Critical Medical Anthropology

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According to the World Health Organization, diseases classified as ‘rare’ are those that affect 65 people in every 100,000, or 1.3 people in every 2,000, and it is estimated that about 8 per cent of the world’s population is affected by some form of rare disease (Huyard 2009). They are generally chronic and/or degenerative conditions, with a high degree of morbidity and mortality and often without cure or effective treatment. It is estimated that there are between 6,000 and 8,000 rare diseases, of which 80 per cent are of genetic origin, and in many cases they are hereditary. In Brazil there are thought to be between 13 and 15 million people with some form of rare disease.\(^1\) Due to the fact that they are not common conditions and the fractured and inequitable nature of the Brazilian healthcare system, obtaining a diagnosis is frequently a lengthy and time-consuming process (Aureliano 2015, 2018; Barbosa 2015). Moreover, there is no effective treatment for the majority of rare diseases currently identified, with only an estimated 10 per cent having a specific drug treatment. In a considerable number of cases this is a high-cost medication (Barbosa and Monsores 2016; Monsores 2013) that is often unavailable for those in the public health system and for those with private health insurance. As a result, for many Brazilian rare-disease patients and their families the only way of accessing medications is through judicialisation: a legal process of seeking the right to healthcare resources.\(^2\)

While the judicialisation of health is a phenomenon that has unfolded across a range of international arenas (Comaroff and Comaroff 2006; Gauri and Brinks 2008; Yamin and Gloppen 2011), the number of individual legal cases in Brazil has risen particularly sharply in the last
decade (Biehl 2013; Biehl and Petryna 2011; Biehl et al. 2009; Ministério da Saúde 2005; Diniz, Medeiros and Schwartz 2012). This emerged initially in Brazil in the context of broadening access to and provision of antiretroviral drugs for those with HIV/AIDS. It has now expanded to include provision of medication and access to health services for other conditions, particularly cancer and rare diseases. Nevertheless, recourse to the judiciary as a health-seeking strategy is debated both inside and outside Brazil, where the tension between individual rights or collective benefits and social justice is frequently contested (Biehl 2013; Ministério da Saúde 2005; Diniz, Medeiros and Schwartz 2012). In this chapter we draw on research that highlights how complex entanglements between the court and the clinic (Harper, Kelly and Khanna 2015) in the context of judicialisation and rare disease in Brazil generate particular kinds of ‘ambiguous political subjectivities’ (Biehl 2015: 169) that require reflective critical engagement. We argue that this raises important questions for critical medical anthropology in addressing, examining and accounting for activism and inequalities.

Drawing from ethnographic research undertaken with patient organisations, and by examining policy documents and popular media discussion, we analyse the cultural and political context in which judicial processes involving the demands of patients with rare diseases are unfolding in Brazil and how this has become an important avenue for accessing health rights. Addressing the intersections in Brazil between rare disease and judicialisation, we explore how government, civil society and the pharmaceutical industry are complexly situated around disputes that involve on the one hand the constitutional right to health and the budgetary limits of the state, and, on the other, the commercial interests of the market. In this way we contribute to wider discussions in anthropology and beyond concerning how rights are legitimated with reference to a humanitarian or a universalist ethos (Ticktin 2011). This has been described by Fassin (2009) as a form of ‘biolegitimacy’, where rights are increasingly legitimised in terms of the ‘suffering body’. Building on work highlighting how ‘affective economies’ have become key strategies for political action in diverse healthcare spheres and specifically the treatment of rare diseases (Buchbinder and Timmermans 2014), we examine how multiple and variable claims about the value or price of life are mobilised as part of the ‘governing work’ (Feldman and Ticktin 2010) that constitutes the terrain of judicialisation and high-cost drugs for rare diseases in Brazil. We illuminate the complex economic and power relations that have placed patients and their families in situations of profound uncertainty and instability, whilst also revealing
the dangers of commodifying health that ultimately weaken the public health assistance offered by the Brazilian state to its citizens. In conclusion, we reflect on how from a critical medical anthropology perspective, expanding rates of judicialisation related to rare diseases in Brazil and a growing economic and political crisis, including the rise to power of the extreme right-wing and authoritarian government led by Jair Bolsonaro, raises further questions about the evolving dynamics between inequities, social justice and activism.

The chapter is informed by qualitative ethnographic research that has been undertaken since 2013. This research has aimed to understand how the question of judicialisation is being constituted among health professionals, in the media, in legal domains and principally among people living with rare genetic diseases in Brazil. It has included an examination of the discourse and practice of judicialisation on the internet and within high-profile Brazilian media outlets (*Folha* and *O Globo*), as well as fieldwork with patients’ associations, at scientific congresses and public policy meetings and in public hospitals. The community encompassed by this analysis is therefore heterogeneous with respect not only to rare diseases themselves but also to different interests and investments and the material conditions of working lives and lived social contexts. Patients in doctors’ offices or involved in support networks do not always participate in scientific or political events concerning rare diseases, nor are they necessarily included, acknowledged or directly involved with either the pharmaceutical industry or the state. We argue that an understanding of and perspective on how people are variably positioned in relation to the phenomenon of judicialisation, including those with variable access to the health system and with particular needs for treatment and care, have implications for how the politics of rare diseases in Brazil are perceived and experienced. The first part of this chapter demonstrates how the history of Brazilian sanitary reform, social medicine and the establishment of the constitutional right to health is central to understanding how judicial strategies have emerged in dialogue and how they have, in some cases, come to substitute the logic of public health.

**The Brazilian healthcare system: Sanitary reform, the 1988 Constitution and Sistema Único de Saude (SUS)**

During the last four decades of the twentieth century the Brazilian health system underwent several transformations, with the current model consolidated in the latter part of that period, following the move towards
In this sense the history of the reform of the Brazilian health system provides an important context that has both informed and propelled judicialisation.

In the first decades of the twentieth century, access to social and civil rights, including the right to health, was established through labour agreements for specific categories of work, including civil servants, bank officers and others. Other workers, or people with more informal work arrangements, continued to depend on precarious public assistance, through voluntary contributions to social security or philanthropic institutions and paid services. This model, which linked access to health with a job position, offered a fragmented and unequal public service. As a result it facilitated, both directly and indirectly, the expansion of private health services, which continued to grow both during and beyond the period of military government in Brazil, from 1964 to 1985. While the state widened healthcare assistance, extending social security to rural workers, it also financed private health organisations, reformed private hospitals and provided subsidies or discounts for companies able to provide health assistance to their employees. This system also led to the concentration of health services in urban centres that housed the majority of the formally employed population and healthcare companies, thereby creating a centralised system that was focused on hospital medical assistance.

However, from the 1970s onwards, the struggle for democratic openness became linked to the health reform movement in Brazil. This movement included broad sectors of civil society, from grassroots movements to unions, from the middle classes to health managers. These groups demanded a care model that considered health a social and political concern, and were connected to a progressive agenda that emphasised access to health as a basic human right. Several actions were taken by civil society groups to consolidate health reform, including the Eighth National Health Conference (1986) which eventually provided a framework for the current public health system known as the Sistema Único de Saúde or SUS. In 1988 a new Brazilian constitution was established, and despite the expansion of the private health system, new healthcare reform was approved. Health came to be defined as the right of the citizen and an obligation of the state. However, the constitution was reformed at a time of deep economic recession as well as hyper-inflation and when there was an expanding neoliberal political agenda increasingly attuned to the market; this has made implementation of the healthcare reform uneven and difficult.

Since the beginning of the twenty-first century, with greater economic stability and the reorganisation and activism of different social
movements, the Brazilian public health system has expanded its scope and reach. One example of this was the National Neo-natal Screening Programme (PNTN), popularly known as the national *teste do pezinho* or ‘blood spot test’, which tests all newborns in the country for certain diseases (including some considered rare, such as phenylketonuria). Another illustration was the approval in 2000 of a new mental health policy that aimed to consolidate the psychiatric reform movement in Brazil. Finally, also under the leadership of the governing Workers' Party, which began in 2003, so-called ‘popular pharmacies’ were created, and the free production and distribution of medicines for prevalent diseases such as hypertension and diabetes was expanded.\(^5\)

In parallel with these developments there has also been, somewhat paradoxically, a growth and expansion of legal actions against the state for the right to access medicines and treatments not offered by the SUS. This is because of a stated scarcity, poor management of resources or because these have simply not been incorporated into the public health system. The judicialisation of health began in the 1990s with the HIV/AIDS movement, but in the following decade it assumed greater proportions involving, mainly, cancer patients and those with rare diseases. It has also emerged in close connection with new forms of capitalisation of the health market by private-sector interests, represented especially by the pharmaceutical industry.

**Judicialisation: Between global innovations and local boundaries**

The judicialisation of health has grown exponentially in Brazil in the last 10 years (Biehl 2013; Biehl and Petryna 2011; Biehl et al. 2009; Diniz 2009). The constitutional premise that the state must provide healthcare to every Brazilian citizen has led many to seek and in some cases successfully secure this legal right through the Brazilian courts. This recourse to the judiciary and the legal system in Brazil is focused on access to medicines, but it also frequently includes non-medicated treatments, hospital services and sometimes routine health technologies.

In practice the phenomenon of health judicialisation began with the implementation of SUS in the 1990s, and was initially informed by the Brazilian HIV/AIDS movement. With the development of drugs for treatment and control of the disease, HIV virus carriers in Brazil were among the first to lodge judicial claims for the right to access to medicines and healthcare. This demand was built, mainly, from the collective
mobilisation of organised groups of civil society. The first successful action was in 1996, the same year the Brazilian National Congress passed law 9313, which obliged the state to provide antiretroviral (ARV) drugs. In this sense, the initial movement towards the use of judicialisation for access to drugs such as ARVs leveraged the construction of a specific public policy for this population, supported by financial agreements with the World Bank (Ministério da Saúde 2005).

From 1999, with the value of the dollar rising, the Brazilian state began to claim that there was a lack of resources to maintain the HIV/AIDS programme. The demand from NGOs linked to the ‘global’ HIV/AIDS movement was then directed to challenging patent monopolies as a means of guaranteeing access to drugs in Brazil and in other developing countries. These challenges were ultimately successful, precipitating the internal production of medication and helping to sustain a policy of free distribution of these drugs in Brazil. The pharmaceutical industry, however, developed and in fact continues to develop new, more effective drugs, ensuring that, despite a commitment by the government to provide free access to certain medication, there continue to be new lawsuits brought to the courts by Brazilian HIV-positive patients seeking to access the most up-to-date medication. Thus, even within the context of a well-established national treatment programme, such as HIV/AIDS initiatives, the Brazilian state continues to be subject to legal demands for drugs.

Currently, however, processes of judicialisation in Brazil are dominated by cases concerning new drugs for treatment for cancer and rare diseases. In the case of rare diseases, lawsuits can involve the right to have a genetic test as well as access to basic health services such as physiotherapy and the use of drugs not yet approved in Brazil, or those approved but not yet included on the SUS lists (Diniz, Medeiros and Schwartz 2012; Boy et al. 2011; Boy and Schramm 2009). These lawsuits involve individual patients, families and collective claims, including from patient associations. Despite structural and financial constraints, such associations have played an important role in the Brazilian political arena, informing the construction of public policies for people with rare diseases (Grudzinski 2013; Barbosa 2015). However, it is important to note that unlike many Euro-American patient associations (Rabeharisoa et al. 2014), Brazilian patient associations are not mobilised around finding a cure for rare diseases. Rather, as the work of Grudzinski (2013) shows, they are engaged in efforts to legally oblige the state to care for those affected by rare diseases and their families; most frequently this translates into having access to high-cost drugs.
Since the 1990s, with the implementation of SUS, legislation has responded to the activism and engagement of Brazilian patients’ associations, to focus state resources and attention on rare diseases, even before this term became common. For example, in the 1990s medicines for treating a particular rare condition, Gaucher disease, were included in the federal government’s Exceptional Medicines Programme, following legal action against the state by a patient association (Boy et al. 2011). Similarly, efforts by other patient associations have led to the regulated inclusion of rare diseases such as cystic fibrosis and phenylketonuria in national programmes of neo-natal screening along with a specified treatment protocol. However, this has not prevented new legal demands for conditions which are at least nominally now included in public health programmes – a situation generated by both a lack of available medicines and a demand for newer and potentially more effective medications.

Thus there are two processes that fuel the growth of health judicialisation in Brazil, whether for antiretrovirals, cancer medications or rare disease medications: the expanding development of new high-cost drugs at a global level (not always with guarantees of long-term effectiveness), and the management of state resources at the local level.

**Global innovation, costly drugs and the promise of health**

By investing in the development of new drugs, the pharmaceutical industry seeks not only to improve technologies and to develop medicines, but also to renew its patents, guarantee competitiveness in the global market and increase profits (Gagnon 2015). The history of HIV/AIDS in Brazil is a useful example of this. As treatments initially caused profound side effects, there were continued efforts to develop newer medications, but at a speed which was not always accompanied by the ability of either government or individuals to purchase or acquire the drug. The breaking of patent monopolies, which was so crucial for enabling the effectiveness of the Brazilian treatment programme in the case of ARVs, is therefore constantly confronted by the emergence of new drugs, which promise fewer side effects, but at a cost that is usually unfeasible to meet the demand of all patients.

For cancer, new drugs arise continuously. The case of anti-cancer drugs in the UK is emblematic of this difficult equation between the high cost of new technologies, the urgency for patients of acquiring them, their not always proven efficacy and state budgetary limits. In 2010, the
UK government set up the Cancer Drug Fund (CDF). The fund’s expected value was £50 million but it reached £340 million by 2016. The CDF was a parallel investment to the government’s unique cancer treatment programme, created exclusively for new drugs, with the promise of faster treatment pathways. Critical reviews of the programme have challenged this investment – noting, among other indicators, that the effectiveness of the drugs selected is not always known (Aggarwal et al. 2017). Of 47 drugs recommended by the CDF, only 18 (38 per cent) were statistically significant in promoting patient survival. The review also showed that many drugs were approved without studies that presented statistical data for survival rates. According to Aggarwal et al. (2017), doctors are prescribing drugs to avoid ‘moral blame’ or the accusation that they have not done enough to test or know whether a particular drug can bring some benefit, even if studies provide little evidence that this is the case.

The dynamics between the struggle for access to ‘life-saving’ medication by cancer patients and the acceleration and timing of drug production is mirrored but also made more complex in the context of rare diseases, given that for the vast majority there are no medications. In 1983, the US government launched the Orphan Drug Act to stimulate research and production of rare-disease drugs by offering subsidies to pharmaceutical companies and market exclusivity. The initiative was followed by other countries such as Japan (1993), Singapore (1997), Australia (1998) and the European Union (2000). The term ‘rare disease’ emerged from a raft of new international legislation that allowed state governments to offer economic incentives for pharmaceutical companies to develop medicines. As the work of Huyard (2009) demonstrates, ‘rare disease’ was a concept that emerged from and was directly linked to the market for orphan drugs and was thus based in economic rather than clinical logic.

Brazil is no exception. Here, as elsewhere, the process of having a drug approved and included in the public health system involves conflicting and contrasting dynamics between the interest of government, the pharmaceutical industry and patients’ urgent desires and needs for treatment. These are shaped by and further inform legal and economic disputes involving patients, government and the pharmaceutical industry concerning access to these drugs.

Laboratories must request to register new drugs with the Agência de Vigilância Sanitária (ANVISA), a sector of government that regulates the commercialisation of any drug in Brazil. The petition to register a drug needs to be based in clinical trials, after which the price for new medicines is further defined, and where industry will suggest a price to commercialise the drug in the country. At this point, government will try
to lower the price, in an effort to include the drug in the programmes of the national health system too. In different events that we have followed in Brasilia and in interviews with government representatives, it was suggested that pharmaceutical companies do not routinely apply for registration of new drugs for rare diseases. It is claimed by government officials that this is a situation that stimulates judicialisation internally, as soon as the drug is approved by international organisations. The government’s argument is that for industry, judicialisation is more profitable, as once a court order is issued it must be fulfilled in a short time, preventing the negotiation of the price.

The pharmaceutical industry, for its part, says that it seeks to register drugs, but that this is compromised by bureaucratic processes and the current criteria for registration. Materials published by Interfarma, an international company that brings together several Brazilian laboratories, state that the pharmaceutical industry does not support judicialisation but that in the face of delays by the Brazilian federal state in approving new drugs, families have no alternative but to resort to judicialisation, which they consider a ‘democratic instrument’ for accessing rights to medication (Interfarma 2016). Another complaint by the pharmaceutical industry, also endorsed by patient associations, is that current norms in Brazil to validate research and clinical trials make it difficult to analyse and approve medications for rare diseases. They ask for alternative standards for registering these drugs and other criteria, such as not requiring a high number of participants to validate a study, since most rare diseases affect only up to a few hundred people. Brazilian rare-disease patient associations have also raised questions about the legal obligation for pharmaceutical companies to offer the drug to study participants indefinitely if they are proved effective since, the associations argue, this discourages laboratories from conducting clinical trials in Brazil (Castro 2015; see also Aureliano 2018).

The Brazilian government’s argument is that there are no resources to cover the costs of incorporating all the medications developed as soon as they are approved in their countries of origin, so they have to individually analyse cost-effectiveness as well as demonstrate the efficacy of medication. In their defence, they evoke the notion of ‘possible reserve’ (a reserva do possivel; see Chiavassa et al. 2014) to secure the constitutional right to health, and to emphasise that while individual demands are infinite, state resources are finite. The argument that judicialisation is contributing to the dismantling of the SUS provokes in turn both malaise and indignation from patients or their families with rare diseases, who find themselves situated quite literally in the middle of this contested terrain.
This is therefore a domain where, because of the role of the Brazilian Defensoria Pública (which provides free juridical assistance to patients and publics), the judiciary has effectively, as Flores (2016) points out, become an agent within the state to litigate against the state. That is where state agents both argue against and defend the state in the case of access to health and medicines. As a result it is not perhaps surprising to find that an affective discourse concerning ‘life’ and ‘value’ is appropriated by the different social actors encompassed by and constituted within these processes. While in general there is a sense of opposition to judicialisation – whether from within patient associations, government or industry – each of these spheres nevertheless defends itself in this process, putting to work legitimating social and moral categories in particular ways. Social theorists have become increasingly interested in how human life is not simply constituted (or denied) through the workings of biopolitics (Foucault 1976; Agamben 1998) but how it has become part of a governing apparatus in terms of sustaining but also sometimes contesting power and inequalities (Fassin 2009). Building on work in Brazil that has considered how the power ‘of life’ and not simply the power ‘over life’ has made ‘biolegitimacy’ a powerful tool in particular fields of social policy and practice (Maluf 2015), we examine how patients and patient associations mobilise affective articulations of ‘life’ and ‘value’ in their efforts to pressure the public and the judiciary in seeking to oblige the state to pay for high-cost drugs.

‘My life has no price’: Rare diseases in the Supreme Court and the value of life

In 2016 two lawsuits concerning access to medication reached the Brazilian Federal Supreme Court (STF). In one, the state of Rio Grande do Norte questioned the obligation to provide a high-cost drug to a patient with cardiomyopathy and pulmonary arterial hypertension who had obtained, through a separate judicial process, the right to the drug, which was not currently available in the SUS. The other action was a patient from the state of Minas Gerais, who had been seeking through local state judicial processes to have access to a drug that was not yet approved in Brazil for the treatment of chronic kidney disease. The patient had turned to the STF in a further effort to gain access to this medication.

The public unfolding of these different lawsuits in the Supreme Court in 2016 mobilised rare-disease patients from all over Brazil, leading to a social media campaign focused around the slogan ‘my life has no
Imagine you – or someone you love – with a serious, chronic and rare illness. Now imagine that the remedy is too expensive, much more expensive than you can afford. And, finally, imagine that even the courts cannot force the state to supply this medicine. This is precisely the risk we are facing today in Brazil. The Federal Supreme Court will decide whether governments are obligated or not to provide expensive medicines to people who need them and who do not have the financial means to get them. These are high-cost drugs that are not yet included in SUS and those that do not yet have Anvisa’s approval.

In 2016 patients held a vigil in front of the STF and achieved wide coverage of the case in the media, which focused on the high costs of health judicialisation in Brazil. However, only three votes were handed down by judges in relation to the two lawsuits, and one minister called for more time to better analyse the process. While the legal action on both cases has been suspended, with no date as yet for when it will be resumed, the public campaign and its messages about the value of life in the context of rare diseases have continued, spilling out far beyond the domain of popular and social media. It has been a prominent feature at several rare-disease events held in 2017 and 2018, and a key campaigning message for a diverse range of individual and umbrella rare-disease patient organisations.

The motto of the campaign mobilises the concept of ‘life’ as a ‘value’ that cannot be measured in monetary terms. The argument of patients and public defenders is that the Brazilian government cannot consider the concept of the ‘possible reserve’ to deal with the demands of patients with rare diseases, since the state budget is not more important than the life of patients. Public advocates who work with patients rebut the thesis of the ‘possible reserve’ with another legal concept, also drawn from German jurisprudence, the ‘existential minimum’ (minimo existencial). This asserts that ‘the state has a duty to allow its jurisdictions to enjoy their fundamental social rights at a minimally acceptable level so that they have a dignified life’ (Chiavassa et al. 2014). Access to medicines that, in theory, allow, prolong or improve the quality of life of people would therefore be a fundamental right, situated within the existential minimum that the state must provide.
The notion of a life/death scenario along with the idea of ‘dignified’ life is most visibly evoked in the discourse of patients and their legal representatives and in public debate. But it is also present, albeit in more collective terms, in the rhetoric of the public lawyers who defend the government and who seek to avoid prosecution by patient litigants, as this statement by one Brazilian state lawyer illustrates:

The state defends the right for the planning and organisation of the [health] system to be maintained, so that it is possible to serve the community. One is not here, in any way, disregarding the serious situations that affect the Brazilian citizen, but the fact is that the resources of the state are limited. It is necessary to have a regulated [health] system to serve the community [emphasis added].

We see therefore here a dispute between the Brazilian state and rare-disease patient associations that is framed through narratives about the value of life and the financial means of maintaining it, with emotional appeals that move between despair and hope and which, at the same time, speak of individual and collective forms of social justice.

Ambivalence and the ‘moral criminalisation’ of rare-disease activism

In the materials we analysed, it was evident that patients and their families are aware that the value of their lives oscillates when assessed by the market and public health. In certain circumstances, instead of being perceived as victims they are seen as destabilising the public health system, accused of causing damage to the community in their efforts to ensure their treatment through judicialisation. This awareness was reflected in the comments of one patient association leader at a rare-disease event in Rio de Janeiro in March 2017:

I do not like the word judicialisation, because I think that judicialisation is used precisely to criminalise whoever turns to justice for the constitutional right to health […] it is as if it were something that would break the SUS, that would end the financing of the Unified Health System. There are treatments that are more expensive, but it is not by choice […] if I could I would treat myself with aspirin, but I did not choose the treatment […] who would want to have a rare disease and need medicine for life? That will often partially
solve your problem, it will give you better quality of life, but it will not solve your problem fully. So it seems like we’re going there to ask a privilege for a few people. The people you see talking, even the Supreme Minister saying ‘a few people want to take the right to have a hospital bed’, that’s not it, that’s not it at all.

In striking contrast to the situation of HIV/AIDS activism in Brazil in the 1990s, there is a sense among rare-disease patients of being stigmatised for pursuing their right to health through the judiciary. The self-defensive tone evident in these comments reflects how the discussion in the media is often presented in terms of rare-disease patients draining resources from the SUS and undermining the health system as a whole, or limiting others’ rights by personally advocating for expensive medicines. Yet at the same time these comments also suggest such patients and those involved with patient associations are profoundly reflective in confronting contested debates concerning judicialisation.

While there are clearly alignments between the pharmaceutical industry and some rare-disease patients’ interests in seeking to obtain medications, there is a diversity of response, with many of these individuals and organisations determined not to ignore the economic interests of the industry. On the contrary, some clearly recognise that these are profit-seeking companies, and may try to disassociate themselves from any idea that are being financed by the pharmaceutical industry to pursue a process of judicialisation. This is evident in the criticism of the sociologist Barbosa (2015), who is also the father of a girl with a rare disease and founder of a major Brazilian patient association. He is particularly critical of what he calls the ‘utility model of care’ for the rare disease, centred on drugs. For him, the perception of care as access to medicines is far removed from what he proposes as a holistic approach to care: an approach that he suggests might be especially important given that in most cases concerning rare diseases there are no available remedies.

Nevertheless, for those conditions where there is a possibility of using a drug, patients and their families enthusiastically receive the results regarding research and the development of new drugs. In a scenario of desperation, often where nothing or very little exists, the possibility of participating in a clinical study is also perceived with interest and the approval of a new drug abroad shapes an unending hope of healing or improving the quality of life of a patient or family member with a rare disease.

In interviews with leaders of patient associations and by following the public debate on newspapers, it is possible to understand that
judicialisation for many patients is not something sought or always desired. Rather it is for many the only possible way of accessing some form of treatment. Many, particularly parents and especially mothers of patients with rare diseases, who make up a significant portion of the Brazilian rare-disease activist community, are aware of the moral criminalisation of patients who seek access to medications and services in this way. In the context of our interviews a number commented further on this.

I’m really afraid to hear someone talk about judicialisation, because as a patient if we go somewhere where we talk about this topic, we are really thought as the biggest thug, the biggest enemy, persona non grata in society.

(patient in an event about rare diseases in Rio de Janeiro, March 2017)

The cost [of judicialisation] is much higher, nothing is solved, the patient is not making money, the patient is gaining health. So if we are to blame for our interest in saving the lives of our children then I am guilty, mainly because I was one that judicialised to get my son’s treatment and he did for six years […] I do not think it’s right that I have to judicialise to get my son’s treatment, I do not think so, but I have no other way, what should I do? I will wait, [but] if there is already a law, constitutionally a right to health and life, which in fact does not work, I expect the sky to fall before they take pity! No, if I have the option to prosecute, I will go to court, it is not right what they say about the judicialisation.

(leader of a patient association who has a son with rare disease)

As these comments suggest, a notion of responsibility (frequently translated as ‘maternal’ responsibility, given the gendered profile of many involved in patient associations) is often evoked in efforts to pursue the right to life in these reflections by patients involved in associations. Similarly for adults with rare diseases, the expectation of a decent or ‘dignified’ life is central to an argument that is used to justify the judicial pursuit of care and medication. With the motto ‘my life has no price’, families with rare diseases aim to encourage the Brazilian state to attend to a basic right that the lack of a medicine can limit, namely the right to life and health.
The ‘exceptional’ market value of rare-disease lives in Brazil

For those who produce drugs capable of saving patients’ lives or providing them with better conditions, life and health have significant monetary value. For the pharmaceutical industry, rare diseases have become a highly attractive and lucrative market. In 2016, an American executive from the pharmaceutical industry at a speech in Brasilia explained to the audience that the market for rare diseases in Latin America was estimated at about 37 to 50 million patients. While quantifying the data, the speaker evoked human rights and compliance with international treaties on economic, social and cultural rights to argue that national governments should bear the costs of such demand. He called attention to the construction of a public agenda to finance the purchase of medicines. Thus, a representative of the market advocated for public financing to provide resources for private initiative. At one point, he explicitly stated that developing ‘diagnosis and treatment for very few patients is very expensive’, before rhetorically asking, ‘Who will pay the bill?’

His speech was not lost on the patient activists who were present, especially those who are directly affected by rare diseases or who are relatives of people with rare diseases for which there is no drug treatment. In his blog, one such activist later responded to the talk he had witnessed, highlighting how this reflected and informed differences amongst rare-disease associations in the way they perceive the role of pharmaceutical companies:

This ‘business in search of profit’ was explicit in one of the lectures, the one made by Dr Fernando Ferrer of Multinational Partnerships, who ended his speech inviting multinational businessmen from the pharmaceutical industry to invest in Latin America, as it would be an excellent business opportunity here in the field of rare diseases. I believe that these differences are reflected inside the rare diseases field where they fit into the political struggle between the public health model (universal, for all, and therefore state) and the private health model (only for those who can afford it). (https://amanf.org.br/2016/10/, accessed 31 October 2019).

Industry representatives do not deny that their companies are looking for profit. In material published in 2017 by EvaluatePharma, a company dedicated to providing guidance to pharmaceutical investors, orphan
drugs are presented as a major potential market niche. The 26-page report shows in detail the potential and actual profits from this market, which by 2022 will, according to its estimates, generate $209 billion, accounting for 21 per cent of all medical prescriptions worldwide. While it mentions all the benefits and subsidies offered by governments of various nations with legislation like the Orphan Drug Act, more affordable pricing for these drugs is not at issue in this document. Instead, fiscal and financial incentives and market exclusivity are listed as yet another way to boost profits.9

Gagnon (2015) argues that the pharmaceutical market today is marked by ‘nichebusters’, which have become more profitable than the earlier model of ‘blockbusters’, produced for prevalent diseases and sold to thousands of people. Over the years, patent infringement and loss of sales exclusivity have made so called blockbuster drugs unprofitable. The alternative profit-seeking pathway is to develop new patents, but this is not always feasible when previous cheaper drugs remain in the market. Blockbusters have thus lost competitiveness on the global stage, and specific niche markets, such as rare diseases, have become the focus of industry.

Thus, if for the state and patient associations the life of patients with rare diseases should not have a price, for the pharmaceutical industry it has, by contrast – and somewhat ironically, given the campaigning slogan of rare-disease associations in Brazil – exceptional value. In all rare-disease events in Brazil the industry is present or represented. Its largest representative in the region is Interfarma, a pharmaceutical research association that brings together 51 national and international laboratories, among them giants such as Bayer, Novartis and Sanofi. Among the materials published by Interfarma is a special issue on the judicialisation of medicines (Interfarma 2016). In this document, the company says it is against judicialisation, but it affirms that it exists because of ‘failures’ of the Brazilian public health system. It presents official data on the costs of judicialisation for the government’s budget and understands that the best way to stop this process, which is considered harmful to every society, is to create more effective and quicker ways of incorporating medicines into SUS. It is unclear how prices would change as a result, although it is mentioned that this would ‘enable’ price negotiation.

The state in turn, in its defence, always claims that industry is not interested in registering medicines. In 2017, some changes were made to speed up the registration processes for orphan drugs. Even with these changes, the government says that few companies seek to register these drugs, and when they do, requests are not always properly substantiated or documented and are as a result eventually turned down.
The whole process is slow, and patients find themselves in the midst of an economic and bureaucratic dispute between government and business. The former seeks to ensure adequate allocation of finite resources and constantly argues that paying dearly for drugs for rare diseases limits other health actions that would reach a larger number of people, such as vaccination programmes and basic care. The industry also appeals to the small number of patients to justify abusive prices. In this equation, where a few people are seen as too expensive and quantified in monetary terms, life ceases to be a value in itself but becomes a commodity, qualified according to perspectives of economic management and profit.

**Concluding comments and future developments**

We have seen in this chapter how the value of life and the forms of ‘bio-legitimacy’ (Fassin 2009; Maluf 2015) this entails are multiple and contested across the diverse terrain in which judicialisation is unfolding in relation to rare diseases in Brazil. Patients caught in the midst of this dispute see their lives quantified and valued in different ways: on the one hand as expense and cost, and on the other as an inestimable individual value, masking possibilities of profit and financial interests. The Brazilian state alleges that judicialisation impacts the budget of the public health system, causing damage to the community, since the money spent to meet judicial demands entails a cut in other services. As one government representative put it in one of the hearings observed in Brasilia, managing the health bill is like carrying out a ‘Sophie’s choice’ (uma escolha de Sofia) given the budgetary limits of the state. The ‘life’ that is valued here is that of the greatest possible number of people who can be served with these limited resources. Industry, in turn, bets on the unique character of an individual life and the possibility of its extension at any cost. Publicity produced by industry is routinely aimed at the general public, usually focusing on particular cases of improvement in the quality of life, with the use of individual life histories highlighting elements related to family and work. Nothing is said in these contexts about the soaring costs of drugs and their possible limited benefits.

While illuminating how the ethical value and category of ‘life’ gains traction across different spheres of social action in the context of contestation and debates concerning judicialisation and rare disease, this chapter has also aimed to further contextualise how we might understand the way that particular forms of activism and inequalities inform these developments. Whilst an affective discourse of life and value in pursuing access
and rights to medication is prominent, these do not, as Buchbinder and Timmermans (2014) suggest, serve to ‘obscure’ fiscal costs and opportunities of public health programmes; rather, in Brazil, they are brought into sharp relief. We see very clearly in the Brazilian context the complex ‘paradoxes and prospects of citizenship’ (Petryna and Follis 2015) or what Biehl describes as the ‘ambiguous political subjectivities’ (2015) at stake in the judicialisation of health in relation to rare disease. Shaped at the nexus between the state, patient associations and the judiciary, such activism can facilitate access to urgent healthcare in the context of a fractured healthcare system, even as it does little to redress underlying structural inequalities. The sense of being left with little choice but to judicialise was conveyed by one rare-disease patient in an interview with a major newspaper: ‘I do not want to be demanding an unapproved drug, except that the company has no interest in approving it in Brazil. My life cannot wait until the company has an interest. We are hostage to industries and government’ (our emphasis).

The activism of rare-disease patients in Brazil confronts serious challenges. Some are similar to those which the HIV-positive community in Brazil faced in the mid-1990s in their efforts to arouse the interest of the pharmaceutical industry and to get the state to build a solid policy of assistance. Nevertheless, this is quite a different context. People with rare diseases, because of an increased and highly diverse variability and specificity in terms of the condition (often undiagnosed) and treatment (often non-existent and of uncertain efficacy), confront different problems and challenges. Without the large media appeal that HIV/AIDS had or which certain forms of cancer now have, nor the possibility of more effective cure or control, it is very difficult to raise public awareness. Equally problematic are the market protections provided by legislation in the countries where the drugs are produced, and patent monopoly, which make it more difficult to put pressure on the industry to demand the reduction of drug prices or challenge patents, as happened in the case of HIV/AIDS in Brazil.

The wave of austerity policies in Brazil during the last few years has not diminished cases of judicialisation – in fact, quite the opposite. However, with the worsening of the political and financial crisis in Brazil it is not surprising that the Supreme Court has not, to date, been very swift to judge lawsuits such as those outlined earlier. The enactment of Constitutional Amendment 95 (EC 95) in 2017, which freezes social investments for 20 years, has already had consequences for healthcare in Brazil, with drastic reductions in budgetary resources. Brazilian states and municipalities cannot shore up this situation, given the fall
in revenues as a result of recent austerity policies, which in turn affects health budgets. Judicial proceedings continue to be filed, but they no longer have the same effects, and even the drugs already approved or intended to be purchased are not being bought in the necessary quantities. In October 2017, one of the authors attended an event organised by a large association of patients, which brought together associations from Latin America in Rio de Janeiro. At the close, a manifesto was read that would be delivered to the Senate the following week. This highlighted that for the year 2017 substantial cuts were made in the acquisition of nine medicines for rare diseases, meaning that dozens of patients would have their treatments stopped if new purchases were not authorised.

In 2017, Directive 199, which legally instituted the national policy of guaranteeing care for people with rare diseases, was reviewed. This legislation had envisaged the accreditation of centres in Brazil aimed at providing integrated public health services for patients with rare diseases, as well as providing funds for staff costs, routine examinations and treatment. Seven such centres were planned across the country, but only one of them has thus far secured some of the resources budgeted for these developments. The others continue to function as before, without new financial and resource contributions and facing the same challenges in efforts to care for patients with rare diseases. In May 2018, at an event organised by the authors to return research data to participants from a number of patient associations, we were informed that Directive 199 was revoked and incorporated into other legislation in a new document published by the federal government a few days before the meeting. The leaders of the associations lamented that as soon as the directive had begun to be implemented, it was appropriated by new management that has shown little interest in strengthening SUS. On the other hand, in July 2018 the federal Senate approved a complementary bill that intends to institute the National Policy for Rare Diseases in the SUS. It is envisaged that actions aimed at the care of people with rare diseases will be implemented within three years. However, the text of the bill does not clarify how resources will be allocated for this process: a significant challenge, given the promised freezing of public spending on health for the next 20 years.

The current political and economic scenario in Brazil, including the presidential victory in 2018 of the extreme right-wing politician Jair Bolsonaro who has declared a commitment to ‘eliminate activism’,10 points to the ongoing process of dismantling SUS, the commercialisation of health and the promotion of healthcare companies to the detriment of users. This reflects not only the growing entrenchment of a neoliberal
agenda but also the active erosion of many public healthcare benefits and rights. In this process, the place of people with rare diseases in Brazil remains uncertain, raising further questions about how justice can continue to be sought in a context of increasing and ongoing limits to health rights and resources.

Notes

2. As the work of Sesia (this volume) shows, judicialisation is also a much wider phenomenon and can be a mechanism for seeking redress for victims of human rights violations in healthcare contexts.
3. But this has not been the case everywhere: see for instance Sesia (this volume) for an account of how judicialisation in Mexico was initially articulated in the context of ensuring access to healthcare resources for indigenous communities.
4. In Brazil, all people with a formal job (in a company or factory, for example) contribute to social security, a tax collected to provide retirement income to employees in the future. This social security is controlled by federal government. Self-employed workers may choose whether they want to contribute to social security.
6. This is a legal term that arose from a case in West Germany in 1972 involving young adults who, having failed the admission process at the public university, legally appealed the decision, evoking the precept of a fundamental law which guaranteed German citizens the choice of profession, workplace and training. The German justice system denied the request, instituting the theory of the ‘possible reserve’ that limits the state’s action to address the constitutional right of private interest above the right of the majority. In Brazil, the theory is associated with the scarcity of public resources and consequent inability to fulfil all the demands related to social rights.

References


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