Alternatives to Decentralization of Pharmaceutical Policies in Brazil: Case Studies of HIV/AIDS and Tuberculosis

by

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Abstract
Increasing attention has been paid to decentralized health care systems in order to evaluate health outcomes. In Brazil, state-run pharmaceutical assistance falls within the scope of a decentralized health care system, also known as SUS (Brazilian Unified Health System). The research intends to shed light on pharmaceutical policy implementation in Brazil through SUS, and argues that it can be used as a guide for institutional reform. This will be accomplished by reviewing the weaknesses and strengths of the SUS decentralized structure as revealed in the pharmaceutical policy responses to HIV/AIDS and tuberculosis. Under the assumption of pharmaceutical assistance improvement conditioned to re-centralization of some functions; it can be argued that a balanced approach to decentralization is more desirable to the pharmaceutical sector than the existing decentralized system. The aim of this study is to highlight the advantages of establishing a hybrid system for pharmaceutical assistance. This in turn, will provide the national government with an alternative to improve drug accessibility.
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INTRODUCTION

The constitutional mandated decentralization of Brazil’s state-run health care system has evolved extraordinarily since 1988 with respect to financing, management, regulation and democratic participation. However, gaps in service provision, especially in pharmaceutical assistance, still exists hindering public health efforts to contain epidemic diseases such as tuberculosis.

This thesis argues that this is chiefly due to institutional arrangements of the current decentralized system, and that in order to improve equity in pharmaceutical assistance, it is best to retreat from an inflexible mode of decentralization. The pharmaceutical sector differs from other health care sectors given its complexities and vulnerabilities, and this justifies the need for a differentiated framework. Different settings call for different responses and it is up to governments to efficiently respond to that. The promise of universal and scaled-up pharmaceutical access for all can only be achieved through a balanced system, neither absolutely decentralized nor centralized.

Historically, decentralization\(^1\) or devolution of health services\(^2\) has often been touted as an innovative public health reform. Despite the lack of consensus on an appropriate methodology for assessing the effectiveness of decentralization in the health care sector, there is substantial factual evidence to support the idea that inefficient health service delivery (mainly pharmaceutical assistance) is intrinsically connected to decentralization, especially in developing countries.

The promises that decentralized health systems would improve resource allocation, foster accountability, and increase cost-effectiveness of health investments, have not always materialized as expected. Decentralization, once pursued by most Latin American countries with the aim of enhancing health care services and promoting re-democratization to overcome

\(^1\) There is no universally agreed definition of the term 'decentralization'. However, the term is commonly used to describe a wide variety of power transfer arrangements. Policy options for decentralization range from the transfer of limited powers to lower management levels within current health management structures and financing mechanisms to extensive sectorial reform efforts which reconfigure the provision of even the most basic services.

\(^2\) Health devolution as defined in this research is a proxy for decentralization of health services from federal government to subnational levels. See W.E. Oates, “Searching for the Leviathan: An Empirical Study”. (1985) American Economic Review, 75 at 750. Oates defines health devolution as autonomy of sub-central governments or the strength of subnational power in the form of employment of control as well as devolved regulatory and taxation powers.
Authoritarian political regimes, has instead obstructed the delivery of essential health care services, such as access to medicines.

Brazil provides an excellent case study for assessing the practical implications of decentralization in health care delivery. The coexistence of decentralized and indirectly centralized \(^3\) health care policies in Brazil provides useful insights about the need to adjust the initial decentralized format for healthcare delivery. Additionally, the country has vigorously abided by the recommendations of both donor agencies and the World Health Organization, for the past 25 years.

In practice, decentralization of the health care system has resulted in uncoordinated actions and has exacerbated jurisdictional tensions between the federal and subnational levels of government, which inevitably led to a lack of federal oversight of policy implementation. Decentralization has also excessively expanded the discretionary powers of municipalities. These developments are particularly troublesome in the Brazilian context where corruption schemes at local government levels are as endemic as the diseases this study seeks to evaluate.

The relevancy of limiting the thesis to assessing governance and accountability issues in the pharmaceutical sector can be justified on the basis of the vulnerability of this particular sector to corruption. As Cohen et al posits, pharmaceutical systems are often the target of corruption and mismanagement practices by virtue of: (1) the profitability of the pharmaceutical sector; (2) a lack of “checks and balances” of government regulation; and (3) supply chain complexities involving many parties.\(^4\) The main consequence of pharmaceutical system corruption is poor

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\(^3\) The concept “Indirect centralization” used by Gomez, in this context meant the centralization of HIV/AIDS national bureaucracy, mainly achieved by conditioning federal fiscal transfer to compliance with programs’ mandates. In addition to that, Gomez posits that the government strengthened the cooperation and dialogue with AIDS NGOs to oversee AIDS policy implementation. This strategy as espoused by Gomez was an efficient step towards Brazil’s successful response to HIV/AIDS. See E.J. Gómez, “Pursuing Centralization amidst Decentralization: The Politics of Brazil’s Innovative Response to HIV/AIDS.” (2011) Journal of Politics in Latin America 3:3 at 98. “Indirect centralization” in healthcare policies in Brazil was first pursued by the Brazilian government for HIV/AIDS national programmes as an attempt to improve the effectiveness of policy implementation.

pharmaceutical coverage\textsuperscript{5} or assistance, which is especially acute when considering the demand of medicines to fight epidemic communicable diseases in resource-scarce nations like Brazil.

This study examines health systems from the perspective of governance, drawing on the knowledge and experience garnered over the past 25 years of pharmaceutical policy implementation for strategic diseases. It does so primarily through an examination of the effectiveness of the Brazilian government in expanding pharmaceutical coverage under decentralization and then under “indirect centralization”. This study borrows the concept of “indirect centralization” from Gomez and expands it to include other aspects of health policy implementation, such as governance and accountability aimed broad institutional reform.

Specifically, this thesis analyzes the impact of decentralization on pharmaceutical coverage for HIV/AIDS and tuberculosis (TB). It is worth noting that HIV/AIDS and TB have been two of the most significant public health threats in Brazil over the last 20 years. The choice of these two diseases for the purpose of this study can also be justified on the basis of their similar features: both are epidemic communicable diseases currently classified under the government’s strategic programs\textsuperscript{6}. I argue that, decentralization of pharmaceutical services in Brazil has ultimately given disproportioned attention to HIV/AIDS to the detriment of other diseases that require strategic and prioritized attention, such as TB.

The weaknesses of decentralization will be revealed through a two stage comparison of pharmaceutical coverage for both HIV/AIDS and TB: (1) under decentralization (SUS default rule); and (2) under indirect centralization, later pursued by SUS for both diseases. The focus of analysis will be the monitoring and surveillance mechanisms used to mitigate corruption and to increase accountability of local health authorities in charge of almost all phases of the

\textsuperscript{5} Pharmaceutical coverage as broadly defined in this research is the ability of a State to provide access to medicines to its citizens through the public healthcare system, free of charge or by imposing user fees.

\textsuperscript{6} According to the Ministerial Decree n. 204 of 2007 (Portaria n\textsuperscript{a} 204/GM/MS, de 29 de janeiro de 2007, S. IV, articles 24 -27, de 29.01.07) the strategic component of the Brazilian pharmaceutical assistance entails an indirect type of centralization, through centralized procurement while management, storage and distribution of medicines remain decentralized. Prior to 2007, all phases of policy implementation for HIV/AIDS and TB were decentralized.
“pharmaceutical assistance cycle”. This analysis will utilize literature reviews of health policy scholars on governance and accountability with respect to the SUS.

This thesis concludes that decentralization is inefficient in terms of delivery of pharmaceutical services and that indirect centralization of pharmaceutical services per se will not suffice to address the bottlenecks of the sector. Data provided in further chapters of this thesis will demonstrate that the improvements of TB’s pharmaceutical coverage under indirect centralization are not as significant as those observed for HIV/AIDS. As a result, there is a need to circumscribe differential aspects of HIV/AIDS indirect centralization in contrast with TB’s indirect centralization, in order to provide theoretical support for the introduction of a “hybrid system”. That is, what is needed is an approach, such as the one applied to HIV/AIDS, that efficiently balances decentralized and centralized health functions and engages civil society in both democratic decision-making processes and policy implementation.

Arguably, TB’s indirect centralization differed from HIV/AIDS in a sense that the institutional arrangements of TB’s policy implementation were incipient. For instance, there was a lack of grassroots groups engaged in the decision making processes and allocation of financial resources with respect to TB and capacity building investments were inconsistent at best. Additionally, and most importantly, there was insufficient federal oversight of TB’s policy implementation.

This thesis maintains that the institutional arrangements put in place by the Brazilian government for HIV/AIDS indirect centralization has contributed to scaling up access to AIDS medicines, and that this format is ideal for increasing access to medicines for other diseases. This thesis will also prescribe institutional and normative reforms.

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7 The Brazilian National Policy of Medicines (Portaria nº 3.916/GM, de 30 de outubro de 1998, D.O.U. nº 215-E, S 1, p. 18-22, de 10.11.98 - Ministerial Decree 3.916 as of 1998) redefined the pharmaceutical assistance and considers it as a cycle of activities dedicated to individual and collective health promotion, prevention and recuperation, centered on medication and destined to support community health (Brazil, 1998). The concept of pharmaceutical assistance is now not limited to the production and distribution of medicines. The cycle of activities of pharmaceutical assistance consists of the following: planning, selection, acquisition, storage, health professional training, and distribution to SUS local pharmacies, dispensation and assistance to patients (Pharmaco-vigilance and Pharmaco-therapeutic follow up).
Overview

This research project is structured by the following research questions: (1) Which components of decentralization serve as impediments to efficient pharmaceutical policy implementation?; (2) Which health functions should be re-centralized in order to achieve optimal pharmaceutical coverage for SUS end users?; (3) Has there been any improvement in pharmaceutical coverage since the government pursued indirect centralization of the HIV/AIDS and TB national programmes? If so, was the improvement of TB in pharmaceutical coverage under indirect centralization comparable to that of HIV/AIDS? And (4) How was the indirect centralization of HIV/AIDS different from that of TB and how can the success of HIV/AIDS be used to improve pharmaceutical coverage for other diseases?

Answering these questions will ultimately show that the constitutionally mandated mode of decentralization is inefficient in terms of access to medicines and that indirect centralization per se will not suffice to improve Brazil’s poor pharmaceutical assistance. By shedding light in the unique arrangements of re-centralization of AIDS bureaucracy, an ideal and more balanced framework for decentralization will be accomplished, also referred in this thesis as a “hybrid system”.

With respect to the methodological approach, this research project will rely on an exploratory analysis, mainly adopting a qualitative approach. The methodology includes a literature review focusing on findings from health policy scholars, and on how those findings contribute to justifying the recommendations of this thesis.

The contribution of the research is primarily the establishment of a framework for institutional reform in Brazil, but its findings may be generalizable to other countries, especially countries in Latin America. The lessons drawn from the outcomes of Brazil’s health system will be useful even for nations with more diverse institutional arrangements for funding and delivery of pharmaceutical services, as there is a growing trend for health reforms focused on adjusting the balance between decentralization and centralization.

Chapter one will provide a general background of decentralization processes in Brazil and of the SUS pharmaceutical sector. The SUS institutional structure will also be detailed, with particular
focus given to the deficiencies of the decentralized mode of policy implementation in the realm of pharmaceutical assistance. By illustrating the limitations of the process of health devolution a complex web of inter-governmental processes will be revealed.

Chapter two will compare pharmaceutical coverage in the two stages of policy implementation (decentralized and indirectly centralized stage) for HIV/AIDS and TB. It will take into account the existing structure for pharmaceutical assistance for the two diseases, namely the activities under the strategic pharmaceutical component in terms of drug acquisition, distribution, and dispensing schemes. This section of the thesis aims to ascribe advantages to re-centralized mechanisms (mainly centralized procurement) in improving pharmaceutical assistance. In this sense, it is relevant to acknowledge that both epidemic diseases (HIV/AIDS and TB) were initially subject to SUS decentralized modes of policy implementation and therefore had insufficient governmental oversight. However, at a later stage the federal government partially regained control over policy implementation for those diseases, shifting the decentralized policy mode towards an indirect type of centralization through centralized procurement of medicines. Variations in pharmaceutical coverage for HIV/AIDS and TB under indirect centralization will also be examined linking indirect centralization to health outcomes.

Chapter three will examine the distinct aspects of HIV/AIDS policy that have most likely contributed to Brazil’s HIV/AIDS policy garnering an international reputation as a policy model to respond to highly infectious epidemic diseases. This chapter will also link the inefficiencies of Brazil’s pharmaceutical assistance to lack of governmental oversight at subnational levels of policy implementation. Attention will be paid to corruption and mismanagement of resources most prevalent in the public pharmaceutical sector. The strategies used by AIDS bureaucrats and the central government will be revealed in subsections of this chapter.

Chapter four will discuss prescriptions for institutional and normative reform with the intent of providing a framework that would suit Brazil and other countries facing governance problems with a decentralized mode of health policy implementation. This chapter concludes by arguing that special attention should be given to decentralization as a reasoned response to the problem of insufficient pharmaceutical coverage in sub-national levels. The facts and observations presented in the earlier chapters suggest that the introduction of a hybrid system or indirect
centralization, such as the one implemented for HIV/AIDS in Brazil, is more desirable in order to improve pharmaceutical coverage to ultimately achieve SUS’s goal of universal pharmaceutical coverage.

This thesis concludes by reflecting on the benefits of introducing a “hybrid system” with the aim of addressing the disparities in pharmaceutical assistance in Brazil. The framework proposed for broad institutional reform is particularly well-suited to Latin American countries, although the study’s findings are not necessarily restricted to Latin America.
Chapter 1
Decentralization and The Pharmaceutical Sector in Brazil

The effective provision of pharmaceutical assistance within the Brazilian Unified Health System\(^8\) (SUS) still poses one of the greatest challenges to the Brazilian government. Studies carried out in Brazil have shown that, on average, 40% of the medicines prescribed in public primary health care were not available when needed.\(^9\) In order to understand the decentralized health system, it is essential to briefly contextualize both the SUS and its pharmaceutical assistance from its genesis, structure and development.

1.1 Background

Article 196 of the 1988 Brazilian Federal Constitution enshrines health both as a right guaranteed for all, and an obligation of the state.\(^10\) This right includes access to medicines. Thus, one of the primary tenets of this new constitution was the de jure establishment of free, universal healthcare. Since the enactment of the federal constitution in 1988, the Brazilian health system has been a mixed system, in which public and private healthcare providers coexist. The public health sector operates through SUS institutionalized by the 1988 Federal Constitution and regulated by Laws 8080\(^11\) (September 19, 1990) and 8.142\(^12\) (December 28, 1990).

The SUS operates under two categories of guiding principles: ethical and doctrinal principles and organizational principles. The ethical and doctrinal principles are: universality which means universal access to health services at all levels of health assistance; integrality which means

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\(^8\) In this research “SUS” will be used as a proxy for “Brazilian Unified Health System”.


\(^10\) Constitution of the Federal Republic of Brazil, (Brazil, 1988) Title VIII, C. II, art. 196.

\(^11\) Law 8080, Brazil 1990, preamble (Lei no. 8.080, de 19 de Setembro de 1990, D.O.U. de 20.9.1990 - Brazil) provides for the protection, promotion of health, organization and operation of health services under the SUS.

\(^12\) Law 8142, Brazil 1990, preamble (Lei no. 8.142, de 28 de Dezembro de 1990, D.O.U. de 28.12.1990-Brazil) provides for the community participation in the management of SUS, and intergovernmental transfer of financial resources to health services and other provisions.
SUS provides a full range of health services set to prevent and cure, such as pharmaceutical assistance among others; and equity which means equality in service provisions regardless of the level of income of the SUS users. For the purpose of this paper, I will focus the attention on organizational principles, particularly the guiding principle of decentralization. The organizational principles include: democratic community participation which entails the administration of the SUS with the inclusion of representatives of workers, employers, retirees and government agencies; regionalisation and the establishment of hierarchy aiming at tailoring healthcare services to the needs of each region, in compliance with SUS hierarchical structure; and finally, political and administrative decentralization, understood as the redistribution of power and redefinition of responsibilities down to Brazil’s 26 states and 5,500 municipalities.

Access to medicines through SUS is regulated by the National Pharmaceutical Assistance Policy (Política de Assistência Farmacêutica – “AF”). AF is defined by the Pan American Health Organization (PAHO) as “the set of actions aimed at health promotion, protection and recovery for individuals and the public at large by considering drugs an essential ingredient and fostering their access and rational use”. AF’s financing covers nearly 50% of the total health expenditure. Strategic and high-cost drugs (e.g. HIV/AIDS and tuberculosis medicines) accounted for 66.4% of the federal expenditure on drugs in 2005.\(^\text{13}\)

With respect to financing of publicly pharmaceutical assistance, revenues are derived from social security taxes, corporate taxes, taxes on financial transactions, and others. The federal government provides the majority of the financial resources while the municipalities and states supplement pharmaceutical budgets through local tax revenues. The municipal level is the final destination for resources collected through taxes. Additionally, funds for medicine acquisition are to be directly transferred from the federal government to municipalities, in an attempt to avoid the costs of bureaucratic fiscal transfers to states and then to municipalities.\(^\text{14}\)


SUS delivery of public pharmaceutical services is formally shared by federal, state, and municipal levels of government. As of 1998, a National Medicine Policy was created by Law-Decree GM/MS No. 3,916\textsuperscript{15}, which formally established the guidelines for the delivery of public pharmaceutical assistance under the decentralized SUS system. Operations within the Brazilian health system such as health planning and the provision of health services are managed primarily at municipal levels. Finally, federal and state governments have the primary responsibility for overseeing the health system, with the MOH and the state health secretariats taking lead roles. At the federal level, the MOH is responsible for the health sector. The MOH has counterparts at the state and municipal level which are organized into Secretariats.

SUS governance structure and pharmaceutical assistance management are as follows:

1.1.1 SUS Governance Structure

Figure 1\textsuperscript{16} borrowed from Noronha et al shows that there are primarily three instruments of intergovernmental regulation of the Brazilian health policy: health councils, the ministry of health alongside with local health secretariats and Managers’ Commissions.


The Tripartite Inter-Management Commission (CIT) is where the three-tier managers (the MOH, the state and municipal secretariats of health) set the guidelines for policy implementation (Ministerial Directive 1180/1991). CIT decides on issues related to the national health policy, the role of each level of government, and the decentralization process of the health sector. CIT’s meetings are conducted monthly and the reports are publicly available for consultation. The CIT counterpart operates at state and municipal levels through the Bipartite Inter-Management Commission (BIT) and its function is equivalent to the first of the two-tier managers. The CIT and BIT are technical joint commissions created to facilitate vertical negotiations between the three levels of government in the realm of SUS healthcare.

In addition to the two Manager’s Commissions, CIT and BIT, there are two other forms of accountability included in SUS legislation; one is the discretionary power of the MOH to issue Ministerial Directives and Norms to regulate states and municipalities and the other is civil society oversight through National, States and Municipal Health Councils (Law 8080/90 and 8142/90). Health Councils were created with the aim of enabling the citizens to take part in health governance and oversight. In accordance with Law 8142, it consists of representatives of citizens, government, health professionals, providers and producers of health services. To ensure these councils are working, federal fiscal transfers for healthcare to subnational levels are not made unless these councils are in full operation. Fiscal transfers are conditioned on the approval of the health budget and the conclusion of the accountability process by Health Councils. Thus, the three Health Councils are also entitled to health spending supervision. Recognizing the importance of Health Councils to guaranteeing federal fiscal transfers, subnational managers used their dominant political influence to secure privileged positions in the SUS participatory infrastructure of both Health Councils and National Councils, arguably one of the causes of

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19 Law 8142/90 stipulates the participatory ratio of Health Councils in a sense that 50% of the seats are allotted to SUS users (civil society participation), 25% of representatives of workers, and the remaining 25% is shared between health service providers and government representatives. Supra note 14 at 1781.
partiality in deliberations. Conass (National Council of Health Secretariats) and Conasems (National Council of Municipal Health Secretariats) are private legal entities whose primary function is to ensure equal levels of participation of health secretariats in decision-making processes. Their responsibilities entail fostering horizontal negotiation by building political consensus amongst all stakeholders of participatory mechanisms. In practice Conass and Conasems also function as advisory boards issuing recommendations on regulatory demands/inquiries. Miranda points out that the main issues brought to these National Councils, at least with respect to SUS regulations are related either to out-of-date legislation that is deemed inapplicable to respond to the current health care context, or legislation that overlaps in content, thereby creating a confusing scenario for policy implementation. The excessive legal bureaucracy SUS managers are constantly faced with delay health policy implementation which consequently compromises public health strategy.

Most literature to date ascribes the shaping of the Brazilian health policy agenda to governance councils. However, if we account for the effectiveness of social participation and control at local health councils, then the findings in the literature are mixed and inconclusive. I argue that, despite the fact that governance institutions provided venue for cooperation and dialogue between government and society, their practical effectiveness in social participation is ambivalent for a number of reasons. First, subnational managers most often withhold the control of deliberations due to a greater scale of representation coupled with greater articulation power in SUS technical matters. Consequently, citizens’ representatives are left aside in the process of establishing a health agenda, as well as in most of the relevant deliberative decision making processes.

Nonetheless, it is relevant to point out that the experience with direct HIV/AIDS grassroots participation in Health Councils is an exception to the rule and has been heralded as both unique and extremely effective. To begin with, the establishment of HIV/AIDS’ own policy making committee which takes part in deliberations of health councils and commissions. HIV/AIDS

advocates were organized collectively through NGOs, in which the leadership was knowledgeable both in terms of the flaws of AIDS policy implementation and of technicalities of the SUS management.

Therefore, even with a flawed structure for participatory governance, there is still space for civic engagement and consensus building in policy making. The experience of HIV/AIDS suggests that sharpening our emphasis in grassroots participation as opposed to individual participation in health councils and commissions is key to democratic health policy shaping and oversight. It should be mentioned that strategies of HIV/AIDS advocates were not limited to the previously mentioned channels of formal participation. Indirect and informal forms of governance and accountability were also in place. Moreover, noteworthy is the fact that HIV/AIDS national program has successfully made use of the existing legal provisions of decentralization such as the SUS structure for governance and oversight to effectively reach its goal of shaping a renowned mode of policy implementation. And the outcomes of that are materialized in an outstanding pharmaceutical assistance for HIV/AIDS medicines, especially when compared to the pharmaceutical coverage for other prevalent diseases.

1.1.2 SUS Pharmaceutical Assistance Structure

Having explained the SUS governance structure, the next part will explain the design of pharmaceutical assistance in order to demonstrate that it is complex at best, which in turn justifies close scrutiny over policy implementation.
The structural design of pharmaceutical assistance as shown in Figure 2, based on Araújo et al.’s concept of pharmaceutical assistance can be used to describe SUS’ cycle of pharmaceutical assistance in compliance with Law-Decree 3916/98, also known as the National Policy of Medicines. Accordingly, pharmaceutical assistance is composed of two distinct complementary sub-areas. One area is related to medication management – which includes production (when possible), selection, programming, acquisition, storage, distribution from the MOH to local Health Secretariats, and dispensing to end users. The other is related to the use of technology in patient assistance that ensures the correct use of medication, and follows up with standard drug registering criteria. The processes of pharmacotherapeutic follow-up,


Ibid at 826

Supra note 15

Drug registering criteria and licensing of national pharmaceutical laboratories are set by ANVISA (Brazilian Health Surveillance Agency). The agency is also responsible for establishing regulations applicable to
interventions (when necessary), pharmacovigilance and pharmaceutical indications follow dispensation to end users. Pharmaceutical care is a tool for the technology of rational use of medication, and dispensation is the point of intersection between these two areas.

Pharmaceutical assistance within the SUS is still deemed to be unaccomplished and underdeveloped, and for that reason, it has been subject to constant adjustments made through regulations. The consequence of this constant adjusting include: duplicity in regulations, as well as difficulty in policy implementation and oversight. There are many stakeholders involved and the cycle in itself, from production (or procurement) to dispensation is complex. Given that it is the most profitable sector of healthcare, it is also particularly vulnerable to corruption and financial mal-practice.

The decentralization of pharmaceutical assistance alongside with other sectors of the health care system, however does not explain the vulnerabilities of the pharmaceutical sector and does not explain worsening health equity in terms of access to medicines. In this sense, the Brazilian government has come to recognize that decentralization as mandated constitutionally is not the best alternative to deliver pharmaceutical services. Attempts to re-centralize some health functions have been made to improve pharmaceutical coverage.

1.2 Decentralization Process

This next subsection details the historical path of the Brazilian state-run pharmaceutical assistance, from the transition of a highly centralized system to one that was absolutely decentralized, and then an attempt to harmonize both systems. Emphasis will be given the process of decentralization through the genesis of the SUS system.

clinical trials and drug pricing, which is carried out by the Chamber of Drug Market Regulation (CMED). Together with states and municipalities, the agency inspects factories, monitors the quality of drugs, exercises post-marketing surveillance, takes pharmacovigilance actions, and regulates drug promotion and marketing.
Figure 3 will provide a chronology of the major milestones, starting with centralization to the first attempts at indirect centralization.

The implementation of pharmaceutical policies in Brazil as shown in Figure 3 has ranged from a highly centralized contributory system serving only formal sector workers under CEME and Farmacia Basica program, to a decentralized universal system under SUS’ pharmaceutical assistance, and then finally an indirectly centralized system, used solely for diseases classified under the government’s strategic programme. It is worth noting that regardless of the fiscal and administrative decentralization enacted with SUS, the federal government retained the authority to legislate and regulate health care policies without any veto power being granted to subnational levels of government.

In the 1970’s, Brazil was under a politically authoritarian military regime, and public health care services were highly centralized and administration was rigidly hierarchical, hindering health policy implementation. The first national public pharmaceutical assistance launched in 1971 amidst this contentious period of dictatorship was CEME (Central de Medicamentos), and its primary mission was to supply lower socio-economic strata with essential medicines. Because of its excessively bureaucratic procedures, CEME proved to be inefficient both in terms of
governmental cost in sustaining it as well as for its slow paced drug distribution and dispensation to end-users. Additionally, the procurement methods applied by CEME’s agencies were viewed as non-transparent and corrupt. CEME was later replaced by the Farmacia Basica Program, which was also highly centralized and inefficient.

In 1977, the federal government issued Brazil’s national list of publicly-funded essential medicines. The list followed a national epidemiological survey and compiled this data with the information obtained from health secretariats of each municipality. The RENAME list represented an important framework to guide future health policies as it identified the medicines needed to control the main diseases in the country. As the RENAME list only included essential medicines, and given an order to comply with SUS principle of integrality, the government later decided, under SUS directives, to extend pharmaceutical coverage to treat diseases not classified as the most prevalent and that only affect a limited number of patients.

Decentralization of health services was initially perceived as a promising alternative to public healthcare to overcome the nearly two decades of highly centralized, excessively bureaucratic military government. The enactment of the 1988 Federal Constitution was a hallmark to the transition from a dictatorship to a federal democracy. Within this context, health emerged as one of the most important social components to be addressed in the new constitution, alongside education and social security. Most importantly, the deliberations for the 1988 constitution were viewed by most as a leeway to needed health reform. As such, the legislature devoted a whole section in the social welfare chapter to health and as a result paved the road to the formal institutionalization of the SUS. However, it was only with further regulation of SUS by Law 8080/1990 that the highly centralized structure was dismantled and health functions were transferred to the Ministry of Health and local health secretariats.27

The tapestry of circumstances and negotiations that shaped the design of the new constitutional order is particularly relevant for present purposes. Negotiations between state governors and municipal mayors regarding jurisdiction and health service delivery preceded the 1988

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constitutional deliberations. The strong lobbying of regional interest prevailed, substantiated in constitutional provisions that guaranteed discretion over finances, management and policy implementation without the corresponding fiscal responsibility or accountability for resource management. It is believed that in the realm of decentralized health services, the pharmaceutical sector was the target of local politicians, especially given that it is the one sector that requires more funding, meaning more federal fiscal transfers to states and municipalities. Regional interests alone, however cannot account for the push for decentralization, rather it was the convergence of interest and factors that culminated with a framework for institutional reform.

At the federal level, for instance, an indirect incentive to pursue decentralization stemmed from international pressure, with loans for health programs being conditional. The guidelines from international donor agencies, such as the World Bank and the International Monetary Fund, for decentralization of public services in Latin America implied that governments, in both developed and developing countries carry out health sector reforms that introduce a neo-liberal model of public management, particularly one that emphasized the decentralization of public services. The experiences with decentralization in Latin America were later touted later in the 1990’s Washington Consensus as innovative ideas of policy decentralization. It is undisputable that the World Bank directives to developing countries favoured decentralization as part of their “new governance” agenda. And, given the crucial role international funding play in health care reforms in any resource-scarce country like Brazil, the national government did not oppose the World Bank’s loan conditions. The shortcomings of the “one size fits all” donor agencies recommendations for decentralization is it failed to take into account the complexities of the health sector as well of the recipient countries’ political context, an especially important point for post-authoritarian states in which democracy was still in its infancy. In these countries the necessary conditions for decentralization to emerge were overlooked and the practical results of decentralization were seriously compromised. For example, conditions such as effective downward accountability, a subnational infrastructure for health care reform, and the existence

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of a legal comprehensive framework for decentralization are all necessary to ensure effective decentralization, but are often absent.

From civil society’s perspective, decentralization was viewed in Brazil as an alternative to overcome the authoritarian political regime in place during the 1970’s and 1980’s. The political context of dictatorship featuring highly centralized and inefficient governmental structures for healthcare delivery, strengthened the democratic aspirations for a more participative and egalitarian state. This reactionary movement of civil society was called “Movimento Sanitarista”. The political interest of all levels of the government coupled with civil society’s assumption that decentralization and re-democratization processes go hand in hand, culminated with the enactment of the 1988 Federal Constitution\textsuperscript{30}, which included decentralization of the health care system as one of its tenets. Given the widespread agreement about decentralization, since 1988, institutional decentralization has been one of SUS principles that has advanced the farthest and at a relatively fast paced fashion compared to other SUS principles, as both democracy advocates and the government at all levels agreed upon it.

Although the quick transition to decentralization in itself has arguably not adversely affected the quality of healthcare in Brazil, decentralization allowed subnational governments to gain fiscal and policy autonomy with inadequate accountability mechanisms to ensure the quality in the provision of health care services. Compounding the problem, many states and municipalities lacked the capacity to comply with federal regulations and laws, which are excessively complex and at times overlapping and conflicting. For instance, the SUS normative framework was consolidated through “Normas Operacionais Basicas - NOB” (Basic Operational Norms) which consists of an array of national laws and regulations. This set of norms has been constantly amended by successive governments from different political parties, each adding or removing layers of bureaucracy and procedures for health care delivery. The frequent changes in health

\textsuperscript{30} The Brazilian Federal Constitution is the foundation and source of the legal authority underlying the existence of Brazil and the federal government of Brazil. It provides the framework for the organization of the Brazilian government and for the relationship of the federal government to the states, to citizens, and to all people within Brazil. The Constitution was ratified on October 5, 1988, by the 1988 Constituent Assembly. It establishes the Social Security system, Public Health system, Public Pension system, and contains provisions concerning education, culture, science and technology, and sports policies. Article 196 is placed under Title VIII—social order; chapter II—social security; section II—health. Constitution of the Federal Republic of Brazil. Brazil 1988, Title VIII, c.II, art. 196.
legislation constantly posed as a threat of undermining the strategies of the government and civil society. Although health authorities tend to use the constant influx as an excuse to avoid long-term commitments, this burdens civil society as it faces the challenge of keeping up with a myriad of normative technicalities preventing accountability measures. The problems with expanded autonomy of subnational governments and compliance issues will be further detailed in subsection 1.5.

Other milestones of the pharmaceutical system were Ordinance 2.577/06\(^{31}\) which established the National Program for Exceptional Medicines (medicines for the treatment of diseases such as HIV/AIDS, malaria, TB, influenza and meningitis) and the National Medicine Policy enacted in 1998 through Law-Decree 3.916\(^{32}\), with the aim of establishing guidelines for drug safety, efficiency and quality, and set the benchmarks for the periodic update of the RENAME list by the MOH. With respect to the Popular Pharmacy Program (PFPB) and indirect centralization of strategic health programs was only mentioned in Figure 3 as time-line reference given that they will be properly detailed in the following sub-sections.

Moreover, the disorderly fashion in which authority and management were decentralized has contributed to exacerbating cross-nation health inequalities, an already common feature of the Brazilian system. As such, even under the auspices of a democratic decentralized State, poor pharmaceutical results flagged the need for a coherent and alternative health-policy framework. Within the pharmaceutical sector, the Brazilian Popular Pharmacy Programme (PFPB) was the first attempt to retreat from an absolute decentralized mode of policy implementation, and it was through PFPB that the federal government decided to recentralize medicine procurement, thus moving away from SUS procurement decentralization at different government levels. Accordingly, tender processes for procurement must comply with the procedural standards of the Federal Law 8.666\(^{33}\), although subnational governments retain substantial discretion over the criteria for procurement.

\(^{31}\) Ordinance no. 2577 (Brazil, 2006), D.O.U no.45 of 04.03.2006.

\(^{32}\) Supra note 15

The next section will use the PFPB to demonstrate why indirect centralization is the most optimal way to enhance equity in pharmaceutical assistance. It should be stressed upfront that PFPB is a co-payment governmental initiative, and therefore drug dispensing is neither universal nor free of charge, as is the case of SUS pharmaceutical assistance. Consequently, the PFPB does not address the problem of inequitable access to pharmaceutical services.

1.3 Popular Pharmacy Program (PFPB)

In 2004, the Brazilian government launched the “Programa Farmacia Popular do Brazil – PFPB” (Popular Pharmacy Program) with the aim to expand access to medicines to middle income individuals. A reversion to the model of centralized procurement by the federal government was implemented as one of PFPB’s cornerstones, as it has proven to be the most efficient solution in a country like Brazil with heterogeneous demands for pharmaceuticals. Since the programme’s launch, there has been a shift in the targeted users of PFPB, as the program poses no restriction on lower-income individuals who would be willing to pay for medicines. That is to say, gradually an increasing number of SUS’ users (who are mostly low income individuals) have consistently relied on PFPB as an alternative for accessing essential medication that are not made available by the public sector. This phenomenon raised questions as to the failure of the current decentralized public system of drug distribution.

In light of the establishment of the PFPB, it would seem that the Brazilian MOH deems centralized procurement as a better approach for ensuring standardization of pharmaceutical products throughout the country, as well as a better bargaining tool for purchasing medicines on a large scale. It also increases the concentration of skilled human resources and facilitates training for drugs experts. From a cost-effectiveness perspective, this approach allows for

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34 PFPB’s model of indirect centralization should be understood as a combination of centralized procurement and programming with decentralized management (drug distribution and dispensing).
35 PFPB’s system is primarily based in co-payment and it is targeted at a share of the population that theoretically are not SUS end users with a monthly income of 4 to 10 minimum wages and that the acquisition of medicines would impair the family budget. PFPB in contrast with SUS medicine dispensing is not absolutely free of charge. The Brazilian federal government subsidies to PFPB’s medicines range from 10 % to 90%.
advantageous price reduction for essential medicines. Thus, the supply of medicine at low cost is made possible.

Partnership with the private sector has also been a key factor for PFPB. A joint management was established between the Brazilian MOH, private pharmacies, and Fiocruz (Fundacao Oswaldo Cruz) for the implementation of PFPB programme. PFPB’s success signals, on one hand, recognition from the State that a decentralization process for drug acquisition and distribution is faulty at best and does not adequately respond to society’s demands. On the other hand, PFPB provides a relevant example of a public-private partnership in the context of re-centralization of pharmaceutical assistance.

There are several reasons why PFPB stands out as a success in the context of drug accessibility. Santos et al. suggests that the drug consumption pattern of PFPBs is on equal footing with the most demanded medication in the public sector. Additionally, in contrast with SUS, PFPB’s availability of medicines is continuous which is mostly desirable for patients with chronic diseases. The PFPB programme is also innovative and successful to the extent it applies the conveniences of two systems, namely, centralized procurement and decentralized management and distribution. From this standpoint, perhaps the launching of the PFPB programme serves as an indicator of the shift from predominantly decentralized system towards a “hybrid system”.

The next section examines the Brazilian government’s move towards indirect centralization with Law-Decree no. 204/2007, considered a normative milestone for the pharmaceutical assistance of strategic diseases.

1.4 Indirect Centralization

In light of evidence demonstrating PFPB’s optimal centralized procurement, the federal government decided in 2007 to prioritize the provision of some though not all medicines under centralized procurement, a phenomenon also known as indirect centralization. This was

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38 Law-Decree no. 204, Brazil 2007, D.O.U. no. 22-1 of 31.01.2007.
primarily accomplished through the enactment of Law-Decree no. 204 in 2007, which divided SUS pharmaceutical assistance into three components:

**Strategic Component** - Medicines for *strategic programs* (tuberculosis, leprosy, HIV/AIDS, endemic diseases (e.g. malaria), diabetes, blood factors illnesses, and hypertension) are 100% funded by the federal government. All medicines under this component are subject to centralized procurement. The federal government is exclusively responsible for purchasing medicines and partially responsible for the distribution to subnational levels. The medicines storage and dispensing to end-users remain within the scope of local health secretariats.

**Specialized Component** - Medicines for diseases such as Chronic renal disease, hepatitis, others. This component provides medicines for diseases classified in three categories. The financing for drug procurement is shared among the MOH, states and municipalities, in compliance with intergovernmental agreements. Some medicines are also subject to centralized procurement, although others are decentralized to subnational levels through local and regional health secretariats. Medicines distribution is exclusively decentralized.

**Medicines for Essential Pharmaceutical Care** - Basic or essential medicines remained subject to the SUS general rule of decentralized procurement. A total of R$ 7,10/inhabitant/year is provided for, with half being funded by the federal government and the other half shared by the state and municipalities. Therefore, drug acquisition depends on federal fiscal transfers to local and regional health secretariats.

Prior to the enactment of Law-Decree no. 204/2007, the financing of pharmaceutical assistance was carried out individually. Each health program (e.g. national programs for diabetes, TB, hypertension, etc.) had its own regulation specifying financing, procurement, storage and

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39 Law-Decree no. 204, Brazil 2007, c.1, s.4, art. 24-27
40 *Strategic programs* are considered to be endemic diseases as long as they have treatment protocol issued by the Ministry of Health, and diseases that entail socio-economic impact. In Ministry of Health. Evaluation of Pharmaceutical Assistance in Brazil: structure, processes and results. (Brasília: PAHO, 2005) at 84. Online: <http://bvsms.saude.gov.br/bvs/publicacoes/avaliacao_assistencia_farmaceutica_estrutura_resultados.pdf >. (Retrieved in October 18, 2012).
41 *Ibid* at 84
42 Law-Decree no. 3.237, Brazil 2007, art.4.
43 *Supra* note 30 at 85
distribution. The federal government by organizing health programs in clusters of pharmaceutical assistance enable the optimization of both the financial implementation and procurement.

Despite the success, the government’s decision not to extend centralized procurement to all components, especially given the evidence of the outstanding pharmaceutical outcomes achieved through PFPB’s centralized procurement, raises some serious questions. It can be argued that political trade-offs played a significant role in the government’s decision to maintain procurement for essential medicines under the control of states and municipalities.

The most current legislation regarding the management of decentralized pharmaceutical assistance service is the Law-Decree no. 3237/2007\(^{44}\), whereby municipalities are deemed responsible for handling the financial resources and for the cycle of pharmaceutical assistance, which includes selection, acquisition, schedule and distribution of drugs. It should be noted that Law-Decree no. 3237/2007 does not apply to strategic medicines\(^{45}\), which includes medicines for TB, Leprosy, HIV/AIDS, Endemic diseases, Diabetes, Blood factor illnesses and Hypertension, in accordance to Law-Decree no. 204. The provision in Law-Decree no. 3237/2004 that introduces the requirement of qualification and professional training for civil servants responsible for activities related to the cycle of pharmaceutical assistance, applies to all components (strategic medicines, high cost medicines and medicines for essential pharmaceutical care).

The next section examines some of the main issues with the pharmaceutical sector in order to illustrate why decentralization is one of the reasons why Brazil’s pharmaceutical demands are not being met.

1.5 Main Issues of the Sector

Decentralization of the health care system is a crucial reason for the inefficiency of the SUS policy implementation reducing access to medicines to end users. While decentralization has

\(^{44}\) Supra note 42
\(^{45}\) Strategic medicines also known as “Medicines for Strategic Programs” set forth in Law-Decree no. 204, 2007.
contributed to advancing the re-organization of the pharmaceutical assistance system, the promise that decentralization would enable more responsive public services attuned to local needs has not been fulfilled as expected. This is reflected in the existing gap between society’s pharmaceutical demands and delivery of services. Illustratively, the SUS only provides 25% of all the medicine prescribed.46

Under the SUS decentralized health care system, most municipalities and states have been incapable of satisfactorily undertaking responsibilities entailed by the cycle of pharmaceutical assistance. This cross-nation discrepancy in policy implementation was chiefly due to heterogeneity of cultural values, political, and economic and social factors within a nation as large as Brazil. Municipalities with greater levels of civil engagement, stronger mechanisms of accountability and with a more sophisticated apparatus for capacity building, benefited the most from decentralization. However, this was not the case for most municipalities, especially the less populated ones and most far reaching geographically, which in turn account for more than two thirds of all municipalities in Brazil. More importantly, the vertical devolution of health services requires capacity from states and municipalities to organize a procurement process efficiently ensuring availability of medicines continuously. PAHO’s report on public policies and health systems suggest that under certain circumstances, decentralization has led to increases in the cost of medicines because the economies of scale that result from the consolidation of demand are lost, particularly for more expensive drugs.47 In all cases, decentralization requires a combination of skilled professionals to undertake public health management, primarily procurement and steady funding source.

In terms of the possible causes for the ineffectiveness of decentralized structures in most Latin American countries, Gomez suggests an array of factors that include: poor timing of decentralization, that is, the fast paced timing of decentralization relative to low levels of administrative capacity a de-concentration of authority without policy autonomy, and poor managerial know-how, and infrastructure.48

47 Ibid at 354
Regardless of the causes, a poorly designed decentralized health system entails the following: insufficient enforcement of drug regulations as well as monitoring of subnational policies; insufficient and sometimes inappropriate supplies (both quantitative and qualitative) of publicly-funded medicines; continuity of drug supply subject to political interests; weak human and institutional capacity for drug procurement at state and local levels; poor inter-governmental coordination to curb corruption and fiscal misbehaviour at subnational levels; and continuity of funding is incorrectly tied to political parties' interests.

More importantly, corruption, which is widespread in decentralized systems, deprives citizens of access to health care and is often regarded as the main reason for the mismatch between increased spending in the health sector and a lack of improved health outcomes. One must keep in mind that a governmental response to any epidemic disease undeniably requires an increase of funds for medicines; however, scaling up funds without establishing anti-corruption mechanisms simply allows more opportunities for corrupt officials to siphon off significant amounts of public resources through informal channels. Diversion of budgetary allocations in itself is not the only corrupt practice. Other common forms of corruption include: the diversion of medicines for resale, unofficial reimbursements, distribution of publicly-funded medicines to be used in political campaigns in return for political support, and the granting of personal favours to health care workers in order to access costly medicines. The consequence of these harmful practices is that it renders both prevention and treatment programmes ineffective and redundant. Therefore, governmental lack of attention to corruption can indirectly contribute to an increase in infection rates and in mortality rates when relatively low-cost medicines are not available. Hence, monitoring and oversight are of utmost importance, especially in the context of a state-controlled health care system.

Molina examines the surveillance and monitoring systems of Colombia’s decentralized health care sector, and found that Colombia lost national authority to subnational levels of government.\(^\text{49}\) By that I mean, with the advent of decentralization and consequently the delegation of prerogatives to lower levels of government, the central government became

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significantly constrained in terms of taxation, formulation of budgets and most importantly, control over policy implementation. Molina also notes that national, state and municipal health authorities have not been able to carry out effective surveillance and monitoring processes of all the various actors that are involved in the health care sector. Municipalities’ financial audit processes are mostly ineffective and limited, as is the national monitoring process over policy implementation at lower levels of government. This empirical evidence on the Colombian experience reflects the pattern of decentralization of health systems in most Latin American countries and suggests that the main shortfalls of the system lie within inefficient surveillance and monitoring mechanisms over policy implementation. In addition, uncoordinated actions between Colombia’s subnational and federal levels of government have resulted in local and regional health secretariats’ inability to comply with national health program’s policy mandates, worsening health inequities and contributing to the lack of credibility of national health programs. The experiences with decentralization in Colombia and Brazil are similar in a sense that the intergovernmental cooperation was not advanced enough to coordinate actions among different activities, sectors and organizations. In Brazil similarly to Colombia, with decentralization, subnational levels of government, especially municipalities, were constitutionally granted significant fiscal and policy autonomy with virtually no accountability mechanism or federal oversight over policy implementation. Article 18, Title III, Chapter 1 of the 1988 Federal Constitution of Brazil, sets out that:

“The political and administrative organization of the Federative Republic of Brazil comprises the Union, the states, the Federal District and the municipalities, all of them autonomous, as this Constitution provides”.

It should be noted that while considerable autonomy was conceded to municipalities, this did not mean that the central government was constrained in terms of its overarching responsibility for defining the SUS system through top-down regulations and laws. Municipalities cannot override federal health laws which set the minimum standards for health policy, and are binding on states and municipalities. Nonetheless, leeway exists for states and municipalities within the broad latitude of how to fulfill their obligations under federal legislation. For instance, they are not constitutionally bound to follow the programs developed at the center and may elect to opt-out from complying with the national programs directives on the best interest of municipality or

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50 Ibid at 11
51 Ibid at 12
region on basis of local health demands. Another constraint on subnational units’ autonomy was the Constitutional Amendment no. 29\textsuperscript{52} in 2000, which established percentages of revenues to be spent on health, by states and municipalities. Arretche briefly discusses this and identifies that “Since federal requirements for minimum spending levels were instituted, inequality in health financing across Brazil has sharply diminished”.\textsuperscript{53} Following the same reasoning, I argue that by limiting subnational units’ discretionary power over resource allocation, better health outcomes can be achieved.

Notwithstanding this, policymaking authority for tax creation has also been significantly expanded with decentralization, and is another loophole that needs to be addressed. In other words, states and municipalities can increase their revenues by creating new taxes whilst having relatively some autonomy to decide on resource allocation. Fiscal autonomy is a contentious topic, and one that it is hard to obtain consensus on, given that it involves a wide array of political interests. The argument that subnational political elites posit to withhold fiscal autonomy is that federal transfers have become regressive overtime, making it nearly impossible for municipalities to top-up health funding for health policy implementation. However, with the current economic boost in Brazil allied to the federal government’s commitment to create a dedicated funding for health, the argument used by political elites will soon be out-dated and will not be available as an excuse for failing to reform health financing.

I argue that the problem is rather subnational units’ expanded autonomy coupled with weak oversight mechanisms from the federal government, which substantially contributed to a lack of compliance with national policy guidelines. In addition to that, a mix of diverse political interests coupled with jurisdictional tension over responsibilities, raises accountability issues and confuses public health authorities and citizens as to who bears responsibilities for health care, resulting in a fertile ground for elite capture of SUS management through local governments.

Although there are numerous flaws of SUS decentralized system, it is worth examining the arguments in favour of decentralization of the health care sector. There is a body of public health

\textsuperscript{52} Constitutional Amendment no. 29, (Brazil, 2000), D.O.U no. 178-E of 14.09.2000.

literature in favour of decentralization, often on the grounds that subnational levels of government have a deeper knowledge of the needs of local populations, which would justify decentralized procurement on the grounds that it allows for a closer matching between supply and demand, as well as a reduction in overspending. However, it should be noted that most empirical and theoretical studies on decentralization hardly recognize, much less emphasize, the extent to which most governments waste and mismanage public resources by political misbehaviour. Thus, I part company with the existing literature favouring decentralization, as it does not take into account institutional arrangements and circumstances peculiar to most Latin American countries, such as prevailing political and governance issues.

A question that remains to be answered is that, why in light of the government’s own evidence that absolute decentralization is not the most efficient policy means for pharmaceutical assistance, has there been an unwillingness to reform the SUS in a manner that would allow indirect centralization to be applied more diseases than just the ones ranked as strategic? Pierson posits that re-centralization is not pursued because the perceived political costs associated with institutional change outweigh the political benefits of doing so. Along the same lines as Pierson, I argue that the failure to re-centralize in Brazil is chiefly due to a lack of political incentives. On this account, local legislatures would be opposed to any shift that could eventually impact their control over health programmes implementation as that would also mean the loss of political resources during elections. In Brazil, it is a common practice for elected state governors and mayors to target health budgets toward the most popular health programmes (pharmaceutical related ones), especially in pre-election periods, in order to assure re-election. This type of electoral clientelism, also known as political patronage, affects the continuity of public health policy implementation and contributes to corruption. Additionally, the constant turnover of the public health staff, a typical feature of the political patronage system, prevents long term returns from investments made in training and capacity building. This in turn, affects the administrative

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55 The term “governments evidence” of the flaws of decentralization can be translated in the establishment of “Farmacia Popular do Brasil” (PFPB) established by Decree n. 5090 dated May 20, 2004; through which the government pursued centralized procurement as an attempt to improve access to medicines.
and technical capacity of health authorities responsible for relevant functions of the cycle of pharmaceutical assistance.

Alongside the electoral clientelism and political patronage, the centralization of health care is often historically linked to federalist authoritarian regimes that democracy advocates aggressively struggled to overcome, both in the fiscal and administrative contexts. Most decentralization advocates argue that centralization has been equally ineffective in terms of public health response to overall health threats. Thus, there is little support for re-centralization of health care both domestically and internationally, necessitating alternative solutions for overcoming decentralization’s constraints without necessarily resorting to a reversal towards centralization. This is particularly acute in terms of pharmaceutical related policy reform as pharmaceuticals accounts for nearly 50% of health care expenditures of health secretariats.

As Bremner suggests, “decentralization and re-centralization go hand and hand, and reform involves a permanent process of adjusting the mix”. Accordingly, Berkman et al states that seeking an appropriate “balance between centralized functions such as planning, standards and budgeting, and decentralized functions, primarily implementation, is a problem all national health systems confront.” Saltman et al summarizes this balanced approach, by stating:

“Decentralization is not a static organizational attribute, but it reflects a permanent process of re-adjusting the mix, the balance between decentralizing and centralizing forces in every health system. Any particular fixed equilibrium is fragile and will build up pressures internally that will contest the existing alignment, eventually forcing a re-alignment and an equally fragile new equilibrium”.

Along the same lines as Bremner, Berkman et al and Saltman et al, this thesis suggests that the solution lies with neither decentralization nor re-centralization, but rather a mix of centralized and decentralized control, in which the level of decentralization would vary depending on the sub-function. For instance, in the pharmaceutical sector it is widely accepted that centralized procurement is more likely to achieve best results in terms of negotiating with pharmaceutical companies.

Health care systems should be flexible enough to readily adjust to new contingencies such as the emergence of new diseases or the on-going spread of an existing one. For instance, in cases of health epidemics such as HIV/AIDS and TB, the government’s delayed response could potentially harm society in general by exposing millions of citizens to a disease outbreak. In this sense, health care reforms are instrumental in both impact and design and should be tailored to the various settings within a nation to gain legitimacy as a broader institutional change.

In an attempt to move beyond this dichotomy of centralization over decentralization, the next chapter sheds light on the rationality of pharmaceutical policy implementation in Brazil, utilizing the case studies of HIV/AIDS and TB. It should be stressed upfront that the insufficient pharmaceutical coverage for strategic diseases was also observed under indirect centralization or centralized procurement. This in turn, raises questions as to the distinct aspects of pharmaceutical policy implementation for HIV/AIDS under indirect centralization that could potentially explain HIV/AIDS’ pharmaceutical coverage, one that stands out domestically and internationally.
Chapter 2
Case Studies of HIV/AIDS and TB

The Brazilian government has enacted a strategic program that classify some diseases as being entitled to differential policy implementation through an exceptional management and funding scheme, that is partially centralized by the federal government. In accordance with national legislation\(^1\), some circumstances justify a centralized mode of medicines acquisition, namely that the disease in question is a serious public health concern and that the disease has the potential to strike local communities, regions or in some cases, the whole nation. Additionally, a special centralized approach also applies to individualized diseases that, despite affecting an insignificant number of people, nonetheless require long and permanent treatment with high-cost drugs or with non-commercialized drugs.

The treatment of both HIV/AIDS and TB are under the government’s strategic health component and are subject to a centralized mode of medicines acquisition and a decentralized mode of policy implementation. Thus, theoretically there should be asymmetries in pharmaceutical coverage as both diseases mandate the same policy implementation scheme in accordance with Law-Decree no. 399/2006 (Pacto pela Saude – Pact for Health)\(^2\) and Law-decree 204/2007\(^3\).

Nonetheless, in contrast to HIV/AIDS, TB is still considered a challenge to public health in Brazil. Of the 22 countries that account for 80% of the reported cases of TB globally, Brazil ranks 15th.\(^4\) And although TB is a curable disease, a significant difference from AIDS, is that it still results in thousands of deaths per year, largely due to inaccessibility to pharmaceutical treatment.

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\(^1\) Law-Decree no. 204, Brazil 2007, c.2, s.4, art. 25 (Pharmaceutical Service Funds)
\(^2\) *Pacto pela Saude (Pact for Health)* through Law-Decree no. 399, Brazil 2006.
\(^3\) *Supra* note 49. The Brazilian Ministry of Health organized and categorized drug acquisition resources in the *Bloco de Financiamento da Assistência Farmacêutica* (Pharmaceutical Service Funds) ranked HIV/AIDS and Tuberculosis under the pharmaceutical service strategic component.
Pharmaceutical coverage of TB when compared to pharmaceutical coverage for HIV/AIDS, reflects the inequitable access to pharmaceutical assistance in Brazil and the biased prioritization of some public health concerns to detriment of others. As will be demonstrated bellow, the federal government has clearly prioritized the HIV/AIDS National Program whereas the TB National Program has been long neglected, and this likely would persist had not a scientific breakthrough revealed that TB was the main cause of AIDS related deaths. Hence although the government regarded the two diseases differently, they are in fact intrinsically connected. Outcomes of pharmaceutical coverage obviously signal the pattern of biased policy prioritization, worsening the already inequitable access to medicines that is likely inevitable in a country as large as Brazil and with such extreme income inequality.

With respect to HIV/AIDS, The UNAIDS latest report (2009) observed that:

The National STI/AIDS program maintained the expenditures of its subprograms from 2008 to 2010. They worked in a more efficient way, carrying out more -but individually less costly- activities. Supplies of antiretrovirals, reagents, and other materials provided by the federal government continue to be ample. Treatment programs covered 192,000 people with anti-retroviral therapy, well above 90 percent of all in need of such support. There had been no reports of shortages of anti-retroviral drugs or of any other supplies provided by the national program. Fund transfers from the federal government to state and municipal governments remained the same as in previous years.65

In contrast, the 2009 USAIDS’ Tuberculosis Profile Report stated that:

Tuberculosis (TB) remains an important public health problem in Brazil, which ranks 15th on the list of 22 high-burden TB countries in the world. Brazil accounts for 31 percent of all TB cases in the World Health Organization’s (WHO’s). Brazil adopted DOT (directly observed treatment) in 1998. As of 2009, DOTS population coverage is of 75 percent.66

While this thesis section provides a summary of each national program, it is helpful to analyze them separately taking into account particularities of each program’s pharmaceutical assistance.

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2.1 HIV/AIDS National Program

**Medicines** – The identification of medicines used for AIDS treatment is defined by the National Coordination of STD/AIDS pursuant to the recommendations of the Technical Advisory Committee on Antiretroviral Drugs. Medicines are only made available after the approval of the Brazilian MOH.

**Programming** – Programming is done by the National Coordination of STD/AIDS based on the total number of patients on antiretroviral treatment and on the type of therapeutic treatment. The accuracy of this data depends on monthly reports prepared by the state and municipal programs of STD/AIDS.

**Procurement and Distribution** – The Brazilian MOH is directly in charge of the procurement for antiretroviral drugs (centralized procurement). Distribution to states and municipalities is done by the National Coordination of STD/AIDS as well as by the State Health Secretariats.

**Dispensing to end users** – The dispensing of pharmaceuticals is overseen by Drug Dispensing Units (UDM – Unidade Dispensadora de Medicamentos) which verify if the patients’ drug prescription meets the criteria established by the MOH.

**Information System** – The control of pharmaceutical procurement, distribution, dispensing, supply and recall is carried out through a computer-based system known as SICLON (Logistic Medication Monitoring System) that feeds a HIV/AIDS national database. The novelty of this system is that all the data collected is available on the internet providing means for citizen monitoring of HIV/AIDS pharmaceutical assistance.

2.1 Tuberculosis National Program

**Medicines** – The selection of medicines follows the WHO’s protocols for TB treatment.

**Programming** – Programming is done annually by the MOH in collaboration with TB’s state and municipal programs. It is based on the number of TB reported cases by region and it depends on the availability of stocked drugs.

**Procurement and Distribution** - The Brazilian MOH has been directly in charge of the procurement for TB drugs (centralized procurement) since 2007, in compliance with Law-Decree 204. Distribution for TB medicines is substantially more bureaucratic than that of HIV/AIDS
medicines. After centralized procurement, medicines are sent to TB’s state programs on the condition of drug storage capacity. The distribution of medicines from state programs to municipalities is conditioned to the epidemiological data provided by those.

**Dispensing to end users** – DOT (Directly Observed Treatment) for TB was launched in 1998 based on a recommendation from the WHO (World Health Organization), and it consists of the following fundamental elements: diagnosis through bacteriology among respiratory symptomatic individuals and contacts, availability of TB drugs, supervised treatment where patients take medicine dosages in the primary healthcare units, drug resistance control, and use of a robust information system for disease surveillance. Given that the success rate of treatment depends on the correct intake of TB medicines, non-compliance not only increases the risk of treatment failure but also increase the development of drug-resistance TB strains. Hence, to ensure treatment compliance, the MOH has mandated that drug dispensing required the intake of medicines at a healthcare unit, under the supervision of SUS health practitioners. DOT, as recommended by the WHO is a crucial step to containing the widespread of TB, thus it can be inferred that the availability of TB medicines is extreme importance to responding to TB’s outbreak.

**Information System** – All patients’ data collection is done through appointment with the physician. TB’s mandatory reporting is to be done through a registry database of PNCT (National Program to Control TB). The information system for TB surveillance is known as SINAN (National Reporting System for TB Cases).

Moreover, the history of the government response to TB, from Brazil’s first National Campaign against Tuberculosis in 1946 up until the latest “Stop TB” Campaign of 2004, demonstrates inconsistencies in terms of policy implementation. The government’s responses have ranged from a highly centralized, well-funded TB national program under a military regime in the 1960’s and 1970’s to a decentralized, underfunded national program in the late 1980’s. This has proven to be an obstacle to the eradication of the disease, as TB treatment strongly depends on the continuity and monitoring of pharmaceutical treatment. As a result of decentralization of administrative health functions to the state and municipal levels, the national capacity to coordinate TB control was weakened. Further, due to reduced financial resources, surveillance activities diminished and the quality of TB control substantially deteriorated. Then around late

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67 Supra note 52 at 200
2000, in the face of unacceptable epidemiological results of TB infection rate and with the scientific findings correlating AIDS deaths to TB infection, the federal government decided to pursue indirect centralization of TB’s national program. Like HIV/AIDS, there were significant improvements of pharmaceutical coverage for TB after the government decided to regain control over some aspects of policy implementation.

2.3 HIV/AIDS vs. Tuberculosis

Figure 4 demonstrates the convergences and divergences in pressures and resources that shaped the national programmes implemented for each disease. Emphasis will be given to differences that might arguably be correlated with different health outcomes. Not considered here, but also of importance, are factors such as donor agency funding, which would have been used to influence the policy making process of HIV/AIDS, more specifically.

<table>
<thead>
<tr>
<th>Decentralization</th>
<th>HIV/AIDS National Programme</th>
<th>TB National Programme</th>
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<tbody>
<tr>
<td>Strong Federal Oversight</td>
<td>Decentralized Procurement</td>
<td>Decentralized Procurement</td>
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<tr>
<td>Weak Federal Oversight</td>
<td>Decentralized Planning, Management, Distribution</td>
<td>Decentralized Planning, Management, Distribution</td>
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<tr>
<td>Underfunded</td>
<td>Well-funded (World Bank Loan)</td>
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<tr>
<td>Lack of Managerial Capacity</td>
<td>Investment in Training &amp; Capacity Building</td>
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<tr>
<td>Lack of Civil Society Engagement</td>
<td>Participation of Civil Society via NGOs</td>
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<tr>
<td>Unconditioned Fiscal Transfer</td>
<td>Fiscal transfer conditioned to results</td>
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<tr>
<th>Indirect Re-centralization</th>
<th>HIV/AIDS National Programme</th>
<th>TB National Programme</th>
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<tbody>
<tr>
<td>Strong Federal Oversight</td>
<td>Centralized Procurement</td>
<td>Centralized Procurement</td>
</tr>
<tr>
<td>Weak Federal Oversight</td>
<td>Decentralized Planning, Management, Distribution</td>
<td>Decentralized Planning, Management, Distribution</td>
</tr>
<tr>
<td>Benefited from the Global Fund to Fight HIV/AIDS</td>
<td>Well-funded (World Bank + Global Fund)</td>
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<tr>
<td>Interest in TB on the part of AIDS organizations/NGOs</td>
<td>Partnership with Civil Society through NGOs</td>
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<tr>
<td>Increased Fiscal Transfer to States and Municipalities</td>
<td>Fiscal transfer conditioned to results</td>
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<tr>
<td>Investments in Human Resources</td>
<td>Consolidated Human Resources Capacity</td>
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The summarized data from the study of Gomez et al shown in Figure 4 contradicts the common notion that the effectiveness in responding to an epidemic disease is predominantly linked to an
increase of funds available. With Gomez et al, this thesis argues that scaling up budgets without paying due regard to institutional arrangements, such as the peculiarities of the decentralized framework provides results in a biased analysis of health policies. Therefore, Figure 4 identifies not all but what is considered to be the most relevant aspects of AIDS and TB national programs.

It is of paramount importance to highlight that in the case of TB, even under indirect centralization, pharmaceutical assistance is subject to a weakly monitored system, and health secretariats in charge of TB’s pharmaceutical assistance lack managerial human resources to efficiently undertake policy implementation. Additionally, TB’s national program featured fragmented funding, few TB-oriented NGOs to pressure the government for policy reform, and a lack of political desire for a prompt response.

One of SUS ongoing challenges in controlling the wide spread of TB is to maintain the quality of TB diagnosis and treatment, in which the continuity and availability of TB drugs play a significant role. Given that Brazil has 5600 municipalities, a well-coordinated system is needed to monitor and evaluate the TB drug accessibility at municipal levels so as to allow for timely support where results fall below set standards. Therefore, the main challenges with respect to controlling the spread of TB is related to overcoming ineffective health service performance and inconsistencies with the availability of TB’s medicines.

The drawbacks of the decentralized system for TB were that municipalities not only did not prioritize TB control but also were unable to follow the required national guidelines mainly due to funding restraints and a lack of technical and managerial capacity for implementing the National Plan for Tuberculosis Control. Hence, the challenge for the Brazilian MOH is to coordinate efforts in order to maintain a balance between TB health activities at all levels of government. TB health activities are as follows: epidemiologic surveillance actions, drug

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procurement and supply, technical support and supervision of information systems and lab support, as well as monitoring and evaluation of municipal-level TB policy implementation.

This can be contrasted with HIV/AIDS, where there is federal oversight of program implementation through a strong monitoring system as well as specialized managerial capacity. Additionally, most often leaders of HIV/AIDS NGOs are in charge of program implementation at local levels which makes HIV/AIDS national programs more tailored to the needs of end users. Thus, the HIV/AIDS national program has proven to be quite successful in that respect whereas the TB national programme (Programa de Controle da Tuberculose) is still falling behind what is expected of a response to an epidemic threat.

Intriguingly, both HIV/AIDS and TB were, at some point, subjected to a type of policy implementation considered an “indirect type of centralization” which combines centralization and decentralization” functions. The timing component for this governmental strategic shift may have contributed to differentiated outcomes for the diseases in question. For instance, the government decided to pursue indirect centralization for TB but did so at a later stage, when the TB national program was placed under the scrutiny of international organizations.

Significant improvements in pharmaceutical coverage were observed in this second stage, in which the implementation of both HIV/AIDS and TB programs had been partially re-centralized. However, TB’s pharmaceutical coverage improvements have been minimal when compared to HIV/AIDS improvements. This does not mean that there have not been improvements in TB’s pharmaceutical coverage under indirect centralization. It has just not been comparable to those experienced by HIV/AIDS coverage.

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69 E.J Gómez in "Overcoming Decentralization’s defects: Discovering Alternative Routes to Centralization in a Context of Path Dependent HIV/AIDS Policy Devolution in Brazil." (2011) Journal of Politics in Latin America 3.3 at 95, points out one of the key aspects of HIV/AIDS policy implementation is “centralization” or as he calls “indirect centralization”. He argues that: “Indirect centralization is achieved through the provision of conditional-based grant assistance to state and municipal health departments as long as they comply with the national program’s policy mandates. This is designed not to reduce sub-national fiscal autonomy and capacity, as typically envisioned in a fiscal re-centralization scheme, but rather to augment sub-national fiscal revenues in a conditional, controlled manner.”
This poses an intriguing set of questions: if both diseases are placed on an equal footing concerning policy implementation schemes, then why has HIV/AIDS national program achieved a remarkable 90% pharmaceutical coverage whereas TB’s pharmaceutical coverage is still falling below the set standards? This fact is particularly interesting given that HAART (Highly Active Anti-retroviral Therapy) is disproportionately more costly than TB treatment.\(^7\) Thus, theoretically it would be less strenuous for the government to expand pharmaceutical coverage for TB as opposed to HIV/AIDS. Under these circumstances, what were the differentiated features of HIV/AIDS indirect centralization that made it stand out in terms of pharmaceutical coverage? The next chapter will address the possible causes for this asymmetry in pharmaceutical coverage.

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\(^7\) HAART (Highly Anti-retroviral Therapy) treatment cost is of about US$ 10,000 – US$ 15,000 a year per patient. It is a life-time treatment. Tuberculosis treatment cost in turn is of about US$ 3,000 a year per patient. TB’s treatment lasts up to 2 years.
Chapter 3
Distinct Aspects of HIV/AIDS National Program

In order to make sense of the existing gap in pharmaceutical coverage for HIV/AIDS and TB, it is relevant to examine the distinct features of HIV/AIDS policy implementation that made it to stand out, both nationally and internationally.

The targeted and prioritized HIV/AIDS program is unique to the extent that it provides a balance between centralized functions such as budgeting and procurement, and decentralized functions, primarily storage and distribution of medicines.71 Thus, the differentiated aspects of HIV/AIDS indirect centralization that might explain the discrepancy in pharmaceutical coverage in comparison with TB, are as follows: (1) an efficient accountability mechanism achieved by strengthening federal oversight, mainly to curb corruption and resource mismanagement; (2) fiscal transfers conditioned on adherence to the MOH’s policy mandates; (3) civil participation through partnerships with NGOs, and (4) training and capacity building provided to health officials of lower-tier governments.

Special attention should be given to the establishment of an innovative form of policy monitoring mechanism enabling federal oversight of subnational health functions that remain decentralized. That is, the federal government effectively controls subnational HIV/AIDS programs by combining the use of conditional federal earmarked transfers 72 and by delegating powers to HIV/AIDS NGOs to monitor subnational policy implementation. For instance, federal transfers are conditioned on the states and municipalities complying with HIV/AIDS national guidelines. Each subnational unit is required to develop and submit detailed annual policy goals to a central bureaucracy. This provision is known to be highly effective because it promotes tailored subnational planning for policy implementation. It also allows state and municipal governments to decide on allocation of these resources according to the needs of the people living with HIV/AIDS (PLWHA). This is especially relevant given Brazil’s disparate regional differences in terms of infection rates and pharmaceutical needs.

71 Supra note 48 at 1171
72 Earmarked transfers were introduced through Ministerial Directive 2313/2002 also known as Plan of Actions and Goals (PAG).
In addition, national HIV/AIDS programs bureaucrats argue that earmarked transfers have been efficient in fostering political commitment at subnational levels to comply with HIV/AIDS guidelines. With the creation of earmarked transfers funding for health was substantially increased which consequently resulted in local and regional dispute over revenues. It is believed that this has been an indirect incentive for subnational HIV/AIDS bureaucrats and politicians to comply with national mandates, at least in the initial moment of earmarked transfers. Local politicians were targeting increases in revenue and overlooked the responsibilities of meeting annual goals and reporting results back to the central HIV/AIDS program.

Another control mechanism recently introduced to HIV/AIDS national programs concerns how federal transfers are not deposited in public health accounts as general health purpose funds (SUS general rule). Rather they are transferred into specific accounts, which are electronically accessible to the federal government to check cash flow at any time. This monitoring system of HIV/AIDS funding has served as an efficient mechanism for civil society oversight as well as allowing for AIDS national bureaucrats to better coordinate national efforts.

In 2006, the provisions for earmarked transfers were modified by Law-Decrees 399/2006 and 699/2006. HIV/AIDS earmarked transfers were to be made via the “health surveillance function”, as opposed to the “general health purpose function” as suggested by the MOH. The government’s decision to link HIV/AIDS earmarked transfers to the health surveillance function was greatly influenced by officials that advocated that by doing so, subnational governments would have no leeway not to commit to AIDS national goals. It should be noted that under the “general health budget” regional and local governments have more opportunities to decide on resource allocation, which consequently makes it more difficult for officials and society to keep track and monitor health spending. Finally, in 2012 the Brazilian MOH once again signaled for the inclusion of HIV/AIDS earmarked transfer within the general health budget alongside with the budget for other diseases. And once again, civil society organized through HIV/AIDS NGOs was greatly opposed to the government’s attempt to terminate AIDS specified earmarked

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73 See M. Arretche, “Federalism, bicameralism, and institutional change: general trends and one case-study,” (2011) Brazilian Political Science Review, 5 at 14. Arretche’s findings suggest that in the absence of HIV/AIDS earmarked transfers, states and municipalities would have little incentive to prevent the spread of HIV/AIDS thus the provisions of health services to respond to the disease would be considerably unequal.
transfers. They claimed that with this move HIV/AIDS national program would inevitably be dismantled. Earmarked transfers should thus be understood as an indispensable strategy of HIV/AIDS national program.

Equally as important as the earmarked transfers themselves are, the conditions imposed to ensure transfers, namely, a requirement for effective policy implementation and compliance with the national directives. In this sense, Gomez brilliantly points out that one of the key aspects of HIV/AIDS policy implementation is “indirect centralization” through “conditional-based transfers”. He argues that:

“Indirect centralization is different from fiscal re-centralization in that sub-national fiscal autonomy is not reduced through a reduction in fiscal transfers and limits on spending and borrowing through hard budget constraints. During a process of indirect centralization, federal fiscal transfers, often through the constitution, for healthcare and other social welfare policies persist; moreover, in this process the central government creates new fiscal policies that augment its authority without interfering with existing fiscal transfer arrangements to the states. More specifically, indirect centralization is achieved through the provision of conditional-based grant assistance to state and municipal health departments as long as they comply with the national program’s policy mandates. This is designed not to reduce sub-national fiscal autonomy and capacity, as typically envisioned in a fiscal re-centralization scheme, but rather to augment sub-national fiscal revenues in a conditional, controlled manner.”

I, however, argue that the practical implications of conditional earmarked transfers have been partially effective given the weak technical capacity of subnational units to comply with rules and procedures that are most often unclear and excessively bureaucratic. The World Bank in one of its evaluation reports of the Brazilian health care system noted that regional and local healthcare officials are unable to develop financial planning, due to the lack of predictability over the amount to funding to be transferred annually. Additionally, state and local health secretariats lack the capacity and the incentive to comply with the federal guideline for collecting

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74 Supra note 57 at 2
the basic information that is required for the central government to monitor and evaluate subnational HIV/AIDS policy performance.  

Additionally, political compliance to national policy directives is even a greater problem. The temporary feature of state governors and mayors elective positions serves as a disincentive to commit to long-term health goals. Rich et al exemplifies this by noting it is a common practice for mayors in most municipalities in Brazil, especially the less populated ones, not to make use of HIV/AIDS earmarked federal transfers, and often leave them in the bank account to avoid the strenuous process of developing accountability reports. They prefer instead to divert local resources from other health programs, ones with less rigid accountability regulations, to provide for the matching funds required for HIV/AIDS program implementation. In this sense, I find it relevant to reproduce an excerpt of an article that reveals this common practice in most municipalities in Brazil. It states:

“For two years now, AIDS activist have denounced that specific HIV/AIDS funds had been kept for months or even years – without clear justification - in the coffers of states and municipalities across the country. We have tirelessly demanded the creation of a mechanism to compel States and Municipalities to spend these AIDS federal funds as required. In August 2012, the amount of these funds accumulated at decentralized levels was around 135 million Reais (US$70 million.)”

To date, the problem of HIV/AIDS funds being inappropriately withheld has not been addressed. In 2012, the Brazilian MOH made a commitment to issue on ordinance to allow for the use of these funds. However, to date, it has not issued any such ordinance.

Nonetheless, attempts have been made to address the lack of political compliance and weak subnational capacity. The national HIV/AIDS bureaucracy have attempted this primarily by strengthening HIV/AIDS policy coordination between different levels of governance, different types of state agencies, and of states and municipalities. It has attempted to support capacity building through technical knowledge spillover through intergovernmental interaction as well as building stronger ties to pressure politician to comply with HIV/AIDS program directives.

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77 Ibid
78 In Supra note 64, online: UNGASS AIDS Forum < http://ungassforum.org/media/news/news.php?id=292 > (Retrieved in March 16th, 2013)
79 Supra note 64 at 16
3.1 Other Factors

In light of the indicators that might have substantially contributed to asymmetries in pharmaceutical coverage such as: availability of international and domestic funding, conditioned fiscal transfers from federal government to subnational levels and health staff capacity building, I argue that a combination of factors should be considered rather than one factor alone. It is undeniable that the number of factors that can influence health outcomes can be significantly high. Nonetheless, this thesis advocates that special attention should be given to governance issues as it is known to be one of the main challenges of SUS health policy implementation.

Kaufmann et al suggests that governance consists of six dimensions: (1) voice and accountability, (2) political stability and commitment, (3) government effectiveness, (4) regulatory quality, (5) rule of law, and (6) control of corruption. This framework, when applied to a comparison of the study cases HIV/AIDS and TB, portrays the many different aspects of HIV/AIDS policy implementation that are superior to those of TB. This is primarily because in the Brazilian context all dimensions of the governance framework can be reduced to who has controlling political leverage, and thus can capture social policies. Institutional analysis can provide enlightenment as to the type of interest groups that most often exert political leverage over health policies. Contrary to common belief, political power over health care policies does not reside exclusively with economic elites. Multi-national pharmaceutical companies and donor agencies also play a relevant role in shaping and influencing social policies either through lobbying or negotiations with the federal government. Whatever the source of pressure, health demands must inevitably be channelled through the political institutions in charge of legislating and ensuring the implementation of health policies. Moreover, political institutions are often biased when mediating social demands, are influenced by political interests of either political parties or influential interest groups. In other words, political institutions do not respond consistently to different kinds of pressure, and that has been highlighted in the different policy framework for HIV/AIDS in contrast with that of TB.

In face of this myriad of actors and stakeholders potentially shaping health care policy and regulations, it is relevant to outline the bottleneck of the system so that we are able to draw
conclusions with respect to interest groups’ incentives or lack of incentives to tackle governance issues.

3.2 HIV/AIDS Governance

There is significant theoretical and empirical evidence to link the main challenges of health care delivery in developing countries to corruption and mismanagement of public resources. With regards to resource mismanagement, I argue that the lack of funding to carry out health programs in Brazil is not a problem in itself. It should be noted that Brazil is the second largest recipient of international health funding from the World Bank. In addition, the country has the highest Gross Domestic Product (GDP) ratio in Latin America. In 2010 Brazil’s GDP ratio was $2.09 trillion which was considered higher than of 17 OECD (Organization for Economic Co-operation and Development) countries including Australia, Canada, Japan, New Zealand, Spain, Switzerland and the United States. According to the Brazilian Tax Planning Institute (IBPT), the country’s tax burden as of 2011 reached 36% of its GDP which ranked the country 12th amongst the 30 countries with the highest tax burden in the world. Additionally, Brazil could alternatively make use of at least seventeen public laboratories linked to states, federal universities and the armed forces. All of these laboratories possess great technical capacity to manufacture generics in order to produce off-patent medicines domestically and therefore facilitate access to pharmaceutical for the most prevalent diseases. And yet, the population is having increasing difficulty in accessing even the most essential medicines. Thus, neither the availability of funds nor a lack of manufacturing capacity for generics stands as the main reason for poor pharmaceutical coverage. The root of the problem may be a combination of inefficient allocation and mismanagement of existing resources.

Corruption plays a crucial role with respect to mismanagement of resources and ultimately might be one of the reasons why increased spending in healthcare often does not correlate with improved health outcomes. Corruption broadly defined, includes absenteeism, informal

80 OECD – Organization for Economic Co-operation and Development, “Revenue Statistics in Latin America (1990-2010)” joint publication by CIAT (Inter-American Centre of Tax Administrations), ECLAC (Economic Commission for Latin America and the Caribbean) and the OECD (Organisation for Economic Co-operation and Development) online: OECD < http://www.oecd.orgctp/tax-global/Brazil%20country%20note_EN_final.pdf >.

81 The 36% tax burden of Brazil’s GDP considerably exceeds the average of emerging economies.

82 Instituto Brasileiro de Planejamento e Tributacao, online IBPT’s website < http://www.ibpt.com.br/>
payments, and diversion of public resources. In Brazil for instance, 14 civil servants were jailed and 25 MOH employees fired for embezzling US$637 million in the last decade through bribes and price fixing related to reimbursement listings.\(^{83}\) The most recent report on perceived corruption ranks Brazil in 69\(^{th}\) place.\(^{84}\) The Corruption Perception Index (CPI) Score used by Transparency International to rate countries relates to the perception of the degree of corruption at different levels of society. It ranges from 0 (highly corrupt) to 10 (highly clean). Brazil scores 3.9. This in turn, illustrates the prevailing corruption pattern in place in Brazil, which is without a doubt more harmful in a sensitive area such as the pharmaceutical sector where diversion of budgetary funds are not only more easily made but can also potentially impact health outcomes.

In this sense, good governance is crucial for ensuring effective pharmaceutical assistance and returns on investments in a sector that requires more allocation of financial resources than other health care sectors. In that sense, the international community has vigorously pledged its support in helping Latin American countries tackle governance issues through a number of guidelines prepared by the WHO (World Health Organization), UNAIDS (Joint United Nations Programme on HIV/AIDS) and PAHO (Pan American Health Association), as well as through the World Bank and Global Fund grants that are conditional on accountability assessments. Nevertheless, corruption still prevails not only as a common political and administrative practice, but also as a firmly rooted core value of most Latin American countries. Thus, it is arguable that the international community has been inefficiently addressing governance issues by perceiving it separately from the institutional arrangements that are intrinsically connected to it, and consequently largely neglecting decentralization as one of the causes of governance issues. The problem with the lack of concern for national institutional arrangements in health care delivery is that scarce resources are wasted. Moreover, courts’ and administrative bodies’ functions have become compromised by an upsurge of claims demanding health services enshrined in the constitution as an enforceable social right. It is important to highlight that most legal claims


related to the right to health in Brazil demand medicines that are supposed to be available through SUS.

Altogether, the findings presented in this thesis indicate that health policy implementation under a predominantly decentralized system depends considerably on the level of coordination amongst the three levels of government. Social participation either through formal channels (Health Councils) or informal channels is also extremely relevant. Donor agencies likewise play a significant role in pressuring the recipient government to set a comprehensive framework of governance and financial accountability to help minimize the risk of corruption.

With respect to the role of transnational pharmaceutical corporations it is still an idealistic view that a global governance framework will ever be agreed on, especially given that interest in profits outweighs ethical principles of human welfare. On this front, the government should strive to establish a framework of anti-corruption interventions and build institutional ethical standards through strong laws and regulations, for instance, a conflict of interest policy.

HIV/AIDS bureaucracy has made to use of an array of mechanisms to tackle corruption and mismanagement of resources, which have proven to be largely effective. In sum, conditional earmarked federal transfers, civic engagement through NGO’s in participatory intergovernmental institutions such as Health Councils, and the creation of HIV/AIDS special committee to follow-up on policy implementation are just a few examples of policy oversight that stretches far beyond the governmental sphere.

Furthermore, HIV/AIDS audit reports available at the MOH official website, as well as annual reports submitted to PAHO, WHO and the World Bank provide valuable transparency. Information on HIV/AIDS funding, resource allocation and spending are democratically accessible to all citizens. From participating in decision-making processes, shaping health policy to overseeing policy implementation, it can be argued that citizen participation in HIV/AIDS pharmaceutical assistance excels when compared to other pharmaceutical-related health
programs. And this is chiefly due to an innovative partnership the federal government established with organized civil society to coordinated response at a central level.\(^{85}\)

The next section will consider another distinct feature of HIV/AIDS national program that has helped to secure the commitment of local politicians and health authorities in complying with existing HIV/AIDS guidelines and regulations.

### 3.3 HIV/AIDS Policy Coordination

The federal HIV/AIDS bureaucracy has used a relatively simple but effective strategy to improve the quality of state and local HIV/AIDS programs. Namely, it mobilizes grassroots groups to be policy allies that are responsible for monitoring and shaping the design of health policies. Theoretically as well as practically, this inclusion of civil society in state matters is ideal. Grassroots groups are better equipped in acknowledging the needs of society and the flaws of policy implementation, as in most cases their members are also recipients of policies. This is a perspective that health officials and decision makers often lack. Health officials are also typically the ones that withhold technical expertise of the SUS system, in addition to having the power to regulate it. The synergy of interests between state and organized civil society when harmonized has proven to be most beneficial as observed for HIV/AIDS.

The role that grassroots groups play in HIV/AIDS policy coordination is a prime illustration of how societal corporatism\(^{86}\) is paving the way for a new trend in relations between state actors and non-state actors. Grunig maintains that societal corporatism:

> “brings an essential element of collectivism into the commonly individualistic world view of most Western organizations and that collaboration, as the core of what political scientists call societal corporatism, is the key element of democratic societies”\(^{87}\)

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\(^{85}\) See A. Nunn, *The politics and history of AIDS treatment in Brazil* (Springerverlag: New York, 2008) at 47.


The implications of this new concept of governance which has as a fundamental principle democratic participation can be best exemplified, within Latin America, by the government’s response to the HIV/AIDS epidemics in Brazil. In addition to a drastic reduction in infection rates, the success of the program is also reflected in the scale-up access to HIV/AIDS medicines through the state-run health system. Certainly, civil participation hinges on the presence of NGO’s and on political will to allow for such coalition, something that ultimately has been lacking in TB.

It instructive to note how civil engagement in policy matters came to be and what incentives led central bureaucrats to seek this alternative for HIV/AIDS. The mobilization of civil society was pursued through both formal channels (participatory governance councils and commissions) and informal channels. Examples of informal channels include the creation of debate and working groups and autonomous commissions, such as the National AIDS Council (CNAIDS), the Commission for Engagement with Social Movements (CAMS), the Commission for Inter-Sectorial Monitoring of STD/AIDS policy and others. It should also be noted that among the various existing Committees, the HIV/AIDS bureaucracy was highly influential in the deliberations of the Committee on Pharmaceutical Assistance.

This thesis argues that contemporary scholarship on Brazilian health care policy does not do justice to the importance of civil engagement in HIV/AIDS participatory governance. This is not to say that civil society participation per se is sufficient to justify compliance of subnational units to national AIDS policy, but rather it was a combination of factors that accounted for the coordinated response observed at all levels of government. Instead the argument here is that while civil participation was not sufficient for the success of HIV/AIDS national program, it was a necessary component. Without it, health outcomes, such as pharmaceutical coverage would have been very different.

Altogether, the formal and informal channels of state-society interaction provided a fertile ground for local civic groups to act as government whistleblowers of SUS management malpractices. Since the national HIV/AIDS program was put in place in 1986, the program has

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88 Supra note 64 at 13
faced many challenges and setbacks with the inflexible legal framework of decentralization, mostly with respect to subnational AIDS programs. However, the government’s decision to recentralize some functions has minimized health inequities and in this sense, a “coordinated response at a central level” was crucial.

With respect to the incentives for HIV/AIDS bureaucrats to look into civil society participation, there are a number of factors that influenced AIDS officials and the central government to mobilize existing grassroots groups, and in some cases even contributed to the creation of new groups. For instance, when it was learned that TB was the most common AIDS co-infection, as well as the main cause of AIDS deaths, there was a push for the creation of TB NGOs. Prior to this there were only a few and those that existed had no vocal constituency. Some new TB NGOs were actually the result of subdivisions made to some HIV/AIDS NGOs. It is almost as if TB had been incorporated in the agenda of HIV/AIDS NGOs. Nonetheless, the current scenario in Brazil is that of a proliferation of health-related NGOs, some even state-run.

There is some skepticism in understanding the initial incentives for HIV/AIDS NGOs to receive support from outside and inside the state, which is a plausible argument given that the common notion is that the interest of state bureaucrats and political elites most often do not match the interests of civil society. However, the case of HIV/AIDS civic participation contradicts the prevailing notion that civic groups are anything but political allies to state bureaucrats.

This thesis suggests that successful citizen participation in HIV/AIDS policy coordination was chiefly due to not one but a combination of factors. First, outside political pressure from international health organizations and donor agencies compelled the central government to show results in HIV/AIDS policy implementation. Thus outside influences can account for the political willingness and commitment of bureaucrats to ensure efficient HIV/AIDS policy implementation. Second, central government did not have full control over policy implementation in the context of a decentralized health care system while at the same time fiscal and administrative re-centralization was neither desirable nor feasible. Building consensus for a

\[89 \text{Supra note 73 at 93}\]
constitutional amendment under the auspices of a recently enacted constitution was simply not an option.

Thus, the only alternative envisioned by the central bureaucracy to ensure that HIV/AIDS policy implementation would be distinct than those of other diseases, was to rely on indirect control. And that was achieved through the participation of civil society in all levels of the government, all health commissions and councils. An excerpt from a paper of Rich worth reproducing states:

One strategy, emphasized by national AIDS bureaucrats, is to local grassroots movements to act as watchdogs and policy advocates—monitoring subnational government behavior, sanctioning the politicians who fail to comply with national standards, and pursuing legislative and judicial policy protections. A political alliance between national bureaucrats and local civil society groups thus presents a surprising solution for national executives to a seemingly intractable subnational governance problem.  

Empowerment and capacity building of NGOs leaders by the central government was one the cornerstones of the HIV/AIDS national strategy to foster participative governance. Investments in HIV/AIDS NGOs were justified on the basis of civic organizations’ lack of skills to effectively take part in deliberations in the political arena. Training civic groups to act as political advocates required bureaucrats to invest time and resources, which in time paid off. Thus, contrary to common belief, the Brazilian response to HIV/AIDS emerged from top-down with state-sponsored NGOs acting as political allies.

Moreover, the importance of emphasizing HIV/AIDS policy coordination through civic participation is justified by the peculiarities of the Brazilian decentralized system. A system in which the process of devolution of fiscal and administrative functions was disorderly, uncoordinated and poorly regulated. The participation of civil society through NGOs enabled adjustments in a decentralized framework by ensuring accountability of state and non-state actors. The arguments in this thesis subsection are aligned with the ideas espoused by Rich and Gomez, in a sense that policy implementation depends on a coordinated response amongst the all levels of government.

90 Supra note 64 at 18
The next section draws on the impact of external aid to the HIV/AIDS National Program.

3.4 HIV/AIDS Funding

Unlike health programs for other diseases, Brazil’s HIV/AIDS national program relied on financial resources from both within and outside the country. There is no doubt that the magnitude of financial resources to respond to HIV/AIDS epidemic was far greater than those of any other health treat in Brazil. Donor funding for HIV/AIDS was comparable to or exceeded the amounts allocated by the national government to the entire health sector.

In the initial phase of the HIV/AIDS program (1986), the government paid little or no attention to the widespread of the disease. As such the MOH made it clear that, despite acknowledging the seriousness of HIV/AIDS, it was not the government’s priority. The government’s initial refusal to respond to the disease played a determinant role in the emergence of the epidemic in Brazil around the early 90’s. On the face of soaring infection rates, the government and external donor agencies began to negotiate a plan for financial assistance. Around 1990, the recently institutionalized HIV/AIDS National Program was on the verge of being dismantled and it was only in 1992, with the World Bank’s first aid assistance of $250 million that the Program was restructured.

It is arguable that Brazil benefited from the global trend of scaling up response to HIV/AIDS worldwide, and this in turn has brought vast resources to bear in the fight against HIV/AIDS. Brazil like most Latin American countries had at the time a weak capacity and infrastructure to manage the significant amount of financial resources it was receiving. Properly, this in turn raised concerns about its capacity to allocate resources rationally. As Dongbao et al suggests the “limited absorptive capacity” in developing was not to be overlooked. “Donor funding for HIV/AIDS was comparable to or exceeded the amounts allocated by the national government to the entire health sector in some countries”.\(^9\) To address this problem, donor agencies imposed a number of conditions on recipient countries, mainly with respect to the necessity of establishing

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accountability measures and an anti-corruption framework. General guidelines were provided through donor agencies’ reports; however each country had the discretionary power to tailor these directives in accordance to national demands, which in most cases the countries themselves had no data or benchmarks available to evaluate. Nonetheless, I argue that these guidelines were to be used further as a tool to shape national policy and in some cases constitutional health reforms.

In Brazil, a number of international institutions were involved in HIV/AIDS programming including USAID, UNESCO, UNICEF and UNDCP, ILO, WHO/PAHO, IMF and the World Bank. Amongst these, the World Bank has been without a doubt the most relevant one in providing funding for the fight against AIDS in Brazil, as it is the multilateral institution that provides the greatest funding to Brazil. The financial assistance provided can be divided in three main aid packages or loans:

The first World Bank loan was for project AIDS I (1994-1998) and consisted of US$160 million. These funds were mainly allocated to establish programs to prevent HIV transmission and treat opportunistic infections, as well as to establish a network of national labs. A percentage of the resource was destined to provide AZT (Zidovudine Antiretroviral Drug) to pregnant women and antimicrobial drugs for bacterial STDs and opportunistic infections. The second loan was for project AIDS II (1998 - 2003) and consisted of US$165 million. Altogether, both loans funded the development of prevention services, epidemiological surveillance, and capacity building.

The third loan (2003-2006) was intended for project AIDS III, and consisted of US$200 million, with US$166.1 million allocated to specifically improve the quality of prevention, treatment, and care services, US$9.54 million for scientific and technical development, and US$24.37 million for strengthening program management. AIDS pharmaceutical assistance is included in treatment.

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92 The Brazilian government supplemented the first loan with US$90 million thus the first investment to the HIV/AIDS National Program totalled US$250 million.
94 The Brazilian government supplemented the second loan with US$135 million thus the first investment to the HIV/AIDS National Program totalled US$300 million.
95 Supra note 81 at 52
96 Ibid at 52
Through a national initiative known as *Brasil: Contas Nacionais* (Brazil: National Accounts), the national expenditures related to HIV/AIDS is consolidated at all levels of the government. According to its report the HIV/AIDS budget was US$436 million as of 1998, of which the federal government spent US$352 million (81 percent) on treatment; US$42 million (10 percent) on prevention; US$41 million (9 percent) on institutional development; and US $1 million (0.2 percent) on surveillance. The cost of ARVs alone represented 69 percent of total costs.\(^97\) With the current trend of scaling up access to ARVs, it is estimated that the current cost with ARV is beyond 69 percent. This in turn proves the importance of HIV/AIDS program for pharmaceutical assistance.

The positive impacts of HIV/AIDS external funding are irrefutable in enabling the existing structure of the National HIV/AIDS Program insofar that in its absence, the country would not have been able to respond to the epidemic timely and effectively. Health outcomes for HIV/AIDS are far better than those of any other disease, and most importantly, Brazil is also no longer classified as target country for AIDS outbreak control. This thesis argues that funding alone is not sufficient for ensuring outstanding health results and for the internationally renowned model of policy implementation. Funding only provided the tool for the implementation of innovative strategies towards indirect centralization.

The next Chapter identifies potential health care policy alternatives and implications for the sector.

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Proposals for reform should be framed so they enhance efficiencies in the already existing decentralized mode of policy implementation through recentralization of some health functions such as what exists with HIV/AIDS. This is particularly relevant to Brazil’s resource-limited setting, which is one of the main challenges in the fulfillment of SUS principle of universal access to medicines. Although SUS principle of universal access to pharmaceuticals enshrined in the constitution might be seen as utopian, medicines accessibility should be effectively granted to all citizens afflicted by epidemic diseases so as to prevent the widespread of the disease.

Thus, the practical aspect of adopting this re-adjustment approach to decentralization revolves around performance (drug shortage, waiting list to have access to pharmaceuticals), accountability and equity issues. Most importantly, with the projected introduction of new and more efficient therapeutic treatments such as gene-customized pharmaceuticals, the need for a more administratively competent and more economically optimal service delivery will be essential. In this sense, the proposed “hybrid system” would, on one front, keep administrative decentralization and strengthen fiscal decentralization while, on another front, recentralize procurement, policy oversight and policy-making autonomy. The recentralization aspect espoused by this thesis is supported by the emerging literature in health policy. For instance, Chapman Osterkatz notes:

Of particular interest for Brazil (given that the intergovernmental balance of authority in health policy remains in flux), outcomes were substantially improved when the scope of decision-making at the subnational level was restricted, particularly by spending requirements, accountability mechanisms, and management oversight from the center.98

To facilitate the understanding of the proposed hybrid system, the following discussions is divided in three parts: (4.1) will examine functions that should remain decentralized (4.2) will examine functions that should be recentralized (procurement, policy making authority, oversight), and (4.3) will consider any additional recommendations.

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4.1 Functions that should remain decentralized

4.1.1 Management

SUS administration of pharmaceutical services should remain decentralized as it contributes to speeding up service delivery for three reasons:

1. Decentralization in administration and service provision allows for a more equitable geographical/spatial service provision based on the health needs of the local population as well as closer monitoring of service providers. Subnational autonomy should be constrained by efficient federal oversight; however, otherwise it will open the floodgates to administrative malpractice. Therefore, matching administrative discretion with accountability mechanisms is key to any decentralized health system. Additionally, this thesis cautions against granting unlimited subnational authority over recruitment of human resources as it is common for SUS local health authorities to maintain strong links with governors and mayors as political allegiances.

2. Decentralized administration also fosters the empowerment of the low-income social strata to be involved in decision-making processes through state and municipal health councils. The proximity with the administration of pharmaceutical services allows for a better understanding of the system and is decisive for the improvement in transparency, responsiveness and accountability of both the local government and health secretariats responsible for the provision of services.

3. Administrative decentralization can contribute to reduce “layers of bureaucracy” and “diseconomies of scale” in health service provision which have hampered the previously highly centralized Brazilian health care system. With regards to rigid federal regulations that most often encompass a superfluous degree of bureaucracy, this thesis notes that local units tend to replicate central bureaucracy rules and this in turn calls for drastic changes in the existing legislation so as to improve the accessibility to pharmaceutical services.

4.1.2 Financing

As demonstrated in previous chapters of this thesis, availability of financial resources can undermine the implementation of policies by subnational levels of government. In this sense, the existing fragmented scheme of healthcare financing poses a challenge that ought to be properly addressed. Article 55 of the Temporary Constitutional Provisions Act (ADCT)\textsuperscript{100} sets forth the ratio of federal transfers to health care (30 per cent of national social security funds). However this transfer has not yet been implemented and remains an issue to be resolved by future governments. The most significant attempt to redress this inconsistency in social security federal transfers has been the creation of CPMF (Provisional Contribution on Financial Transfers). Nonetheless, Constitutional Amendment 21\textsuperscript{101} modified CPMF redirecting its revenues to pensions and welfare. This constitutional provision has had an unprecedented impact on health care, specifically for the poorest municipalities as they heavily rely on federal transfers due to their incapacity to generate sufficient tax revenues. For the purpose of enlightenment, tax revenue capacity is often linked to the income level of the population and in Brazil municipalities have sharp contrasting fiscal capacities. In sum, decentralization coupled with regressive financing from central government has exacerbated distributive asymmetries in health care. This trend has been especially troubling in the pharmaceutical sector as access to medicines is the cornerstone of any health system. And despite the fact that states and municipalities are granted greater autonomy for tax creation, most municipalities are still incapable of generating tax revenues to match the health needs of their population. Thus, this thesis suggests strengthening financing decentralization with a stronger commitment of the federal government to increase its share in subnational health budgets.

4.2 Functions that should be recentralized

4.2.1 Procurement

In contrast to centralization or decentralization, this thesis advocates the introduction of a “hybrid system” that seeks the advantages of SUS’s decentralization default rule with an

\textsuperscript{100} Constitution of the Federal Republic of Brazil, (Brazil, 1988) Temporary Constitutional Provisions Act (ADCT), art. 60.

\textsuperscript{101} Constitutional Amendment no. 21, (Brazil, 1999), D.O.U of 19.03.1999.
advantageous feature of a centralized health care system, namely centralized procurement. In terms of a hybrid system, one reform that stands out is: a centralized drug acquisition arrangement. This thesis assumes that the benefits of centralized procurement outweigh the advantages of decentralization advocated by some scholars. That is, as pointed out by Dimitri et al, Edler et al and Albano et al, centralized procurement potentially (1) increases the bargaining power of national agencies, (2) reduces drug prices through economies of scale, (3) speeds up the process of negotiations, (4) fosters research and development of neglected diseases given the incentive on pharmaceutical companies to negotiate with governments on a large scale basis; and most importantly (5) generates greater transparency and measurability of governments negotiating procedures as it is easier to keep track of a unified source of negotiation as opposed to many regional and municipal agencies negotiating separately. Additionally, the appraisal of the technical and financial requirements of procurement can be quite complex. The recentralization of this health function is justifiable as local government may face hurdles in building specialized expertise compromising the ability of local governments to comply with existing regulations.

The Brazilian experience with centralized procurement for anti-retroviral medicines provides a good example of the benefits of this type of procurement method. For instance, the national government has been able to substantially reduce anti-retroviral prices mainly due to negotiations and centralized procurement with international pharmaceutical companies. According to data provided in a study by Bermudez et al.\textsuperscript{102}, the price of Zidovudine\textsuperscript{103} has dramatically fallen during the 10 year period from 1988 to 1998. Government centralized purchases of ARVs was the most important factor that contributed to Zidovudine price decrease.

And perhaps a centralized procurement model could also be extended to essential medicines allowing the government to efficiently allocate health resources to ameliorate accessibility barriers to medicines for other diseases. With regards to centralized public procurement for medicines, Everard posits:


\textsuperscript{103} Zidovudine is also known as a nucleoside analog reverse-transcriptase inhibitor (NRTI), a type of antiretroviral drug used for the treatment of HIV/AIDS infection.
Public procurement for an entire public health service should as far as possible be centralized nationally; decentralization of government administration may be a laudable aim, but if it means that drug purchasing will henceforth be handled by twenty or more inexperienced and small provincial bodies the quality of procurement can hardly be expected to improve.\textsuperscript{104}

4.2.2 Policy-Making Authority

In a setting where there is a risk of elite capture of social programs, such as the case of Brazil and most Latin American countries, regulatory and policy-making authority should be constrained by a central government. Centralization, in this sense is crucial to maintaining equity in service provision and standardization of regulations. For instance, since federal requirements for minimum spending levels were instituted, inequality in health financing across Brazil has sharply diminished\textsuperscript{105}. Borrowing Arretche’s findings of health decentralization, “equitable results are most likely when central government regulations limit the scope of policy autonomy of subnational units”\textsuperscript{106}. Additionally, the regulation of pharmaceutical services is multilayered and quite complex, thus it requires extensive technical expertise and knowledge. This in turn justifies the centralization of regulatory authority. Bossert along the same lines as Arretche notes that the broader the scope of subnational decision-making autonomy (mainly in planning and financing) the better the performance at local level. Conversely, the more autonomy granted to local authorities for procurement and management of human resources, the poorer the performance.\textsuperscript{107} The experience with HIV/AIDS programs in Brazil reflects these findings in the literature as policy-making authority has remained mostly under the control of the MOH and the HIV/AIDS National Commission.


\textsuperscript{105} Supra note 42 at 621


4.2.3 Policy Oversight

In terms of federal oversight of decentralized subnational health functions, the proposed hybrid system advocates for a monitoring scheme applied to HIV/AIDS national programs. This would include a combination of conditional federal earmarked transfers with delegation of SUS managerial functions to NGOs through partnerships. Conditional federal earmarked transfers, as detailed in earlier section of this thesis, is a new innovative funding mechanism used by the central bureaucracy which transfers money to the HIV/AIDS National Programme with less limitations that allows for the government to maintain close oversight on how the funds are administered and spent. It can be inferred that this funding strategy is a particularly efficient resource for federal oversight as it provides a strong incentive for subnational bureaucrats to comply with national guidelines. Needless to say that for this strategy to work it is essential that national health programmes work in partnership with organized civil society that have a strong capacity to monitor health authorities. Otherwise, for diseases that have no or small grassroots groups to monitor policy implementation, the promises of federal conditional earmarked transfers as oversight mechanisms loses much of its coercive power, as they will probably just be an incentive to local disputes for revenues which would later be subject to administrative malpractices. In Brazil, it is a common practice the circumvention of auditing procedures by both politicians and higher health authorities. And even more common are leakages of federal transfers to municipalities that end up allocating health resources for other programs with more political visibility (such as building stadiums or roads). In this sense, there is also a need to empower weaker NGO’s to foster greater democratic participation of civil society in holding the government and health authorities responsible for administrative malpractice.

4.3 Additional Recommendations

4.3.1 Participation of Civil Society

As explained in earlier sections, the mere existence of formal channels for social participation such as health councils is presumably insufficient as mechanism of social control over policy implementation. Furthermore, there is substantial empirical evidence ascribing the degree of success of health councils in engaging civil society in participatory governance to the existence of strong and politically influential NGOs as well as to political will. Drawing attention to HIV/AIDS, the federal government has complemented the formal channels of participatory
councils with informal channels of participation through policy commissions, specialized HIV/AIDS council (CNAIDS – National AIDS Council) and collaborative working groups. Thus, there is a need for a new paradigm for state-society collaboration, especially in the Brazilian pharmaceutical sector. Moreover, NGOs could be used as whistleblowers in relation to sub-national policy implementation and as observed with HIV/AIDS, NGOs would also report their initiatives back to the national program. Another novel democratic participatory mechanism currently applied in Indonesia and the Philippines is the “Civil Society Procurement Monitoring (GSPM) Tool”, and could also be applied in Brazil as a complementary tool to curb corruption and resource mismanagement in the pharmaceutical sector. “This tool is designed to support Civil Society Organizations (CSO) in their efforts to recognize the red flags of corruption in public procurement. The tool has the following components: a procurement monitoring guide, country-specific monitoring guides, a monitoring assistant; a learning community, and online training.”

Despite the fact that there is no blueprint to tackle corruption in the health sector, tools such as GSPM and other efforts applied elsewhere to harness public budgets and data for public use have proven to be effective in improving accountability.

4.3.2 Training and Capacity Building

At the time the government decided to pursue decentralization, states and municipalities were neither administratively nor technically capable of undertaking the provision of health care services. In this sense, the level of skills and competencies of SUS staff and NGOs leaders play a significant role not only in empowering organized civil society but also in the delivery of pharmaceutical assistance ensuring the quality and the continuity of health service provisions. A study conducted in the state of Sao Paulo regarding the quality of public healthcare for HIV/AIDS patients found adherence to treatment improved with better quality of care.

Hence, strengthening the implementation of health programs through capacity building is of paramount relevancy at municipal and state levels. A unique aspect of the Brazilian health system also worth considering is the high turnover of SUS staff, as well the changing roles of health ministries and regional health secretariats. In this context of constant shifts of decision makers, investments in training are lost. The solution envisaged for this problem would be a

108 Gateway Transparency online: <http://gateway.transparency.org/tools/detail/597>

comprehensive framework for skill transfer on a regular basis so as to optimize federal investments in capacity building.

4.3.3 Sharing of Transnational Experience

International experiences and standards should be evaluated, and appropriate best practices applied to the Brazilian context. Most comparative studies on decentralization processes in Latin America suggest that SUS impediments to equity are similar to those of other Latin American countries, which in turn point to a fertile ground to share cross-national experiences. For instance, in Bossert’s comparative analysis of decentralization of publicly funded health services in Chile, Colombia, Bolivia and Argentina, there are relevant insights from Latin American countries that have tackled the health care devolution processes in terms of their weaknesses and strengths in the context of newly democratized countries\(^\text{110}\). Argentina for instance has been highly successful in implementing the Remedi\textregistered{}r Programme in its pharmaceutical sector. According to the findings of Homedes et al, the increased access to pharmaceuticals observed with Remedi\textregistered{}r’s launch depended on political commitment, engagement of civil society in policy implementation, and a combination of methods to control the rising cost of medicines, including centralized international competitive bidding processes for drug procurement.\(^\text{111}\)

4.3.4 Strengthening the Role of Donor Agencies

There is also a role for international donor agencies to take a greater role in overseeing health programs in recipient countries. Taking into account the degree of involvement of donor agencies in the implementation of the HIV/AIDS National Program and how effective it has been in terms of providing guidelines for policy implementation, oversight and evaluation; it seems clear that the coordination of assistance provided by donor agencies potentially affects the outcomes of health programs. One must also keep in mind that the greater availability of funds for health programs is a double-edged sword: while it fosters high quality programmes it can also result in an increase in corruption levels skewing financial and institutional development. Therefore, donor agencies must coordinate their support to ensure that the financial aid provided


to the recipient country is safeguarded against corruption. The conditionality of funding in developing and less developed countries is of prime importance given weak institutional arrangements coupled with increased levels of corruption. As Jain posits, conditional transfers or “budget support” is preferable to “project assistance” in aligning the goals of donor agencies with those of recipient countries.\footnote{See S. Jain, “Project Assistance versus Budget Support: An Incentive-Theoretic Analysis of Aid Conditionality”. (2007) Review of World Economics 143:4.at 711} They argue that this harmonization of goals prevents “leakages” to corruptive political schemes and most importantly improves the efficacy of the financial aid.\footnote{Ibid. “Leakages”- Term used by Jain, Sanjay.} 

4.3.1 Legal Framework for the Pharmaceutical Sector

Definitions of responsibilities in the existing pharmaceutical laws and regulations are often blurred or are subject to many modifications and regulations overtime. This can result in duplication of services and even worst, lack of medicines being supplied justified given the unclear regulations with respect to who bears each responsibility in the cycle of pharmaceutical assistance. The pharmaceutical sector is distinct in a variety of ways as demonstrated throughout this thesis, but most importantly it is highly vulnerable to corruption and other administrative misbehaviours due to the chain of stakeholders’ relations and complex procedures that it entails.

The starting point of the proposed legal framework could be an assessment of pharmaceutical policy best practices such as HIV/AIDS, while learning from unsuccessful practices in order to minimize inconsistencies in existing laws and regulations. Normative reform should address which functions should be recentralized and which should remain under the auspices of decentralization. For instance, both national and international experiences have shown that procurement of critical inputs such as medicines should be centralized for economies of scale and standardization purposes.

With respect to the legislative procedure for a normative health reform, constitutional amendment would not be applicable for a number of reasons. First, the principle of decentralization is embedded in the 1988 Brazilian constitution, which makes amendments
towards reversing decentralization nearly impossible. Principles or constitutional features may not be breached or altered if they propose the abolition of the federal system, direct secret universal periodic votes, and the separation of powers or human rights in accordance to the Constitution of Brazil, art 60(4).114 Thus attempts to recentralize the health care system through constitutional amendments would be deemed as unconstitutional. Additionally, distribution of authority between all levels of the government is considered to be the cornerstones of the Brazilian federalism, which in turn is an entrenched clause in the constitution.115 Entrenched clauses are irrevocable, thus not subject to constitutional amendments. Article 60 of the 1988 Constitution of Brazil, states:

The Constitution may be amended on the proposal of:
I. at least one third of the members of the House of Representatives or of the Federal Senate;
II. the President of the Republic;
III. more than one half of the Legislative Assemblies of the units of the Federation, each of which expresss itself by a simple majority of its members.
(1) The Constitution may not be amended during federal intervention, state of defense or state of siege.
(2) The proposal is discussed and voted in each Chamber of Congress, in two rounds, and it is considered approved if it obtains three-fifths of the votes of the respective members in both rounds.
(3) An amendment to the Constitution is enacted by the Presiding Boards of the House of Representatives and of the Federal Senate, with a respective sequence number.
(4) No resolution is discussed concerning an amendment proposal which tends to abolish:
I. the federative form of the State;
II. the direct, secret, universal, and periodic vote;
III. the separation of the Government Branches;
IV. individual rights and guarantees.
(5). The subject dealt with in an amendment proposal that is rejected or considered impaired cannot be the subject of another proposal in the same legislative term.116

Therefore, any attempts to modify the distribution of authority within federal, state and municipal governments would clash the constitutional provisions for amendments. It should be noted that to-date there has not been any legislative attempt to reverse decentralization through constitutional amendments.

Second, even if it was possible to reverse decentralization through constitutional amendment, this would require special procedures include majorities in the legislature, or, a referendum submitted to the people. In this sense, achieving broad political consensus for reform of a politically-sensitive matter such as health care and pharmaceutical services would not be an easy task.

The experience with HIV/AIDS legislative efforts to recentralize some functions, in this sense, also provides useful insights as to the strategies used for this purpose. For instance, nearly all HIV/AIDS health care provisions aiming to reassert control over subnational actors with respect to the SUS were achieved through the enactment of decree-laws by the MOH. This delegation of legislative powers to the executive branch to implement policies via decree, has proven to be an efficient solution, in a sense that, it unburdens the legislative branch and that in terms of health care matters, the MOH is the most suitable governmental institution to propose changes. Law-decrees or ministerial decrees are a strategic mechanism used by central bureaucracy to circumvent the strenuous legislative procedures and the risks of proposing constitutional amendments. Moreover, this thesis argues that the normative establishment of the proposed “hybrid system” is possible given the prior experience with HIV/AIDS policy.
Conclusion

Altogether the findings of this thesis indicate that there is no such a thing as an ideal proxy for decentralization because there is a wide range of institutional arrangements that should be taken into account. The level of effectiveness of decentralization depends considerably on the institutional arrangements used in its implementation, such as the level of civic engagement, the existing structure for capacity building, health funding, political commitment to comply with regulations and guidelines, and arguably most importantly, oversight over policy implementation, both horizontal and vertical. In the pharmaceutical sector, more specifically, successful implementation of policies to increase access to medicines, such as has been the experience in HIV/AIDS pharmaceutical policy, has provided an excellent study case to examine the positive and negative features of decentralization. Overall the experience of HIV/AIDS signals the need for an innovative framework to improve and enhancing health equity within the SUS.

Simply overhauling the existing decentralized system is neither advisable nor an easy fix. The prescription for reform in this thesis, calls for incremental institutional changes to decentralization. These are identified as the most beneficial route towards optimal healthcare delivery, and are intrinsically linked to governance as demonstrated in previous chapters.

Nonetheless, experience suggests that an alternative arrangement, such as the one applied to Brazil’s HIV/AIDS program, can succeed in balancing the fundamental elements of decentralization and recentralization. Successful balancing also depends on consistency and alignment of objectives between civil society and governments as well as on a national and international political commitment to promptly respond to epidemic diseases. In this sense, lessons from the HIV/AIDS program implementation in scaling up access to AIDS medicines should be considered as a framework for institutional and normative reform within the pharmaceutical sector.

The findings of this study further pointed out that some aspects of the SUS healthcare system should remain decentralized such as management and financing. Results have shown
recentralizing the management of the pharmaceutical policy implementation would inevitably be burdensome for central bureaucracy that already struggles to manage other health sector inefficiently. It would mean a reversal to the centralized authoritarian system which has proven excessively bureaucratic and highly vulnerable to corruption. The counterargument is that the cycle activities in the pharmaceutical sector is complex at best and involves many stakeholders, which in turn would justify recentralization. However, I argue that the in the absence of a comprehensive regulatory framework and of monitoring mechanisms for accountability purposes, recentralization of SUS management would be superfluous and health equity matters would remain unresolved. With respect to financing, a detailed analysis of SUS health funding as espoused in previous chapters of this study demonstrates that, with regional and local disparities in generating tax revenues coupled with a reduction in federal transfers, subnational governments have been incapable of adhering to federal directives for health programs. Furthermore, the government has so far not fully addressed the problem of lack of funding source exclusively for health. There is some hope that the currently approved provisory measure to fund public services with oil revenue\textsuperscript{117}, headed by Brazil president Dilma Rousseff, will unburden the SUS. Nonetheless, I argue that increasing funding will not suffice, if resource mismanagement is not taken into account. Thus, recommendations revolve around improving governance by engaging civil society in policy implementation and policy-making, investing in training and capacity building of SUS health related personnel, sharing transnational experience with decentralization, strengthening the role of donor agencies in ensuring the proper use of financial aid within recipient countries and finally establishing a normative framework of decentralization that will prevent settle the problem of regulatory duplication. More specifically, within the pharmaceutical sector, the functions that should be recentralized includes: procurement, policy-making authority and policy oversight.

A “hybrid system” as proposed, does not imply a reversal of decentralization, but rather builds on prior successful experiences of indirect centralization of HIV/AIDS policies. The unique institutional arrangements of HIV/AIDS program could ultimately be applied to other prevalent strategic diseases (e.g. malaria, leprosy, focal endemics, leishmaniasis and Chagas disease), where there is a high demand for medicines even though the diseases have been classified as priority (Strategic Component).

\textsuperscript{117} 25\% of oil revenue is to fund the state-run health system (SUS)
This approach would not only provide the national government with an alternative solution to improve drug accessibility but would also be helpful to other nations seeking to balance decentralization with re-centralization of some health care system functions. A balanced approach to decentralization is more desirable to the pharmaceutical sector than the current SUS decentralization general rule. Distributive social justice and equity in decentralized health systems is not a pipedream. It is rather a matter of institutional and normative adjustments.
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Books


**Articles**


