Policy Essay

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Between Policy and Justice: The Brazilian National Policy on Pharmaceuticals

With around 190 million inhabitants, Brazil is one of the fastest growing pharmaceutical markets in the world. Annually, domestic pharmaceutical sales amount to approximately U.S. $15 billion and the country also imports an estimated U.S. $4 billion in pharmaceuticals (SINDUSFARMA 2010). The consumption of medicines is unequally distributed, with the richest 15 percent of the population consuming 48 percent, and the bottom 51 percent consuming only 16 percent (Dias 2006). To remedy this, the public healthcare system, Sistema Único de Saúde (SUS), provides medicines for free for those individuals who cannot afford them but have a medical prescription confirming their need. In 2007, SUS distributed more than 443 million free medicines throughout the country (DATASUS 2007).

In recent years, Brazil has seen a dramatic increase in the number of individuals who attempt to procure access to medicines through judicial lawsuits. Lawsuits generally involve individuals who were eligible for free medicines but failed to obtain medicines through the public healthcare system, either because the required medication was not covered under public pharmaceutical distribution lists or because covered medicines were not dispensed in a timely and consistent manner. Courts, by and large, have tended to rule in favor of the plaintiffs and mandate the provision of treatment by the state. While the judiciary has an important role in guaranteeing access to medicines for the population in Brazil, its role in case-by-case treatment decisions may interfere with the implementation of state health policies.

This paper explores the relationship between the state and the judiciary

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in the provision of medicines in Brazil. It assesses strategies through which the state can improve efficiency in providing medicines and recommends that, in addition to guaranteeing individual rights, courts should also enforce the effective implementation of state health policies.

I. Context and Overview

The Brazilian Unified Health System (UHS) was created under the country's 1988 Constitution, which established health as a basic right and placed onus on the state to provide health care (Ribeiro 2009). The Organic Law of Health,[1] passed in 1990, identified pharmaceutical policies as one of the UHS responsibilities, though the government did not create a National Policy on Pharmaceuticals until 1998 (see Ministry of Health 1998).

One of the core characteristics of the UHS is decentralized provision of health care. As such, the responsibility for the provision of medicines is divided between the federal, state, and municipal governments. The federal government is responsible for financing higher cost and higher complexity treatments (i.e. "exceptional medicines"); the state government provides intermediate cost and medium-complexity treatments (i.e. "special medicines"); and the municipal governments provide "basic" drugs for lower cost and lower complexity conditions (i.e. "essential medicines") (Ministry of Health 1998). These lists of medicines for public distribution, created by the Ministry of Health in collaboration with state and municipal administrations and health experts, have been updated three times since the 1998 publication of the National Policy on Pharmaceuticals, which is not as frequently as the two-year interval recommended by the World Health Organization (Informe ESNP 2006; Pepe 2009).

Currently, obtaining drugs from public lists requires that individuals first receive a prescription and medical report from a UHS physician and subsequently visit a public pharmacy to collect the drug. All applications for special and exceptional medicines are reviewed by medical experts who evaluate the appropriateness of each request. In practice, the process from the initial filing of the documents to the actual delivery of the drug may take several months. Frequent stock shortages may further postpone or interrupt access to treatment and have negative consequences for the patients. A study from the World Health Organization analyzing 32 essential medicines found that only 30 percent of them were available for distribution in Brazil's public pharmacies (Mendis et al. 2007). Furthermore, the decentralization of pharmaceutical provision may generate variations in the ease of access between municipalities, regions, and states due to differences in local procedures and administrative efficiency.

Patients unable to obtain drugs from the UHS may seek judicial recourse, citing the right to health guaranteed by the Constitution. As a result, the number of lawsuits seeking to procure access to medicines has markedly increased. The state of Rio de Janeiro, for example, experienced a threefold growth in the number of lawsuits requesting medicines between 2000 and 2002 (Messeder et al. 2005). Similarly, the number of lawsuits in the state of Rio Grande do Sul increased by a factor of five between 2002 and 2006 (Biehl et al. 2009). The escalating number of lawsuits generates significant costs for public budgets. Ministry of Health estimates showed an increase of 2,000 percent in federal expenditures associated with court-attained drugs over a three year period (Collucci 2009). States have also been impacted. In Rio Grande do Sul, for example, court-attained drugs constituted four percent of all health care expenditures projected for 2008 (Biehl et al. 2009).

Up to two-thirds of medicines requested in lawsuits are part of public pharmaceutical distribution lists (Vieira and Zucchi 2007). Their procurement through courts may demonstrate a failure of any of the three levels of government to guarantee access to treatment. It may also reflect a lack of information among UHS providers on public health policies and the accompanying administrative procedures for pharmaceutical distribution (Vieira and Zucchi 2007). The fact that the majority of drugs in question are under the state's responsibility suggests that identifying and correcting system failures and improving existing administrative procedures for requesting and distributing drugs could go a long way in reducing lawsuits and related costs.

Furthermore, judicial procurement of medicines that are not part of public distribution lists may reflect the fact that public lists are not necessarily comprehensive or reflective of current population needs. Messeder et al. (2005) found that when these off-list medicines were included on public distribution lists, there was a subsequent decrease in their judicial demand. However, because judicial decisions with regard to medicines are decided on a case-by-case basis, court rulings do not directly guarantee improvements in the public provision of medicines.

II. Analysis

The judicialization of access to health is a matter of concern in Brazil. The escalating number of costly lawsuits may reflect failures of the public healthcare system. Courts play an essential role in guaranteeing patients' right to health as specified by the Constitution. Their rulings, however, may pose significant problems for public health policies.

First, in guaranteeing access to treatment, the courts' interpretation of the constitutional right to health frequently overlooks established public health policies. Judicial decisions about pharmaceuticals may potentially conflict with the country's national policy on pharmaceuticals, which has been legally established by ministerial decrees, federal and state laws, and whose importance in guaranteeing the right to health is embedded in the Constitution.[2]

An example of this tension is that the distribution of responsibility between the three levels of government—a core principle of the UHS—is frequently overlooked by courts. The state may be mandated to provide medicines that are of municipal or federal responsibility and vice versa. This may create budgetary problems and confound the process of decentralization, acting as a disincentive for some administrations to fulfill their responsibilities (Vieira and Zucchi 2007).

Another example is Brazil's 1999 Generic Drug legislation,[3] which directed the government to acquire generic, as compared to brand-name, medicines (Dias 2006). Court-backed judicial determinations that mandate the provision of brand-name drugs by the state potentially contradict this legislation. Similarly, the role of the National Health Surveillance Agency[4] in approving and registering pharmaceuticals for sale in the country is challenged by judicial determinations that mandate the provision of drugs not yet approved by this agency (National Health Surveillance Agency 2010). Up to three percent of lawsuits related to medicine access in the state of São Paulo request drugs that are unregistered for sale in Brazil. Although no specific data on these drugs are available, such drugs are typically granted by courts' decisions (Chieffi and Barata 2009).

Evidence-based therapeutic guidelines issued by the Ministry of Health (see Ministry of Health 2002) are yet another example of such a conflict. These guidelines focus on the rational use of high-cost "exceptional medicines" distributed by the UHS. They are implemented by UHS medical experts through their review of patients' applications for "exceptional" drugs. The main goal of these therapeutic guidelines is to guarantee safety and effectiveness of prescriptions through the clear establishment of disease diagnostic criteria, recommended treatments and adequate dosages, and follow-up and monitoring of results, among others. Judicial decisions regarding drugs included in these therapeutic guidelines are not subject to expert scrutiny and may ignore recommendations by the Ministry of Health. Additionally, court decisions on medical treatments may fail to account for the existence of a public program for the given condition and the presence of an alternative treatment in one of the UHS distribution lists.

It must be noted that, as a general rule, lawsuits requesting pharmaceuticals are based on the allegation of risk of death or irreparable harm. These allegations understandably tend to prevail over arguments about administrative policies. Very often, however, the allegation of risk is not based on official medical documents which should accompany the lawsuit. These documents may not be present at all, or the prescribing physician may not have provided comprehensive information in the medical reports, forcing courts to perform uninformed and rushed decisions (Terra et al. 2009a).

Second, judicial mandates for drug provision may disproportionately hurt public budgets. Spending on court-attained drugs is more expensive than spending through administrative pharmaceutical policies. The state of São Paulo, for example, spent approximately U.S. $9,000 per judicial patient in 2006, while spending approximately U.S. $1,000 per patient on UHS programs for high-cost "exceptional" medicines (Chieffi and Barata 2009).

The process of acquiring medicines from UHS distribution lists favors generic drugs, is performed in bulk based on a competitive bidding process, and is tax-exempt. The purchase of medicines as determined by judicial decisions has to be completed in a short time-frame (usually 2-5 days) and frequently involves brand-name drugs. This leaves no time for price competition and forces the state to buy from the market on a case-by-case basis that is not tax-exempt. Also, many court-attained drugs are not part of public pharmaceutical distribution lists. These drugs, therefore, have no ongoing procurement processes (Chieffi and Barata 2009).

The sequestration of funds from state budgets to attend individual cases is a common practice in judicial rulings and constitutes another way by which judicial mandates may interfere with public budgets (Terra et al. 2009b). Through this practice, funds are transmitted directly to the plaintiffs for the acquisition of medicines, authorizing them to buy from the market medicines that could be more cheaply acquired through administrative health policies. This may disorganize budget management and divert funds from other health priorities.

Lastly, courts may mostly benefit socially apt individuals who are comfortable navigating the legal system. This scenario clashes with the core principle of the UHS to promote health equality (Chieffi and Barata 2009).

III. Policy Recommendations

Given that financial resources allocated to the health care system in Brazil are limited, their utilization should follow from careful planning in line

with national policy priorities. The following policy recommendations will better preserve the integrity and original mandate of the UHS to increase pharmaceutical access and health provision in Brazil.

- **A more effective implementation of existing pharmaceutical policies is imperative.** Public administration structures at the federal, state, and municipal levels should be reviewed in order to promote more timely and efficient processing, approval, and delivery of drugs. More efficient, regular, and robust budget analyses should be conducted to guarantee funds for regular drug acquisition processes. These analyses should not only build on information from previous periods, but also on the epidemiological profile and judicial demands of the population.

- **Mechanisms of monitoring and control of the delivery of medicines should be implemented at each level of government in order to facilitate the flow of information and enforce participation at all levels.** A national database should be created to integrate information on the medicines distributed by states, municipalities, and the Ministry of Health. This information should be accessible to courts, helping to inform judicial decisions and promote accountability. Data from legal cases should be systematically used by policy makers to monitor system efficiency, review public health priorities, and update population health needs, as well as to conduct better budget estimates for medicines whose distribution is UHS's responsibility.

- **Besides guaranteeing individual rights on a case-by-case basis, courts should uphold the original intent of UHS and guarantee care not only for the plaintiff, but also for all individuals who need that same drug**. In the case of listed medicines, courts should enforce the decentralization process by mandating the provision of drugs by the level of government responsible for each list. Also, courts should enforce treatment criteria established by the Ministry of Health's guidelines, requesting independent expert opinions in unclear cases or a review of the guidelines in light of new medical evidence. As for off-list medicines or drugs not registered for sale in the country, courts should demand expert assessment of their safety and efficacy before ruling for or against their provision for individual plaintiffs. The UHS should ensure that the incorporation of new medicines on public distribution lists is performed more frequently, based on the best available medical evidence (Banta 2009).

IV. Conclusion

The phenomenon of the judicialization of access to medicines may reflect inconsistencies and failures in the provision of drugs by the UHS. More effective processes for the analysis and distribution of drugs are imperative. Moving forward, courts should reorient their decisions toward enforcing policy implementation. These changes would likely promote a better use of existing resources, increase the number of individuals served by the country's health system, and represent an important step toward reducing health inequalities in Brazil.

Notes

[1] Federal Law 8080, September 19, 1990.

[2] According to Article 196 of the 1988 Federal Constitution, "Health is a right of all and a duty of the state, guaranteed by social and economic policies aiming for the reduction of the risk of disease and other injuries and for the universal and egalitarian access to actions and services for its promotion, protection and reestablishment."

[3] Federal Law 9787, February 10, 1999.

[4] Federal Law 9782, January 26, 1999.

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