

Right-to-Medicines Litigation and Universal Health Coverage: Institutional Determinants of the Judicialization of Health in Brazil

MARIANA P. SOCAL, JOSEPH J. AMON, AND JOÃO BIEHL

Abstract

Over the past three decades, Brazil has developed a decentralized universal health system and achieved significant advances in key health indicators. At the same time, Brazil's health system has struggled to ensure equitable and quality health services. One response to the broad promises and notable shortcomings has been a sharp rise in right-to-health litigation, most often seeking access to medicines. While much has been written about the characteristics of patient-plaintiffs and the requested medicines in right-to-health litigation in Brazil, little research has examined potential community-level and institutional drivers of judicialization and their role as mechanisms of accountability. To explore these dimensions, we used a mixed-effects analytical model to examine a representative sample of lawsuits for access to medicines filed against the state of Rio Grande do Sul in 2008. We found that the presence of a Public Defender's Office was associated with a sevenfold increase in the likelihood of a municipality having a medicine-requesting lawsuit. This effect was maintained after controlling for a series of municipality characteristics. As low- and middle-income countries seek to achieve universal health coverage within the framework of the Sustainable Development Goals, Brazil's experience may be illustrative of the challenges that health systems will face and the institutional mechanisms that will emerge, advancing accountability and individual patients' interests in response.

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Introduction

Universal health coverage (UHC) has become a rallying cry and pillar of the Sustainable Development Goals. Operationally, it can mean both focused reforms and sweeping health system changes. In its simplest formulation, UHC is understood as access to affordable, quality health services for all.¹

Over the last three decades, among low- and middle-income countries, Brazil has been at the forefront in creating a universal health system (Sistema Único de Saúde, or SUS) grounded in the recognition of a right to health for all.² With significant investment, Brazil has increased life expectancy (from 65 to 75 years), reduced infant mortality (from 53 to 14 per 1,000), and pioneered pharmaceutical access initiatives.³ In recent measures of UHC, Brazil received a 77 out of 100 in its UHC service coverage index, with scores for different services including 88 (family planning), 90 (antenatal care), and 96 (child immunization).⁴

Alongside these achievements, the country has faced major challenges: sustaining funding, building robust institutions and regulatory mechanisms, and ensuring equitable quality of care. The decentralization of care delivery has often occurred without adequate technical capacity, and the growing privatization of services has jeopardized efficiency and entrenched inequalities around the axes of race, gender, and region.⁵ These trends are especially evident around pharmaceutical access: many Brazilian patients go to public pharmacies only to find that the medicines they were prescribed are out of stock or are not included in governmental drug formularies.⁶

One mechanism that emerged to address some of these challenges has been the phenomenon of right-to-health litigation (often referred to as the "judicialization of health").⁷ Highly contested and methodologically constrained, the debates over the whys, the hows, and the effects of this ever-expanding phenomenon have been marked by polarized arguments about equity, bureaucratic autonomy, resource allocation, and efficiency.⁸ Many scholars and government officials have advocated for the containment and management of right-to-health litigation.⁹ In contrast, our previous work has

advanced an understanding of such litigation as a heterogeneous phenomenon and as a critical dimension of the country's democratic life, enabling legal empowerment, fostering social mobilization, and working as a mechanism (albeit precarious) of accountability.¹⁰ From this perspective, judicialization contributes to the struggle to define the contours and components of the country's constitutionally mandated right to health alongside subsequent laws, Ministry of Health policies, and Supreme Court rulings that have advanced an expansive right to access to treatments.

While past studies of judicialization in Brazil have emphasized individual characteristics of patient-litigants and the types and costs of the medicines requested, in the present study we seek to identify how community-level and institutional determinants might influence right-to-health-litigation. As low- and middle-income countries invest in and develop stronger health systems, more attention should be paid to understanding Brazil's experience in developing a universal health system and to the governmental and civil society mechanisms that arose to address its shortcomings and constraints. With hundreds of thousands of lawsuits seeking access to medicines annually, judicialization has played a central role in Brazil by mediating individuals' access to health care. As low- and middle-income countries expand their efforts to establish UHC, and their populations face an increasing burden from non-communicable diseases, the potential role (and limits) of judicialization as a mechanism of accountability deserves close scrutiny, especially in light of current trends in pharmaceutical globalization and the privatization of health care.11

Neoliberal reforms, access to medicines, and judicialization in Brazil's national health system

Two concurrent and paradoxical trends informed the structure of Brazil's universal health care system in the early 1990s. On one hand, there was a trend toward a greater recognition of the government's role in the fulfilment of social rights in a democratizing Brazil. On the other hand, a neoliberal theory of government emphasized decentralization and the outsourcing of state functions to the private sector.¹² Nowhere was this conflicting direction more evident than in the question of pharmaceutical access.

From its inception, access to medicines was an integral part of Brazil's national health system, SUS. Over time, with the introduction of drug-specific programs and policies and patient activism, access to medicines became an even larger component.¹³ In the 1990s, community health boards (Conselhos de Saúde) were created at local, regional, and national levels to ensure accountability within SUS. They were designed to set priorities and to monitor the implementation of health policies.14 These participatory mechanisms, however, have not alleviated major problems related to the lack of infrastructural investments (with public services outsourced to private providers) and the effective regulation of public and private health care actors. Thus, the country still sees large regional disparities in health care delivery and in health outcomes, with poorer regions and lower socioeconomic population groups disadvantaged the most.15

Even outside SUS, access to medicines has remained a core responsibility of the state. Private health insurance plans were introduced in the country in the late 1980s to complement SUS and to provide specialized and expedited care for higher-income segments. However, privately insured individuals (who now constitute about 24% of the population) have continued to benefit from SUS through access to state-subsidized medicines, since private insurance plans do not cover outpatient drugs.16 This benefit, combined with the tax deductibility of health insurance premiums, puts a strain on state health expenditures while also lowering tax revenues. Of particular demand are increasingly high-priced specialty drugs such as treatments for diabetes, hepatitis C, and cancer.

In the mid-1990s, after Brazil signed the TRIPS agreement and began to see a successful response to HIV/AIDS with expanded access to antiretroviral drugs, an understanding of a right to medicines emerged. With exponentially increasing drug costs

(due to tightening intellectual property laws for medicines and Brazil becoming a major market for global medicines), judicialization expanded to new patient populations, with people using the courts to seek access to medicines they were unable to find in public pharmacies. The arguments advanced in lawsuits drew on those used by HIV/AIDS activists, and the phenomenon grew especially quickly in the southern and southeastern regions.¹⁷ Recognition of a right to medicines was endorsed by a ruling by the Supreme Court in 2000 concerning a patient's access to a new antiretroviral drug and describing the HIV/AIDS pharmaceutical assistance program as the actualization of the government's duty to implement programmatic norms that secure the health of the population.18 With such programs, as Justice Celso de Melo argued, the right to health ceases to be "an inconsequential constitutional promise."19

Patient-plaintiffs in Brazil obtain legal representation from private lawyers or public legal services, such as the independent Public Prosecutor's Office (Ministério Público) and local branches of the Public Defender's Office (Defensoria Pública). The Public Prosecutor's Office operates at both the federal and state levels and is charged with defending the rights of minorities and civil society more broadly. The Public Defender's Office promotes individual rights and provides free legal representation to individuals who earn below a certain income threshold (three times the minimum wage). Public Defenders' Offices are present in all Brazilian states and in most large cities and are meant to guarantee the constitutional promise of a right to access to justice. Historically, lawsuits for access to medicines have been filed against the state, even when the drug has not been part of SUS's formularies or when the plaintiff had a private health insurance plan. Since the early 2000s, courts have continued to consistently rule in favor of patient-plaintiffs, based on the interpretation that the right to state-provided medicines is part of the constitutional right to health.20

The state of Rio Grande do Sul, where we have been carrying out research for the past decade, has the highest number of right-to-medicines cases in the country.²¹ In 2016, for example, this state of over million inhabitants had 61,000 legal cases for access to medicines, costing 4% of the state's entire health budget that year.²²

Case study: Institutional determinants of judicialization in southern Brazil

Numerous investigations have described the characteristics of right-to-medicines litigation in Brazil. While some studies have found that judicialization is driven primarily by better-off individuals seeking expensive off-formulary treatments, others have found that judicialization serves mainly low-income individuals who are seeking inexpensive medicines that should have been available in SUS pharmacies.²³ When examining the legal and medical services most frequently involved, some scholars have suggested that judicialization is driven largely by physicians seeking to promote high-cost treatments and private lawyers specializing in health-related lawsuits, while other scholars have highlighted the important role played by SUS doctors and public defenders in encouraging patients to file lawsuits.24

Less closely examined has been the influence of community-level characteristics (such as socioeconomic development) and institutional factors (such as the presence of health and legal systems).25 For example, some studies have suggested that regional differences in health budgets and in SUS's administrative capacity might be drivers of judicialization.26 From this perspective, judicialization could be seen as a response to a population's health needs being insufficiently or inadequately fulfilled by state services at the local level.²⁷ Alternatively, the characteristics and accessibility of the legal system at the local level may influence individuals' ability to "enter justice" (entrar na justiça, as plaintiffs generally call it—that is, to have their health claims addressed by the judiciary).28

In the context of what has been at times a polarized and overly narrow debate, broadening the understanding of judicialization beyond individual cases, types of medicines requested, and their immediate costs is timely and analytically significant.

Methods

To assess the possible influence of community-level and institutional factors on judicialization, we re-examined lawsuits for access to medicines filed against the state of Rio Grande do Sul in each of the state's 496 municipalities in 2008. This representative sample was collected through a systematic survey of lawsuits on which we have previously reported. Methods from our research are described in detail elsewhere.29 Briefly, the survey collected data from the State Health Secretariat's electronic registry, a database that records all medicine-related lawsuits filed against the state and includes information on plaintiffs' municipality of residence. In this analysis, we used plaintiffs' municipality of residence as the unit of analysis and considered municipalities with at least one medicine-requesting lawsuit to be positive cases. The research was reviewed and approved by the Institutional Review Board of Princeton University and by the Health Secretariat and the General Attorney's Office of the state of Rio Grande do Sul.

Our analysis focused on the availability of health services and the presence of a Public Defender's Office at the level of the municipality and health administrative region (HAR, or Coordenadorias Regionais de Saúde). Each HAR is responsible for managing and implementing state-sponsored health service delivery, including medicines, in the municipalities it covers.30 The location of Public Defender's Offices was obtained from the Rio Grande do Sul Public Defender's Office website.31 Availability of health services, defined as the number of facilities providing health services per 1,000 inhabitants, was obtained from a national health services survey known as the Pesquisa Assistência Médico-Sanitária.32 We also examined several demographic, socioeconomic, and health characteristics of the municipalities, which we obtained from the Brazilian Census and the Ministry of Health's epidemiologic surveillance system.33 All 496 municipalities had full information, and there were no missing data.

Although the decision to submit lawsuits is made by patients and their sponsors (such as physicians and legal representatives), a patient's

likelihood of filing a lawsuit depends on the availability of such services in their community. Higher availability of health services in a given locale, for example, could be associated with a greater demand for pharmaceuticals and the increased likelihood of judicialization. Lower availability of health services could also be associated with a greater likelihood of judicialization as a means to fulfill the unmet health needs of a local population. In turn, higher availability of legal services could be associated with a higher likelihood of judicialization through increased access to legal representation.

In this study, we focused our analysis on outcomes and determinants at the community (municipality) level. Our analysis assumes that patients with the same individual characteristics would have different likelihoods of filing a medicine-requesting lawsuit, depending on the community level determinants and the characteristics of the health services and legal system of the municipality where they live.

Figure 1 displays the conceptual framework that guided our analysis. This theoretical scheme was adapted from Ronal Andersen and John F. Newman's framework entitled "Societal and Individual Determinants of Medical Care Utilization" and is used here to represent the "claims formation stage" of the litigation process.³⁴

Controlling for demographic and socioeconomic characteristics, we implemented multi-level random effects logistic regression analyses grouped at the HAR level. The adjustment for municipality characteristics was implemented because these characteristics may simultaneously influence the likelihood of a municipality having a medicine-related lawsuit and the municipality having greater availability of health services or a Public Defender's Office. There is also the possibility that the administrative capacity of the health system at the municipality level may play an independent role, as indicated by the municipality's membership in a given HAR.

We tested the robustness of our results with sensitivity analyses using fixed-effects models for HAR and by repeating all models without the capital city of Porto Alegre (population of about 1.4 million), the only municipality with more than one Public Defender's Office. All statistical analyses were implemented using Stata statistical package release 12 (StataCorp, College Station, TX).

Results

In 2008, over half of Rio Grande do Sul's 496 municipalities were classified as urban (N=275, 55.5%), with an average of 21,000 inhabitants per municipality (range: 1,200–1.4 million) (Table 1). The state

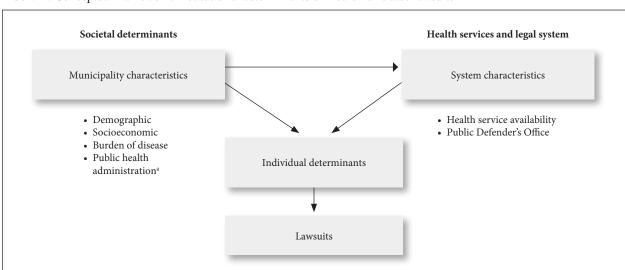


FIGURE 1. Conceptual framework: Institutional determinants of medicine-related lawsuits

^a In Brazil, public health administration is represented at the local level by health administrative regions (Coordenadorias Regionais de Saúde).

had a higher level of socioeconomic development than most states in Brazil, with an illiteracy rate among adults of 6.8% (range: 1–20% among municipalities) and monthly income of R\$742.83 (US\$462.50) (representing 1.8 times the national monthly minimum wage of R\$415.00, or US\$ 258.39, at the time).³⁵ The state had a crude mortality rate of 703.2 per 100,000, which varied between 120 and 1,200 deaths per 100,000 population among municipalities. Overall, 153 Public Defender's Offices were present in the state, with at least one Office present in 31% (N=153) of the municipalities. There were, on average, 59 health services per 100,000 inhabitants (Figure 2).

Ninety-two percent of lawsuits were found outside the capital city of Porto Alegre. About 45% (N=223) of municipalities had at least one lawsuit for access to medicines (Figure 3). Municipalities with lawsuits had an average of 28.5 lawsuits per 100,000 inhabitants (range: 1.5–168.6). Although the state capital had the highest number of lawsuits, when adjusted for population size it ranked 20th in lawsuits per 100,000 people. The municipalities

with the highest density of medicine-requesting lawsuits were smaller municipalities, geographically scattered across the state.

In a bivariate analysis, municipalities with medicine-requesting lawsuits had higher populations (40.9 \pm 109.9 vs. 6.0 \pm 7.5 thousand inhabitants, p<0.0001) and higher mortality rates (7.23 ± 1.47 vs. 6.87 ± 1.85 deaths per thousand, p=0.014) than municipalities without lawsuits (Table 2). Municipalities with lawsuits were more likely to be urban (26% vs. 59%, p<0.0001) and had lower illiteracy rates (6.2% vs. 7.3%, p=0.0006) and higher income levels (R\$765.4 ± 199.7 vs. 724.4 ± 213.1, p=0.028) than those without lawsuits. Municipalities with lawsuits were more likely to have a Public Defender's Office (59% vs. 8%, p<0.0001) and had lower availability of health services (0.52 \pm 0.26 vs. 0.64 \pm 0.38 services per 1,000 inhabitants, p<0.0001) than those without lawsuits.

When controlling for all other characteristics in a multi-level random effects logistic regression model, municipalities with at least one Public Defender's Office were about seven times more likely

Table 1. Descriptive characteristics of Rio Grande do Sul's 496 municipalities

Characteristic	Metric	Value	
Demographics			
Population	Avg (sd)	21.6 (75.8)	
Mortality rate ^a	Avg (sd)	703.2 (169.6)	
Socioeconomic			
Urban ^b	N (%)	275 (55.5%)	
Illiteracy rate ^c	Avg (sd)	6.8% (3.3%)	
Per capita income ^d	Avg (sd)	R\$742.83 (208.00)	
Service availability			
Health servicese	Avg (sd)	59.02 (33.6)	
Public Defender's Office ^f	N (%)	153 (31%)	
Lawsuits			
Has medicine-related lawsuit	N (%)	223 (45%)	

Notes: A new municipality was created in the state of Rio Grande do Sul after the data collection for this study, bringing the current total to 497 municipalities. Avg: average; sd: standard deviation.

^a Crude mortality rate: total deaths per 1,000 inhabitants

^b Municipality has predominance of urban areas

^c Percentage of the adult population that cannot read or write

^d Average per capita income in 2010 Brazilian reais

e Health services per 100,000 inhabitants

f Municipality has at least one Public Defender's Office

to have a medicine-requesting lawsuit than municipalities without it (odds ratio: 6.95, 95% CI: 3.2-15.1) (Table 3). Municipalities with greater availability of health services were less likely to have a lawsuit, yet this association was not shown to be statistically significant (odds ratio: 0.56, 95% CI: 0.27-1.17). Population size (odds ratio: 1.04, 95% CI: 1.01-1.07 per 1,000 population), mortality rate (odds ratio: 1.17, 95% CI: 1.01-1.34 per 1,000 individuals), and urban characteristics (odds ratio: 1.01, 95% CI:1.00-1.03 as compared to rural) continued to be associated with a greater likelihood of lawsuits. Neither of the variables associated with socioeconomic status, illiteracy, or per capita income was significantly associated with the presence of a lawsuit in the municipality. After adjusting for all characteristics, belonging to the same public health administration region explained 15% of the municipality's likelihood of having a lawsuit (intraclass correlation coefficient: 0.15, 95% CI: 0.06-0.33). The different models implemented in the sensitivity analysis did

not significantly change the results.

Analysis

Amidst global efforts to implement universal health care systems, the Brazilian experience of the last three decades is emblematic of the challenges that governments face in ensuring equitable and efficient health systems, while addressing an expansive, constitutionally mandated right to health and dealing with an accelerated political economy of pharmaceuticals.36 In our previously reported work, we found that judicialization was geographically widespread in southern Brazil and that the majority of litigants were poor and older individuals with chronic diseases, seeking access to medicines that were already on governmental formularies and should have been available in local public pharmacies. Overwhelmingly, local judges ruled in favor of patient-plaintiffs, deeming their demands constitutionally legitimate.³⁷

Our empirical findings here suggest that the

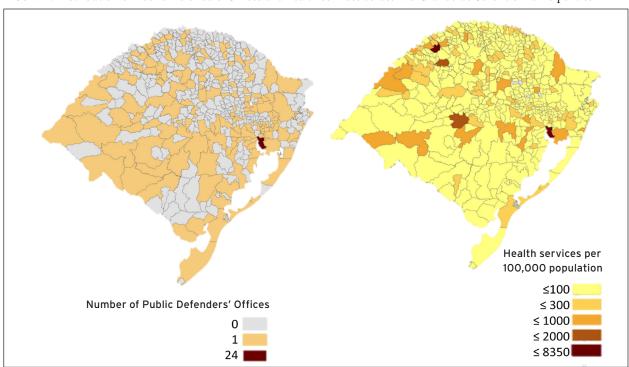


FIGURE 2. Distribution of Public Defenders' Offices and health services across Rio Grande do Sul's 496 municipalities

Sources: Defensoria Pública do Rio Grande do Sul. Available at http://www.defensoria.rs.def.br/inicial; Instituto Brasileiro de Geografia e Estatística, Pesquisa de Assistência Médico-Sanitária (2009). Available at https://www.ibge.gov.br/estatisticas-novoportal/sociais/saude/9067-pesquisa-de-assistencia-medico-sanitaria.html.

presence of a Public Defender's Office in a municipality is a major determinant of the likelihood of judicialization. Although this study implemented a cross-sectional analysis—which does not allow for the establishment of causative relationships between the institutional factors that we examined and the occurrence of judicialization—two main findings suggest that it is likely that the presence of Public Defenders' Offices helped enable judicialization, and not the other way around. First, our fully adjusted models indicated that two municipalities with the same characteristics—same population size, mortality rates, and urban/rural characteristics-have significantly different likelihoods of having a medicine-related lawsuit, depending on the presence or not of a Public Defender's Office. Even if the presence of a Public Defender's Office in the municipality was initially a response to population needs, it still plays an important role in

enabling patient-plaintiffs to file lawsuits. Second, the Public Defender's Office is not the only form of legal representation available for low-income individuals in Rio Grande do Sul. When filing a lawsuit for access to medicines, low-income individuals may also be represented by a private lawyer and have their legal fees reimbursed by the state, as long as they request it as part of their lawsuit, present proof of need, and the judge approves it.

Judicialization as a mechanism of universal health coverage accountability

Charged with a mandate to represent vulnerable individuals and uphold justice, public defenders have accepted health-related lawsuits as part of their commitment to institutionally sustaining advancements in socioeconomic rights and promoting state accountability.³⁸ This accountability is

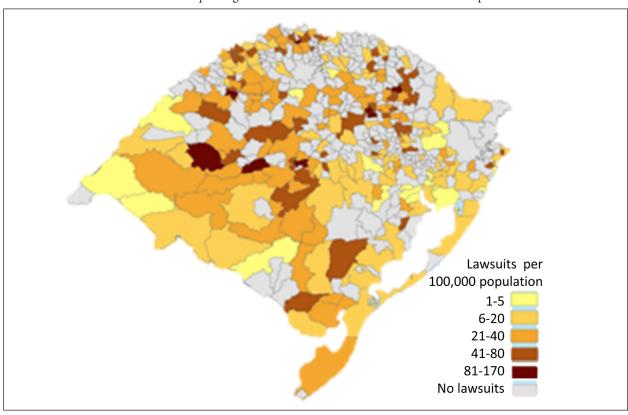


FIGURE 3. Distribution of medicine-requesting lawsuits across Rio Grande do Sul's 496 municipalities

Source: Authors' analysis of a representative survey of all medicine-requesting lawsuits filed against the state of Rio Grande do Sul (for a full description of the survey, see J. Biehl, M. Socal, and J. Amon, "The judicialization of health and the quest for state accountability: Evidence from 1,262 lawsuits for access to medicines in southern Brazil," Health and Human Rights Journal 1/18 (2016), pp. 209–220).

TABLE 2. Characteristics of Rio Grande do Sul municipalities with and without lawsuits

Characteristic	Municipalities with lawsuits (n=223)	Municipalities without lawsuits (n=273)	p-value
Demographics			
Population ^a	40.6 (109.9)	6.0 (7.5)	<0.0001
Mortality rate ^b	7.23 (1.47)	6.87 (1.85)	0.017
Socioeconomic			
Urban ^c	74% (44%)	41% (49%)	<0.0001
Illiteracy rate ^d	6.2% (2.8%)	7.3% (3.7%)	0.0006
Per capita income ^e	765.4 (199.7)	724.4 (213.1)	0.0286
Service availability			
Health services ^f	52.49 (25.85)	64.37 (37.98)	<0.0001
Public Defender's Office ^g	59% (49%)	8% (27%)	<0.0001

^a Total population, in thousands

Table 3. Factors associated with higher likelihood of lawsuits among Rio Grande do Sul municipalities: Results from fully adjusted multi-level random effects

Variable	Coefficient	95% confidence interval	p-value
Demographics			
Population ^a	1.04	(1.01-1.07)	0.02
Mortality rate ^b	1.17	(1.01-1.34)	0.031
Socioeconomic			
Urban ^c	1.01	(1.00-1.03)	0.022
Illiteracy rate ^d	0.97	(0.89-1.06)	NS
Per capita income ^e	0.99	(0.86-1.14)	NS
Service availability			
Health services ^f	0.56	(0.27–1.17)	NS
Public Defender's Officeg	6.95	(3.2–15.1)	<0.0001
Constant	0.09	(0.01-0.56)	NS
N		496	

Notes: Multivariable multi-level random effects logistic regression model. The independent variable is the presence or absence of medicine-requesting lawsuits in a municipality. All the listed characteristics are included as fixed-effects regressors. The model includes a random intercept for health administrative region (HAR). Coefficients represent expected change in the odds of lawsuits associated with a 1-unit change in the variable, keeping all other characteristics constant. NS: not statistically significant (p-value >0.05). N=496 municipalities.

^b Crude mortality rate: total deaths per 1,000 inhabitants

^c Municipality has predominance of urban areas

^d Percentage of the adult population that cannot read or write

^e Average per capita income in 2010 Brazilian reais

f Health services per 100,000 inhabitants

g Municipality has at least one Public Defender's Office

^a Total population, in thousands

^b Crude mortality rate: total deaths per 1,000 inhabitants

^cMunicipality has predominance of urban areas

^d Percentage of the adult population that cannot read or write

^e Average per capita income in 2010 Brazilian reais

^fHealth services per 100,000 inhabitants

g Municipality has at least one Public Defender's Office

manifest in two ways: first, it provides a measure of whether the state is fulfilling its constitutional obligations and administrative functions; and second, it pressures the state to respond to the rapidly changing landscape of population health needs and transparently and effectively address the incorporation of new technologies in the health system. In focusing on accountability within existing political and economic systems and sustaining hard-fought basic rights, the Public Defender's Office thus elicits a vision of justice and political engagement at a local scale that includes the urgent need for health systems reform.³⁹

If universal health coverage goes beyond access to minimum public health services and essential medicines and seeks to address the chronic, non-communicable diseases that are increasingly the cause of morbidity and mortality in low- and middle-income countries, then the increasing "pharmaceuticalization of health" must be anticipated.40 Innovative treatments are available in the global market at ever-increasing speeds and heftier price tags. Incorporating these technologies into what can be offered to populations is a particular policy challenge for countries such as Brazil, which has become the world's fifth most profitable and rapidly growing pharmaceutical market.⁴¹ In this context, some scholars have argued that judicialization fails to act at the scale needed to combat neoliberally inflected policies.⁴² That is, judicialization should focus more on court cases that seek structural changes to the political economy of medicines or on lobbying legislative bodies to take such steps as reforming patent laws and imposing regulations on price.

While judicialization might have the indirect effect of temporarily improving health care delivery, medicines granted by courts are often not fulfilled by the government, leaving patients with a legal victory but no treatment.⁴³ Or courts are slow to act, while patients suffer waiting for a resolution.⁴⁴ In a previous study we documented some responsiveness by the government to litigation, with several of the most sought-after medicines that were initially not on drug formularies later

officially included, thus increasing the likelihood of availability.45 While this is not a direct consequence of judicialization, it is a consequence of the expansion in the services and products provided by the public system that has occurred because of judicialization. Moreover, the lack of private insurance coverage for outpatient drugs in Brazil has left a gap that further challenges public policy and strains government budgets. Small steps have been taken in recent years by advancing regulations requiring private insurers to expand their benefits packages and include some high-cost drugs in their covered services.46 Having private insurers cover drugs helps expand opportunities for Brazilians to finance the drugs they need, helps open new markets, and helps develop new opportunities for price negotiations with pharmaceutical companies.

It is easier to sue for medicines than for the improvement of public health services, and although massive individual right-to-health litigation may not represent sustainable structural change, it nonetheless helps strengthen the right to health and human rights more broadly, as seen in the institutional work of Public Defender's Offices in southern Brazil. This work recognizes the fundamental importance of the State and its right-to-health obligations. Without establishing these obligations and institutionally sustaining advancements (albeit limited) in socioeconomic rights, pressing for governments to recognize their duty to challenge drug patents and negotiate pricing seems fanciful at best.⁴⁷

There is indeed a sentiment across many sectors in Brazil that there should be a more effective way to address government malfunction and the privatization of SUS other than the judicialization route, but the answer from officials and scholars has often been that the better way is limiting access to justice and hoping that pharmaceutical delivery systems improve, either with expert advisory panels or on their own.⁴⁸ While better prioritization (that is, rationing) might be necessary, empowering expert advisory panels to determine what medicines should be provided by the state would not directly change the current dynamic in which

courts judge that the state's constitutional obligation to fund UHC at 15% of GDP is not being met and that individuals' right to health includes medicines not on government formularies. If the recommendations of such panels were to constrain access to medicines, this might be considered a failure to progressively realize the right to health and in violation of Brazil's treaty obligations under the International Covenant on Economic, Social and Cultural Rights. Expert panels might alternatively be charged with assessing the efficiency of the government's pharmaceutical supply chain system, the influence of the pharmaceutical industry, the government's use of (or failure to use) TRIPS flexibilities, or potential legislative policies and legal reforms around the coverage of medicines by private insurance. Local accountability efforts such as judicialization may not be the most efficient or all-encompassing political mechanism, but it is a critical element of a progressive rights movement and conduit of legal empowerment and a broader democratization of society.

Lawyers and legal services have played a role in Brazil in defining access to medicines in landmark cases going back to rulings on the free provision of antiretroviral therapy as a component of the right to health. In recent years, the legal pathway for access to medicines has allowed patients with hypertension to receive the basic drugs that were missing in their local public pharmacies, as well as patients with rare genetic disorders to receive the newest treatments in the field before their conditions become irreversible.⁴⁹ Although our data is from 2008, the mechanism of judicialization for accountability remains ever more relevant.

Legal empowerment as a grassroots strategy to expand health care has been documented globally, with, for example, *defensores de saúde*, or health advocates, in Mozambique supporting clients at the village level to resolve specific grievances with respect to health services, and "street lawyers" (*Gadejuristen*) in Copenhagen who provide legal education and sterile injecting equipment to drug users.⁵⁰ In Brazil, lawyers have also represented patients seeking broader protections such as access to

information, transportation, specialized care, and family planning for those affected by the Zika virus.⁵¹ In addition, legal empowerment demonstrates that the assumption that social rights litigation "benefits those in the 'middle' of the social spectrum because the poor have less access to courts" is fundamentally a product of the lack of options for access to legal representation.⁵² Such lack can be successfully mitigated by institutions such as the Public Defender's Office, which reinforce the "right to remedies" of individuals left out and left behind as policy makers (and often, international experts and norm-setting organizations) define what is, and what is not, included in universal health coverage.

As mentioned above, the role of public defenders and lawsuits as mechanisms of accountability for a functioning health system have limits—and inefficiencies. In order to effectively improve and expand Brazilians' access to medicines, other accountability mechanisms ought to be engaged as well: the Public Prosecutor's Office (Ministério Público), which represents vulnerable communities (including children, the elderly, and traditional populations); the community health boards (Conselhos de Saúde) that are SUS's main accountability channel by design; state legislators and government health administrators who have the power to set up stronger mechanisms for prioritization and resource allocation; and civil society organizations, such as those representing Zika-affected families.53 These mechanisms may target different shortcomings of universal health care systems, such as improving quality of care, transparency of decision-making, responsiveness, and resource allocation. They may also help expand the range of benefits offered from low-cost, low-complexity technologies toward increased access to high-cost and high-complexity ones.

Conclusion

Within global discussions of universal health coverage, the scant attention given to law has focused mostly on enabling legal environments and progressive health laws.⁵⁴ There has been little con-

sideration of accountability mechanisms in general or access to legal services in particular. Our study demonstrates that the Public Defender's Office plays an important role in right-to-health litigation, expanding it to geographically and socioeconomically diverse environments.

The volume of court cases is itself pressure on both the judiciary and the legislature to adopt structural reforms. Until now, this pressure has been insufficient to match the power of lobbyists and special interests who oppose such reforms, but it may not always be so. While it may be more strategic in the long term to fight for patent law reforms and hope for timely and effective implementation, those putting forward individual lawsuits seeking medicines actually embody structural vulnerabilities. They speak to the urgent need to strengthen public health systems and guard them against private cooptation.⁵⁵ The immediate need for human rights advocacy and legal access for multitudes of individual patients is clear.

The role of judicialization and of the Public Defender's Office in improving accountability in access to medicines and overall health care delivery in Brazil should be further investigated. We contend that a combination of "real-time, comprehensive data collection multi-disciplinary academic research, robust public debate and media attention are needed in order to identify and strengthen these emergent accountability mechanisms aimed at both public and private health care institutions."56 In addition, policy makers aiming to improve access to care and pharmaceuticals in Brazil should consider the impact of judicialization and improve policy design and regulatory oversight based on the information generated by this process, with the normative ambition of achieving transparent, accountable, and participatory priority setting that promotes substantive human rights.

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