On the Judicialization of Health and Access to Medicines in Latin America

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Abstract: In a context of rapid technological innovation and expensive new products, the paper calls for the generation of real-world data to inform decision-making and an international discussion on the affordability of new medicines, particularly for low- and middle-income countries. Without these, the challenges of health judicialization will continue to grow.

Introduction

In this paper, the judicialization of health refers to the increasing involvement of courts on issues related to health and healthcare with the goal of protecting citizens' health rights. Accordingly, professional negligence or medical malpractice are not included in this definition of health judicialization.[1]

Often, courts are called upon to ensure citizens' access to essential health services and resources when there's a perceived failure of state action or a violation of health rights. Issues stemming from flaws and inefficiencies in the delivery of healthcare services, the availability of essential medicines, and other covered procedures contribute to the rise of health judicialization. Consequently, this phenomenon can be viewed as the most visible expression of citizens in the pursuit of their health rights.

The impact of health judicialization on the healthcare sector is substantial. It can override, alter, or reverse allocation and prioritization decisions made by policymakers, potentially leading to tensions between two independent branches of power. Furthermore, considering the costs associated with litigation over medications, medical devices, and procedures, judges' decisions can have a significant budgetary impact.

One of the primary challenges posed by health judicialization is the reconciliation of individual and collective priorities and rights. While courts often deal with specific individual medical cases, sometimes involving quality of life or life-threatening situations, state actions are guided by a collective perspective. Universal healthcare systems establish priorities based on the relevance of morbidity and mortality, comparing the outcomes of health technologies with existing alternatives while considering their budgetary implications. Ultimately, health judicialization may underscore the conflict between the regulatory authority of the state and the autonomy of physicians in making decisions about patient treatment.[2]

Why Is Health Judicialization So Prevalent in Latin America, and What Are Its Underlying Reasons?

The phenomenon of health judicialization can be attributed to an interplay of structural factors, both internal and external to the health sector. On the one hand, some of the factors contributing to judicialization are associated with weaknesses in healthcare systems, including: underfunding or resource misallocation; inadequate or inefficient service provision and

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subpar quality of care; deficiencies in critical resource availability and flawed pharmaceutical policies; shortages or insufficient distribution of healthcare personnel; managerial inefficiencies; and inadequate information systems, among others.

On the other hand, some of the factors driving health litigation are external to the sector's policy and decision-makers and are beyond their control. One critical factor is the utilization of marketing strategies by industries to promote healthcare technologies and treatments to physicians, patients, and other influential stakeholders. These strategies frequently involve economic incentives and the funding of scientific research and publications authored or supported by influential medical professionals or professors from prestigious universities. Additionally, commercial and intellectual property regulations and agreements also play a role in restricting access to more affordable alternative technologies, such as generic or biosimilar medicines.[3]

Although these factors are common in many developing economies, the phenomenon of health judicialization is particularly pronounced in Latin America due to certain distinctive characteristics of the region. Estimations based on data from the late nineties through the first decade of the new millennium reveal that, on average, there were 1,800 health rights litigations per million inhabitants per year in Colombia, 206 per million in Brazil, 109 per million in Costa Rica, and 29 per million in Argentina. In contrast, South Africa and India had *cumulative* figures of 0.3 and 0.2 health rights litigations per million inhabitants for the same period, respectively.[4]

To underscore the significance of this phenomenon in the region, available data reveal a remarkable surge in health litigations in recent years:

- In Colombia, the number of right-to-health litigations increased by 119% between 2010 and 2019, resulting in a 98% rise in the litigation rate per population during the same period.[5]
- Brazil witnessed a 130% growth in right-to-health lawsuits between 2008 and 2017, compared to a 50% increase in the overall number of lawsuits during that same time.[6]
- Uruguay experienced a surge in litigations related to medicines, soaring from 100 to 550 in just three years from 2016 to 2019, leading to an almost fourfold increase in spending on high-cost drugs.[7]
- The number of health litigations against Costa Rica's Caja Costarricense de Seguro Social increased by 144% between 2009 and 2019. Spending on medicines resulting from these lawsuits accounted for over 11% of the institution's total budget for medicines in 2021, compared to just 2% before 2015.[8]

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The key legal foundation underlying the judicialization of health in Latin America stems from the recognition of health as an individual right, rather than merely a societal value, within the laws and constitutions of most countries of the region. Furthermore, in addition to constitutional recognition of health as a fundamental right, the legal frameworks of many Latin American nations incorporate provisions, commonly known as "writs of protection" (*recursos de amparo* or *tutelas*), that facilitate judicial protection for citizens. These legal arrangements, coupled with a significant degree of judicial activism, where judges actively engage in monitoring and shaping public policy,[9] and the presence of a dynamic civil society, provide citizens with effective legal tools and low barriers to seek redress when they perceive inadequate health-

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care policies or discriminatory practices that infringe upon their health rights.

Advancements in socioeconomic conditions and healthcare have led to an increase in life expectancy in Latin America. This has, in turn, resulted in rapid population aging and a higher prevalence of noncommunicable diseases.[10] The complex nature of these diseases, coupled with the development of new and expensive medical technologies for their diagnosis and treatment, poses both technical and financial challenges to healthcare systems. This situation has created a disconnect between citizens' needs and expectations and the healthcare systems' capacity to meet these demands, thus serving as a potential catalyst for judicial claims.

Moreover, the funding and organizational models used by many Latin American countries to provide access to pharmaceuticals differ from those employed by most universal healthcare systems in developed countries within the Organization for Economic Cooperation and Development (OECD). In Brazil, for example, the management of the pharmaceutical supply chain and the distribution of medicines to patients are handled by public facilities.[11] Nevertheless, these services are often overwhelmed with various responsibilities, leading to frequent shortages or limited availability of essential drugs.[12] This lack of essential drugs are significant drivers of judicialization, as will be shown below. In contrast, in European countries, Australia, Canada, and other OECD-affiliated universal healthcare systems, medicines covered by the healthcare system are dispensed through private community pharmacies and publicly financed via reimbursement systems.

Types of Litigation

Figure 1 provides an illustration of four potential scenarios that can lead to judicialization, considering two key factors. Firstly, it assesses whether a health good or service is classified as essential by the health system and whether the system has committed to providing it to its beneficiaries. Secondly, it examines whether individuals have access to the said good or service:

- In the first scenario, depicted in the northeast quadrant, litigation is unnecessary because patients already have access to the health goods and services provided by the health system.
- Quadrant two represents a scenario with the potential for allocative inefficiency or resource wastage. Here, individuals have access to health goods and services that the health system's assessment and prioritization frameworks have categorized as nonessential.
- Quadrants three and four represent the two primary forms of health judicialization. In the former, patients turn to the courts to access goods or services that the health system does not provide due to various reasons: (1) the system's evaluation process has determined that they do not offer greater benefits than existing alternatives; (2) these goods or services are not considered an epidemiological priority from a collective perspective; (3) they are economically unfeasible for the country; (4) they are new, and their safety and cost-effectiveness have not yet been evaluated by the health system; or (5) inefficiencies or technical limitations have hindered the health system from offering these goods or services to patients. In this regard, litigations that align with the scenarios outlined in quadrant three depict situations characterized by a direct conflict with the priorities set by the health system. These litigations correspond to judicialization types B and C as defined in the taxonomy established by Freiberg and Espin.[13] In fact, one could argue that they essentially constitute the judicialization of the country's health policies and prioritization decisions.
- In the last scenario, quadrant four, patients resort to the courts to obtain health goods and services that the health system is expected to provide but fails to do so for the reasons outlined in the previous section (referred to as judicialization type A in the taxonomy by Frieberg and Espin mentioned above).

The significance of this last type of litigation cannot be overstated. A sample of the 2021 health judicialization data collected by Colombia's Constitutional Court, for instance, reveals that approximately 74% of the lawsuits pertain to services, goods, or inputs that are included in the benefit package but have either been delayed or not provided to patients.[14] In the northern Brazilian state of Pará, nearly 70% of litigation cases revolve around medicines listed in the country's covered drugs or essential medicines list.[15] Similarly, data from 2010 in the southeastern state of Minas Gerais indicates that roughly half of the cases involved medicines found in the essential list.[16]

Discussion

Medicines are among the most commonly litigated subjects. In Colombia, for instance, they often represent the first or second most frequent cause of litiga-

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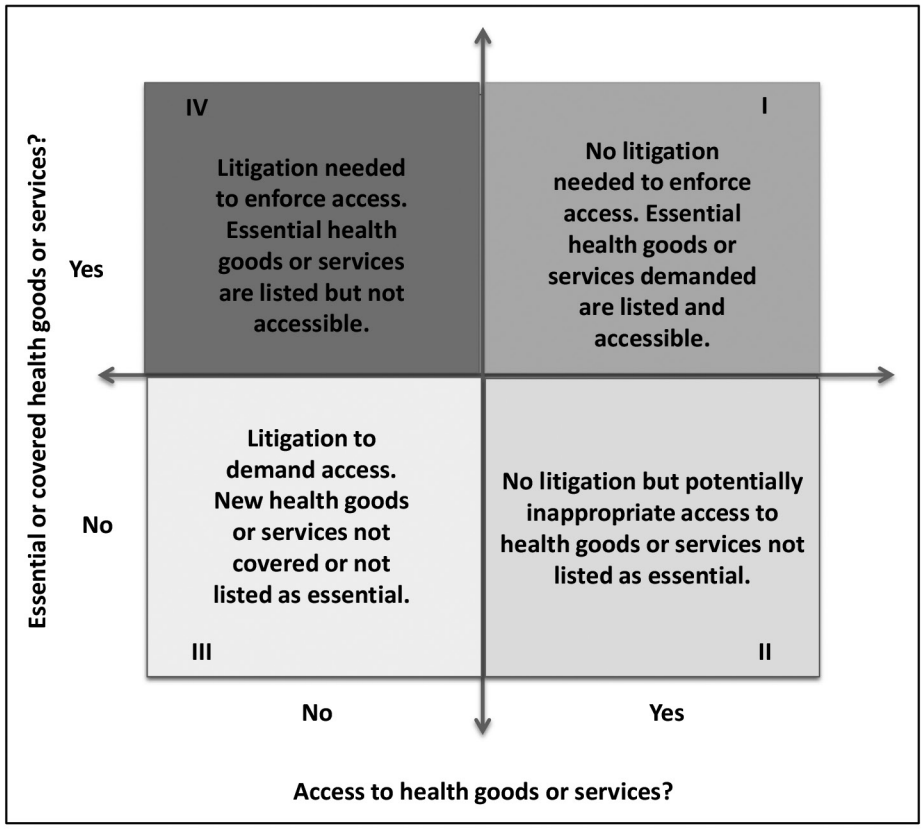
Figure 1



Source: Based on L. Cubillos, M.-L. Escobar, S. Pavlovic, and R. Iunes, "Universal Health Coverage and Litigation in Latin America," *Journal of Health Organization and Management* 26, no. 3 (2012): 390-406.

tion, accounting for approximately 25% of all cases.[17] Since the provision of healthcare is inseparable from access to medicines, these technologies are regarded as an integral part of the fundamental right to health, safeguarded by the constitutional and legal frameworks of Latin American countries. Consequently, the lack of access to medicines constitutes a direct violation of the right to health.

As discussed in another paper within this series, out-of-pocket expenses incurred by families constitute a significant portion of Latin America's overall healthcare expenditures, with medicines being the largest single out-of-pocket expense for families. In this context, the inability to access medicines can impose a substantial financial burden on families and serve as a driving force behind their recourse to the judicial system. Health judicialization, therefore, can facilitate access to both newly developed and established medicines for individuals who might otherwise be unable to afford them. This is particularly advantageous for patients requiring high-cost treatments, such as those with rare diseases, cancers, or other life-threatening conditions, as well as cases where limited treatment options exist.

Physicians play a pivotal role in health judicialization, especially when concerning medicines, as the entire litigation process hinges on the presence of a valid prescription. Marketing strategies and the financing or support to individual physicians, medical societies, and patient organizations are some of the ways in which the pharmaceutical industry may influence physicians and patients to demand, including through the courts, their products over alternatives already present in the health system's benefit package. A 2009 survey of American doctors found that almost 84% of physicians had some financial interaction with the pharmaceutical, medical supply, medical device, and biological industries.[18] The impact of these strategies is well documented and show that they play an important role in the prescribing behavior of physicians and the diffusion of information regarding new products. Prosser and colleagues, for instance, show that specialists are significantly more likely to prescribe off-label and serve as opinion leaders for the pharmaceutical industry compared to other provider groups.[19]

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These strategies may even influence the professional development of doctors, as marketing strategies often rely on hiring renowned medical speakers associated with academia/universities to lead continuous training programs. These practices contribute to the construction of a common agenda across medical societies, patient organizations, and physicians, which, sometimes can lead to conflicts of interests and potentially to supply-induced demands, some manifested through judicialization, as they conflict with current protocols and guidelines. Physicians may, for instance, insist on prescribing new or brand-name drugs instead of approved generics and biosimilar drugs, even resorting to litigation to assert their medical authority over patient care. This can occur in scenarios marked by uncertainty, insufficient evidence, or instances where treatments are not listed or have been denied due to high cost-effectiveness ratios.

Growing awareness of the potential bias and conflicts of interest resulting from these practices has led to the implementation of measures aimed at increasing transparency in financial relationships between professionals and the medical industry. For example, the United States government introduced the Physician Payments Sunshine Act (PPSA) in 2010.[20] Over time, academic institutions, journals, and professional organizations have also adopted conflict-of-interest and transparency policies to counteract the industry's influence on medical education and research.[21]

In Latin America, Colombia implemented a resolution in 2018 that mandates medical companies (including pharmaceutical firms, importers of pharmaceutical products, medical device manufacturers, etc.) to disclose payments and transfers of goods and services to physicians. In 2016, the state of Minas Gerais in Brazil approved a regulation requiring companies to report information about donations or benefits provided to healthcare professionals, such as conference registrations, trips, gifts, research funding, and more. The regulation also stipulates that the state is responsible for making this information publicly accessible by publishing it on official websites. Chilean doctors established in 2012 the non-governmental organization *Médicos Sin Marca* (Doctors without a Brand) with the goal of promoting a clinical practice that is free from the influence of propaganda and incentives from the pharmaceutical and medical device industries. In 2016, *Médicos Sin Marca Colombia* was also established.

Furthermore, the potential influence of the biomedical and pharmaceutical industries can be present even before a medicine becomes classified as essential within a country. Typically, when a pharmaceutical regulatory agency accepts a new molecular entity (NME), it implies that an analysis of its patents and clinical studies has been conducted, with results published and presented in medical journals and conferences.[22] When an NME is submitted for evaluation to be included in the health system, it is presented as an innovation and an improvement over existing technologies. To be granted NME status, the drug must demonstrate chemical differences. However, it is common to encounter analogous products with minor molecular differences that request and receive NME status. Additionally, some drugs may be prescribed for uses other than those for which they were originally approved, a practice known as off-label prescription or use. For instance, many NMEs developed for late-stage diseases, such as those used in cancer treatments, are often marketed directly to patients and physicians for use in the early phases of treatment, expanding the user base and increasing the budgetary impact on the healthcare system.

All these scenarios create opportunities for litigation. Drugs that have not demonstrated additional health benefits compared to existing technologies or medicines with minor variations from established alternatives are pursued through legal action. Judges are then asked to authorize the prescription and dispensation of a drug for a purpose different from its original approval by health authorities. Health judicialization, in this sense, can lead to unexpected financial burdens on healthcare systems, as they may be compelled to provide costly medications not initially budgeted for or to cover treatments that were not originally planned. This can strain healthcare budgets and potentially affect the allocation of resources for other health interventions. Moreover, the often short time limits imposed by judicial orders hinder the health sector from following typical procurement procedures or negotiating discounts, forcing governments to pay higher market prices for drugs provided through judicialization.[23] Consequently, governments may be pressured to incorporate these drugs to mitigate the financial burden imposed by judicialization. It is not surprising, therefore, that health judicialization has a substantial budgetary impact. For example, in the state of Sao Paulo, Brazil, the costs associated with judicialization accounted for 4% of the state's total health budget in 2016. In the state of Santa Catarina, this proportion increased from 1% in 2004 to 8% in 2016. In Uruguay, in 2019, approximately 53% of expenditures on high-cost medicines were due to judicialization, and in Costa Rica, if the current trend continues, expenditures by the Caja Costarricense de Seguro Social on medicines through judicialization

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in 2030 could represent 25% of the institution's total spending on medicines.[24]

Final Reflections

Addressing the determinants of health litigations described in quadrant four in Figure 1 — those cases in which health systems violate citizens' rights by not providing medicines included in their benefit packages or lists of essential medicines — should be a top priority for Latin American policy makers. Fortunately, there are already successful examples that could serve as a basis for adaptation and scaling up. In Colombia's department of Caldas, for instance, more than 82% of cases presented to the health system between November 2018 and May 2019 were resolved within 48 hours without the need for litigation. Similarly, in Brazil, specifically in the state of Rio Grande do Sul, administrative measures introduced enabled the state to address 85% of the judicial demands presented in the state's capital in 2015.[25]

Considering the significant policy and budgetary impact of health judicialization, and given that in most cases judges tend to rule in favor of the patient — for example, in Colombia, 75% to 87% of cases favor the claimant; in Costa Rica, these numbers nearly reach 90%; in Brazil, they range between 70% and 100%;[26] and in Argentina, this proportion is estimated to be around 89%[27] — governments in the region have proposed training programs for judges on health topics and evidence-based medicine, and/or have developed tools and mechanisms to support judges in their decision-making process to uphold their authority and maintain a health system-based decision-making logic. In Brazil, the National Justice Council (CNJ), the technical secretariat of the country's Supreme Court, recommended the establishment of technical support centers in each state to assist magistrates in resolving health-related demands. These centers, known as NAT-Jus, prepare technical notes for judges, with the expectation that decisions will be made with more information and confidence.[28] The CNJ is also promoting national agreements outlining the criteria that judges throughout the country should consider when authorizing treatments or new technologies.[29]

While these measures may have merit — as judges may lack adequate evidence-based medical knowledge and information to make urgent decisions relying exclusively on a physician's report — they are incomplete and are likely to have a limited impact. Firstly, because they ignore the fact noted earlier in this paper that judicialization would not exist without a prescription from a doctor; and secondly, because most judicial decisions have swift effects, with expenditures happening immediately. When stronger medical evidence is presented, patients have already received the technology demanded, limiting the feasibility of reversing the decision if found incorrect. In this sense, singling out the judge as the weakest link within the health judicialization process is an error.

The first thing that needs to be recognized is the fact that physicians and other health decision-makers also need more knowledge and better information. The rapid technological innovation of recent years has produced extremely expensive and highly specific drugs. More and more, biological medicines based on molecular targets defined by genetics are used in

The first thing that needs to be recognized is the fact that physicians and other health decision-makers also need more knowledge and better information. The rapid technological innovation of recent years has produced extremely expensive and highly specific drugs. More and more, biological medicines based on molecular targets defined by genetics are used in complex clinical conditions such as some types of cancer, diseases that compromise the immune system, inflammatory or infectious diseases, and the so-called orphan diseases. The high cost of these medicines, combined with the fact that these diseases can also have significant social repercussions and/or a serious risk of death, creates the perfect scenario for health judicialization associated with the third (southwest) quadrant of Figure 1 and helps explain the very rapid growth of litigations presented earlier in this paper.

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However, health decision-makers — whether they are health professionals making decisions for individual patients, such as physicians, or those responsible for carrying out health technology assessments (HTAs) that recommend the incorporation of medicines — often have to rely on limited information derived from increasingly smaller clinical trials, surrogate outcomes, questionnaires, or even population characteristics and types of care that differ significantly from what is seen in Latin American and other developing countries.[30] This means that HTA personnel often lack the appropriate real-world data to measure and estimate the cost-effectiveness of these drugs accurately in terms of improving survival rates and patients' quality of life within each country and context. These issues can only be addressed by generating real-world data that can be used for informed decision-making. As much as the citizens of Latin America need better access to medicines, they also need access to medicines that will have the expected beneficial impact on them.

Finally, it must be emphasized that new drugs are frequently very expensive and unaffordable for many public health systems, especially those in low- and middle-income countries, and can act as barriers to their incorporation by healthcare systems, thus perpetuating obstacles to accessing medicines and contributing to judicialization. This is an international problem that requires further debate on the necessity of mechanisms for price regulation and changes in pricing strategies.

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22. Examples of regulatory agencies include the FDA (Food and Drug Administration) in the United States; the EMA (European Medicines Agency) in Europe; or the ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) in Argentina; the ANVISA (Agência Nacional de Vigilância em Saúde) in Brazil; the INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos) of Colombia, among others in the region. New molecular entity (NME) is a broader term that encompasses both a new chemical entity (NCE) and a new biological entity (NBE).
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