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Legal Remedies

Therapeutic Markets and the Judicialization of the Right to Health

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[–] Abstract and Keywords

In 1996, Brazil became the first developing country to adopt an official policy granting free access to antiretroviral drugs through its broad-reaching but ailing public health care system (SUS). In the wake of the country's highly publicized antiretroviral drug rollout, public health and care have become increasingly pharmaceuticalized and privatized, and the rights-based demand for drug access has migrated from AIDS to other diseases and patient groups. A growing number of citizens are acting within the state to guarantee their right to health, understood as access to medicines of all kinds, whether or not they are available in official drug formularies. This chapter examines the political subjects that emerge from this complex law–state–market ecology and shows how in this new chapter in the history of the right to health, the judiciary has become a crucial arbiter and purveyor of care and technology access.

Keywords: Brazil, public health, global health, public health care system, antiretroviral drugs, health rights

> Justice does not exist! Human Rights do not exist. What matters is jurisprudence. This is the invention of Law. … The challenge is to create and not to make Human Rights applicable. It is a matter of inventing jurisprudences so that, for each case, such and such thing could not have been possible. … Many times, life can be seen case by case. … It is not a matter of right of this or of that, but of situations that evolve … to struggle for jurisprudence … to create the right.
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> —*Gilles Deleuze*[1]

Entering Justice, One by One

Seven children lie in a hospital room, each hooked up to an intravenous drip.[2] Their parents stand near them, bantering with each other and with the doctors who circulate in and out. Every week these parents bring their young children, who suffer from a disorder called mucopolysaccharidosis (MPS) here, to the Research Unit of Hospital Universitário, a public teaching hospital in Porto Alegre, the capital of the southern state of Rio **(p.326)** Grande do Sul, Brazil.[3] The children are receiving enzyme replacement therapy (ERT), which can cost up to US$200,000 dollars per year per patient.[4]

MPS encompasses a group of inherited metabolic disorders in which mucopolysaccharide, a complex carbohydrate, builds up in body tissues in a dangerously nonmetabolized form due to the lack of activity of a specific enzyme (Beck 2007). MPS disorders affect approximately 1 in 25,000 individuals (Clarke 2008) and usually manifest in early childhood. They are characterized by skeletal and joint deformities, stunted growth, and facial changes caused by accumulation of mucopolysaccharide in the underlying facial bone. MPS leads to neurological, cardiovascular, and respiratory impairments, as well as liver and spleen enlargement and hearing loss. Severe cases are fatal in the first decade of life and milder cases may entail a normal lifespan but have significant disease morbidity (Clarke 2007). MPS disorders are not curable, but ERTs have proven useful in reducing some of their symptoms, improving quality of life, and, in certain cases, increasing lifespan.

All the children with MPS in this room are patient-litigants. Their parents are suing the government so that they can receive treatment for life. Between 2008 and 2011, we spoke to multiple actors involved in this new and increasingly ubiquitous practice of litigation against the state for treatment access, a phenomenon known as the “judicialization of the right to health.” Though patients are suing all levels of government for everything from baby formula to complex surgeries, a large portion of lawsuits are for medicines.

Brazil is among the approximately one hundred countries that recognize a constitutional right to health (Gauri and Brinks 2008:1). An important part of this right is access to medicines. Although Brazil has one of the world’s most advanced HIV/AIDS treatment programs, many of its citizens still go to local pharmacies only to find that essential medicines are not available. With a population of almost 200 million and an economy on the rise, Brazil is one of the fastest growing pharmaceutical markets in the world today. Doctors increasingly prescribe and patients demand new medical technologies.

The US Food and Drug Administration (FDA) and the Brazilian National Health Surveillance Agency (ANVISA) have approved some MPS treatments; others are still in clinical trials.[5] Biotechnology companies are **(p.327)** entering the field of orphan disease treatments, breaking new ground beyond the blockbuster model of drug development (Petryna 2009).[6]

Doctors at Hospital Universitário were excited about the possibility of finally offering patients something more than just an accurate diagnosis of their genetic ailment. But they were also cautious about hyped claims of efficacy. “It is a new world,” said Dr. Maria, who monitors these children. “I think we are bringing new things from genetics to SUS [Brazil’s Unified Health System]. Some here were in clinical trials, but all are SUS patients now. To guarantee treatment access and to follow up on the effectiveness is very problematic.” The interests of clinical

research, public health, and biomedical markets fold into the injured bodies of these young patient-citizen-litigants.

The children here come from low-and middle-income families that would never have been able to afford these genetic therapies on their own. They obtain them as a result of lawsuits their parents have filed against the state of Rio Grande do Sul in the name of the right to health. Article 196 of the 1988 democratic constitution affirms health as a right of the people and a duty of the state, "guaranteed by social and economic policies that reduce the risk of disease and other adversities and by universal and equal access to actions and services" (Constituição Federal do Brasil). The parents told us that, in order to make the claim, they must have a diagnosis and medical documents proving the benefits of the costly treatment. In most cases, district judges immediately issue injunctions that force the state to provide the treatment for a month or two. A final ruling by the higher courts might take several years as state prosecutors file multiple appeals, expert-committees review medical evidence, and the case might find its circuitous way to the country's Supreme Court in Brasília, the country's capital.

Only one of the seven children has some of her infusions paid for by the drug manufacturer. Rita, who is twelve years old and "in a near-vegetative state" (according to her mother Ilse), took part in the first clinical trial that led to drug approval in Brazil. In 2004, after the trial ended and the trial sponsor stopped providing the enzyme on a compassionate-use basis, Rita became one of the first MPS patient-litigants in the state. She won an initial court injunction that had to be periodically renewed, since state prosecutors were appealing the ruling. A physician told us that, in the meantime, the manufacturer had agreed to share the cost of Rita's **(p.328)** treatment with the state, most likely to avoid becoming a defendant in the higher court. For all of these children, the uncertain and potentially fatal natural history of their disease now meshes with hope-inspiring, cutting-edge genetic therapies and a time-consuming juridical quest. The critical question of who will pay for the therapy—the family, the government, or the manufacturer—is bound to the emerging field of jurisprudence over the right to treatment.

The three-hour infusion time is over and the children are awake, talking and playing—all except Rita. Ilse caresses her daughter's face. Like all the MPS children in the room, Rita's stature is short and her head is enlarged. Her facial features are coarse and her skeleton slightly deformed. Her mental development "was delayed," Ilse states. A red folder containing the latest medical records and court rulings lies at Rita's feet. "After the study ended, we contacted a private lawyer, Mr. Moura, and we filed a lawsuit against the state to get the enzyme. Other parents followed suit," Ilse states. "Rita is a citizen. Here in Brazil, she has the right to health." Ilse, like the other parents in the infusion room, uses the expression *entrar na justiça* "to enter the judiciary" (or literally, "to enter justice") to refer to their lawsuits.

All over Brazil, patients are turning to courts to access prescribed medicines (Azevedo 2007; Colluci 2009). Although lawsuits secure access for thousands of people, at least temporarily, this judicialization of the right to health generates intensely complex sociomedical realities (as embodied by the MPS families) and significant administrative and fiscal challenges which, officials argue, have the potential to widen inequalities in health care delivery (Ferraz 2009). In this chapter, we explore how right-to-health litigation became (in the wake of a successful universal AIDS treatment policy) an alternative route for Brazilians to access health care, now understood as access to medicines that are either on governmental formularies or are only available through the market. Is the judicial system an effective venue in which to implement

socioeconomic rights? Which practices of citizenship and governance are crystallized in these struggles over drug access and administrative accountability?

Government-purchased medicines make up a formidable market in Brazil and, as we will show, treatment litigation takes place in the context of a dysfunctional decentralized public health system. The role of market forces in judicialization—a mix of pharmaceutical marketing strategies **(p.329)** targeting physicians' prescriptions and fueling patient demand, as well as limited regulatory oversight—must not be overlooked, either. But a key point here is that low-income patients are not just waiting for new and high-cost medical technologies to "trickle down": they are using public legal assistance and the levers of a responsive judiciary to gain full access now.

The twin phenomena of the *pharmaceuticalization* of health care and the *judicialization* of socioeconomic rights raise crucial issues that are at the heart of global health debates today: technology access and care delivery, the financing and sustainability of treatment programs, the strengthening of health systems, and the improvement of outcomes. We need a deeper understanding of the political economy of pharmaceuticals that informs large-scale treatment initiatives, and we need to know how information, science, and technology impact health systems and life projects on the ground.

Pharmaceuticalization and Judicialization

Brazil's adoption of a constitutional right to health in 1988 was accompanied by the creation of the Sistema Único de Saúde (SUS), extending health coverage to all citizens. To improve the management of the public health care system, the Ministry of Health divided responsibilities for pharmaceutical distribution among three levels of government as part of a broader process of decentralization. While the federal government retained some of its central role in financing public health (administering some high-priority disease programs that required high-cost treatments), state and municipal health secretariats had to develop new structures to assess health needs and to administer federal and local funds for drug provision. Through this infrastructure, citizens are guaranteed access to medicines specified on formularies drafted by government administrators.[7] These actions delegated responsibility, but they did not ensure sustainable funding and technical capacity at local levels. Medications are frequently out of stock and lists of newer, high-cost medicines are infrequently updated (Campos 2007; Homedes and Ugalde 2005). A private health care system exists as well but does not cover medicines, and many health providers participate in both systems.

(p.330) AIDS activists were among the first to successfully equate the constitutional right to health with access to pharmaceuticals (Scheffer, Salazar, and Grou 2005). And in 1996, at a time when global responses to HIV/AIDS were largely prevention-based, Brazil became the first developing country to sign into law and enact a policy of free and universal distribution of antiretroviral drugs (ARVs). In the years that followed, Brazil has seen unprecedented alliances among activists, government reformers, multilateral agencies, and the pharmaceutical industry, and it asserted itself as a leader in the global push to universalize access to AIDS treatment. An incremental change in the concept of public health materialized through the AIDS policy (Berkman et al. 2005; Galvão 2002; Okie 2006; Parker 2009; Scheffer, Salazar, and Grou 2005). In terms of both delivery and demand, public health is now understood less as prevention and primary care and more as access to medicines and community-outsourced care—that is, public health has become increasingly pharmaceuticalized and privatized (Biehl 2007).

Treatment access is a central tenet of global health activism and interventions today (Adams, Novotny, and Leslie 2008; Brown, Cueto, and Fee 2006). Public-private health initiatives are booming and drug companies are rebranding themselves as global health companies, making older treatments more widely available and expediting access to newer ones. Some critics contend that public-private treatment partnerships can be used by corporations as a good public relations move, offsetting public scrutiny of the pharmaceutical industry's political influence and the opaqueness of its drug-pricing practices (Applbaum 2010; Samsky 2011). Companies can, of course, also use such partnerships to gain footholds in developing country markets, to influence national drug policies, and to improve drug distribution networks.

Such is the case of Brazil. From a market perspective, it is once again the country of the future. The federal government has successfully juggled demands for market openness *and* poverty reduction: it has strategically withdrawn from strict market regulation, and while championing much-needed social policies, it has consolidated itself as a strong state, way beyond a minimally involved neoliberal one. In 2009, Brazil's GDP was US$1.796 trillion, and its GDP per capita was, US$10,427, ranking 103rd in the world (World Bank 2009). In 2004, about 20 percent of the population lived below the poverty line, a number that had fallen to 7 percent **(p.331)** by 2009. Brazil's income inequality (as measured by the Gini coefficient) is one of the highest in the world, but according to the World Bank, it has been falling due to "low inflation, consistent economic growth, well-focused social programs, and a policy of real increases for the minimum wage" (World Bank 2009).

Today, a variety of actors—patient associations, industry advocates, and public health physicians—have vested interests in making high-technology medicine accessible to all. In the process, the country is becoming a profitable platform for global medicine. About half of the adult population takes medicines on a daily basis (Carvalho 2005). And this is where the state comes into the picture: pharmaceutical access.

In a conversation about unequal drug pricing worldwide, a pharmaceutical executive suggested that his company was adapting to the human rights and social justice frameworks that had successfully politicized access to treatments and health care in the recent past. Referring, for example, to the ongoing struggle over continued access to state-of-the-art antiretroviral therapies in Brazil, he said rather bluntly that his company had co-opted the activist role. To make government act properly, he suggested, "You don't need the activists, just buy our drugs and you will save money." Yet, we know that drug prices in Brazil are 1.9 times higher than in Sweden and 13.1 times higher than the world index (Nóbrega et al. 2007).

Brazil is now experiencing the types of problems and conflicts that other middle-and low-income countries treating AIDS are beginning to face. It has an inexpensive first line of ARVs, but a growing number of patients are starting new, more expensive drug regimens, either because of drug resistance or because newer patented drugs have fewer side effects. Between 2004 and 2005, the cost of treating a single AIDS patient rose from US$1,220 to $2,577, and the total cost of providing AIDS therapies more than doubled from 193 million to 414 million dollars (Nunn et al. 2009). In 2009, thirty-two different drugs were available in the Brazilian HIV/AIDS program: 59 percent of them (19 drugs) were imported, and their cost comprised 72 percent of the total amount spent.

State-purchased high-cost medicines now make up a formidable market in Brazil—one that has grown from US$208 million in 2004 to $377 million in 2005. In 2002, the Health Ministry spent more than US$1 billion on essential and high-cost drugs. In 2007, it spent about US$5 billion.[8] Drug expenditures grew 252 percent between 2002 and 2007 (Vieira 2009).

(p.332) The rights-based model for demanding AIDS treatment access has been taken up by other patients' groups that are now also claiming the right to pharmaceuticals in courts. People of all social and economic backgrounds are mobilizing for increased and sustained access to drugs that either are covered by government programs and are not available to them, or are for specialized treatments not yet included in official formularies. (These include treatments for prevalent as well as uncommon and rare disorders, among them diabetes, bipolar disorder, asthma, hepatitis C, and such rare genetic disorders as MPS.)

Ana Márcia Messeder and her colleagues (2005) profiled this medical-judicial phenomenon in the state of Rio de Janeiro. The authors identified a total of 2,733 medicinal lawsuits filed between January 1991 and December 2002 and analyzed a representative sample of 389 of them. The majority of cases were initiated by public defenders or pro bono lawyers from nongovernmental organizations (NGOs) or universities, and only 16 percent of the lawsuits came from patients being treated outside of SUS. Until 1998, plaintiffs almost exclusively demanded medications for HIV/AIDS.

Beginning in 1999, two years into the universal AIDS treatment policy, there was significant diversification in the kinds of treatments and pathologies that were the subjects of right-to-health litigation. The diseases now included diabetes, cancer, and other conditions besides HIV/AIDS. As more and more patients adopted the rights discourse and legal practices pioneered by AIDS activists, the number of lawsuits dramatically increased. In 1995, only four such lawsuits were filed against the state of Rio de Janeiro. In 1997, this number had increased to 314, and in 2002 it was 1,144. In their study, Messeder and colleagues show that patients were "exerting greater organizational and lobbying skills to secure their rights" (2005:532), but public defenders and judges lacked clarity about the division of pharmaceutical responsibility among various administrative levels. Indeed, they were found to show "disregard for the rational use of medicines and for possible harms that come with misprescription and misuse" (2005:533).

These Brazilian patient-litigants were exhibiting knowledge and skill that their class position typically did not confer and were working within the state, challenging public health administrations to fulfill their mandates. Though the public debate over judicialization has tended to focus on **(p.333)** demands for experimental and high-cost drugs, two important studies of right-to-health litigation (from the state of Rio de Janeiro, Pepe et al. 2010; and from the municipality of São Paulo, Vieira and Zucchi 2007) show that in the majority of cases, the drugs requested were already part of drug formularies and that about three-quarters of the off-list drugs requested had publicly available generic equivalents. This newer phenomenon—demanding access to drugs already on official formularies—could be an indicator of the failures of municipal administrations (the alleged providers) and state health secretariats (the supposed cofinancers) to fulfill their public health duties.

While claims for pharmaceutical access have migrated well beyond HIV/AIDS and right-to-health litigation has become an alternative pathway for accessing healthcare in Brazil, a ruling by the Supreme Court in 2000 concerning a patient's access to a newer antiretroviral drug still constitutes the precedent for judicial intervention in both state and federal courts. In his ruling, Justice Celso de Mello understands the AIDS pharmaceutical assistance program as the

actualization of the government's constitutional duty to implement policies that secure the population's health. As the concrete embodiment of the need for "programmatic norms," the AIDS program acquires an inherent judicial value in Mello's ruling. As soon as citizens in need have medicines, the government's legal responsibility for implementing programmatic norms that secure health is fulfilled and ceases to be "an inconsequential constitutional promise." In this rendering, the immediate assurance of the right to health through pharmaceuticals circumvents questions about the limitations of policy and resources, as well as the evidentiary basis of new drugs' efficacy.

Public health actors and institutions around the globe are currently struggling with how to guarantee the human right to health and fulfill promises for increased access to treatments while contending with the perennial debates over prevention versus treatment and the limitations of delivery systems. As the judicialization of the right to health grows in volume and importance in Brazil, it signals the beginning of a new chapter in the construction and management of the country's universal health care system, as well as of the evolving pharmaceutical sector of its economy—the eighth-largest pharmaceutical market in the world (with an estimated total market value of US$30 billion in 2012 according to the Sindicato das Indústrias Farmacêuticas do Estado de São Paulo). **(p.334)** Brazil's response to the judicialization of the right to health is an important litmus test for other low-and middle-income countries where increased pharmaceutical access is underway.

Right-to-Health Litigation

Young Rita's legal process, like that of the other patients receiving enzyme replacement therapy at Hospital Universitário, remained unresolved. The paperwork had grown "to half a meter high," in the words of Mr. Moura, the lawyer who represented several of these families. Mr. Moura sees litigation as the only way forward, because "the state does not fulfill its role. Health is the duty of the state and the right of the patient." He insists that in almost all cases initial rulings are in favor of the patients. Genetic therapies are a new threshold in the judicialization of the right to health, he adds. Why? "Because these are medicines with a *slightly* elevated cost."

Brazilian states are seeing the number of successful lawsuits brought in their courts reaching into the tens of thousands, a process that is redefining the roles and responsibilities of the state, altering administrative practices, and encroaching upon health budgets. With a population of 11 million, the state of Rio Grande do Sul faces one of the highest numbers of health-related lawsuits in the country (Hoffmann and Bentes 2008). In 2009 alone, there were over 12,000 lawsuits in the state seeking access to medicines, a staggering increase from 1,126 in 2002. In 2008, the state spent US$30.2 million on court-mandated drugs, an expense that represented 22 percent of the state's expenditure on medicines for that year (Biehl et al. 2009).

Consider Lizete, who is suing the state for medication to treat her pulmonary hypertension. She is fifty years old and lives with her husband, a taxi-driver, in one of the shanty towns of Porto Alegre. Lizete found out she was HIV-positive in 2002. Unlike her AIDS therapies, which she receives for free at the local health post, the drug that she most urgently needs is not offered through the public system and would cost her about US$1,300 a month. On her doctor's advice, Lizete went to the public defender's office, where she qualified for free legal representation, and sued the state. She initially lost her lawsuit, but later won on appeal. Though a district judge ordered the state to begin immediate provision of the medication, **(p.335)** when she was interviewed in August of 2009, several months had passed and Lizete had yet to receive the

drug. She had hoped to get better so that she could return to work and better care for her eleven-year-old adopted son.

Past research has suggested that right-to-treatment litigation is for the most part a practice of the financially better off (Chieffi and Barata 2009; Da Silva and Terrazas 2011; Vieira and Zucchi 2007) and that low-income patients tend to sue for low-cost medicines, while higher-income patients tend to sue for very expensive medicines (Da Silva and Terrazas 2011:12). By contrast, an analysis of information we collected from 1,080 medicinal lawsuits against the state of Rio Grande do Sul[9] suggests that patients who procure treatments through the courts are mostly poor individuals who are not working and who depend on the public system for both health care and legal representation (Biehl et al. 2012). Among the plaintiffs who reported their employment status, more than half were retired and about a fifth were unemployed. Among those who reported income, over half earned less than the monthly national minimum wage (about US$300) and relied on the free legal services of public defenders.

Roughly two-thirds of the medicines requested in our database were already on drug formularies. About a quarter of lawsuits were exclusively for access to on-list, high-cost drugs, though low-cost essential medicines were frequently requested alongside other medicines. Off-list drugs requested by plaintiffs were also often low-cost and many had been available in the market for a long time. This suggests that government pharmaceutical distribution programs are failing to fulfill their role of expanding access and rationalizing use (DECIT 2006; Guimarães 2004).

Moreover, judges at district and higher court levels almost universally grant access to all medicines requested, recognizing that their provision is consistent with Brazil's constitutional right to health. For example, in almost all of the 1,080 lawsuits examined, district judges granted plaintiffs an immediate injunction for access to medicines; in cases where the initial ruling was in favor of the provision of medicines, the state's higher court upheld the decision most of the time.

According to legal scholar David Fidler, developments in health jurisprudence "have produced open-source anarchy and a more elastic relationship between power and ideas in global politics." In such an elastic relationship, "changes in material capabilities of state and non-state actors, **(p.336)** and changes in the world of ideas, have more impact on each other than in the closed, state-centric system that prevailed during the Cold War" (Fidler 2008:410). Fidler recognizes a "deeper importance for law in public health endeavors within and between countries" (Fidler 2008:394; see also Fidler 2007).

Anthropologists John and Jean Comaroff have been attending to such a "judicialization of politics" in post-apartheid South Africa and how it has affected social mobilization, particularly in the field of HIV/AIDS. Class struggles, they argue, "seem to have metamorphosed into class actions. Citizens, subjects, governments, and corporations litigate against one another, often at the intersection of tort law, human rights law, and the criminal law, in an ever mutating kaleidoscope of coalitions and cleavages" (Comaroff and Comaroff 2006:26; see also Vianna and Burgos 2005; Yamin and Parra-Vera 2010).

Right-to-health litigation speaks to a productive "open-source anarchy" (Fidler 2008) at both macro and micro levels in Brazil as well. Interviews we conducted with judges, attorneys, and public health officials revealed divergent and conflicting views on the litigation pathway that, as we have been suggesting, has become an alternative route to health care. Many judges working

on right-to-health cases feel they are responding to state failures to provide needed drugs and that these waves of lawsuits are a milestone in the democratization of a culture of rights. Whether this goal can be attained through individual claims, however, is contested. The fact is that judges employ idiosyncratic rationales and create their own standards in adjudicating right-to-health cases. They cite the “risk of death” and the “right to life” and base their rulings for the most part on jurisprudence (such as Justice Mello’s, referred to earlier) and personal experiences—they cite specific tragic stories in which they think treatment provision would have made a difference.

Administrators, on the other hand, contend that the judiciary is overstepping its role and that judicialization skews budgets and increases inequalities in health care access. Some acknowledge, however, that legal pressure has improved the distribution of some drugs. In the meantime, private law offices specializing in right-to-health lawsuits, such as Mr. Moura’s, have multiplied, and local public officials are capitalizing politically on such court cases, using them to gain media attention and popular support. Many patients are indeed poor and are represented in court by **(p.337)** attorneys from the state’s independent public defense office. The public defenders we interviewed see their work as a mode of guaranteeing accountability; they also seek greater visibility and political significance within state institutions for themselves. Patient associations play a highly contested role. Officials claim that at least some of them are funded by pharmaceutical companies eager to sell the government high-cost drugs whose efficacy might be questionable and widespread prescription unwarranted.

Judicialization has indeed become a parallel infrastructure in which various public and private health actors and sectors come into contact, face off, and enact one-by-one rescue missions. In April 2009, the Brazilian Supreme Court held a rare public hearing to examine the pressing challenges posed by right-to-health litigation.[10] Public health officials, lawyers, physicians, activists, and academics testified before the Court, providing varied viewpoints and recommendations on how to respond to the enormous judicial demand for medical goods. An immediate outcome was a long-overdue updating of formularies for specialized high-cost drugs. The Brazilian National Council of Justice also issued a set of recommendations for local judges, asking them to attend more carefully to scientific evidence and to strive for “more efficiency” when ruling over health-related cases.[11]

If access to AIDS therapies was the litmus test of the right to health in the 1990s, now it is access to genetic therapies. The latest right-to-health landmark ruling involved a request for a medicine to treat a genetic disease. This treatment was not recommended by the Ministry of Health’s therapeutic guidelines and was not publicly available. In March 2010, the court rejected the argument that the state was not responsible and decided in favor of the provision of the high-cost therapy. In his ruling, Justice Gilmar Mendes stated that once the disease was medically confirmed and treatment was indicated, the “Ministry of Health’s therapeutic guidelines can be questioned.” Moreover, “the state has to provide resources, not only to support and fund the provision of universal care for its citizens, but also has to provide variable resources to attend to the needs of each individual citizen.”

There is a heated debate in Brazilian courts on the positive duty the constitutional right to health imposes on the state and the extent to which the courts must enforce this right. But the country is yet to have a substantial public debate about the meaning of the right to health in light of new **(p.338)** medical advancements. Although a “right to pharmaceuticals” is being consolidated in Brazil, the various branches of government have yet to develop robust health

technology assessments. Moreover, bolder regulatory steps in drug pricing are needed, along with a reconsideration of the responsibilities of private health insurance plans in covering drug costs (which they currently do not). Attention must also be paid to broader aspects of the right to health, including structural-rights interventions and social determinants of health, such as education, water, sanitation, vector control, air pollution, and violence prevention. Meanwhile, hard-to-pin-down patient-citizen-consumers draw from human rights language and jurisprudence and make governments work for them as they negotiate the vagaries of the market and survival.

To look at the ways and means of right-to-health litigation is to enter an intensely contentious political-economic-experiential field. Here the penetration of market principles in health care delivery is unexpectedly aligned with the juridical subject of rights. The rational choice-making economic subject (necessarily a consumer of technology) is also the subject of legal rights. This dual subject position complicates Michel Foucault's concept of biopower—the way in which natural life has become an object of modern politics (1980; 2007). In judicialization we do not see a top-down biopolitical model of governance in which population well-being is the object of knowledge and control, but rather a contestation over the utility of government by multiple private and public stakeholders. There is an economic reason within governmental reason.[12] At stake here are the ways in which government (qua drug regulator, purchaser, and distributor) facilitates a more *direct* relationship of atomized subjects of rights/interests to the biomedical market in the form of technology access alongside the continual creation of commercial horizons.

Patient-Citizen-Consumer

Rita has a "severe case" of MPS, Dr. Maria tells us. "She walked until she was four," her mother Ilse adds. "She even went to nursery school, but now her whole body is damaged. The organs, liver, and spleen have enlarged, and she also has respiratory problems." Ilse insists that Rita improved while in the clinical trial, but that she also knew that the enzyme **(p.339)** does not "stop the neurological damage." Later Dr. Maria told us that she believed that in Rita's case, the neurological damage was so far along that the enzyme would not be effective. Yet all of the parents we spoke to suggested that not obtaining this treatment (whose access they had to renew periodically in the courts) would be unconscionable or tantamount to killing their children.

Dr. Daniel Muller, who coordinates MPS trials at Hospital Universitário, does not see high-tech treatments for MPS as magic bullets. "They can stabilize the disease," he told us, "or maybe lead to small improvements." He also emphasized the need for a community genetics approach: "We have tools to go to the community and to work preventatively at the level of prenatal screening and early care of the child." But while new genetic diagnostics are now beginning to circulate in the public health care system, "doctors cannot offer termination of pregnancy as an option," he added, "given this predominantly Catholic country's anti-abortion laws."

The therapeutic imperative voiced by the families we spoke to—"we would do anything and go anywhere to get the treatment"—is embedded in a complex medical-legal-religious context, a "conservative continental problem" in Dr. Muller's words. To complicate matters further, the family's affective tissue has become a catalyst for a grassroots and somewhat troubling uptake of high-tech treatments. According to Dr. Muller, many families make "emotional rather than rational" decisions: "Even though we have clinical scales to differentiate between severe, intermediate, or mild forms of the disease that can help us to decide which cases should or

should not be treated … today, with judicialization, treatment depends on the family and on the judge's understanding. If we don't give the family a prescription, they can go to another doctor."

The initial MPS clinical trials in which Rita participated tested the efficacy of the enzyme on older children and young adults. Now that it is approved and in the market, new trials are testing its safe use in younger children. The study that Dr. Muller coordinates at Hospital Universitário has attracted twelve new families from all over Brazil and also from Chile and Bolivia, he told us.

Whether such trials are a public good or an exploitative mechanism is a complicated matter (Petryna 2009). Pharmaceutical companies are increasingly enlisting specialized public treatment centers in middle-income countries, such as the genetics service at Hospital Universitário, to run **(p.340)** trials. These centers have highly qualified staff and the capability of recruiting specific patient pools. For example, there are some six hundred patients diagnosed with MPS 6 (one of the subtypes of the mucopolysaccharidoses) globally, and a quarter of them live in Brazil. As clinical trials unfold and evidence is produced, they morph into powerful marketing tools as multiple players struggle to make the treatment standard via a protocol and reimbursable by insurance companies (in the United States) or by the government (in countries like judicialized Brazil).

Ilse stated that taking care of Rita is "my work, full time." Her second husband, Rita's father, is the breadwinner. After discovering the girl's condition and wishing to avoid "the 75 percent chance of having another MPS child," the couple adopted a son. He brings "joy to the house," Ilse said. The parents want the courts to grant the treatment for Rita's "whole life" (*vida inteira*). The mother continued, "She will not be cured of her MPS. There is no cure. But she needs the enzyme." For Ilse, the therapeutic imperative is not a push for cure but an effort to keep Rita alive. Arguably, here the biopolitics of the state is tied to technology access and "making live and letting die" has become a familial affair. "The state should give it to her. It's stressful to have a sick child and to have to fight for her to get the medicine which she has a right to. It is Rita's right as a Brazilian citizen. But we must always fight with judges, prosecutors … it is so exhausting. This is my work, day and night."

Mirta and her two children with MPS come from the rural town of Fronteira. Her first child "had it too, but she died at the age of three. She would be twenty-two years old now. There was no treatment at the time." When asked their age, Jessica mumbled a number to which the mother said *mais alto*, louder. "Ten." Pedro was eight. Their infusions had just ended and both were watching cartoons on TV.

"It is a struggle," Mirta said, conveying how her family had to learn to operate as dual subject of rights and interests in this therapeutic state-market complex. "Every week we leave Fronteira at 1:30 am. The city hall transports us by van. We get here at 6:30 am and when the infusion ends we return home." Mirta's husband manages garbage collection for the town. "Jessica walks, but Pedro walks very little. They go to school in the afternoon." When asked what she does for a living, Mirta plainly states, "I take care of them." We had heard that these children are having **(p.341)** difficulties accessing enzyme replacement therapy. "Yes," Mirta says, "We have to sue all the time."

For years, Jessica and Pedro had been coming to the genetic service for clinical observation and palliative care. When a study was launched to test the enzyme, "They did not meet the age criteria of six and above," Mirta lamented. She interpreted this exclusion in constitutional terms:

"They did not have *the right to be researched*." Excluded, the family kept a close eye on the MPS study. Once it was published and the therapy was approved by ANVISA and available in Brazil, "the doctors called us and asked if we wanted *entrar na justiça* [to file a lawsuit] to see whether we could get it. Of course, we said yes. The doctors and the MPS association are in constant contact with us."

There is no pre-given biopolitical population to which these atomized subjects of rights belong. And so, in their private efforts to become such subjects, these children and guardians have to rely on temporary collectivities such as the patients' associations that crop up at the intersection of patient/family demand, pharmaceutical marketing, and legal activism. Mirta is thankful for the lawyer whom the "MPS association hired for us," but she cannot recall his name or the terms in which Jessica and Pedro's cases were argued before judges who were ruling on their claims. Nor did she have a clear sense of how to act in her scripted legal subject position, and she suffered from the constant uncertainties and court fights that renewing access to the ERT entailed. "Jessica got the treatment for ninety days and Pedro for forty days. Their cases never fall into the hands of the same judge."

Technology Access and Privatized Health

The issue of treatment continuity weighs heavily on doctors who place their patients in clinical trials or who prescribe these genetic therapies. Several of the doctors we interviewed mentioned that when studies end, trial sponsors sometimes do continue to provide the drug for a while, either as part of an extended-access or compassionate-use program. “But all this is at the company’s discretion.” Dr. Maria emphasized that these children’s biologies are wrecked by treatment discontinuity: “Sometimes **(p.342)** they get it, sometimes they don’t.” Pedro and Jessica suffer from a “complete lack of consistency” of access to the therapy.

Not only are these children’s biologies precariously tethered to new medical commodities, but the timing of rulings and court injunctions unleash their own kinds of hazards. “Patients go for some time without the treatment until a court injunction comes,” Dr. Maria told us. Doctors provide crucial means of veridiction for patients’ legal claims for treatment, but then the courts become battlefields of veridiction-falsification as the state’s general attorney’s office has created a taskforce of rotating medical experts who support or disqualify claims for treatment access and efficacy.

Conflicts over evidence in courts create yet another set of medical problems. According to Dr. Maria, “It is worse to have the treatment and stop it than to not have it. When treatment is interrupted and then restarted when a new ruling or injunction comes, patients almost always have an adverse reaction to the therapy. The protein in the therapy is foreign to their bodies. In the medical reports we file as part of the lawsuit, we try to make the case that treatment should not be interrupted, but we know that this argument does not necessarily work.”

How does the celebrated economic equation “more technology equals better health outcomes” (Cutler and McClellan 2001; Cutler, Deaton, and Lleras-Muney 2006) square with the judicialization of health care? A major challenge facing clinicians such as Dr. Maria and her colleagues is how to assess whether the enzyme is actually improving the patient’s condition. Even in the therapy’s postmarketing stage, patients remain in a kind of experimental state. “What does the treatment actually improve in the patient? They have had the disease for a very long time, eight or nine years, and have had very little treatment over those years. We know that the enzyme improves lung function. But when it comes to other markers, we need more time to really assess its effect.” The one-by-one judicialization of pharmaceutical access thus seems to open an additional tenuous space between treatment and research, a tenuousness that might well be replaced by standardized protocols and new regimens in the future. But we wondered to what extent parents were aware of the experimentality (Petryna 2009) that is going on in the bodies of their children-litigants. How can we facilitate a more informed public debate about the lived uncertainties of the science, effectiveness, and true costs of therapeutic advancements?

(p.343) Parents at the hospital’s genetic unit have crafted their own informal measures of the effectiveness of enzyme replacement therapies. Mirta, for example, mentions her children’s increasing “alertness and dexterity” as well as minor details such as “the hair softening.” Parents use various subjective criteria to index the negative impact that the legal odyssey is having on the children: “We know that this ongoing litigation is not good for their health. I can see the difference,” Mirta continues. “When Jessica and Pedro don’t have the therapy, they are compromised. They should take it continuously.”

As families push through courts and medical-legal paperwork, their “biotechnical embrace” (DelVecchio Good 2007) strengthens. Meanwhile, the questionable efficacy that the doctors delivering the ERT are aware of becomes less and less an object of concern. When all goes well in this makeshift drug delivery system, Mirta adds, “The judge stamps our claim and we ourselves get the money and give it to the hospital which in turn buys the enzyme. The treatment costs 18,000 dollars per month, 36,000 dollars for both of them. It is a lot, right?”

Not even siblings with the same disease, like Pedro and Jessica, constitute a legitimate collective in this privatized and malleable right-to-health enterprise. Dr. Maria underscores the medical and juridical confusion: “One of the most difficult realities we face is that judges give different rulings for each MPS patient. Here we have the case of two siblings who both have MPS 6. They have different judges and each one gives treatment for different time periods.” According to the lawyer, Mr. Moura, however, this is actually the best legal strategy: “I am against collective lawsuits. Each MPS patient is unique and takes different dosages, and their particularities might play against them if it were a collective case.” For him, individual lawsuits could potentially circumvent the narrow criteria used in expert committee reviews and state prosecutors’ appeals to “postpone treatment more and more.” Arguably, the state and its legal surrogates are putting into circulation epistemic collectives that spring from a strategic deployment of evidence-based medicine. These virtual collectives (standing for a knowable population of needs that is no more) clash with the subject positions articulated by desperate patients and families within their temporary medical-legal and activist networks.

Pedro and Jessica did not have the right to clinical research, but they did have their constitutional right to health. As their mother puts it: “They **(p.344)** should get the medicine *pra vida inteira* [for the whole life] so that we would not have to always activate the judiciary *pouco a pouco* [little by little].”

This family had a sense that their fight would only become more intense as right-to-health jurisprudence was evolving unpredictably. The state’s highest court had recently ruled in favor of the government and held an MPS drug manufacturer responsible for the treatment costs of a child who had been in a clinical trial. State prosecutors requested and the court mandated that the manufacturer provide the patient with free treatment for life, even if this was not stipulated in the informed consent. To justify the decision, the State High Court wrote that “it is unacceptable for the manufacturer to use human beings as ‘guinea pigs’ in its studies and then leave people who were of vital importance helpless to obtain an extraordinarily expensive product, especially when health improvements were observed and patient expectations were raised” (Tribunal de Justiça do Estado do Rio Grande do Sul 2009).

Coda

With the global expansion of biomedical markets and their encroachment in public health care systems, we see significant institutional displacements and novel citizen-state-market formations. In the Brazilian case, the market finds utility in the government as a drug purchaser and distributor and in specific mobilized communities. These communities, cast as therapeutic market segments, use lawmaking and jurisprudence in order to be seen by the state and to make it act biopolitically. Government is thus geared less toward population health as a means of achieving productivity and control and more toward facilitating or triaging the relationship of rights-bearing subjects of interest to the biomedical market in the form of technology access.

People’s life chances and health outcomes are overdetermined by what kind of market and juridical subjects they are able to become by appealing to the judiciary and government as well as to research and health industries. We have to attend to forms of statecraft (national and regional) and jurisprudence as well as to the political subjectivities that are built into this new apparatus of interests and rights if we are to understand both the **(p.345)** possibilities that have opened up and the exclusionary dynamics at work in Brazil and elsewhere. Thus, from the perspective of judicialization, health in the time of global health is a painstaking work in progress by monadic juridical subjects in relation to therapeutic markets, ailing public health infrastructures, and fragile medical collectives. This essay has drawn attention to the precariousness of biopolitical interventions, showing how they are constantly entangled with and shaped by other (often economic) imperatives. The stories of patient-litigants and their families also point to the power of biotechnology to remake human and social worlds as it opens up new spaces of ethical problematization, desire, and political belonging. It is at the intersection of the therapeutic imperative, the biotechnical embrace, and the reason of the market that the intensity of survival becomes visible.

Notes

(1.) Retrieved 2/21/2011 from http://www.oestrangeiro.net/esquizoanalise/67-o-abecedario-de-gilles-deleuze.

(2.) An earlier version of this chapter appeared in *Social Research* (2011, 78[2]: 359–86).

(3.) We are deeply grateful for the research and editorial assistance of Mariana P. Socal, Roberta Grudzinski, Alex Gertner, Joshua Franklin, Jeferson Barbosa, Ramah McKay, and Peter Locke. We also acknowledge the support of the Ford Foundation and the Health Grand Challenges Initiative and the Woodrow Wilson School at Princeton University. Except in cases where individuals or institutions chose to be identified, we maintained their anonymity to the extent possible by using pseudonyms.

(4.) In discussing the pharmaceuticalization of health care and the judicialization of the right to health in Brazil, we draw from Biehl’s book *Will to Live: AIDS Therapies and the Politics of Survival* (2007) and Petryna’s book *When Experiments Travel: Clinical Trials and the Global Search for Human Subjects* (2009). We also draw from a multidisciplinary study on right-to-health litigation that is under way in southern Brazil and that is coordinated by Biehl.

(5.) The first MPS treatment was approved by the FDA in 2003 (laronidase for MPS I), followed by two other drugs approved in 2005 (galsulfase for MPS VI) and 2006 (idursulfase for MPS II). These drugs were approved by ANVISA in Brazil in 2006, 2009, and 2008 respectively.

(6.) The 1983 U.S. Orphan Drug Act provides incentives for the development of drugs to treat rare diseases affecting “less than 200,000 persons in the U.S.” or “more than 200,000 persons in the U.S., but for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for such disease or condition will be recovered from sales in the U.S. of such drug.” These incentives include tax credits for clinical research and seven years of market exclusivity for an FDA-approved drug.

(7.) The federal government acquired high-cost medicines in exceptional circumstances since the 1970s, but it was not until 1993 that an official program for the acquisition of these high-cost medicines (Programa de Medicamentos Excepcionais*)* was created (Ministry of Health 2010a).

The federal government ceded the administrative responsibility of this program to state health secretariats, but without a well-defined cofinancing mechanism. Although many drugs were included in the program's initial formularies, only a few were effectively distributed to the population, due to erratic and irregular acquisition and distribution processes. In 2002, the Exceptional Medicines Program was extended to include ninety-two drugs and more precise criteria were formulated to inform their distribution (Souza 2002). Finally, in 2006, the Ministry of Health issued a Ministerial Decree (Portaria GM nº 2577 de 27 de Outubro de 2006) outlining the specific objectives and responsibilities of the States and the Federal government in regard to the Exceptional Medicines Program (Ministry of Health 2010). Currently, 110 therapeutic products (including medicines, biological products, and nutritional formulas) are included in the program, which is now called the "Specialized Component of Pharmaceutical Assistance" (Ministry of Health, 2010a).

(8.) In 2007, four drugs were responsible for 28 percent of the Health Ministry's drug expenditures: imiglucerase, epoetin alpha, human immune-globulin, and interferon alpha-2b.

(9.) See http://www.princeton.edu/grandchallenges/health/research-highlights/aids/.

(10.) For a detailed review of the public hearing, see: http://www.stf.jus.br/portal/cms/verTexto.asp?servico=processoAudienciaPublicaSaude.

(11.) In 2010, the Brazilian National Council of Justice issued a recommendation for judges to always verify at the National Commission of Research Ethics (Comissão Nacional de Ética em Pesquisas [CONEP]) if the requested drug was "part of experimental research programs" of the pharmaceutical industry and that, in that case, judges should mandate these industries to assume treatment continuity. (Recomendação nº 31, de 30 de março de 2010. DJ-e nº 61/2010, em 07/04/2010, p. 4–6. Available at: http://www.cnj.jus.br/index.php?option=com_content&view=article&id=10547:recomendacao-no-31-de-30-de-marco-de-2010&catid=60:recomendas-do-conselho&Itemid=515.)

(12.) In his 1978–79 lectures at the Collège de France, Foucault argued that we can adequately analyze biopolitics only when we understand the economic reason within governmental reason: "Inasmuch as it enables production, need, supply, demand, value, and price, etcetera, to be linked together through exchange, the market constitutes a site of veridiction, I mean a site of veridiction-falsification for governmental practice. Consequently, the market determines that good government is no longer simply government that functions according to justice" (2008:32).

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