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A Judicial Reinterpretation of the Brazilian Constitution's Right to Health Care

In recent years, there has been a spike in right-to-health litigation in Brazil wherein citizens seek court orders mandating that certain medications be dispensed through the public health system (Sistema Único de Saúde—"SUS"). Now a ubiquitous term, the "judicialization of health care" ("judicialização da saúde") is often considered to be a last resort for citizens when the state fails to meet their needs. The critical issue is that patients have been using free legal assistance and a responsive judiciary to procure costly drugs and treatments that are not included on the list of pre-approved drugs and treatments covered by the SUS. Consequently, the SUS is required to fund high-cost drugs that meet the needs of a small group of people, but are not necessarily of broader use to the collective citizenry. Furthermore, many court-backed judicial determinations that mandate the provision of certain drugs may contradict administrative policies and challenge cost-cutting governmental efforts.

Given the increasingly dire state of the Brazilian economy, there are concerns over the budgetary burden imposed on the SUS by judicial procurement. In the near future, Brazil's Federal Supreme Court (Supremo Tribunal Federal—"STF") will be voting on whether the SUS should cover high-cost drugs not included on government formularies. If the judiciary reinterprets the constitutional right to health care and limits its scope, there could be broad implications for the demand of non-formulary drugs.

The Judicialization of Health Care

The 1988 Brazilian Constitution declared health a "right of all persons and the duty of the State," which prompted the creation of the SUS, extending health coverage to all citizens. The Constitution underscored the autonomy of the judiciary from the government, which established the public defender's offices to give the indigent access to the justice system. The right to medication as part of the constitutional right to health stems from the passage of a landmark law in 1996 establishing free universal access to antiretroviral therapies for HIV-infected individuals, as well as from Ministry of Health policies and a 2000 ruling by the STF.

The federal, state and municipal governments are responsible for purchasing and distributing SUS medicines according to specific drug formularies. In general, the formularies comprise generic drugs bought in bulk in a tax-exempt, competitive bidding process. The federal government is responsible for financing higher cost and more complex treatments (*i.e.*, "exceptional medicines"), while the states oversee the distribution of these federally subsidized treatments. The state governments provide intermediate-cost and medium-complexity treatments (*i.e.*, "special medicines") that do not appear on the federal or municipal formularies. The municipal governments cover low-cost "basic" drugs that are dispensed at local public pharmacies.

There are three broad categories of requests from Brazilian citizens who rely on judicial procurement to obtain medication. The first category encompasses patients who seek an out-of-stock product that is already on the SUS formularies list. The second category includes patients who seek products that have yet to be approved by the National Health Surveillance Agency (Agencia Nacional da Vigilância Sanitária—"Anvisa"), which is responsible for the regulation and approval of pharmaceutical drugs. Because federal law prohibits the supply of medicine that is not authorized by Anvisa, neither the SUS nor health insurance companies will readily supply a drug that has yet to be registered with the agency. However, if a judge determines that no other therapeutic alternative is available for a plaintiff, the court may grant an injunction to access medicine not yet cleared by Anvisa. The third category comprises



patients who search for drugs that have been approved for sale in Brazil by Anvisa, but are not yet included on the SUS list. The high costs resulting from the judicialization of health care are generally attributed to this last group.

When a citizen is granted an injunction, the government deposits money in the plaintiff's account to pay for the medication. These transfers are commonly referred to as "deposits to judicial accounts." The purchase of a court-granted medication occurs two to five days after the injunction is granted, and generally involves brand-name drugs not included on SUS pharmaceutical distribution lists. This short time frame thus forces the state to buy from the market on a case-by-case basis, which eliminates price competition and results in inflated drug prices. The occurrence of "deposits to judicial accounts" increased 227% from 2012 to 2015, leading to the distribution of \$440 million reais (approximately USD \$143 million).

Intermediary Role of the Judiciary

There is consensus among public administrators that the judiciary is overstepping its role by promoting the judicialization of health care. The district and appellate judges who preside over the lawsuits in question have given broad deference to physicians' prescriptions and individual circumstances, which undermines state efforts to rationalize pharmaceutical use and curb high spending. Furthermore, the judges' limited technical expertise and lack of understanding of the SUS's drugs selection process pose significant administrative and economic challenges.

The judicial procurement of medicine frequently overlooks and contradicts established public health policies. For example, generic drugs were approved in Brazil in 1999 under Law n. 9.787/1999, which instructed that the government give preference to generic drugs. However, in reality, court-backed judicial determinations often grant injunctions for brand-name drugs, which are not likely to be available yet in generic form. By distributing drugs that have not yet been approved by Anvisa, courts also challenge the agency's role in regulating efficacious and safe pharmaceutical drugs. Courts often fail to enforce the Ministry of Health's guidelines for treatment criteria that mandate independent expert opinions and reviews of new medical evidence. Critics recommend that if this practice continues, the courts should demand expert assessment of the safety and efficacy of off-list medications or drugs not registered for sale in the country before ruling for or against their provision for individual plaintiffs.

In September 2016, the eleven judges of the STF—the "ministers"—were slated to vote on whether the government should pay for high-cost drugs and treatments not included on government formularies. Ultimately, only three ministers voted in September, as one minister, Teori Zavascki, requested to delay the vote. Zavascki later died in an airplane accident in January 2017, and the vote was never rescheduled among the remaining ministers. On February 22, 2017, the Senate approved interim President Michel Temer's nomination to replace Zavascki, Alexandre de Moraes. Although a rescheduling of the vote on the judicialization of health care has not yet been announced, many observers predict that it will occur within the year.

Paradigm Shift Implications

A vote by the STF to prohibit the SUS from paying for high-cost drugs and treatments excluded from government formularies could result in more limited access to specialty pharmaceuticals for Brazilian citizens. However, the practice of seeking medication through judicial procurement likely will not cease, as citizens will continue to file lawsuits to obtain out-of-stock drugs that are already registered with the SUS. Thus, as part of any consideration of whether to pay for specialty pharmaceuticals, the SUS should consider the need to regularly incorporate new medicines into its public distribution lists. If the SUS decides to include new medicines more frequently, pharmaceutical marketing efforts may shift to formulary access discussions. For their part, pharmaceutical manufacturers should closely monitor the judicial procurement system in Brazil and be mindful of the dynamics involved in formulary placement in this complicated market.