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Courts as healthcare policy-makers:
the problem, the responses to the problem and problems in the responses

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Abstract: This article starts by analysing healthcare litigation in Brazil by means of a literature review of articles that contribute with empirical findings on this phenomenon. Based on this review, I argue that health care litigation in Brazil makes the public health system less fair and rational. In the second part of this article, I discuss the three most overarching responses to control the level of litigation and its impact on the public health system: (i) the public hearing held by the Supreme Federal Court and the criteria the court established thereafter; (ii) the recommendations by the National Council of Justice aimed at building courts' institutional capacity; and (iii) the enactment of the Federal Law 12.401/11, which created a new health technology assessment system. I argue that latter is the best response because it keeps the substantive decisions on the allocation of healthcare resources in the institution that is in the best position to make them. Moreover, this legislation will make the decisions about provision of health treatments more explicit, making easier for courts to control the procedure and the reasons for these decisions.

Keywords: Courts; healthcare policies; right to health; Brazil; health technology assessment

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1 Introduction

Imagine a healthcare policy with the following features. First, scientific evidence plays almost no role in this policy because previous analysis of treatments' effectiveness or safety is not an essential requirement for their provision. Second, the treatments' cost-effectiveness will not be assessed either. The price of a treatment and its affordability in comparison to the benefits it can deliver are not relevant. Thus, the efficiency in the public spending – treating more people, and possibly better, with the same amount of resources – is ignored by this policy. Third, there will be no public procurement. The suppliers can basically charge the price they want and the authority has almost no room for negotiation because they cannot refuse to buy it. Fourth, a very significant amount of the health budget will be allocated for this policy. Fifth, the distribution of beneficiaries in this policy will not be made according to any coherent principle of distributive justice in health, but according to the capacity to access legal representation. Finally, no matter if other needs are more urgent, the wish of elected representatives or other stakeholders, or the possibility of better alternative use of the resources, the health authorities will have to implement this policy, and immediately. Health authorities can only act reactively, which means they cannot make any plan for the implementation of this policy, but only follow the orders from a group of public servants (judges) whose job is basically to receive demands from those who can reach them via a lawyer.

From any perspective this would be a bad policy and would never fulfil the criteria of a fair (according to a reasonable principle of distributive justice and a mutually acceptable procedure) and rational (based on robust scientific evidence and maximizing the benefits that can be provided given a certain amount of resources) public health system. However, this is how Brazilian courts are allocating a significant amount the public resources when enforcing the right to health as an individual entitlement to receive healthcare from the State. Courts, through the adjudication of hundreds of thousands of individual cases, have become a major player in healthcare policy in Brazil.

These lawsuits in which claimants demand from the State the provision of a certain health treatment based on their legal entitlement to receive health care from the public health system I will call healthcare litigation. These lawsuits are generally lodged by those negatively affected by decisions that deny the provision of a health treatment by the public health system because of limited resources or because health authorities are not convinced that it is effective or cost-effective.

Healthcare litigation is the confluence of two phenomena that have been expanding globally in the last decades: health care costs and judicial review. The former is the result of an ageing and better informed population that, coupled with the constant development and marketing of new health technologies expanding what is possible to do to improve people's health, increase the mismatch between the healthcare patients expect to receive and the care public health systems can afford to provide (Coulter & Ham, 2000; OECD, 2006). The latter is the expanding review power of courts to issues of public policies that in the past were left to the complete discretion of politicians and bureaucrats (Tate & Vallinder, 1995; Hirschl, 2008).

In many jurisdictions both phenomena meet and healthcare policies become one areas towards which the judicial power is expanding. The involvement of courts in decisions about the provision of healthcare has caught the attention of many specialists, especially those interested in the debate about social rights adjudication. For instance, Yamin & Gloppen (2011), Gauri & Brinks (2008) and Langford (2008), have all published collections that analyse the judicial protection of social rights in several countries. In many of them, healthcare stands out as one of the most judicialised policies. Lawsuits claiming health treatments were also researched by other scholars in specific jurisdictions such as Brazil (e.g., Ferraz, 2011B), Colombia (e.g., Landau, 2012), Canada (e.g., Flood & Chen, 2010), South Africa (e.g., Young, 2012; Liebenberg, 2010) and India (e.g., Fredman, 2010).

This article will focus exclusively on the case of Brazil. The Brazilian Federal Constitution declares that the right to health is a fundamental right of all and a duty of the State, and established a public health system based on the principles of universality, equality of access and comprehensive coverage. Based on the Constitution, some citizens who were denied a certain health treatment by the public health system have lodged lawsuits against the State, claiming that they have the right to receive any treatment they need, free of cost. Brazilian courts, in most cases, have accepted these claims to order the provision of treatments by the public health system, which led to an astonishing increase in the number of lawsuits, as well as in the amount of resources spent by the government to comply with judicial decisions.

This article aims firstly at understanding healthcare litigation in Brazil by means of a comprehensive review of the literature that contributes with empirical findings about what is demanded by claimants; their socio-economic profile; the economic impact on the public health budget of the decisions; and how courts judge the cases. Even though a lot has been written on healthcare litigation in Brazil and a substantial amount of data is available, an effort to gather, organize and analyse systematically all this information is necessary.

In Brazil there is a national health system (the *Sistema Único de Saúde*), but the responsibility for provision of health services is shared by every component of the federation. Therefore, there are more than 5,500 municipalities, 26 states, the Federal District and the federal government that can be sued by patients willing to access treatments not provided by the public health system². Given that researchers always restrict their analysis to one component, a literature review is essential for a more reliable account of the phenomenon nationally. Moreover, most of the research was published in Portuguese language, which can be an obstacle for academics willing to use the case of Brazil for comparative study, but who do not master the language. I expect this article to make a vibrant and controversial case accessible for a broader audience.

Based on the literature review, I argue that health care litigation in Brazil is making the public health system less fair and rational. Courts are creating a two-tier public health system – one for those who can litigate and have access to any treatment irrespective of cost, and the other for the rest of the population who has access to restricted care – and compels the provision of drugs based on poor evidence and without considering cost-effectiveness or public health priorities. This is not a new argument, healthcare litigation in Brazil has been used to vindicate the concerns about the capacity and legitimacy of courts to adjudicate social rights and as an example of what courts should not do (see, for instance, Ferraz, 2009; Ferraz, 2011A; Ferraz, 2011B; King, 2012: 84; Tobin, 2011: 208-209; see, however, Brinks & Gauri, 2012; Young, 2012: 200).

However, a more comprehensive, systematic and up-to-date review of the literature, as the one I propose in this article, brings stronger evidence and more sophisticated analysis to sustain the core of the argument that health care litigation makes the public health system less fair and rational; suggests a more nuanced view on some of the conclusions of former works (e.g., the claims regarding litigants' socio-economic profile); and points out to some elements that should be given more importance to understand the phenomenon (e.g., the role of pharmaceutical companies in encouraging litigation).

In the second part of this article, based on the premise that healthcare litigation is a problem because it makes the public health system less fair and rational, I present and discuss the three most overarching responses to control the level of litigation and its negative impact on the public health system. Two of them came from the judicial branch itself: (i) the public

² The Brazilian courts have constantly decided that a citizen can judicially claim health treatment against any level of government (Wang et al., 2012). This means that a citizen, for instance, can sue the City of Sao Paulo, the State of Sao Paulo or the Federal Government. He can also sue two of them or even all of them.

hearing held by the Supreme Federal Court (STF) and the criteria the court established thereafter to define a sphere of self-restraint for courts; and (ii) the recommendations by the National Council of Justice (CNJ) aimed at building courts' institutional capacity. The third response was the enactment of the Federal Law 12.401/11, which created a new institution responsible for health technology assessment system and a new administrative procedure to decide on the incorporation of health treatments in the public health system.

The responses from the judicial branch (STF and CNJ) share the premise that better informed, trained and assisted courts, deciding under certain constraints, can overcome courts' lack of institutional capacity to decide on the allocation of healthcare resources and, hence, prevent litigation from making the healthcare system less fair and rational. The legislative response, on the other hand, aims at making the administrative procedure more impartial, robust and transparent in order to convince courts to be more deferential to what was decided in the administrative level.

I argue that, from the perspective of comparative institutional analysis (Komesar, 1994), the legislative response is the best because it keeps the substantive decisions about the allocation of healthcare resources in the administrative level, where authorities have the best conditions to make them. Moreover, because the legislative response will make the decisions about provision of health treatments more explicit, it makes easier for courts to control the procedure and the reasons for health authorities' decisions. By attributing to each institution what it can do best, the legislative response can transform a pattern of case-law that is currently making the public health system less fair and rational into one that can have the opposite effect on public policies. The responses from the Judiciary, on the other hand, are still expecting courts to deal with the most complex issues regarding the allocation of scarce resources in healthcare, which they are comparatively less suitable to do, even if they constrain their sphere of review or have their institutional capacity improved.

This article does not argue that the case of healthcare litigation in Brazil is a silver bullet against social rights adjudication or the involvement of courts in the control of social policies and the allocation of scarce resources. This article should be read as a warning that guaranteeing a certain treatment to individuals via the judicial process can create an overall disastrous outcome for the public health system. It also presents and discusses some responses to control the level of litigation and its negative impact on the public health system, which can be a useful experience for countries where healthcare litigation presents the same features as in Brazil. What Ferraz (2009: 34) described as the "Brazilian model" of health care litigation – prevalence

of individualized claims demanding curative medical treatment and an extremely high success rate for the litigant – fits the description of healthcare litigation in other jurisdictions such as Argentina, Costa Rica and Colombia, which allowed King (2012: 84) to conclude that it should actually be called the “Latin American model” of health care litigation.

2 Healthcare litigation in Brazil: what it is and why it is a problem

In this section, I analyze the health care litigation in Brazil by answering the following questions: what is demanded by claimants?; what is the litigants’ socio-economic profile?; what is the economic impact of the decisions on the public health budget?; and how do courts judge the cases?

The analysis will be based on the data available in the state, municipal and federal levels. Even though I will be only looking at a few domestic jurisdictions, they provide a representative portrait of the state of art of health litigation in Brazil. According to Ferraz (2011A), most of the litigation is concentrated at the federal level and in the states of Santa Catarina, Rio de Janeiro, Minas Gerais, Sao Paulo, Rio Grande do Sul, Parana and the Federal District. With the exception of the state of Parana, about which no comprehensive research was found, the literature used in this section provides data on the states where health care litigation is most frequent, the Federal Government and the Federal District. There is also data about the capital cities (where the population is concentrated) of three of these states, which allows the analysis of the phenomenon at the municipal level (see Table 1).

2.1 What is demanded

Health litigation in Brazil is mainly focused on the provision of curative medical treatments (especially drugs) for individuals (Ferraz, 2011). The first health litigation cases started in the mid-1990’s and were mainly claims for HIV drugs (Scheffer *et al.* 2005).

After 1995, a significant number of new drugs for HIV were developed and proved to

bring a significant increase in patients' life expectancy and an improvement in their quality of life. In that period, the Brazilian policy for HIV included the provision of drugs free of charge, albeit not the then more modern treatments that patients were willing to use in the place of, or in combination with, those already provided. Therefore, some HIV patients went to courts claiming that their right to health was being violated because the treatments available in the public health system were no longer effective for them and thus, they needed the most modern drugs. And because courts were deciding in favour of patients, these first cases were followed by more litigation with the same claim. Cases demanding HIV drugs were predominant during the first years of health litigation in Brazil. For instance, in the Supreme Federal Court, from 1996-2004, one third of healthcare litigation cases were claims for HIV drugs (Wang, 2009). In the state of Rio de Janeiro, from 1991 to 1998, more than 90% of the lawsuits claiming drugs were lodged by HIV patients (Messeder, 2005). As a result, in 2001, 80% of the HIV policy budget was spent to comply with judicial decisions ordering the provision of drugs, mainly those not included in the public health system then for regular provision (Scheffer *et al.* 2005).

The HIV patients' successful litigation in all levels of the judicial branch has become an example for patients suffering from other diseases. Nowadays, the variety of diseases to which treatments are demanded is huge and ranges from very rare diseases (e.g., Gaucher's disease, Duchenne muscular dystrophy, epidermolysis bullosa) to diseases that affect a large sector of the population. Currently, research shows that most lawsuits demand drugs for chronic diseases, such as diabetes, cancer, arthritis, hepatitis C and arterial hypertension, alongside other health problems related to the digestive system and metabolism, the cardiovascular system and the nervous system (See Table 1).

Similar to what happened with litigation for HIV drugs, the main driver of healthcare litigation is the set of new drugs that are not included in the pharmaceutical policy of the public health system. The percentage of cases in which claimants demanded drugs not included in the public health system's pharmaceutical policy is high – 80.6% in the State of Rio de Janeiro, 92.5% in the City of Rio de Janeiro and 66.2% in the Federal District. Other articles, instead of analysing the percentage of lawsuits in which a non-included drug was demanded, assessed the percentage of non-included drugs among all drugs judicially claimed – 66.2% in the State of Santa Catarina; 68% in the City of Florianopolis; 77% and 66.2% in the State of Sao Paulo; and 38% in the City of Sao Paulo (See Table 1).

It is important to highlight the difference between these two methods for calculating

the data. The second method - which counts the number of non-included drugs among all those judicially claimed - underestimates the importance of the claim for new drugs as the main driver of right to health litigation. In many cases, patients demand more than one drug. For example, in the case of the State of Rio de Janeiro (Pepe *et al.*, 2010), it was found that among the drugs judicially claimed, 52% were not included in the pharmaceutical policy. However, when analysing the number of cases in which at least one of these drugs is claimed, the number rises to 80.6%. Sant'Anna (2009) found similar information: 42.6% of the claimed drugs are not included in pharmaceutical policies whereas 81.2% of the lawsuits demand at least one of these drugs. An analogous situation was found in the State of Sao Paulo. Wang, Terrazas & Chieffi (2012) found many cases in which patients were litigating for drugs already provided by the public health system, including very basic, cheap and essential medicines. After analysis, they found that in 87% of them the already included drugs are claimed together with non-included drugs. But why does it happen?

One explanation is that when people go to court to litigate for an expensive medicine, they make the most of their effort and include all the medicines that are in the same medical prescription that contains the expensive drug that is really motivating the litigation (Wang, Terrazas & Chieffi, 2012; Machado, 2010). People would do it because if they have a judicial decision in their favour, they will receive all the drugs altogether and without queue or bureaucracy. The Federal Government, for instance, when complying with a judicial decision, delivers the drug by mail to the patient's house (BRAZIL, 2013). Moreover, patients make sure that their supply will not be interrupted, since health authorities will not stop providing the drugs because disobeying a judicial decision (contempt of court) is a criminal offense in Brazil. Then, in some cases, drugs included in the pharmaceutical policies are "free riders" and are claimed together with drugs not provided by the health system.

It was also noticed that in many cases, patients went to courts claiming drugs that belong to the pharmaceutical policy because they were prescribed for off-label or off-protocol use. Off-label use means the prescription of a drug for unapproved clinical indications or unapproved subpopulations (Stafford, 2008). Off-protocol use means the prescription of drugs that are incorporated in the public health system to patients who do not meet the clinical criteria established by clinical protocols. For instance, Macedo *et al.* (2010: 709) analyzed lawsuits for high cost drugs that are incorporated in the public system and found that in 81.3% of the cases, the clinical guidelines did not recommended their use for claimants' health needs. Similar findings were presented by Machado *et al.* (2011); Wang, Terrazas & Chieffi (2011);

Figuiredo (2010); Messeder *et al.* (2005). This is strong evidence that in the majority of cases in which patients went to courts claiming the supply of drugs already included in the pharmaceutical policy, they were actually claiming the right to receive the drug for off-label or off-protocol use.

There are also a small percentage of litigants claiming drugs that are not registered at the Brazilian National Health Surveillance Agency (ANVISA), the agency responsible for barring unsafe and unproven drugs for use in the country (See Table 1). In cases where courts order the provision of drugs not registered at the ANVISA or authorise off-label and off-protocol use, they are ordering the provision of treatments the effectiveness and safety of which have not been tested or proved.

In these cases, besides the risks for patients, the cost can be very expensive. For example, in the State of Sao Paulo, around £14.6 million was spent to comply with judicial decisions ordering drugs for cancer from 2005 to 2006. However, 17% of this amount was spent on drugs without scientific evidence that they could bring any benefit to patients who were claiming them, either because the drug was not registered at the Brazilian National Health Surveillance Agency (ANVISA) or because it was not recommended for the patients' kind of cancer according to clinical guidelines (Lopes *et al.*, 2010). Similar data was found by Vieira & Zucchi (2007): 3 out of 10 kinds of drugs for cancer provided by the City of Sao Paulo in compliance with judicial orders were not registered at the ANVISA and most of rest lacked evidence of their efficacy for the claimants' cases. It is also important to highlight that drugs for cancer are extremely expensive. In the City of Sao Paulo, just 7.2% of the drugs supplied to comply with judicial order were drugs for cancer, although 75% of the total spent to buy judicially ordered medicines was spent on oncology drugs (Vieira & Zucchi, 2007). Thus, even though drugs for cancer were not so relevant in quantity, they had the most significant impact in terms of budget expenditure with healthcare litigation.

Besides drugs, there are other examples of decisions that ordered the provision of other kinds of treatments without evidence of safety and effectiveness. In the case STA 223, the Supreme Federal Court decided that the health system should pay for a surgery that could only be provided by an American surgeon, who had to be brought to Brazil with all the expenses (flight, hotel and a US \$150,000 treatment) paid for by the State. The surgery was not approved by the American FDA and was never evaluated by the ANVISA. Another example is the case RE 368546, in which the Supreme Federal Court decided that 6 people had the right to receive treatment for pigment rethinosi in Cuba, with all the expenses (flight, hotel, treatment) covered

by the State, in spite of the medical consensus that the treatment for pigment retinosis in Cuba does not work. The Brazilian Ophthalmology Association, the institution that represents ophthalmologists in the country, participated in the judicial procedure and confirmed before the Court that the treatment is ineffective. Nevertheless, the Supreme Federal Court decided that the patients' right to health included the right to receive treatment abroad, even when there is strong evidence that it is ineffective.

The assessment of effectiveness and safety of a treatment is important and should be one of the first things to be taken into consideration when designing healthcare policies. However, there is another aspect that cannot be neglected: the treatments' cost-effectiveness. Even if it is proved that a new treatment is safe and effective, it is important to assess whether it is better than the existing treatments and, if the new treatment is more effective, whether its costs compensate the gains. Ideally, patients should be cared for with the best treatments available, but the scarcity of resources is a ubiquitous reality and should be taken into consideration by those who decide which drugs should be provided to patients.

Ferraz & Vieira (2009) calculated that if the public health system in Brazil decided to supply all hepatitis C and rheumatoid arthritis patients (1% of the population) with the most modern (and expensive) drugs for these diseases, then 4.32% (around £35.8 billion) of the Brazilian GDP would have to be spent on these drugs. This is more than what the federal government, all states and municipalities together spend on healthcare. This means that if no rationing was made in these cases, the health system would have to spend on 1% of the population more than what is spent on the public health system as a whole. The modern drugs for hepatitis C and rheumatoid arthritis – Pegylated Interferon; Infliximab; Etanercepte and Adalimumab – are some of the most judicially claimed drugs and are commonly granted by courts in Brazil.

According to Machado *et al* (2011) and Vieira & Zucchi (2007), among the drugs provided by judicial order that are not included in pharmaceutical policy, between 73% and 80% of them have cheaper alternatives available in the public healthcare system. Similarly to what happened in the case of HIV drugs, patients are demanding modern (and usually more expensive) treatments which are allegedly better than the already provided drugs.

The case of the analogous insulin is another interesting example. Analogous insulin are the most litigated treatment in the state of Sao Paulo and the cities of Sao Paulo and Rio de Janeiro (Afonso & Terrazas, 2011; Wang *et al.* 2011; Figueiredo; 2010; Wang & Ferraz, 2013). The public policy for diabetes offers human insulin to patients, but litigants want to

have free access to so-called analogous insulin, which is much more expensive, but the use of which is more convenient (Siebenhofer, 2009). The Brazilian Ministry of Health has steadily refused to provide the analogous insulin claiming that there is no scientific evidence that it is more effective than human insulin for the control of diabetes (BRAZIL, 2008). Even though it is not explicitly stated, the fact that analogous insulin is much more expensive than the human version is certainly an important reason for not providing what some patients (and their doctors) prefer. Just to give an example of the impact that the substitution of analogous insulin for their human versions would cause, in 2011 approximately 4,8 million vials of NPH insulin (a human insulin) were supplied by the public health system in the state of São Paulo, which total cost was about 15 million *Brazilian Reais* (around £5 million). If the public health system had provided the analogous insulin *glargina* instead of the NPH, the cost would have increased to 936 million *Brazilian Reais* (around £ 300 million), which means that the expenditure would have been 62 times higher³. For most judges, however, if the patient has a prescription for the analogous insulin, then the right to health will trump rationing considerations (Wang *et al.* 2011).

Norheim & Gloppen (2011) evaluated some of the litigated drugs in terms of priority for the population. They calculated the Quality Adjusted Life Years (QALY) for each disease and, based on the country GDP per capita, created thresholds to grade health treatments according to levels of priority for the population. Applying this methodology to a sample of litigated drugs in Brazil, Norheim & Gloppen (2011: 313) concluded that most of them should be classified as having a low priority, since they provide small or marginal health benefits at a high opportunity cost for the healthcare system.

The case STA 558, judged by the Supreme Federal Court, is one extreme example of how expensive a treatment granted judicially can be. Two patients who suffer from a very rare disease - *Epidermolysis bullosa dystrophica* - lodged a lawsuit to oblige the health system to supply them with the treatment that would give them a better quality of life and longer life expectancy. The cost of the treatment for each patient, according to health authorities, was calculated in £360,000 per year. Nevertheless, the Court decided it was the duty of the State to provide the treatment to these patients.

3 This data was calculated and provided by Ana Chieffi, pharmacist of the State of Sao Paulo Secretary of Health.

2.2 *Who demands*

Are these individuals using courts to claim health treatments the worst-off who found in the judiciary an institutional voice for their unaddressed health needs and as a means of putting pressure on sluggish and unresponsive governments and bureaucracy? Or are they the most privileged who have more information and resources to afford the costs of litigation for drugs that their private health insurance does not provide them and that are too expensive for an out-of-pocket payment?

This question is important in a country characterized by huge social inequalities (Brazil still has one of the highest GINI indexes in the world (UNDP, 2010: 27)) and health inequalities, where the poor have a higher probability of being sick and a lower probability of accessing healthcare (Medici, 2011; Piola *et al.*, 2009).

Three papers tried to analyse litigants' income (Biehl *et al.*, 2012; Afonso da Silva & Terrazas, 2012; Wang & Ferraz, 2013⁴). However, the problem with this variable, as stated by all these authors, is the risk that people will under declare their income when responding to surveys. For instance, in the sample analysed by Biehl *et al.* (2012) more than 50% of the litigants declared to have an income of less than one minimum wage. However, only 18% of them declared to be unemployed and the majority of litigants were pensioners. Since no employee or pensioner can legally receive less than a minimum wage in Brazil, there seem to be some inconsistency in these data.

Some researchers have tried to use other proxies for socio-economic condition. They identified the profile of litigants by analysing the type of legal representation (private or public lawyers); source of medical prescription (private or public health unit); and area of residence. The type of legal representation and the source of medical prescription are used as a proxy of social economic conditions, as it is assumed that poor people, in general, cannot afford a private lawyer and all the costs related to litigation; and neither purchase private health insurance or treatment in private health units. These are the most common proxies used to estimate socio-economic condition by researchers because this information is normally available in legal processes.

⁴ This research surveyed only the cases in which patients were represented by public lawyers in the City of Sao Paulo. Therefore, it is not representative of the whole population of litigants.

2.2.1 Legal representation

The data gathered on this variable shows that, with the exception of the City of Rio de Janeiro, the State of Rio de Janeiro and the State of Rio Grande do Sul, most of the litigants are represented by private attorneys (See table 1). For some researchers, this indicates that litigation is driven by people with a privileged background because they can afford private legal representation (Afonso da Silva & Terrazas, 2011; Machado *et al.*, 2010; Vieira & Zucchi, 2007; Chieffi & Barata, 2009).

It is true that we can presume that those represented by public lawyers⁵ are below a certain poverty threshold; otherwise they would not be eligible for free legal aid. It is also true that this threshold may vary according to each state's law on legal aid. For example, in Rio de Janeiro, the threshold is higher and some people who receive free legal aid there would not be eligible for it in other states (Pepe *et al.*, 2010). This can partially explain why Rio Grande do Sul and Rio de Janeiro (both the State and the City), seem to be outliers when it comes to patients' legal representation.

But is it true that those represented by private attorneys are well off? The literature tends to think so, but this idea has to be taken with a pinch of salt (Medeiros *et al.*, 2013). The role of NGOs has also to be considered because some of them may actually help to fund litigation.

Afonso da Silva & Terrazas (2011) assessed the role of NGOs by asking litigants directly whether someone else was paying for their lawyers. They found that more than 20% of litigants received free legal assistance provided by NGOs, which covered all the litigation costs. Interestingly, most of the individuals that affirmed that their demands were filed by an NGO acknowledged either that they do not even know the name of the association, or that, although they knew its name, they did not know where it was located. What is more, those who could not even remember the name of the NGO sponsoring the litigation were claiming drugs for rheumatoid arthritis. The authors suggest that the only answer to this puzzle situation is that the associations are sponsored by pharmaceutical companies that through judicial orders want to compel the public health system to buy their drugs.

Marques & Dallari (2007) analyzed in depth 31 lawsuits that judged the State of Sao

⁵ Public lawyers are public attorneys responsible for representing litigants that declare themselves unable to afford private lawyers and the costs of litigation.

Paulo Court of Appeal and found that almost 24% of them were sponsored by NGOs. Sant'Anna (2009) also analyzed a small number of cases (27) in depth and found that 50% of the patients represented by private lawyers were sponsored by an NGO. Messeder et al. (2005) found that some of the private law firms representing litigants claiming treatments from the public health system have connections with patients' NGOs.

The relationship between the pharmaceutical industry and NGOs that claim to represent patients is well known (Folha de Sao Paulo, 2008; Lopes et al., 2010; Soares & Deprá, 2012). Moreover, suspicious connections between pharmaceutical companies and health litigation are also being investigated by the police. The companies are being investigated for funding individual lawsuits claiming their own drugs as a strategy to defraud public procurements and compel the public health system to buy treatments that are either experimental, not cost-effective or have cheaper alternatives (O Estado de São Paulo, 2008).

Finally, even if an NGO does not directly sponsor litigation, it can promote litigation in other ways. For example, there are NGOs representing diabetes patients, sponsored by pharmaceutical companies, who engage in campaigns to inform patients about the benefits of new kinds of insulin not provided by the public system and about the possibility of having access to these through courts. They also recommend some law firms to patients and, for those who cannot afford a private lawyer, the NGOs suggest that they apply for free legal assistance from public lawyers⁶. Coincidence or not, analogous insulin is the most litigated drug in the State of Sao Paulo and in the cities of Sao Paulo and Rio de Janeiro (See table 1). It is also the most litigated drug by public lawyers in the City of Sao Paulo (Wang & Ferraz, 2011).

Another piece of evidence of the relationship between pharmaceutical companies and health care litigation was raised by Lopes *et al.* (2010). They analyzed 1,220 cases and found that one physician was responsible for 40% of the prescriptions of a certain drug and one lawyer alone was responsible for 70% of the demands for another drug. Moreover, just five attorneys were responsible for most of the lawsuits claiming oncology drugs. They suggest that some physicians and lawyers may be in direct or indirect relationship with pharmaceutical companies (Lopes *et al.*, 2010: 625).

Chieffi & Barata (2010) analyzed 1,309 lawsuits and found a similar phenomenon. They found that 36 lawyers were responsible for 76% of the lawsuits. Among these 36

⁶ This information was given by Adriana Daidone, lawyer and member of two important NGOs that represent diabetes patients in an interview made in her office in July, 2009. The interview was conducted by Octavio Ferraz and myself.

lawyers, 11 of them were responsible for 47% of the cases. For some drugs, more than 70% of the lawsuits claiming them were lodged by the same lawyer. The authors also suggest that these lawyers are working for pharmaceutical companies and using courts to oblige the public health system to buy drugs that are not included in pharmaceutical policies. In one of the most comprehensive studies of the phenomenon in the State of Sao Paulo, Filho *et al.* (2010) analysed 20,000 cases during 5 years and found that just 27 lawyers were responsible for 25% of the lawsuits (5,000 lawsuits).

Medeiros *et al.* (2013) analysed 166 claims for drugs for a rare disease (*Mucopolysaccharidosis*) lodged against the Federal Government. The treatments for these diseases are very expensive: almost R\$220 million (£73 million) was spent to comply with the decisions ordering their provision in these 166 lawsuits. It was found that more than half of the suits were filed by only three lawyers and one single lawyer represented 36% of the patients. Considering the concentration of lawsuits under the representation of a few lawyers, the geographic dispersion of the population that suffers from *Mucopolysaccharidosis*, and the fact that the treatments for this disease is monopolised by a few companies, the authors suggest that there is a network connecting patients and lawyers. They also suggest that this network is probably funded by pharmaceutical industries or the companies that distribute these drugs (Medeiros *et al.*, 2013).

One article published by a weekly magazine in Brazil (Epoca, 2012) illustrates the link between patients, pharmaceutical companies, doctors, lawyers and NGOs. A patient was diagnosed with a very rare disease called *Paroxysmal Nocturnal Haemoglobinuria (PNH)* and there are two types of treatment available: a bone marrow transplant (offered by the public health system) or the drug *Solaris* (which is not registered in Brazil). According to the article, there are *pros* and *cons* for each treatment. However, the difference in cost is striking: the transplant would cost the health system £16,000, whereas the treatment with *Solaris* would cost £266,000 per year for the rest of the patient's life. The patient could have received the transplant free of charge from the health system, but he was encouraged "by many people" to sue the State in order to receive *Solaris* free of charge. He was recommended to a doctor, a specialist in treating PNH with *Solaris*, who explained this drug's benefits and prescribed it. This doctor also recommended to the patient a lawyer who is a specialist in claiming this drug via courts. Interestingly, this doctor did not charge patients any fee. He affirms that he does it "out of scientific interest", in spite of the fact that he is paid by the pharmaceutical company who owns the marketing rights to *Solaris* to "give talks about the drug for other doctors". The

lawyer he recommended to his patient is paid by an NGO that, coincidentally or not, is funded by the same pharmaceutical company.

2.2.2 Source of prescription

In Brazil there is a universal public health system. Nevertheless, a significant part of the population who can afford it pays private health insurance in order to avoid waiting lists and other forms of healthcare rationing, and also because they expect to receive better healthcare quality. In Brazil, there is a clear association between high income and access to private health insurance (Mello *et al*, 2010; FUNDAP-CEBRAP, 2009)⁷.

Why would someone with private health insurance sue the public health system in order to get a drug? The answer is straightforward: most private insurance contracts do not cover the provision of drugs for outpatients. According to a survey led by a think tank in Brazil (FUNDAP-CEBRAP, 2009), only 7% of those insured by private health care are covered with the supply of drugs, which probably also explains the fact that pharmaceutical policy is used by people from high income backgrounds, more than any other public healthcare policy (FUNDAP-CEBRAP, 2009). Hence in most cases, people will have to pay for drugs prescribed by private doctors in spite of having private health insurance. Therefore, if the drug is too expensive (e.g. drugs for cancer) or if they have to be used during long term (e.g. insulin for diabetes), it would be rational to have them provided by the public health system. Therefore, if the public system denies the drug, going to the courts presents itself as an alternative.

The regional variation on this variable is does not allow the drawing of definitive conclusions (see Table 1). In some areas, around at least half of those who receive treatments through courts had their prescription issued by a private health unit. This allows some authors to conclude that the fact that the majority of those who benefited from health litigation have

⁷ It is important to remark that access to private health insurance has been increasing in Brazil recently. This is partially because poverty is decreasing in the country, which allows people to purchase more services such as private health insurance. However, it is also because insurance companies are offering a wide range of cheaper health insurances that are affordable for low-income people but, on the other hand, offer a lower of coverage. It was noticed that people with middle income actually frequently use both public and private health services (FUNDAP-CEBRAP, 2009), which may indicate that for them, public and private systems are complementary. Future research will have to take this element into consideration. Instead of simply differentiating among those with or without health insurance, some index concerning the quality of the health insurance will have to be used.

access to private healthcare, means that litigation benefits “the middle-class and the upper-middle-class above all or, at the most, workers employed in big companies, which usually provide health insurance for their employees” (Afonso da Silva & Terrazas, 2012).

Even though it is reasonable to assume that those who have access to private healthcare probably belong to more privileged sectors of the population, can we assume that those who have prescriptions from public health units belong to the least privileged sector of the population, because they do not have access to private health insurance? The answer is even less conclusive than might have been thought because patients who have private health insurance may have presented a prescription from a public hospital for four main reasons.

Firstly, in some cases, courts ask claimants to present a prescription from a public health unit as a guarantee against fraud. Public lawyers also require patients to present a prescription from a public health unit. Secondly, in terms of litigation strategy, having a prescription from a public health unit is a good argument to use against health authorities’ decisions to deny treatment. In some cases, patients remark on the contradiction between having a prescription from the health system and, at the same time, having the drug denied by the same system. For these two first reasons, even if a patient is not a regular user of the public health system, it is thought a good litigation strategy to go to a public health unit to get the prescription⁸. Thirdly, there are some very expensive and technology-intensive treatments that are not covered by health insurance, such as organ transplantation, dialysis and treatment for cancer, but are covered by the public health system. This means that even people who can afford private insurance may have to use the public health system for some high cost treatment not covered by insurance companies (FUNDAP-CEBRAP, 2009). Finally, experimental treatments and cutting edge technologies in health are usually applied in hospitals associated with public universities, which are centres of excellence and are reference points for both the public and the private healthcare sectors in Brazil. This may explain why a significant number of those who have prescriptions from public units come from university hospitals (Afonso da Silva & Terrazas, 2011; Messeder *et al.*, 2005; Vieira & Zucchi, 2007, Romero, 2008; Biehl *et al.*, 2012; Medeiros *et al.*, 2013).

⁸ It is not uncommon in Brazil that doctors work in the public system and also at private health units or have their own clinics. In this case, patients do not even need to go to a public health unit for a prescription from a public health unit.

2.2.3 Place of residence⁹

At the national level, Ferraz (2011) found a high concentration of lawsuits in states with a better Human Development Index (HDI). The ten states with better HDIs in Brazil constituted 93.3% of the lawsuits at federal level, whereas only 6.7% of the lawsuits came from the seventeen states with a lower HDI. This correlation remains when adjusted for population size (Ferraz, 2011: 88).

At the local level, the data on litigants place of residence is available only for the City of Sao Paulo. Vieira & Zucchi used the Index of Social Exclusion (*Índice de Exclusão Social*) and found that in the city of Sao Paulo, 63% of litigants live in areas with the least social exclusion, namely the best areas of the city. To the authors, that means that litigation is being used by those who are already well-off.

Similar findings were published by Chieffi & Barata (2009). They used the Index of Social Vulnerability for the State of Sao Paulo (*Índice Paulista de Vulnerabilidade Social*). This index ranges from 1 to 6, where “1” is for areas where social vulnerability is the lowest and “6” are areas where social vulnerability is the highest. According to Chieffi & Barata, 74% of the litigants live in areas 1, 2 or 3, which correspond to areas with low levels of social vulnerability. Compared with the distribution of the population as a whole, where 53% of the population lives in these areas, they concluded that well-off people are over-represented in health litigation. They also found that most of the drugs for cancer – the most expensive drugs – are claimed by patients in areas 1 and 2 and that analogous insulin – the most claimed drug – is claimed by patients concentrated in area 2.

Wang & Ferraz (2013) analyzed the cases represented by public defenders in the city of Sao Paulo. Because only those below a certain threshold of poverty are eligible to receive this public service, it was expected that those represented by public defenders would be poor and living in the least privileged areas of the city. They found that, in terms of income, most of them are poor according to the most commonly used threshold of poverty, which is actually lower

9 Even though an area of residence is widely used as a proxy for people’s socio-economic condition, this data has to be taken with a pinch of salt because each area can be internally unequal: well-off people can live in not so good areas and worse-off people may live in privileged areas. However, I consider area of residence a good proxy because people’s quality of life is partially caused by reasons that are geographically determined, for example, access to schools, basic sanitation, healthcare facilities and other public services. In addition, the access to these services, which is geographically distributed, can impact on individuals’ quality of life.

than the one used by the Public Defenders' Office in Sao Paulo to select eligible applicants for legal aid. However, those living in areas where the Human Development Index is low and where the Health Need Index¹⁰ is high, are less than 50% of the litigants represented by public attorneys and people from these areas are also underrepresented when compared with the population of the city as a whole.

At least in the City of Sao Paulo, there is evidence that citizens from the better-off areas of the city are overrepresented among litigants. Similar analysis should be made in other areas, especially those in which most patients are represented by private attorneys and used private healthcare, in order to answer some questions that were left open by the state-of-the art in the research on healthcare litigation in Brazil.

2.3 How courts judge

In Brazil, healthcare litigation cases can be judged by many courts. Each one of the 27 states and the Federal district has a State Court of Appeal (*Tribunal de Justiça*) and hundreds of local-level courts. In the whole country, there are also five Federal Courts of Appeal (*Tribunal Regional Federal*) and hundreds of federal local-level courts. Moreover, there is the Superior Court of Justice and the Supreme Federal Court¹¹.

It would be impossible to undertake such a Herculean piece of research that would entail in analysing every court. It would also be unnecessary since a good amount of data have been produced on this issue. Besides relying on the existing data, I will focus on the Supreme Federal Court (STF) – the last court of appeal and the constitutional court – case-law.

Duran *et al.* (2004) analyzed 144 cases demanding HIV drugs that were not included in public policy for HIV treatment and found that the Sao Paulo State Court of Appeal judged 85% of them in favour of the patient. Moreover, in lower courts, the rate of success is

10 The Health Need Index (Índice de Necessidade em Saúde) was developed in order to identify which areas of the city of Sao Paulo should be prioritized in the distribution of health care services. It is calculated using data related to demographic, epidemiologic and social conditions in each district. The districts are distributed according to the level of their health needs. The higher the HNI, the more urgent are the population health needs (Wang & Ferraz, 2011).

11 For a good description of the Brazilian judicial system in English language see Taylor (2008: ch.2)

absolute: all cases were judged in favour of the patient. The court's predominant view is that the right to health is an individual right and only in a small number of cases did it considered that economic and policy reasons can be used to justify the non-supply of a drug needed by a patient.

Marques & Dallari (2007) analyzed cases judged by lower courts in the State of Sao Paulo and found that patients won in more than 90% of the cases and that in more than 80% of the decisions, the judge affirmed that the patient's right to comprehensive health care should be guaranteed and moreover should not be restricted by budgetary or policy concerns.

Pepe *et al.* (2010) and Santa'Anna (2008) found that, in the State of Rio de Janeiro, the patients won 100% of the cases in lower courts. Santa'Anna (2008) found that patients won all the cases in the Court of Appeal. In the sample analysed by Ventura *et al.* (2010) in the City of Rio de Janeiro, all the claimants had injunctions decided in their favour. At the State of Rio Grande do Sul, in 93% of the cases the claimant had an injunction granted by the court, in 96% of them the final ruling in the lower courts were completely or partially in favour of patients, and 89% of the cases that reached the Rio Grande do Sul Appeal Court were decided in favour of patients (Biehl *et al.*, 2012).

Wang *et al.* (2011) analyzed how 12 courts (Supreme Federal Court, Superior Court of Justice, 5 State Courts of Appeal and 5 Federal Courts of Appeal) judged cases in which analogous insulin was demanded. 502 cases were analysed and it was found that patients won in 88% of them. Furthermore, in 5 courts, the rate of success was 100% and in 2 of them, it was more than 95%. The case of the analogous insulin is especially interesting because, as already discussed, there is scientific debate about the benefits of their use as a substitute for regular insulin. This is an argument used by health authorities in courts to justify the non-provision of the analogous insulin. But in 84% of the cases, courts considered that it is up to patients' doctors, rather than health authorities, to decide which treatment should be given to them. Hence, according to the courts, as long as patients have a prescription affirming that the analogous insulin is necessary, the public health system should provide it. In most cases, courts also considered that the cost of the treatment does not justify the non-provision of a treatment that may protect patients' health and life. Lastly, in many cases, courts have disregarded the "cost of the treatment" argument because, according to the judges, health authorities could not prove that the supply of the insulin to a specific patient would have a significant impact on the public health budget and possibly impair the provision of health services to other citizens.

Similar finding regarding the quality of evidence used by courts was found by Ventura *et*

al. (2010): in 97% of the cases judges decided based solely on the medical information provided by the claimants' doctors and no further evidence regarding the quality of the treatment, the real need of the patient and the alternative treatments.

2.3.1 The Supreme Federal Court (STF) case-law¹²

Supreme Federal Court health care litigation case-law is very similar to the other Brazilian courts in terms of the patients' success ratio. In almost 90% of cases the patient won the treatment claimed before the Court. Among the rest, there are some cases of partial success – treatments were provided under certain conditions, such as the limits established by a clinical guideline – and only 4 cases in which the patient's claim was completely dismissed.

Besides the quantitative analysis, the importance of the STF – which is the last court of appeal and the constitutional court – makes it necessary to carry out a qualitative analysis of its case-law. STF health care litigation case law can be divided into three phases: (1) non-acceptance of healthcare rationing; (2) recognition of the need for rationing, but unwillingness to establish standard criteria; and (3) establishment of criteria to define cases in which rationing decisions should be judicially reviewed.

During the first phase, from 1997 (when the first case was judged) to 2006, the STF judged 31 cases and always decided in favour of the patient. It also refused to admit the need for health-care rationing. The Court constantly reaffirmed that the right to health should not be subject to limits imposed by the scarcity of resources and budgetary constraints. In the first case (PET 1246), in which the claimant suffered from *Duchenne Muscular Dystrophy* and demanded the public health system to pay for an experimental treatment only available in the United States (the costs included transportation, treatment and foreign living expenses), the Court made a statement that was constantly quoted in subsequent decisions by other courts and by the STF itself:

[In choosing] between protecting the inviolability of the right to life, an inalienable Constitutional fundamental right, and a financial and secondary interest of the State, I believe — once this dilemma is established — ethical and legal reasons leave the judge with only one possible option: unwavering respect for life. (PET 1246)

¹² This section reproduces excerpts of an article I published at the *Health Economics, Policy and Law* (see Wang, 2013)

This interpretation of the right to health was reaffirmed in other cases decided during the same period, in which the STF declared that the right to health cannot be subject to limits imposed by the scarcity of resources and budgetary constraints. It said that “limitations of public resources” and “problems with the public budget” cannot restrict the right to health (for instance, RE 195192, RE 198263 and RE 342413). The Court stated that “in such an important topic as health, there is no space for less important debates about legislation or public resources, it is a matter of priority” (RE 198263).

The second phase started in February 2007, when the STF judged the first two cases in which it upheld the government’s decision not to fund a treatment – STA 91 and SS 3073 (the patients were suffering from chronic renal disease and cancer, respectively). In both cases, the Court recognized that the public health system should be managed so as to “rationalize the cost-benefit of the treatments that will be offered free of charge to the population, in order to benefit as many people as possible” and that the right to health should be “concerned about public policies that will affect the population as a whole and not individual cases”. The Court also gave the power to set priorities in healthcare allocation back to the health authorities, stating that the public health system should only be obliged to supply medicines already included in its pharmaceutical policy. It seemed that the Court was making a U-turn and reversing the opinion presented in previous cases.

However, in subsequent cases, the STF has retreated from its more deferential stance to governmental policy choices and returned to an approach that has focused on the specific needs of the applicant patient rather than on public policy concerns. Neither the decision, nor the arguments and criteria have been the same. There has been no reference to previous arguments that affirmed that the right to health should be concerned with the population as a whole and not with individual cases. In some cases - SS 3205, SS 3158, SS 3429, SS 3452, STA 181 - the Court has even ordered the health system to provide medicines that were not included in pharmaceutical policy, thus violating the criteria it had itself established. From 2007 until 2009, besides STA 91 and SS 3073, two more rationing decisions were upheld by the Supreme Federal Court: SS 3263 and STA 185. In both cases, patients were claiming non-life-saving treatments: drugs for female infertility and sex reassignment surgery respectively.

In sum, during this second phase, although the need to set criteria for restricting the judicial intervention in reviewing rationing decisions was recognized, the court was still going back and forth between recognizing an unlimited individual right to health and admitting that resources are scarce and hence priorities should be set.

In April and May 2009, the STF held a public hearing with public health experts, public

authorities, legal scholars, representatives of legal professions, and civil society to discuss the health care litigation phenomenon. According to the then President of the Court, the aim of this was to supply the STF with “technical, administrative, scientific, political and economic” information in order to help the Court judge these cases (Mendes, 2009).

In March 2010, based on the information gathered in this public hearing, the STF judged several cases in which it established guidelines defining those treatments citizens can demand from the public health system. This inaugurates what I am calling here the third phase in the STF health care litigation case law. The Supreme Federal Court stated that the health system cannot supply all the treatments patients demand and that priorities in health care should be set, especially to avoid forcing the provision of drugs the evidence of which is not proven (see section 3.1.1). However, even after the public hearing and establishment of the criteria, the STF was still unwilling to show restraint and follow the criteria formerly established to judge health litigation cases. The scarcity of resources and the lack of scientific evidence were not acceptable reasons to deny healthcare.

It is also worth mentioning again and quoting the case RE 368546, in which the government was obliged to provide treatment for pigment rethinosi in Cuba for 6 people despite scientific consensus that it is ineffective. One of the Justices (Marco Aurelio) undermined the extensive evidence against the effectiveness of the treatment and the objections against its high costs for the public health budget by affirming that:

I cannot accept that the lack of economic resources can be articulated to deny health care for a citizen (...) according to what I read in the media, the successful treatment to this disease is indeed in Cuba.

Similarly, another Justice (Luiz Fux) reasoned that

I am very determined when it comes to hope. I never believed in the version that the pigment rethinosi could not be cured in Cuba. Quite the opposite, I think that they [Cubans] are specialists in this area and there should be hope concerning the cure.

Thus, after almost 15 years going back and forth in trying to establish criteria for the judicial review of rationing decisions, and in spite of the public hearing held by the court, the interpretation that the right to health entitles patients to receive any health treatment they need, because people’s health and life trump “financial and secondary interests of the State”, is still an approach that is prevalent within Brazil’s highest court.

2.3.2 Collective claims

Even though health care litigation in Brazil is mainly driven by individual lawsuits, there are also cases of collective claims, normally demanding access to drugs not regularly provided by the public health system¹³ to a group of identified patients or to all patients in a given jurisdiction (which can be a city, a state, the Federal District or the Federal Government). The former are very similar to individual lawsuits and the only difference is that there is more than one claimant. Courts decide these cases in the same way as they decide individual claims. The latter lawsuits, on the other hand, raise different issues because they are more structural in the sense that they are not a dispute between two parties and may cause far-reaching reform that aims at affecting a multiplicity of parties (Fiss, 1982: 123). These are the cases that will be analysed in this section.

I decided to analyse the cases demanding structural enforcement separately due to their small number and also because of the way courts judge these cases. The same courts that show almost no restraint in reviewing rationing decision in individual cases are reluctant to decide in favour of claimants when the claim is collective. The rate of success in collective claims is much lower than in individual ones (Hoffman & Bentes, 2010: 224-225; Wang & Ferraz, 2013; Wang et al., 2011).

As already shown, in individual cases courts tend to ignore the economic impact of the decisions on the public health budget, the impact of the expenditure to comply with judicial decisions on the other users of the public health system, the need of health authorities in terms of setting priorities in health expenditure, and the capacity and legitimacy of courts to assess scientific data and to make allocative decision. Conversely, in collective claims all these elements are considered by courts to justify their deference to a rationing decision made by health authorities (Hoffman & Bentes, 2010: 224-225; Wang et al., 2011).

As shown by Wang et al. (2011), some of the same courts that grant access to analogous insulin to practically any patient who goes individually to claim them because they have the right to health, turn down claims for the incorporation of these insulin among the treatments that are regularly provided by the public health system. Courts tend to argue that resources are scarce and courts are not in the best position to second-guess the decisions made by health authorities.

¹³ There are also lawsuits requiring the improvement of health facilities (see Wang & Ferraz, 2013).

Two recent decisions by the Supreme Federal Court (STF) make clear the preference for adjudicating the right to health individually rather than collectively: SL 256 and STA 424. The latter involved a request for universal provision of three medicines (not incorporated in the public health system) for treating *microcephalia*. The former was a complaint to oblige the public health care system to pay the transport, food and accommodation costs of any patient of the city of *Araguaína* who needed to receive treatment in another city. The STF rejected both claims, arguing that the judiciary should not require health care authorities to fulfill duties that are overly ‘general’, because this may unduly affect the public budget and would be an ‘obstacle to the adequate provision of public services by the Public Administration’. In these cases, the Court argued that a judicial decision cannot order the health care system to provide the treatments requested to all patients who need them because it would “impair the regular functioning of health system administration, reduce efficiency in patient care and limit the available resources”.

Nonetheless, both decisions emphasized that the drugs, in one case, and the transport, food and accommodation, in the other, must be provided if the need is proved individually. In the case SL 256, apart from the general demand for the health care system to pay for the transport, food and accommodation for all citizens of *Araguaína*, there was also a request for the provision of these services to particular individuals, which was granted by the Court.

The fact that courts decide individual and collective cases differently can be explained by the fact that in individual lawsuits there is the impression that an individual decision has no potential to cause much impact, whereas a collective claim can have large-scale policy implications (Landau, 2012). This impression is false because the aggregate effect of individual lawsuits can be enormous, as will be shown in the next section.

2.4. *Economic impact*

Health litigation has been growing steadily in Brazil in recent years, as well as the economic impact of the decisions on the public health budget. At the federal level, the Ministry of Health expenditure to comply with judicial decisions ordering the supply of health treatments increased from R\$ 2.5 million (£830 thousand) in 2005 to R\$ 266 million (£86 million) in 2010: a solid 10,540% increase in six years. The aggregate expenditure by the Federal Government

from 2003-2011 was *circa* R\$ 588 million (£196 million), 85% of which was spent in 2009-2011 (the figures were calculated by using the data provided by the Ministry of Health, see BRAZIL, 2013). The impact of a few very expensive drugs is also noteworthy: in 2011, the amount spent with the 20 most expensive drugs, that were claimed by 632 patients (0,05% of the total of litigants in that year), represented 78% of the total spent by the Ministry of Health to purchase drugs in compliance with judicial orders. Ferraz (2011: 81) found that the amount spent by the Federal Government with these drugs in 2009 was equivalent to 0.4% of the Ministry of Health total budget and 4% of its budget for drugs. This figure is certainly higher now given the increase in the amount spent to comply with judicial decisions.

At sub-federal level – states and municipalities – the sheer scale of the impact of health care litigation is also impressive. The State of Minas Gerais had a massive increase in expenditure to comply with health litigation decisions. The amount increased from R\$ 8.5 million in 2002 (£2.8 million) to R\$ 42.5 million (around £14 million) in 2008 and R\$ 61.5 million (£20.5 million) in 2010 (Machado *et al.*, 2011; Castro, 2011).

The State of Sao Paulo spent R\$400 million (£133 million) in 2008, R\$512.5 million (£170.8 million) in 2009, and R\$ 700 million (£233.3 million) in 2010 (Filho *et al.*, 2010; Epoca, 2012; BRAZIL, 2013). The number of drugs the supply of which was ordered by judicial decision increased from 799 in 2005 to 14,563 in 2010: a 1,722.65% increase in 5 years (Filho *et al.*, 2010). Filho *et al.* (2010) found that the State of Sao Paulo spends 4.5 times more to comply with judicial decisions than on hospitalization for organ transplantation. The total amount is also equivalent to 90% of what was spent with 123 million clinical diagnoses made by the public health system in the whole State of Sao Paulo; 28% more than what is spent on dialysis; and 29% more than what is spent on chemotherapy and radiotherapy. The most recent data indicate that the amount spent by the State of Sao Paulo on health care litigation in 2010 represents almost 50% of the whole budget for the pharmaceutical policy (Epoca, 2012). Currently, there are 25,000 patients receiving drugs through litigation whereas the population of the State is more than 41 million (Epoca, 2012). In other words, 0.0006% of the population is using the equivalent almost 50% of what is available to provide drugs the rest of the people in the State of Sao Paulo.

In the State of Santa Catarina, the amount spent increased from R\$ 38,362.07 (£12,700) in 2001 to R\$ 6,510,045.48 (around £2.2 million) in 2004 (Pereira *et al.* 2010) and, according to more recent data, R\$ 93 million (£31 million) were spent in 2010 (CNJ, 2011). Another interesting finding in the State of Santa Catarina is that the drugs claimed through courts are getting more and

more expensive. In 2001, the average cost per drug was R\$ 2,019.06 (£673), whereas in 2004, it increased to R\$ 8,157.95 (£2,719). That means that not only are more drugs being litigated for, but also that more expensive drugs are being claimed through litigation (Pereira *et al.*, 2010).

At the Federal District, according to Santos (2006: 13), the number of lawsuits demanding health care increased from 281 in 2003 to 682 in 2007. The amount spent on drugs the supply of which was demanded by the Court is equivalent to 70% of the budget for essential drugs and 34% of the budget for high cost drugs which are included in the pharmaceutical policy. The number of lawsuit in the State of Rio Grande do Sul increased from 1,126 in 2002 to 17,025 in 2009 (a 1,412% increase) (Biehl *et al.*, 2012). The amount spent by State of Rio Grande do Sul with health treatments ordered by courts in 2008 represented 22% of the total amount spent by the State on pharmaceutical drugs and 4% of the state's projected health budget for that year (Biehl *et al.*, 2009).

At municipal level, the increase in litigation and its costs are also relevant. In the city of Florianopolis, there was a 3944% increase in expenditure with drugs ordered by judicial decision: from R\$3,398.96 (£1,130) in 2003 to R\$137,429.05 (£45.6 thousand) in 2006 (Leite *et al.*, 2009). In the City of Sao Paulo it was estimated that the amount to comply with health litigation decisions in 2011 was around R\$ 8.9 million (around £3 million). This amount represented 10% of city's budget for the pharmaceutical policy in that year (Wang *et al.*, 2011). In cities with smaller budgets, the impact of health care litigation can be even more dramatic. For example, in *Buritana*, a small city of 15,000 inhabitants, more than 50% of the budget for drugs was spent providing treatment ordered by the courts and one single patient won in court the right to receive a treatment that will cost the municipality 16% of its entire budget for drugs (Epoca, 2012).

In 2009, a survey sent by email and post to all the 5,564 Brazilian cities tried to measure the impact of health litigation at municipal level. 24% (1,276) of the cities answered the survey. It was asked whether there was an increase in health care litigation and in the economic impact of the phenomenon on their budgets. The result was that more than 50% of the cities affirmed that they were facing an increase in health care litigation cases. One third of the respondents affirmed that health litigation was an "important problem" for them. Respondents were also expected to provide information concerning the number of lawsuits they had to respond to and the amount of money that was spent to comply with cases decided in favour of patients. The result was that the number of lawsuits and the amount spent to comply with decisions in the 1st semester of 2009 had already outpaced the total amount in 2007 and also not far from the total in 2008 (Ferraz, 2011).

Even though there has never been an attempt to measure the economic impact of the health care litigation phenomenon in the whole country, the Ministry of Health calculated, based only on the data provided by the Federal Government plus nine states (which means that the expenditure in 17 states, the Federal District, and 5,500 municipalities were not included), that the amount spent in 2010 was approximately R\$950 million (£316 million). Because of the missing data, this figure is seriously underestimated. Nonetheless, it represents one-seventh of the whole national budget for the pharmaceutical policy in that year (BRAZIL, 2013).

3 Responses to the problem and the problems in the responses

Health care litigation consumes a significant, and increasingly large, amount of the public health budget, which is spent to provide treatments without a proper appraisal of their safety, effectiveness, cost-effectiveness or their priority regarding the population's health needs. Courts are also distributing health care without concerns of distributive justice, since resources are allocated according to the capacity to litigate, and creates a potentially unsustainable situation for the public health system. Therefore, it is necessary to change this pattern of case law and, in this section, I analyse the most comprehensive proposals that were put forward aimed at doing so.

They come from the highest institutions of the judicial branch – the Supreme Federal Court (STF) and the National Council of Justice (CNJ) – and from federal legislation – the Federal Law 12.401/11. All these proposals have in common the fact that they try to establish a sphere of judicial restraint, in which courts should defer to the decisions made by health authorities. Thus, they try to oppose the Brazilian courts' prevailing interpretation that there is an individual right to receive health care that cannot be restricted by health authorities' priority setting decisions or the lack of scientific evidence. These proposals reaffirm the idea that health authorities are the primary decision-makers regarding the provision of health care, and that they are only obliged, *prima facie*, to provide the treatments that are already incorporated by the public health system.

However, they disagree on what courts should do when there are claims for drugs not incorporated in the public health system's pharmaceutical policies. And this is a central issue since, as discussed in section 2, these claims are the main drivers of health care litigation in Brazil.

3.1 Self-restraint and institutional capacity: responses from the Judicial branch

Concerns about courts' lack of institutional capacity and the limits of the adjudicative process are some of the most common critiques against courts deciding on the provision of social policies. Judges, according to this argument, have no knowledge and neither the expertise, qualification or experience to decide on multifaceted issues of policies, especially those involving the allocation of scarce resources. They are trained in law and legal process, and this is their field of expertise. Besides the problem with judges' expertise, qualification or experience, the adjudicative process itself may also add some obstacles. The judicial process is not suitable to deal with polycentric problems because it "cannot encompass and take into account the complex results" that may arise from a judicial decision that, in practice, will probably "involve many affected parties and a somewhat fluid state of affairs" (Fuller, 1978: 394). The adversarial model of adjudication reduces problems that affect an enormous number of people to bilateral disputes and is poorly prepared to gather and analyses complex social data. Courts will know a lot about a case, but little about its milieu and will not be able to see the trade-off problems that they are dealing with, such as the competition for budgetary resources or political follow-through (Horowitz, 1982: 137). Moreover, there is the problem of representativeness, "since courts do not choose their cases, but instead cases choose their courts" (Horowitz, 1982: 136).

On the other hand, those who advocate for a more active role of courts in social rights adjudication affirm that courts, when protecting civil and political rights, also deal with complex issues that may be very similar to those raised by social rights adjudication. Thus, the judicial protection of social rights creates challenges for courts that are not so different from those they commonly face (Langford, 2008). Furthermore, judges can be provided with relevant information by the parties, their lawyers, witnesses and court appointed individual experts and bodies (Nolan at al., 2007: 14-15). Some individual judges can also specialize in social rights adjudication through experience and legal education, in the same way that they specialize in other different fields of law (Nolan at al., 2007: 15). Finally, the judicial process can be made more participatory – open to *amici curiae* and public hearing – to enable courts to deal with the complex issues brought before them in cases involving social rights (Mantouvalou, 2010; Gargarella, 2011).

The responses to healthcare litigation advanced by the Supreme Federal Court (STF)

and the National Council of Justice (CNJ) are inserted into this debate about the capacity of courts and the adjudicative process to decide properly on the provision of welfare policies. Both institutions recognize that courts have institutional limitations and therefore can only be secondary decision-makers on the issue of health care provision, but, at the same time, they try to overcome these limitations in order to give to courts a prominent role in the judicial review of rationing decisions on a case-by-case basis.

The responses advanced by the STF and the CNJ can be better understood as complementary parts of the same policy engaged with healthcare litigation. This is not surprising since there is a strong connection between both institutions. The CNJ is a formally autonomous institution, but it is expected that the STF, especially its president, will have a significant influence on the CNJ. According to the Article 103-B of the Federal Constitution, the presidency of the CNJ, which has a great deal of responsibility in setting the institution's agenda, will be chaired by the president of the STF. Moreover the STF has the prerogative to appoint other two members of the CNJ. The affinity between the recommendations of the CNJ and the decisions of the STF will be made clearer in the next sections.

3.1.1 The Supreme Federal Court (STF): public hearing and self-restraint¹⁴

The Supreme Federal Court is the last court of appeal in the Brazilian judiciary and the constitutional court. It promoted a public hearing in 2009 with health experts, public authorities, academics, lawyers and civil society gathered to supply the Court with “technical, scientific, administrative, political and economic” information regarding healthcare litigation cases (Mendes, 2009). In total, 50 specialists were heard by the STF.

The public hearing was motivated by acknowledgment that the healthcare litigation were having a significant impact on the public health system and that the court needed support from different specialists and stakeholders in order to make better decisions (Mendes, 2009). Justice Gilmar Mendes, the then president of the STF, held the public hearing and declared in his opening speech that “either the idea that courts should have no role on health care issues or that there is a right to any health treatment is untenable” and that a balanced view should be

14 This section reproduces excerpts of an article I published at the Health Economics, Policy and Law (see Wang, 2013)

found, taking into consideration “all the judicial decisions’ implications without compromising (...) the right to health” (Mendes, 2009: 9). Lastly, he affirmed that he expected the “public hearing would result not only in technical information conducive to assisting in the court’s analysis of the cases, but also in support for a broader and pluralist debate for the improvement of health policies” (Mendes, 2009: 10).

Accordingly, if public health policy is a complex issue in which judges are not knowledgeable and the adjudicative process is unable to grasp all its complexity, then a participative and plural forum with specialists and stakeholders is arguably a sound alternative to compensate for the court’s lack of institutional capacity and the narrow limits of adjudication.

Moreover, initiatives like the public hearing can be seen by those who advocate for a more active role for courts not only as a device to defend them against critiques concerning their institutional capacity and legitimacy, but also as a tool for helping courts to implement their potential for enhancing democracy and participation. According to this argument, there is an expectation that courts can be a forum to ensure that norms are created and applied through a deliberative process or, in other words, a “collective and inclusive discussion” (see Gargarella, 2011: 237-238 and also Nolan, 2011: 194-195). Courts can fulfil this task, for instance, by promoting open discussion about the solution to rights violation via public hearings. The public hearing on health care litigation organized by the Brazilian Supreme Federal Court was praised by analysts as a good example of what courts should do in regard to the protection of the right to health (Gargarella, 2011: 237; Nolan, 2011: 195).

In this subsection, I will not discuss whether the expectation that courts can create collective and inclusive discussion is sound and neither will I look here at whether the public hearing is conducive to reach this goal. I will just analyse the only direct consequence of the public hearing for the Supreme Federal Court itself: the establishment of some criteria to guide the court in cases involving health care litigation. Based on the conclusions drawn from the information presented by the speakers in this public hearing, in March of 2010 the STF judged nine cases and established guidelines defining those duties citizens can immediately demand from the public health system¹⁵. The same criteria were reaffirmed in further decisions¹⁶.

In these cases, the Supreme Federal Court stated that, even though the health system cannot supply all treatments patients demand and that priorities in health care should be set,

15 STA 175, STA 211, STA 278, SS 3724, SS 2944, SS 2361, SS 3345, SS 3355 and SL 47.

16 STA 260, STA 283, STA 424, STA 434, SL 256, SS 3941, SS 4045, SS 3962, SS 3852 and SS 3989.

courts have the power to oblige the public health system to offer a treatment needed by the patient but denied by the government if:

- 1) It has its safety, efficiency and quality recognized by the Brazilian National Health Surveillance Agency (ANVISA), which excludes experimental treatments.
- 3) It is already included in the public health policies, which means included in the public health system – the National Health System (SUS) – official list of medicines and treatments and recommended by clinical guidelines.
- 4) In the case the petitioner claims for a treatment not included in the public health system (SUS), she has to prove that (A) no treatment is offered; or (B) the treatments already offered are not appropriate to her; and
- 5) The non-included treatment has to be successfully used “for a long time” by patients who can afford it but its inclusion in the official lists and clinical guidelines by the health bureaucracy is “very slow”.

The Chart below, based on the criteria set by the STF in these decisions, illustrates the way they are expected to be applied in health care litigation cases.

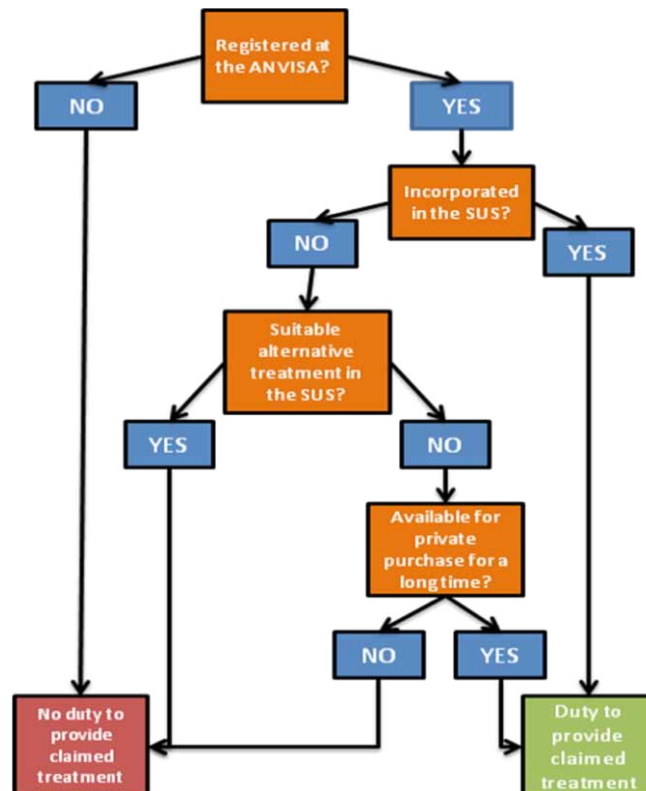


Chart 1

The STF, therefore, admitted that the public health system has to set priorities in the allocation of scarce resources and, thus, not all claimed treatments can be offered by the public health system. This may seem a trivial statement of what is widely recognized elsewhere (even in the most developed countries), namely that no health system can afford to offer all health treatments to all health needs for every citizen. But, as already discussed, this statement has not been widely accepted by courts in Brazil, not even the Supreme Federal Court itself.

The first criterion established by the court is hard to disagree with: the public health system should not be obliged to supply medicines that are not registered by the National Health Surveillance Agency (ANVISA), i.e., treatments whose efficiency and safety are not scientifically demonstrated.

The STF also established that the government cannot deny citizens treatments already incorporated in the public health system. Hence, once a drug or treatment is included in the official list of treatments or recommended by clinical and therapeutic protocols, its provision by the State becomes a legal entitlement for citizens. According to the Court, judgments ordering the provision of treatments in these cases are more legitimate because they are not setting priorities for health care allocation in place of health authorities. Rather, courts are simply enforcing a policy established by the public health system itself.

The problem with this criterion is that it does not consider cases in which the treatment offered by the public health system cannot be provided in quantities that ensure universal provision. In these cases, health systems must ration, not by excluding the treatment or medicine from the range of treatments it offers, but by either selecting beneficiaries according to their clinical characteristics or establishing waiting lists (Syrett, 2007: 46-50). Thus, that a treatment is included in the official list or recommended by clinical and therapeutic protocols does not always preclude the need for rationing. If courts consider that the access to a treatment incorporated in the public healthcare system is always judicially enforceable, they may be simply allowing litigants to “jump the queue” in the access to health care.

In the cases when the treatment was not incorporated, the STF suggests that the court should check whether there is an effective alternative treatment provided by the public health system. If not, and the claimed treatment has been available for private purchase and used by patients who can afford it, then its provision should be judicially ordered.

It was not said, however, how the court will assess whether the alternative treatment offered by the public health system is an effective alternative, especially when there is scientific disagreement on this issue. It is not clear either if the alternative offered by the public health

system has to be only effective for the patient's health problem or, at least, as effective as the claimed treatment. A new treatment may be marginally better than the already provided one, but at a much higher cost. The decision about whether a new treatment that is more effective but more expensive should be provided in the place of another that is less effective but cheaper (in other words, if an increase in price is justified by the improvement in effectiveness) is one of the main concerns of health economists and one of the biggest challenges for health systems around the world (see Schmidt & Kreis, 2009; Sorenson & Chalkidou, 2012).

Even though the STF was not clear about what an "adequate alternative" means, the criterion that allows the court to oblige the supply of a treatment for no reason other than that it has been available for private purchase for a long time (although not specified how long) is also deeply problematic because it rules out cost-effectiveness analysis and policy considerations in deciding on the provision of health care. The fact that a drug is available for private purchase means only that it is efficient and not harmful (according to the National Health Surveillance Agency – ANVISA), but says nothing about its cost-effectiveness, level of priority and affordability for the public health system.

New technologies can be effective and safe, but can also be extremely expensive (especially when protected by intellectual property rights that grant pharmaceutical companies monopolies, effectively ruling out the possibility of cheaper alternatives) and increase the costs of health care, which makes rationing and priority setting even more necessary. The provision of all new existing health technologies is not only unfeasible, but may also make the public health system inefficient because a huge amount of resources may be used to produce marginal health benefits for the population. In this case, the opportunity costs can be very high, which is unfair with those who may have been potentially benefited by the alternative use of the resources.

In conclusion, the criteria established by the STF still allow the adjudication of the right to health as an individual right and ignores issues that should be central in any health policy: opportunity costs, cost-effectiveness analysis, priority setting, robust scientific evidence and reasonable principles of distributive justice. As Daniel Callahan affirmed (2011: 172-174), thinking about medical care in terms of a set of individual rights to benefits rather than from the perspective of a societal good rules out from the start the possibility of choosing the treatments that will do the most good from a population perspective and thus makes the control of costs in health care impossible. I would also add that it precludes any debate about the fairest way to distribute health care resources.

3.1.2 The National Council of Justice: building courts' institutional capacity

The National Council of Justice (CNJ) is an agency created in 2009. It is composed of 15 members, most of them judges, and the presidency is chaired by the Justice President of the Supreme Federal Court (STF). According to the Federal Constitution, the CNJ is part of the Brazilian Judicial branch, but has no judicial power and cannot review judicial decisions. It is responsible for regulating the administrative and financial activities of the judiciary and the enforcement of judges' professional duties. It can issue resolutions and recommendations for courts in order to improve their functioning in terms of strategic planning and administration. The CNJ's recommendations, as the name says, are not binding on courts.

The CNJ issued Recommendation 31/2010 proposing some policies to control the effects of health care litigation in Brazil. The proposals reinforce and complement what was already put forward by the STF and are, according to the Recommendation itself, derived from the public hearing promoted by the STF. For the reasons already presented, the affinity between the CNJ and the STF was to be expected. The President of the CNJ at the time when the Recommendation 31/2010 was issued, Justice Gilmar Mendes, was also the President of the STF who organized the public hearing on right to health and the Justice who wrote the decisions in which the criteria mentioned in the subsection above were established.

Recommendation 31/2010 "recommends to courts the implementation of measures aiming at supporting judges and other legal professionals, in order to assure better solution for the judicial claims regarding healthcare". The document affirmed that some of the main problems regarding health care litigation in Brazil were (1) the lack of clinical information available to judges concerning these cases and (2) the claim for drugs not approved by the National Health Surveillance Agency (ANVISA). The Recommendation also stated that the health authority's managerial capacity, the already existing public policies, the organization of the public health system, and the need to guarantee the sustainability and manageability of the National Health System have all to be respected and taken into consideration by courts.

Therefore, the CNJ recommended that the Brazilian courts should:

- a) Make technical support from doctors and pharmacists available to assist judges in assessing the clinical evidence presented by the litigants in healthcare related cases;
- b) Advise judges to, among other things, analyze the cases based on complete and comprehensive information; avoid the provision of drugs not registered at the ANVISA

or experimental drugs; and consult, whenever it is possible, health authorities before an interim decision be made;

- c) Include medical law legislation as a subject to be examined in the public entrance exams for judges;
- d) Promote tours that will take judges to visit public health units.

Recommendation 31/2010 also recommended that the schools responsible for preparing those admitted in the public entrance exams to become judges¹⁷ should include Health Law (Medical Law) in their curricula. These schools should also organize seminars with judges, public prosecutors and health authorities in order to promote common views in the field.

The CNJ's recommendation tries firstly to establish a sphere of deference by reinforcing the idea formerly established by the Supreme Federal Court that courts should consider the choices made by health authorities and "avoid" the judicial provision of treatments not registered by the ANVISA. The CNJ also added that judges should be better informed about the claims and consult health authorities "whenever it is possible" before making an interim decision so as to filter out claims for treatments based on insufficient evidence about their safety or effectiveness.

The CNJ, however, innovated in trying to build courts' institutional capacity to decide on the provision of health treatments¹⁸. It emphasized that judges need to be better trained and more knowledgeable about the legislation concerning health care, the functioning of the health care system and public health related issues. It is not clear, however, what is intended with the attempt to make judges more knowledgeable in these topics. Better training and more knowledge are certainly good in themselves, but how can they impact on health care litigation? Two answers present themselves.

Firstly, judges who know more about the health care system would be more deferential to the health system's rationing decisions. They will understand, for instance, that the public health system has to make "tragic choices" (Calabresi & Bobbit, 1978), there are opportunity costs, rationing is necessary, and decisions on the provision of healthcare are normally not arbitrarily made. This interpretation would be harmonic with the suggestion brought by Recommendation 31/2010 that courts should consider health authority's managerial capacity,

¹⁷ In Brazil, lower level courts' judges are chosen via public entrance exams.

¹⁸ Some courts have already implemented some of the recommendations made by the CNJ. The Courts of Appeal in the States of Rio de Janeiro and Rio Grande do Sul created "technical support services" composed by doctors, nurses, pharmacists and nutritionists to advise judges in health care litigation cases (Valor Economico, 2010).

the already existing public policies, the organization of the public health system and the need to guarantee its sustainability and manageability. Thus, making courts more knowledgeable about the public health system and public health issues will give them a broader perspective to the problem than one that is narrowed to their decision on a claim for the fulfilment of an individual need. Therefore, that would avoid the prevalent interpretation that the right to health means that whenever there is a health need, there is an individual right to receive health care irrespective of the costs.

The other alternative is that better trained judges can make good substantial decisions since they are more capable of second-guessing health authorities' decisions concerning the provision of health treatments. Given that the CNJ's recommendation was created in the same context of the STF public hearing, this interpretation is probably sound. According to the criteria established by the STF, courts can always order the provision of treatments incorporated in the public health system's policies and, when there is evidence that the patient needs the claimed treatment and no effective alternative is offered, non-incorporated drugs can also be provided via judicial order.

Thus, the effort to train judges in health law and health related issues may be an attempt to provide them with information and expertise to decide if the alternative treatment offered by the public health system is effective or if the patient really needs the treatment available in the private market but not provided by the public health system. By the same token, the recommendation to make technical support from doctors and pharmacists available to assist judges in health care litigation cases has the same purpose of helping them to identify when there is actually an unfulfilled health need.

This is an argument commonly raised by scholars who advocate that courts are capable to adjudicate social rights. If, generally speaking, what impairs courts from dealing with factual problems is the judges' lack of training and the absence of a dedicated staff to acquire and evaluate factual information (Yowell, 2012), then the proposals advanced by the CNJ to build institutional capacity seem plausible: train judges and surround them with doctors and pharmacists who can provide technical advice. As Nolan, Porter & Langford (2007: 15) put it:

If the courts are considered capable of evaluating and drawing conclusions on the basis of complex technical and medical evidence in, for example, a criminal or tort law context, then there can be no presumption that they are unable to do so in a social and economic rights context.

However, I argue that it is not a good policy to expect better trained judges, surrounded by doctors and pharmacists, to be able to make scientifically sound decisions and thus avoid some of the problems caused by the complex issues regarding health care litigation.

Even if we try to reduce claims to healthcare to a mere medical/scientific issue, it would be unrealistic to expect that a group of doctors and pharmacists will have the needed diversification of expertise to be able to make a comprehensive scientific assessment of the effectiveness of all treatments that are being litigated for. This task is even more daunting considering that the main driver of litigation is a wide array of new medical technologies for a huge diversity of health problems. These new treatments' effectiveness and safety may still be controversial in the scientific literature and the amount of information may be insufficient to draw safe conclusions. There are also epistemological concerns that could be raised. How are these health professionals going to make the assessments? Based on which methodology and data? What are their qualifications and what kind of conflict of interests might they have? What are the risks of courts misrepresenting or misunderstanding the research results? How will courts balance evidence pointing to different conclusions?

The already mentioned example of the litigation for analogous insulin can illustrate this problem. The Brazilian public health system provides regular insulin for the treatment of diabetes, but patients go to courts claiming the provision of analogous insulin because they allegedly reduce the cases of hypoglycemia, a side-effect caused by the treatment with insulin. There is an enormous scientific controversy on whether analogous insulin reduces the cases of hypoglycemia when compared with the regular version. A research analysing how courts deal with this scientific uncertainty showed that, in some cases, judges require assistance from an expert doctor to decide whether the analogous insulin should be provided. The result is that the scientific controversy is reflected in the different answers given by the experts: some say the analogous insulin should be provided and others that it should not because it is not better than regular insulin (Wang et al., 2011). Thus, when courts require the support of an external expert, there is an "expert lottery" and the access to the analogous insulin through courts may depend on the expert to which the case is sent for analysis.

Nonetheless, let's assume for the sake of the argument, that courts manage to create a system that is good enough to assess health technologies' effectiveness and safety and health professionals working for the court are able to decide grounded on good scientific evidence about the treatment. That will still not solve all the problems caused by health care litigation because the provision of health care in the public health system is not merely a medical problem

that science can solve. It is also a matter of public policy. Doctors and pharmacists will not be able to conduct research about cost-effectiveness, its affordability given the budget made available for health care, the opportunity costs of providing the claimed treatment, its level of priority regarding the other health needs of the population, the expected impact on public health, and the opinion of other stakeholders.

Even if we add health economists to the group of legal experts to produce cost-effectiveness analysis of the claimed treatments, it would still be naïve to expect that their decision would give a ready-made answer to whether or not a treatment should be provided. Priority setting involves problems of social fact (e.g. how a certain disease affects the population's health), polycentricity (e.g. the socio-economic effects of providing a given treatment on the public health system) and morality (how to distribute health care fairly given that we cannot give everything to all) that cannot be reduced to a technical decision that can be objectively made by a body of experts attached to courts.

Decisions on public policies have to rely on scientists and social scientists, but it is also an issue that is inescapably speculative and the impact of which is hard to predict. As affirmed by Davis (1971: 118), these cases involve the exercise of an informed judgment that takes into consideration not only knowledge and understanding of general facts and scientific information, but also experience, intuition, estimation and guessing. This is the role of managerial capacity to make and review decisions according to the consequences and to respond promptly to changing circumstances. And this is also the importance of the decisions' procedural legitimacy. Since there is no unequivocal right decision, it is essential that it is made according to a fair and open procedure (Daniels, 2009; Daniels & Sabin, 2008).

From this perspective, the expectation that courts make good administrative and political decisions with better trained judges and expert assistance, but without the other benefits of an administrative expertise and flexibility (King, 2012: ch. 8 and 9) and a politically accountable and representative process, seem untenable. Moreover, those advantages of the political and administrative decisions may be undermined by decisions of reviewing courts which reverse their decisions from the political and administrative sphere based on a different source of evidence (Davis, 1971; Vermeule, 2009: 50).

To overcome some of these obstacles, one could imagine the CNJ recommending that health economists be invited to advise courts about the treatments' cost-effectiveness, and public health specialists, epidemiologists, health authorities and civil society to advise about the treatments' priority for public health. Let's say that it could be accomplished through the

organization of public hearings (similar to the one organized by the Supreme Federal Court) for every health care litigation case or the creation of a “bureaucracy under judicial auspices” that could then provide research service and fact finding resources on empirical and social facts, as suggested by Davis (1971) in his seminal article and recently advanced by Yowell (2012).

This transformation of courts into a quasi-legislative or quasi-executive institution would probably be unfeasible, considering the time and resource constraints on conducting such a comprehensive and reliable analysis for each treatment in every lawsuit. Monahan & Walker (2007) made the following caveat about the use of social sciences in courts: it may be an inefficient use of courts’ time and, I would add, resources. According to them:

The same testimony about the same research studies must be heard in case after case whenever a framework for a given type of factual determination is sought. Second, introducing frameworks as social facts is expensive. The pool of expert witnesses is limited to a small group of basic researchers in each topical area and those researchers must be transported and paid to repeat their testimony in each new case (Monahan & Walker, 2007: 161)

Even if we assume, for the sake of the argument, that it would be feasible to create such a complex decision making system, it can be called into question whether it would be rational to create it to decide on the provision of healthcare in each case instead of relying on the procedure used by health authorities, who have the bureaucratic structure and expertise to do so. I will discuss this argument further in the section that follows.

3.2 Health technology assessment system and control of procedure: the Federal Law 12.401/11

The Federal Law 12.401/2011 was based on two draft bills proposed in the Senate: the 338/2007, by the Senator Flávio Arns (hereafter Arns’ Bill); and the 219/2007, by the Senator Tião Vianna (hereafter Vianna’s Bill). Both draft bills declare explicitly that the fact that patients are going to courts to claim drugs that are not provided by the public health system is the main justification for their enactment. Nevertheless, they put forward different solutions for this problem.

In his official justification for his draft bill, the Senator Arns declares that he agrees with those patients who litigate for health treatments that the access to health care cannot be restricted

by clinical protocols and official lists of treatments. According to him, the official lists of treatments are not frequently updated, restricting patients' access to new technologies. Furthermore, the draft bill aims at tackling the problem that the assessment and incorporation of health technologies is not made through a formal administrative process, which means that there is no deadline for the assessments to be concluded by, no right to administrative appeal, no participation from civil society and the decisions are made exclusively by the Ministry of Health.

Arns' Bill, therefore, declared that "[I]t is guaranteed that the provision of drugs and health products that belongs to the lists created by the National Health System's authorities does not exempt the State from providing other drugs and health products that are not included in these lists". It also proposed the creation of an institution - composed of representatives from the government and civil society - responsible for assessing health technologies and deciding on its inclusion in the public health system's lists of treatments. Such decision would be made in 180 and through a formal administrative procedure open to public participation and based on scientific and economic analysis.

Even after this administrative procedure was established, health authorities would nevertheless still not have the final word on the provision of a health treatment. The draft bill stated that the fact that the assessed treatment was not included in the official lists would not exempt the public health system from providing it if (1) the previously incorporated treatments are not effective and (2) there is a medical prescription declaring that the treatment is necessary to avoid death or serious harm to the patient's health. Thus, the Arns' Bill was proposing something similar to the criteria established by the Supreme Federal Court and the National Council of Justice: the patient's needs declared by a doctor to prevail over rationing decisions or scientific dispute; and courts to be the institution responsible for guaranteeing this.

Vianna's Bill had a different entry point. In the draft's justification, Senator Vianna affirmed that the provision of drugs ordered by courts is forcing the public purchase of high cost treatments whose effectiveness is not always proven. According to him, this is harmful for the public health system because it gives to pharmaceutical companies the power to lobby patients and doctors trying to convince them that the treatment they sell is the best and that patients can access these treatments for free through courts. Senator Vianna concluded the draft bill's justification affirming that because resources are scarce, priorities have to be set by the public health system in order to benefit the largest number of people.

Vianna's Bill proposed that the public health system should only provide treatments that are incorporated in the official lists of treatments and prescribed by doctors working for the

public health system. It also excluded experimental and aesthetic treatments from the public health system coverage, as well as any other treatment not registered at the Brazilian National Health Surveillance Agency (ANVISA), the public agency responsible for barring unsafe and unproven drugs for use in the country. Thus, Vianna's Bill would give health authorities the final decision on the provision of health care and would make non-justiciabl claims for drugs not incorporated in the public health system's official lists.

In spite of the different perspectives and opposing proposals, both draft bills were analysed conjointly by the National Congress because, according to the Senate, "they legislate about the same issue". Vianna's Bill was rejected and the Arns' Bill was approved and enacted with amendments to become the Federal Law 12.401/2011. Vianna's Bill was formally turned down, but all the proposals it put forward were introduced as amendments to Arns' Bill. Thus, the Federal Law 12.401/2011 as enacted is actually an amalgam of both draft bills: it incorporated the rule that the public health system should only provide treatments that are incorporated in the health policies (as proposed by the Vianna's Bill) and also created an institution responsible for assessing health technologies through a formal administrative procedure (as proposed by Arns' Bill).

As seen in Section 2, comprehensive coverage is one of the principles underpinning the Brazilian public health system. This is often interpreted by courts as meaning that the public health system is obliged to provide any treatment a patient may need, no matter if they are incorporated or not in the public health system's lists of treatments or clinical protocols. To avoid this unrealistic interpretation, the Federal Law 12.401/11 established in Art. 19-M that:

[t]he comprehensive therapeutic care (...) encompasses: I – the provision of drugs and health care related products according to the therapeutic guidelines established by the clinical protocol for the disease or ailment to be treated (...); II – the provision of therapeutic procedures (...) incorporated in the lists issued by the National Health System's federal health authority.

The Federal Law 12.401/11 also established that in cases for which there is no clinical protocol, the provision of treatments will be made according to the official lists of drugs issued by the National Health System (Article 19-P). It also banned the provision of or reimbursement for experimental treatments and drugs not registered at the ANVISA or not authorized by it (Article 19-U).

These rules are not so different from those established by the STF's criteria, which were confirmed by the CNJ's recommendation: the government should provide treatments registered at the ANVISA and incorporated in the public health policies. The difference is the

regime proposed for the treatments without registration, off-protocol or not incorporated in the public policy, which are the main drivers of healthcare litigation. The CNJ and the STF give to courts the power to decide in these cases, whereas the Federal Law 12.401/11 does not allow this exception.

It established that the incorporation, exclusion or alteration of new drugs, products or procedures, by the National Health System, as well as the creation or alteration of clinical protocols or therapeutic guidelines, are under the responsibility of a new institution: the National Council for Incorporation of Technologies in the National Health System (hereafter CONITEC). The treatments' assessment will be based on the scientific evidence regarding the treatment's effectiveness, accuracy and safety. Economic analysis will also be taken into consideration and assessed drugs will be compared with those already incorporated in terms of costs and effectiveness (Art. 19-Q).

It also established that the incorporation, exclusion or alteration of treatments has to be made through an administrative procedure that is open to public participation by means of public audiences and public consultancy. Moreover, the decision has to be made within 180 days starting from the beginning of the administrative process, and extended by a further 90 days, if necessary, and interested parties have the right to administrative appeal against the institute's decisions.

The Presidential Decree 7646/2011, that regulates the Federal Law 12.401, also added that the impact of the incorporation of treatments on the public health system should be taken into consideration. This decree regulated the functioning of CONITEC and established that it is under the structure of the Ministry of Health and is composed of representatives from many health related public institutions and civil society, but with most of the members being affiliated to the Ministry of Health. This Decree also added that the CONITEC's reports will be forwarded to the Ministry of Health Secretary for Science and Technology for the final decision on their incorporation. Thus, after the CONITEC's scientific and economic assessment of the health technology, the final decision falls to be made by the Ministry of Health. If the Secretary for Science and Technology decides to incorporate the assessed drug or create a clinical protocol and therapeutic guideline, it has to be made available in the National Health System within 180 days (Article 25).

This new system for health technology assessment was based on Arns' Bill. However, there are some differences that make clear the intention of the Federal Law 12.401/11 to give the power to decide on the provision of healthcare back into the hands of health authorities rather than courts, as had been suggested in the draft bill.

Before the final version of the Federal Law 12.401/11 was approved, the President of the Republic vetoed the article which stated that, if the deadline for the conclusion of a technology's

assessment was reached and no decision had been issued, then the technology should have to be available in the public health system until the decision be eventually published by the Ministry of Health Secretary for Science and Technology (Art. 19-R, §2). She also vetoed the Art. 19-S, which says: “The economic impact of the incorporation of a drug, product or procedure to the lists of the National Health System is not a reason to deny its incorporation or to justify its exclusion from the lists, except when disease or ailment against which the product is aimed at is fully and explicitly encompassed by clinical protocols and therapeutic guidelines”.

The justifications given by the President of the Republic for both vetoes are very similar. The President asserted the importance of scientific and economic assessment of a health technology before any decision on its provision is made. Providing non-assessed treatments “can bring risk to patients’ health and is an inadequate way to allocate public resources”. Likewise, not being able to consider the economic impact of a treatment to decide on the incorporation of a treatment “would impair the public health system from negotiating reduced prices with suppliers in order to optimize and rationalize the allocation of public funds”.

Differently from the criteria established by the Supreme Federal Court and the recommendations of the National Council of Justice, the Federal Law 12.401/2011 establishes a different regulation for the treatments not incorporated in public health policies. According to the Supreme Federal Court and the National Council of Justice, the last word on the provision of non-incorporated drugs would be given by courts, who, if convinced that the patient needs the treatment, can order their provision by the public health system. Conversely, the Federal Law 12.401/11 does not permit such an exception. It opts, instead, for creating a specialised institution (CONITEC) and an administrative process through which decisions about the incorporation of new technologies is to be made. It was also envisaged as a way to bring more plurality to the system by including representatives of civil society, practitioners, states and municipalities in the discussion about the incorporation of new technologies in the public health system. The reform, thus, was intended to accelerate the incorporation of new technologies and make it more open for participation and control from other stakeholders apart from the Ministry of Health.

According to the first Director of CONITEC, Clarice Petramale, the pressure for the incorporation of new health technologies comes from many groups in society, including patients, pharmaceutical industries and practitioners, but she was especially concerned with the demands via courts because they compel the provision of drugs assuming “the right to health as an individual rather than a collective right” (Petramale, 2011). According to her, there is a common opinion among judges and civil society that if a high cost drug is not provided, it is because the

“public health system is badly managed or because the public policy does not fulfil the constitutional requirements”. Within this context, according to her, “it is necessary to review the public policies for health technology assessment” by increasing the number of clinical protocols and updating them more frequently and making the procedure for incorporation of new technologies more transparent and participative (Petramale, 2011). She also affirmed that the Federal Law 12.401/2011 was a consequence of the debates that took place in the public hearing on this topic organized by the Supreme Federal Court in 2009.

Thus, considering the history of the Federal Law 12.401/2011 and the analysis of its first director, it is possible to affirm that the government is working on the assumption that a better process for health technologies assessment is conducive to promote a more deferential attitude from courts and, consequently, control health care litigation and reduce its impact on the public health policies. This conclusion is also underpinned by the General Solicitor of the Union’s (hereafter AGU) new strategy for responding properly to these lawsuits.

After the enactment of the Federal Law 12.401/11, AGU, the institution responsible for the legal representation of the federal government, issued several Legal Advices (*Pareceres*¹⁹) stating that the institution and the administrative procedure created by the Federal Law 12.401/11 should be mentioned and explained to courts in healthcare litigation cases so as to defend health authorities decisions against judicial review.

The Legal Advice 810/2012 affirms that judicial claims for drugs are mostly based only on a medical prescription and hence the attorneys that represent the government (i.e., member of the AGU) should, among other things, take into consideration if the assessed drug was already assessed by CONITEC in order to respond to the lawsuit. The benefits of mentioning CONITEC in the legal disputes is stated in the Legal Advice 803/2012, which affirms that, in response to the increase in the number of lawsuits claiming treatments against the public health system, it is important to make reference to the procedure created by the Federal Law 12.401/11 to demonstrate that the National Health System’s pharmaceutical policy is based on “the scientific consensus based on scientific investigation, methodologically stringent and free from economic interests and subjectivisms”

The same idea was also expressed in Legal Advice 805/2012, which affirms that, given the procedure created by the Federal Law 12.401/11, “it can be legitimately assumed that when a treatment is included in a clinical protocol it is safe, effective, has the best cost-effectiveness

19 In spite of being called “advices”, they bind all the attorneys of the AGU

for the public health system and, hence, should have preference in relation to other treatments (...). The Legal Advice concludes by saying that the public attorneys, when defending the public health system against claims for drugs not incorporated in the public health policies, should provide convincing scientific evidence in order to prevent courts from ordering the provision of drugs whose effectiveness was not robustly proved.

The idea that the Law 12.401/11 brings new elements that should be taken into consideration by courts when judging health care litigation cases was expressed in the Legal Advice 804/2012. According to this document, the Federal Law 12.401/11 overcame any doubt about “the legitimacy of the technical criteria chosen by the public health system (...) to guarantee that the treatments offered by the public health system are safe, effective and, at the same time rationalize and optimize the allocation of financial resources”. The same document also suggests a different role for courts in health care litigation cases: judicial review should be used to order the assessment of the claimed drug (start a new procedure according to the Federal Law 12.401/11) and control the legality and reasonableness of the administrative decision to incorporate or not the claimed treatment.

Finally, the Legal Advice 804/2012 states that since stakeholders can initiate an administrative procedure, and this procedure has to be concluded under certain time constraints, there is no reason for courts reviewing rationing decisions.

According to these Legal Advices issued by the AGU, the government made clear its strategy to use CONITEC and the new administrative procedure to convince courts not to review their rationing decisions. It is expected that a more legitimate administrative procedure – more transparent, participative, accountable, timely and scientifically sophisticated – will promote a more deferential attitude from courts and that courts will control the procedure of the administrative decision, rather than making the decision in the place of health authorities.

4 Conclusion

Healthcare litigation in Brazil is mainly driven by individual litigants claiming access to drugs not included in the pharmaceutical policies or for off-label/off-protocol use of those already included. Brazilian courts, in most cases, rule in favour of claimants considering the right to health as an individual entitlement to any treatment prescribed by a doctor, even if the

evidence on safety, effectiveness or cost-effectiveness of a treatment would not recommend its provision. This individual right to health that trump priority-setting decisions made by health authorities, as interpreted by most judges in Brazil, is incompatible with the idea of public healthcare system as a common good that has to be fairly and efficiently distributed among all those who need it.

This sort of judicial claim and decision has been increasing at an astonishing rate and hence creating a very significant budgetary impact on the public health system, compelling the expenditure of resources based on poor scientific evidence regarding the quality of the treatment and the real needs of patients, which makes the provision of treatments via courts unsafe for the litigants themselves. Public funds have also been spent with almost complete disregard of the needs and wishes of the rest of the population, the budgetary capacity of the government, the opportunity costs for the public health system, and the public health priorities. Therefore, I argue that healthcare litigation makes the public health system less rational in the sense that an enormous amount of resources is being spent in a way that does not maximize the benefits that it could have provided.

There is also evidence, although less conclusive, that healthcare litigation privileges mostly the better-off. It would be sensible, however, to expect that health care litigation will progressively become a phenomenon less restricted to this group. The information about the possibility of accessing health care through courts is becoming widespread; there has been significant improvement in the institutions that promote access to justice in Brazil; and pharmaceutical companies have incentives to stimulate (occasionally by funding) litigation. This can make health care litigation less unequal in one aspect, but does not obliterate the unfairness it produces. The mere fact that litigation creates a two-tier public health system is problematic enough in terms of fairness. It distributes resources according to an arbitrary principle – the capacity to litigate – without regard to others in the same condition or the other needs of the population. The fact that more people happen to have the capacity to litigate and go up to the upper tier created by health care litigation means that it will affect more severely the rest of the population. Moreover, given that litigation is mainly driven by individual claims, courts will compel the increase in the expenditure in goods that can be individually consumed (e.g., drugs) rather than in common and public goods that benefit whole populations (e.g., preventive health programs). The fact that socially privileged groups are the main beneficiaries of litigation, as it seems to happen currently, just increases the unfairness created by healthcare litigation.

It would certainly be possible to cherry pick some decisions in which the application

of the right to health as an individual trump delivered a right decision, i.e., granting health care for a patient who was denied a treatment that was actually safe, effective, cost-effective, affordable and needed. This denial could happen either out of intransigence, incompetence, inattentiveness²⁰, bias or malice; or because the data on these treatments were not available at the moment of the decision. However, this is not a good argument to justify courts applying the right to health like most of them do in Brazil. If courts order the provision of almost any treatment that patients claim, then both right and wrong decisions will be delivered without criteria to distinguish between them. A broken clock will tell the right time twice a day, but it is still not a reliable device for knowing the time. What is needed is a procedure that allows a more rational and fair allocation of resources. This was not provided by courts and it is also difficult to envisage how judges willing to enforce social rights individually could do a better job, even when better trained or assisted.

This connects to my argument that the responses from the STF and the CNJ are incomplete. They are aware of the problems of legitimacy and institutional capacity that can be raised when courts review health authorities' decisions on the allocation of healthcare resources. Nevertheless, they state that courts should have the power to review the rationing decision and order the provision of a treatment if the patient alleged needs are not fulfilled by what is regularly offered by the public health system. Thus the STF and the CNJ insist on interpreting the right to health as the trump of the individual to access health treatment, in spite of the policy considerations that have to be observed when it comes to managing a public health system. There is a mismatch between the idea that, for reasons of legitimacy and institutional capacity, some decisions are better made by health authorities and therefore should be respected, with them being eventually nevertheless given to courts to review rationing decisions whenever a judge is convinced that the treatment is necessary for the patient.

The STF tried to bypass this inconsistency by basing its criteria on the public hearing held to discuss the topic with specialists and stakeholders in order to bring legitimacy, information and expertise to the court. The CNJ, in its turn, put forward recommendations to increase courts' institutional capacity by training judges to be more knowledgeable on healthcare related subjects and by making doctors and pharmacists available to advise them. The idea is that if courts want to control public policies, which encompass factual, polycentric and morally complex issues, they have to go beyond the limits imposed by the traditional adjudicative model

20 Intransigence, incompetence and inattentiveness were categories borrowed from Young (2010: 417).

and incorporate elements that are normally present in the administrative and legislative arena.

As Horowitz (1982: 141) observed, “[I]nstitutions in competition with each other tend to resemble each other. Each assumes the characteristics of the other in order to minimize competitive disadvantages”. Thus, if courts want to review rationing decisions, they may try to emulate the ideal conditions for making a good administrative or political decision on this subject. As courts try to control health authorities’ substantial decisions, they tend to become more like health authorities. This is perceived as a way to make sure that health authorities do a good job and, if they do not, to substitute judicial rulings for their decisions.

However, assuming that “just societies are based not on the announcement of broad principles but on the design of real world institutional decision-making processes and the designation of which process will decide which issues” (Komesar, 1994: 5), then courts have to ask themselves whether, and under which circumstances, they can do a better job than the primary decision-maker (Komesar, 1994: 207).

Why should courts be concerned with building institutional capacity and legitimacy to make substantial decisions on the provision of healthcare when there is an institution created and structured specifically to make these decisions? If the administrative procedure is good (transparent, accountable and based on robust evidence and fair principles), then why replicate it under the auspices of courts? It would be naïve to expect that courts create a procedure to decide on the provision of health care that is better than the one that can be made at the administrative level. It would be unnecessarily costly and practically unfeasible to create a procedure for health technology assessment in the judicial level to judge the cases, ignoring what was decided by health authorities in the administrative level.

If health authorities’ procedure is defective (wrong factual assessment, limited access to stakeholders, lack of due appraisal of all relevant information, or discriminatory treatment), then it would be better if courts controlled the procedure, occasionally ordering the decision to be remade, rather than ignoring more or less entirely what was decided by health authorities in the administrative level and trying to decide from scratch. Instead of engaging with scientific issues (to assess whether treatment A is better than B) or moral, economic and policy reasons (to balance the needs of a claimant against those of others and the budgetary capacity of the state), which courts are ill-suited to do if compared health authorities, courts could do a better job in overseeing and scrutinizing the procedure through which these decisions were made and guarantee the adequate conditions for a fair and rational decision making procedure.

This does not mean that a sphere of non-justiciability in which primary decision-makers

have a *lettre blanche* should be created, but simply that the quality of the public authorities' inquiry into the specific case should be taken into account by courts and, if persuasive reasons can be formulated, should deserve judicial respect for epistemic reasons (Kavanagh, 2010: 248; Allan, 2011: 98).

Epistemic deference would not reduce the role of courts in the protection of the right to health, but certainly entails a significant change in the way this right is interpreted by courts. Instead of judging the right to health as an individual trump against the public health system, it should be applied as the right to access a healthcare system in which resources are distributed according to a fair process, which includes duties of transparency, use of adequate scientific evidence and principles of justice, participation of stakeholders, and accountable decision-makers (Daniels, 2009: 328-330).

This is the move in healthcare litigation that is expected by the enactment of the Federal Law 12.401/11. This legislation facilitates control of procedure in healthcare litigation cases by creating a new scheme for health technology assessment that is more open, transparent, accountable and scientifically robust. This is along the lines of Daniels & Sabin's guess that courts will be less likely to substitute their own decisions about the provision of new technologies if they see health authorities using "robust, careful, deliberative procedures and base their conclusions on reasonable arguments that appeal to the evidence produced in the evaluations" (Daniels & Sabin, 2008: 50).

Future research will tell if the legislative response to healthcare litigation in Brazil, which I argue is the best if compared to the current situation or the responses from the Judiciary, was actually effective in convincing courts to become more deferential to health authorities decisions for epistemic reasons and, therefore, reduce the negative impact of healthcare litigation on the public health system.

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Table 1 – Empirical research on health litigation in Brazil²¹

Paper	Location	Period	Number of cases	Most prevalent disease among litigants	% drugs not registered at the ANVISA	% of lawsuits claiming drugs not included in health policies	% of litigants represented by private lawyers	% of litigants with prescription from private practice	Expenditure to comply with judicial decisions (Brazilian Reais)
<i>BRAZIL (2013)</i>	Federal Government	2009-2011	34,500	not available	not available	not available	not available	not available	501,635,002.66
<i>Afonso da Silva & Terrazas (2012)</i>	State of Sao Paulo	2007	160*	Diabetes (23.7%); Cancer (20%); Arthritis (18%)	not available	not available	60	60.6	not available
<i>Biehl et al. (2010)</i>	State of Rio Grande do Sul	2002-2009	1,080*	Circulatory system (21%); endocrine, nutritional and metabolic (13%); mental and behavioural (12%)	not available	56%	34.7	36.8	not available
<i>Ferraz (2011)</i>	Federal Government	2003-2009	5,323	Rheumatoid arthritis; Mucopolissacaridosis; Diabetes; Hepatitis C	not available	not available	not available	Not available	159,000,000
<i>Machado et al (2011)</i>	State of Minas Gerais	2005-2006	827	Rheumatoid Arthritis (23,1%); Diabetes (6,5%); Arterial Hypertension (5,5%)	5	56,7**	60,3	70.5	73,800,000 (2005-2008)
<i>Macedo et al. (2011)</i>	State of São Paulo	2005-2009	81*	Not available	not available	66.2**	not available	Not available	not available
<i>Filho et al. (2010)</i>	State of São Paulo	2005-2010	23,003	Diabetes	not available	not available	not available	60	512.550.717,72***
<i>Pepe et al. (2010)</i>	State of Rio de Janeiro	2006	98*	Arterial hypertension (11.3%); Diabetes(9.2%)	1	80.6	17	Not available	not available
<i>Pereira et al. (2010)</i>	State of Santa Catarina	2003-2004	622	Arthritis; Hepatitis C; Arterial Hypertension	1.4	62.2**	59	55.8	9,494,645.97
<i>Ventura et al. (2010)</i>	City of Rio de Janeiro	2007-2008	289*	not available	not available	not available	not available (although it is suggested that most litigants received legal aid)	not available	not available
<i>Figueiredo (2010)</i>	City of Rio de Janeiro (State of Rio de Janeiro)	2007-2008	1,263*	Digestive system and metabolism (21,6%); Nervous system (14%); Infectious diseases (8,6%)	0.4	92.5	not available	9.5	not available
<i>Chieffi & Barata (2009)</i>	State of Sao Paulo	2006	3,007	Digestive system and metabolism (17%); Cardiovascular system (17%); Nervous system (16%)	3	77**	74	47	65.000.000

21 In this table were included only the articles that analysed healthcare litigation in a certain jurisdiction without limiting the scope to a subgroup of patients or diseases.

<i>Sant'Anna (2009)</i>	State of Rio de Janeiro	2006	27*	Cardiovascular system; Nervous system; Respiratory system	0	81.5	29.6	44.4	not available
<i>Leite et al (2009)</i>	City of Florianopolis (State of Santa Catarina)	2003-2006	2,426	Diabetes; Arterial hypertension; Cancer	not available	68**	not available	Not available	374,659.21
<i>Romero (2008)</i>	Federal District	1997-2005	221*	HIV; Cancer; hepatitis C; Arthrosis	not available	not available	not available	21	not available
<i>Vieira & Zucchi (2007)</i>	City of Sao Paulo (State of São Paulo)	2005	170	Diabetes only (37%); Cancer (22%); Arterial Hypertension and Diabetes (9%)	2	38**	54	40.8	867,000
<i>Marques & Dallari (2007)</i>	State of Sao Paulo	1997-2004	31*	not available	not available	not available	67.7	not available	not available
<i>Santos et al. (2006)</i>	Federal District	2005-2006	160	Arthritis; Ankylosing Spondylitis; Osteoporosis	not available	66	78.8	42.5	19,920,000
<i>Messeder et al (2005)</i>	State of Rio de Janeiro	1991-2002	389*	Nervous system (21%); Cardiovascular system (17.5%); Digestive system and metabolism (15.8%)	not available	not available	27	16	not available

*value based on a sample, does not represent the total number of cases in the period.

** percentage of drugs among all those demanded, not percentage of lawsuits claiming drugs not included in health policies.

*** average per year.