, 2009; Brugha, 2008; Fleming, 2005). Baker and Ombaka (2009), for example, explain how donation partnerships influence treatment protocols (adopting specific guidelines based on the donated drug) or may cause a government to delay or deny generic drug registrations.

Bartsch (2006) and Smith (2010) warn that these processes open up considerable space for private business actor inclusion in domestic authority arrangements, thus violating what Krasner (1999) defines as "Westphalian sovereignty"[151] (p. 20). Furthermore, states in which sovereignty is "weakly institutionalised" (Biersteker & Hall, 2002, p. 222) are particularly vulnerable to these violations. Partnerships, therefore, have the potential to undermine and/or reconfigure domestic policy autonomy, particularly within the global South. This is hardly consistent with an apolitical functional narrative of partnerships and private authority in global health governance.

Partnerships also have the potential to overwhelm the capacity of national health systems (Caines & Lush, 2004) through transaction costs and coordination challenges.

[150] This is more so the case in privately hosted partnerships. Publicly hosted partnerships, such as the RBM and Stop TB, are under the financial control of the WHO.

[151] Westphalian sovereignty refers to "political organization based on the exclusion of external actors from authority structures within a given territory" (Krasner, 1999, p.20). .

Studies report that while partnerships provide benefits to state and interstate institutional partners, they also create transaction costs (Biesma, et al., 2009; Brugha, 2008; Conway, et al., 2006; Pinheiro, 2008). Public authorities and P^3H beneficiaries[152] bear significant costs around meeting attendance, reporting requirements, and policy and/or regulatory changes. Pinheiro (2008) claims that many of these costs exceed the value-added effects.

Governments are also facing challenges with managing multiple P^3Hs in crowded national health governance environments. Studies report challenges and costs associated with coordination (Conway, et al., 2006; Fleming, 2005; MacLean & MacLean, 2009; Yamey, 2002), which are particularly acute in weak and/or overextended governance climates. Ultimately, governments may struggle to coordinate and absorb large influxes of partnerships, funds, donors, and nongovernmental organisations, many who bring their own reporting, governance, and policy expectations and obligations.

Given the issues with country ownership, policy distortion and reorientation, and transaction and coordination costs, partner relations can be prone to tension (Bartsch, 2006) and mistrust (Caines & Lush, 2004; J. Naimoli, 2009). Relational challenges arise as a result of ambiguity around partner roles and responsibilities (Buse & Harmer, 2007; Conway, et al., 2006), misalignment of partner goals (Biehl, 2007), poor communication and feedback mechanisms (Caceres, et al., 2010; Conway, et al., 2006), and lack of sensitivity or appreciation for local and cultural contexts (Chataway, Brusconi, Cacciatori, Hanlin, & Orsenigo, 2007).

[152] This includes public and private organisations that benefit from partnership activity. Nongovernmental organisations, for example, who receive funds or services under the auspices of a P^3H, are also usually required to submit reports to the partnership administration.

Effective policy and/or legislative frameworks to guide partnership design, governance, and evaluation might help address relational and institutional challenges; however, few states have implemented such frameworks.[153] In the absence of legal and policy frameworks regulating accountability, transparency, and governance, partnerships inevitably proceed in an ad hoc manner with potentially problematic consequences.

Public-private partnerships and global health governance agendas, capacities, and objectives.

This section analyses intersections between P^3Hs and health governance agendas, capacities, and objectives. The literature around this theme ultimately identifies public-private partnerships as undemocratic mechanisms that facilitate the growth of private power and authority in global health governance and open up significant space for private actor influence in global policymaking and agenda-setting. The literature flags these transformations as potentially pushing health governance further away from "Health for All" and towards a bio-medical, technological, and privatised model of public health.

Many of the concerns raised in the section on governing arrangements are highlighted within larger debates on democratic deficits in global health governance. Poor or problematic representation, accountability, and transparency speak to more universal concerns with legitimisation and democratisation in hybrid modes of governance. Public-private partnerships operate in the shadows of hierarchy (Börzel & Risse, 2005) and legitimacy, which authorise partnership operations but also relegate

[153] See the HENNET (2008) study, *Public-private partnerships: Analytical report on the findings from the study tour to the African region*. Nairobi: Ministry of Health/Government of Kenya.

them to the hinterland of public accountability and evaluation. Partnerships straddle the boundaries between public and private, borrowing legitimacy from public authority or acquiring it through social practices, but do not adhere to formal measures and mechanisms of political accountability and responsiveness. As a result, Cutler (2002) argues that private authorities are not entitled to act authoritatively for the public. However, P^3Hs do act authoritatively. They provide expertise, set agendas, establish limits for action, provide intermediate public goods, and supply services.

Furthermore, Cutler (1999b) cautions against conflating the public and the private under public-private partnerships and assuming that these actors operate with common interests and goals. Private business actors seek to gain authority and legitimacy (Benedicte Bull & McNeill, 2007) and minimise their exposure to public regulation and scrutiny (Cutler, 1999b). Public authorities, however, derive authority to create and implement rules, policies, and standards in the public interest through democratic processes of legitimation. The delegation of governance responsibilities to private actors thus challenges notions of democratic legitimacy (Bartsch, 2008; Cutler, 2002). While public and private actors may share specific functional goals under the auspices of partnerships, these goals do not negate their larger overriding strategic goals and interests. The challenge with P^3Hs is that their undemocratic character leaves little opportunity to flesh out these goals, detect conflicts of interest, and potentially strengthen their legitimacy as mechanisms of global health governance.

The very notion of win-win implies that private business actors respond to incentives in P^3Hs, including tax breaks, image promotion, branding, and new policies

and infrastructure, etc. These are important strategic benefits for private business actors, but they do not fully capture the scope and transformation of private business power and authority that P^3Hs afford. In addition to potential growth in direct (material) power, Fuchs and Lederer (2007) argue that public-private partnerships support the growth of structural power and thus the reach of private business interests in public authority and social life. In David Levy's (1997) work he encounters the same 'win-win' discourse in environmental management and sustainability. He asserts that the win-win discourse serves to "universalise corporate interests and avert deeper questions about potential structural conflicts between profit maximisation and environmental goals" (p.140). The win-win and *trasformismo* strategy of partnership (or in Levy's case environmental CSR and management) represent a form of foreclosure (Levy, 1997), or alternatively, a 'freezing' (Soederberg, 2007) of the contestations which underlie their institutional forms, and inherent conflicts and tensions with social goals such as health care and human rights. These effects tend to be ignored or significantly downplayed when P^3Hs are viewed through functional and problem-solving lenses. The functional narrative, therefore, aligns with the larger hegemonic project around maintaining the dominant neoliberal accumulation strategy. Faubion (2011) warns that this progression is symptomatic of trends in global health governance that focus on altruism and are relatively indifferent to systemic agendas and effects.

Furthermore, at this point, there is limited evidence with which to assess the impact of P^3H interactions with global public policy. There are reasonable theoretical concerns, yet insufficient empirical work exists from which to draw conclusions. Susan

Sell's (1999; 2004) work on the influence of pharmaceutical and information technology firms in negotiations around TRIPs is instructive; similar studies on public-private interactions in health governance will be critical to advancing this research agenda.

Some scholars have argued that P^3Hs promote normative agendas in global health governance consistent with neoliberal values and private business actor interests. Applbaum (2009) and Biehl (2007) identify *pharmaceuticalisation* as a private business actor agenda that promotes the use of pharmaceuticals to address ill health, supplanting other health promotion strategies. Pharmaceutical firms, according to Biehl (2007), work through P^3Hs to gain legitimacy. Applbaum (2009) goes further to suggest that pharmaceutical firms are attempting to position themselves as the "savio[urs] of mankind" (p. 90).

The promotion of pharmaceuticals to address all manner of ill health and disease not only serves the commercial interests of pharmaceutical firms; it also corresponds to trends in the depoliticisation and biomedicalisation of disease. These trends attempt to delink social and systemic processes and conditions from health outcomes and reorient responsibility for health primarily to the individual. The social determinants of health,[154] however, are social, economic, political, and environmental in nature; accordingly, responsibility for health does not lie solely within the purview of individuals or the health sector. Depoliticisation of disease, however, precludes social pathologising and focuses

[154] In 1986, an international agreement known as the 'Ottawa Charter' specified prerequisites for health, including peace, shelter, education, food, income, a stable eco-system, sustainable resources, social justice, and equity (WHO, 1986). The 2008 WHO Commission on the Social Determinants of Health referred to these and other social determinants of health in their final report and recommendations (WHO, 2008).

predominantly on individual pathologies and recourses. Pharmaceuticalisation and biomedicalisation provide individual treatments for pathologies without considering underlying political, social, economic and environmental factors that precipitate disease and ill health. Medical products and technologies are thus at the forefront of these normative and strategic agendas, as are their scientists, manufacturers, and investors.

Public-private partnerships emerge from and reinforce these trends. Many new P^3Hs have strong pharmaceutical, biomedical, and technological components and objectives. For example, the GAVI Alliance, IAVI, AAI, ACHAP, DPP, and MMV focus primarily on delivering medical products and technologies to developing countries. These types of interventions may be critically important, but they also express normative agendas and policy preferences for medical and technological interventions in global health governance. Accordingly, P^3Hs may reinforce trends in depoliticisation, biomedicalisation, and pharmaceuticalisation of health and wellness thus advancing broad neoliberal values and agendas.

Conclusion

A survey of the practical, strategic, and normative contributions, controversies, and consequences arising from P^3Hs and private authority in health helps destabilise the dominant functional and win-win logic. There are compelling reasons to adopt P^3Hs, particularly in light of gaps in critical research, goods, and services in developing countries. There are also real and potential unintended practical, strategic, and normative consequences for national and global health governance. These concerns with P^3Hs do not negate their practical and strategic contributions, but rather draw critical attention to

their limitations as an institutional mechanism, and to broader implications of corporate structural and discursive power in health governance action and inaction. The next three chapters explore these debates through detailed case studies and, in Chapter Seven, through a discussion on empirical and theoretical applications and policy and practical implications of the study findings and conclusions.

Chapter 5: Case Study 1- The Accelerating Access Initiative

Chapter Three described how social contestation and ensuing *trasformismo* strategies engendered pricing, licensing, financing, and normative concessions and commitments in HIV treatment access. Many access partnerships, including the four investigated in this study, emerged during this era of intense social contestation, offering new patent, pricing, and health system and delivery concessions and initiatives. These strategies, exercised under the auspices of P^3Hs (and pharmaceutical firm commercial programmes), represented an attempt to accommodate expanded access to ARV medicines and Diflucan in Sub-Saharan Africa and in the global South. However, as these next two chapters demonstrate, these partnerships largely reflect bilateral, narrow (breadth of coverage and contribution), and private business actor tactical approaches to global health. Furthermore, the cases corroborate many of the concerns with P^3Hs highlighted in Chapter Four, including issues with governance, representation, transparency, accountability, goals, reporting, evaluation, and transaction costs. Although pharmaceutical firms envision an important role for themselves in global health, and specifically in HIV/AIDS treatment access, these partnerships are unconvincing in their commitment and their capacity to expand access to HIV and AIDS medicines within Sub-Saharan Africa and the global South.

The next two chapters contain within-case and cross-case analyses of the four case studies of access P^3Hs. This chapter investigates the AAI and associated strategies of the participating firms. Chapter Six investigates the African Comprehensive HIV/AIDS

Partnership, the Diflucan Partnership Program, and the Secure the Future Partnership. The cases are divided in this manner to accommodate analyses of eight separate pharmaceutical firm strategies under the auspices of the AAI in Chapter Five, while the three cases in Chapter Six involve one firm per case. Chapters Five and Six are structured identically in terms of three sections investigating 1) partnership histories, objectives, and rationales, 2) governance and operational information, including specific partnership strategies and approaches, 3) analyses of practical, strategic, and normative contributions and controversies and limitations. Chapters Five and Six each conclude by highlighting themes and implications from within and cross-case analyses.

History, Rationale, and Objectives of the Accelerating Access Initiative

As discussed in Chapter Three, the AAI traces its history to the discovery of HAART, delay and denial in treatment access in Sub-Saharan Africa and throughout much of the global South, and the ensuing contestation and crisis. It traces its operational origins to the original Drug Access Initiative, developed in 1998 by UNAIDS as a pilot project to expand ARV access within Côte d'Ivoire, Uganda, Vietnam, and Chile (Brousselle & Champagneb, 2004). The DAI was the first partnership to pilot differential pricing for ARV medicines (WHO/UNAIDS, 2002a). Early evaluations, however, concluded that prices under the DAI did not decline to levels that were affordable for participating states, thus forming a key barrier to access (ibid.). Consequently, the partnership lost momentum and did not expand to other countries.

Around the same time, social and legal contestation was mounting against pharmaceutical firms and governments. Growing networks of civil society orgnaisations

protested the 1998 lawsuit filed by the South African Pharmaceutical Manufacturers Association against the Government of South Africa.[155] These organisations also protested USTR trade pressures and other tactics used in support of PMA-affiliated firms and their lawsuit. Growing global awareness of the PMA case and issues surrounding HIV/AIDS and treatment access prompted calls for industry and political changes to ARV access, including price reductions, patent flexibilities, expanded use of the TRIPs flexibilities, and increased generic competition through compulsory and voluntary licensing. Multiple representatives from originator firms conceded that these demands propelled firms into action. Dr. Jon Pender, Director of Government Affairs and Global Access with GSK, stated:

> There has always been a healthcare crisis in the developing world; what has changed is that HIV/AIDS is making things worse and it came to the attention of the developed world and there was increased scrutiny on pharmaceutical companies. (personal interview, September 4, 2008)

Others described intense pressure from both developing and advanced capitalist states (Respondents 29-1; 64-1, personal interview, March 24, 2011; April 5, 2011). Dr. Pender remarked, "Industry did not handle this scrutiny very well; its response was very high handed and basically said 'go away' to the activists" (personal interview, September 4, 2008). The PMA case, in particular, noted one executive, was creating "misery" for the firms (Respondent 51-1, personal interview, April 7, 2011). The AAI was seen by firms as a way to restore reputational damage (Respondent 72-1, personal interview, April 27, 2011), protect bottom line considerations (Respondent 26-1, personal interview,

[155] For more information on this lawsuit, see Chapter Three, pp. 87 & 91-92.

August 25, 2008), and engage more effectively in access issues (Respondents 26-1; 29-1; 51-1; 72-1, personal interview, August 25, 2008; March 24, 2011; April 7, 2011; April 27, 2011). Indeed, almost all pharmaceutical firm representatives emphasised the genuine commitment of their firm to expanding global treatment access. While many admitted that the firms had responded to intense social pressures, they also affirmed their critical role in global treatment access.

Pharmaceutical firms were also facing potential competition from Brazil and Thailand, who were engaging in large-scale generic production and distribution of ARV medicines at significantly lower costs than originator ARV prices (WHO/UNAIDS, 2002a). These states confirmed that large-scale treatment was not only possible; it was also affordable when pursued through compulsory licensing and generic production. In the context of a convergence of social contestation and the growing threat of generic competition, five originator firms began engaging in talks with five UN agencies on developing a global health partnership to support enhanced access to ARVs.

Announced in May 2000, the Accelerating Access Initiative comprised five originator pharmaceutical firms and five UN organisations. The UN orgnaisations included the UNAIDS Secretariat, the WHO, UNFPA, UNICEF, and the World Bank (WHO/UNAIDS, 2002a). The five firms, who were also parties to the PMA lawsuit underway in South Africa, included Boehringer-Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck, and F. Hoffmann-La Roche ("Roche"). To the disappointment of civil society organisations, the AAI focused principally on pricing and did not address

broader issues of access such as affordability, availability, and accessibility, as shaped by patent monopolies, patent abuses, and market failure.

A month after the announcement, UNAIDS formed a formal contact group for the AAI. By November, bilateral (firm-by-firm, country-by-country) pricing negotiations had begun between firms, UN agencies, and participating states (Respondent 65-1, personal interview, March 30, 2011; Sturchio, 2004; WHO/UNAIDS, 2002a). Initial price reduction offers arrived in January 2001(WHO/UNAIDS, 2002a) and offered ARVs at approximately 10-20% of the cost in North America and Europe (ibid). However, these prices still presented barriers to implementing large-scale public-sector treatment programmes, and UNAIDS initiated discussions with generic producers (ibid.).

In November 2001, UNAIDS transferred responsibility for the AAI to the WHO, at which point UN involvement began to wane. Following the UNGASS Declaration and calls from WHO and UN leadership, political momentum had begun to build around ARV treatment access in the global South. The AAI, however, had ambiguous potential as a vehicle for expanded ARV access given continuing high prices, minimal voluntary licensing, and sluggish negotiation processes. WHO turned its attention towards generic producers in India and elsewhere to pursue treatment objectives.

The development of the Global Fund in 2002 and PEPFAR in 2003 provided new stimuli for treatment access programmes. Initially, PEPFAR relied principally on originator medicines (Dietrich, 2007), however, over time, the situation reversed and generics now constitute over 76% of all treatment purchases (Holmes, et al., 2010). This confluence of forces— new normative commitments (including the 3 x 5 initiative

launched in 2003), the turn to generics, and bilateral and public-private financing bodies—enlarged the field of producers and diminished the AAI's singular importance. Ten years following its inception, the AAI is still in existence but has since transformed into an informal partnership, more aptly characterised as eight separate partnerships.

Although the AAI originated with five pharmaceutical firms, by 2008, it had expanded its membership to 10 (see Table 5-1). AAI membership technically stands at seven firms as a result of changes in member composition. In 2010, Gilead Sciences ("Gilead") terminated its membership in the AAI and ViiV Healthcare[156] ("ViiV") assumed membership for GSK and Pfizer. Given these recent developments, Gilead and ViiV are included, bringing the total to eight firms in this study.

Table 5-1: AAI Pharmaceutical Firms Members and Date of Joining the AAI

Join Date	Pharmaceutical Firm
2001	Abbott
2000	Boehringer-Ingelheim
2000	Bristol-Myers Squibb
2000	F. Hoffman-La Roche
2004	Gilead Sciences
2000	GlaxoSmithKline
2005	Merck
2008	Pfizer
2006	Tibotec
2010	ViiV HealthCare

Sources: Respondents 14-1; 26-1; 29-1; 30-1; 64-1 (personal interview, April 20, 2011; August 25, 2008; March 24, 2011; September 4, 2008; April 5, 2011).

[156] ViiV HealthCare is a specialised HIV/AIDS firm developed by GSK and Pfizer. GSK and Pfizer hold 85% and 15% stake in ViiV HealthCare, respectively.

Objectives and principles.

The AAI identified two major objectives. The first was to improve "access to and availability of a range of medicines" (WHO/UNAIDS, 2002a, p. 4). The second was to "implement public-private cooperation in ways that respond to the specific needs and requests of individual countries, with respect for human rights, equity, transparency and accountability" (ibid.). The AAI, therefore, positioned itself as a functional mechanism and a normative agenda within global health governance.

To realise these objectives, the AAI developed six operating principles (see Table 5-2). These principles affirm a number of objectives around treatment access, including the need for expanded political commitment and governance capacity, multisectoral responses, strengthened logistical and distribution systems, and new financial resources to support treatment access programming. The first five principles address many of the access dimensions identified in Figure 1-3 (Chapter One) and emphasise the importance of effective governance, financing, delivery, and implementation systems to ensure access affordability, availability, accessibility, and acceptability.

Table 5-2: AAI Partnership Operating Principles

Principles
1. Unequivocal and ongoing political commitment by national governments is essential for success.
2. Strengthened national capacity is crucial for delivering care and treatment on an equitable basis.
3. Engagement of all sectors of national society and the global community is essential in facilitating access to treatment.
4. Efficient, reliable, and secure distribution systems are necessary to ensure that medical supplies and other consumables are made available to people who need them.
5. Significant additional funding from new national and international sources is necessary for long-term success.

6. Continued investment in research and development by the pharmaceutical industry on innovative treatments is critical to expanding the global response to HIV/AIDS. Therefore, intellectual property rights should be protected, in compliance with international agreements, since society depends on them to stimulate innovation.

Source: WHO/UNAIDS (2002a, p. 4).

The first five principles, however, are conspicuously devoid of reference to private business member responsibility. Principles 1 and 5 reference national and international responsibility for enhanced political commitment and resource generation, yet omit mention of pharmaceutical firm responsibility around patents, pricing, or manufacturing. Indeed, the lone reference to pharmaceutical firms in Principle 6 reinforces IPR protection and advances a normative statement about its role in the HIV/AIDS pandemic and, more broadly, in global health innovation. Amidst an ongoing high profile lawsuit against the Government of South Africa and civil society activism around alleged patent abuses by these five firms, this sixth principle comes across as a suspiciously instrumental tactic for safeguarding IPR interests.

The AAI charter lacks any commitment for expanding the reach of intellectual property other than through defensive tactics. Although AAI objectives specify an important role for the partnership in access to medicines, this role translated narrowly into negotiations around drug pricing. Alternative access strategies would ultimately be very slow to develop and would appear unsystematically across AAI pharmaceutical firm members. The next section of the chapter discusses these and other strategies.

AAI Governance and Operations

The AAI is an informal, publicly hosted Global Health Partnership without legal status. The partnership has been hosted by UNAIDS and the WHO, who perform

Secretariat responsibilities and coordinate AAI activities. The AAI Secretariat worked[157] on alongside a contact group (WHO/UNAIDS, 2002a) comprised of government representatives, member firms, NGOs, and people living with HIV/AIDS. The contact group provided information and feedback on the status of the partnership (ibid.). In addition to the contact group, three working groups oversaw implementation of AAI operations. The country support working group includes representatives from member firms, UNAIDS, the WHO, and UNICEF and was responsible for conducting consultations and negotiations with participating states. The communications group included all partners and managed internal and external communications. The procurement group involved four UN agencies: UNAIDS, UNICEF, UNFPA, and the WHO; these organisations develop and implement procurement plans (ibid.).

The five member firms indicated that they would only negotiate lower drug prices on a bilateral basis with UN facilitation. Thus, in order to engage in negotiations, governments first worked with UN consultants from a country support working group who were responsible for relaying their interest in the AAI to the UNAIDS Executive Director (WHO/UNAIDS, 2002a). Consultants worked with governments to develop delivery and implementation plans for ARVs, which were vetted by UN agencies and member firms (ibid.). At that point, firms entered into bilateral discussions with governments while UN staff played facilitative roles. Firms agreed to supply one or more

[157] The governance structures described herein are no longer operational. The AAI is currently (2011) governed by a committee composed of representatives from the member firms and WHO and/or UNAIDS representatives. Chairmanship of the committee rotates every six months and the committee corresponds through email/Internet communications (Respondent 64-1, personal interview, April 5, 2011).

ARVs at discounted prices over a negotiated timeframe, typically 12 months (ibid.), and the UN and governments managed procurement processes.

This bilateral approach to medicines access, however, proved to be slow and labour intensive (Respondent 74-2, personal interview, October 30, 2008; WHO/UNAIDS, 2002a). Governments had to negotiate with multiple firms to obtain a full complement of ARVs for treatment programming. Furthermore, countries within the same region might pay different prices for each medicine, with little to no transparency across individual medicines and firms. A regional approach offered a more streamlined and potentially transparent approach to pricing and procurement. In May 2002, the Caribbean Community and the Economic Community of Western African States entered negotiations with the AAI (WHO/UNAIDS, 2002a). This approach transferred technical and coordination responsibilities to regional bodies and allowed UN agencies to move to pooled procurement of ARV medicines; although, pricing negotiations continued on a bilateral basis (WHO/UNAIDS, 2002b).

Within the first few years, the AAI had generated substantial interest from governments in the global South. By the end of 2002, over 80 governments had expressed interest in engaging in discussions with member firms and the AAI concluded 19 supply agreements (WHO/UNAIDS, 2002a). Member firms provided significant discounts for their ARV medicines, although they remained unwilling to provide medicines at cost (Waldholz, 2000a). These discounts were initially offered exclusively to public sector and nongovernmental organisations (Van der Borght et al., 2009). In some cases,

governments subsidised the cost of treatment programmes, in others, individuals were required to contribute to treatment costs.

Chapter Three referred to the slow progression of the AAI, citing only 27,000 patients on ARV treatment within the first 18 months of the partnership (WHO/UNAIDS, 2002a). While this figure represents a tiny fraction of overall treatment needs, it signifies a ten-fold increase from baseline treatment figures (ibid.). Therefore, despite pharmaceutical firm rhetoric that weak health infrastructures—not affordability—was a primary barrier to access[158]; the AAI confirmed the central importance of affordability.

Although early AAI negotiations centred on drug pricing, commercial and social pressures prompted firms to expand their scope of commitments to treatment access. Intensifying generic competition, originating chiefly from India, put downward pressure on originator ARV drug prices (Waning, Diedrichsen, et al., 2010). In an effort to compete with generics producers, AAI firms offered deeper discounts and nonprofit pricing on ARV medicines. Firms also introduced patent flexibilities, including voluntary licensing, nonassert and nonenforcement declarations, and technology transfer programmes. These strategies aimed to mollify continuing civil society activism and protect commercial interests in emerging markets.

[158] Interviews with AAI member firm representatives (Respondents 26-1; 29-1; 30-1, personal interview, August 25, 2008; March 24, 2011; September 4, 2008) as well as analyses of position papers (Abbott, 2009; BMS, 2005a; Gilead, 2010; GmbH, 2011; Roche, 2009a, 2009b; Tibotec, 2010) pinpoint health system deficits as key barriers to medicines access.

Pricing and patent flexibility strategies.

Although characterised as a Global Health Partnership, the AAI has come to embody a patchwork arrangement of eight bilateral partnerships/programmes.[159] Although they are individually committed to AAI objectives, they are loosely tied to one another, partly as a result of proprietary and antitrust limitations but also given fundamental divergences in public and private interests around access to medicines. The next section will explore the AAI partnership in its contemporary form as an arrangement of eight largely disjointed pharmaceutical firm programmes containing a mix of pricing and patent flexibility strategies.

Differential pricing.

Although the DAI was the first UN partnership to introduce differential pricing, the AAI institutionalised this approach for ARV medicines pricing among participating firms. Differential pricing, also known as Ramsey pricing, allows firms to adjust pricing based on expectations around demand elasticity in markets (Danzon & Towse, 2003). Thus, in lower income markets where demand is more elastic, prices are set lower to allow for generate higher consumption. Higher prices in higher income markets help recoup research, development, and production costs (ibid.). The five original AAI pharmaceutical firm members adopted this pricing approach and four of the five newer

[159] The IFPMA directory classifies pharmaceutical firm access programmes as partnerships in their annual Health Partnerships Directory. This study refers to the AAI as the partnership arrangement and individual programmes operating under the AAI banner.

AAI members practice Ramsey pricing for ARVs.[160] However, there is considerable variance among the firms' pricing approaches, eligibility criteria, and geographical scope. Table 5-3 compares individual firm strategies around pricing and patent flexibilities.

[160] Technically, Pfizer offers differential pricing on its ARV medicines through ViiV HealthCare. However, Pfizer's ARV medicine maraviroc, which was approved by the FDA for use in 2007 and is indicated for use in treatment experienced patients, is not currently offered at differential prices (Respondent 64, personal interview, April 5, 2011).

Table 5-3: AAI Member Pharmaceutical Firms' Access Strategies[161]

Firm	Access pricing strategies and scope					Patent flexibility strategies and scope			
	Differential pricing strategy	Eligibility first-tier	Number of eligible first-tier countries	Eligibility second-tier	Number of eligible second-tier countries	Nonassert declarations offered	Voluntary licenses offered	Number of licenses granted	Technology transfer arrangements
Abbott	Yes	Africa, LDCs	69	LIC, LMIC	45	No	No	0	No
Boehringer Ingelheim	Yes	LDCs, LIC[162], Africa	80	MIC	63	Yes	No	0	Yes
BMS	Yes	LIC; SSA	57	Southern Africa	9	Yes	Yes	2	Yes
Gilead	Yes	LIC, HIV prevalenc	107	LMIC, HIV	23	No	Yes	13	Yes
Merck[163]	Yes	LDCs	84	LMIC	51	No	Yes	5	Yes
Roche	Yes	LDCs, SSA	63	LIC, LMIC	91	Yes	No	0	Yes
Tibotec	Yes	LDCs, SSA	63	No second tier	N/A	No	Yes	Multiple	Yes
ViiV (Pfizer/GSK)	Yes	LDCs, SSA, Global Fund projects	69	No second tier	N/A	No	Yes	11	No

[161] Data for this table has been obtained from 1) pharmaceutical firm documents and information obtained from firm websites, 2) pharmaceutical firm profiles from the 2010 Access to Medicines Index (www.accesstomedicines.org), and 3) Médecins Sans Frontières' Access to Medicines Campaign (2010) publication, "Untangling the Web of Antiretroviral Price Reductions." The data were retrieved in April 2011 and are current as of that date with the following exceptions: 1) country eligibility numbers are current as of July 2010, and 2) number of licences are current as of January 2011.

[162] Lower income (LIC), lower-middle income (LMIC), and middle-income countries (MIC) refer to World Bank income classifications. SSA refers to the 48 countries in Sub-Saharan Africa. See http://data.worldbank.org/about/country-classifications for World Bank income classification.

[163] Country eligibility is specific only to efavirenz and indinavir as eligibility differs across Merck's four ARVs.

Each AAI member firm offers differential pricing on ARV medicines, also referred to as sustainable (ViiV), preferential (Abbott), tiered (Gilead) and fair (Roche) pricing (Abbott, 2009; Gilead, 2011; Roche, 2009b; ViiV, undated). These approaches typically establish two tiers of pricing for lower income markets, although Tibotec and ViiV each offer only one tier. Firms provide a single price per tier based on predetermined eligibility criteria.

Differential pricing eligibility reflects a mixture of economic and geographic criteria; the exception is Gilead, which considers countries with a high HIV prevalence rate eligible regardless of income (Respondents 14-1; 58-1, personal interview, April 20, 2011). Firms combine economic indicators (LDCs or World Bank income classification) and geographic criteria (Sub-Saharan Africa/Africa) to determine first-tier eligibility. Second-tier eligibility is determined exclusively by economic criteria, primarily World Bank criteria. The only exception is BMS's Southern Africa category. The second tier provides discounted prices up to lower-middle income (Abbott, Gilead, Roche) and middle-income classifications (Merck and Boehringer Ingelheim). BMS, ViiV, and Tibotec[164] negotiate discounts on a case-by-case basis for countries not covered by their eligibility requirements.

These pricing approaches demarcate clear boundaries around the scope of the accommodation strategy. Firms offer their lowest prices to the poorest countries in the world (Gross National Income of < $1005 per capita) and countries within Sub-Saharan

[164] Janssen-Cilag, a Tibotec affiliate, conducts these negotiations (Respondent 72, personal interview, April 27, 2011).

Africa. Only Gilead accounts for what seems like an obvious criterion, HIV prevalence, in determining eligibility for its lowest available prices. Moreover, only Gilead and Boehringer Ingelheim provide nonprofit pricing to low-income countries; otherwise, firms provide their lowest possible price to LDCs and countries in Sub-Saharan Africa. Nonprofit pricing is, therefore, primarily reserved for the poorest of the poor and for countries hardest hit by the epidemic (Sub-Saharan Africa). Among the firms, Gilead, Boehringer Ingelheim, and Merck, respectively, offer the most extensive coverage for differential prices, while BMS's approach is the most restrictive.

Although the firms' differential pricing approaches appear consistent with global health needs, they impose important geographic and equity implications for ARV access. These pricing approaches exclude most middle-income countries (with the exceptions of Boehringer Ingelheim and Merck) and as a result exclude large populations of people who are in need of access to medicines. Middle-income countries, such as China, have large populations of people living with HIV/AIDS and large populations of people living in poverty. At the end of 2009, there were approximately 740,000 people in China living with HIV/AIDS (UNAIDS & WHO, 2010). Although poverty rates have been declining since 1981, in 2005, 16.3% of the population lived on less than $1.25 per day, and 36.9% on less than $2.00 per day (Ravallion, 2011). Furthermore, China continues to have high levels of income inequality and rural poverty (ibid.). Other middle-income countries, including the Russian Federation, Colombia, and Mexico, also have significant income

inequality and poverty[165] as well as large populations of people living with HIV/AIDS.[166] Tahir Amin, co-founder and Director of Intellectual Property for the civil society organisation, I-MAK,167 argued that these pricing approaches "make a mockery of the term access" (personal interview, March 24, 2011) and questioned "if pharmaceutical companies care about access, why not include [middle-income] countries?" (ibid.).

AAI member firms representatives stated that they are aware of the implications of access pricing strategies. Representatives cited real and potential commercial benefits (Respondents 30-1; 58-1; 72-1, personal interview, September 4, 2008; April 20, 2011; April 27, 2011) as the primary reason for excluding these countries from differential pricing schemes. Only one firm—GSK—is actively examining pricing strategies for middle-income countries, including in-country tiered pricing and market segmentation (Respondent 64-1, personal interview, April 5, 2011).

Furthermore, only one AAI firm, Abbott, offers prices on its ARVs that are consistently competitive with generic producers. Appendix C provides a list of ARV medicines produced by AAI member firms.[168] Appendix C contains a table which lists the drug by originator, drug and dosage, lowest available (first-tier) originator price, and

[165] Measured by poverty headcount ratio at $\leq$ $1.25/day and $2.00/day and GINI index. Data available at http://data.worldbank.org/country.

[166] At the end of 2009, 980,000, 220,000 and 160,000 people were living with HIV/AIDS in the Russian Federation, Mexico, and Colombia, respectively. See www.unaids.org under "countries".

[167] Website: www.i-mak.org.

[168] Data obtained from the 2010 Médecins Sans Frontières survey of originator and generic ARV prices. Retrieved from www.utw.msfaccess.org.

lowest available generic price. This table provides information for 65 drug and dosage combinations across 19 single ARVs and 6 double or triple dose combinations. It also supplies the percentage difference between the lowest available originator and generic price for each of the 37 drug and dosage combinations where both a generic and first-tier originator price are listed.[169] The table shows that in 31 out of 37 (83.7%) applicable cases[170], originator prices were higher than their generic equivalents. Furthermore, generic prices ranged from 13.7% to 84.7% less than originator prices (averaging 55%). In the six instances where the originator price was less than the generic, the percentage difference ranged from 3.9% to 289.2% (averaging 78%).[171] These findings around originator/generic price differentials are consistent with other studies by Waning, et al. (2009; 2010), although the Waning, et al. (2009) study observed larger[172] price differentials.

Ultimately, AAI access pricing has not been competitive with generic production and has had limited utility as a strategy for expanding access. Generic competition, accelerating particularly in 2001 and 2002, has been integral to global treatment scale-up (F. Orsi & D'Almeida, 2010; t'Hoen, 2009). Generic producers now supply over 80% of global ARV medicines (Waning, Diedrichsen, et al., 2010). AAI member firms'

[169] Of the total 65 drug and dosage combinations listed in Appendix C, there were 37 instances where both an originator and a generic pharmaceutical firm supplied prices.

[170] With the exception of Abbott's ARVs and one formulation of Roche's saquinavir.

[171] Author calculations based on MSF data.

[172] The percentage difference ranged from 23-498% for 15 out of 18 differentially priced originator ARVs when compared to generic equivalents (Waning, et al., 2009).

representatives report decreasing demand for differentially priced ARV medicines (Respondents 8-1; 14-1; 26-1; 30-1; 37-1; 51-1; 64-1, personal interview, August 15, 2008; April 20, 2011; August 25, 2008; September 4, 2008; August 15, 2008; April 7, 2011; April 5, 2011). One pharmaceutical firm respondent remarked that volumes "had gone down drastically" over the past several years (Respondent 64-1, personal interview, April 5, 2011). This respondent acknowledged that the firm was not able to remain competitive with generic producers, but identified key factors, including higher manufacturing, operating, and shipping costs, which are built into originator ARV prices. One respondent rebuffed this explanation, claiming that originator firms "don't really care about the margins; [the] price that they charge has very little relation to the actual cost of the drug" (Respondent 12-2, personal interview, March 31, 2011). Other civil society respondents argued that firms could reduce prices by either making use of their generic subsidiaries or by subsidising access pricing from profits generated from sales of ARVs in high income markets (B. Baker; J. Berger, personal interview, September 23, 2008; November 30, 2007). Ultimately, this is the concept behind Ramsey or differential pricing; higher income markets allow firms to recoup research, development, and manufacturing costs. It seems feasible that firms could have provided earlier and deeper price reductions and been competitive with generic producers.

As a result of trends in originator prices, the AAI began to lose credibility as a mechanism for treatment scale-up. However, given patent monopolies, many of which had not yet expired, pharmaceutical firms continued to be subject to civil society demands for non-pricing-related reforms. Civil society organisations argued that stall tactics

created critical barriers for treatment access. For example, refusals to issue voluntary licenses and delays in drug registration often prevented usage of the originator drug as well as country approvals for generic production.

Chapter Three identified cases in which states (e.g. Thailand, Brazil, and South Africa) and civil society secured new patent flexibilities, including compulsory and voluntary licensing arrangements from AAI member firms. In the wake of these changes and continuing social and commercial pressures, AAI member firms unsystematically adopted patent flexibilities for their ARV medicines, including patent nonenforcement, voluntary licensing, and technology transfer arrangements.

Patent nonenforcement.

Chapter Three discussed the BMS decision to issue a nonenforcement declaration for its d4T medicine in South Africa. A patent holder may issue a nonenforcement or nonassert declaration to a country or group of countries, allowing generic producers to manufacture the patented medicine (IFPMA, 2010b). The patent holder may attach certain conditions to the offer, including regulatory and quality assurance requirements (ibid.). Although similar to a voluntary license, a nonenforcement declaration applies normally to all qualified producers within the applicable jurisdiction. The nonenforcement declaration provides assurances to producers that they will not be subject to legal action should they produce the patented drug for sale.

Only three of the eight AAI member firms (Boehringer Ingelheim, BMS, and Roche) commit to patent nonenforcement in least developed and developing countries. These offers however, are subject to geographic and drug limitations. BMS provides

immunity-from-suit agreements only for firms located in Sub-Saharan Africa, and only for its d4T and ddl products (BMS, 2010a). BMS has committed to extending their offer for its second-line ARV, atazanavir, but only for firms operating in Sub-Saharan Africa (BMS, 2010b). Boehringer Ingelheim also issued an offer in May 2007 for nonassert declarations for their ARV medicine, nevirapine. Their offer is more generous than the BMS offer; BI allows WHO pre-qualified firms in least developed, low-income, and African countries to produce nevirapine. This offer will eventually extend to its ARV, tipranavir, but as of May 2011 there is no agreement in place (Respondents 5-1; 51-1, personal interview, April 7, 2011). Roche has committed not to file or enforce patents in LDCs and Sub-Saharan Africa (Roche, 2009a, 2009b), making it the only AAI firm to do so. While BMS and BI have committed to nonenforcement, the distinction between not enforcing and not filing is important. In 2016, least developed countries will be required develop or align patent legislation in compliance with the TRIPs Agreement. If originator firms are able to patent their drugs in LDCs, these countries will no longer be able to import generic ARVs without first developing legislation to make use of TRIPs flexibilities.

Several civil society respondents were critical of nonenforcement declarations, arguing that least developed countries are currently not obliged under international law to patent these drugs or that the drugs are not yet patented in countries where offers have been made, making the offer of nonassert redundant. Civil society respondents claimed that firms "put up iron walls around patents" (Jonathan Berger, personal interview, November 30, 2007) when it is in their strategic and commercial interests to do so.

Nonenforcement declarations, for example, have never been extended to middle-income countries. Moreover, several AAI member firms have aggressively filed and enforced their patents in these countries.

Tahir Amin highlighted key patent cases in India with AAI member firms Abbott, Gilead, and GSK. These firms filed patent applications in India that were subsequently opposed by civil society groups through pre-grant oppositions.[173] In one case, India's patent office rejected Gilead's application for the widely used ARV[174] tenofovir disoproxil fumarate (TDF), stating that it did not constitute an invention under Indian law. Gilead filed an appeal and threatened to allow voluntary licenses with Indian generic producers to lapse ("Gilead pushes for patent for HIV drug in India," 2007).

While there has been no decision yet on the Gilead appeal, Amin warns that even if the appeal is rejected, "patent applications don't just disappear," noting that the firm filed three divisional applications for the same patent (personal interview, March 24, 2011). Similarly, despite rejection by the Indian patent office for a patent on a new formulation of LPV/RTV, Abbott has attempted to submit patent applications for these drugs on 75 different occasions (I-MAK, 2010). As these cases illustrate, AAI firms have vigorously defended their IPR in middle-income, TRIPs-compliant countries with drug

[173] Indian patent offices allow parties, including civil society and nongovernmental organisations, to file a statement in opposition against pending patent applications. The patent office will consider the pre-grant opposition in deliberations prior to granting a patent to an applicant (Orsi et al, 2007).

[174] Newly revised (2009) WHO guidelines recommend the use of TDF in first-line regimens and advise phasing out d4T (BMS's ARV) from first-line regimens (AMFAR, 2010). These changes significantly increase the importance and application of TDF in global HIV/AIDS treatment.

manufacturing capacity, and have refused to extend their accommodation strategies to groups or places where firms have strong commercial incentives.

Voluntary licensing and technology transfer agreements.

Similar to a nonenforcement declaration, a voluntary license is a formal agreement listing specific terms between the patent holder and a generic producer. Voluntary licenses grant generic producers, primarily in India and South Africa, the right to produce and sell a patented drug within specified markets. These agreements usually involve royalty payments to the patent holder. AAI member firms have sparingly negotiated voluntary licenses (see Table 5-3), several of which followed formal complaints by civil society organisations.[175] Gilead, the market leader among AAI firms (Respondent 1-5, personal interview, March 24, 2011), has granted 13 licenses to Indian generic firms to produce TDF for sale in 94 countries. Licensees pay a 5% royalty on sales of finished products (Respondent 58-1, personal interview, April 20, 2011). ViiV has issued 11 licenses, the first of which was granted by GSK in 2001. ViiV licenses are royalty free; however, licensees may only sell product in first-tier countries (Respondent 64-1, personal interview, April 5, 2011).

Tibotec and BMS have issued a small number of licenses to producers in South Africa and India to produce their ARVs. Tibotec also issued licenses for generic producers for its drug TMC 278, while it is still in the drug pipeline (Tibotec, 2010).

[175] See Chapter Three regarding the complaint to the South Africa Competition Commission involving GSK and Boehringer Ingelheim. A 2007 TAC complaint to Competition Commission over Merck's refusal to issue voluntary licenses for their drug, efavirenz also resulted in four new licenses (Heywood, 2009).

Accelerating generic production of a drug that has not yet entered the market is an unprecedented move. Tibotec attaches a small royalty (2-5%) to the license; other license terms such as time or geographic limitations have not been published (Respondent 72-1, personal interview, April 27, 2011). Tibotec's other voluntary licenses are more appropriately characterised as commercialisation agreements permitting Aspen Pharmacare (South Africa) and Emcure (India) to produce and distribute darunavir and etravirine in first-tier countries (MSF, 2011a).

Voluntary licenses have been criticised similar to pricing and patent flexibility strategies: licenses are geographically restrictive, exclude middle-income countries, and are not always required by national patent law. In terms of the latter, the collection of royalties for products that are not patented in the producer's country is, according to Tahir Amin, analogous to asking someone to "pay rent for something you do not own" (personal interview, March 24, 2011). This is often the case for licensees, particularly in India, where originator firms do not hold patents. Critics have also pointed to controversial licensing terms, including provisions prohibiting licensees from engaging in patent oppositions, restricting the supply of active pharmaceutical ingredients[176] to approved firms and markets, and requiring licensees to purchase active pharmaceutical ingredients from originator suppliers (B. Baker; T. Amin; Respondent 12-2; personal interview, September 23, 2008; March 24, 2011; March 31, 2011). Some of these

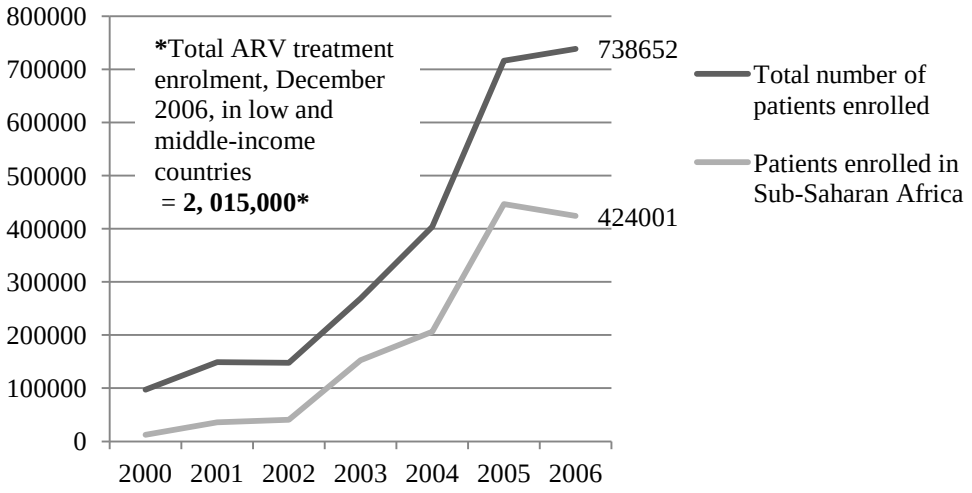
[176] An active pharmaceutical ingredient is a "substance or mixture of substances… intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body" (WHO, 2003, p. 126).

provisions, such as engaging in patent oppositions, have been removed because they constituted anticompetitive practices (T. Amin, personal interview, March 24, 2011).

Licenses, however, can potentially help expand treatment access by supporting generic production and competition. Additionally, licenses often come with technology transfer arrangements in which originators supply licensees with technological expertise and information for drug production and manufacturing. Gilead and Tibotec, for example, provide licensees with a technology transfer package (Respondents 14-1; 72-1, personal interview, April 20, 2011; April 27, 2011). Six AAI firms also participated in other forms of technology transfer with generic suppliers, including technical training, product development partnerships, and support for manufacturing practices.

This investigation of AAI operations and strategies has revealed challenges in realising partnership objectives for enhanced global treatment access. The arrangement of eight bilateral programmes has yielded expanded access to originator medicines through differential pricing and licensing strategies (see Figure 5-1). However, generic suppliers who provide lower prices and fewer restrictions have eclipsed AAI access figures. As shown in Figure 5-1, as of 2006, the AAI accounted for approximately 35% of total enrolment figures in low and middle-income countries. AAI enrolment data after 2006 is not available; however, multiple pharmaceutical firm respondents indicated that differentially priced ARV volumes have been declining since this period.

Figure 5-1: Patient Enrolment through AAI Member Firms' Access Strategies



Note: AAI enrolment data are not available after 2006.
Sources: Sturchio and Khalil (2005) and WHO (2005, 2006a, 2006c).

The AAI partnership, however, has generated other practical, strategic, and normative contributions. The next section discusses AAI contributions, challenges, and consequences in national and global governance of ARV treatment access.

AAI Practical, Strategic, and Normative Contributions

Although the AAI has had diminishing and limited success as a mechanism to expand treatment access in the global South, many firm respondents claimed that it performed an important role as a catalyst for global scale-up. Reductions in drug prices allowed governments to contemplate large-scale treatment programmes and mobilise requisite resources and infrastructure (Respondent 29-1, personal interview, March 24, 2011; Sturchio, 2004). The partnership also created new spaces for industry and UN dialogue and collaboration (Respondent 29-1, personal interview, March 24, 2011).

Several firm respondents also emphasised the partnership's role in prompting new business models and market expansion. Engagement through the AAI encouraged firms to employ differential pricing approaches for ARV medicines and explore patent flexibilities. Many of these firms have since developed access programmes which are now typically housed within commercial operations rather than through a CSR or government relations department, which, according to a Clinton Foundation (CHAI) representative, "is a positive development for sustaining access programmes" (Respondent 1-5, personal interview, March 24, 2011).

The AAI also compelled pharmaceutical firms to think seriously about expanding access to their medicines in developing countries, or what more than one pharmaceutical firm respondent referred to as "non-traditional markets" (J. Pender, personal interview, September 4, 2008). Prior to the AAI, one firm respondent suggested that very few firms had "any imagination for this" (Respondent 29-1, personal interview, March 24, 2011). After joining the AAI, many pharmaceutical firms broadened their access strategies, joined product development partnerships, and engaged in other public-private interaction in global health. Thus, the AAI may have helped mobilise efforts to expand treatment access, new forms of public-private interaction, and commercial activity in global health.

AAI Practical, Strategic, and Normative Challenges and Consequences

This study has emphasised the importance of going beyond functional and value-added evaluations of public-private partnerships in health. Therefore, the AAI should be evaluated not only in terms of its value-added contributions as measured by the number of treatment enrolments, but also with respect to the correspondence between partnership

objectives and practical, strategic, and normative contributions and outcomes. This chapter argues that the AAI's limited and diminishing success in fulfilling its objectives is the result of its bilateral, narrow, and private business actor tactical approaches to treatment access. Its chief successes lie in its role in mobilising new governance and normative agendas in global health, which ultimately may present practical, strategic, and normative consequences for national and global health governance.

The AAI has had limited success in realising its objectives around global treatment access and forging new forms of public-private cooperation "to respond to the specific needs of individual countries, with respect for human rights, equity, transparency and accountability" (WHO/UNAIDS, 2002a, p. 4). For the former, simple accounting confirms that the AAI represents a modest and diminishing contribution to global treatment access. Differential pricing has not been competitive, and while licensing, particularly by Gilead, has expanded generic production, studies (Waning, Diedrichsen, et al., 2010; Waning, et al., 2009) have shown that Indian generics producers have been at the forefront of expanded ARV supply.

Broad consensus among civil society, government, and knowledgeable observer respondents confirmed that the differential pricing strategy has limited utility to expand access; rather, "robust generic competition" (Respondent 12-2, personal interview, March 31, 2011) has been integral to drug affordability and availability. However, patent monopolies inherently limit the field of producers, potentially driving up prices and undermining affordability. Given firms' unwillingness or inability to offer competitive prices, the AAI failed to significantly expand access to originator medicines. Firms have

been more successful in enhancing access through voluntary licensing and patent nonenforcement; however, given the scale and scope of need, current licenses and restrictions are not sufficient to meet current and future treatment needs.

The second objective of the AAI, to develop a partnership governed by principles of human rights, equity, transparency, and accountability, has also confronted serious challenges. First, the partnership has suffered from governance and operational challenges, particularly around representation, leadership, accountability, and coordination. Operating under weak governance guidelines, AAI partners interacted only minimally (Respondent 26-1, personal interview, August 25, 2008), had challenges working through disputes (Respondent 29-1, personal interview, March 24, 2011), lacked support and leadership from UN agencies (Respondent 29-1, personal interview, March 24, 2011; WHO/UNAIDS, 2002a), and frequently conducted negotiations outside of UN oversight (Krikorian, 2002).

Furthermore, countries are poorly and inequitably represented in the AAI partnership, with bilateral bargaining processes compromising country negotiating positions (Thomas, 2002) and tiered pricing leaving countries essentially at "the mercy of companies" (T. Amin, personal interview, March 24, 2011). Ultimately, given the inaccessible and unaccountable governance structure of the AAI (see Table 6-2, Chapter Six), it is difficult to assess country representation and bargaining positions.

These challenges have undermined partnership transparency and accountability. Furthermore, individual firms within the partnership unsystematically adopted transparent governance practices. For example, there have been issues with pricing transparency both

in the early years of the AAI when negotiations determined ARV prices and later when firms developed standardised approaches using pricing tiers. It has been difficult to discern the mechanisms for price setting. A former pharmaceutical executive admits, "pricing by pharma is very unique... it tends to resemble something like throw the dart and that looks good..." (Respondent 29-1, personal interview, March 24, 2011). Currently, 50% of the AAI firms (Abbott, BI, Gilead, Merck, and ViiV) publish first-tier prices, yet none of the firms defines nonprofit prices. It is not clear if prices are ex-factory prices or include other costs. Poor pricing transparency complicates purchasing decisions and obstructs comparisons across firms to support treatment programme affordability.

There is also a critical absence of transparency around voluntary licensing and technology transfer arrangements. Voluntary licenses, in particular, have very poor transparency. Firms rarely disclose licensing terms, including restrictions or requirements around agreement duration, geographic scope, products, and marketing. Several public authorities and civil society and knowledgeable observer respondents agreed, "As a general rule, these agreements are not publicly available" (Respondent 12-2, personal interview, March 31, 2011). Furthermore, very few firms provide anything more than brief descriptive accounts in annual pharmaceutical CSR reports on their technology transfer policies and initiatives. These reports offer no specifics on transfer of technology, human, organisational, or informational resources, and thus it is difficult to gauge contributions supplied through these arrangements.

The AAI's limited success in achieving its objectives is rooted in its bilateral, narrow, and tactical accommodation strategy. The AAI came to resemble an arrangement

of eight disjointed programmes, rather than a broad coordinated partnership. The unsystematic approach to treatment access and the patchwork arrangement of disparate access programmes meant that partner states could not expect transparency, cohesion, or accountability through the Secretariat, firms, or UN agencies.

Primarily bilateral relations demanded a country-by-country approach in which countries conducted labour-intensive and time-consuming negotiations with multiple firms in order to secure supply agreements for each medicine (WHO/UNAIDS, 2002a). Voluntary licenses have also been negotiated on a case-by-case basis. The newly formed Medicines Patent Pool[177] provides a facility for sharing intellectual property on HIV medicines. To date, however, the Pool has had limited buy-in from AAI firms and other originator pharmaceutical firms. Only one firm, Gilead, has agreed to license its patents to the pool; however, these licenses have met with criticisms similar to those identified throughout this chapter (I-MAK & ITPC, 2011; T. Rosenberg, 2011).

Although collaboration challenges are partly a function of sensitivity around anticompetitive practices, they also reflect the AAI's failure to rationalise negotiations, obtain pricing transparency, and implement rigorous accountability procedures, including giving, taking, and holding to account. The AAI Secretariat reported only sporadically on partnership activities, while partners individually reported (with varying degrees of detail and transparency) through commercial or CSR annual reports. The AAI lacked formal

[177] Established in December 2009 by the UNITAID Board of Directors, the Medicines Patent Pool engages with ARV patent holders to explore possibilities of licensing their patents to the Pool. The Medicines Patent Pool then negotiates licenses with interested generic producers. For more information, see: www.medicinespatentpool.org.

procedures for dispute resolution and/or sanction (holding to account), and failed to provide equitable and representative procedures for taking account of governance and negotiation processes.

These challenges, in part, reflect the reality that commercial firms are primarily independent and competitive, not collaborative, entities. A former Boehringer Ingelheim employee emphasised, "there's no such thing as the pharmaceutical industry that acts in a coordinated manner; that image is false" (Respondent 29-1, personal interview, March 24, 2011). This respondent stressed that AAI firms "are led by some pretty big egos. These were five highly competitive companies that agreed to come together—that in itself was extraordinary" (ibid.). Their willingness to come together under the AAI banner, however, appears more symbolic than purposeful. Firms continued to behave as independent and competitive entities, failed to disclose pricing information, and prioritised commercial interests over access and partnership goals.

Consequently, many of the access strategies and approaches pursued by AAI member firms were narrow in terms of scope of contribution and coverage, making their overall contribution to AAI objectives similarly narrow. Although individual firms' access programmes vary in terms of scope and eligibility, all have geographic restrictions that discriminate between the very poor or the richer poor (lower-middle income and middle-income countries) (Krikorian, 2002). While eligibility criteria provide differential prices, patent nonenforcement, and minimal voluntary licensing to Sub-Saharan African countries, programmes exclude large populations of people living with HIV/AIDS in lower-middle income and middle-income countries. Several AAI firms also recently

announced reversals in price discounts for middle-income countries. Abbott no longer provides discounts on one of its drugs to low and lower-middle income countries, and ViiV announced in July 2011 that it would no longer negotiate discounts with middle-income countries. Merck has also announced that it will not provide discounts on raltegravir to 49 middle-income countries (MSF, 2011b). MSF (2011b) notes that middle-income countries like Brazil pay approximately $5,800 per patient per year for raltegravir, while it is offered to LDCs at $675. The first-tier price, however, is still significantly higher than common first-line generic regimens[178] (ibid.).

Conclusion

The UNGASS vision of treatment for all and the UNAIDS concept of universal coverage did not narrowly imply treatment only for the very poor or the very rich. The AAI strategy, therefore, has had important equity distributional consequences for treatment access. The AAI also opted to approach access in narrow terms, defining affordability and availability as primarily relating to pricing, and secondarily to restrictive patent flexibilities. This accommodation strategy offered modest concessions, while neutralising and co-opting elements of the social struggle through adoption of a new policy paradigm and a more 'socially tolerable' approach to pricing and patent flexibilities. This strategy also helped to minimise pharmaceutical firm exposure to political pressures, recoup reputational losses, protect patent monopolies, and foreclose broader deployment of TRIPs flexibilities or reforms. The AAI has not been convincing

[178] Raltegravir, an integrase inhibitor, is a third-line drug (MSF, 2010).

in either its capacity or its commitment to expand access to older and newer HIV medicines; the former is predominantly dispatched through generic competition, while the latter continues to see high prices and a small supply of generic producers. As a result, LDCs and Sub-Saharan African countries may continue to rely on the AAI to access newer medicines, but at a substantial cost. Several representatives from AAI firms, meanwhile, indicated that they feel that there is no longer a need for the partnership. The AAI remains operational, but is under review (J. Pender; Respondent 64-1, personal interview, September 4, 2008; April 5, 2011).

The AAI prompted new governance and normative agendas in global health and represented one of the first large-scale public-private interactions in HIV/AIDS treatment access. Thus, while AAI practical and strategic contributions to global treatment access cannot be discounted, ultimately the partnership's prospects as a mechanism for expanding treatment access are constrained by its narrow, bilateral, tactical, and weak governance and accountability framework.

Chapter 6: Case Studies 2, 3, and 4; African Comprehensive HIV/AIDS Partnership, Diflucan Partnership Programme, and Secure the Future Partnership

This chapter investigates three access-oriented public-private partnerships: the African Comprehensive HIV/AIDS Partnership, the Diflucan Partnership Programme, and the Secure the Future Partnership. Two of the case studies (ACHAP and STF) provide funds and supports to enhance access to ARV treatment and HIV prevention and care in selected countries in Sub-Saharan Africa. The Diflucan Partnership Programme donates an antifungal medicine for the treatment of two AIDS-defining illnesses, and supports health system capacity building through educational and training programmes in multiple countries in the global South. As in Chapter Five, this chapter proceeds with historical and operational investigations and subsequent within and cross-case analyses of practical, strategic, and normative contributions, challenges, and implications.

Case Study 2: African Comprehensive HIV/AIDS Partnership (ACHAP)

ACHAP history, rationale, and objectives.

Similar to the other cases in this study, the African Comprehensive HIV/AIDS Partnership is an access partnership that evolved in an era of intense social pressures which exposed global inequities in access to HIV medicines and positioned originator pharmaceutical firms within the nexus of this crisis. Merck, specifically, was not only a party to the South African Pharmaceutical Manufacturers Association lawsuit, but also a focus of civil society contestation. Merck's drugs, EFV and IDV, first patented in 1993 and 1996, respectively, had come under scrutiny for high prices and monopolistic supply (MSF, 2010). Merck respondents reflected on this period and described the firm as

"frustrated with being blamed so much" (Respondent 42-1, personal interview, June 23, 2008) and feeling compelled to engage in access issues (Respondent 26-1; 37-1; 42-1, personal interview, August 25, 2008; August 15, 2008; June 23, 2008).

Despite activist demands for pricing and patent reforms (that went unheeded for several years prior before Merck joined the AAI), the firm decided to embark upon a new P^3H with the Government of Botswana: the African Comprehensive HIV/AIDS Partnership. According to respondents, Merck felt that it was not sufficient to provide price reductions or other flexibilities and needed "to link prevention, care, and support" (Respondent 42-1, personal interview, June 23, 2008) and decided on a P^3H model as a "way to test this hypothesis and learn more about how our medicines got to the people" (Respondent 26-1, personal interview, August 25, 2008). Merck clearly understood the need to engage in access issues during this period of crisis, yet did not wish to offer more significant accommodation to oppositional demands. Instead, they opted to respond to social contestation through a single-country partnership which would offer medicine and resource infusions to Botswana- an upper middle income country - and an enhanced presence for the firm in a high profile issue and country.

To proceed with partnership plans, Merck approached private foundations and requested support for their proposed P^3H. In January 2000, the Gates Foundation awarded US$50 million to the partnership (Respondent 37-1, personal interview, August 15, 2008). In July 2000, representatives from Merck, the Gates Foundation, and the Government of Botswana agreed to a US$100 million (US$50 million each from Merck and the Gates Foundation), five-year, P^3H with the objective of enhancing access to

HIV/AIDS prevention, treatment, and support services (Respondent 26-1; 42-1, personal interview, August 25, 2008; June 23, 2008; Ramiah & Reich, 2006). Within months of the agreement, President Mogae announced that Botswana would become the first state in Sub-Saharan Africa to offer a national publicly subsidised ARV treatment programme. To support this effort, Merck agreed to donate two of its ARVs (EFV and IDV) to the Government of Botswana (Respondent 8-1; 42-1, personal interview, August 15, 2008; June 23, 2008). In January 2002, the Infectious Disease Care Clinic became the first national site to offer ARV treatment (Wester et al,) and by December 2004, the programme had expanded to 32 sites (Ramiah & Reich, 2005).

The ACHAP vision of providing a comprehensive approach to HIV/AIDS prevention, care, support, and treatment was implemented through grants to local and international private, community-based, and nongovernmental organisations, as well as through direct financial, technical, and human resources support to Central and District levels (Moeti, 2009; Ramiah & Reich, 2005). The first round of grants supported nine projects (see Table 6-1) totalling US$13.3 million and the second round, beginning in 2003, supported 13 projects totalling just over US$7.3 million (Moeti, 2009).
five years, however, the ACHAP had only been able to spend 30% of its funds, and the partners agreed to an extension to 2009 (Respondent 42-1, personal interview, June 23, 2008). In 2009, the ACHAP extended another five years with the award of an additional US$29.9 million grant (Moeti, 2009). Merck announced that it would continue to donate two of its ARVs but intended to scale back the donation over a five-year period (Respondent 49-1, personal interview, April 29, 2011).

ACHAP governance and operations.

Former board members and Merck employees admitted that ACHAP governance proceeded with only an agreement in place to work together on broad partnership goals, a small group of five Directors, and very few specifics (Respondent 26-1; 42-1, personal interview, August 25, 2008; June 23, 2008). In the partnership's early years, the Board of Directors chiefly consisted of representatives from Merck and the Gates Foundation; and developed strategies and planning, vetted grant proposals, and assumed financial control for the P^3H (Ramiah & Reich, 2006). The Board of Directors has never had representation the Government of Botswana, who was supposedly "fine with that" (Respondent 42-2, personal interview, June 23, 2008). Currently, Merck employees occupy 40% of Board positions, Gates Foundation representatives occupy 20%, and representatives from academic and nongovernmental organisations occupy the remaining 40% of seats.[179]

In 2004, the ACHAP established the Madwike Forum, a governance structure with representation from the Government of Botswana, ACHAP Board of Directors, and the Botswana National AIDS Coordinating Agency. The Madwike Forum meets biannually to discuss strategies, review budgets, address partner concerns, and evaluate progress (Busang, 2008; Moeti, 2009). Local administrative operations in Gaborone are implemented by a management team and led by a project leader (Ramiah & Reich, 2006), who reports to the Board of Directors. The ACHAP office in the USA controls

[179] As of June 2011, the ACHAP Board of Directors includes representatives from Merck, two private sector organisations, the Gates Foundation, the African Leaders Malaria Alliance, the University of Botswana, Health Systems Trust in South Africa, and the Harvard AIDS Institute. For more information, see: http://www.achap.org/achap_content.php?cid=52.

partnership funds and transfers them to the Gaborone office to support operational costs and grant funding (Respondent 42-1, personal interview, June 23, 2008).

As noted in Table 1-1 and Table 6-1, the ACHAP has provided funds and support for capacity building, health resources, and health care services. It has funded training and education programmes for health professionals (through KITSO and staff secondments),[180] technical and policy capacity building (human resource secondments and salary support), salaries for health professionals (grants, secondments, and salary support), and laboratory equipment, including CD4 machines, medical supplies, and infrastructures (Moeti, 2009). For example, the ACHAP funded the development of a nationwide clinical laboratory centre, the construction of resource centres and ARV treatment buildings, and upgrades to treatment sites (Respondent 8-1; 42-1, personal interview, August 15, 2008; June 23, 2008; Moeti, 2009). It has also provided funding and donations for health and treatment services as well as psychosocial and socioeconomic programme funding through its grantees.

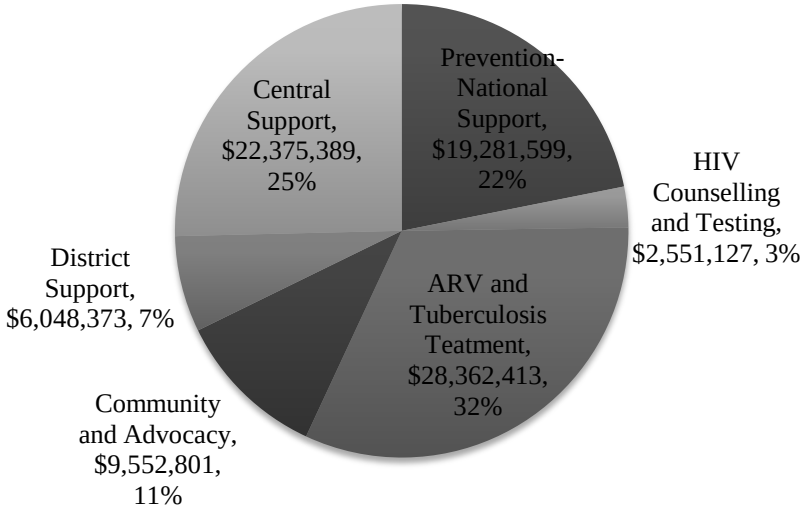
KITSO was an instrumental ACHAP grantee in support of the partnership's objectives for expanded access to HIV care and treatment. Supported by a US$6.7 million grant, and in partnership with the Harvard HIV/AIDS Institute, KITSO has collaborated with clinics and hospitals and provided training for health professionals on HIV/AIDS

[180] The ACHAP seconded employees from Merck and from the Gates Foundation to Central and District level offices in the Government of Botswana (Moeti, 2009). The ACHAP reported that it trained over 500 government, NGO, and other actors in project management, monitoring and evaluation, leadership skills, media relations, and computer skills (Distlerath & Macdonald, 2004).

disease management and treatment, thus supporting government efforts to expand treatment sites and access (Bussmann et al., 2008; Wester, Bussmann, et al., 2005).

At the end of 2009, the ACHAP had disbursed US$104 million across six programmatic areas, including HIV prevention, testing, ARV and tuberculosis treatment, advocacy and mobilisation programmes, and Central and District level supports, with the latter accounting for the largest funding category (see Figure 6-1). In addition, Merck donated US$66.9 million worth of ARV medicines (Moeti, 2009).[181]

Figure 6-1: ACHAP Expenditures, 2001-2009



Source: Moeti, T. L. (2009). ACHAP Final Annual Progress and Expenditure Responsibility Report, 2001-2009 *Return of a Private Foundation, Form 990-F, Department of the Treasury, Internal Revenue Service*. Whitehouse Station, NJ: Merck Foundation

In 2009, the ACHAP entered its second, and likely final, stage, and maintains support of ARV treatment activities and some continuing grants (Moeti, 2009). The Government of Botswana has begun transitional activities, including absorbing ACHAP-

[181] The 2009 501(c)(3) filing for Merck Foundation included a final report for the ACHAP covering partnership activities from 2001- 2009. This report listed the value of ARV donations at US$66,947,020.67, but did not indicate if the valuation is based on wholesale, retail, or differential prices.

supported positions and moving to new procurement options with the phase out of Merck's donation (ibid.).

Case Study 3: Diflucan Partnership Programme (DPP)

DPP history, rationale, and objectives.

In 1999, prior to the development of the Diflucan Partnership Programme, worldwide sales of Diflucan were US$1002 million (Perez-Casas, et al., 2001). During this same period, Pfizer priced this drug at approximately US$17 per day (real dollars) in South Africa (J. Berger, personal interview, November 30, 2007; ACT-UP, March 22, 2000). This price, however, was two and half times the average daily wage in South Africa; and given lifelong treatment needs for cryptococcal meningitis[182], was prohibitive for many people (ACT-UP, March 22, 2000). Pfizer respondents acknowledged that the firm was under considerable pressure to lower their prices and issue voluntary licenses (Respondent 3-5; 7-1; 10-; 24-1; 39-1; 44-1, personal interview, August 19, 2008; July 23, 2008; March 25, 2011; March 31, 2011; March 31, 2011). Several denied, however, that the DPP was a response to these pressures, or as Professor Brook Baker from Health GAP charged, a vehicle to avert generic entry and protect patents (personal interview, September 23, 2008). Instead, respondents claimed that "we [understood] the concerns of the advocacy community... and were trying to be a good corporate citizen" (Respondent 7-1, personal interview, July 23, 2008) and "do something meaningful" (Respondent 24-1, personal interview, March 25, 2011). Pfizer respondents underscored the firm's caring

[182] Treatment for cryptococcal meningitis requires lifelong suppressive therapy (Perez-Casas, et al., 2001).

culture and frequently appeared frustrated by the so-called "vilification of [their] industry" (Respondent 7-1, personal interview, July 23, 2008). However, several of the respondents discussed the highly political character of HIV treatment access and the choice of a donation programme as a mechanism to avoid further scrutiny of Pfizer pricing and licensing practices. Dr. Anne Reeler of Axios International (former DPP Administrator), for example, claimed that a donation programme would be "unassailable," "cleaner and simpler," and allow Pfizer to brand its drugs in partner countries (personal interview, August 19, 2008).

Civil society organisations, including the TAC and MSF, greeted Pfizer's offer with scepticism. The TAC issued a press release denouncing the offer as a means to avoid reasonable patent and pricing flexibilities, protect patents, and insulate the firm from further scrutiny on drug pricing (TAC, 2000). Mark Heywood, Executive Director of the civil society organisation Section 27 (formerly AIDS Law Project)[183] suggested, "if [Pfizer] had lowered its price to what generic makers charged, it would have shown the world what its profits were... people elsewhere might have started wondering why it has to charge so much" (Quoted in: Harris, 2001, p. A1). Jonathan Berger from civil society organisation, Section 27, interpreted the offer as a way to protect Pfizer's monopoly on fluconazole in South Africa given that the patent was due to expire shortly[184] (personal

[183] Section 27, based in Johannesburg, provides legal support to the Treatment Action Campaign and other civil society organisations on issues relating to HIV and the law. Website: www.alp.org.za.

[184] Pfizer's patent on fluconazole in South Africa expired in 2001, and elsewhere by January 29, 2004. For a backgrounder on fluconazole, including patent number and status, see: http://www.cptech.org/ip/health/fluconazole/info.html.

interview, November 30, 2007). MSF also issued a press release underlining concerns with the sustainability of a donation programme and called for alternative access reforms, including price reductions and patent flexibilities (MSF, April 3, 2000).

Details soon emerged regarding the terms of the DPP, which prompted continuing protests. Pfizer's offer contained several restrictions, including time limits (two years), costs (limited to US$50 million), use of the drug only for cryptococcal meningitis (despite other indications for people living with HIV), and treatment sites (only in public sector clinics) (J. Berger, personal interview, November 30, 2007; Waldholz, 2000b; Zimmerman, 2000). Civil society organisations criticised these terms and called upon the Government of South Africa to issue compulsory licenses for generic production or parallel importation (MSF, June 20, 2000).

Following months of protests and key events[185] such as the Christopher Moraka Defiance Campaign, the importation of generic fluconazole from Thailand, and a filing to the regulatory authority in South Africa, the Government of South Africa and Pfizer finally settled on an agreement for the DPP in December 2000. The DPP would donate Diflucan for the treatment of cryptococcal meningitis and oesophageal candidiasis with the objective of increasing drug access (Respondent 24-1, personal interview, March 25, 2011) and "improv[ing] the quality of life of people living with HIV/AIDS and suffering from HIV-related opportunistic infections" (Pfizer, 2010). The DPP included the donation and a training programme for health workers in the treatment of opportunistic infections.

[185] Chapter Three overviewed these events.

The P^3H was limited to two years and restricted to distribution only to public sector treatment sites (Respondent 7-1, personal interview, July 23, 2008). In June 2001, Pfizer announced expansion of the DPP to the 13 countries in the South African Development Community (Pfizer, 2010). The following December, the programme expanded to 49 high-HIV-burden LDCs (ibid.). In June 2004, the DPP opened eligibility to all developing countries with HIV prevalence above 1% and to nongovernmental health care delivery organisations (ibid.). As of 2011, the DPP continues to supply Diflucan to partner countries; however, following a review in 2008 (Pfizer, 2010), it now operates in maintenance mode (ibid.) and is attempting to reduce expenses (Respondent 24-1, personal interview, March 25, 2011).

DPP governance and operations.

Pfizer Worldwide Philanthropy, headquartered in New York City, governs the DPP with input from leadership from commercial departments (Respondent 7-1, personal interview, July 23, 2008; Pfizer, 2010). Local Pfizer offices in partner countries coordinate DPP activities, but generally do not engage in high-level governance or decision-making (Respondent 7-1, personal interview, July 23, 2008).

The South African Ministerial Working Group, formed in 2001, coordinates DPP activities, including drug distribution, training, and reporting activities (Respondent 39-1, personal interview, March 31, 2011). The group is comprised of representatives from provincial health departments, Correctional Services, Military Health Services, NGOs, and Pfizer (Pfizer, 2010). It meets only as issues arise, although, in the early years, it met quarterly or biannually (ibid.). While the South African Ministerial Working Group

serves as a model for similar groups in other countries, only a few countries have local DPP governance structures; otherwise, partnership administration is subsumed within national HIV/AIDS units (ibid.).

The DPP employs the services of consulting and nongovernmental organisations to coordinate donation, training, and evaluation activities. From 2003 to 2008, Axios International, a consulting firm headquartered in Paris, France, processed applications, managed the ordering and refill process, and conducted monitoring and evaluation (A. Reeler, personal interview, August 19, 2008). Furthermore, until 2008, IMA World Health, a faith-based NGO in New Windsor, Maryland, coordinated product distribution to partner countries (Respondent 7-1, personal interview, July 23, 2008). IMA World Health worked with the International Dispensary Association in Amsterdam to warehouse, package, and transport Diflucan product to partner countries (ibid.). In 2008, Pfizer transferred DPP administration responsibilities to Direct Relief International, an NGO in Santa Barbara, California (Pfizer, 2010).

The International Dispensary Association delivers six-month supplies of Diflucan to a country's port of entry, which must enter without additional taxes or duties (Respondent 7-1, personal interview, July 23, 2008; Wertheimer, et al., 2004). The local Pfizer office, Central Medical Stores, or the Ministry of Health process shipments and prepare product for distribution (Respondent 39-1, personal interview, March 31, 2011).

From 2001 to 2005, the International Association of Physicians in AIDS Care developed and implemented DPP training programmes (Respondent 24-1, personal interview, March 25, 2011; Pfizer, 2010). Training included educational materials,

information on patient diagnosis, and care and treatment protocols (ibid.). Materials are still available through Direct Relief International; however, the DPP no longer offers the training component.

At the end of its tenth year, Pfizer reported that the DPP had provided over US$1.1 billion worth of product to 2400 sites in 63 partner countries and trained 20,000 health professionals (Pfizer, 2010). The section following the Secure the Future case study provides within-case analyses of DPP contributions, challenges, and implications.

The DPP is a complex case of accommodation; conceivably Pfizer could have simply reduced the price of fluconazole to a more socially tolerable (affordable) level and avoided the administrative costs of a more complicated donation partnership programme. Indeed, their decision provides evidence of a strategy of *trasformismo*; the firm pursued a strategy which would maximise corporate legitimation, neutralise social pressures, co-opt government and civil society into its strategy, and offer enhanced control to the firm over both the South African market for fluconazole and its usages.

Case Study 4: Secure the Future Partnership (STF)

STF history, rationale, and objectives.

The Bristol-Myers Squibb Company and Foundation launched the Secure the Future Partnership in May 1999 in South Africa—approximately 15 months after the filing of the PMA lawsuit, to which BMS was a party. BMS holds patents on three ARVs: stavudine, didanosine, and atazanavir (MSF, 2010). Stavudine, at the time an integral

first-line drug,[186] came under civil society scrutiny for its high pricing and monopolistic supply (ibid.) Thus, in addition to protests for its involvement in the PMA lawsuit, the firm faced growing criticism on pricing and patent inflexibilities for this important ARV drug (Respondent 17-3, personal interview, November 20, 2007).

An STF Programme Executive explained that although the firm had been subjected to growing civil society criticism and demands, the decision to engage in a P^3H had more to do with changing global political environments (Respondent 6-1, personal interview, August 1, 2008). The respondent explained that Kofi Annan's statement that "no company and no government can take on the challenge of AIDS alone" (Annan, 1999) and call for "corporate America to do something about the plight of HIV/AIDS" (Respondent 6-1, personal interview, August 1, 2008) inspired BMS leadership to explore proposals for a new P^3H. Peter Dolan, CEO of the BMS Foundation indicated that the firm wished to develop partnerships to "help extend and enhance life and to make a difference ("Secure the Future: An interview with Peter Dolan, Chairman and Chief Executive Officer, Bristol-Myers Squibb Foundation," 2005). Similarly, then, to the ACHAP and DPP, BMS engaged in an access accommodation strategy by developing an on-the-ground presence in high burden, high profile countries while deflecting demands for broad changes to ARV pricing and patents. BMS selected South Africa as one of its first P^3H site, a country which was the site of both growing social contestation from the TAC and MSF, and a high profile lawsuit to which BMS was a party.

[186] In 2010, the WHO recommended phasing out stavudine from first-line regimens (MSF, 2010).

BMS proceeded by forming a technical advisory committee to devise recommendations and cultivate linkages with potential partners (Respondent 6-1, personal interview, August 1, 2008). The committee selected five countries in Southern Africa: South Africa, Lesotho, Botswana, Namibia, and Swaziland. BMS committed US$100 million over five years to the Secure the Future partnership. In 2001, with the support of an additional US$15 million grant, the STF expanded to four countries in West Africa: Burkina Faso, Côte d'Ivoire, Mali, and Sénégal (ibid.).

The objectives of the STF partnership are to "form strong partnerships with the government, organisations, and communities to find innovative, replicable, and sustainable solutions to manage the impact of HIV/AIDS" (BMS, undated). The STF also explicitly focuses on enhancing access to comprehensive HIV care and treatment for women and children in Sub-Saharan Africa (Respondent 6-1, personal interview, August 1, 2008; BMS, 2009c).

One of the first STF activities involved constructing a new HIV Reference Laboratory in Gaborone in 2000 (BMS, 2009a). The Government of Botswana had recently announced a national ARV treatment programme and welcomed the offer from BMS to fund construction of the Laboratory (ibid.). A significant proportion of STF activity between 1999 and 2003, however, involved grant-making to NGOs and researchers. The partnership funded medical studies, an HIV Research Institute, and community outreach programmes (Respondent 6-1, personal interview, August 1, 2008).

In 2003, STF allocated US$30 million for six pilot community-based treatment programmes in five countries (see Figure 6-2) (BMS, 2005b, 2009b). The programmes

provided ARV treatment services as well as testing, health status monitoring, and psychosocial support for patients and families (BMS, 2005b). They also provided health care, community mobilisation, and socioeconomic support, including HIV prevention, food parcels, and income-generating projects. STF also allocated funds to support the development of paediatric ARV treatment clinics, known as Children's Centres of Excellence, to provide care and treatment for HIV-positive and HIV-exposed children (Respondent 33-5, personal interview, November 7, 2008).

STF funded the construction and equipping of Centres of Excellence in Botswana, Lesotho, Swaziland, Uganda, Tanzania, and Malawi. In 2003, the first Centre of Excellence opened in Gaborone (BMS, 2009a) as well as the first community-based treatment clinic in Namibia (BMS, 2009b). ARV clinics in Kwa-Zulu Natal (South Africa), Maseru (Lesotho), Mbabane (Swaziland), Bobirwa Sub-District (Botswana), and Koulikoro District (Mali) and Children's Centres in Lesotho and Swaziland began providing services shortly thereafter, with all centres operational by 2006 (BMS, 2009a). Children's Centres of Excellence in Uganda and Tanzania began offering services in 2008 and 2011, respectively (BMS, 2009a, 2011).

Although STF was originally limited to five years, the partnership initiated new funding commitments from 2003 to 2006, some of which extended to 2011. In 2006, STF announced five-year funding for a Pediatric AIDS Corps programme to support recruitment of up to 250 doctors to provide a minimum of 12 months of service at a Children's Centre of Excellence (Respondent 50-5, personal interview, June 30, 2010).

STF also funded an NGO Training Institute to support capacity building in local NGOs in partner countries (Respondent 6-1, personal interview, August 1, 2008; BMS, 2009c).

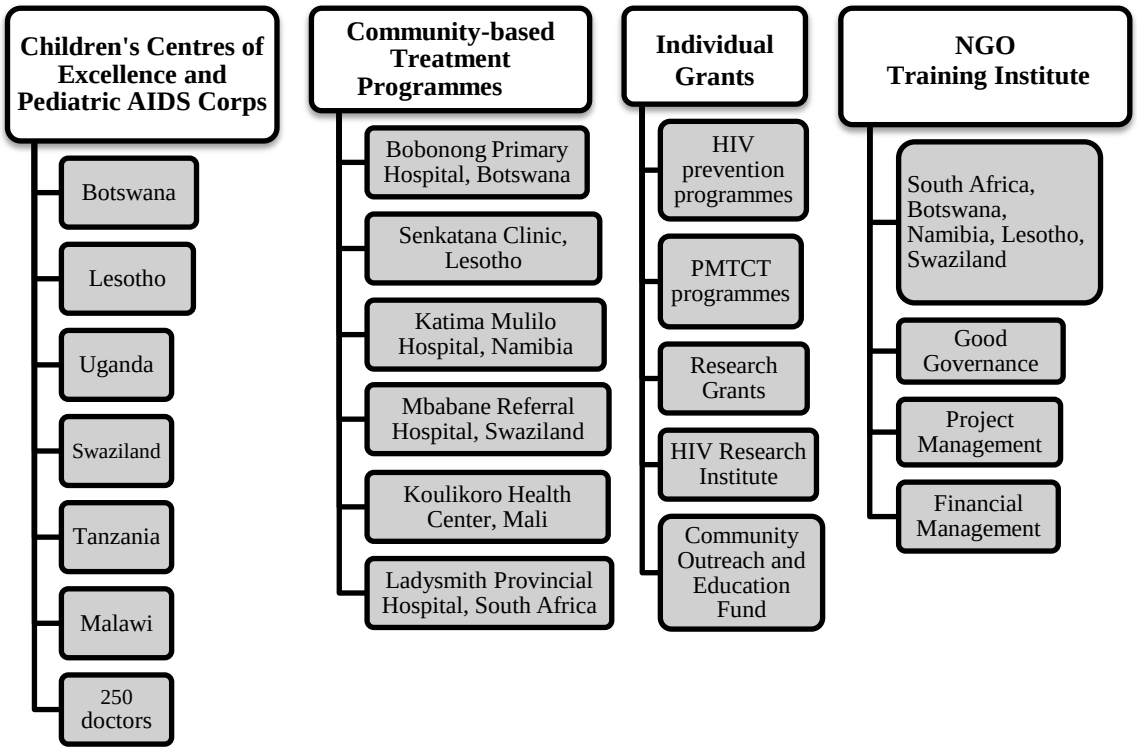
In 2008, STF transformed into a US$2 million skills transfer initiative (Respondent 6, personal interview, August 1, 2008), which recruited 50 faculty members from across Sub-Saharan Africa to offer technical assistance to 11 partnerships in seven countries (BMS, 2009c). There have been no indications from respondents or documentation whether BMS intends to pursue new P^3Hs or other initiatives under its original objectives for expanded access to HIV care and treatment.

STF governance and operations.

STF governance, similar to the DPP, operates without an independent Board of Directors. Foundation and CSR staff in New York and Johannesburg administer the partnership with high-level policy decisions originating from both locations (Respondent 6-1, personal interview, August 1, 2008). STF staff receive grant recommendations from an independent advisory board comprised of representatives from partner countries, who according to an STF Executive "become the mouthpiece for their country" (ibid.).

The STF has focused its grantmaking efforts across four programming areas; Children's Centres of Excellence, community-based treatment programmes, individual grant programming streams, and an NGO training institute (see Figure 6-2).

Figure 6-2: Secure the Future Partnership Sponsored Programmes



Sources: BMS (2009a, undated).

The STF conducts these activities through primarily grant-making activity. Accordingly, it disburses funds to partner countries and grantees, but is not responsible for service delivery or programme administration. BMS staff may participate in project design and management; however, public, private and NGO partners conduct day-to-day administration of programme activity. As an example, STF supplied US$2 million for construction of the Lesotho Centre of Excellence, the Government donated the land, and the Baylor International Pediatric AIDS Initiative oversees operations with Ministry support (Respondent 33-5, personal interview, November 7, 2008; Mizwa, 2008). The Ministry of Health provides an annual subvention to cover operational costs (Respondent

33-5, personal interview, November 7, 2008) and supplies medicines (Respondent 43-5, personal interview, November 7, 2008). The Ministry also pays the salaries of local staff, including support staff, pharmacy technicians, and nurses. Baylor and the STF (through the Pediatric AIDS Corps) fund salaries for clinic doctors (ibid.). Although terms vary across STF-sponsored treatment centres, the Lesotho Centre represents a characteristic Centre of Excellence model and is similar to the community-based treatment model.

The STF also provided grants to NGOs, community-based organisations, and medical and academic institutions to conduct HIV prevention and community outreach programmes and research activities. In total, the STF funded 90 research studies and 1000 community outreach programmes (Respondent 6-1, personal interview, August 1, 2008).

The NGO Institute developed a range of tools and training programmes to support capacity building in local organisations in five countries (see Figure 6-2). The Institute operated as a virtual programme with materials freely available for online download.[187] There is, however, no available data on the programme's reach or implementation, and BMS documentation provides only one reference to Swaziland as an implementation site, and no other details (BMS, undated).

As of 2009, the STF had awarded 230 grants in four programming areas, to a total of US$150 million. Although I obtained BMS Foundation 501(c)(3) tax returns for the years 2003-2009, it was not possible to disaggregate individual grants, and the information was not available through via the STF website or from respondents. The STF

[187] See http://www.securethefuture.com/ngo/.

partnership no longer provides funding to major programme areas, although many formerly sponsored programmes remain operational.

These value added effects are substantial and many of the sponsored programmes, including the Children's Centres of Excellence, have been hailed as important successes in enhancing treatment access (discussed later in the Chapter). The next section of the chapter provides within and cross-case analyses of case studies' practical, strategic, and normative contributions, challenges, and implications.

ACHAP, DPP, and STF Practical, Strategic, and Normative Contributions

Practical and operational contributions.

The three case studies in this chapter provide extensive value-added contributions to HIV treatment access. Partnerships donate HIV medicines, including ARVs and fluconazole, construct and/or upgrade healthcare and treatment facilities, develop and support HIV prevention, care, and treatment programmes, and offer education and training programmes for health practitioners and nongovernmental organisations. Partnership respondents and documentation claim that these practical contributions support expanded treatment access, strengthen health systems capacity building and governance, and reduce HIV transmission, morbidity and mortality.

ACHAP documentation claims that partnership efforts in conjunction with the Government of Botswana's commitment to universal ARV treatment helped prevent 53,000 deaths between 2000 and 2007 (Moeti, 2009). Furthermore, the ACHAP claims that it supported expanded treatment coverage from 5% in 2000 to 80% in 2007 (ibid.). Merck respondents maintained that the ACHAP also strengthened health systems through

training programmes, clinical preceptorships,[188] and technical and human resources support to Central and District offices within the Ministry of Health (Respondent 26-1; 42-1, personal interview, August 25, 2008; June 23, 2008).

Respondents from the DPP made similar claims on the partnership's impacts on health system strengthening and access to fluconazole. Dr. Anne Reeler (personal interview, August 19, 2008) pointed to studies (Reeler et al., 2004; Vian, et al., 2007) which demonstrated that the DPP, particularly through its training component, supported capacity building by equipping health professionals with new skills and tools for diagnosing and managing the treatment of opportunistic infections. Another respondent pointed to expanded access to fluconazole and declining levels of morbidity and mortality related to cryptococcal meningitis and esophageal candidiasis (Respondent 24-1, personal interview, March 25, 2011). This respondent remarked that the partnership's chief successes lie in its capacity to "help thousands of patients and reach people who would otherwise never have access to this drug" (ibid.).

The STF partnership and ARV treatment clinic staff concurred that the partnership's most important contribution has been expanded access to treatment and, consequently, declining morbidity and mortality. BMS documentation (2009a, 2009b) reports that ARV treatment programmes have expanded access for adults and children,

[188] The ACHAP provided funds for health practitioners in Botswana to receive training and mentorship in HIV/AIDS care and treatment with experts from outside Botswana (Respondent 42, personal interview, June 23, 2008).

the latter of which is a severely underserved population in global treatment access.[189] BMS and partner documentation claim that STF sponsored community based treatment programmes provided HIV-related health care services to 17,000 people, of which 8000 had been placed on ARV treatment (BMS, 2009b). BMS (2009a) estimates that the Centres of Excellence deliver care and treatment to over 28,000 HIV-positive children, half of which receive ARV treatment. These Centres have also achieved high rates (greater than 95%) of treatment adherence, and have significantly reduced mortality rates for children accessing clinic services (ibid.).

A Centre of Excellence physician and the Baylor International Pediatric AIDS Initiative Executive emphasised the role of STF financial support for the construction of "state of the art clinics" (Respondent 33-5, personal interview, November 7, 2008) that help to "attract and retain excellent health professionals in resource-limited settings" (Respondent 50-5, personal interview, June 30, 2010). Ministry of Health respondents from Lesotho and Swaziland agreed that STF funds provided added value to health systems (Respondent 57-2; 62-2, personal interview, May 25, 2009; November 12, 2008; "Government efforts in Lesotho: An interview with Dr. Motloheloa Phooko, Minister of Health and Social Welfare, Lesotho," 2005; Understanding HIV in Swaziland: An interview with Dr. John M. Kunene, Principal Secretary, Government of Swaziland, Mbabane, Swaziland," 2005). Partnerships clearly provide considerable value-added funds, products, infrastructures, and supports within national health governance.

[189] In 2007, only 8% of children in low and middle income countries in need of ARV treatment had access (Dionisio et al., 2007). This figure was even lower in 2003, when STF opened its first Centre of Excellence in Gaborone. BMS (2009a) estimated paediatric ARV coverage in 2003 at 2%.

Strategic and normative contributions.

Respondents identified partnership strategic contributions to addressing health gaps and deficiencies, including supports for health policy development, implementation, and innovation. As with the AAI, respondents stressed innovative strategic partnership contributions to national and global health governance. ACHAP respondents and documentation highlighted the partnership's role in mobilising and supporting the Government of Botswana's national ARV treatment programme. Although a former Merck employee and ACHAP board member acknowledged that the national programme was conceived prior to ACHAP, this respondent suggested that "the availability of ACHAP resources influenced [the Government's] confidence in being able to provide ARVs to their population" (Respondent 42-1, personal interview, June 23, 2008). An ACHAP evaluation study by Ramiah and Reich (2005) supports this claim, arguing that the partnership "played an important role" (p. 550) in the roll-out of the national treatment programme. This evaluation study was funded through an ACHAP grant.

If indeed the ACHAP performed important roles in the implementation of the national treatment programme, and, conceivably, Merck's donation of ARVs as well as an infusion of US$100 million buttressed government commitments, then its strategic contribution may arguably extend beyond Botswana to other developing countries. Botswana was the first African state to offer a publicly subsidised national treatment programme. Wester et al. (2005) argue that its success confirmed that large-scale treatment programmes were possible in resource-limited settings, thus prompting other countries to expand access to treatment. ACHAP, therefore, not only supported and

possibly mobilised treatment access in Botswana, but also may have had an indirect effect on treatment agendas in Sub-Saharan Africa and elsewhere in the global South.

Respondents and partners made similar claims about the role of the STF partnership in mobilising and expanding paediatric treatment. A paediatrician at the Lesotho Children's Centre of Excellence stressed that prior to the Centre very few children had access to paediatric care, let alone treatment, noting that the national referral hospital had only one staff paediatrician in 2005 (Respondent 43-5, personal interview, November 7, 2008). Through STF funding, the Lesotho Centre is now staffed with seven nurses, twelve doctors, four social workers, five pharmacy technicians, and various support staff (Respondent 33-5, personal interview, November 7, 2008). The other five STF partner countries also experienced paediatric treatment gaps and health human resource shortages; they now report substantial expansion in treatment access and health human resources as a result of STF support (Respondent 50-5, personal interview, June 30, 2010; BMS, 2009a).

Chapter Four noted that P^3Hs may help to prompt action in neglected policy areas and around specific diseases. State and interstate, pharmaceutical firm, and partnership respondents provided support for these claims and argued that additional resources, as well as private business actor involvement in ACHAP and STF countries, mobilised treatment access agendas and programmes. A former Minister of Health in Lesotho stated that "Secure the Future has really broken the ground for us in Lesotho, and we mean to forge ahead in rolling out [paediatric treatment]" ("Government efforts in Lesotho: An interview with Dr. Motloheloa Phooko, Minister of Health and Social Welfare, Lesotho,"

2005, p. 47). Dr. Gabriel Misango Anabwani, Director of the Botswana Centre of Excellence, remarked that the STF "catalyze[d] and transform[ed] HIV care on our continent, especially in Southern and Western Africa" ("The pursuit of excellence: An interview with Dr. Gabriel Misango Anabwani, Director, Botswana-Baylor Children's Clinical Center of Excellence, Gaborone, Botswana," 2005, p. 50).

Chapter Four also suggested that P^3H activities tend to draw upon diverse groups of public and private actors, thus empowering "old and new actors" (Brugha, 2008, p. 72). The ACHAP, STF, and DPP partnerships relied on diverse groups of actors for programme development and implementation and empowered public and private actors through grant making to existing research and outreach programmes, training and educational programmes, and capacity-building supports in national health governance.

For the latter, case study partnerships supplied expertise, mentorship, and efficient business strategies to build national governance capacity. The ACHAP partnership seconded technical and policy experts to government ministries to assist in the development of the National HIV/AIDS Strategy (Respondent 42-2, personal interview, June 23, 2008). Seconded staff also assisted the Ministry of Health in developing a national monitoring and evaluation system (Distlerath & Macdonald, 2004). DPP and STF partnership respondents referred to partnerships' roles in building health system capacity through training programmes for public sector officials. Dr. John Kunene, Principal Secretary of Health in Swaziland, notes that STF-supported training has "had a significant effect in Swaziland...[and] has helped us build knowledge and capacity" ("Understanding HIV in Swaziland: An interview with Dr. John M. Kunene, Principal

Secretary, Government of Swaziland, Mbabane, Swaziland," 2005, p. 48). Partnerships, therefore, may provide important strategic contributions, including policy and programmatic action in health systems and capacity building.

Many private business actor respondents argued that private business approaches and efficiencies were instrumental to strategic contributions and transformations. Private business actor respondents from Groups 1 and 5 universally referenced business "approaches," "efficiencies," and/or "competencies" as key strategic contributions in public-private partnerships. Many of these respondents alluded to inefficient and complex organisational procedures and cultures in government Ministries, juxtaposing these qualities against private business rationality, efficiencies, concern for market forces and profitability, and attention to performance metrics and outcomes.

ACHAP respondents and documentation maintained that the partnership's success in supporting HIV prevention and treatment and building governance capacity originates from its reliance on private business "skills and resources" (Respondent 26-1, personal interview, August 25, 2008) and "mode of working" (Moeti, 2009). BMS leadership suggested that the success of the STF partnership resulted from "treat[ing] philanthropy as if it were a business enterprise" ("Secure the Future: An interview with Peter Dolan, Chairman and Chief Executive Officer, Bristol-Myers Squibb Foundation," 2005).

Ramiah and Reich (2005) highlight the ACHAP's intervention in the construction of ARV treatment clinics as an example of uniquely private business efficiencies. The ACHAP provided funds for the construction of clinics, but when ACHAP leadership learned that public tendering procedures would add 18 months to the construction

timeline, they petitioned the government to transfer construction to the ACHAP. After the government agreed to their request, clinics were completed within three months (ibid.). A former Merck employee and ACHAP board member alluded to this event as an example of "private sector efficiencies" (Respondent 26-1, personal interview, August 25, 2008).

Another former ACHAP board member and Merck employee listed private business core competencies, including market segmentation, customer profiling, and project management tools, as important resources for developing innovative strategies for HIV prevention and treatment (Respondent 42-1, personal interview, June 23, 2008). The private sector, argued another Merck employee, should be regarded as an important participant in health governance, and not simply a "source of money and drugs" (Respondent 8-1, personal interview, August 15, 2008).

Although firm and partnership respondents identified private business actor modalities as strategic contributions to global health, these modalities also express normative priorities and thus present implications for the potential business transformation of statehood and governance. Chapter Seven elaborates on these issues and considers the transformative effects of growing private authority in health on public authority, normative agendas, and global health priorities, strategies, and outcomes in national and global health governance. The next section explores case study partnerships' practical and strategic challenges and implications.

ACHAP, DPP, and STF Practical and Strategic Challenges and Consequences

This section presents study findings on case study partnerships' practical and strategic challenges and implications. For the former, it surveys operational challenges,

transaction costs, and absorptive limitations and implications. This section also presents findings on strategic challenges and implications associated with governance, partner relations, and coordination and alignment with national health governance. The findings offer robust support for the one of the study's central arguments: while partnerships provide value added and limited strategic contributions to HIV treatment access, they largely reflect bilateral, narrow, and private actor tactical approaches to global health.

Practical and operational challenges.

Respondents detailed diverse operational challenges relating to governance, delivery, and implementation dimensions of access (see Figure 1-3). Multiple respondents cited governance challenges, specifically navigating overextended, under-resourced, and complex national health governance structures and processes. Respondents identified challenges with slow and inflexible bureaucratic processes (Respondent 35-3; 62-2; 73-4, personal interview, July 29, 2008; November 12, 2008; October 28, 2008; Moeti, 2009), lack of capacity at central and district levels (Respondent 22-2; 26-1; 36-2, personal interview, November 4, 2008; August 25, 2008), and severe shortages in health system resources. STF and ACHAP documentation detail human resource shortages, particularly for skilled personnel (BMS, 2004, 2009b; Moeti, 2009). BMS documentation noted that staffing levels in STF had been inadequate to meet patient needs, which resulted in staff burnout and disappointing enrolment in ARV treatment (BMS, 2004, 2009b).

ACHAP and DPP respondents and documentation identified governance and delivery issues with inadequate health infrastructure and systems. In her study on the DPP, former DPP administrator Heather Houlihan from Axios International and Pfizer

colleagues Konji Sebati, and Joseph Saba (2004) documented problems with drug registration, forecasting, distribution, and technical capacity in partner countries. A DPP Programme Executive commented, "Many developing countries do not have clear drug regulatory processes," complicating efforts to register the donated product, which is distinct from the retail product (Respondent 7-1, personal interview, July 23, 2008). Dr. Anne Reeler from Axios listed challenges with governance capacity, overextended Ministry leadership, confusing clinical guidelines, and inadequate diagnostic and health care infrastructure (personal interview, August 19, 2008). STF respondents and documentation described similar challenges with health infrastructure and logistical systems in partner countries.

Respondents, though, were often sensitive to government partners, commonly noting that Ministries of Health contend with difficult governance climates and competing health priorities, including HIV/AIDS and other infectious and noncommunicable diseases. A respondent from Partners in Health, a US-based NGO with health service operations in Lesotho and Malawi emphasised:

> Ministries of Health [in Lesotho and Malawi] have quite a few problems in addition to HIV/AIDS …there are many problems as well as many vertical programs coming in to the country. There are massive health care and human resource shortages and Ministries are very overwhelmed. (Respondent 27-3, personal interview, August 6, 2008).

Multiple respondents observed these challenges not only within governance and delivery dimensions of treatment access, but also around implementation, including professional, socioeconomic, sociocultural, and psychosocial issues, strategies, and supports. Respondents recounted access barriers highlighted in Chapter One around stigma, transportation, poverty, malnutrition, drug adherence, language barriers between

patients and staff, lack of training opportunities for health professionals, and staff attrition and burnout (Respondent 18-5; 22-3; 27-3; 33-5; 38-4; 42-1; 43-5; 54-1, personal interview, May 26, 2009; November 4, 2008; August 6, 2008; November 7, 2008; July 30, 2008; June 23, 2008; November 7, 2008; November 5, 2008).

Consequent to complex governance, delivery, and implementation challenges, partnerships often confront absorptive capacity issues in developing countries. The ACHAP extended its term because after five years it was only able to disburse 30% of its funds, which a former Merck employee and ACHAP board member attributed to "limited absorptive capacity in Botswana" (Respondent 42-1, personal interview, June 23, 2008). However, as discussed in Chapter Four, studies have shown that partnerships themselves can overwhelm health systems through resource diversions and transaction costs, which limit absorptive capacity (Caines & Lush, 2004; Conway, et al., 2006).

Although pharmaceutical firm and partnership respondents readily identified governance, delivery, and implementation challenges in partner countries, they were less inclined to self-reflexivity around partnership governance, delivery, and implementation implications and transaction costs. These include reorientation and/or diversion of human, political, financial, and administrative resources in support of partnership activities.

Dr. Anne Reeler from Axios acknowledged criticisms that the DPP involves "a separate prescription pad" (personal interview, August 19, 2008), "a separate stream to purchase medicines" (Respondent 7-1, personal interview, July 23, 2008), and "burdensome reporting requirements" (ibid.). These requirements, argued a respondent from civil society organisation Section 27, generate "huge administrative costs" for

governments and health care facilities (J. Berger, personal interview, November 30, 2007). In order to receive donated product, health professionals and governments must adhere to "strict conditions on medical treatment and recordkeeping" (B. Baker, personal interview, September 23, 2008) and develop separate procurement systems. A physician in Lesotho indicated that their clinic no longer uses the donated DPP product, explaining:

> The reporting system was too cumbersome; they require that you register with them, use a different prescription pad, and there is a huge amount of paperwork... I believe that it is Pfizer's way of not getting it to you. It is very strange to us and no longer worth the time of our hardworking staff. (Respondent 27-3, personal interview, August 6, 2008).

A physician at an HIV treatment clinic in Malawi offered similar criticisms and accentuated the challenges of fulfilling DPP requirements in resource-limited settings: "It's a ridiculously cumbersome process for places that are understaffed. Even though the programme is free, it comes with a heavy bureaucracy. We bring in generic fluconazole as a stopgap" (Respondent 35-3, personal interview, July 26, 2008). A pharmacist at an ARV treatment clinic in Lesotho suggested that DPP requirements could potentially undermine treatment access:

> Picture a health centre running with no electricity, no water, a nurse and nurse's assistant, who then must complete all this reporting. Everyone wants accountability but it is getting to the point where it is becoming a barrier to treatment. Nurses will shut down clinics for three days to do their reporting. (Respondent 48-3, personal interview, July 14, 2008)

Diversion of health human resources may occur through these processes or from public health systems to partnership activities. The ACHAP has been criticised for recruiting staff from public sector clinics and agencies (Moeti, 2009); and while STF-funded clinics rely on a mix of local and expatriate health staff, respondents report tensions between fulfilling human resource needs and avoiding diversion from health systems (Respondent 33-5, personal interview, November 7, 2008).

Firm and partnership respondents were aware of many of these criticisms and tensions, yet rarely could provide details or metrics on partnership terms and transaction costs, including administrative costs, reporting documentation and frequency, and human resource policies and metrics. Inability or reluctance to furnish this information has several potential origins, including apprehension with the researcher's use of the data, privacy and confidentiality, failure to collect data, and governance deficits and challenges. The latter includes representation, accountability, transparency, and monitoring and evaluation procedures. Partnerships confront these and other challenges and implications, including public-private interactions and impacts on health governance. The next section explores related findings from the ACHAP, DPP, and STF case studies.

Governance and strategic challenges and implications.

Chapter Four reviewed partnership governance critiques emerging from public health and critical literature. Findings from the case studies corroborate documented governance deficiencies and concerns with P^3H design, accountability, and outcome orientations. Table 6-2 lists six partnership design, governance, accountability, and outcome orientation categories and sub-criteria that emerged from the literature review. The categories and sub-criteria are assembled in a cross-reference framework are adapted from Buse and Tanaka's (2011) GHP evaluation framework. Findings from Table 6-2 suggest that the case study partnerships have largely emerged as ad hoc and insufficiently participatory, transparent, and accountable mechanisms, which lack adequate monitoring and evaluation procedures and equity and human rights considerations and assessments.

Table 6-1: Partnership Case Studies' Design, Governance, and Accountability, and Equity Practices

	AAI	ACHAP	DPP	STF
Partnership Design and Strategic Development				
Ex ante risk, equity, and needs assessments precede partnership implementation				
Ex ante design develops governance, accountability, transparency, monitoring and evaluation, and equity components				
Joint and participatory development of partnership guidelines/terms				
Governance and Representation				
Board of Directors with shared decision-making authority		✓		
Country-level partner representation on Board of Directors				
Alternative governance structure with country-level representation	✓	✓	✓	✓
Accountability				
Reports on partnership plans, strategies, and outcomes, at regular intervals				
Procedures for dispute/complaint/feedback investigation and resolution				
Mechanisms to ensure fulfillment of partner roles and responsibilities				
Transparency				
Guidelines/memoranda are publicly available				
Grant-making and/or negotiation guidelines are publicly available			✓	✓
Transparent governance procedures, including publicly available agendas and minutes of governance meetings				
Partnership financial reports are publicly available				
Partnership has a dedicated, public website		✓		✓
Monitoring and Evaluation				
Activities subject to monitoring and evaluation procedures	✓	✓	✓	✓
Procedures examine efficiency (costs), quality (service), equity, and impacts (practical, strategic, normative)				
Monitoring and evaluation conducted by impartial third-party agent(s)				✓
Equity and Human Rights				
Policies and procedures to enhance global health equity and equitable access to programmes				
Partnership employs measures to assess impacts on equity and human rights				
Conducts equity and human rights impact assessments at regular intervals				

In terms of design and implementation, respondents confirmed that partnerships rarely conducted ex ante evaluations and needs assessments. A former Merck employee and ACHAP board member recalled, "ACHAP came together very quickly. We did not set out five year action plans; we started with an agreement to work together" (Respondent 42-1, personal interview, June 23, 2008). As has been argued throughout this dissertation, partnerships emerged from macrohistorical and sociopolitical conditions of contestation and change, and thus evolved as ad hoc accommodation strategies. That partnerships have inadequate ex-ante design is unsurprising given these formative conditions. Furthermore, and perhaps partly as a result of adversarial relations, partnership development and governance either excluded or provided minor consultative and/or governance roles for civil society and government representatives. Pharmaceutical firms in the case study partnerships thus assumed primary responsibility for partnership design and governance while implementation activities are predominantly conducted by nongovernmental third parties. Although UN agencies had more substantial roles in the development of the AAI, bilateral negotiations and antitrust limitations erected considerable boundaries around the scope of UN power and authority in implementation and evaluation.

Partnership governance has therefore suffered from legacies of ad hoc, discretionary, and thin design and development, and weak or absent country ownership. Only one of the four case study partnerships (the ACHAP) has an independent board of directors, although it does not have representation from the state. All partnerships, though, developed alternative governance structures to allow for country-level

representation in decision-making and implementation activities. AAI working groups, the ACHAP Madwike Forum, the DPP Ministerial Working Groups, and STF International Advisory Boards offer forums to collect partner experiences, feedback, and recommendations for grants and other decisions. Alternative governance structures, however, do not offer substantive or high-level participation in policy- and decision-making, financial control, or administrative apparatuses of partnership governance. The groups convene infrequently, exercise advisory rather than decision-making authority, and wield no financial control over partnership activities. Country ownership and policy autonomy in partnerships is therefore weak or nonexistent and subject to the discretionary authority of pharmaceutical firm foundation staff and leadership.

Table 6-2 illustrates that partnership case studies lack rigorous accountability procedures for giving, taking, and holding to account. While partnerships report on progress, they do so infrequently and unsystematically. None of the partnerships furnish annual reports with operational, strategic, or financial details. Furthermore, if procedures for dispute investigation, complaint, and feedback mechanisms exist, none of the documentation or respondents provided such information. Respondents also were unable to describe procedures for holding partners to account for their roles and responsibilities. A former ACHAP board member stated that the Board has "moral accountability to the Government of Botswana" (Respondent 42-1, personal interview, June 23, 2008) but could not elaborate on specific procedures for holding Merck, the Gates Foundation, or the Government of Botswana to account for their responsibilities and obligations.

Accountability obligations and channels aligned unidirectionally along financial relationships. Thus, respondents described accountability obligations and reporting requirements for grantees and country partners, but were unable to comment on internal (to partners and beneficiaries) or external (to affected groups and individuals) private authority accountability obligations, other than ambiguous moral obligations to partner countries and concrete internal accountability obligations to shareholders. As noted in Chapter Four, deficient accountability procedures and expectations lend themselves to poor transparency, monitoring, and evaluation practices.

All four case study partnerships practice poor transparency and rarely publish data and details on their activities. Only the DPP[190] and STF[191] publish basic grant- and decision-making guidelines. Although three partnerships (the AAI is the exception) have either a dedicated webpage or sub-page, the information provided lacks depth and breadth in all cases. Even the STF website, which is by far the most comprehensive, does not publish annual reports, listing only six STF-authored publications, seven grantee publications, and several NGO Training Institute resources, for US$150 million worth of partnership activity. [192] The website identified a few of the 230 grants but did not provide detailed information on grantees, use of funds, or evaluation activities. Furthermore, partnerships do not publish annual financial reports, list individual grantees, or

[190] See: http://directrelief.org/DiflucanPartnership/EN/Apply.aspx.

[191] See: http://www.bms.com/foundation/Pages/bristol_myers_squibb_foundation_grants.aspx.

[192] Author calculations. See: http://www.securethefuture.com/publications/. There are five additional short (two-page) primers on country partner demographic data and basic partnership descriptions located here: http://www.securethefuture.com/partners/program_partners.shtml.

disaggregate funding commitments. Likewise, none of the partnerships publish terms or guidelines, nor make available governance agendas or minutes. It is therefore difficult to obtain and evaluate programmatic, financial, and governance goals, strategies, and decisions, other than through sparse and sporadic publications.

While each of the four case studies indicated that activities were subject to monitoring and evaluation practices, these practices are commonly conducted internally and unsystematically by partnership employees and affiliates. For example, the AAI Secretariat and/or firm representatives (i.e. Jeffrey Sturchio, former VP of Corporate Responsibility at Merck) authored partnership reports that contained limited evaluation components (Sturchio, 2004; Sturchio & Khalil, 2005; WHO, 2005, 2006a, 2006c; WHO/UNAIDS, 2002a). Pfizer and Axios employees conducted several evaluation and impact studies on the DPP (Diese, Sebati, Meyer, & Taunyane, 2004; Houlihan, et al., 2004; Reeler, et al., 2004; Wertheimer, et al., 2004). Yale University's Center for Interdisciplinary Research on HIV/AIDS conducted monitoring and evaluation activities for STF programmes (Hartwig, Rosenberg, & Merson, 2006; A. Rosenberg, 2006), yet, provided only three evaluation reports on their website.[193] ACHAP employees and board members also conducted and presented evaluation and impact research at scientific conferences or in academic journals (See: Distlerath & Macdonald, 2004; Moeti, 2007; Pillai & Fantan, 2004; Sturchio, 2008a, 2008b).

[193] See: http://cira.med.yale.edu/research/project_page.asp?projID=98. A Secure the Future respondent (personal interview, August 1, 2008) claimed that the Centre had produced 40 evaluation reports, but indicated that they were not available for inspection.

While it is common for employees from business, nongovernmental, or government organisations to conduct and disseminate research on organisational activities and impacts, these studies do not satisfactorily serve as a proxy for independent monitoring and evaluation. Independent and structured data collection frameworks supply partnerships with critical information on governance and quality assurance and impact data and insights. Single sponsored studies may produce helpful data, but they also tend to resemble public relations material, listing partnership successes and value-added contributions, while lacking in rigour and detail. Ultimately, weak or absent accountability, transparency, and monitoring and evaluation practices in case studies undermine partnership governance, self-reflexivity, and democratic potential.

Attention to equity considerations has been largely absent from partnership design and outcome orientations. Although a central objective for each of the partnerships is to expand access to medicines, none of them developed measures and performed assessments on equitable access to programmes and services. Partnerships do not sufficiently interrogate impacts and outcomes, other than value-added impacts, and therefore overlook critical interfaces with national and global health equity and governance. The final subsection discusses findings on public-private interfaces in partnerships and challenges and implications in health governance.

Public-private interfaces and implications for national and global health governance.

A review of the literature on public-private interfaces and challenges in Chapter Four identified several themes, including coordination, alignment, policy autonomy and

country ownership, transaction costs, system distortions, relational issues, and impacts on local markets and the private sector. Findings from the case studies corroborate many of these concerns, indicating that while P^3Hs offer value-added and some strategic contributions; they also generate real and potential practical, strategic, and normative implications for national and global health governance.

Broad consensus emerged among respondents that coordination and alignment presented key challenges in partnership negotiation, implementation, and management. Respondents described crowded and complex governance environments in which overextended government officials painstakingly managed donors, Global Health Initiatives, local and international NGOs, community and faith-based organisations, civil society actors, and public-private partnerships. Public authorities from Lesotho and Malawi (10 respondents in total) described qualitative and quantitative growth in private business actor activity in health governance in their countries in the past 10 years.

States are therefore charged with the task of mapping, coordinating, and reporting on country-level partnership activity, in addition to normal governance responsibilities. Several respondents (from civil society and state institutions) noted that Ministries of Health and National AIDS Coordinating Agencies in Malawi and Lesotho have faced challenges in discharging coordination responsibilities, including mapping partnership activity (Respondent 36-2; 53-2; 57-2; 74-2, personal interview, November 4, 2008; September 1, 2009; May 25, 2009; October 27, 2008), "enormous data collection and verification" (Respondent 36-2, personal interview, November 4, 2008), coordinating

meetings (ibid.), and managing poorly harmonised partner reporting requirements (Respondent 36-2; 57-2, personal interview, November 4, 2008; May 25, 2009).

Public authorities, knowledgeable observers, and civil society respondents observed that these challenges create consequences for national health governance, including poorly integrated and aligned services and programmes (Respondent 6-1; 18-5; 34-5; 36-2, personal interview, August 1, 2008; May 26, 2009; July 15; 2008; November 4, 2008) and system distortions, including resource diversions, service redundancies, and geographic and population disparities or inequities (Respondent 52-2; 57-2; 62-2, personal interview, September 1, 2009; May 25, 2009; November 12, 2008). Public-private partnerships can create "huge distortions in the health system," claimed a public sector official in Lesotho, pointing to the STF-sponsored Senkatana Clinic: "STF is transferring over, but they have seen declines in service levels. Countries simply cannot provide the same level of support that partnerships do" (Respondent 62-2, personal interview, November 12, 2008). As of result of these challenges, Ministries of Health and health systems, therefore, observed a public sector official from Lesotho, often become "dysfunctional seas of confusion" (Respondent 68-2, personal interview, July 8, 2008).

Partnership agenda-setting and relational issues compound these challenges and can undermine partnership efficacy. Government and civil society respondents[194] reported issues with partner agenda-setting behaviour: "Partners are often found pushing the Ministry [of Health] and wanting to have more of their agenda in place," observed a

[194] Refers to respondents participating in publicly hosted partnership meetings and forums.

Clinton Foundation employee in Malawi (Respondent 18-5, personal interview, May 26, 2009). Public and political authorities from Malawi and Lesotho concurred, citing "substantial pressure" (Respondent 52-2, personal interview, September 1, 2009) from partners who "bring their own agendas" (Respondent 36-2, personal interview, November 4, 2008). Respondents and studies from the ACHAP reported somewhat aggressive agenda-setting behaviour. Ramiah and Reich (2005) stated that the ACHAP "pushed government agencies to pursue new ideas and act quickly" (Ramiah & Reich, 2005, p. 550), which was not always received positively. One official commented, "[The ACHAP] wrote the mobile populations proposal themselves, and said, 'You should do this and that.' That attitude doesn't go down well here"'(Quoted in:Ramiah & Reich, 2006).

Public authorities noted that more aggressive agenda-setting behaviour is more readily observable in operational P^3Hs. Partnerships such as the AAI and DPP are relatively disconnected from local governance processes and thus interact infrequently with public partners. These arrangements do not imply that private actors do not engage in agenda-setting, but rather that the behaviour is not readily visible, is tied to structural power, and/or takes place in inaccessible high-level governance forums and negotiations.

Tensions between partners around individual agendas and expectations are symptomatic of broader relational challenges in partnerships. Public authorities and private business actors repeatedly described relational challenges, particularly scepticism and mistrust between partners. Respondents described tense situations in "being at the table with people who do not really want to be at the table with you" (Respondent 44-1, personal interview, March 31, 2011). Private business actor respondents explained that

public authorities and civil society actors were often deeply sceptical and mistrustful of their intentions and motivations (Respondent 6-1; 10-1; 44-1; 24-1, 29-1, 56-4, personal interview, August 1, 2008; March 31, 2011; March 31, 2011; March 25, 2011; March 24, 2011; July 9, 2010; Diarra, 2001). Respondents noted that relational challenges often frustrated communication efforts and prolonged negotiation or implementation while partners developed mutual confidence.

Tensions also arose between private business actor partners and nongovernmental groups operating in partner countries. Ramiah and Reich (2006) describe tense relations between the ACHAP and NGOs, such as when the partnership initiated a condom distribution programme without consulting an NGO who was already conducting similar programmes. The authors note this example as indicative of a general trend of resentment among development organisations arising from programme duplication, and given ACHAP's sizeable funds and authority in national health governance (ibid.). Ministry of Health officials from Lesotho and Malawi confirmed that partnerships and NGOs in Lesotho engage in comparable competitive and territorial behaviour (Respondent 53-2; 57-2, personal interview, September 1, 2009; May 25, 2009).

Challenges and controversies in partner agendas and relations compound overextended health governance environments. State and interstate institutions contend with growing private authority, much of which necessitates mapping, coordinating, and negotiating among numerous partners and stakeholders. Whilst several public authorities expressed the sentiment that they were "appreciative of help" (Respondent 52-2, personal interview, September 1, 2009), they also underscored the urgency of health crises facing

their countries and concurrent deficiencies in local human, financial, and technical resources. Summarising their predicament and offering her observations on P^3Hs, Stephanie Nolen, author of *28 Stories of AIDS in Africa* and former Globe and Mail Bureau Chief for Africa, stressed, "desperation gives you little ability to negotiate about the kind of help you're going to get" (S. Nolen, personal interview, December 3, 2007). Thus, predictably, under these conditions, and compounded by deficiencies and challenges in partnership governance, coordination, and integration, public and private authorities can expect to confront complex operational, strategic, and relational challenges in their roles and responsibilities in health governance.

Conclusion

This chapter investigated three P^3Hs operating in Sub-Saharan Africa and elsewhere in the global South. Each partnership provided substantial (minimum of US$100 million valuation) practical and strategic resources in support of objectives for expanding access to HIV medicines. This dissertation has argued that partnership appraisals, however, need to extend go beyond value-added accounting and consider real and potential implications of private authority and P^3Hs in national and global health governance. This chapter has investigated and evaluated intended and unintended consequences- particularly around governance, accountability, equity, and public-private interfaces - of partnerships in health governance. The findings lend further support to the study's central arguments that while partnerships provide value-added and limited strategic contributions to HIV treatment access, they may also generate real and potential

practical, strategic, and normative challenges and implications and reflect bilateral, narrow, and private business actor tactical approaches to global health.

The case studies reflect a predominantly bilateral approach to partnership. Partnerships employ firm-by-firm, country-by-country, and grant-by-grant approaches; there is no evidence of collaboration or coordination among firms other than through the disjointed AAI framework. There is also clear evidence of discrimination and low-hanging fruits; firms are willing to engage either with the poorest of the poor in partnerships such as the AAI, or with the darlings[195] of international development (e.g. Mali, Tanzania, Uganda, Botswana, and South Africa) in operational P^3Hs. These selection patterns, however, do not necessarily match epidemiological priorities, promote global treatment access, nor address the most difficult health governance environments.

Furthermore, in exchange for relatively modest cash and in-kind contributions, partnerships extract tactical and legitimation returns, including brand and image promotion, patent and/or pricing protection, and enhanced political and shareholder credibility. These returns support bottom line considerations by "build[ing] trust in our business… to safeguard our license to operate in the long term" (Andrew Witty, CEO of GSK, quoted in: GSK, 2010, p. 1). Although pharmaceutical firms contribute funds through corporate social responsibility, philanthropic giving, and partnership activities, these contributions represent a very tiny fraction of annual revenues and net earnings. As

[195] This term is borrowed from commonly used terms 'aid darlings' and 'aid orphans' which describe states that are favoured or neglected, respectively, in terms of donor aid priorities. For more information, see Rogerson, A. & S. Steenson. (2009). Aid orphans. Whose responsibility? *Development Brief* Retrieved from http://www.oecd.org/dataoecd/14/34/43853485.pdf.

a percentage of net earnings from 2008, nine pharmaceutical firms reinvested between 0.09% and 5.6%, averaging 1.22% on total philanthropic giving (which includes funds provided to partnerships) net earnings, in 2009.[196] If you exclude firms based outside the US (Roche, BI, and GSK),[197] the figure drops to 0.68% and averages US$34.2 million per firm,[198] of which a fraction goes towards partnerships. BMS and Merck's cash contributions to the ACHAP and STF, for example, averaged US$6.3 million and US$15 million per year, respectively.[199] Merck's $6.5 contribution to the ACHAP in 2009, therefore, represented 0.05% of its net earnings; or expressed differently, for every dollar Merck earned in 2009, the firm spent one-twentieth of one penny on the ACHAP. The equivalent figure for BMS in 2008 was 0.28% or just over one-third of every penny earned was used to support the STF. When both cash and in-kind (products and services) contributions to partnership activities are included, the average annual valuation for was approximately US$15 million for BMS/STF, US$17.1 million for Merck/ACHAP and

[196]Author calculation based on figures collected from 2008 annual financial reports for nine AAI pharmaceutical firms (excluding ViiV Healthcare) and the 2009 501(c)(3) filings from each of the firm's private foundations in the US.

[197] These firms have registered private foundations in the US, but may also have private foundations in the country in which the firm is headquartered. Private foundation financial activity in the US, therefore, may not provide an accurate representation of the full scope of activity. US-based firms and their private foundations, however, provide financial support to DPP, ACHAP, and STF partnerships, as evidenced in their annual 501(c)(3) filings from 2002 to 2009.

[198] This figure does not include Patient Assistance Programmes; programmes that subsidise or donate (based on income criteria) medicines to eligible individuals (normally in the US, Canada, and Western European countries).

[199] Merck's total contribution as of December 31, 2009 (excluding donated drugs) was US$57.1 million over nine years (Moeti, 2009). BMS's total contribution was US$150 million over 10 years (BMS, 2010a).

US$110 million from Pfizer/DPP.[200] These figures represent 0.39%, 0.26%, and 1.2%, respectively of firm net average annual earnings.[201] These figures demonstrate that partnership contributions, despite the immediate needs they might address, actually represent a very small fraction of firm earnings. However, relative to the wealth of the populations that partnerships serve, the price tag is obviously very high. This inequity gets to the heart of structural inequality that ultimately drives necessity and partnerships.

These partnerships offer substantial legitimation, neutralisation of contestation, and reputational benefits, for a rather modest, and commercially unobtrusive investment. The selection of a P^3H model, at least initially, prior to pricing and patent concessions through the AAI, temporarily allowed firms to avert broader and potentially more costly commercial concessions. The next and final chapter in this dissertation explores these issues, summarises study findings, presents practical, policy, and theoretical implications, and offers recommendations for future research questions and agendas.

[200] Pfizer (2010) declared the value of DPP donations at US$1.1 billion; and over 10 years, this produces the figure of US$110 million. However, it is unclear whether this was calculated using ex-factory costs of production or at wholesale or retail prices. Furthermore, Pfizer does not disclose DPP administrative costs including consulting and programme administration costs.

[201] Author calculation based on figures from annual financial reports. Each figure represents average earnings based on the reference period of partnership contributions. For example, the figure for Merck/ACHAP is calculated by averaging Merck's earnings over the eight-year period from 2001 to 2009.

Chapter 7: Study Findings, Arguments, Implications, and Recommendations

The year 2011 marks the 30th anniversary of the first five cases of HIV/AIDS, a discovery that portended a global pandemic. Thirty years into the pandemic, approximately 30 million people have died from AIDS-related diseases and another 34 million are currently living with HIV/AIDS (UNGA, 2011). The impacts of the pandemic have been and will continue to be disproportionately borne by the parts of the world, which as a result of conditions of structural inequality, disciplinary neoliberalism, new constitutionalism, and the material and structural power of capital, are in inferior political and economic positions from which to launch and sustain effective responses. Globalisation, underwritten by neoliberal policy prescriptions and constraints, generated and intensified these conditions leading to growing power and authority of business, constraints on public authority, and global hierarchies and inequalities. These transformations intersected with a global pandemic to midwife new configurations of public and private power, authority and relations.

In these contexts, public-private partnerships in health emerged as an institutional experiment, ostensibly to address health governance gaps and failures, including access to HIV and AIDS medicines in the global South. This study has investigated the growth and roles of private authority and P^3Hs in health governance through the lens of four cases of access P^3Hs operating in Sub-Saharan Africa and elsewhere in the global South. This final chapter provides a summary of the study, its key findings, central arguments, and implications and recommendations for policy and practice, theory, and research.

Summary of Study

Although several studies detailed early concerns with this institutional experiment, the velocity and volume in growth of P^3Hs eclipsed its critics and critiques. Hundreds of public-private partnerships have emerged and are heralded as functional and problem-solving embodiments of a new global health governance framework (Aginam, 2007; Brundtland, 2002; Conway, et al., 2006). Endorsed by an urgent, functionalist narrative, though; what began as an institutional experiment has transformed into institutionalised practice.

Throughout this dissertation, I have challenged this functional narrative, and examined the rise of private authority and P^3Hs within a critical political economy framework of analysis. Through the application of a qualitative research approach in a collective case study design, four access partnerships- the Accelerating Access Initiative, African Comprehensive HIV/AIDS Partnership, Diflucan Partnership Programme, and the Secure the Future Partnership- were investigated to test and explore functionalist claims, documented concerns, and other practical, strategic, and normative implications. Investigations employed triangulation techniques, including documentation, direct observation, and elite interview data obtained from 75 interviews. Aspects of the research process, however, contain some noteworthy limitations, which will be discussed later in the chapter.

The study posed two central research questions and several sub-questions. The central questions ask, "What explains the growth of private authority in health, particularly in the form of public-private partnerships?", and "What are the intended and

unintended consequences of private authority in health, as evidenced through the lens of public-private access partnerships, for national and global health governance?" The first question is addressed through macrohistorical and microperspectival investigations into the growth of private authority through intersections in functionalist, power, and historical analyses of transformations in world order, global health, and access to HIV medicines. Microperspectival rationales frequently converged with macrohistorical and political economy analyses.

The second central question is explored through a literature review and within and cross-case analyses. In the literature review, I examined the intended and unintended consequences of private authority and P^3Hs by exploring authoritative modalities of private pharmaceutical authority, conceptual configurations of P^3Hs, and practical, strategic and normative debates identified in the literature. Subsequently, I reviewed within and cross-case findings, drawing out intended and unintended practical, strategic, and normative implications of partnerships. This chapter summarises key study findings and central arguments; the former is taken up in the next section and presented in the order of central research questions with reference to sub-questions.

Review of Key Findings

Analyses of macrohistorical trends in a changing world order revealed that governance gaps and failures have predominantly emerged as consequences of exploitative and inequitable hierarchies in past and present global political economy. I argue that a changing world order marked by disciplinary neoliberalism, new constitutionalism, and growing direct, structural, and discursive power of capital

produces growing power and authority of private business, as well as constraints on public authority. These conditions reconfigure public and private power and authority, and contain contradictory tendencies generating new social and global hierarchies, inequalities, exploitations, and social resistance. In the history and political economy of access to HIV/AIDS-related treatment, contradictory tendencies manifested in new civil society networks and activism, which contested growing private authority, political neglect, and structural inequality. This history of treatment access from 1987 to 2011 reveals a governance architecture shaped by structural inequality, social contestation, changing normative and governance environments, and new forms of private authoritative action in global health.

Each of the chapters following the introductory chapter respond to the first cross-case question on mapping the blurred and shifting boundaries in the conceptual, normative, and practical architecture of health governance. A literature and conceptual review of private authority demonstrated that private actors acquire and exercise authority as a result of perceived sociopolitical, economic, or technological expertise (Hall & Biersteker, 2002b; Porter, 2008) or implicit or explicit delegation by states (Hall & Biersteker, 2002b; Kobrin, 2007), or through repeated historical practices (Kobrin, 1997). Furthermore, throughout the dissertation I discussed growing private authority and note emerging constitutive, methodological and integrative mechanisms of private authoritative action in global health. The dissertation demonstrates that pharmaceutical firms have engaged in many areas of authoritative action vis-à-vis partnerships as a result of a combination of perceived expertise, financial and scientific largesse, and implicit and

explicit (by invitation and/or consent) delegation by state and interstate institutions. The findings, however, point to key macrohistorical and sociopolitical relations and processes, including *trasformismo* strategies, which shape the conditions under which private authority emerges.

The findings illustrate that each of the case study partnerships emerged during a period of escalating social contestation around access to medicines. Although many private business respondents acknowledged these pressures, the majority downplayed events, furnishing altruistic and partnership metaphors and rationales. Several private business respondents, however, acknowledged that social contestation played decisive roles in prompting initial pricing concessions, and subsequently, public-private partnerships. In particular, social and legal action, or the threat of action against pharmaceutical firms, featured prominently and consistently in macrohistorical and micro level (respondents) accounts of partnership histories, origins, and rationales.

Case study partnerships shared common objectives, goals, and criteria for participation, yet pursued these through diverse strategies, including differential pricing and patent flexibilities, donations, health system supports, and service delivery. As access partnerships, their objectives were to develop new modes of public-private cooperation to enhance and expand access to HIV/AIDS related treatment, including ARVs and fluconazole. Two partnerships (ACHAP and STF) also sought to expand access to HIV prevention, care, and support services, and three partnerships (excluding AAI) funded and coordinated training and educational programmes for health professionals and other populations. All partnerships combined practical and strategic contributions, including

goods and services, as well as supports and involvement in health policy development, implementation, and/or innovation.

There was also moderate evidence that partnerships mobilised action in neglected policy or programme areas, around specific diseases, and in public and private business governance modalities. For the latter, pharmaceutical firms, many for the first time, engaged in P^3Hs with UN agencies or developing country governments to develop strategies and programmes to expand access to HIV-related medicines and services. Firms previously engaged only minimally in developing countries; partnerships, claimed several respondents, enlarged firms' interest in these markets, and prompted development of new access strategies and commercial departments, as well as participation in emerging hybrid governance arrangements around communicable diseases and policy issues. Partnerships also served as experimental entities, yielding information and learning on best practices and operational and relational challenges. They also allegedly aroused the imaginations and political will of other developing countries, producing bandwagoning effects in treatment access agendas.

Data from partnership documentation and respondents supplied practical contributions and corresponding impacts and valuations. With the exception of the AAI[202], I presented data on valuation of firm cash and in-kind contributions. These

[202] Firms did not provide information on differential pricing discounts, ex-factory costs, and retail prices, therefore making it impossible to estimate the historical and current value of discounts. As detailed in Chapter 5, several AAI firms now publish their differential prices, but only ViiV HealthCare discloses ex-factory costs of production.

contributions, while substantial and supportive within often narrow applications and/or contexts, represent a small fraction of pharmaceutical firm earnings.

Furthermore, the literature and findings suggest that partnerships conform to minimalist expectations around design, governance, accountability, equity, and human rights considerations and procedures. Within and cross-case analyses found partnerships to be insufficiently participatory and representative, with weak and/or deficient country ownership, accountability, transparency, and monitoring and evaluation practices, and narrow outcome orientations. Study findings further point to serious partnership challenges and consequences, including operational challenges, transaction costs, absorptive limitations, and relational challenges. Partnerships confront governance, delivery, and implementation challenges, but are usually able to navigate these problems, particularly through deployment of their vast resources and/or influence within government processes. Where partnerships were unable to mitigate challenges—for example, with absorptive capacity—they initiated internal adjustments. For example, the ACHAP and STF extended their terms, and the DPP necessitated parallel systems for drug distribution and reporting to circumvent national procurement procedures.

Partnerships' exceptionalism and periodic circumvention of health system structures, policies, and priorities produced transaction costs for government partners. Numerous respondents described challenges with growing numbers of vertical partnerships that absorb and divert considerable government mapping, coordination, and reporting energies. These challenges may result in poorly integrated and nationally aligned services, system distortions, service duplications and redundancies, resource

diversions, and geographic and population disparities or inequities. These and other challenges transpire in contexts of crowded, complex, and overextended health governance environments which are prone to inadequate communication and feedback, tensions, and mistrust and scepticism.

Case study findings corroborated many real and potential concerns and challenges with normative and governance impacts and interfaces with national and global health governance, and suggested limited prospects for P^3Hs to substantially expand access. These findings are instructive but not entirely unsurprising. Gramsci's notion of *trasformismo* suggests that while dominant groups will respond to threats to their hegemonic position through accommodative strategies, these strategies are inherently constrained to minimum standards of social tolerability, and thus offer little potential for broad social transformation. They may, as Levy (1997; 2003) suggests generate new internal corporate pressures and expectations for accommodation, yet as this study has shown, this is not automatic. Firms can and have retreated from accommodation strategies through attrition, abandonment, or alteration of their compromises and commitments. In the next section, I present the central arguments of the study relevant to central and cross-case research questions.

Central Arguments of the Study

This section advances the central arguments of the study based on findings generated from data analyses, employing interview, direct observation, and academic and

grey literature and documentation data. The central arguments are presented in the order of the central research questions, with reference to sub-questions.

Central Arguments: Explaining the Growth of Private Authority and Public-Private Partnerships in Health

The first central research question on the growth of public-private partnerships in health was proposed to explore its macrohistorical roots and emergent forms and functions, and to resituate this institutional experiment in the nexus of social relations from which functionalist narratives have abstracted it. I argue that the supposedly unavoidable necessity of private authority under the P^3H model has been driven by structural and normative transformations propelled by a globalising market civilisation. Inherent inequalities and contradictory tendencies prompt new forms of social resistance and contestation, yet as Gramsci might predict, powerful transnational classes engage in *trasformismo* or accommodation strategies to neutralise and co-opt civil society and subordinate classes into participation and acquiescence to the world order. These include access strategies provided through P^3Hs: modest and restrictive pricing and limited patent flexibilities as well as some financial, human, and technical resources, which respond to the context, but not the content, of social contestation.

Public-private partnerships in health emerged from this history as institutional experiments, yet not convincingly as functionalist responses to governance gaps and failures. The history demonstrates that private business actors opted to engage in partnerships in the wake of an unprecedented convergence of social, public, political, and commercial pressures. Thus, partnerships emerged principally from private business actor

tactical self-interest, and secondarily in response to shared concern with activist complaints and demands. Unequivocal rejection of the latter indicates that private business actors did not wish to comply with demands for greater patent flexibilities that would have substantially improved access. Instead, private business actors pursued alternative strategies, including differential pricing, donations, and health care system and delivery supports, through new public-private partnerships.

Although private business respondents provided mixed rationales for engagement in P^3Hs, the preponderance of historical and behavioural evidence and relative calculations lends support for two key arguments. First, although private business respondents indicated that firms want to play meaningful roles in global health, relative calculations point to partnerships as ad hoc accommodation strategies meant to mitigate or avert social and legal action, defend intellectual property rights, protect bottom line considerations, and enhance legitimacy and credibility with shareholders and public sector actors. I do not doubt the authenticity of claims that pharmaceutical firms and their representatives were concerned with the global state of access to medicines. The argument I make here proposes that these concerns were not absent from calculations, but subordinate to the interests of these transnational elites.

Second, we need to be more sophisticated in our understanding of public-private interactions and motivations and go beyond functionalist and rhetorical explanations. Conversely, the reductionist view of all private business activity as motivated by greed and self-interest is also incomplete. Although I argue that, on balance, partnerships emerged from macrohistorical conditions of a globalising market civilisation and micro

conditions of firms' hegemonic interests, this claim implies that governance forms and models cannot be abstracted from macrohistorical contexts nor reduced to the expression of one group of actors' behaviours and preferences. Accommodation strategies, as well as shifting alliances within the historic bloc, result from a complex and continuous struggle over social, political, and economic interests and ideologies. Attention to these contexts and processes offer insights into both prospects and constraints for social transformation.

Central Arguments: Intended and Unintended Consequences of Private Authority and Public-Private Partnerships in Health

The second central research question and second cross-case sub-question are closely connected, interrogating the intended and unintended consequences of private authority and P^3Hs on health governance. Thus, the following section presents central argumentation by first taking into account local and institutional effects and limitations of case study P^3Hs in health governance and then moving into broader systemic questions of intended and unintended consequences of private authority and public-private partnerships in national and global health governance. The section concludes with some comments on projections on the future of access to medicines in the global South.

Practical and strategic consequences of public-private partnerships in health.

A review of functionalist narratives highlights value-added, problem solving, and efficiency advantages of private authority and public-private partnerships in health governance.[203] The challenge with the functionalist approach, as I have argued in this dissertation, is that foregrounding functionality and efficiency has had the effect of

[203] See Chapters Two and Four.

obfuscating or underplaying other critical benchmarks, particularly equity and other distributional consequences in health governance, as well as potentially foreclosing alternative policy options. Thus, while the case study P^3Hs offer value-added and limited strategic contributions, when analytical lenses are expanded and multiplied to incorporate these benchmarks, the case studies are revealed as largely bilateral, narrow (breadth of coverage and contribution), and private actor tactical approaches to global health. The cases also corroborate many of the concerns around P^3H design, governance, accountability, and outcome orientations. Finally, these partnerships confront and generate challenges and consequences in health governance around health policy and system alignment, coordination, absorptive capacity, transaction costs, duplications and redundancies, and geographic and population disparities and inequities. These unintended consequences of case study P^3Hs do not negate their intended practical and strategic contributions in treatment access, but rather draw critical attention to their implications and limitations as an institutional mechanism in health governance, and accordingly, to the import of new approaches to reforms and/or reconsideration of their utility.

Consequences of public-private partnerships extend beyond local and institutional contexts into broader, systemic interfaces with national and global health governance. In particular, there are real and potential consequences of growing private authority and public-private partnerships in health on public authority, normative agendas and priorities, and global health priorities, strategies, and outcomes.

Transformations in public authority.

A functional narrative around growing private authority and P^3Hs positions public and private actors as working collectively and collaboratively in pursuit of shared goals. However, there is considerable divergence in public and private motivations, objectives, and accountability obligations in partnerships. The overarching normative and practical goals for HIV/AIDS treatment access following the UNGASS declaration and initiation of national treatment programmes in developing countries were to place as many eligible persons on ARV treatment as possible. These objectives are subject to governance, financing, delivery, and implementation barriers, however, the UNGASS declaration heralded a new era of expanded commitment to addressing these barriers through additional resources, political will, and capacity-building. UN and WHO leadership called upon private business actors to support these objectives, and according to functionalist accounts, these actors responded with new P^3H initiatives.

I have argued, however, that public-private partnerships, as *trasformismo* strategies, attempt to accommodate some access needs through strategies that are more socially tolerable than previous behaviour, yet stop well short of broad transformations would feasibly have a more substantial impact on social goals. This claim does not imply, conversely, that public sector actors operate universally within the public interest and prioritise treatment access goals ahead of competing policy priorities and interests. The purport of this argument is to underscore inherent contradictions and limitations in public-private accommodation strategies, and call attention to questionable shared goals, and to the substantive and discursive qualities of partnership.

Public authorities derive authority to create and implement rules, policies and standards through democratic processes of legitimation and vis-à-vis notions of accountability and responsibility in public institutions.[204] Private business actors, on the other hand, are not accountable to publics, are not subject to democratic norms (Thompson, 2005), and, as illustrated in this study, exploit these prerogatives through absent or weakly institutionalised accountability obligations. This is clearly an inadequate standard for a governance model engaging in authoritative action in global health, and undermines the democratic legitimacy of health governance. This phenomenon of weakly accountable, participatory, and legitimate governance arrangements is embedded within broader trends and transformations in public authority that relocate governance structures and processes outside the public domain, where they will not be subjected to democratic norms. It also relates to a business transformation of statehood, in which states and inter-state institutions internalise business norms and practices in performance of their duties and expression of policy preferences and priorities.

The growth in private authority and P^3Hs has opened up significant space for private business actor participation in health global governance, and study findings attest to their new and emerging authoritative roles. Furthermore, findings confirm that respondents identified business competencies and efficiencies as key private business actor contributions within P^3Hs and health governance. The inevitable diffusion of

[204] These processes are more strongly institutionalised in some states than in others, however, in principle, there are normative and practical expectations of democratic legitimacy and accountability for public authorities that do not exist for private authorities.

private business values, interests, and agendas into P^3H activities expresses normative priorities and preferences, and enhances exposure of these values within public authority and processes.

Partnerships also establish clear boundaries around governance action and inaction, attaching business-oriented metrics and reporting requirements to the former, and foreclosing policy alternatives around the latter. The selection of P^3Hs as an accommodation strategy successfully helped delay and/or foreclose possibilities for reform in, inter alia, rules and legislation, deployment of TRIPs flexibilities, reforms to the TRIPs Agreement, and more stringent regulatory oversight on corporations.

Instead, private authorities offered partial and limited concessions through P^3Hs, corporate responsibility agendas, and voluntary self-regulating arrangements. These arrangements emphasise business priorities and metrics, including expanded use of technologies in health (MacLean & MacLean, 2009), performance reporting, return on investment criteria (Applbaum, 2009), and emphasis of disease metrics over process-oriented, structural, and social determinants of health approaches. Business approaches may, as Bull & McNeill (2004) suggest, enhance the structural power of bureaucracies and interstate institutions; however, they also potentially re-orient policy agendas and approaches. Growing private authority in health, therefore, generates real and potential implications for normative and governance agendas in public authority, which ultimately shape governance action and inaction in global health.

Transformations and implications for normative agendas in global health.

Trends in growing private authority in health in a framework of weakly accountable, participatory, and legitimate governance arrangements and expanding business transformation of statehood align with transformations in a globalising market civilisation, which relocate governance processes outside public domains and resist or sublimate the interests of working, marginalised, and/or excluded populations to the prerogatives of capital and neoliberal agendas. These prerogatives are further advanced through strategies of philanthrocapitalism, pharmaceuticalisation, and rhetorical partnership agendas inherent in public-private partnerships in health.

I discussed the growth of corporate social responsibility initiatives in the 1990s, and situated these trends within macrohistorical contexts of resistance and demands for reform in the wake of growing material and structural power of private business.[205] Similarly, philanthrocapitalism reflects the inclination of corporations and wealthy individuals to position themselves as good corporate citizens by deploying their vast resources and business approaches to address all manner of social problems (Edwards, 2008). There is a growing trend of private business actors who, through grantmaking (e.g. ACHAP and STF), engage in decision-making on the worthy recipients of vast sums of resources. These organisations exercise authority through not only their material power, but also through structural power around normative and agenda-setting activities. For example, Wilby (2008) argues that contemporary philanthropists increasingly approach philanthropic activity from a business perspective, prioritising return on investment

[205] See Chapter Two.

criteria and metrics over longer-term social and structural transformation. Many P^3Hs adopt these approaches, as evidenced by prioritisation of private business interests, low external accountability obligations, respondents' emphasis on business efficiencies and competencies, and concern with partner reporting practices and disease metrics.

Partnerships also advance normative agendas for the pharmaceuticalisation of health. I referred to pharmaceuticalisation as a business actor agenda that promotes the use of pharmaceuticals to address health, potentially displacing health promotion strategies that focus on the social determinants of health.[206] Case study partnerships have strong pharmaceutical, biomedical, and technological components and objectives. As access partnerships, they predictably focus on pharmaceutical and biomedical interventions. A key controversy with partnerships, however, is unrelated to the question of whether pharmaceutical firms can supply longer-term social intervention and health promotions; clearly, this falls outside of the scope of their competencies. The more critical question considers why a growing number of P^3Hs prioritise pharmaceutical interventions to the relative marginalisation of other social interventions. A reasonable conclusion is that many of these partnerships have key personnel and funding from biotech and pharmaceutical firms. The implications are twofold: first, pharmaceutical firms' scientific and material power strongly shapes partnership activities, and consequently pharmaceuticalisation agendas and priorities in global health, and second, responsibilities for addressing the social determinants of health—ultimately the roots of

[206] See Chapter Four.

disease and inequality—are left to states and interstate institutions, and other actors. Considering the growth in private authority in health and the concomitant shrinking and/or reorientation of public sector health governance priorities and responsibilities, this does not bode well for the future of global health.

The public-private partnership model, therefore, presents important unintended implications and consequences for health governance priorities, strategies, and outcomes. The model prioritises pharmaceutical, biomedical, and technological interventions and solutions, and targets these primarily at the poorest of the poor (where structural and social determinants of health interventions are most urgently needed), or in countries where firms have potential tactical and commercial interests. Partnerships rarely provide direct financial aid and capacity building for health systems; typically engaging in vertical interventions that exist alongside national health systems. Furthermore, many have emerged as ad hoc, concessionary, and temporary entities with poor ex-ante design, governance, accountability, and equity considerations and procedures. Accordingly, they face considerable operational and relational challenges, and generate transaction costs, absorptive limitations, system distortions, and other coordination and alignment challenges in health governance.

Under a functional narrative, the partnership label subsumes intended and unintended consequences under an amorphous mixed actor configuration of theoretically shared responsibilities and goals. The partnership label, therefore, obfuscates relations of power and inequality, divergences in interests, and distributions of costs and benefits. Among the case studies, the term “partnership” appears to be a misnomer, a designation

more rhetorical than substantive. Although, technically, these partnerships were co-regulating entities, in each case, public sector partners' policy and decision-making roles were negligible; the pharmaceutical firms exercised primary authoritative roles. Although partners may report to one another, there is minimal ongoing dialogue or formal administrative or decision-making roles for public sector partners. Moreover, private business actors' core contributions in partnerships centre on financial competencies: their ability to leverage their material power and subsequently claim accomplishments that have been predominantly attained by grantees and public sector institutions. Although the concept of partnership does not necessarily entail that methodological responsibilities are equally divided, it connotes equality in relations, representativeness, and commitment to one another and broader partnership goals. The case studies in this dissertation fail these conceptual criteria. Thus, partnership does not appear to be an appropriate term to characterise these arrangements, as it overstates their substantive qualities and underplays their real and potential integrative and normative implications.

Fundamentally, philanthrocapitalism, pharmaceuticalisation, and discursive partnership framings do not address the contradictory tendencies of capitalism and structural inequality; they reinforce their licence to operate and accelerate. In so doing, these agendas legitimise private authority without sufficient consideration and evaluation of the intended and, particularly, the unintended consequences in health governance. The functional narrative of partnerships, therefore, is implicated in accepting, or at minimum internalising, private business actor contributions as partial, limited and functioning within the boundaries of self-interest, self-defence, and self-regulation. The narrative

recognises partnership contributions as value-added and supplemental, transformative only to the point of the end users, with minimal or no structural impacts. The implications are that partnerships and private authorities may continue to offer predominantly bilateral, narrow, and tactical contributions in a framework of poor governance, accountability, and equity considerations and obligations, while advancing private business interests, structural power, and authority. These normative and governance agendas and narratives push global health governance in the direction of expanded depoliticisation, hybridisation, commodification, and technological agendas, which ultimately obfuscate critical questions—and potential transformations—in the historical and material roots of inequality, disease, and poverty.

In summary, I have argued that growing private authority and public-private partnerships in health have emerged from macrohistorical conditions of a globalising market civilisation and micro conditions of private business actor tactical self-interest and self-defence. I have also argued that while partnerships offer some value-added and limited strategic contributions, they largely reflect bilateral, narrow (breadth of coverage and contribution), and private business actor tactical approaches to global health, and are unconvincing in their commitment and their capacity to expand access to HIV medicines. Ultimately, this study demonstrates that public-private partnerships in health present important practical, strategic, and normative implications for national and global health governance that necessitate new approaches to reform and/or reconsideration of their experimental utility.

Projections on the future of access to medicines in global health.

What future then for access to medicines? I argue that critical challenges remain in achieving universal treatment access, for which partnerships are unconvincing in their commitment and their capacity to address, particularly with regard to the governance dimension of access and pharmaceutical firms' and partnerships' interpretation and agenda and boundary-setting activities around medicines affordability and availability.

Key imperatives for scaling up treatment access include sustainable and affordable supply of HIV medicines, health systems strengthening, governance capacity building, and guarantees for sustainable funding. There are also significant challenges with the proliferation of regional and bilateral trade agreements that contain enhanced intellectual property rights protections, which threaten to undermine access to medicines. Civil society has been critical of IPR measures in agreements recently under negotiation, including the Anti-Counterfeiting Trade Agreement, the Trans-Pacific Partnership Proposals, the European Union-India Free Trade Agreement, and the European Union-Mercosur Free Trade Agreement. (See: D'Amour, 2011; HAI, 2011; Sell, 2008).

Questions also remain around the future of access to ARVs, including pricing and production of improved first line, second line, and pediatric medicines. While Indian generic producers supply the bulk of HIV medicines to developing countries, legal challenges to Indian patent law[207], patent evergreening practices, and an approaching 2016 deadline for TRIPs compliance for least developed countries, potentially threaten this essential source of generics production. Partnerships and originator firms have made

[207] Discussed in Chapters Two and Five.

it clear that they do not intend to offer patent or pricing flexibilities to middle-income countries, and may continue to downgrade pricing and patent flexibilities in low- and low-middle income countries. All partnerships, however, have lost momentum and are scheduled to be phased out entirely.

The future for access to HIV medicines may see substantially higher prices for improved first line and second line medicines, and continuing challenges around supply and pricing of pediatric medicines. Global Health Initiatives such as the Global Fund will continue to have a substantial impact through their critical roles in financing and coordination. However, case study partnerships, and potentially other access partnerships[208], offer little prospect to address governance, delivery, financing, and implementation challenges for access to ARVs (and potentially other HIV medicines) on a broad scale or at operational levels.

Access to ARVs will foreseeably rely on a precarious model of marketplace managers (Clinton Foundation, UNITAID, the Global Fund, and the Medicines Patent Pool), uncertain generic production, and ambiguous donor and global health partnership commitments. The future for access to other essential medicines may, however, be shaped by expanding differential pricing arrangements across a variety of medicines for communicable and non-communicable diseases. As patents expire and demand from low and middle-income markets grows, originator firms are signalling that they will offer extend accommodation strategies to a wider range of medicines. (See recent

[208] As noted in Chapter One, the case study approach may yield naturalistic generalisations to the larger population of cases. The literature review in Chapter Four also provides support for this claim.

annoucements detailed in: Jack, 2011a; Jack, 2011b) Differential pricing arrangements for ARVs, however, will likely follow the status quo or perhaps decline or lapse altogether given diminishing commitments to the AAI partnership and/or new eligibility restrictions.

The future of global health and access to medicines will also be shaped by normative and policy agendas, as well as priorities and social contestation around their boundaries and implications. The future for access to medicines to a certain extent will be contingent on the growth and sustainability of civil society contestation and accountability functions. In a globalising market civilisation, prospects for social and structural transformation for expanding access to treatment will be subject to these and other normative and structural constraints and possibilities.

Practical, Policy, Theoretical, and Research Implications and Recommendations for Public-Private Partnerships and Private Authority in Health

Given practical, strategic, and normative challenges and consequences of public-private partnerships for health governance, what is the way forward? Richter (2003) has argued that UN agencies should abandon the public-private partnership paradigm, while Buse & Waxman (2001) recommended a moratorium while further research is conducted. Since the time of these proposals, however, the number of P^3Hs has swelled; a development that has not coincided with significant research or reformist initiatives. Indeed, Buse and Tanaka's recent (2011) study highlighted the same widespread P^3H governance and accountability issues that Buse and Walt (2000a, 2000b) detailed 11 years ago in their landmark studies. The challenges with reforming partnerships originate

with securing buy-in from participants, and structural and normative constraints that dismiss or resist calls for a new ethic and politics of responsibility and accountability. The former may be easier to address, but persistent status quo among both necessitates abandonment of the policy paradigm altogether. Given the relatively poor and slow record of internal partnership reforms, even within the existing constraints it is possible to conceive of new internal and external reform approaches that could be implemented with reasonable practical, political and financial facility, which may offer enhanced external accountability, oversight, and equity-inspired transformations to partnerships' outcome orientation.

Practical and policy implications and recommendations for P^{3}Hs and global health governance.

Partnerships can, with practical ease, adopt and apply a new ethic of accountability and responsibility to augment internal and external accountability obligations. Several organisations from within health fields or across other governance areas can provide a range of supports and best practices in accountability. The ISEAL Alliance[209], for example, identifies a number of tools to enhance accountability and confidence-building measures in public-private collaboration, including credibility tools (e.g. codes of ethics, common certification requirements), reporting tools and frameworks, and engagement strategies for internal and external stakeholders. One World Trust, a non-profit global leader in accountability and global governance, has developed accountability frameworks and tools that can be adopted for use in public, private, and

[209] See: http://www.isealalliance.org/.

hybrid organisations (Blagescu, de Las Casas, & Lloyd, 2005).[210] At minimum, these practices require that partnerships enhance procedures for giving, taking, and holding to account through wider engagement with and responsiveness to internal and external stakeholders and affected individuals and groups.

These reforms are necessary, but not sufficient to ensuring accountable, effective, and equitable public-private partnerships in health. A "Public-Private Partnerships in Health Development, Governance, and Accountability Framework", presented in Appendix D offers a preliminary research protocol and a design, governance, and accountability evaluation agenda for P^3Hs, researchers, scholars, and monitoring bodies. This framework lists three key categories, 1) design and strategic development, 2) governance, and 3) accountability, and sub-criteria for each category. The framework identifies research and evaluation indicators that support the development of new research protocols and evaluative criteria for P^3Hs and other monitoring bodies. Furthermore, the framework highlights strategies for implementing proposed measures in new or existing P^3Hs. The criteria listed in the framework correspond with the key issues and deficits raised in the P^3H literature and case study findings (see Table 6-2). The framework also incorporates Barr's (2007) recommendation for enhanced equity evaluation component, yet goes a step further by proposing that P^3Hs include equity and human rights needs and impact assessments in P^3H design, strategy, and organisational effectiveness development and planning. Thus, P^3H activity will be guided by risk, needs,

[210] For more information on One World Trust tools and publications, visit: http://oneworldtrust.org/.

and impact assessments originating at country and/or international levels, and will focus on addressing these needs within a global health equity and human rights orientation. Accordingly, these criteria require that P^3Hs detail not only value-added contributions, but align these contributions to national and global health equity needs and objectives.

Throughout this dissertation, I have underscored the need for a UN/WHO framework on the design, implementation, and evaluation of partnerships, including an equity evaluation component, as well as a component that addresses interfaces of private authority and P^3Hs within state and interstate institutions. The UN-Business office already collects basic public-private partnership details; its mandate could feasibly be enlarged with support from university collaborating centres or other neutral third parties to collect, synthesise, and possibly arbitrate partnership governance, evaluation, and impact data and reporting. In addition, a UN agency or neutral third-party agency could work towards developing a new 'Global Health Partnerships Index' which, similar to the Access to Medicines Index[211], would collect and evaluate information on P^3H design, governance, accountability, transparency, monitoring, evaluation, human rights, and equity impacts. The Index would serve as a form of external accountability, and transparently disclose, compare and rank partnership performance across a range of indicators. These institutions (UN Business office and the staff at the Global Health

[211] The Access to Medicines Index Foundation is a nonprofit organisation funded by the Bill and Melinda Gates Foundation, bilateral and regional aid agencies, and nonprofit groups. An external third-party agency collects and synthesis data on originator and generic pharmaceutical firms and their policies, and performance in enhancing access to medicines in developing countries. For more information, visit: www.accesstomedicineindex.org

Partnerships Index) may also provide consultative advice, best practices, and resource material to emerging and reforming P^3Hs.

I have also underscored the need for more sophisticated analyses of public and private motivations and constraints for engagement in hybrid governance modalities. Although argumentation has focused on private authority in health, there is ample evidence that transformations in health governance cannot be understood strictly through reference to private business motivations. Public authorities have been complicit, often activist participants in soliciting private business actor participation in global health, while concomitantly neglecting to develop and observe public-private interaction and accountability mechanisms. However, reluctance to engage in more stringent oversight of private and hybrid governance activities is related to macrohistorical trends and normative and structural constraints that elevate the status and power of private business through the loosening of regulatory obligations, new constitutionalist agreements, and the disciplinary effects of neoliberalism on political autonomy. Thus, while I propose new and enhanced accountability practices and reforms, and echo Türmen's (1999) call for more effective global health governance with new rules and regulatory frameworks, these critical objectives may face neglect, resistance or dilution.

The challenge, therefore, will be to advance and support forms of civil society resistance and contestation that transcend the situated state and its proclivities around global capital, and articulate and construct a vision and movement for an alternative

future based on a new politics and popular common sense[212] of accountability, responsibility, and social justice. In global health, the new politics and popular common sense prioritise health as a human right, as expressed through normative, policy, and structural transformations, including responsive, inclusive, and sustainable forms of political and economic organisation. Procedural and incremental reforms may improve governance effectiveness and legitimacy, but they will fall short, as Cutler (1999b) warns, of "providing justice of outcomes in any substantial way" (p. 317). Cutler's claim raises important theoretical, ontological, and epistemological questions around the *who*, *where*, and *how* of achieving improved social justice outcomes in global health.

Theoretical implications of P^{3}Hs and private authority in health governance.

The traditional state-centric perspective in international health governance, particularly as expressed in the 1978 Alma-Ata Declaration[213] on *who* is responsible for advancing social justice objectives and outcomes in global health, recognises authoritative action in health as the domain of the state and inter-state system. Governments organise and regulate their health systems and, where necessary, coordinate with international organisations, such as the WHO, for purposes of monitoring and controlling health and disease within their boundaries. Functionalist perspectives,

[212] This term originates from Antonio Gramsci's (1971) conceptualisation of the popular common sense as a set of universalised principles which help to secure broad social consensus with the world order.

[213] The Alma Ata Declaration (WHO, 1978) declared health a fundamental human right (section I), and affirmed the essential and primary role of government (section IV) in supporting the "attainment of the highest possible level of health" (section I).

however, regard these arrangements as elastic and variable and accommodate new actors, forms, boundaries, and priorities, in pursuit of utilitarian goals in health governance.

These perspectives intersect with the neoliberal popular common sense, which vests significant responsibility for health outcomes at the level of the individual 'consumer', by abstracting the individual from their social position and environment and assigning atomistic, market-oriented, and pharmaceuticalised interventions. Accordingly, health justice outcomes, according to neoliberal popular common sense, emerge from minimal state and interstate interventionist roles, market forces, and growing private authority and hybrid governance arrangements.

A critical political economy framework challenges functionalist and neoliberal narratives, and affords ontological and epistemological relevance to marginalised populations and approaches in inquiry. Critical political economy is blatantly normative, and envisions an alternative world order emerging from civil society resistance and counter-hegemonic projects. The ontological unit of inquiry, or the question of *who* (and *where*), is concerned with social and political forces and relations, and not exclusively with state or interstate institutions, as in mainstream theorising. Therefore, the application of a critical political economy framework necessitated situating public-private partnerships within broader macrohistorical trends and social relations. It also entailed the application of Gramscian and Gramscian inspired concepts and frameworks for problematising the growth of private authority and specific institutional forms and concessions. Gramsci's *trasformismo* concept offers insights to the origins, possibilities, and limitations of new private and hybrid accommodation strategies as transformative

approaches towards social goals. The concept draws our attention to its possibilities for internal and external reform pressures, and to the limitations and distributional consequences of accommodation. As Levy (1997) notes, it carves a cognitive path between functionalist problem-solving optimism and cynical green or red-washing (in application to HIV/AIDS).

Furthermore, analyses of public-private partnerships in health provide ontological relevance to private authority, highlight the direct and structural power of private business actors, and reveal their interests, values, and authoritative character and transformative potential in global governance. Study findings confirm the conceptual and theoretical complexities of typologising and mapping public and private interests, values, and interfaces in global governance. I have also cautioned against unsophisticated typecasting of private interests and motivations in governance. This warning extends to similar questions on the public realm, and cautions against unsophisticated projections of public actor interests, values, priorities, and boundaries. Moreover, given that this dissertation has evaluated and applied equity, governance, and accountability criteria and benchmarks to public-private partnerships, it follows that the caution I extend here warrants theoretical and empirical interrogation of public authorities' roles, interests, and behaviour in health governance.

These and other questions around public and private authority confirm a critical need to problematise concepts of accountability, legitimacy, and publicness in governance, as well as Cartesian dualisms (public/private, insider/outsider, etc.), and to enlarge ontological and epistemological approaches to explore emergent forms of social

relations . Critical analyses of private authority challenges prevailing conceptual, ontological and epistemological approaches, however, there is a need to conduct more work on developing conceptual, analytical and theoretical criteria and approaches for analysing actor interests, interfaces, and dialectics in governance.

I contend, however, that scholars and practitioners need to be cognisant of the limitations and implications of the global health governance construct. Borrowing from Susan Strange's (1982) characterisation of regime theory as woolly, the global health governance construct confronts similar challenges with imprecision and ambiguity. The concept captures the plurality and diversity of health issues, actors, and rules, but in the absence of a definable architecture (Fidler, 2010b), and the difficulties mapping its actors, interests, and activities, it can be similarly criticised for its wooliness. Some have also criticised that GHG literature overstates the role of nonstate actors (Ricci, 2009) or minimises the role of the state (Aginam, 2007). In addition, I propose that the GHG construct tends to presents a woolly, functionalist, and idealised sphere of mixed actors working toward global health goals. In reality, global health governance is a messy and contested space, operating within structural and normative constraints and possibilities. I therefore return to the definition of global health governance I proposed in Chapter 1 as encompassing:

> constitutive, methodological, and integrative transformations in authoritative activities in global health, and the historical and social relations underpinning governance definitions, deliberations, action and inaction, as well as the consequences arising from these processes.

This space, or architecture, presents policy, practical, and theoretical questions that will continue to be explored through maturing research agendas. In the following

section, I reflect on the study's research process and limitations, and propose recommendations for future research.

Comments on challenges and future needs in the conduct of research on P^{3}Hs and private authority in health governance.

The research process for this study has been guided by an evolutionary qualitative research process which entailed a marked learning curve and a flexible and organic research approach. The research material was often technical and complex, originating in medical and health sciences, business, and nonprofit domains. Data collection not only supplied information and responses, but also helped to generate questions. The challenge with this approach is that it may result in an unsystematic data set.

Issues with respondent bias compound these challenges. This dissertation has advanced several claims around partner motivations and rationales, claims that have necessarily factored in respondent bias in the evaluation of evidence and relative calculations. Elite interviewees tend to develop attachments and justifications to their organisations and roles, and are often exceptionally cautious and defensive with their responses. These issues might have been mitigated to a certain extent by cultivating a deeper rapport with respondents over a longer period of interaction. Data collection processes, including field site visits[214] and telephone interviews, however, did not allow for this potentially critical rapport building.

Furthermore, in the introductory chapter, I pointed to a low response rate among public sector respondents. A low response rate produced insufficient data from which to

[214] I was in the field for weeks at a time, but moved from site to site, often covering large distances.

draw conclusions on some central and subresearch questions. It was not possible, for example, to assess public sector motivations and rationales for participation in P^3Hs. Furthermore, although public sector respondents detailed normative and governance implications with growing private authority and P^3Hs, these findings are preliminary and warrant further research. Moreover, some of the public sector respondents were not able to discuss questions on the AAI; too much time had lapsed between negotiations and the interview, or it was difficult to locate the exact person(s) involved in AAI negotiations. This study and others would benefit from a diverse array of public sector respondents and insights on P^3H interfaces with public authority.

Ultimately, an organic research approach coupled with outsider status, an impersonal telephone interview medium, respondent bias, and low response rates in a key respondent group created some limits in data systematisation and scope. The systematic application of triangulation and verification techniques, however, has significantly helped mitigate these issues and challenges. Comprehensive literature reviews, interviews, member checks on interviews, and thick descriptions of case studies and historical and contextual accounts produced a rich, diverse, and reliable data set. I am confident that triangulation techniques and the systematic application of four verification techniques meet qualitative research standards for verification and reliability.

Challenges in the research process for this study yield several recommendations. First, although this study employed a collective case study design, for a small, single investigator study, an intrinsic within-case study would have been a feasible alternative research design option. Establishing a longer-term fieldwork base site may have

generated a more detailed investigation and helped avoid issues with outsider status, transitory and multiple fieldwork requirements, and respondent response rates. A collective case study design offered contextualisation and comparability in access partnership histories, operations, strategies, and outcomes, and was the preferred choice for this study. Future research revisiting partnerships using an intrinsic case study approach is recommended.

This recommendation also speaks more generally to research needs on public-private partnerships and private authority in health. There is, however, a need for more detailed within and cross-case studies on P^3Hs, including Global Health Partnerships and Initiatives. This research needs to include, and go beyond, investigations of governing arrangements, and examine histories, motivations, interfaces, and normative underpinnings. Secondly, research is urgently needed on the roles and interfaces of private authority in national and global health policymaking. Private business actors may provide representation, expertise, authorship, and so forth in governance forums; however, there is a limited evidence base from which to assess their roles and interactions, the nature and degree of their authority, and their effects on policy deliberations and outcomes. Case study findings disclosed relational challenges with agenda-setting behaviour, communication and coordination, and issues around trust. These findings are conceivably naturally generalisable to broader public-private collaboration issues, however there is insufficient data available to explore and substantiate these questions across a larger population of partnerships and private authoritative action in health governance.

Furthermore, investigations need to explore the role of other private business actors in health governance, including private foundations, food and beverage, agribusiness, and tobacco industries. Researchers have been developing interesting research questions and agendas around these private business actors and supplying new empirical contributions; but while it may be forthcoming, there is not yet sufficient theoretical engagement in these studies. Empirical and theoretical engagement with private authority in health governance will be critical to making sense of its messy and contested architecture, and current and future policy and normative trajectories.

Conclusion

This dissertation concludes with a departure from academic text to more personal reflections—although as the research is situated in a critical theoretical framework and qualitative approach, it proceeds from the understanding that the political is personal. Over the last several years of postgraduate study, I have travelled to multiple countries to conduct research, and over the course of this work, have been privy to public and private hardships and struggles. One in particular has always stayed with me. In 2004, during a fieldwork trip to Ghana, a young woman with two children who was dying of AIDS asked why she would not have access to medicines to save her life. I did not have adequate answers for her then, and the answers that this dissertation has revealed are even more disconsolate. Her life and millions of others' have been cast off as casualties of a perverse equation of structural inequality, disciplinary neoliberalism, new constitutionalism, and the direct and structural power of capital.

Civil society activists advanced social movements in treatment access and disrupted, but did not destabilise, this equation. Their efforts joined with public outcry, political mobilisations, and Indian generic producers—the global pharmacy to the poor—to facilitate major changes in treatment access. I have witnessed these changes, and known of lives saved—of the Lazarus effect of treatment. It seems unimaginable, in these contexts, to question the role of partnerships in health governance; the value-added effects are important, if not critical, contributions. Indeed, as much as I have challenged the functionalist narrative around public-private partnerships in health, this dissertation has also paid attention to functionalist explanations and deliberation. Social problems demand solutions. When the 'problem' is a global pandemic, the solutions will be complex and resource-intense.

However, it is my contention (and aspiration) that this dissertation advances important caveats to myopic perspectives on partnerships, raises flags around failures to question the macrohistorical and political economy roots of inequality and disease which drive necessity, and questions if whether moving further down this governance path will generate more of the same. Thus, while solutions matter, they ultimately spring from historical and social relations, and therefore attention to the latter matters equally significantly if we are to understand how we got here, where we may be headed, and how we may be able to change course. In this last chapter, I have presented policy, theoretical, and research implications to the issues raised in this dissertation; I hope I have impressed upon the reader the critical urgency for their simultaneous consideration and pursuit.

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Appendix A: Interview Respondents

Respondent Identification Number	Respondent Group	Name	Organisational Affiliation	Role	Respondent preference for in-text citation
1	5		Clinton Foundation (CHAI)		Organisational affiliation only
2	3				Anonymous
3	5	Dr. Anne Reeler	Axios International	Chief Technical Officer	Name, affiliation, and role
4	1				Anonymous
5	1				Anonymous
6	1		Bristol-Myers Squibb Foundation/STF		Organisational affiliation only
7	1		Pfizer, Inc.		Organisational affiliation only
8	1		Merck Company		Anonymous
9	4	Dr. Brook Baker	Northeastern University/ Health GAP	Professor	Name, affiliation, and role
10	1		Pfizer, Inc.		Organisational affiliation only
11	3				Anonymous
12	2				Anonymous
13	3	Ms. Cheryl Snyder	Partners in Health	Lesotho Coordinator	Name, affiliation, and role
14	1				Anonymous
15	5				Anonymous
16	4	Dr. David Moore	BC Centre for Excellence in HIV/AIDS	Research Scientist	Name, affiliation, and role
17	3		Treatment Action Campaign		Organisational affiliation only
18	5				Anonymous
19	3				Anonymous
20	3				Anonymous
21	3				Anonymous
22	3	Dr. Evi Eggers	Médecins Sans Frontières	Field Coordinator	Name, affiliation, and role
23	3				Anonymous
24	1		Pfizer, Inc.		Organisational affiliation only
25	2				Anonymous
26	1	Former Employee	Merck Company/ ACHAP		Organisational affiliation and role only
27	3				Anonymous
28	3				Anonymous
29	1		Boehringer Ingelheim		Organisational affiliation only

30	1	Dr. Jon Pender	GSK, Inc.	Director, Government Affairs, Global Access, IP & HIV/AIDS	Name, affiliation, and role
31	3	Mr. Jonathan Berger	AIDS Law Project	Senior Researcher and Director	Name, affiliation, and role
32	4	Dr. Julio Montaner	BC Centre for Excellence in HIV/AIDS	Executive Director	Name, affiliation, and role
33	5		Lesotho Children's Centre of Excellence	Pediatrician	Organisational affiliation and role only
34	5				Anonymous
35	3				Anonymous
36	2		National AIDS Commission (Lesotho)		Organisational affiliation only
37	1				Anonymous
38	4				Anonymous
39	1		Pfizer, Inc.		Organisational affiliation only
40	3				Anonymous
41	3				Anonymous
42	5		Merck Company/ ACHAP Board of Directors		Organisational affiliation and role only
43	5		Lesotho Children's Centre of Excellence	Pediatrician	Organisational affiliation and role only
44	1		Pfizer, Inc.		Organisational affiliation only
45	5				Anonymous
46	3				Anonymous
47	3				Anonymous
48	3				Anonymous
49	1				Anonymous
50	5		Baylor Pediatric AIDS Initiative	Programme Executive	Organisational affiliation and role only
51	1		Boehringer Ingelheim		Organisational affiliation only
52	2				Anonymous
53	2				Anonymous
54	3	Dr. Natalie Vlahakis	Médecins Sans Frontières	Medical doctor	Name, affiliation, and role
55	3				Anonymous
56	4	Dr. Peter Singer	MRC Global, University of Toronto	Executive Director	Name, affiliation, and role
57	2				Anonymous
58	1				Anonymous

59	5				Anonymous
60	1				Anonymous
61	4	Dr. Robert Hogg	BC Centre for Excellence in HIV/AIDS	Director of the Drug Treatment Program and Population Health	Name, affiliation, and role
62	2				Anonymous
63	2				Anonymous
64	1				Anonymous
65	1				Anonymous
66	4	Professor Solomon Benatar	University of Toronto	Professor	Name, affiliation, and role
67	4	Ms. Stephanie Nolen	The Globe and Mail	Johannesburg Bureau Chief	Name, affiliation, and role
68	2				Anonymous
69	3	Tahir Amin	I-MAK	Co-Founder and Director of Intellectual Property	Name, affiliation, and role
70	2				Anonymous
71	3		Dignitas International		Organisational affiliation only
72	1		Tibotec/Johnson & Johnson		Organisational affiliation only
73	4	Professor William Bicknell	Lesotho-Boston Health Alliance	Director	Name, affiliation, and role
74	2				Anonymous
75	4				Anonymous

Appendix B: Interview Guide

Core Questions

C1	Question regarding treatment of data (anonymous, name/affiliation, affiliation).
C2	What is your current position/role and how long have you been in this position? (If C2 < 12 months) Where were you employed prior.. ?
C3	Can you tell me more about [organisation/partnership/project]? (Prompt for history, operations, governance, funding, etc.).
C4	Why did your organisation decide to develop/or engage with this partnership/program/campaign? Can you describe the history?
C5	Can you outline some of the key objectives or goals from this partnership?
C6	What are the [organisation's] roles and responsibilities?
C7	As a participant in [partnership], what do you perceive to be the major incentives and benefits of being part of this partnership?
C8	Can you describe some of the challenges and impacts for your organisation, the health system, access to medicines, other impacts, etc.?
C9	What are some of the key issues and problems surrounding access to essential medicines in low and middle-income countries?
C10	Can you describe the history of these issues in your country? Key historical events or turning points?
C11	How do you perceive the role of civil society in HIV treatment and treatment activism? Same question re: pharmaceutical industry (originator and generic).
C12	Can you describe organisational and/or accountability procedures and obligations? What are the measures of accountability? How and to whom are these reported? What strategies exist for poor performance or disputes? How are these addressed?
C13	What has it been like for your organisation in managing relations with your partners? What are some of the challenges? The successes?
C14	Can you provide a valuation of the firm's costs in the partnership? What other costs, including administrative costs, transaction costs (provide example of existing concerns/criticisms/transaction costs), are borne by partners, including your firm? How does your firm attempt to mitigate or reduce these costs
C15	How do you feel that partnerships might be improved or strengthened to ensure wider access to HIV drugs?
C16	Given my questions in this interview, do you have any suggestions for people who might be potential participants in this study?

Group 1: Private/Commercial Sector Actors/Organisations

B1	What are some of the current criteria for eligibility (and partner selection)?
B2	How does your organisation determine pricing for specific drugs?
B3	How do/did AAI negotiations take place? Who participates? How often? What is the length of the contract and how do terms for re-negotiation take place?
B4	Questions on history and approach to voluntary licenses, patent non/enforcement, technology transfer commitments. Prompt for details, scope, rationale, and current and future commitments.
B5	Can you provide a valuation of the firm's costs in the partnership? What other costs, including administrative costs, transaction costs (provide example of existing concerns/criticisms/transaction costs), are borne by partners, including your firm? How does your firm attempt to mitigate costs?

Group 2: Public Sector (state and interstate) organisations

G1	How are ARV and HIV medicines (fluconazole) procured in your country? Prompt for procedures, funding sources, and key responsibility structures.
G2	Are you experiencing gaps in funding/resources/programmes in terms of rolling out wider access to drug treatments? What role for partnerships?
G3	What is your role in drug pricing negotiation? How do you work to ensure that negotiations are fair and effective to all parties?

Group 3: Nongovernmental and Civil Society Organisations

N1	What is your perspective on why the pharmaceutical industry has increasingly come to the table in UN and other public-private partnerships?
N2	Can you tell me how your organisation manages procurement of ARVS and HIV-related meds? Does your organisation have any experience with the Diflucan Partnership Programme? Can you describe your experience?
N3	I am asking members of civil society and the research community for their perspectives on pricing and patent flexibilities (give examples)? Would you mind sharing your perspectives/insights on these drug access strategies?

Group 4: Knowledgeable observers

K	N/A

Group 5: Other Partnership Representative Organisations

O	See B1-B5 questions

Appendix C: AAI Member Pharmaceutical Firms' and Generic Competitors' ARV Pricing Table

Firm	Drug and dose combination	First-tier originator price US$	Lowest generic price US$ and generic firm	Type of firm (originator or generic) offering lowest price PPY or unit	Percentage difference between lowest originator price and the lowest generic price
Abbott Pharmaceuticals	LPV/r 80/20mg/ml oral solution	176	N/A	Originator	Not applicable
	LPV/r 100/25mg tablet (heat-stable)	165	183 (Aurobindo)	Originator for Category 1, Generic for Category 2 and no restrictions	+10.9
	LPV/r 133/33mg soft gel capsule	500	572 (Cipla)	Originator for Category 1, Generic for Category 2 and no restrictions	+14.4
	LPV/r 200/50mg tablet (heat-stable)	440	457	Originator for Category 1, Generic for Category 2 and no restrictions	+3.9
	RTV 80mg/ml oral solution	0.093	N/A	No generic suppliers listed	Not applicable
	RTV 100mg soft-gel capsule	83	323 (Cipla)	Originator	+289.2
	RTV 100mg heat-stable tablet	83	180 (Matrix)	Originator	+116.9
Boehringer Ingelheim	NVP 10mg/ml suspension	380	58 (Aurobindo)	Generic	-84.7
	NVP 200mg tablet	219	34 (Cipla)	Generic	-84.5
	tipranavir (TPV)	NA	N/A	No generic suppliers listed	Not applicable
Bristol-Myers Squibb	ATV 150mg capsule	353	N/A	No generic suppliers listed	Not applicable
	ATV 200mg capsule	0.602	N/A	No generic suppliers listed	Not applicable
	ATV 300mgcapsule	N/A	256 (Matrix)	No originator price listed	Not applicable
	d4T 1mg/ml powder for syrup	51	44 (Cipla)	Generic	-13.7
	d4T 15mg capsule	0.082	0.024 (Aurobindo CF and Cipla CF)	Generic	-70.7
	d4T 20mg capsule	0.089	0.025 (Aurobindo CF and Cipla CF)	Generic	-71.9
	d4T 30mg capsule	48	20 (Aurobindo CF)	Generic	-58.3
	ddl 2g powder for reconstitution	276	88 (Aurobindo)	Generic	-68.1
	ddl 25mg tablet	212	115 (Cipla)	Generic	-45.8

	dl 50mg tablet	0.158	0.079 (Cipla)	Generic	-50.0
	ddl 100mg tablet	311	188 (Cipla)	Generic	-39.5
	ddl 125mg enteric-coated capsule	N/A	111 (Aurobindo)	No originator price listed	Not applicable
	ddl 150mg tablet	0.308	0.167 (Cipla)	Generic	-45.8
	ddl 200mg tablet	N/A	0.257 (Cipla)	No originator price listed	Not applicable
	ddl 200mg enteric-coated capsule	N/A	0.383 (Aurobindo)	No originator price listed	Not applicable
	ddl 250mg enteric-coated capsule	223	103 (Cipla)	Generic	-53.8
	ddl 400mg enteric-coated capsule	288	132 (Cipla)	Generic	-54.2
Gilead/Bristol-Myers Squibb/Merck	TDF/FTC/EFV 300/200/600mg tablet	613	216 (Matrix)	Generic	-64.8
Gilead	TDF 300mg tablet	204	85 (Matrix)	Generic	-58.3
	TDF/FTC 300/200mg tablet	315	143 (Matrix CF)	Generic	-54.6
GSK	AZT/3TC 60/30mg tablet	N/A	88 (Ranbaxy)	No originator price listed	Not applicable
	AZT/3TC 300/150mg tablet	197	110 (Matrix CF, Ranbaxy, Aurobindo CF)	Generic	-44.2
	ABC 20mg/ml oral solution	230	120 (Cipla CF)	Generic	-47.8
	ABC 60mg tablet	N/A	134 (Cipla CF)	No originator price listed	Not applicable
	ABC 300mg tablet	438	207 (Cipla CF)	Generic	-52.7
Merck	EFV 30 mg/ml suspension	0.094/ml	N/A	No generic suppliers listed	Not applicable
	EFV 50mg capsule	N/A	0.083 (Aurobindo)	No originator price listed	Not applicable
	EFV 50 mg tablet	0.12	0.083 (Matrix)	Generic	-30.8
	EFV 100 mg capsule	N/A	0.15 (Aurobindo)	No originator price listed	Not applicable
	EFV 200 mg capsule	N/A	118 (Ranbaxy)	No originator price listed	Not applicable
	EFV 200 mg tablet	394	110 (Strides)	Generic	-72.1
	EFV 600 mg table	237	61 (Matrix)	Generic	-74.3
	RAL 400mg tablet	1113	N/A	No generic suppliers listed	Not applicable
	IDV 400mg capsule	394	292 (Aurobindo)	Generic	-25.9
Roche	enfuvirtide (enfuvirtide)	NA	N/A	No prices listed	Not applicable

	SQV 200mg hard capsule	1212	1621 (Cipla)	Originator for Category 1, Generic for Category 2 and no restrictions	+33.7
	SQV 500mg tablet	1113	N/A	No generic suppliers listed	Not applicable
	NFV 50mg/g oral powder	2129	N/A	No generic suppliers listed	Not applicable
	NFV 250mg tablet	1566	945 (Cipla)	Generic	-39.7
Tibotec	DRV 300mg tablet	1095	N/A	No generic suppliers listed	Not applicable
	ETV 100mg tablet	913	N/A	No generic suppliers listed	Not applicable
ViiV (GSK as originator- ViiV markets and sells these drugs)	FPV 50mg/ml suspension	648	N/A	No generic suppliers listed	Not applicable
	FPV 700mg tablet	1222	N/A	No generic suppliers listed	Not applicable
	AZT 10mg/ml syrup	234	66 (Aurobindo CF and Hetero CF)	Generic	-71.8
	AZT 60mg capsule	N/A	115 (Aurobindo CF)	No originator price listed	Not applicable
	AZT 100mg capsule	0.122	0.048 (Aurobindo CF)	Generic	-60.7
	AZT 250mg capsule	0.276	N/A	No generic suppliers listed	Not applicable
	AZT 300mg capsule	161	91 (Aurobindo CF; Cipla CF); Matrix (CF); Ranbaxy (CF))	Generic	-43.5
	AZT/3TC/ABC 60/30/60mg tablet	N/A	244 (Matrix)	No originator price listed	Not applicable
	AZT/3TC/ABC 300/150/300mg tablet	653	365 (Matrix)	Generic	-44.4
	ABC/3TC 60/30mg tablet	N/A	175 (Aurobindo CF)	No originator price listed	Not applicable
	ABC/3TC 600/300mg tablet	484	122 (Aurobindo CF)	Generic	-74.8
	3TC 10mg/ml oral solution	84	29 (Aurobindo CF)	Generic	-65.5
	3TC 150mg tablet	64	33 (Cipla CF; Hetero CF)	Generic	-48.4
	3TC 300mg tablet	N/A	24 (Aurobindo CF)	No originator price listed	Not applicable

Note: The percentage difference figure reflects the percentage difference between the lowest available price offered by the originator firm and a generic supplier for the same drug and dose combination. The originator price is typically a Tier 1 price (see Chapter 5 and Table 5-3).
Note: The Gilead/Merck/BMS drug formulation listed in this table is for their fixed dose combination drug, which combines three drugs from Gilead, Merck, and BMS.
Note: The suffix 'CF' refers to prices negotiated under the Clinton Foundation HIV/AIDS Initiative (CHAI).
Source: MSF. (2010). *Untangling the web of antiretroviral price reductions*: 13th Edition. Retrieved from Médecins Sans Frontières: utw.msfaccess.org.

Appendix D: P^{3}H Development, Governance, and Accountability Framework

Category	Criteria	Research and Evaluation Indicators	Implementation Strategies
Design and Strategic Development	Collaborative P3H design	• Internal and external stakeholders identified through collaborative process • Ex-ante committee established • Committee has representation from internal and external stakeholders	• Review of internal and external stakeholders conducted by private business actors and state partners with transparent invitation to civil society organisations to submit potential stakeholder recommendations
	Participatory and consultative public-private partnership design	• Ex-ante meetings to discuss P^{3}H formation • Use of consensus and/or democratic decision-making styles with minimal Executive decision-making	• Ex-ante committee establishes meeting schedule, development timelines, financial arrangements, and decision-making styles
	Conduct of risk, needs, and impact assessments	• Procedures exist for vetting partner selection, including identification of conflicts of interest. • Public authorities have identified potential health governance needs • Needs assessment clearly details prospective risks, costs, and contributions for each partner • Needs and impact assessment includes equity and human rights impact component • P^{3}H details how its activities will reduce global health inequities • Development of short and long-term strategies to monitor and evaluate P^{3}H impacts in health equity and human rights	• Partner selection and vetting procedures undertaken by ex-ante committee Needs and impact assessments may be undertaken by public authorities or by neutral third-party agents to survey existing health governance landscape and identify needs and priorities that align with national strategic planning and objectives, neglected policy and programmatic areas, or global/multilateral initiatives and objectives • Invite stakeholders and other knowledgeable observers to consult in equity and human rights needs and impact assessment
	Alignment, equity, and sustainability in strategic and organisational effectiveness planning	• P^{3}H develops yearly and longer-term (i.e. five year) strategic planning with clear policy, implementation, and evaluation mechanisms • Strategic planning includes explicit equity and human rights orientation, implementation, and evaluation strategies • Strategic planning aligns with national strategic plans and/or global/multilateral initiatives	• Representative and participatory process with private business actors, public authorities, and other internal and external stakeholders • Publication of strategic vision document on partnership website and circulated to internal and external stakeholders
Governance	Effective, representative,	• Board of Directors established with shared	• Ex-ante vetting procedures to help identify

	and ethical governance structure	decision-making authority • Country-level representation on the Board of Directors • Potential conflicts of interest identified and managed through transparent procedures • Public and private partners have joint administrative and financial authority in the disbursement of funds	potential conflicts of interest • Partners work through a consultative process to establish mutually acceptable terms for administrative and financial authority.
	Clearly defined roles and responsibilities for each partner	• P^3H terms, roles, responsibilities, and accountability and dispute resolution procedures are delineated in memoranda of understanding developed in ex-ante design	• Identify best practices in developing memoranda of understanding and partnership terms
	Transparency in governance	• Board of Directors regularly publishes agendas and minutes of meetings	• Publications of agendas and minutes posted on partnership website and circulated to internal and external stakeholder groups
Accountability	Giving account	• P^3H website with detailed information on partnership operations, objectives, terms, governance, and evaluation documentation • Website is updated regularly and decisions and events are circulated to stakeholders.	• P^3H administrative and/or Secretariat staff perform these roles
	Taking account	• Internal and external stakeholders are offered substantive opportunities to consult on design, needs assessment, impact assessment, strategic development, governance procedures, memoranda of understanding, and operations	• Exploration of possible engagement strategies and tools (web forums, social media, questionnaires, surveys, etc)
	Holding to account	• Third-party agents conduct regular monitoring and evaluation of operations, relations, and strategic implementation, including equity and human rights evaluation component • P^3H has established procedures and channels for receiving complaints and feedback • P^3H has established procedures for analysis and response to complaints and feedback	• Exploration of possible feedback and complaint submission and response mechanisms, including, inter alia, web-based forums, community forums, and partnership sub-committees