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Judiciary-Executive Relations in Policy Making: The Case of Drug Distribution in the State of São Paulo

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This paper aims to demonstrate how the responses of public health officials to judicial decisions have shaped drug distribution policies in the state of São Paulo. Data was collected and structured interviews were conducted at the state of São Paulo Department for Health in order to show how different strategies of response to judicial decisions affected the policy of medication distribution by the public sector. We also analysed recent Supreme Federal Court jurisprudence to show how the Court reformed its earlier views on the subject as a result of the demands made by public health officials. It is our understanding that the current literature has failed to produce a more comprehensive view of this phenomenon because of its focus solely on judicial decisions, without taking a step further to analyse how public health officials reacted to them, which would have addressed the compliance problem inherent to positive rights enforcement. Finally, we see this process not as merely positive or negative, but as one that goes beyond the different normative biases present in the literature on the subject, and focus on the mechanisms behind the impact of the judicialization of the right to healthcare on policies of medication distribution.

Keywords: Health policy; Judicial studies; Judicialization of public policies.

Introduction

The subject of the "right to healthcare", also called the "judicialization of the health system", has been increasing in relevance in debates not only amongst Law and

public health specialists, but also among those who analyse public policy. This is because the judicial distribution of drugs not given by the public healthcare system (Sistema Único de Saúde (SUS)) involves an allocation of scarce resources to a policy not always seen as the fairest or most urgent in the eyes of public administrators.

The Law debate frames the problem as one of positive constitutional rights, whereas the debate in the area of public health argues that the matter is a technical one, which needs to be addressed through a public health perspective based on risks and priorities. Aside from these perspectives, this problem has captured the attention of political and social scientists for a simple reason: it entails a political issue that involves decisions taken by political actors – be they members of the Executive, Legislative or Judiciary branch – with consequences for governmental policy agendas, management of public policies and social justice.

However, the focus of the debate has not managed to escape a dichotomy pertaining to the subject of access to medicine through judicial means: either the phenomenon is perceived as a good one, because it guarantees that a constitutional right to healthcare is satisfied by the government, or it is viewed as undue interference by the Judiciary branch in decisions that should be left to elected officials and Executive-led bureaucracies, capable of weighing up technical matters and choosing adequate policies, given overall governmental priorities. Thus, the current debate on the issue either does not perceive problems and contradictions within the phenomenon, which we will call here the judicialization of the right to healthcare, or simply ignores some of its impacts on public policies aimed at guaranteeing rights and therefore improving democracy. Furthermore, the focus solely on judicial rulings has lead scholars to a biased diagnosis of the phenomenon's impact on public policies, because they fail to take into consideration how public administrators' responses to the Judiciary's rulings shape those policies.

This article aims to fill this void by examining how public officials' responses to judicial rulings shape drug distribution policies. We view this process as a dual phenomenon, which generates advances in citizens' rights through the effecting of public policies, but not without contradictions and problems created by the interaction between the Executive and the Judiciary. In so doing, we avoid the dichotomous debate that characterizes the Brazilian literature on the subject, and bring an innovation to the theoretical debate by drawing attention to specific aspects of the judicialization of policies that need to be addressed when the Judiciary acts as a positive enforcer of rights.

We have named this phenomenon the judicialization of the right to healthcare because we perceive it as bringing together characteristics emphasised by the two literatures that have studied it: Law, which terms it the "right to healthcare", and public health, which terms it the "judicialization of healthcare". In our understanding, it is a process of judicialization because it consists in using the Judiciary to gain access to a public policy related to the

distribution of drugs, as perceived by public health studies, but it is also about guaranteeing a right that requires positive policies to secure it.

Aside from this introduction, this paper will be structured as follows: first we will present a critical review of both literatures that have been studying the phenomenon – Law and public administration. After that, we will draw from structured interviews to analyse the strategies of public health administrators in response to judicial rulings, and how they affect drug distribution. Finally, we will conclude with a synthesis of our arguments and findings, demonstrating that the current literature presents a much darker – and less credible – account of this phenomenon.

One Phenomenon, Two Interpretations: Law and Public Health

There are two usual approaches to the judicialization of the right to healthcare: one that perceives it as a virtuous process of guaranteeing a right otherwise overlooked by elected politicians and public officials, and another that qualifies it as a vicious distortion of the relationship between branches of government. There are other ways in which to organize the debate, but organizing it in the following manner makes it easier to highlight two features important for understanding the overall impact of this phenomenon on policies that seek to implement the right to healthcare: 1) identifying the actors themselves and how they frame the phenomenon – almost all the authors in each field either have a background in Law, and usually work as lawyers, public defendants, prosecutors, judges etc, or have a background in medicine and public health, and usually work in the public sector; 2) highlighting the author's position on whether they are for or against the Judiciary deciding about the overall level of healthcare that the government should provide makes it easier to understand the political role of the Judiciary foreseen in each field, and the consequences for the institutional structuring of the State's decision making process.

In the following section we will critically analyse how these two views characterize the phenomenon. Our goal is different from that of these approaches. We seek to better understand how this phenomenon changes the decision-making process and how, in turn, that affects the policies actually implemented. Although we address several of the normative issues raised, especially by the right to health literature, we attempt (not always successfully) to refrain from making any judgments on whether this is a good or a bad thing.

The right to healthcare

In the "right to health" literature it is quite common to find authors defending an even more active judicial role in public policies in general and in drug distribution policies

in particular. They usually steer away from a diagnosis of "collapse" or "insufficiency" of the electoral representative system to seeing in the judicial system a way of supplementing this deficiency, because it is more likely to defend underrepresented minorities.

There are many shades of grey in the opinions of the different authors, who almost always have a background in Law, but when you review the literature it becomes clear that their overall opinion is in favour of the judicialization of the right to healthcare.

Even when they seek a middle ground, their position on the subject is made clear in certain passages. For example, Ventura et al. (2010) ponder several ethical and technical issues related to the Judiciary ordering the State to distribute medicine, but are in favour of the Judiciary's authority to interfere on a case by case basis. The authors organize the debate in the following manner:

> 1. An initial position states that considerations on the efficiency of the implementation of the right (to healthcare) must be restricted to services and goods already provided by the SUS determined by health officials.
>
> 2. A second position defends that the right to healthcare incorporates the guarantee to life and the physical integrity of the individual, and that the judge must consider only the absolute authority of the personal physician assisting the patient/litigator, and thus order the SUS to deliver the medicine to the patient.
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> 3. A third stance defends that the efficiency of the right to healthcare must be as ample as possible, and that the Judiciary must ponder rights, goods and interests at stake on a case by case basis in order to set the contents of the State's obligations to deliver goods and services. (Ventura et al 2010, 86).

The third stance mentioned by the author can be collapsed into the second one, since it authorizes the Judiciary to have the final word on the overall healthcare that society should give its individuals. This is by no means a "relative consensus", as the authors claim a few paragraphs previously (it is maybe so in the jurisprudence, but not in the literature), and this can be exemplified by Vieira's (2008) critique addressed further along, which begs the question: Given that we deal in scarce resources and that healthcare is probably the most costly public policy a country can implement, how much of a health safety net are we as a society prepared to provide for our citizens? Additionally, how can we decide this in a democratic regime in a legitimate way?

The only difference between the second and third opinions as organized by the authors is that the latter asks for the judge's careful consideration of the opinions given by SUS officials, rather than simply complying with the patient's personal physician's opinion. The last word "must" still stand with the Judiciary.

When addressing the issue, Werneck Vianna (2003) argues that functional[1] representation, legitimized by the law and the Constitution, may complement classical electoral representation, because it spurs more individual and group participation in the

political arena through the judicial process.[2] This functional representation in the Judiciary would be typically performed by state bureaucracies in charge of doing so (in Brazil, the Ministério Público, Public Defenders' offices and states' lawyers). In such a context, the opening of various participatory channels (including judicial ones) are beneficial to marginalized groups, and help produce public goods for the less privileged sections of society. On top of that, the construction of a collective civic identity through rights-based activism is in line with acquiring a modern sense of belonging. In this context, identities are formed around mutual interests and more objective demands organized around pre-established rights, as opposed to identities formed around an arbitrary historical narrative of commonly held cultural characteristics.

When talking specifically about the distribution of medication, Wang (2009, 81) argues that the broadening of deliberative and participatory channels, including the Judiciary, can contribute to the improvement of public policies, because "(…) in the Judiciary, the interests of the poor and the less favoured in society may be more easily manifested, which gives this institution a comparative advantage". This advantage is presumably given by intermediary institutional instances that could exert advocacy functions for the less favoured strata of society, reducing organizational costs for them. To prove his thesis, Wang researched lawsuits initiated by the Ministério Público and the Public Defender's office in the state of São Paulo between 1999 and 2008. The author presents as evidence of the beneficial nature of the phenomenon the number of medication and medical supplies demanded and given in these suits, thus supplying a social need for such policies that was going unanswered in the classic representation channels.

Collective vs. individual litigation

Another strain of the right to health literature starts from a more critical diagnosis of the phenomenon, which is also present in the judicialization of the right to healthcare literature. This diagnosis is based on the findings that there are more individual than collective suits being filed and decided in the judicial system. From that empirical finding, authors conclude that by giving medication to individuals who have access to the Judiciary, what is created is, in fact, not a policy to positively enforce the right to healthcare, but a privilege given to those with the resources to endure litigation against the State. For the right to health authors who share this diagnosis, what is needed is a shift in judicial enforcement from individual litigation to start dealing more with collective litigation, thus addressing broader issues with overall impacts and benefits (Lopes 2006; Ferreira et al. 2004).

The issue of individual vs. collective litigation in positive rights enforcement has received much attention in the literature. Recent research on the jurisprudence of the São

Paulo State Court (TJSP) showed the Judiciary's difficulty in acting as a rights enforcer in collective lawsuits, whereas in individual claims it usually favours the plaintiff (Pepe et al. 2010). Analysing the TJSP's jurisprudence on the judicialization of the right to healthcare, Fanti (2009, 33) discovered that 92% of the individual lawsuits against the municipality of São Paulo that asked for drugs to fight AIDS were decided in favour of the plaintiffs.

Caldeira (2008) restricted her analysis to rights enforcement in collective lawsuits (including the right to healthcare, although not exclusively) and concluded that the Court restrains itself more when a collective actor asks directly for the creation of an entire policy, not just for the inclusion of a group of people in a particular programme in existence (public school, housing, hospital…).[3] José Reinaldo de Lima Lopes (2006, 255) argues that this has to do with dilemmas of distributive justice, which become more salient and evident to the judge in collective cases than in individual ones. This happens because many collective cases are not about one individual[4] or group of individuals asking for a public resource, but the suits require the creation of an entire new policy or the reformulation of an existing one. Some examples are lawsuits that asked for the transfer of medical equipment from one place to another, lawsuits that asked for the hiring of more health professionals to a given hospital and lawsuits that asked for a specific part of the budget to be allocated to policies for fighting AIDS. Lopes (2006, 255) concluded: "Our analysis showed that the courts are more comfortable when deciding a case in favour of a single individual, but not so when they are asked to force the revision of entire policies". Ferreira et al. (2004, 25) come to the same conclusion, restricting their analysis to STD/AIDS cases against the municipality of São Paulo.

> We have been able to observe that 93% of the rulings favourable to the plaintiffs were composed of cases that recognized the rights of individuals to healthcare, while only 5% of winning claims were about truly collective rights. As for cases where the court denied the plaintiffs' claim, 53% of them were about collective rights and only 33% dealt with individual rights. .

Lopes (2006, 256) criticizes this conservatism of the courts, claiming that it has to do with a Brazilian judicial culture in which "constitutional doctrine is still based on the concept of individual subjective right and does not incorporate a central problem of the democratic regime, which is the principle of universal and equal enjoyment of a right".

Authors who have studied the issue from a "right to healthcare" perspective view this treatment of collective problems according to an individualistic approach, in a setting of extreme social inequalities, as transforming rights into privileges for those with the resources to fight a judicial battle. This diagnosis is shared by those who study the issue from a "judicialization of healthcare" perspective, who complain about the "random" way

in which courts offer expensive treatments to individuals, without considering a broader logic of public health that deals with a population (for examples see Messeder, Osório-de-Castro and Luiza (2005); Vieira and Zuchi (2007); Chieffi and Barata (2009). Curiously, while the solution given by the "judicialization of health" literature is that courts should stay out of such matters, to Lopes and others from the "right to healthcare" perspective, the remedy is exactly the opposite: courts should make more ambitious decisions on the matter, deciding on collective lawsuits and analysing problems of distributive justice so as to create rights for everyone instead of privileges for a few.[5] Ferreira et al. (2004) reach the same conclusion as Lopes, arguing that the economic rationality of deciding collective lawsuits is better for dealing with a problem on a large scale than on a case by case basis.

In a different diagnosis, Caldeira (2008) raises the issue of substantive representation legitimacy in such judicial collective arrangements, given that the main actors involved in the process are not elected. Not only are judges in Brazil not elected, but the Ministério Público (Prosecutor's office) alone is responsible for over 90% of the collective litigation[6] and its members are also unelected and accountable to no-one other than their own consciences.

Although the recommended treatments diverge, the diagnosis given by the literature that studies the judicialization of the right to healthcare is based on the idea that when judges decide individual cases, they create privileges for the plaintiffs *vis à vis* the rest of the population. This diagnosis focuses only on judicial rulings, without taking into account the reactions of public health officials to the problem. Everything is perceived as if public health officials were inert when facing judicial rulings, merely executing them within their limits. Next, we will see in more detail the interpretation given by the literature from the "judicialization of the right to healthcare" perspective, and after that we will analyse the reactions of public health officials to the phenomenon and how it has affected public health policies.

The judicialization of healthcare

As previously stated, the academic distinction between the "right to healthcare" and the "judicialization of healthcare" in Brazil carries with it a normative dichotomy regarding the role of the Judiciary in guaranteeing the distribution of medicine. We have already seen how the problem is framed by the Law academic community, and now we will critically address the issues raised by the "judicialization of healthcare" perspective.

There seems to be a consensus among the two competing views regarding the moment people started using the Judiciary to obtain medicine: it began with requests for antiretroviral drugs used in the treatment of AIDS. According to Messeder, Osório-de-Castro and Luiza (2005), more than 90% of the lawsuits asking for medicines in the period between 1991 and 1998 requested this kind of drug.

It is worth mentioning that, according to Messeder, Osório-de-Castro and Luiza, (2005) and Scheffer, Salazar and Grou (2005), the Judiciary was an effective instrument used by NGOs that were pressing the Executive for AIDS policies in Brazil, not only in order to guarantee access to drugs, but also as an instrument to institutionalize an effective and comprehensive governmental policy for fighting the disease. It is possible to state that this was the most important success obtained through the mobilization of the Judiciary: the creation of a broad, comprehensive and permanent public policy for treating AIDS carried out by the SUS.[7] According to Fanti (2009), analysing Scheffer, Salazar and Grou (2005), the "transformation" of lawsuits into public policies is a positive aspect of the so-called 'judicialization of healthcare'".

> (...) the medicines that were being requested in the lawsuits were, besides those already mentioned in the official SUS programmes, new "top of the line" drugs and diagnostic supplies and equipments that were not in the SUS programmes and thus were not yet financed by the government. The research then shows that the delay in absorbing new technologies in the SUS is proportional to the growth of litigation asking for these technologies. On the other hand, favourable decisions from the Judiciary in many lawsuits contributed for such medicines and tests to be included in the official policies (Scheffer, Salazar and Grou (2005) apud Fanti (2009)).

When the National STD/AIDS Programme began and the distribution of antiretrovirals was normalized, the proportion of requests for HIV medication decreased, dropping to 14.6% in 2000 (Messeder, Osório-de-Castro and Luiza (2005); Fanti (2009). The success in obtaining AIDS medicine through the Judiciary motivated the use of this avenue to request other kinds of medicine to treat other diseases.[8]

So we can say that the relationship between the use of the Judiciary and regular distribution of drugs by the government is inverted: when medicine is not regularly distributed by the government, the Judiciary is frequently called upon; and when the Executive manages to freely distribute medicine for those who need it, the number of lawsuits decreases.

Although this relationship seems obvious, it is not owed to one single reason: turning to the Judiciary does not mean asking for treatment of a disease, but asking for a specific brand or kind of medicine to treat that disease, even though sometimes the Executive already distributes another type or brand of medicine with the same effect in treating it. This is the case, for instance, of lawsuits that ask for a specific brand of medicine that has the same active chemical principle already present in another drug freely distributed by the SUS. Marques and Dallari (2007, 104), having analysed 31 lawsuits requesting medicines and medical supplies to be financed by the government of the state of São Paulo from 1997 to 2004, showed that in the majority of cases the plaintiff requested medicine from a specific

pharmaceutical lab, regardless of whether it was manufactured by other pharmaceutical labs and already distributed by the SUS. According to the authors,

(…) in 35.5% of the cases the name of the pharmaceutical lab was stated in the lawsuits, and in 77.4% of the cases, the author requested at least one medicine or medical supply from a specific brand. They did not ask that their disease be treated, or even to be treated by a specific chemical compound or type of medicine, they asked for the specific branded drug from a specific pharmaceutical laboratory. (Marques and Dallari 2007, 104)

When requesting a specific branded drug, the patient does not guarantee that he/she will receive the best treatment. According to the research made by Vieira and Zucchi (2007) on 170 lawsuits filed against the Health Department of the municipality of São Paulo, 62% of the requested items[9] out of a total of 282 were included in the SUS's lists of freely distributed medicine.[10] From the remaining 38%, 73% could have been substituted by a similar medicine distributed by the SUS.

When analysing the judicial litigation on distribution of medication in the city of Florianópolis, Leite et al. (2009) also found a lot of overlap between what was being requested and what was already distributed by the SUS. Criticizing the Judiciary, Ferraz and Vieira (2009, 2, emphasis added) talks about a "Brazilian model" of litigation in healthcare, which:

> (…) is characterized by a prevalence of individualized claims demanding curative medical treatment (most often drugs) and by an extremely high success rate for the litigant. This model has been shaped and encouraged largely by the interpretation of the constitutional right to health that was established in the late 1990s at the highest level of the Brazilian judicial system, the Supreme Federal Court (the "Supremo Tribunal Federal" or STF), and later became dominant in the rest of the Brazilian Judiciary. In this interpretation, the right to health is an individual entitlement to the fulfilment of one's health needs with the most advanced treatment available, irrespective to costs.

These findings, however, may not reflect what it is really taking place, because what usually happens is that the plaintiffs ask for the whole treatment when they go to the Judiciary, not just the medication not given by the SUS. That way, when the judge sentences, he/she orders the State to provide the specific previously denied medication and other medical supplies required for the treatment, even though those medical supplies are already given freely by the State (Figueiredo 2010). Either way, the whole process of making the State buy medication it already dispenses, but in specific dosages and of specific brands, creates inefficiencies by raising the cost of acquiring such medical supplies.

According to Ferraz and Vieira (2009), not only the question of the costs of treatment must be taken into consideration, because it means allocating scarce resources from

other healthcare policies, but also the sheer fact that it is impossible to give everybody the newest and most expensive treatments currently in existence for each specific healthcare requirement, especially when there are equally effective lower cost alternatives. So the principle of equality must be addressed, not just the principle of universal care. If the SUS establishes universal and equal care, the government must not be made to give unequal access to health resources by a Judiciary that decides which degree of technological innovation is used to treat every specific disease.[11]

Still on the subject of the kind of medicine requested, not only do plaintiffs ask for specific brands of medicine, but some lawsuits ask for a specific brand of medicine already given by the government, but in a different dosage, or they ask for other medical supplies that have nothing to do with the specific disease being treated. Data from the São Paulo State Department for Health point to the existence of an high number of lawsuits requesting disposable nappies, wet paper handkerchiefs, nutritional supplements and medicine already given by the government in a different dosage. This is the case, for instance, in lawsuits requesting 300 milligram capsules of acetylsalicylic acid to treat patients who require that daily dose (so they only need to take one pill a day), instead of the 100mg capsules already distributed by the SUS (that would require three doses a day). Although the patient needs to take three instead of one, the added unitary cost of buying different kinds of pills does not justify the convenience: the 100mg pill given by the SUS in São Paulo through the Programa Dose Certa (Right Dosage Program) costs the government R$ 0.01 a pill; the 300mg pill granted by the Judiciary costs R$ 0.71. This situation repeats itself in many other cases with much higher costs, such as in the case of cancer medicine. Beside the added product cost, the process of acquiring different dosages and different brands of the same medicine itself requires an allocation of human resources and time to do so, especially because we are talking about spending public money, which requires much slower procedures and added oversight costs to try and avoid corruption.

There are many cases in a grey area, where the medicine or medical supply asked for in the lawsuit is not an innovative option for treating a disease already treated by another medicine distributed by the SUS, but merely a treatment that is more convenient for the patient. So there are many cases where the motivation that leads the patient to the Judiciary is different from that of the early AIDS cases. In the early AIDS cases, the motivation was to try to get the government to start financing the treatment of a disease, thus realizing AIDS patients' right to healthcare. The increase in the judicialization of the right to healthcare lead to the treatment of diseases that were not being treated by the public healthcare system, but it also leads to distortions.

Another aspect of the "judicialization of the right to healthcare" raised by the judicialization of healthcare literature is the lack of ANVISA registration of some judicially

distributed drugs.[12] The commercialization and usage of a drug in Brazil requires an ANVISA certification. Experimental drugs that are not yet certified by the agency may only be used in clinical trials.

On this issue, Vieira and Zucchi (2007, 220) showed that of the 170 lawsuits requesting drugs from the municipality of São Paulo, two anti-cancer drugs acquired through judicial rulings were not certified by the ANVISA, "(...) and most of the other cancer drugs requested lacked more controlled randomized clinical trials to attest their effectiveness". Chieffi and Barata (2009) also demonstrated that, out of the 954 different medical supplies requested in the 9,712 lawsuits researched,[13] 3% were not available for commercialization in Brazil. The fact that the drug was not made available in the national market means that the federal agency charged with the job of certifying a drug for its relative safety and effectiveness had not yet done so. The common use of off-label[14] medication also enhances the dangers (Pepe et al. 2010; Ventura et al. 2010) Furthermore, Vieira (2008, 367) argues that the simple registration of a drug by the agency does not mean that it should be incorporated into the SUS programmes:

> Registration of a pharmaceutical product, in itself, does not mandate its integration in SUS treatments. There is no healthcare system in the entire world that offers its users all the available drugs in existence in its internal market. The costs of doing so are prohibitive and even universal systems in developed countries face problems financing treatments.

Ventura et al. (2010, 85) point out that judges had been ordering public officials to give any medication requested by plaintiffs, without taking into account if the supplies or procedures requested were in accordance with the Clinical Protocols and Therapeutic Guidelines established by the SUS.

The argument is that universal healthcare systems must guarantee treatment of all existing diseases, but not through all available drugs. Cost-benefit as well as safety criteria must regulate the decisions of incorporating new drugs into the public system.

A third problem that deserved the literature's attention was the subject of who was filing the lawsuits. Various pieces of work mention the fact that most of the lawsuits are initiated by individuals and not by collective actors. That is another difference between the early AIDS cases and the more recent ones asking for all kinds of drugs and medical supplies. In the AIDS cases, NGOs were the most common sponsors of litigation. After the first few years of judicialization, other actors emerged and most of the lawsuits were filed under the name of individuals who sought treatment for themselves rather than for some kind of universal policy. In their sample, Marques and Dallari (2007, 105) found that 100% of the lawsuits were filed by individuals.[15]

However, the literature does not mention that any citizen has access to the judicial system through public defenders' offices, so resources are not restricted to those who have money to pay for a private lawyer or have an association pay one for them.

Ferraz and Vieira (2009) shows that although only 26% of the lawsuits filed in 2006 in the state of São Paulo were sponsored by public lawyers, in the state of Rio de Janeiro the figure was 53.5% (1991-2002). But the author questions his own figures, arguing that most public defenders' offices are located within high income neighbourhoods that have restricted access via public transportation, and end up being used by high income individuals. The socioeconomic status of people is usually calculated based on geographical location (see, for example, Machado et al. (2011) and Chieffi and Barata (2009)).

The argument that criticizes the fact that the Judiciary is a venue accessible only to people of a high income seems to miss the point. A person's income does not matter much, since public defence is available to whoever seeks it. Different incomes only mean inequalities in access to information, transportation etc., which might affect a person's ability to seek public defence. Besides, the SUS guarantees integral and universal care to all citizens, not just poor ones. Finally, the fact that many lawsuits are filed by people with relatively higher incomes does not mean that they can finance their medical treatment. Some of the drugs asked for in the lawsuits amounted to treatment costing R$ 20,000.00 (circa US$ 12,000.00) per month. Chieffi and Barata (2009) suggest that such treatments could be financed by high income families, but how many high income families earn more than US$ 12,000.00 a month in Brazil? Should people who earn less than that but more than the average Brazilian income be left out of the public healthcare system?

To sum up, the existing literature points to a series of issues connected to the so-called "judicialization of healthcare": who is responsible for the litigation, if it is an individual or a collective actor; the characteristics of the required drug, if an equivalent freely distributed by the SUS already exists, if the drug is specified by brand or active chemical principle, if the drug is certified by the ANVISA; the socioeconomic condition of the plaintiff, if he/she has or has not got enough resources to acquire the drug by him/herself; the issue of checks and balances and the encroachment of the Judiciary in the Executive's policies, and what happens when the Judiciary ignores technical matters or set priorities by considering public health problems of a specific population in a specific place and time. Those questions, however, leave out a series of issues that deserve our consideration.

Universal, integral and equal right

First, we must consider a normative point that is the cornerstone for the whole SUS system: the idea of a universal, integral and equal right to healthcare, enshrined in the

Brazilian Constitution.[16] The acquisition of "top of the line" expensive treatments and drugs through the Judiciary means allocating resources from broader policies that affect a lot of people to a small part of the population that has access to the judicial avenue. In addition to the inequality problem created by the access to expensive drugs and treatments, it is important to bear in mind that the purchase of drugs mandated by judicial rulings is much more onerous to the State: data from the São Paulo State Department for Health shows that while the average cost of treating a patient with drugs bought in the SUS is R$ 2,500.00 (circa US$ 1,500.00) per year, the average cost of treating a patient with drugs bought because of judicial rulings is R$ 10,600.00 (circa US$ 6,000.00) per year.[17]

Second, it is important to remember that the Constitution and the public health system statute (Law 8.080, from 1990) establish that all three levels of government are in charge of financing pharmaceuticals, but the Judiciary rulings do not take into account the federal division of responsibilities when acquiring the drugs. As a consequence of this, municipalities are frequently required to pay for high cost medicine, although the federal government is responsible for doing so.[18] This not only draws resources from other healthcare priorities, but from other policies as well.

Finally, despite its controversial effects, judicial activism in healthcare seems to also have had a positive effect on creating public goods by interfering in the Executive's agenda. As stated by Messeder, Osório-de-Castro and Luiza (2005, 532, emphasis added), there is a direct correlation between the number of lawsuits asking for drugs and their inclusion in the official financed drugs lists.

> A clear example of that is the current list of exceptional medication. In 2000 the requests for Mesalazin and Riluzol began. In 2001, these requests were maintained and Peg-interferon and Hidroclorate of sevelamer were added. In 2002 there was an increase in the requests for Hidroclorate of sevelamer, Mesalazin and Peg-interferon, and the requests for Levodopa + Benserazid, Infliximab, Sinvastatin and Rivastigmin were added. In the last revision of the list for exceptional medication, all those drugs were added to the programme (PT/GM/MS n. 1.318/02).

It is a big supposition to assume that just because there were lawsuits filed requesting those medicines before they were added to the lists one thing was caused by the other, but the same fact was mentioned to us in interviews at São Paulo's State Department for Health. There, a public official in charge of handling the lawsuits told us that some items were included in the lists in response to the volume of judicial decisions ordering their distribution to individual patients. Therefore, it is not possible to judge the judicialization of the right to healthcare just by its negative effects. It may contribute to the creation of public goods.

The Strategies of Public Health Officials

The fact that the focus of most studies on the judicialization of the right to healthcare has been on judicial rulings has lead to a partial evaluation of the phenomenon. Although the courts order public officials to comply with their decisions, these decisions are still implemented by public health officials, who may respond to the judicialization in different ways. The implementation game seems to be a whole new arena that impacts policy results (see, for example, Bardach (1997) and Patashnik (2003)). Our case is not one in which a whole policy fails to achieve its objectives because of implementation sabotage, nor are we talking about a whole policy formulated by the Judiciary and implemented by the Executive, as is usually the case in the implementation literature, but focusing on the type of response generated by public health officials has lead us to a different diagnosis from the one that cries out that "privileges" are being created by the Judiciary.

In interviews conducted at São Paulo's State Department for Health, we were able to identify three different strategies used by public health officials to deal with the judicialization of the right to healthcare. But before we get to these strategies and how they impact the policies, it is important to understand how public health officials themselves assess having judges tell them what medicine to give to whom.

For São Paulo's Head of the State Department for Health, the main issue has nothing to do with judges telling them to give medicine to people who need it, but who the judges listen to when deciding what kind of medication is to be given. It is his perception that the pharmaceutical industry, as any other industry, is driven by market logic. However, differently from other markets, a product's demand is not defined by its final user, the patient, but by the physician who chooses the medication for the patient. In the whole world, and Brazil is no exception, the pharmaceutical industry spends billions of dollars to market its newer and more expensive products to physicians, but these products do not necessarily bring substantial benefits to patients. This is an argument also made by recent works in the field.[19] "Then comes the doctor, who thinks he is God, to give his opinion to a judge, who is sure he himself is one" (head of the State Department for Health). Evidence of this is the fact that doctors prescribe medication not by its active chemical principle (which can be found in numerous products), but by its brand name. The judge, who does not know anything about the technical side of things, simply orders that the drug in the doctor's prescription that accompanies the patient's lawsuit be given to him/her, often without even consulting public healthcare officials.[20] Further evidence of this is the fact that only a handful of doctors and law firms are responsible for the majority of litigation, and even NGOs that advocate patients' rights are financed by the pharmaceutical industry (Lopes et al. 2010).

According to the head of the State Department for Health, even when the judge has a technical opinion given by public officials, he usually leans towards the patient's doctor's opinion. This happens because there is a general culture of distrust in the Judiciary, who believes the Executive just does not want to give people medicine because politicians want to save money for corruption, or for other policies that can get them more votes. But this perception is changing, because more and more judges, public defenders and prosecutors have been communicating with public health officials, organizing joint seminars, visits to hospitals and pharmaceutical dispensaries, exchanging emails, telephone calls etc. Knowing this, legal tactics have also changed and actors (plaintiffs and their lawyers) are filing lawsuits in courts with judges sympathetic to their demands and avoiding courts and judges who would ask public health officials for information before granting an injunction.

Contrary to the tone of "privilege" of the literature that focuses only on the Judiciary, in cases where public officials perceive some gain to patients with the new medication, they extend its distribution to more people than just those who file the lawsuits. Once a demand is brought to their attention by the Judiciary, their effort is to create a general policy to supply it, except in cases where the public health officials' perception is that the medication asked for is actually harmful to those receiving them through a court order.

Based on this evaluation of the problem, what are the strategies of São Paulo public officials to deal with demands that come through the Judiciary? It is possible to identify at least three different ones, organized according to the disposition of public health officials to supply the medication, and they all affect the policies of drug distribution differently.

No restrictions

First, there are the cases where public officials have no restrictions to supply the medication. Here we have two situations: the one where the drug is regularly distributed by the SUS, but for some reason the patient is having trouble receiving it; and the other where the need for a product is brought to the public health officials' attention by the justice system, and they start distributing it as a regular policy. From 2006 to 2007, São Paulo's State Department for Health detected that many judicial claims that came through the Public Defender's office were made by people who had a need for regularly distributed drugs, but had some kind of problem acquiring them. These people sought the Public Defender's office and that was the start of slow and needless judicial claims that cost all parties their time and resources.

In order to minimize this, in 2007 an administrative counter for pharmaceutical triage was set up in the Public Defender's office to talk to patients, and orient them on how to obtain the necessary medication. The service was transferred to a location of its

own in 2008, which allowed the State's Department for Health to cut costs in two ways: by eliminating litigation costs and by dealing with the problem of different prescriptions asking for different brands of the same medication. This turned out to make the access to medication for people who would otherwise have difficulty obtaining them easier. Some peculiar supplies started to be distributed at this triage centre such as special soy milk for lactose intolerant children, nappies and sunscreen lotion. These supplies and medication became accessible not just for whoever filed lawsuits, but to the population in general.

Useless or harmful

Secondly, there are the cases where public officials believe the required treatment to be either useless or actually harmful to the patients.[21] Curiously, some lawsuits asking for antiretroviral medication fit this category.

As is well known, AIDS is still an incurable disease. With the available treatments the patient becomes chronically ill, with his/her lifespan increased by the antiretroviral drugs. However, as times goes by, the patient creates resistance to the drug, and a new one becomes necessary. New drugs are constantly being developed and Brazil freely distributes antiretrovirals to its AIDS patients, but during the timeframe that it takes for a new drug to get its ANVISA certification (three years) and the creation of a clinical protocol that regulates its distribution by the government (usually one year), the AIDS NGOs use the Judiciary as an avenue to force the government to acquire the drugs for the patients. However, the distribution of a new "top of the line" drug to help patients that have not yet developed resistance to the old medication may render a drug that they will require in future useless.

At the end of 2007, a new retroviral drug called darunavir was certified by the ANVISA, but there was still a known gap of one year before it started to be handed out by the federal government. Aiming at speeding up the process and "preventing litigation" (public official of São Paulo's State Department for Health), the state of São Paulo decided to get ahead of the federal government and create its own clinical protocol to start distributing the new drug to patients on whom the other medications no longer had an effect. Because of this, according to data provided by the São Paulo State Department for Health in 2008, only five lawsuits were filed requesting darunavir from the state of São Paulo. In these cases, the São Paulo State Department for Health decided to fight the lawsuits, arguing that providing the drug to those patients would harm them in the future, because they would be useless when they needed them the most. The result of these cases was in favour of the State, although there were other episodes when that was not the case, and the resistance of the government to provide the medication restricted its access only to those who filed

the lawsuits, although one could hardly make the point that the ones who had access to drugs in such a situation are "privileged".

Grey area

Finally there is a "grey area" of drugs and other medical supplies that, despite providing some benefit to the patient, have prohibitive costs when there are other available options regularly distributed by the government. In the view of the head of São Paulo's State Department for Health, "It amounts to the same thing as wanting to create a policy for public transportation that involves paying cabs for workers who need to commute between cities. What the government does is provide buses and trains, either by itself or by regulating how the private initiative does so, and that involves a fee. Is it more pleasant for the worker? Of course not, but you don't see anybody going to the Judiciary to ask for government-paid cabs" (interview with the head of São Paulo's State Department for Health).

An example of these cases is the "glargina insulin", commercially known as lantus. According to the head of São Paulo's State Department for Health, currently about half of the litigation against the state asks for this kind of insulin (the other half are cancer drugs). Insulin is a medical supply used by diabetes patients to control their level of blood glucose. Because diabetes has no cure, once diagnosed the patient has to take the insulin for the rest of his/her life. Currently, there are two types of insulin being regularly distributed in the state of São Paulo and both of them require two or three daily applications by injection, which causes the patients minor discomfort. According to the head of São Paulo's State Department for Health, lantus offers at least two advantages in comparison to other insulin: first, its effects last for 24 hours, so only one dose a day is required, and second, it allows for better control of glucose levels, especially when combined with "rapid action" insulin. This diminishes the risks of hyperglycaemic crisis. The cost of lantus insulin is about 27 times higher than the cost of the regular ones for the government, so it is resistant to substituting its regularly distributed cheaper options. In their perception, the costs outweigh the gains of doing so.

Another example in this same category is the vaccine against the "sincicial virus" (VSR). The vaccine is actually an artificial defence called palivizumabe. It is an artificial antibody manufactured outside a person's body and then given to them to inhibit the virus. This virus presents itself initially as a common cold, but in people with other respiratory problems or some kind of immunodeficiency, especially premature babies, it can evolve to more serious problems that may result in death. The only known treatment against the virus itself is a preventative one, using palivizumabe, but a single immunization costs R$ 5,000.00 (circa US$ 2,200.00) and that makes a widespread immunization policy prohibitive.

In these cases, although the medication provides marginal gain to a person's health, the cost/benefit perception by the Executive is that the distribution of these drugs is unjustified. What is the strategy of São Paulo's State Department for Health to deal with this type of litigation, then? There are two strategies in such cases: the first is to create a clinical protocol to limit and regulate the drug's distribution. The second is the creation of a medical committee to evaluate requests for drugs that are not usually distributed by the SUS. This committee is tied to the pharmaceutical triage process, but it only acts in cases where the requests are outside the normal protocols. If the committee's evaluation is positive, then that cuts down litigation costs for the administration and speeds up the distribution of the medication for the patient. If, however, the committee's evaluation is negative, at least there is a better technical reason to accompany the administration's response when the request finally turns into a lawsuit. This is in tune with the latest STF/CNJ (National Council of Justice) ruling that requires better technical reasoning to be given in judicial sentences. According to the head of São Paulo's Department for Health, there is even the possibility that this committee might become one of those mentioned in the CNJ's "recommendation",[22] in charge of helping the Judiciary decide the cases.

As for the creation of clinical protocols as strategic action taken by public officials to limit litigation, they both create a policy of distributing the medication regularly to patients, thus solving the "privilege" problem, and justify limiting the distribution of medication to those people and illnesses described in the protocol. According to one of the public health officials interviewed, that was the case with palivizumabe. The vaccine started to be requested in lawsuits and they created the clinical protocol to respond to the rising litigation. The state of São Paulo freely distributes the immunization to premature children up to the age of one, or children of up to two years who have some type of congenital heart disease or chronic pulmonary disease, between April and September, as it is a seasonal virus. This year a national programme will probably be launched. In the lantus case, São Paulo's Department for Health is studying the possibility of creating a specific clinical protocol to distribute the new insulin to small children, athletes and pregnant women who are known for having more trouble controlling their levels of blood glucose.

Sometimes the creation of a clinical protocol does not change the litigation. In the palivizumabe case, the evaluation made by interviewees in São Paulo's State Department for Health is that

> This did not change the level of litigation, because the lab that produces the immunization employs three law firms, so they keep searching for people to file the lawsuits in their name. Just yesterday, 25 new lawsuits were filed. I am not even going to bother to respond to them, but they are going to have to go to the centre where this vaccine is administered, so as not to create special treatment, and also because it is a complicated vaccine to give. Sometimes we give the mother a R$

> 5000,00 vial and she comes back to us because her paediatrician does not know how to give it to an infant (interview).

With the new cancer drugs it is the same dynamic, because labs, physicians and patients press the government to acquire new and more expensive drugs through the Judiciary; and the Executive responds by creating clinical protocols that at the same time generalize the policy to encompass those who do not have access to the Judiciary, and also by restricting it according to technical reasoning. This dynamic, of the creation of new clinical protocols for the distribution of new drugs after an initial volley of litigation, was also detected in the state of Minas Gerais by Machado et al. (2011, 594), but the authors raise concerns about this process

The SUS, which is in charge of guaranteeing access to health for everyone, has become a great market for the pharmaceutical industry's release of new products that are not always in the best interest of the health necessities of the overall population.

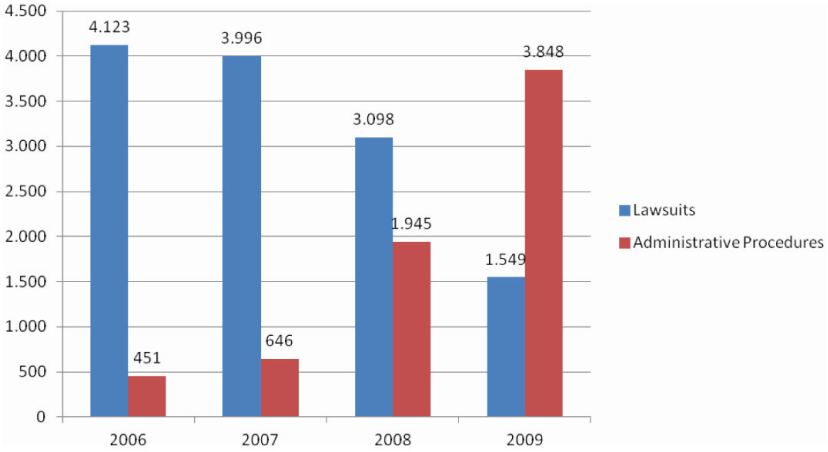
We do not want to get into the merit of the need for all diabetic patients to have access to lantus insulin and all the toddlers and other people with immune, respiratory or heart problems to have access to palivizumabe. What we want is to draw attention to the fact that, in both cases, the creation of a clinical protocol was at least partially motivated by the litigation, but this had the effect of expanding the access to more people than just those with access to the justice system. In these cases, a policy was created.

In time, the São Paulo State Department for Health's tactics have managed to transform litigation into internal administrative procedures, thus submitting the distribution of these drugs to the Executive's internal logic and logistics, cutting costs and minimizing the "privilege" problem.

The emergence of litigation for medication is also intrinsically connected to the social actors interested in sponsoring it. This makes obvious sense if we pay attention to the fact that the principles of the SUS were put in place in 1988, but litigation only started in 1996 and has intensified only very recently. This gap happened because, after the NGOs demonstrated that the Judiciary was a venue to help create policy, other organized actors with resources and interests of their own started to use it as well. So to try to diminish litigation, public health officials have also tried to identify and deal directly with these organized interests and "understand the local dynamics", as one of them put it. Besides the agreement with the Public Defender's office that originated the pharmaceutical triage policy, public health officials have also tried to talk to members of the Ministério Público and NGOs. In some cases it works and in others it does not, and since every public defender and prosecutor has a great deal of independence to act according to his/her own conscience, the result is suboptimal.

In the Araçatuba municipality, the levels of litigation have raised because of two Public Defenders. In Campinas and Franca, the numbers dropped because the two State Judges refuse to give injunctions to anything, so all the plaintiffs come to file suits in the state's capital as a legal tactic. I know this because the lawsuits are filed here, but I have to deliver the medicine in Campinas, and we fight because they are not supposed to do that. The number one municipality in litigation in the State is São José do Rio Preto, because of an NGO, and the second place goes to the Riberão Preto municipality, because of a Prosecutor. (interview).

Graph 1. Number of lawsuits and administrative procedures in the state of São Paulo, 2006-2009



Source: State of São Paulo Department for Health.

	Lawsuits	Administrative procedures
2006	4,123	451
2007	3,996	646
2008	3,098	1,945
2009	1,549	3,848

The STF's Response

This interaction between judges and public administrators has recently resulted in a modulation of the STF's positioning on the matter. In a recent ruling, the Brazilian Supreme Court's full bench denied nine appeals made by State and federal governments asking to overturn decisions of lower courts that determined the purchase of medication not distributed by the government for patients afflicted with different diseases. Justice Gilmar Mendes was the rapporteur for the cases[23] and the ruling was unanimous. The Supreme Court (STF) had already dealt with the matter in several other cases,[24] but the difference

with this one was that the Supreme Court went well beyond a simple "yes" or "no" answer to respond to whether the government should or should not buy the medicine for the patient in question, but enacted guidelines on how judges and public officials should interact when faced with the problem.

The ruling was accompanied by a comprehensive vote by the rapporteur that was not contested in any of its points by his ten colleagues, save by doubts raised by justice Ellen Gracie (she voted with the rapporteur anyway), who raised concerns regarding the court's new way of dealing with the matter, that changed from analysing every appeal that made its way to the Court, to a broad-based guideline type of ruling.[25] A quick transcript of the justice's words is worth noting:

> Is it possible to produce a ruling of general repercussion that effectively treats fairly all the myriad of cases so different from each other, in which circumstances are oftentimes unique? Maybe if we reduce it to a general category, say, diabetes patients who ask for drugs and devices to perform daily tests – that would be a homogeneous enough category where we could render a unique solution. The diseases brought to the Judiciary vary too much, as do the medications asked to treat them. (STA 175…, justice Ellen Gracie, 105)

When dealing with the issue of the Judiciary's legitimacy for positively guaranteeing a right to healthcare – in our case, by instructing the governments to acquire the medicines required by the patients –, the Supreme Court followed its previous jurisprudence, confirming its legitimacy to do so. The interpretation connected the "right to medicine" to the constitutional individual right to life, as well as the idea of the universal, equal and integral constitutional right to healthcare.

> It seems obvious that the inexistence of a clinical protocol in the SUS does not allow for the violation of the principle of integrality contained in the system, nor does it justify any difference between the options available to the user of the private and the public system. In these cases, administrative omission when dealing with a specific pathology may be the object of judicial challenge, both by individual and collective lawsuits. (STA 175 …, justice Gilmar Mendes, 24, original emphasis).

However, the court's ruling also made clear that, if there already is an alternative effective medicine distributed by the public health system, there should be a preference for it regardless of what was requested by the patient. The STF did not stipulate who should determine the effectiveness of the alternate drug or its necessity, if the patient's physician or doctors employed by the State. "So, we can conclude that, generally speaking, the SUS's standard option for treatment should be favoured when its inefficiency is not proven, regardless of the patient's option for treatment" (STA 175…: 22-23, original emphasis).

Another issue raised was the topic of drugs that were not certified by the ANVISA. On that, the STF decided that it was only possible to give certified medicine for treating a patient because "the certification of the ANVISA is a necessary condition to attest the safety and benefit of a given product, as it constitutes the first requisite for a drug to be incorporated and distributed by the SUS (Laws 6360/1976 and 9782/1999)".

The necessity of certification for judicially obtaining a drug was a controversial issue. Some judges would ignore it and some would require it (Vieira and Zucchi 2007). Fanti (2009) had already identified a tendency by the federal Judiciary (as opposed to São Paulo's State Judiciary) to demand more information from public officials before granting an injunction, and refuse it when the drug that was asked for was not certified by the ANVISA (Fanti, 2009).

Another recurring matter dealt with by the Supreme Court had to do with who should bear the cost of the drug: the federal, state or municipal government. Since the SUS is managed with resources from all three levels, it is not clear who should pay for the required treatments in each case. The lower courts already had well established jurisprudence on the matter (Fanti 2009), and the STF merely repeated it. It basically stated that the plaintiff could require any of the three levels of government to pay for his/her medications, because the constitutional responsibility for the right to healthcare was a shared one, regardless of the fact that, in actuality, responsibility for acquiring and distributing drugs is divided within the government, with the federal government being responsible for the higher cost drugs.

Lastly, there was the issue of whether the Judiciary should only deal with individual claims or also treat collective problems. On that, the court's ruling wasn't of much help, aside from a general preoccupation with the necessity for careful examination of proofs, mentioned expressively when the ruling deals with the possibility of the use of collective action to supplement administrative omission:

> (…) regardless of the case being brought to the attention of the judicial system, the premises here analysed are clear on the necessity of carefully analysed evidence in health cases, so that we do not have standardized claims accompanied by standardized rulings that do not dwell on the minutiae of each case, preventing the judge from reconciling the subjective nature, be it individual or collective, and the objective nature of the right to healthcare. (STA 175, 24, original emphasis).

In the same month that the STF made its ruling, the Conselho Nacional de Justiça (National Council of Justice (CNJ)) also edited a "recommendation" (Recomendação no. 31, March 2010), a tool aimed at advising lower courts and judges on how to deal administratively with an issue. The CNJ is directly connected to the highest instances of the Brazilian Judiciary, so its "recommendation" carries the weight and support of

the jurisprudence of Brazil's highest courts, especially that of the Supreme Court, whose president also sits as president of the CNJ.[26] The coordination between these two institutions is even more evident when we observe the time frame between the STF's ruling and the CNJ's "recommendation", and the fact that the rapporteur, justice Gilmar Mendes, was also the president of both institutions at the time.

The contents of the CNJ's recommendation are very similar to the STF's ruling, asking for better technical and evidentiary care on the decisions regarding the distribution of medicine to patients. It expressly asks that judges "consult public health officials before deciding on granting injunctions" (Recomendação CNJ no. 31, 3). It also recommends that courts reach agreements with the objective of creating independent medical and pharmaceutical councils to aid in the analysis of specific cases. The technical knowledge on diseases and the effects and risks of drugs are at the core of the issue, because judges have to rely on expert opinion in order to justify either giving or denying a patient medicine. Usually, the judges trust the patient's physician's opinion blindly. Lastly, the "recommendation" reinstates the argument that judges should not order the purchase or allow the use of drugs that are not certified by the ANVISA.

The innovation brought by the CNJ's recommendation is related to a suspicion that pharmaceutical labs were using the State, through the Judiciary, to finance experimental treatments for new drugs. In the phase of clinical trials on human beings, laboratories must freely give the new drug that has not yet been certified by the ANVISA to people who will participate in tests, in order to evaluate its effects. Even after the trial is over, the pharmaceutical company has to keep up the treatment of the test subjects, and give them access to the fruits of the research (National Health Council Resolution no. 196/96). Registration and inspection of clinical trials are carried out by a federal agency called National Commission of Research Ethics (CONEP); however, the records of the research are sealed. When we interviewed public health officials in the Health Department of the State of São Paulo, they informed us that by cross-referencing data from patients who are currently receiving experimental medication in the state of São Paulo due to a judicial order, and the number of patients known to be participating in trials for the introduction of the same drug in the Brazilian market, according to the CONEP, it is possible to presume that the laboratories are using the Judiciary to have the government pay for clinical trials. This was a concern addressed by public health officials to the justices of the Supreme Court in an audience held in February 2010 (public audience no. 4 of 2010, also cited in the CNJ recommendation). To prevent this from happening, the CNJ's recommendation asks that judges and lower courts "check with CONEP to see if the plaintiffs are participating in clinical trials for the requested drug, in which case the laboratories should assume the costs of the treatment".[27]

The recent STF/CNJ indicates an inflection from the former jurisprudence, which usually gives the requested medicine to the patient without consulting public officials or questioning if there is an equivalent cheaper medicine already distributed by the SUS, even when the drug was not registered at the ANVISA. Those were complaints long made by public health officials, whose reactions to the first wave of decisions on the issue lead to some changes in interpretation by the courts. We still do not know if this recent stand taken by the STF/CNJ will be followed by lower courts and judges, since in Brazil the principle of staire decisis does not exist,[28] and there are almost no internal controls of members of the Judiciary (Taylor 2008). The recent decision also signals a much broader-based way of acting by the Supreme Court when deciding constitutionality in cases that come to its attention via the diffuse system of constitutional review.[29]

Conclusion

This article has sought to emphasise, both in its critical review of the literature and through empirical research at São Paulo's State Department for Health, that the judicialization of the right to healthcare must not be viewed as exclusively positive or negative simply because it creates rights, or because of privileges or undue interference between governmental branches. The issue is more complicated than that, because it produces public goods, but it can also be questioned as it ignores the problem of limited resources. The process also cannot be characterized as one that creates "privileges", because the responses by public health officials to the judicial decisions end up creating policies to guarantee rights that are not restricted just to those who seek out the Judiciary. In order to understand the mechanics of how the Judiciary affects policy making, it is important to highlight compliance issues of how the administration responds to judicial decisions.

Among the effects that resulted from the judicialization of the right to healthcare in São Paulo we can mention the creation of the administrative service and the triage system, as well as the introduction of new drug dispensing protocols. There was a collective effect produced by various individual victories in the Judiciary, stimulating the creation of public policies by the administrators at the state's Executive.

What our work has shown, through the data collected at the Department and the analysis of the Supreme Court/CNJ jurisprudence, is that the relationship between the Judiciary and the Executive on the issue of dispensing medication was, at first, one of conflict, but afterwards it became more "complementary". The Executive responded to judicial activism by creating more efficient policies and providing more access to medication for its citizens; the Judiciary keeps pushing for the distribution of new medications and medical supplies, but now it pays more attention to technical issues argued for by the Executive's

administrators, and has actually reduced its activism because the Executive has become more active in drug dispensing policies. From the citizens' point of view there seems to be an improvement in policies that grant access to healthcare.

This does not mean that conflicts have ceased to exist. This complementary relationship must not be viewed as a harmonious one. Friction between the two branches of government are created with every new drug and with every new issue brought to the courts, sponsored by interested collective actors or pharmaceutical companies. The interaction between the Judiciary and the Executive, however, seems to be different from where they started off and that is still portrayed by the literature: an Executive obligated by a Judiciary to act in a technically inconsequential manner or, to the opposing view, poorly preoccupied with the health of the citizens, having to be "pushed" by the Judiciary to actually guarantee rights. At least in the case we studied, the relationship between the Judiciary and the Executive has been a much more positive and cooperative one.

And the future of the judicialization of the right to healthcare? Well, we share the head of São Paulo's State Department for Health's view that this process

> Will not end and maybe it should not end. If there is an ill person who needs medicine and the State, for some stupid reason, is not providing it, then we need to go there and help that person. But, as everything in life, I bet that it will decrease when judges start to realize that not everything should be given to everybody, every time they want it. When they realize that there are some interests pushing this process that do not have the patients' best care in mind, although sometimes these interests coincide. And when they start to trust us more to advise them on the reasons as to why some medication should not be distributed. This change is still incipient, but it has already begun. (interview).

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Notes

1 Someone who has the function of a representative, his/her job having been given to him/her by a legal instrument and not by vote or another substantive connection between represented and representative.

2 "Combining electoral and functional forms of representation, complex sovereignty expands the participation and capacity of society to influence the political process in a modern process that seems not to admit taking steps back, because it favours society's self-presentation through all available institutional channels (…). We are not talking about a 'migration' of the locus of

democracy to the Justice system, but of its enhancement through a generalization of forms of representation, which may be activated both by political citizenship inside the classical sovereign representative system and through 'social representation'." (Vianna 2003, 371, author's emphasis, free translations by the authors of this paper).

3 Caldeira analysed 656 decisions by the São Paulo State Court between 1985 and 2006.

4 Paradoxically, there are collective cases where the beneficiary is just one individual. See Caldeira (2008).

5 "To deal with collective suits, the courts should show that the division of costs they are proposing is better and more adequate to the law and the Constitution than the alternatives" (Lopes 2006, 256).

6 Data from São Paulo.

7 It is important to remember, however, that using the Judiciary was not the only tactic that social actors used to obtain political mobilization in the fight against AIDS.

8 Or, as Ventura et al. (2010, 78) point out, "in fact, it seems that this segment managed to establish a positive relationship between the access to the justice system and the effecting of the right to health".

9 In this case, the number of items is superior to the number of suits, because a single suit may ask for multiple items. According to the authors, 20% of the suits asked for more than four items.

1 Most likely, the medicines were already included for distribution in the SUS lists, but for some reason the patients were having difficulties getting them, or the prescribing physician had no knowledge that the medication was freely distributed by the SUS, or even, the drug started being freely distributed after the suit was filed (Vieira and Zucchi 2007).

11 Ferrazand Vieira (2009) adds that "the minority of individuals and (less often) groups who are granted this unlimited right via the Judiciary are therefore privileged over the rest of the population".

12 We will return to this subject when we analyse the STF/CNJ decision.

13 Lawsuits filed in the city of São Paulo in 2006.

14 The off-label use occurs when a medicine is used for the treatment of an illness other than the one to which its use was originally assigned in the clinical protocol.

15 Of these, 67.7% were represented by private lawyers and 23.8% had the support of an association (Marques and Dallari 2007, 104).

16 Article 196 of the Brazilian Federal Constitution of 1988: "Everyone has a right to healthcare and the government must provide it through social and economic policies that reduce the risk of disease and other ailments, and also guarantee universal and equal access to actions aimed at improvement, protection and recuperation.". Article 198: "The policies and healthcare services integrate a hierarchical and regionalized network, and constitute a unique system, organized according to the following directives: I – decentralization, with a single authority in each level of government; II – complete care, with priority to preventative measures without prejudice to assistance services; III – community participation." (emphasis added).

17 These data were provided by the São Paulo State Department for Health.

18 In some municipalities the impact is significant. When asked about this issue, the head of the

Department for Health for the State of São Paulo told us that, in some cases, a single judicial decision determining that a municipality buy drugs to treat a patient amounted to a 10% impact on the municipality's overall budget for health policies.

19 See, for example, Baptista, Machado and Lima (2009). "However, marketing and pressure from the pharmaceutical industry on doctors, NGOs, institutions and HIV/AIDS carriers to incorporate new medications and exams must be considered the origin of many of these suits, no matter the issues related to the rational use of medical procedures and the possible damage associated to inadequate prescriptions and misemployment. This same situation can be applied to present orders in other conditions such as neoplasia and rare diseases with experimental or expensive treatments".

20 This concern was addressed in the CNJ recommendation. See section 3.1.

21 The examples here are prosaic ones. There are, for example, several lawsuits asking for a product called "Lorenzo's Oil" to treat a rare degenerative disease called adrenoleukodystrophy (ADL). According to public health officials at the Department, there is not a shred of scientific evidence that the oil actually works. It only became known because of a Hollywood film that tells the story of a mother's struggle to cure her son. The film implies that the boy's condition could be treated with the oil, and it is said to be based on a true story. When the first lawsuits were filed, the oil was only manufactured at a University in Germany and had to be imported.

22 We will analyse these decisions later on in this paper.

23 STA 175, 211 and 278. Suspensões de Tutela 3724, 2944, 2361, 3345 and 3355. See http://www.stf.jus.br/portal/cms/verNoticiaDetalhe.asp?idConteudo=122125.

24 See RE 556.886/ES (adenocarcinoma de próstata); AI 457.544/RS (artrite reumatóide); AI 583.067/RS (cardiopatia isquêmica grave); RE 393.175-AgR/RS (esquizofrenia paranóide); RE 198.265/RS (fenilcetonúria); AI 570.455/RS (glaucoma crônico); AI 635.475/PR (hepatite "c"); AI 634.285/PR (hiperprolactinemia); RE 273.834-AgR/RS (HIV); RE 271.286-AgR/RS (HIV); RE 556.288/ES (insuficiência coronariana); AI 620.393/MG (leucemia mielóide crônica); AI 676.926/RJ (lipoparatireoidismo); AI 468.961/MG (lúpus eritematoso sistêmico); RE 568.073/RN (melanoma com acometimento cerebral); RE 523.725/ES (migatia mitocondrial); AI 547.758/RS (neoplasia maligna cerebral); AI 626.570/RS (neoplasia maligna cerebral); RE 557.548/MG (osteomielite crônica); AI 452.312/RS (paralisia cerebral); AI 645.736/RS (processo expansivo intracraniano); RE 248.304/RS (status marmóreo); AI 647.296/SC (transplante renal); RE 556.164/ES (transplante renal); RE 569.289/ES (transplante renal).

25 The justice's inclination for more case-by-case handling of litigation involving distribution of medicine was identified as early as 2007 by Leite et al. (2009).

26 The National Council of Justice (CNJ) is composed of fifteen members, of whom nine are magistrates. Aside from occupying its presidency, the Supreme Court also nominates two more magistrates to the CNJ, selected among the states' courts. The Superior Federal Court and the Superior Labour Court each nominates three more magistrates, two from their own ranks. The remaining members are selected by the Senate (1), the Lower Legislative House (1), the Ministério Público (2) and the Brazilian BAR Association (2).

27 Item I, "b.4" of the Recomendação (CNJ... http://www.cnj.jus.br/atos-administrativos/atos-da-presidencia/322-recomendacoes-do-conselho/12113-recomendacao-no-31-de-30-de-marco-de-2010). (emphasis added).

28 As strange as this may seem, it means that lower judges and courts are not bound by and do not necessarily follow the interpretations given by upper courts and the Supreme Court. The

only exception being if the Supreme Court creates a Súmula Vinculante ("Binding Decision"), which was not the case here.

29 The Court also exercises concentrated "European type" reviews. For more information, see Taylor (2008) and Arantes (1997).

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