JUDICIARY-EXECUTIVE RELATIONS IN POLICY MAKING:
THE CASE OF DRUG DISTRIBUTION IN THE STATE OF SÃO PAULO

Vanessa Elias de Oliveira – Universidade Federal do ABC (UFABC)
vanessa.oliveira@ufabc.edu.br
Rua Santa Adélia, 166, Bairro Bangu, Bloco A, sala 607-1 – Santo André/SP CEP 09210-170

Lincoln N. T. Noronha – Universidade de São Paulo (USP)
lincolnnoronha@gmail.com
R. Dr. Franco da Rocha, 487. São Paulo/SP CEP 05015-040

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ABSTRACT

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. In order to do so, we collected data and conducted structured interviews at São Paulo’s State Secretary of Health, to show how different strategies of response to judicial decisions affected the policy of medication distribution by the public sector. We also analyzed recent Supreme Court jurisprudence and showed how the Court reformed its earlier views on the issue in connection to public health officials’ demands. It is our understanding that current literature has failed to produce a more comprehensive view of the phenomenon because of its focus solely on the judicial decisions, without taking a step further and analyzing how public health officials reacted to them, thus addressing a compliance problem inherent to positive rights enforcement. Finally, we perceive this process as not a merely positive or negative one, going beyond the different normative biases present on the literature on the subject, and focusing on the mechanics behind the impact of the judicialization of the right to health care on distribution of medication’s policies.

KEY WORDS:
Health Policy, Judicial Studies, Public Administration
1. Introduction

The subject of “right to health care”, also called “judicialization of the health system”, has been gaining relevance in debates not only amongst Law and public health specialists, but has also among those who analyze public policy. That is because the judicial distribution of drugs not given by the Unified Health 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 the public administrators.

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

However, the focus of the debate has not been able to escape a dichotomy on the subject of access to medicine though judicial means: either the phenomenon is perceived as a good one, because it guarantees that a constitutional right to health care be satisfied by the government, or it is viewed as an undue interference of the Judicial branch in decisions that should be left to elected officials and Executive led bureaucracies, capable of weighting technical matters and choosing adequate policies given overall governmental priorities. In this sense, the current debate on the issue either doesn’t perceive problems and contradictions with the phenomenon, which we here will call judicialization of the right to health care, or simply ignore some of its impacts on public policies aimed at guarantying 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 the public administrator’s responses to the judiciary’s rulings shape those policies.

This work aims to fill this void by examining how public official’s responses to judicial rulings shape drug distribution policies. We view this process as a dual phenomenon, which produces advances to citizen’s rights through the realization of public policies, but not without contradictions and problems generated by the interaction between the Executive and Judiciary. By doing so, we avoid the dichotomous debate, characteristic of the brazilian literature on the subject, and innovate in the theoretical debate by drawing attention to specific aspects of the judicialization of politics that need to be addressed when the Judiciary acts as a positive enforcer of rights.

We have named this phenomenon judicialization of the right to health care because we perceive it as bringing together characteristics emphasized by the two literatures that have studied it: Law, which names it “right to health care”, and public health, which names it “judicialization of health care”. In our
understanding, it is a process of judicialization, because it consists of using the judiciary to gain access to a public policy related to the distribution of drugs, such as perceived by the public health studies, but it is also about guaranteeing a right that requires positive policies to secure it.

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

2. One phenomenon, two interpretations: Law and Public Health.

There are two usual approaches for the judicialization of the right to health care: the one that perceives it as a virtuous process of guaranteeing a right otherwise overlooked by elected politicians and public officials; the other one qualifies it as a vicious distortion of the relationship between branches of government. There are other ways to organize the debate, but doing so in this manner makes it easier to highlight two important features to understand the overall impact of this phenomenon on the policies that seek to implement the right to health care: 1) identify the actors themselves and how they frame the phenomenon: almost all of the authors in each field have a background either on law, and usually work as lawyers, public defendants, prosecutors, judges, etc, or have a background on 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 health care that the government should provide makes it easier to understand the political role of the judiciary foreseen in each field, with consequences for the institution structuring of the State’s decision making process.

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

2.1. The right to health care

In the “right to health” literature it is 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 from a
diagnosis of “collapse” or “insufficiency” of the electoral representative system, and see in the judicial system a way of supplementing this deficiency, because it is more prone to defend underrepresented minorities.

There are a lot of shades of gray among the different authors, whom almost always have a previous formation in law, but when you review the literature, it becomes clear that the authors have an overall opinion for the judicialization of the right to health care.

Even when authors seek a middle ground, their position on the subject is made clear in several passages. For example, Ventura et al (2010) ponders several ethical and technical issues related to the judiciary ordering the State to distribute medicine, but is in favor 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 about the efficiency of implementation of the right (to health care) must be restricted to services and goods already provided by the Unified Health System, determined by health officials.

2. A second position defends that the right to health care 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, ordering, thus, the UHS to deliver the medicine to the patient.

3. A third stance defends that the efficiency of the right to health care must be as ample as possible, and that the judiciary – on a case by case basis – must ponder rights, goods and interests at stake, to fix the contents of the State’s obligations on the delivery of goods and services.” (p. 86)

The so called “third position” made by the author can be collapsed in the second one, in that it authorizes the judiciary to have final word over the overall health care that society should give its individuals. That is by no means a “relative consensus”, as the authors claim a few paragraphs before (maybe in the jurisprudence, but not in the literature), and that can be exemplified by Vieira’s (2008) critique addressed further down (pg. 12), which begs the question: Given that we deal in scarce resources and that health care is probably the most costly public policy a country can implement, how much, we as a society, are prepared to provide as a health safety net for our citizens? Furthermore, how can we decide that, in a legitimate way, in a democratic regime?

The only difference between the second and third opinions as organized by the authors is that it asks for the judge’s careful weighting of the opinions given by UHS officials, and not simply comply to the patient’s personal physician’s opinion. The last word still “must” stand with the judiciary.
When addressing the issue, Werneck Vianna (2003) argues that functional 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. This functional representation in the judiciary would be typically performed by state bureaucracies in charge of doing so (in Brazil, the Ministério Público, the Public Defendant’s Offices and State’s Lawyer’s). In such context, the opening of various participatory channels (including judicial ones) are beneficial to marginalized groups, and help produce public goods to less privileged portions of society. On top of that, the construction of a civic collective identity through rights based activism would be in line with acquiring a modern sense of belonging. In this context, identities would be 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) argues that the broadening of deliberative and participatory channels, including the judiciary, can contribute to the betterment of public policies, because “(...) in the judiciary, the interests of the poor and the less favored in society may be more easily manifested, which gives this institution a comparative advantage” (Wang, 2009: 81). This advantage would presumably be given by intermediary institutional instances that could exert advocacy functions for this less favored stratus of society, reducing organizational costs for them. To prove his thesis, Wang researched lawsuits brought to justice by the Ministério Público and the Public Defendant’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 representative 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 health care literature. This diagnosis is based on the findings that there are more individual than collective suits been 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 in fact is not a policy to positively enforce a right to health care,

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1 Someone who has the function of a representative, its job, given to him by a legal instrument and not by a vote or some other substantive connection between represented and representative.

2 “Combining electoral and functional forms of representation, complex sovereignty expands participation and the capacity of society to influence the political process, in a modern process that seems to not admit steps back, because it favors society’s self-presentation through all available institutional channels (...). We are not talking about a ‘migration’ of democracy’s locus to the Justice system, but its enhancement through generalization of forms of representation, that may be activated both by political citizenship inside the classical sovereign representative system, but also through ‘social representation’.” (Vianna, 2003: 371. Original emphasis. All the translations were freely made by the authors of this paper).
but a privilege given to those with the resources to endure litigation against the State. To the right to health authors that share this diagnosis, what is needed is a shift in judicial enforcement from individual litigation to start dealing more with collective litigation, thus addressing broad issues with overall impact and benefits (Lima 2006, Ferreira and others 2004).

The issue of individual vs. collective litigation in positive rights enforcement has been given wide attention in the literature. Recent researches made on the jurisprudence of São Paulo’s State Court (TJSP) showed the judiciary’s difficulties of acting as a rights’ enforcer in collective lawsuits, whereas in individual claims it usually favors the plaintiff (Pepe et al., 2010). Analyzing the TJSP’s jurisprudence on judicialization of the right to health care, 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 favor of the plaintiffs.

Caldeira (2008) restricted her analysis to rights enforcement on collective lawsuits (including, but not only, the right to health care) and concluded that the court refrains itself more when the collective actor asks directly for the creation of an entire policy, and not just for the inclusion of a group of people in a particular existing programs (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 individual ones. That happens because a lot of collective cases are not about one individual4 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. 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 piece of the budget to be allocated to policies for fighting AIDS. Lima concluded “Our analysis showed that the courts are more comfortable when deciding a case in favor of a single individual, but they are not so when they are asked to force the revision of entire policies”. Ferreira et all (2004) gets to the same conclusion restricting their analysis to DST/AIDS cases against the municipality of São Paulo. “We have been able to observe that 93% of the rulings favorable to the plaintiffs were composed of cases that recognized the rights of individuals to health care, while only 5% of the victorious claims were about truly collective rights. As for the cases where the court denied the plaintiffs’ claim, 53% of them were about collective rights and only 33% dealt in individual rights.” (Ferreira et all, 2004: 25).

Lima 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” (Lima, 2006: 256).

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3 Caldeira analyzed 656 decisions from the São Paulo’s State Court between 1985-2006.
4 Paradoxically, there are collective cases where the beneficiary is just one individual. See Caldeira, 2008.
The authors that have studied the issue in a “right to health care” perspective this treatment of collective problems according to an individualistic approach in a place of extreme social inequalities transform rights in privileges of those with resources to fight a judicial battle. This diagnosis is shared by those that study the issue in a “judicialization of health care” perspective, who complain about “random” way in which courts offer expensive treatments to individuals, without considering a broader logic of public health that deals with a population (for example Messeder, Osório-de-Castro and Luiza, 2005; Vieira and Zuchi, 2006 e 2009; 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 Lima and others from the “right to health care” perspective, the remedy is exactly the opposite: courts should give more ambitious decisions on the matter, deciding over collective lawsuits and analyzing problems of distributive justice so as to create rights for everyone instead of privileges for a few. Ferreira et al., (2004) reaches Lima’s conclusion arguing that the economical rationality of deciding collective lawsuits is better for dealing with a problem in large scale than in a case by case basis.

In a different diagnosis, Caldeira (2008) raises issues of substantive representation legitimacy in such judicial collective arrangements, given that the main actors involved in the process were not elected. Not only judges in Brazil are not elected, but, among those entitled to file a collective lawsuit, the Ministerio Público (Prosecutor’s Office) is responsible for over 90% of all the collective litigation, and its members are also unelected and are accountable to no one besides their own consciences.

Although the recommended treatments diverge, the diagnosis given by the literature that studies the judicialization of the right to health care is based on the idea that when judges decide individual cases, they create privileges for the plaintiffs vis a vis the rest of the population. That diagnosis focuses only on the judicial rulings, without taking account the reactions of public health officials to the problem. Everything is perceived as if the public health officials were inert when facing the 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 health care” perspective, and after that we will analyze the reactions of the public health officials to the phenomenon, and how it affected public health policies.

2.2. The Judicialization of Health Care

As previously stated, the academic distinction between “right to health care” and “judicialization of health care” in Brazil carries with it a normative dichotomy regarding the role of the judiciary in guaranteeing the distribution of medicine. We have already seem how the problem is framed by the Law academic

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5 “To deal with collective suits, the courts should show that the division of costs they are proposing is better, more adequate to the law and the constitution than the alternatives” (Lima, 2006: 256).
6 Data from São Paulo.
community, and now we will critically address the issues raised by the “judicialization of the health care” perspective.

There seems to be a consensus between the two competing views regarding the moment when people started using the judiciary to obtain medicine: it begins with the requests for anti-retroviral 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 asked for this kind of drug.

It is worth mentioning that, according to Messeder, Osório-de-Castro and Luiza (2005), Scheffer, Salazar and Grou (2005), and Ventura et al. (2010), 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. According to Fanti (2009), analyzing Scheffer, Salazar and Grou (2005), the “transformation” of lawsuits in public policies is a positive aspect of the so called “judicialization of health care”.

“(…) the medicine that were being requested in the lawsuits were, besides those already mentioned in the official SUS programs, new “top of the line” drugs and diagnostics supplies and equipments that were not in the SUS’s programs and thus were not yet financed by the government. The research than shows that the delay in absorbing new technologies to the SUS is proportional to the growth of litigation asking for these technologies. On the other side, favorable decisions from the judiciary in many lawsuits contributed for such medicine and tests be included in the official policies” (Scheffer, Salazar e Grou, 2005, apud Fanti, 2009).

When the distribution of the anti-retrovirals is normalized, starting with the National Program of STD/AIDS, the proportion of requests for HIV medicine decreases to 14,6% in 2000 (Messeder, Osório-de-Castro e Luiza, 2005; Fanti, 2009). The success in obtaining AIDS medicine through the judiciary motivated the use of this venue to ask for other kinds of medicine to treat other diseases.

So we can say that the relation between use of the judiciary and regular distribution of drugs by the government is inversely related: when medicine is not regularly distributed by the government, the

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

8 In the same sense, as pointed out by Ventura et al. (2010), “In fact, it seems that this sector was successful in establish a positive relation between access to justice and effectiveness of the right to health” (op.cit., p.78).
judiciary is frequently called upon; and when the Executive manages to freely distribute the medicine for those who need it, the number of lawsuits diminishes.

Although this relation seems obvious, it is not so for a single reason: turning to the judiciary does not mean asking for the 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 the disease. This is the case, for instance, of lawsuits that ask for a specific brand of medicine that has the same active chemical principle already inserted in another drug freely distributed by the SUS. Marques and Dallari (2007: 104), analyzing 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 requests the medicine of a specific pharmaceutical lab, regardless if they are 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 asked that their disease were treated, or even that they were treated by a specific chemical compound or type of medicine, they asked for the specific branded drug from the specific pharmaceutical lab.”.

When requesting a specific branded drug, the patient does not guarantee that they will have the best treatment. According to the research made by Vieira and Zucchi (2007) on 170 lawsuits filed against the Health Secretary of the municipality of São Paulo, 62% of the requested items\(^9\), in a total of 282, were present in the SUS’s lists of freely distributed medicine\(^10\). From the 38% left, 73% could be substituted by similar medicine distributed by the SUS.

Analyzing the judicial litigation on distribution of medication in the City of Florianópolis’, Leite et al. (2009) also finds a lot of overlapping between what is being requested to the judges and what already is distributed by the SUS. Criticizing the judiciary, Ferraz (2009) talks about a “Brazilian model” of litigation in health care, 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 Tribunal (the “Supremo Tribunal

\(^9\) 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 4 items.

\(^10\) Most likely, the medicine 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 e Zucchi, 2007).
Federal” or STF), and later became dominant in the rest of Brazilian judiciary. In this interpretation, the right to health is an individual entitlement to the satisfaction of one’s health needs with the most advanced treatment available, irrespective to costs” (Ferraz, 2009: 2, emphasis added).

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, and not just the medication not given by the UHS. That way, when the judge sentences, it 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 the Ferraz (2009), not only the question of the costs of the treatments must be taken into consideration, because it means allocating scarce resources from other health care policies, but also the sheer fact that it is impossible to give everybody the most new and expensive treatments currently in existence for each specific health care requirement, especially when there are lower cost equally effective alternatives. So, the principle of equality must be addressed, not just the principle of universal care. If 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 disease11.

Still on the subject of the kind of medicine requested, not only do the plaintiffs ask for specific brands of medicine, 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 Secretary of Health Care of the State of São Paulo point to the existence of an elevated number of lawsuits that require disposable diapers, wet paper handkerchiefs, nutritional supplements and medicine already given by the government in a different dosage. That is the case, for instance, of lawsuits requesting 300 milligram capsules of acetylsalicylic acid to treat patients that require that daily dose (so he 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” costs the government R$ 0,01 a pill; the 300mg pill granted by the judiciary costs R$ 0,71. That situation repeats itself in many other cases with much superior costs, such as the case of cancer medicine. Besides the added product cost, the

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11 Ferraz (2009: 02) 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”.
process itself of acquiring different dosages and different brands of the same medicine requires 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 to 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 the early AIDS cases. In the early AIDS cases, the motivation was trying to get the government to start financing the treatment of a disease, thus realizing AIDS patients right to health care. The increase in the judicialization of the right to health care lead the treatment of diseases that weren’t being treated by the Unified Health System, but it also lead to distortions.

Another aspect of the judicialization of the right to health care raised by “judicialization of health care” literature is the lack of ANVISA registration of some judicially given drugs\(^\text{12}\). The commercialization and usage of a drug in the country requires an ANVISA certification. Experimental drugs that aren’t yet certified by the agency may only be used in clinical trials.

On that 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 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, from the 954 different medical supplies requested in the 9,712 lawsuits researched\(^\text{13}\), 3% were not available to 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 has not yet done so. The common use of off-label\(^\text{14}\) medication also enhances the dangers (Pepe et al, 2010; Lopes et al, 2010).

Furthermore, Vieira (2008) argues that the simple registration of a drug by the agency does not mean that it should be incorporated in the SUS programs:

“Registration of a pharmaceutical product, in itself, does not mandate its integration in SUS treatments. There is no health care 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

\(^{12}\) We will come back to this subject when we analyzed the STF/CNJ decision

\(^{13}\) Lawsuits filed in the city of São Paulo in 2006.

\(^{14}\) The “off label” use of a medicine occurs when it is utilized to treat a disease different from that for which it was initially established in the protocol.
and even universal systems in developed countries face problems to finance treatments.” (Vieira, 2008: 367).

Ventura et al. (2010) point out that judges have been ordering public officials to give any medication requested by plaintiffs, without taking into account if the supplies or procedures requested are in accordance with the Clinical Protocols and Therapeutical Guidelines established by UHS (op.cit., p.85). The argument is that universal health care 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 in the public system.

A third problem that deserved the literature’s attention was the subject of who was filling the lawsuits. Various works 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, the NGO’s were the most common sponsors of litigation. After the first few years of judicialization, other actors emerge and most of the lawsuits are filed under the name of individuals that seek treatment for themselves rather than some kind of universal policy. In their sample, Marques and Dallari (2007: 105) found that 100% of the lawsuits were filed by individuals. To the authors, when the judiciary tells the Executive how to spend its Money based on individual cases, that interferes with the Executive’s ability to implement more general health policies based on principles of public health. The risk is that the judicialization of health care may create privileges for a small portion of the population.

However, the literature does not mention that any citizen has access to the judicial system through public defendant’s offices, so resources are not restricted to those who have money to pay for a private lawyer or have some association pay one for them. Ferraz (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 that number is 53,5% (1991 – 2002). But the author questions his own numbers, arguing that most of public defendants’ offices are located within high income neighborhoods that have little access via public transportation, and end up being used by high income individuals. Social economical status of people is usually calculated base on geographical location (see, for example, Machado et al, 2010, and Chieffi and Barata, 2009).

The argument that criticizes the fact that the judiciary is a venue accessible only to high income people seems to miss the point. A person’s income doesn’t matter much, since public defense is available to whoever seeks it. Different incomes only means inequalities in access to information, transportation, etc. which might affect a person’s ability to seek public defense. Besides, the Unified Health System

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15 Of these, 67,7% were represented by private lawyers and 23,8% had the support of some association (Marques and Dallari, 2007: 104).
guarantees integral and universal care to all citizens, not just poor ones. Finally, the fact that many lawsuits are filed by people with relative higher income does not mean that they can finance their medical treatment. Some of the drugs asked for in the lawsuits amount to a R$ 20,000,00 (circa 12,000,00 US dollars) treatment 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 12,000,00 US dollars a month in Brazil? Should people that earn less than that but more than the average Brazilian income be left out of Unified Health System?

To sum up, the existing literature points to a series of questions connected to the so called “judicialization of health care”: who is responsible for the litigation, if it is an individual or a collective actor; the characteristics of the required drug, if it already exists an equivalent freely distributed by the SUS, if the drug is specified by brand or active chemical principle, if the drug is certified by ANVISA; the socio economic condition of the plaintiff, if he has or hasn’t enough resources to acquire the drug by himself; the issue of checks and balances and the encroachment of the judiciary in the Executive’s policies, that happens when the judiciary ignore technical matters or priorities set 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 health care, enshrined in the Brazilian Constitution. The acquisition of “top of the line” expensive treatments and drugs through the judiciary means allocating resources from broader policies that affected a lot of people to a small part of the population that has access to the judiciary venue. In addition to the inequality problem created in 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 São Paulo State’s Secretary of Health Care shows that while the average cost of treating a patient with drugs bought in the SUS system is R$ 2,500,00 (circa 1,500,00 US dollars) per year, the average cost of treating a patient with drugs bought because of judicial rulings is R$ 10,600,00 (circa 6,000,00 US dollars) per year.

Second, it is important to remember that the Constitution and the Unified Health System statute (Law 8.080, from 1990) establish that all three levels of government were in charge of financing

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16 Article 196 of the Brazilian Federal Constitution of 1988 “Everyone has a right to health care and the government must provide it through social and economical policies that reduce the risk to disease and other ailments, and also guarantee universal and equal access to actions aimed at improvement, protection and recuperation. Article 198 “The policies and health care services integrate a hierarchical and regionalized net, 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 preventive measures without prejudice to assistencial services; III – community participation.” (emphasis added)

17 These data were provided by the São Paulo State’s Secretary of Health Care.
pharmaceuticals, but the judiciary rulings do not take into account the federal division of responsibilities when acquiring the drugs. As a consequence of that, municipalities are frequently required to pay for high cost medicine, although the federal government is responsible for doing that\textsuperscript{18}. That not only draws resources from other health care priorities, but from other policies as well.

Finally, despite of its controversial effects, judicial activism in health care seem to also have had a positive effect in creating public goods, by interfering in the Executive’s agenda. As stated by Messeder, Osorio-de-Castro and Luiza (2005: 532), 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 started the requests for Mesalazin and Riluzol. In 2001, these requests are maintained and Peg-interferon and Hidroclorate of sevelamer are added. In 2002 there is an increase in the requests for Hidroclorate of sevelamer, Mesalazin and Peg-interferon, and the requests for Levodopa + Benserazid, Infliximab, Sinvastatin and Rivastigmin are added. In the last revision of the list for exceptional medication, all those drugs were added to the program (PT/GM/MS n. 1.318/02)” (emphasis added).

It is a long 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 the São Paulo’s State Secretary for Health Care. 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 health care just by its negative effects. It may contribute to the creation of public goods, although some of the requested medications have a public distributed substitute and others are not certified by ANVISA for their effectiveness and safety.

3. The strategies of public health officials.

The fact that the focus of most of the works done on judicialization of the right to health care has been directed to the judicial rulings has lead to a partial evaluation of the phenomenon. Although the courts order the public officials to comply with their decisions, these decisions are still implemented by the public health officials, who may respond to the judicialization in different ways. The implementation

\textsuperscript{18} In some municipalities, the impact is significant. When asked about that issue, the head of the Secretary of Health for the State of São Paulo told us that, in some cases, a single judicial decision determining a municipality to buy drugs to treat a patient amounted to a 10% impact on the municipality’s overall budget for health policies.
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, such as is usually the case with implementation literature, but to focus in the type of response generated by public health officials has lead us to a different diagnosis than the one that cries out that “privileges” are being created by the judiciary.

In interviews conducted at São Paulo’s State Secretary for Health, we were able to identify three different strategies used by public health officials to face the judicialization of the right to health care. But before we get to these strategies and how they impact on the policies, it is important to understand how the public health officials themselves diagnose the fact of having judges telling them what medicine to give to whom.

To São Paulo’s Head of the State Secretary for Health Care, 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 to people. It is his perception that the pharmaceutical industry, as any other industry, is driven by market logic. However, different from other markets, the demand of a product 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 different, the pharmaceutical industry spends billions of dollars to market their newer and more expensive products to physicians, but these products don’t necessarily bring considerable benefits to the patients. This is an argument also made by recent works in the field19. “Then comes the doctor, who thinks he is God, to give his opinion to a judge, who is sure of it” (Head of the State Secretary for Health Care). Evidence of that 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 doesn’t know anything about the technical stuff, simply orders that the drug in the doctor’s prescription that accompanies the patient’s lawsuit be given to him, many times without even consulting public health care officials20. Further evidence of that is the fact that only a handful of doctors and lawfirms are responsible for the majority of litigation, and even NGOs that advocate patient’s rights are financed by the pharmaceutical industry (Lopes et al, 2010).

According to the Head of the State Secretary for Health Care, even when the judge has a technical opinion given by public officials, he usually leans toward the patient’s doctor’s opinion. That happens because there is a culture of general distrust in the judiciary, who believes the Executive just doesn’t want

19 See, for example, Baptista, Machado and Lima (2009). “However, marketing and pressure from the pharmaceutical industry over 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 That concern was addressed to in the CNJ recommendation. See section 3.1.
to give people medicine because politicians want to save a few bucks for corruption or other policies that can get them more votes. But this perception is changing, because more and more judges, public defendants and prosecutors have been communicating with public health officials, organizing joint seminars, visits to hospitals and pharmaceutical dispensaries, exchanged emails, phone calls, etc. Knowing that, legal tactics have also changed and actors (plaintiffs and their lawyers) are filling the lawsuits in courts with judges sympathetic to their demands, avoiding courts and judges that would ask public health officials for information before granting an injunction.

Contrary to the “privilege” tone of the literature that focuses only in the judiciary, in the cases where public officials perceive some gain to the 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 that are receiving them through a court order.

Based on this evaluation of the problem, what are the public officials of São Paulo’s strategies to deal with the 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 differently the policies of drug distribution.

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 SUS, but for some reason the patient is having trouble acquiring 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 Secretary for Health Care detected that many judicial claims that came through the public defendant’s office were made by people that had a need for regularly distributed drugs, but had some kind of problem acquiring them. These people sought the public defendant’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 inside the public defendant’s office to talk to the patients, and orient them how to get the necessary medication. The service was transferred to its own location in 2008, and it allowed the State’s Secretary for Health Care to cut down costs in two ways: by eliminating litigation costs, and also dealing with the problem of different prescriptions asking for different brands of the same medication. That turned out to facilitate access to medication to people that otherwise had difficulty obtaining them. Some peculiar supplies started to be distributed at this triage center such as special soy milk for lactose intolerant children,
dippers and sunscreen lotion. Those supplies and medication became accessible not just for whoever filled lawsuits, but to the population in general.

**Useless or Harmful.**

Second, there are the cases where public officials believe the required treatment is either useless or actually harmful to the patients. Curiously, some lawsuits asking for antiretroviral medication fits this category.

As is well known, AIDS is still an incurable disease. With the available treatments the patient becomes chronically ill, having his lifespan expanded by taking the antiretroviral drugs. However, as times passes, the patient creates a resistance to the drug, and a new one becomes necessary. New drugs are constantly being developed and Brazil freely distributes the antiretrovirals to its AIDS patients, but during the timeframe that 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 a venue to force the government to acquire the drugs to the patients. However, the distribution of a new “top of the line” drug to help patients that haven’t yet developed a resistance to old medication may turn useless a drug that they will require in the future.

At the end of 2007, a new retroviral drug called *darunavir* was certified by 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, quote, “prevent litigation” (São Paulo’s State Secretary for Health Care’s public official), the state of São Paulo decided to get ahead the federal government and created its own clinical protocol to start distributing the new drug to patients that were no longer affected by the other medications. Because of that, according to data provided by the São Paulo’s State Secretary for Health Care’s, in 2008 only 5 lawsuits were filed requesting *darunavir* to the State of São Paulo. In these cases, São Paulo’s State Secretary for Health Care decided to fight the lawsuits, arguing that providing the drug to those patients would harm than in the future, because they would be useless when they needed them the most. The result of these cases was in favor of the State, although there are other episodes when that is not the case, and the resistance of the government to provide the medication restricts its access only to those that filed the lawsuits, although one could hardly make the point that the ones who had access to drugs in such situation are “privileged”.

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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 Secretary, there isn’t a shred of scientific evidence that the oil works. It only became known because of a Hollywood movie that tells a story of a mother’s struggle to cure his son. The movie implies that the boy’s condition can be treated by the oil, and it is said to be based on a true story. When the first lawsuits were filled, the Oil was only manufactured at a University in Germany and had to be imported.
Grey Area.

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

An example of these cases is the “glargina insulin”, commercially known as lantus. According to the head of São Paulo’s State Secretary for Health Care, currently about half of the litigation against the State asks for this kind of insulin (the other half are cancer drugs). The 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 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 via shots, which causes the patients a minor discomfort. According to the head of São Paulo’s State Secretary for Health Care, lantus offers at least two advantages in comparison to other insulin: first, its effects lasts for 24h, so only one dose a day is required, and second, it allows for a better control of glucose levels, especially when combined with “rapid action” insulin. That diminishes the risks of hyperglycemic 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 substitute its regular distributed cheaper options. In their perception, the costs outweighs 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 defense 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 preventive one, using the palivizumabe, but a single immunization costs R$ 5.000,00 (circa 2.200,00 US dollars) and that makes a widespread immunization policy prohibitive.

In these cases, although the medication provides some marginal gain to a person’s health, the cost/benefit perception of the Executive is that the distribution of these drugs is unjustified. What is, than, the strategy of São Paulo’s State Secretary for Health to deal with this type of litigation? 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 distribute by the SUS. This committee is tied to the pharmaceutical triage process, but it only acts in cases where the requests are outside normal protocols. If the committee’s evaluation is a positive one, than 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. That is in tune with the latest STF/CNJ ruling that requires better technical reasoning to be given in the judicial sentences. According to São Paulo’s Health Secretary, there is even the possibility that this committee becomes 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 a strategic action taken by the public officials to limit the litigation, they at the same time create a policy of distributing the medication regularly to patients, thus solving the “privileges” problem, but also justify limiting the distribution of the 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 asked for 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 year, or children up to two years that have some kinds of congenital heart diseases or a chronic pulmonary disease, between April and September, because it’s a seasonal virus. This year a national program will probably be launched. In the lantus case, São Paulo’s Secretary for Health Care 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 doesn’t change the litigation. In the palivizumabe case, the evaluation done by interviewees in São Paulo’s State Secretary for Health Care is that “This did not change the level of litigation, because the lab that produces the immunization has three offices, so they keep searching for people to file the lawsuits in their names. They have three law firms and just yesterday, 25 new lawsuits were filed. These I am not even going to bother to respond, but they are going to have to go to the center where this vaccine is administrated, so as not to create special treatment, and also because it is a complicated vaccine to give. Sometimes we give the mother a R$ 5,000,00 vial and she comes back to us because her pediatrician doesn’t know how to give it to an infant”.

With the new cancer drugs it’s the same dynamics, 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 beyond those who have access to the judiciary, but also restricting it according to technical reasoning. This dynamics where the creation of

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22 We will analyze these decisions further down.
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 (2010), 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 releasing 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 immunologic, respiratory or cardiac problems have access to palizumabe. What we want is to call the attention to the fact that, in both cases, the creation of a clinical protocol comes at least partially motivated by the litigation, but that has the effect to expand 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’s State Secretary for Health Care’s tactics have managed to transform the litigation in internal administrative procedures, thus submitting the distribution of these drugs to the Executive’s internal logic and logistics, cutting down costs and minimizing the “privileges” problems.

[GRAPHIC 1]

The emergence of litigation for medication is also intrinsically connected to the social actors interested in sponsor it. That makes obvious sense if we pay notice to the fact that the principles of SUS were set in place in 1988, but the litigation only started in 1996 and only very recently have intensified. That 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 the litigation, the 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 defendant’s office that originated the pharmaceutical triage policy, the public health officials have also tried to talk to Ministerio Público members and NGOs. In some cases it works and in some cases it doesn’t, and since each public defendant and each Prosecutor have a great deal of independence to act according to his own conscience, the result is suboptimal. “In the Araçatuba municipality, the levels of litigation have raised because of two Public Defendants. 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 the suits in the State’s capital as legal tactics. I know this because the lawsuit is 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 Ribeirão Preto municipality, because of a Prosecutor”.
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 States 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 and the ruling was unanimous. The Supreme Court (STF) had already dealt with the matter in several other cases, but the difference with this one was that, in it, the Supreme Court went well beyond a simple “yes” or “no” answer to respond 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 facing the problem.

The ruling is accompanied by a comprehensive vote of the rapporteur that was not contested in any point by his 10 colleagues, saved by doubts raised by justice Ellen Gracie (she voted with the rapporteur anyways), who raised concerns regarding the court’s new way of dealing with the matter, that changed from analyzing every appeal that made its way to the Court, to a broad based guidelines type of ruling.

It’s worth a quick transcript of the justice’s words:

“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, diabetic 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, and so does the medications asked to treat them.” (STA 175…, Justice Ellen Gracie: 105)

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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 paranoide); 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 (migração 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 marroméo); 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).
When dealing with the issue of the judiciary’s legitimacy for positively guarantee a right to health care – 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 of life, as well as the idea of universal, equal and integral constitutional right to health care. “It seems obvious that the inexistence of a clinical protocol in the SUS does not allow for the violation of the principle of integralty 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 or collective lawsuits.” (STA 175…, Justice Gilmar Mendes: 24, original emphasis).

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

Another issue raised was on the topic of drugs that were not certified by ANVISA. On that, the STF decided that it was only possible to give certified medicine for treating a patient, because “the certification of 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 e Zucchi, 2007). Fanti (2009) had already identified a tendency of the federal judiciary (as opposed to São Paulo’s state judiciary) demand more information from public officials before granting and injunction, and refuse it when the drug that was asked for was not certified by ANVISA (Fanti, 2009).

Another recurring matter dealt 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, in each case, who should pay for the required treatments. The lower courts already had a 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 medications, because the constitutional responsibility to the right of health care was a shared one,
regardless of the fact that in actuality, responsibility for acquiring and distributing drugs was divided within the government, with the federal government being responsible for the high cost drugs.

Last, 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 was not 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 analyzed are clear on the necessity of carefully analyzed 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 health care.” (STA 175: 24, original emphasis).

In the same month that the STF gave its ruling, the National Council of Justice (CNJ) also edited a “recommendation” (Recomendação nº 31, march 2010), a tool that aims 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 the support of the jurisprudence of Brazil’s highest courts, especially that of the Supreme Court, whose President also sits as President of the CNJ. 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 celebrate 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 the core of the issue, because judges have to rely on expert opinion in order to justify either giving or denying a medicine to a patient. Usually, the judges trust the patient’s physician’s opinion blindly. Last, the “recommendation” reinstates the argument that judges should not order the purchase nor allow the usage of drugs that do 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

26 The National Council of Justice (CNJ) is composed of fifteen members, of which nine are magistrates. Besides 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 Labor 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 Ministerio Público (2) and the Brazilian BAR Association (2).
of clinical trials in human beings, labs must freely give the new drug that isn’t yet certified by ANVISA to people that will participate on the tests, to evaluate its effects. Even after the trial is over, the pharmaceutical company has to maintain treatment of the test subjects, and give them access to the fruits of the research (National Health Council’s Resolution nº 196/96). Registration and surveillance of the clinical trials are made by a federal agency called CONEP (National Commission of Research Ethics), however, the records of the research are sealed. When we interviewed public health officials in the Health Secretary of the State of São Paulo, they informed us that by cross-referencing data from the patients that are currently receiving experimental medication in the State of São Paulo, due to judicial order, and the number of patients informed to be participating on trials for the introduction of the same drug in the Brazilian market, according to CONEP, it is possible to presume that the labs are using the judiciary to have the government pay for the clinical trials. That was a concern addressed by the public health officials to the justices of the Supreme Court in an audience held in February of 2010 (public audience nº 4 of 2010, also cited in the CNJ recommendation). To prevent that from happening, the CNJ’s recommendation asks that judges and lower courts “check with CONEP if the plaintiffs are participating in clinical trials for the requested drug, in which case the labs should assume the costs of the treatment”

The recent STF/CNJ indicates an inflexion from the former jurisprudence, which usually gave the requested medicine to the patient, without consulting public officials, without questioning if there was an equivalent cheaper medicine already distributed by the SUS and even when the drug was not registered at ANVISA. Those were complaints long made by public health officials, whose reactions to the first wave of decisions on the issue lead 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, and there are almost no internal controls of members of the judiciary (Taylor, 2008). The recent decision also signalizes a much more broad based way of acting from the Supreme Court, when deciding constitutionality in cases that come to its attention via the diffuse system of constitutional review.

4. Conclusion

This work managed to emphasize, both in its critical review of the literature and through an empirical research at São Paulo’s State Secretary for Health Care, that the judicialization of the right to health care must not be viewed as an exclusively positive or a negative one simply because it creates rights or

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27 item I, “b.4” of the Recomendação. Emphasis added.

28 As strange as this may seem, that means that lower judges and courts are not bound 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 wasn’t the case here.

29 The Court also exercises concentrated “European type” review. For more information, see Taylor, 2008 and Arantes, 1997.
because of privileges or undue interferences between governmental branches. It is more complicated than that since it produces public goods, but it also can be questioned because it ignores the problem of limited resources. The process also cannot be characterized as one that creates “privileges”, because the responses of the public health officials to the judicial decisions end up creating policies to guarantee rights that are not restricted just to those who seek the judiciary. To understand the mechanics of how the Judiciary affects policy making, it is important to highlight compliance issues of how the administration responds to the judicial decisions.

Among the effects that resulted from the judicialization of the right to health care 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 worked has shown, through the data collected at the Secretary 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 has become 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 by the Executive’s administrators, and has actually diminished its activism because the Executive has become more active in drug dispensing policies. From the citizen’s point of view there seems to be an improvement on the policies that grant access to health care.

That does not mean that conflicts have ceased to exist. This complimentary relationship must not be viewed as a harmonious one. Frictions 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 the one 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; on the other side, a judiciary guaranteeing rights by giving people access to policies or, to the opposing view, meddling in technical issues better left to be decided by the Executive. At least in the case we studied, the relation between the Judiciary and the Executive has been a much more positive and cooperative one.

As for the future of the judicialization of the right to health care? Well, we share the Head of São Paulo’s State Secretary for Health Care view that this process “Will not end and maybe it should not end. If there is an ill person that needs a medicine and the State, for some stupid reason, is not providing it, than we
need to go there and help that person. But, as everything in life, I bet that it will diminish 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 why some medication should not be distributed. This change is still incipient, but it has already started.”
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GRAPHIC 1
Number of lawsuits and administrative procedures in the State of São Paulo. 2006 - 2009:

Source: São Paulo’s State Secretary for Health.
<table>
<thead>
<tr>
<th>Year</th>
<th>Value 1</th>
<th>Value 2</th>
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<tr>
<td>2006</td>
<td>4.123</td>
<td>451</td>
</tr>
<tr>
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<td>3.996</td>
<td>646</td>
</tr>
<tr>
<td>2008</td>
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<td>1.945</td>
</tr>
<tr>
<td>2009</td>
<td>1.549</td>
<td>3.848</td>
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