

The Partnership Prescription: Access to HIV/AIDS-related Pharmaceuticals and Global Public-Private Partnerships¹

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Abstract

This paper provides a preliminary examination of the operational and normative issues, prospects and challenges of global public-private partnerships in enhancing access to HIV/AIDS-related pharmaceuticals in low and middle income countries, particularly sub-Saharan Africa. It investigates two public-private partnerships in the treatment of HIV/AIDS and related illnesses and conditions. Global public-private partnerships (GPPPs) in health have been created, purportedly, as a response to both market and government failure to provide health care goods and services, particularly in developing countries. They have been created to address issues of product development (vaccines or pharmaceuticals), improve access to healthcare products, assist with global coordination mechanisms, strengthen health care services, provide public advocacy and education, and for regulatory and quality assurance purposes. In the age of a devastating pandemic ravaging sub-Saharan African countries and populations, the issue of access to essential medicines has profound practical and human rights dimensions. These partnerships have been carved out in a context of social contestation over competing rights of pharmaceutical companies 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. These partnerships represent an attempt to overcome many of the access issues, and this paper explores some of the issues, challenges, and prospects for this critically important endeavour.

1. Introduction

Globalizing forces, including increasing interconnectivity in trade, finance, technology, communications, and population mobility have created impacts and challenges for public health that transcend national boundaries. Neither communicable nor non-communicable diseases (tobacco, food and nutrition related conditions, etc) can be contained or addressed solely within individual states. Furthermore, poverty-related diseases (HIV/AIDS, tuberculosis, malaria, etc), have reached epidemic proportions, and have cross-cutting and complex economic, social, and political determinants and impacts. There is a growing awareness that “institutions matter” in devising responses to complex global health issues (Dodgson, Lee & Drager, 2002; Kickbusch, 1997). One of these, enthusiastically recommended as a model for overcoming existing institutional deficiencies, is the creation of global public-private partnerships in health (GPPPs) (Reinecke and Deng, 2000). A GPPP is a collaborative relationship formed between at least three parties: 1) a corporation or industry association, 2) intergovernmental organizations, and 3) national authorities (Buse & Walt, 2001). Global public-private partnerships are created to develop new products (i.e. drugs and vaccines), improve access to products, assist with global coordination mechanisms, strengthen health care services, provide public advocacy and education, and for regulatory and quality assurance purposes (Nishtar, 2004). GPPPs are seen as a response to both market and government failure to provide health care goods and services, particularly in developing countries. Operating under the premise of ‘mutual benefit’, these

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partnerships are seen to provide needed resources and expertise to developing countries and international institutions in exchange for certain tax, marketing, regulatory, and other benefits to commercial partners. Despite the enthusiasm surrounding GPPPs in health in the UN system, at this stage, no global norms or frameworks have been established to help guide the development, implementation, and regulation of GPPPs. Often; in fact, they operate in a highly unregulated and/or ad hoc fashion. The ‘blind faith’ accompanying the rising popularity of GPPPs has obscured the development of such frameworks, and there is a need for critical literature and evaluations of GPPPs, both for their normative and operational issues and impacts, as well as for how GPPPs may, as a mechanism of global health governance, impact global health outcomes and cooperation.

This paper provides an overview of the emerging architecture in global health governance and situates GPPPs within this architecture. The paper discusses the features and models of global public-private partnerships in health and discusses their real and potential normative and operational implications for national and global health governance. The paper examines two public-private partnerships for pharmaceuticals provision: the Accelerated Access Initiative (AAI) and the Diflucan partnership. The AAI is an initiative hosted by the Joint United Nations Programme for HIV/AIDS (UNAIDS) to facilitate differential pricing negotiations on anti-retroviral therapies for the treatment of HIV/AIDS. The second partnership, the Diflucan Partnership Program, is a partnership between Pfizer and developing states which provides drug treatments for HIV/AIDS-related opportunistic infections. These two GPPPs cover two different models of partnerships (privately and publicly hosted), provide HIV/AIDS-related pharmaceuticals, and are among the more well-established GPPPs and each have been operational for extended periods of time (a minimum of five years). After analyzing the issues and implications associated with GPPPs and the specific cases, this paper considers the prospects and challenges of GPPPs in advancing health as a global public good. An analysis of GPPPs within the framework of the global public goods (GPG) concept provides insight into how these evolving mechanisms of global health governance contribute to global health outcomes and cooperation. Global public-private partnerships in health have real and potential normative and practical implications for national and global health governance, and in their current state, yield little potential for advancing health as a global public good.

2. A Changing Global Order in Health and Health Governance

Globalization has ushered in new challenges for health and is the driving force behind emerging forms of global health governance. Zacher (1999) argues that globalization is reducing the capacity of the state to provide for the health of their domestic populations. Increasing transborder flows of people, information, products (i.e. tobacco, alcohol), externalities (i.e. pollution), create increases in health risks for domestic populations, and thus new challenges for national health governance. It has also been argued that globalization is sustaining or exacerbating economic inequalities and poverty in and among states (Dodgson, Lee, & Drager, 2002), and is thus driving health and disease epidemics such as HIV/AIDS, malaria, tuberculosis, and so forth. Disease epidemics in malaria, tuberculosis, and other infectious diseases are exerting enormous pressures on health infrastructures and exacting massive morbidity and mortality tolls. Emerging infectious diseases such as SARS and avian flu have the potential to reach epidemic proportions. Non-communicable diseases including cardiovascular diseases and cancers are also increasing at alarming proportions in developed and developing countries.

Developing countries are expected to experience a double-burden: increasing communicable *and* non-communicable diseases. Lee (1999) argues that globalization is contributing to greater inequities in health, where poor and marginalized countries and populations share an expanding proportion of the global disease and poor health burden.

These trends have exposed the limitations of domestic health governance in a globalizing world. Governments are increasingly looking toward new forms of cooperation such as treaties³, global public policy networks, public-private partnerships (PPPs), and other arrangements to provide health research, services, products, and policy development and coordination. Health care promotion and provision is increasingly characterized by a shift from government to *governance* modalities. Dodgson, Lee, & Drager (2002) distinguish government from governance and describe governance as the “actions and means adopted by a society to promote collective action and deliver collective solutions in pursuit of common goals” (6). Governance can be ‘disentangled’ from government (Reinicke, 1997; Rosenau & Czempiel, 1992) to describe formal or informal activities and mechanisms in the pursuit of social goals and objectives. There has been a growth in the number and influence of non-state actors in health governance (Dodgson, Lee, & Drager, 2002) both at the domestic and the international level, in developed and developing countries. Civil society groups, social movements, private corporations, consultancies, think tanks and research institutes, and religious movements are participating in health governance through their roles in advocacy, policy formation, policy implementation, service and product provision, and research and development. Moreover, many of the health governance functions of the state are being *devolved* to non-state actors (for example, transferring ownership or responsibility for health services to the private sector or non-governmental organizations), or *supplemented* by non-state actors (new combinations of state and non-state actors in health governance). Dodgson, Lee, & Drager (2002) refer to the latter as the “hybridization of governance” (6), which includes the “growing partnerships of public institutions with the private sector” (McBride, 2004,5). This paper conceptualizes global public-private partnerships as the hybridization of governance (Dodgson, Lee & Drager, 2002)

Hybridization and Mixed Actor Governance

The delegation of governance functions to private actors is not an innovative practice. At the domestic level, states have been delegating governance functions to private actors via privatization, de-regulation, and transformations in the public service (i.e. the use of private consultants). Domestic health governance has typically consisted of mixed actors, including public actors (states, bureaucracies, etc) and private actors (community and faith-based organizations, private corporations, health practitioners, associations, etc). Partnerships between the public and private sector (particularly corporations) at the domestic level have become commonplace, particularly in western developed countries. Although these governance combinations are not new at the domestic level, they are relatively new at the international level (Börzel & Risse, 2005; Witte & Reinicke, 2005). These new partnerships are referred to as ‘global’ (rather than ‘international’) public-private partnerships because they involve non-state actors⁴ which are generally of a transnational character. These partnerships delegate specific

³ For example, the Framework Convention on Tobacco Control specifies principles for global tobacco supply and demand reduction. The Framework entered into force in February 2005 and currently consists of 126 parties (as of May 16, 2006).

⁴ Partnerships for pharmaceuticals provision are primarily composed of private sector (commercial and/or corporate foundation) partners.

tasks and roles to private actors, particularly transnational corporations and private foundations. Börzel & Risse (2005) identify three main purposes of global public private partnerships: 1) rule and standard setting, 2) rule implementation, and 3) service provision. Global public-private partnerships are an example of a relatively new form of health governance that involves a combination of state and non-state actors. Under globalization, the traditional state-centric system of international health governance is transforming, both in terms of the complexity of the health challenges that states encounter, and the responses, which are increasingly global and mixed actor in nature. Global public-private partnerships are gaining considerable popularity as an institutional mechanism of global health governance to address global health issues. However, there are a multitude of challenges associated with these new forms of governance, which are explored in the subsequent sections of this paper.

3. Global Public-Private Partnerships in Health: An Overview

Global public-private partnerships are voluntary and collaborative relationships (Dodgson, Lee, & Drager, 2002; Nelson, 2002) that bring together state and non-state actors to undertake specific functions in health governance. Nelson (2002) suggests that partners agree to “share risks, responsibilities, resources, competencies and benefits” (47). There is considerable confusion, as well as controversy surrounding the definition and parameters of global public-private partnerships. Richter (2004) suggests that the term “partnership” for these configurations is ‘value-laden’ (47) because it assumes that the roles, responsibilities, and benefits of partnership are equal. Hence, the use of the term ‘partnership’ carries a positive or neutral connotation, which potentially obscures the negative or problematic aspects of the arrangements. Martens (2003) criticizes the term, noting that it elevates and legitimizes the status of private actors, while concomitantly downgrading the status of the public sector in the area or issues of health governance are addressed by the partnership. At a meeting of public-private partnerships participants involved in drug delivery, Buse (2001) reflected on some of the confusion surrounding the critical attributes of partnerships. Meeting participants failed to arrive at a consensus on whether partnerships needed to be based on shared goals, shared decision-making, a division of labour, and/or mutual contributions of human, physical, and capital resources (Buse, 2001:7). A more detailed discussion about the appropriateness of the term ‘partnership’ to describe these configurations is beyond the scope of this paper, however, it is important to note that the term, in its most positive or even neutral connotations, inevitably belies the need for more thorough and critical evaluations of the normative and practical implications of GPPPs for national and global health governance.

The proliferation of global public-private partnerships in health reached an apex in 2000, with the addition of 17 new partnerships. Fifty of the partnerships were established between the years 1998 and 2003.⁵ Most of the 92 existing partnerships in health address infectious diseases (see Appendix, Table 1.0), and 19 identify HIV/AIDS as the health condition addressed by the partnership. There are several different configurations of global public-private partnerships; however, Evans & Chen (2005) describe two broad groupings. The first type, partnerships operated by International Agencies, invites participation of private sector actors. These partnerships are under the administrative and financial control the United Nations, or World Bank staff and systems (Evans & Chen, 2005). The Roll Back Malaria Initiative, Stop TB Initiative, and the Accelerated Access Initiative (AAI) are examples of this type of partnership.

⁵ www.ippph.org/index.cfm?page=/ippph/partnerships/date_established

The other grouping includes partnerships that are independently structured non-profit entities with private governance, operations, and financing (Evans & Chen, 2005), such as the Diflucan Partnership, which will be discussed later in the paper.

Rationale for Partnership

The rationale for global PPPs in health is that they are a response to both market failure (Evans & Chen, 2005) and institutional failure or lethargy (Holm, 2001; Evans & Chen, 2005) to provide health care goods and services, particularly in developing countries. Other explanations for the development and growth of GPPPS suggest that neo-liberalism, and its emphasis on the retrenchment of the public sector in social policy and programs (including health) has changed the way people think about the obligations of the state and the potential role of the private sector in health governance (Holm, 2001; Evans & Chen, 2005). Finally, GPPPs are seen as an “unavoidable necessity” in harnessing the necessary resources to address increasingly complex, inter-related, global health issues (Brundtland, 2002). The United Nations lists GPPPs on their list of approaches to make UN agencies more efficient and effective, and increasingly UN agencies are promoting closer ties with the business community (Richter, 2004).

Benefits to the Private Sector

Partnerships afford numerous benefits to private sector partners, including direct financial returns, whether through tax breaks or payment for services or products (for example, some partnerships between pharmaceutical companies and states negotiate discounted drug pricing instead of donations). Buse & Walt (2000) refer to the fact that many of the contributions made by private sector partners are tax deductible. Partnerships allow the private sector to penetrate a market that may have previously been inaccessible, and promote their image and brand (Buse & Walt, 2000). Partnerships provide enhanced corporate legitimacy and authority with institutions such as the United Nations and other bodies (Buse & Walt, 2000). Buse & Walt (2000) note that the costs associated with many of the private sector contributions are relatively small compared to the benefits arising out these partnerships. For example, Bristol-Myers Squibb’s annual contribution of US\$20 million represents 0.1% of the companies US\$18.3 billion in annual sales (Buse & Walt, 2000:706).

Benefits to National and Global Health

Partnerships provide resources to national and global health governance in the form of drugs, supplies, services, or funds (Holm, 2001). Partnerships also provide skills, expertise, and management to health interventions. For example, the African Comprehensive HIV/AIDS partnership (ACHAP)⁶, a partnership between the Bill and Melinda Gates Foundation and Merck Foundation, has provided training to over 500 Government, NGO and other actors in project development, monitoring, evaluation, proposal development, media training, and computer skills, as well as training for over 1200 health care workers.⁷ ACHAP reports that over 12,000 people have been enrolled into the national anti-retroviral treatment program. Partnerships, such as the Mectizan® Donation program, have largely contributed to the eradication of blinding onchocerciasis (Buse & Walt, 2000:706).

⁶ The ACHAP website is located at: www.achap.org

⁷ www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=49&typobj=0

4. Operational Issues and Challenges of GPPPs: Governing Arrangements, Transparency, Accountability, Outcome Orientations, and Sustainability

Much of the criticism launched against public-private partnerships pertains to their governing arrangements. There are concerns with GPPPs in terms of real and potential conflict of interest situations, accountability, transparency, decision-making structures and participation, sustainability, and outcome orientations. In terms of membership, there are substantial problems with the selection and representation of partners. Richter (2004) contends that corporate partners are not adequately scrutinized by international agency partners for potential conflicts of interest. Buse's (2004) study supports Richter's claim, noting that only four (4) out of the nineteen (19) partnerships in his study undertook formal assessments of the background of their commercial partners. Buse (2004) notes that this oversight is occurring in both international agency and non-profit entity partnerships, and suggests that where guidelines exist in international agencies governing corporate selection, "they are not widely adhered to" (238). Furthermore, as Buse (2004) notes, there is a "gross under representation of southern stakeholders" (240) in the governing arrangements of GPPPs. Out of the 92 global public-private partnerships in health listed in the Initiative for Public Private Partnerships in Health (IPPPH) database⁸, all but four (4) have Secretariats in northern countries (North America and Western Europe (see Figure 1.0). What is the nature of 'partnership' and the potential for meaningful involvement and representation in the processes of decision-making for developing countries when the loci of decision-making are concentrated in northern countries?

Kickbusch (1997) argues that one of the critical processes associated with the globalization of health is that decision-making processes are increasingly inaccessible to the public. GPPPs have the potential for exacerbating the problems of transparency and representation in decision-making. While partnerships make basic information (profile, programmes, partners, contacts, public relations material)⁹ available on their websites, few partnerships post annual budgets or program evaluation/impact documentation. Where publications are posted to the website, they largely resemble public relations material detailing the 'successes' of the programs. In a study by Buse (2004) he found that none of the partnerships with independent legal status make available the minutes of their deliberations (237). Buse (2004) also notes that while auditing practices are common in GPPPs, they are not practiced by all partnerships. Buse (2004) concludes that regardless of whether the partnership is a publicly or privately hosted partnership, very little information is made publicly available on the partnerships' governing arrangements.

There is considerable discussion on the issue of accountability of GPPPs in the literature (Nishtar, 2004; Buse, 2004; Evans & Chen, 2005; Buse & Walt, 2000). Questions are raised as to whom the partners are actually accountable to, as well as the availability and employment of reporting mechanisms (Buse, 2004). Are the funders accountable to the partner countries or international agencies or to their own stakeholders? What are the measures of accountability? Are they purely fiscal or are there other evaluations of performance? How and to whom are these

⁸ Initiative for Public-Private Partnerships in Health (IPPPH) database is available to the public, but requires registration with the Secretariat. Permission to use the database was obtained on November 2, 2005. Database:

<http://www.ippph.org/index.cfm?page=/ippph/partnerships>

⁹ See www.achap.org (African Comprehensive HIV/AIDS Partnership); www.securethefuture.com (Secure the Future); www.diflucanpartnership.com Diflucan Partnership, www.lillymdr-tb.com/ Eli Lilly Multi-Drug Resistant Tuberculosis Partnership; www.iavi.org International AIDS Vaccine Initiative, for a small cross-section of partnership websites. Note that not all partnerships have websites.

reported? Who are the partnering countries/agencies accountable to? To their citizens/constituent members and/or the funders? How are these reported? What are the consequences of poor performance by partners? By what criteria are the partners judged on measures of accountability? These and other questions have yet to be resolved and will continue to call into question the legitimacy and feasibility of GPPPs as a mechanism of global health governance.

There are also challenges and controversies with the outcome orientations of GPPPs. Partnerships in general report effectiveness in terms of value-added contributions (see Holm, 2001). Partnerships often report on the number of drug units distributed, the number of personnel trained, the total funds distributed, and other quantitative impacts.¹⁰ For example, the AAI and Diflucan Partnership make this type of information available, but offer very little publicly available information on partnership governing arrangements and other operational aspects. 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 very little empirical data or even anecdotal information on how partnerships interface with national health governance institutions and structures. Very little consideration is afforded to the potential problems or unintended side-effects of partnerships; partnerships tend to emphasize their value-added and functional contributions. Further complicating these issues, Holm (2001) notes that there is very little baseline data upon which to conduct research on the effectiveness of partnerships in their specific contributions to health or health outcomes.

There are serious concerns surrounding the sustainability of the partnerships. Some of the partnerships do not have stated timelines, some have guaranteed drug donation until there is evidence of disease eradication (i.e. Merck & Co. Mectizan® donation), while others have between three and six year life spans, after which the partnership is either terminated, or extended by agreement of the parties involved. Some partnerships, such as Global Alliance for Vaccines and Immunizations (GAVI) have been criticized for not only their organizational sustainability, but for their financial sustainability as well. Nishtar (2004) looks at GAVI as an example of a GPPP that emphasizes high technology vaccines, relies heavily on the private sector, and “runs the risk of compounding health inequities in developing countries” (5). Yamey (2001) makes similar conclusions in his study of GAVI, revealing that the vaccines were being sent to countries that already had some basic immunization coverage, while the poorest countries that lacked even basic immunization coverage (tetanus, polio, diphtheria) were not covered under GAVI. Furthermore, there is a question of whether drug donations are sustainable models for the provision of essential medicines (Gardiner, 2003). These partnerships, despite providing needed resources for the treatment of diseases and health conditions, are nonetheless a charity model of health, rather than a model of global collective action and responsibility for health. This model necessitates dependency on the donor, who may or may not continue their programs upon expiration. Policy levers or instruments compelling the donors to continue their programs are non-existent, and short of moralsuasion and tax-breaks, leave the recipient countries and agencies largely at the mercy of the donors. GPPPs have responded (see Holm, 2001) to criticisms of sustainability, noting that many public sector organizations often do not make program commitments for longer than five years. While public sector organizations 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 public sector

¹⁰ See www.ippph.org health partnerships database for information on partnership impacts (including publications on impact).

organizations that do not necessarily exist in the partnerships, particularly those that are independent non-profit entities.

Normative and Operational Interfaces between National Health Governance and Global Public-Private Partnerships

Interfaces between institutions and structures of national health governance and the partnerships are rarely revealed by the partnerships themselves, and are only beginning to be considered in academic (Nishtar, 2004) and policy (See Holm, 2001; Caines & Lush, 2004) literature. Moreover, very few studies exist that investigate the obstacles and unintended side-effects of implementation, integration, and management of partnerships with existing health governance structures and institutions. Caines & Lush (2004) examine a cross-section of pharmaceutical partnerships in low and middle income countries, and identify several issues with how these partnerships impact health governance. For example, their report reveals evidence that partnerships faced a low level of trust between governments and the pharmaceutical industry, and affected local competition of pharmaceutical sales (Caines & Lush, 2004). Perhaps partly due to the emphasis on the ‘value-added’ aspects of partnerships, very little consideration is given to the actual costs of involvement. Partnerships have the potential to overwhelm the capacity of the national health system (Holm, 2001; Caines & Lush, 2004). Sturchio & Cotarella (undated) note in their assessment of the Merck’s Ivermectin donation program that poor community health infrastructure in many of the countries most affected by river blindness impeded drug distribution. Thus, partnerships, particularly those in developing countries, are likely to confront inadequate health infrastructure, and have the potential to overwhelm already overextended health personnel and infrastructure. Moreover, because very few partnerships¹¹ actually address more than one aspect of health (product development, access to products, health systems and services, research, public information and advocacy, and coordination), the partnerships are, for the most part, vertical programs that require integration into existing health infrastructures and strategies, and could possibly contribute to the fragmentation of health systems (Buse, 2004; Nishtar).

Nishtar (2004) considers the potential normative implications of GPPPS, and argues that they have the potential to alter public priorities, redirect national policies, and shift public responsibility for health to the private sector. GPPPs have the potential to contribute to the further commercialization and privatization of health governance by weakening the role of the public sector in providing essential health services and treatments and by transferring this responsibility to private sectors partners. Given what we already know about some of the negative impacts of economic globalization and global restructuring on national health systems (See Bienan & Shelton, 2001; Birdsall & Lawrence, 1999; Coburn, 2000; Haddad & Mohindra, 2001), are GPPPs contributing to or mitigating against the hollowing out of the state’s capacity *and* autonomy to deliver health services? This is a question for future research, but one that deserves closer investigation. Are GPPPs simply new forms of developing country dependency on developed countries? Given that very few of the partnerships involve real transfers in *knowledge*, or building of new infrastructure, and that the intellectual property generated by these partnerships (i.e. in vaccine development) will be largely retained by researchers in the north, how do these partnerships, beyond the value-added component, contribute to the building

¹¹ Four of the 92 partnerships listed with the IPPPH address more than one aspect of health. Figure obtained from the Initiative for Public-Private Partnerships in Health Database

of equitable, sustainable health systems in developing countries? The literature on public-private partnerships has yet to answer these questions.

Normative and Operational Interfaces between Global Health Governance and Global Public-Private Partnerships

Global public-private partnerships in health have implications for global health governance vis-à-vis their enhanced role in global public policy making. Given their growing popularity as a mechanism of health governance, there are reasonable concerns over enhanced corporate influence in setting the global health agenda (Richter, 2004). Buse & Walt (2000) argue that partnerships have increased corporate influence in policy making at global and national levels. Furthermore, there are implications for global health governance institutions in embracing the use of GPPPs. Richter (2004) argues that GPPPs pose a risk to the “integrity, independence, and reputation” of the United Nations (48). Buse & Walt (2000) question the appropriateness of using public money (in the partnership arrangements) to support corporate legitimacy. These partnerships open up considerable space for private sector influence in global health decision-making, and Buse & Walt (2000) argue that this weakens the ‘universality’ of multilateral institutions, and could potentially undermine traditional support for the UN. The latter part of their argument is rather unconvincing, however, given that governments around the world are increasingly employing public-private partnerships as a mechanism of service delivery. Despite the issues and implications with public-private partnerships, governments and multilateral institutions at this point seem to be readily embracing them. Dodgson, Lee & Drager (2002) argue that there is a need for “consensus about the underlying moral and ethical principles that guide global health cooperation” (21). Currently, the *de facto* consensus in the UN system supports the use and proliferation of global public-private partnerships in health.

At this time, there is very little empirical data available with which to test and assess these claims. This paper forms part of a larger research program that will examine the normative and operational issues and challenges of partnerships through an investigation of two selected public-private partnerships in pharmaceuticals provision: the Accelerated Access Initiative and the Diflucan Partnership. The next section of the paper overviews these two partnerships, including their real and potential normative and operational implications for national and global health governance.

5. Public-Private Partnerships in Health, HIV/AIDS, and Access to Pharmaceuticals

There are approximately 39.5 million people in the world currently living with HIV/AIDS in 2006, 95% of which are living in the developing world and 63% in sub-Saharan Africa (UNAIDS/WHO, 2006). HIV/AIDS claimed 2.9 million lives in 2006, of which over 380,000 were children under 15 years of age. However, in absolute numbers and as a percentage of the total population, the burden of disease has massively and disproportionately fallen to sub-Saharan Africa. HIV/AIDS is a global pandemic that has exacted an enormous toll on individuals, families, communities, organizations and governments. Many of these impacts will not be immediately visible or measurable; they are silent and pervasive. They exist among the families that suffer breakdown, the children left behind, the fields left untended, the government ministries unstaffed, and the weakening of community networks and supports. Because HIV/AIDS largely affects reproductive and productive populations (between the ages of 15 and

49), the implications for children, families, agriculture, education, government, the private sector, and the health sector can be acute and extensive. Whiteside and Barnett (2002) argue that infectious disease epidemics are “deeply rooted in the global social and economic life that we share” (4). The nature and course of a disease epidemic is contingent upon and mediated by social, economic and cultural factors. This is observed with regard to the distribution and effects of HIV/AIDS around the world. The distribution of HIV/AIDS speaks to the distribution of power and wealth around the world. While the epidemic has largely been contained in Western Europe and North America, it has exploded in the developing world. Diseases in the developing world are largely the product of social and economic conditions, whereas diseases in ‘wealthier’ countries are often diseases associated with age and affluence (Whiteside and Barnett, 2002). In Canada and the United States, the top diseases causing mortality are heart disease and cancer, whereas in sub-Saharan Africa, the top diseases causing mortality are HIV/AIDS and malaria.

Scholars investigating impact assessment predict that HIV/AIDS has the potential to neutralize or reverse development gains. Some even went so far as to say that HIV/AIDS threatens to eliminate 25 years of development gains in Africa (Dixon, McDonald and Roberts, 2001). Clearly, a full-scale global response needs to be developed and sustained if there is any chance for stemming or reversing the tide of this devastating pandemic. And fundamentally, access to life-saving treatments for HIV/AIDS remains one of the principal methods for preserving the health of populations *and* countries.

It is now widely acknowledged that over one-third of the world’s population lacks access to essential medicines, including HIV/AIDS-related medicines (Sterckx, 2004). Of this group, over 50% live in the least developed countries in Africa and Asia (Sterckx, 2004). Drug access, particularly for those living in countries with endemic infectious diseases, including HIV/AIDS, malaria, and tuberculosis, has become a matter of life and death. Fifteen years following the first case of AIDS¹², new hope emerged with the advent of highly active antiretroviral therapies. These ARV therapies were successful in providing life-sustaining support for people living with HIV/AIDS. While these therapies have been available since 1996, high prices of these drugs have made them out of reach for the majority of people living with HIV/AIDS. In the western developed world, ARV treatments can cost between \$10,000-15,000 per person per year (Joseph, 2003). In a 1993 Report, “Investing in Health,” the World Bank reported that per capita spending on health was as low as US\$8 in the least developed countries. Clearly, these and other developing countries, as well as countries with economies in transition, were ill-equipped to offer these drugs as part of their health care delivery. Moreover, the high cost of these drugs made them largely prohibitive for the majority of individuals residing in these countries. Currently, 970,000 people in low and middle-income countries have access to anti-retroviral treatment (ARV); however, this means that 8 out of 10¹³ people who need ARV currently do not have access (<http://www.who.int/hiv/facts/cov0605/en/index.html>). If access to ARV remains at this level, approximately five to six million people are projected to die within the next two years (UNAIDS/WHO, 2004). High prices, deficiencies in coordination mechanisms and health infrastructure, and patent protections which restrict generic production of drugs constrain access to these treatments for many states in sub-Saharan Africa.

Pharmaceutical companies initially advanced an economic/property narrative on the issue of drug access. They argued that there was no relationship between the drug prices and access;

¹² The first recorded case of AIDS was in 1981.

¹³ Approximately 85% of people needing ARV coverage did not have access to treatment as of June, 2005. The situation is particularly acute in Africa with 95% lacking coverage in North Africa and 89% in sub-Saharan Africa.

rather, they claimed, that social, political, and infrastructural barriers impeded the broad rollout of complicated HIV/AIDS medications (Gellman, 2000; Joseph, 2003). Eventually, pharmaceutical companies conceded that prices charged for their drugs in developing countries made them largely prohibitive. However, they also argued that patent protection was necessary to stimulate drug research and development. International and domestic civil society organizations, including the Treatment Action Campaign (TAC) in South Africa¹⁴, Oxfam¹⁵, and Médecins Sans Frontières¹⁶ had conceptualized the issue differently and drew attention to the issue of patent protection, patent abuses, and the lack of generic competition in constraining access to HIV/AIDS-related pharmaceuticals. Furthermore, groups, such as the Harvard Consensus group refuted claims that it was not possible to administer widespread HIV treatment in poor countries.¹⁷ The claim by pharmaceutical companies that patent protection is necessary to stimulate research and development has also been challenged.¹⁸ Ultimately, however, the problem became defined as one of affordability for developing countries. The natural solution was therefore to provide deep price discounts or donations to developing countries to enhance access to these drugs. The Accelerated Access Initiative and Diflucan Partnerships emerged in these contexts to provide deeply discounted or donated HIV/AIDS-related pharmaceuticals.

The Accelerated Access Initiative

The Accelerated Access Initiative and the Diflucan Partnership were intended to ‘problem-solve’ the ‘accessibility’ issue of HIV/AIDS related pharmaceutical products. AAI was intended to increase access to anti-retroviral therapies which provide life-sustaining support to people living with HIV/AIDS. The Diflucan Partnership provides fluconazole (brand name ‘Diflucan’), an anti-fungal drug for the treatment of HIV/AIDS-related opportunistic infections. The Accelerated Access Initiative was announced in May 2000 and consists of a partnership between five UN organizations¹⁹ and six pharmaceutical companies²⁰. The partnership, according to the Initiative for Public-Private Partnerships²¹, was intended to address issues of drug access and affordability in the “hardest hit regions of the world.”²² Currently, 17 countries

¹⁴ See <http://www.tac.org.za>

¹⁵ See <http://www.oxfam.org>

¹⁶ See <http://www.msf.org>

¹⁷ Consensus Statement on Antiretroviral Treatment for AIDS in Poor Countries By Individual Members of the Faculty of Harvard University, 2001. See: www.hsph.harvard.edu/bioethics/pdf/consensus_aids_therapy.pdf

¹⁸ For example, Bettcher, Yach & Guindon (2000) argue that the premises of patent protection, (to stimulate innovation and generate money for research and development), fail to recognize that considerable research and development is conducted using government monies, that patents and intellectual property rights are relatively recent phenomena, that innovation and research and development has occurred in the absence of patent protection, and that intellectual property rights are afforded only when a country has achieved a certain level of economic development.

¹⁹ World Health Organization, United Nations Children’s Fund, United Nations Population Fund, the World Bank, and the Secretariat of the Joint United Nations Programme for HIV/AIDS UNAIDS

²⁰ Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, F. Hoffman-La Roche, GlaxoSmithKline and Merck and Co., Inc

²¹ The Initiative (IPPPH), defunct as of December 2004, was set up by the Global Forum for Health Research (http://www.globalforumhealth.org/Site/000_Home.php), an independent international foundation promoting global health research. The IPPPH website is www.ippph.org. The website houses a publicly accessible ‘health partnerships’ database which contains information on global public-private partnerships and is updated by the Global Forum on Health Research.

²² www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=2&typobj=0&id_chapter=abstract

are participating in the AAI (See Table 2.0). The AAI does not have separate legal status, and is coordinated by the Secretariat of the Joint United Nations Programme on HIV/AIDS (UNAIDS) in Geneva, Switzerland. The AAI works with governments, international organizations and the private sector to negotiate differential drug prices. Thus, all funding for HIV/AIDS pharmaceuticals comes from the countries themselves. Although the international public sector partners are involved in negotiating drug discounts, these negotiations occur primarily on a bilateral basis. Differential pricing negotiations are conducted with individual pharmaceutical companies on a country-by-country basis, although there is some indication that the Initiative may be working towards a regional collaboration approach. AAI indicates that these negotiations are available to countries that can “provide proof they have the health services to handle the complicated HIV/AIDS medicines.”²³ This is an important equity consideration of the AAI. Partnerships that select countries on the basis of existing health infrastructure inherently exclude countries that may desperately need discounted drugs, but are unable to access them because of ‘inadequate’ health systems and thus could exacerbate global health inequities. It is important to note that of the 17 countries participating in the AAI, only 6²⁴ are considered ‘high HIV/AIDS burden’ countries by the World Health Organization (WHO, 2005).

The WHO lauds the success of the Initiative, claiming that a total of 427,000 people living with HIV/AIDS in developing countries receive ARV treatment provided by AAI companies.²⁵ It is not clear how many of these people were recipients of treatment as a direct result of AAI-facilitated negotiations. However, the Initiative emphasizes the value-added benefits of the partnerships and claims that since its establishment there has been a 23-fold increase in the number of people receiving treatment from AAI companies.²⁶ The Initiative also claims that it has achieved significant price reductions on HIV/AIDS-related pharmaceutical products.²⁷ The AAI, from a functional or problem-solving perspective, has been quite effective. By negotiating lower drug prices, the Initiative has facilitated greater access to HIV/AIDS-related medicines. However, as discussed in section 4.0, there are normative and operational issues and challenges associated with the AAI. In terms of its governing arrangements, Buse (2004) notes that the executive of the AAI is not accountable to the governing body of the partnership (the Secretariat) but to the host organization. Buse (2004) argues that this limits the extent to which the partners can hold the Secretariat accountable for the workings of the partnership. The AAI also does not make available information on the management of its governing bodies or decision-making processes, nor does it publish (on Internet sites) its sources of funding or negotiated drug prices.

Thomas (2002) identifies real concerns with bargaining procedures and implications of the AAI and criticizes the AAI as an institution which reinforces and perpetuates structural inequality. Thomas (2002) argues that requiring countries to negotiate with individual pharmaceutical companies compromises their negotiating position. Table 3.0 presents total revenues and net incomes of AAI participating pharmaceutical companies from 2004 and 2005²⁸. When contrasting these figures to countries’ GNI and GDP, it can be seen that only 6 of the 17

²³ Ibid.

²⁴ See Table 1.0. High burden countries are identified by ‘hbc’ in the AAI participants column.

²⁵ See AAI fact sheet for more information: www.who.int/entity/hiv/AAI_fs_4Q2005.pdf

²⁶ Ibid.

²⁷ www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=2&typobj=0&id_chapter=impact

²⁸ Pfizer, Inc. is not a participating company in the AAI. Data from Pfizer, Inc is presented in this Table in reference to the Diflucan Partnership.

countries' GNI from 2004 is equal to or greater than the pharmaceutical company with lowest total revenues in 2004 (Boehringer Ingelheim at \$10.3 billion). Furthermore, 7 of the 17 countries are classified as severely indebted by the World Bank, 4 are moderately indebted, and 5 are less indebted (World Bank List of Economies, July 2005). This rather crude comparison nonetheless demonstrates the unequal bargaining positions of developing countries and pharmaceutical companies.

While Buse (2004) notes that the AAI was one of only four partnerships in his study²⁹ to undertake a formal assessment of the commercial partners in the partnership, he also refers to the limited pool of partner choices given the monopoly positions and patent protection afforded to pharmaceutical companies. At this point, there are several normative and operational challenges, including governing arrangements, transparency, sustainability, accountability, southern representation and bargaining procedures, outcome orientations and equity considerations. Continuing research on the AAI will examine the normative and operational interfaces and impacts of the partnership on national health governance, including health systems, policy and decision-making and local pharmaceutical markets and distribution systems.

The Diflucan Partnership

The Diflucan Partnership³⁰ is actually more appropriately conceptualized as a donation programme. It was launched in December 2000 by Pfizer Inc.³¹ in South Africa and has since expanded to over twenty-nine developing countries. Diflucan, also known as fluconazole, is an antifungal medicine for the treatment of fungal opportunistic infections such as cryptococcal meningitis and esophageal candidiasis. These infections regularly present in people living with HIV/AIDS. Although the partnership does not have dollar or time estimates, Pfizer has estimated the total cost of its partnership commitments to be US\$103 million (as of 2004), which represents 0.19% of total revenues for Pfizer in 2004.³² Of what little information is available on the partnership, Pfizer claims that it has distributed 7 million free doses of Diflucan to 1,100 sites in 42 developing countries across Africa, Asia, Latin America and the Caribbean.³³ The programme also trains health personnel in the treatment of opportunistic infections and appropriate dosing protocols. Pfizer, Inc. estimates the initial cost of training at US\$2 million. Weartheimer, Santella & Lauver (2004) note that the program has since expanded and trained and additional 9,000 health care workers. The Diflucan Partnership makes available this type of 'value-added' information on its website, yet like the AAI, offers no information on its negotiating and governing arrangements. Furthermore, there is no empirical data available to assess equity considerations in partnership development (i.e. how are these drugs being made available within the country? and to whom?), or in terms of the impact of partnerships on health governance structures, including policy and decision-making structures, local pharmaceutical markets, and health care systems. Future research will explore how and where this information is made available; for example, which partner is responsible for data collection and publication? And if this data is not collected, has it been in the past and who has been responsible for this type of data collection and publication?

²⁹ Buse's (2004) study undertook an analysis of the governing arrangements of nineteen global public-private partnerships.

³⁰ www.diflucanpartnership.org

³¹ Pfizer, Inc., is the world's largest pharmaceutical company (See Table 2.0).

³² Based on data obtained from Pfizer Annual Report 2005

³³ www.ippph.org/index.cfm?page=/ippph/partnerships/name&thechoice=show&id=73&typobj=0

Pfizer makes their drugs available only to public sector and NGO partners, and thus there are likely effects on local pharmaceutical markets. Furthermore, there is also the question of the long-term sustainability of drug donation models (Gardiner, 2003). In addition to some of the issues identified with public-private partnerships in section 4.0, an analysis of this partnership reveals how social relations figured significantly into its genesis. In South Africa, where the partnership was first launched, initially high prices of fluconazole constrained widespread access. The Treatment Action Campaign launched a major campaign against the high price of fluconazole on March 13, 2000³⁴. Initially, TAC demanded that Pfizer, Inc. reduce its drug prices³⁵, citing significantly lower prices in the public sector in South Africa and internationally³⁶. When Pfizer, Inc., failed to meet their requests, the Treatment Action Campaign demanded generic competition of fluconazole^{37, 38}. The campaign resulted in mass protests to demand that the Medicines Control Council of South Africa grant a 'Section 21' exemption to the generic importation of fluconazole ('biozole') from Thailand. Within weeks of the filing, Pfizer announced that it would donate fluconazole to the public sector for people with cryptococcal meningitis and systemic thrush.³⁹ The donation programme would provide drugs only to the public sector, and Pfizer refused to grant a voluntary license for fluconazole production in South Africa. However, when Pfizer, Inc., failed to roll out its donation programme in a timely manner, TAC began importing generic fluconazole for distribution.⁴⁰ Pfizer eventually responded and accelerated its donation distribution. Because Pfizer's patent on fluconazole expired in 2004⁴¹, it has been eager to gain a market threshold in many other developing countries, and continues to expand its donation programme.

The Diflucan Partnership is therefore not merely a 'functional' or 'problem-solving' response to high drug prices. The partnership is, in some senses, an institutional compromise midwifed by conflict between public and private interests. The South African government has not, and likely will not, exercise its options under the TRIPs safeguards⁴². If the South African government were to exercise its options, this would substantially drive down the prices of the drugs through generic competition. Until such time as Pfizer withdraws from the partnership, the South African government and peoples are beholden to Pfizer, dependent upon its potentially fickle generosity. Pfizer's private interests in the market are secured and enhanced by the partnership⁴³; they are insulated from compulsory licensing and parallel importation and generic competition; the partnership provides much needed favourable publicity, and offers lucrative tax deductions on their donations in the United States, all at very little cost to their bottom line. The

³⁴ Obtained from: www.tac.org.za

³⁵ TAC launched a major campaign on March 13,2000 to reduce the price of fluconazole. In written correspondence to the

³⁶ TAC listed fluconazole at R28.57 per 200mg capsule in the public sector, 80.24 in the private sector, and R1.78 in Thailand.

³⁷ See www.tac.org.za and conduct a search on 'fluconazole'

³⁸ Press release dated November 19, 2000 which indicates that TAC filed a Section 21 Exemption to the Medicines Control Council.

³⁹ Press Release, dated November 28, 2000. www.tac.org.za

⁴⁰ Correspondence on TAC website indicates that Morne Visser, TAC supporter and activist, brought in generic fluconazole on January 13,2001.

⁴¹ See: www.cptech.org/ip/health/fluconazole/info.html

⁴² The Agreement on Trade-Related Aspects of Intellectual Property contains provisions to allow countries to issue compulsory licenses or parallel import patented products in situations of a national emergency.

⁴³ The African markets for pharmaceuticals are very small in comparison to European and North American markets, but have been steadily growing and the demand for pharmaceuticals is projected to increase substantially.

normative and operational impacts of these partnerships for national and global health governance require further investigation, although, it can be argued at this point, that there are important normative and operational issues which necessitate scrutiny, and hence, reform.

6. Concepts of Health and Cooperation in Global Health

Global Public Goods (GPG) Framework for Global Health Cooperation

In traditional economic theory, public goods are goods that are *non-excludable* (no one can be excluded from using them) and *non-rivalrous*, meaning that one person's consumption does not prevent anyone else's (*non-rivalrous*) (Smith, 2003; 475). Public goods are undersupplied by the market because there is no commercial incentive to produce them and thus require public provision or financing (Labonte, 2004). Health economists have long recognized that the provision of health care goods and services often results in a market failure. Market failure occurs when the market fails to efficiently allocate goods and services.⁴⁴ The government intervenes to provide public goods either through direct public provision of the good, through taxation, financing, or licensing (Smith, 2003: 475). Classic examples of public goods are a lighthouse, peace, security, and emergency health services. Health products and services are also undersupplied as a result of government failure. Governments, particularly those in developing countries, often lack the fiscal or organizational capacity to provide for the health of their populations. Hence, the need arises for support from other actors to help promote and protect the health of these populations.

Global public goods are goods whose benefits transcend borders, benefit all countries, population groups, and generations (Türmen, 1999: 9). Global public goods include clean air, and peace and security and can be supplied through transnational agreements and protocols and other forms of collective action (Barrett, 2004). At the global level, there is no equivalent institution with the power to levy taxes to provide public goods. Thus, the global public goods (GPG) concept is intended to provide a rationale and framework for collective action on global health issues. By demonstrating that health risks, particularly in the context of globalization (Türmen, 1999), transcend national borders; the GPG concept encourages the global community to support efforts for disease eradication, health promotion and health protection. The GPG concept is part of the agenda promoted by the United Nations Development Programme (UNDP) (Woodward et al, 2001) and serves as a framework for action, as well as a normative premise and a "paradigmatic shift in the conceptualization of public health" (Brando, 2004:11). Under the UNDP agenda, the GPG concept is intended to improve outcomes in global health as well provide intermediate products and services through collective action.

There are various types of goods, including private goods, national public goods, intermediate public goods, and final global public goods (Kaul & Mendoza, 2003). Intermediate public goods are public goods that are non-excludable, but rivalrous (Brando, 2004). Intermediate public goods are seen to "bring us partially to the goal of global public health" (Brando, 2004:3), by providing health services and products that contribute to global health. Global public-private partnerships provide intermediate public goods, including disease surveillance, disease control, disease eradication or elimination, disease treatment, and resistance avoidance (Barrett, 2004a: 1). Ultimately, however, the pursuit of intermediate public goods

⁴⁴ Ensor, Tim. "Microeconomics and Market Failure in Health." [on-line]. Accessed April 4, 2004. <http://www1.worldbank.org/hnp/hsd/documents/MFailure.pdf>

through global public-private partnerships has several negative externalities for the attainment of global health outcomes and global cooperation in health.

Global public-private partnerships are not *global* in design or implementation. The design and governance of GPPPs is highly asymmetrical, with governance of the GPPPs primarily residing in North American and Western European countries. While some GPPPs can claim that they have incorporated national health governance priorities and voices (for example, ACHAP) in the design and implementation of their programs, GPPPs continue to be criticized for the lack of representation and participation of southern stakeholders in both the design and governance of programs. GPPPs are intended to serve as a pathway to global health outcomes, yet ultimately may reinforce existing power and decision-making imbalances, rather than advancing true global cooperation in health. Global health governance should not serve as a euphemism for ‘northern’ health governance, and thus GPPPs offer little prospect in their current state for broader *global* health governance and cooperation.

Instead of contributing to greater global health cooperation, drug donation programs reinforce the charity model of health, and potentially intensify dependency relations. Few partnerships address state capacity building and health infrastructure development which would support developing states in providing for the health of their populations, and enhance their role in both national and global health governance. While some GPPPs train healthcare personnel and work with national and sub-national health governance authorities and institutions to provide a broader array of services, a large contingent of GPPPs provide vertical programs, which do not, in and of themselves, strengthen health systems. Indeed, these programs often entail significant costs, by requiring states to integrate programs into often overextended health systems. Thus, as an intermediate step towards global health cooperation, GPPPs offer much of the same in the way of existing power and social relations, and thus do not truly advance *global* health cooperation, but rather northern dominance and economic privilege in health governance.

The intermediate goods and services that are provided by GPPPs are largely palliative; they do not address the underlying social determinants of health that render populations, particularly the poor, vulnerable to ill health. The World Health Organization defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”⁴⁵ In policy and practice, health interventions have largely been focused on the latter aspects of the definition. Disease and morbidity eradication have achieved primacy in our notions and evaluations of health as evidenced by the proliferation and increasing reliance on pharmaceutical and therapeutic interventions (drugs, chemical treatments, surgery, etc). The provision of intermediate public goods via global public-private partnerships contains a strong biomedical and technological bias; health interventions are overwhelmingly focused on providing remedies (drugs, health services, vaccines), but very little attention is devoted to health promotion via the social determinants of health. At best, they provide gender or population-sensitive solutions (for vulnerable or marginalized populations), but do not access the root causes of vulnerability to ill health which drive the expression of epidemics and infectious diseases. GPPPs, as a pathway towards global health outcomes, are conceivably matching epidemiological, but not necessarily social priorities of health. If the WHO’s definition is employed as a measure of the effectiveness of GPPPs in advancing global health outcomes, it is clear that they advance a narrow conceptualization of health, and in the case of pharmaceutical companies, advance their own interests for the continued reliance on drug interventions to support health. GPPPs might respond that it is not within their mandate to focus on the social

⁴⁵ World Health Organization (WHO) Constitution (www.who.int/about/definition/en/) Accessed November 19, 2005

determinants of health given their core competencies, and are only in a position to offer biomedical and technological solutions. Global and national health governance institutions are thus left with the task of addressing the most complex aspects of health. Without the attendant national and global health architecture to support and provide interventions to address the social determinants of health, GPPPs role as an intermediate institutional pathway to health leads global health governance largely into the management of illness rather than the promotion and protection of health. The obvious observation arising out of this analysis is that pharmaceuticals *cannot* address the underlying social determinants of health. Thus, for partnerships to be effective in health promotion there must be domestic and international institutions which possess the capacity to provide public health promotion and prevention services which, *inter alia*, access and respond to the social determinants of health, including socio-economic status and income equality, environmental factors, health care services, social inclusion, employment, early childhood care, education, and food security.

Finally, GPPPs do not necessarily include equity considerations in their program design and evaluation. Like the AAI, partnerships often choose countries that already have existing health infrastructure to administer and deliver their programs and products, and thus the poorest countries may be excluded (See Yamey, 2001 for a discussion of GAVI). 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 the outcome and evaluation orientations of GPPPs. As discussed earlier, most GPPPs lack a research or outcome orientation that goes beyond measuring the value-added aspect of the partnership, and fail to consider the negative externalities of partnership, including the potential for compounding health inequities. The global public goods concept has an inherent equity component, in that the goods must be *non-excludable*. Intermediate goods are *non-excludable* but rivalrous; however, GPPPs provide goods and services that are excludable. Global public-private partnerships have the potential to exacerbate health inequities, and thus as a ‘pathway’ to global health outcomes, may undermine global health equity.

This discussion of the conceptualization of health is critical to global health cooperation; because how we conceptualize health will bear profound implications for the types of responses that are employed. Historically, it has been difficult to obtain collective action for public goods. The global public goods concept, as advanced by the UNDP, attempts to provide a framework for collective action based on common need. The global public goods concept, however, does little to advance a policy model based on entitlement or a human right to health. We need new conceptions and theories of global health cooperation, including critical theories that question the interests served by various discourses in the international normative order on health, as well as conceptions of health that explore alternative frameworks for global health cooperation.

7. Conclusions and Recommendations

Given the operational and normative implications of global public-private partnerships for national and global health governance, what is the way forward? What are the implications for policy and practice surrounding GPPPs? Richter (2003) argues that UN agencies should abandon the public-private partnership paradigm altogether, while Buse & Waxman (2001) argue that a moratorium on GPPPs should be imposed while further research is conducted. Reforming GPPPs through transforming their research and outcome orientations would require the full cooperation of partners. At this point, the World Health Organization must develop a framework

for the design, implementation, and evaluation of partnerships, including an equity evaluation component, as well as a component that addresses the interfaces of the partnership with national health governance. At minimum, partnerships must involve national health authorities in their design, implementation, and evaluation. Currently, partnerships often originate at the international level, potentially excluding developing states in these processes (Widdus, 2003). Another recommendation arising from this analysis is that partnerships may need to become larger and involve capacity-building resources and strategies. Health promotion and the control and/or eradication of disease require attention to the underlying social determinants of health which drive disease epidemics. Partnerships need to become more inclusive and representative of developing country interests and the interests of their populations. This may mean that representatives from non-governmental organizations, civil society groups, academia, and other relevant stakeholder groups participate in partnerships at the conceptual/design, implementation, and monitoring stages.

The question of who will monitor global public-private partnerships is a difficult one. The overall trend in health governance is moving towards self-regulation. Governments set standards and verify, collect and distribute reports but private actors must self-regulate (choose when and how to report). However, developing countries do not necessarily have such regulation in place, and even if they do, there may be poor reporting requirements or observation. Therefore, the World Health Organization must exercise leadership in this domain, and appoint some form of oversight body/group to research and report on the partnerships. This would also include compiling and distributing information on best practices, lessons learned, and so forth. Furthermore, the WHO (or another appropriate organization) may work with developing countries to develop regulatory and reporting frameworks. This paper has provided a preliminary investigation and analysis of some of the real and potential operational and normative implications of global public-private partnerships for national and global health governance and thus offers insight into some of the areas that require attention, and possibly reform.

There are significant gaps in our knowledge about global public-private partnerships. Considerably more research needs to be conducted on the partnerships, particularly research about partnerships on the ground (Widdus, 2003). We need to develop criteria and measures of effectiveness for GPPPs to evaluate both the specific contributions of GPPPs to their stated objectives as well as for their contributions to global health goals and cooperation. Furthermore, it is important to challenge the functional narrative of partnerships by investigating and revealing the ethical, social, and normative underpinnings of partnerships.

The knowledge deficit also applies to other institutions and actors of global health governance. While the literature contains a sufficient array of studies examining the individual actors and institutions in global health governance, very few examine the interfaces, conflicts, and methods of cooperation and integration among and between these actors and institutions. Even fewer assess how these contradictions, conflicts, and cooperation affect national health governance or the normative basis of global health governance. Globalization is the driving force behind the emergence of global health governance, and global public-private partnerships give evidence to the emergence of a global polity. Growing interconnectedness between states and non-state actors in health has the potential to yield improvements in global health outcomes and cooperation. However, *dependency* on private sector corporations and actors in global health governance may also result in a weakening of efforts to hold them accountable for their practices and actions (Richter, 2004). While it could be argued that these partnerships reflect the inclination of corporations to become 'good corporate citizens' they are not in and of themselves

a proxy for good corporate citizenship in the global polity. Accordingly, there must be sufficient research and oversight to evaluate and monitor their normative and operational contributions to the emerging global health governance architecture.

The issue of health promotion does not lie solely with the pharmaceutical companies, however. Indeed, this analysis reveals that global health problems, including HIV/AIDS, are more systemic than could possibly be addressed by pharmaceuticals. Thus, systemic problems require systemic solutions, and this entails attention to the global political economy of health which shapes and drives disease patterns *and* access to life-saving pharmaceuticals.

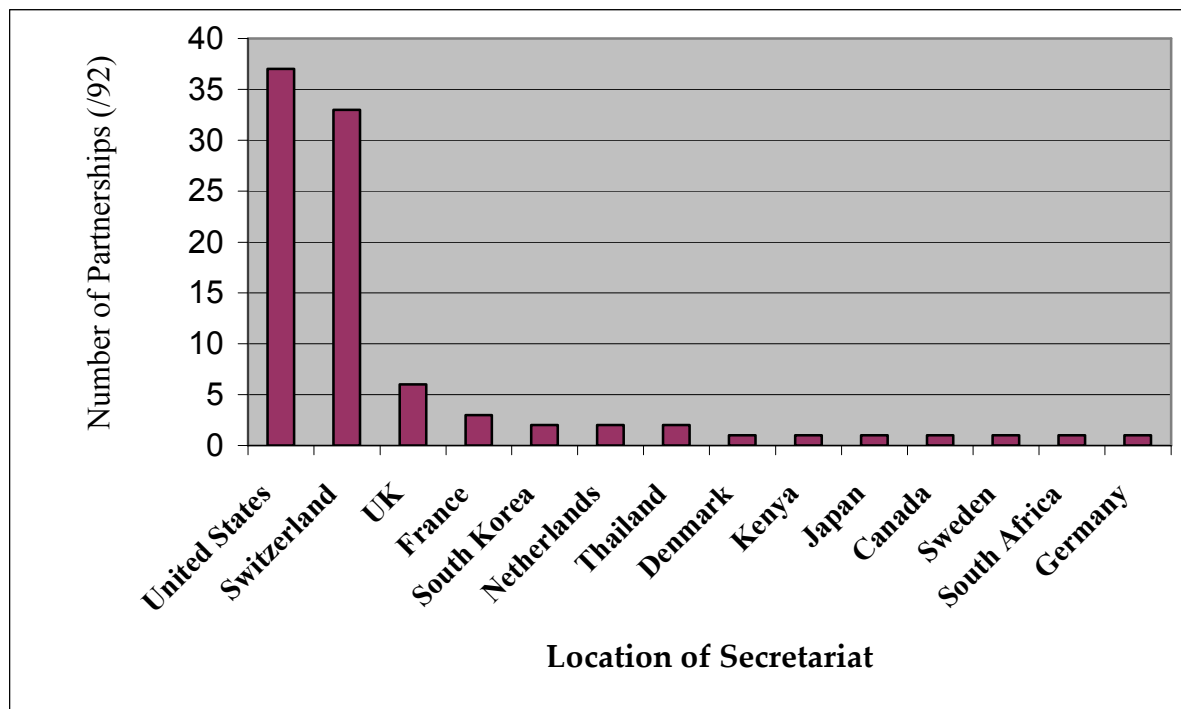
APPENDIX

HIV/AIDS	19
Malaria	15
Tuberculosis	11
Sexually Transmitted Infections	7
Leishmaniasis, Human African Trypanosomiasis	7
Vaccines	5
Blindness, Trachoma, Onchocerciasis (River Blindness)	5
Reproductive Health	4
Micronutrient/Vitamin Deficiency	3
Dengue	2
Guinea worm/Hookworm	2
Lymphatic Filariasis	2
Meningitis	2
Health Systems/Policies	1
Tetanus, Maternal Health, and Neonatal	1
OTHERS – i.e. Leprosy, Digital Divide, Chemical Safety, Lassa 6 Fever, Injection Safety, Polio	6
<i>TOTAL</i>	<i>92</i>

Source: Initiative for Public-Private Partnerships in Health Partnerships Database, 2006.

www.ippph.org/index.cfm?page=/ippph/partnerships/disease

Figure 2.0: Location of Secretariats of Public-Private Partnerships in Health



Source: Initiative for Public-Private Partnerships in Health (IPPPH) database

AAI Participants	2004 GNI- ⁴⁶ Atlas Method (\$US dollars)	2004 GDP (\$US dollars)	2004 GNI Per Capita (\$US Dollars)
Benin	3.7 billion	4.1 billion	530.0
Burkina Faso hbc	4.4 billion	4.8 billion	360.0
Burundi- hbc	669.4 million	657.2 million	90.0
Cameroon- hbc	13.1 billion	14.7 billion	800.0
Chad	2.3 billion	4.3 billion	260.0
Chile	78.4 billion	94.1 billion	4910.0
Republic of Congo	3.0 billion	4.4 billion	770.0
Democratic Republic of Congo	6.4 billion	6.6 billion	120.0
Cote d'Ivoire- hbc	13.3 billion	15.3 billion	770.0
Gabon	5.4 billion	7.2 billion	3940.0
Mali	4.3 billion	4.9 billion	360.0
Morocco	46.5 billion	50.1 billion	1520.0
Romania	63.9 billion	73.2 billion	2920.0
Rwanda- hbc	1.9 billion	1.8 billion	220.0
Senegal	7.0 billion	7.7 billion	670.0
Trinidad & Tobago	11.4 billion	12.5 billion	8580.0
Uganda- hbc	6.9 billion	6.8 billion	270.00

Pharmaceutical Company ⁴⁷	Total Revenues 2005 (\$US Dollars) ⁴⁸	Net Income 2005	Total Revenues 2004 (\$US Dollars)	Net Income 2004
Abbott Laboratories	\$22.3 billion	\$3.3 billion ⁴⁹	\$19.6 billion	\$3.1 billion
Boehringer Ingelheim ⁵⁰	\$12.1 billion	\$2.1 billion	\$10.3 billion	\$1.5 billion
Bristol-Myers Squibb	\$19.2 billion	\$3.0 billion ⁵¹	\$19.3 billion	\$2.3 billion
F. Hoffman-La ⁵² Roche	\$26.9 billion	\$5.1 billion	\$22.4 billion	\$5.3 billion
GlaxoSmithKline ⁵³	\$37.1 billion	\$11.5 billion	\$34.1 billion	\$9.7 billion
Merck and Co., Inc	\$22.0 billion	\$4.6 billion	\$22.9 billion	\$5.8 billion
Pfizer Inc.	\$51.3 billion	\$8.0 billion	\$52.5 billion	\$11.3 billion

⁴⁶ All economic data obtained from the World Bank website on country data:

<http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/0,,pagePK:180619~theSitePK:136917,00.html>

⁴⁷ Financial data from pharmaceutical companies has been obtained from 2005 Annual Reports. All reports are publicly available on company websites: Abbott- www.abbott.com; Boehringer Ingelheim www.boehringer-ingelheim.com; Bristol Myers Squibb- www.bms.com; F. Hoffman-LaRoche- www.roche.com; GlaxoSmithKline- www.gsk.com; Merck and Co., Inc- www.merck.com; Pfizer- www.pfizer.com.

⁴⁸ All figures in the table have been rounded down to the nearest million.

⁴⁹ Net income amounts from 2005 and 2004 are reported as 'after tax' income.

⁵⁰ Amounts in Annual Report presented in Euros. Table reflects conversion to US\$ based on nominal exchange rate of 1.1841 (rate from December 30, 2005). Conversion tables obtained from Bank of Canada Rates and Statistics: www.bankofcanada.ca/en/rates/exchform.html

⁵¹ Net income amounts from 2005 and 2004 are reported as 'after tax' income.

⁵² Amounts in Annual Report presented in Swiss Francs. Table reflects conversion to US\$ based on nominal exchange rate of 0.7598 (rate from December 30, 2005). Conversion tables obtained from Bank of Canada Rates and Statistics: www.bankofcanada.ca/en/rates/exchform.html

⁵³ Amounts in Annual Report presented in U.K. pounds. Table reflects conversion to US\$ based on nominal exchange rate of 0.7598 (rate from December 30, 2005). Conversion tables obtained from Bank of Canada Rates and Statistics: www.bankofcanada.ca/en/rates/exchform.html

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