Institutional Clashes Beyond the Judicialization of Health: Overlapping Powers in the Case of the Cancer Pill

Embates Institucionais para Além da Judicialização da Saúde: Sobreposições de Poderes no Caso da Pílula do Cancro *(PT: 293-312)*

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ABSTRACT

The 1988 Brazilian Federal Constitution institutes the promotion of "universal and equal access" to health care for Brazilian citizens. In this article, we will focus on the use and distribution of medicines as one of the national health system components. The organization responsible for standardizing and regulating the production and consumption of products and services is ANVISA – National Health Surveillance Agency, which works like the FDA (Federal Drug Administration). A unique episode took place in 2015 when a "popular uprising" began to take shape in Brazil around an issue regulated by ANVISA. Cancer patients had started to file lawsuits calling for access and permission to use a drug not authorized by this agency and which, according to the askers, supposedly would cure their disease. This drug is named phosphoethanolamine (popular name, cancer pill). Apart from the efficacy or otherwise of the drug in question, it might be interesting to organizational studies why a government organization may miss legitimation to exercise its legal role due to popular pressure, which strongly diverges from court decisions, especially involving power and legal interpretation. We approach theoretical possibilities about judicialization of health,

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discussing triggers of institutional and social conflicts (a) by surveying studies that deal with judicialization calling for supply or release of medication (b) possible connections already established in the academy with the so-called cancer pill and, finally, (c) relating such situations to the concept of institutional void.

Keywords: Cancer Pill; Judicialization of Health; Institutional Void; Public Administration

RESUMO

A Constituição Federal de 1988 sentencia a promoção do "acesso universal e igualitário" à saúde para os cidadãos brasileiros. Nesse artigo, trataremos do braço da saúde que se serve do uso e da distribuição de medicamentos como componente desse sistema. A organização responsável pela normalização e fiscalização da produção e consumo de produtos e serviços sujeitos à vigilância sanitária é a ANVISA, Agência Nacional de Vigilância Sanitária. Um episódio ímpar deu-se em 2015, quando um "levante popular" começou a tomar forma no país em torno de uma questão muito específica e regulamentada pela ANVISA. Pacientes com cancro passaram a entrar com processos jurídicos com intuito de receber autorização para utilizar um remédio não regulamentado pela agência e que supostamente curaria a sua doença: a fosfoetanolamina. Para além da eficácia ou não do fármaco em questão, parece interessar para os estudos organizacionais como e por que instituições enraizadas no país parecem perder a sua capacidade legitimada de realizar o trabalho para o qual foram criadas, ante a pressão popular, a decisões judiciais divergentes do entendimento do Poder Executivo ou ante a interpretação legal do acesso universal à saúde. Abordamos possibilidades académicas sobre judicialização da saúde, discutindo especialmente os gatilhos de conflitos institucionais que tais ações sociais podem desencadear especialmente (a) pelo levantamento de estudos que tratem da judicialização para fornecimento ou libertação de medicamento (b) possíveis conexões já estabelecidas na academia com a chamada pílula do cancro e, por fim, (c) relacionando tais situações com o conceito de institutional void.

Palavras-chave: pílula do cancro, judicialização da saúde, institutional void, Administração Pública

1. Introduction

In a state of broad attributions, endowed with moral criteria such as social justice and universalism inherent to the *welfare state* (Esping-Andersen, 1991), the provision of social services such as health, education, and security is a sensitive point in public management. The scope of legal attributions can be highly comprehensive, subjective, and no less challenging. Imbued with this principle, the Federal Constitution of 1988, in its article 196, sentences the promotion of "universal and equal access" to health for Brazilian citizens.

According to the Ministry of Health, the SUS – Sistema Único de Saúde (Unified Health System) — encompasses integral, universal, and free health actions, involving the three spheres of Government. It is a very broad spectrum of func-

tions, whose complexity requires the adoption of relevant control mechanisms and ways to maintain the regularity of the activities performed.

In this article, we will deal specifically with the branch of health care that makes use of the distribution and use of medicines as a component of this system. Of special interest is the fact that, in order to exercise its constitutional functions, the Brazilian State uses medicines produced by private laboratories, an arrangement that makes up a triad between private organizations (that are profit-oriented), Public Power (and its constitutional competence) and the users of SUS (the recipients of the medication). Thus, in this facet, private activity directly touches the national public interest.

In Brazil, the role of private enterprise in crucial areas of public management has led to the creation of regulatory agencies. The organization responsible for regulating and supervising the production and consumption of products and services subject to sanitary surveillance (e.g. food and medicine) is ANVISA – Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency). This agency regulates, for example, which medicines can be used in the country, whether they are the product of importation or domestic creation and production (ANVISA, 2018). These drugs, of course, are part of the health service provision, as regulated by art. 200 of the Carta Magna.

It has come to pass that, despite ANVISA's neuralgic performance, the course of medicines procurement, regulation and consumption of medicines sometimes bypasses the involvement of SUS users. A unique episode, and therefore so interesting, took place in 2015, when a "popular uprising" began to take shape in the country around a very specific issue regulated by ANVISA. Cancer patients had started to file lawsuits calling for access and permission to use a drug not authorized by this agency and which, according to the askers, supposedly would cure their disease. This drug is named phosphoethanolamine (popular name, cancer pill).

In fact, the existence of lawsuits for access to medicines and treatments is not new, but in the case at hand, the legal disputes orbited around the core of the regulatory activity: the release of the drug by ANVISA, encompassing the so-called triad of organizations in this sector. The popular desire created an eminent contradiction: the unregulated medicine started to be produced by one of the laboratories of USP – University of São Paulo and distributed to those who had judicially conquered that right.

The media started to report issues pertinent to the case, more and more people filed lawsuits, the social media were filled with disputes and arguments for and against the use of the substance, and finally, the government got involved, creating a commission in the House of Representatives to discuss the matter and also

allocating funds for further research on the supposed cancer-fighting medicine. This dynamic shows the so-called tripartite relationship, in which the regulatory agency becomes an additional element.

Now, beyond the efficacy or not of the pharmaceutical product in question, it seems to be of interest to organizational studies how and why institutions rooted in the country seem to lose their legitimate capacity to perform the work for which they were created, due to popular pressure, judicial decisions diverging from the understanding of the Executive Power, or when faced with the legal interpretation of universal access to health. Or even, in the complex web of organizations involved, and eventual disparate interests, institutional clashes and misty areas about legitimacy arise.

In this study, we address academic possibilities on judicialization of health, leaving the traditional arguments on the subject and discussing especially the triggers of institutional conflicts that such social actions can trigger especially (a) by surveying studies dealing with judicialization for supply or release of medication (b) possible connections already established in academia with the so-called cancer pill and, lastly, (c) relating such situations with the concept of institutional void. According to Rodrigues (2013), we understand these institutional voids as 'spaces' between rules/standards and their compliance and, according to the author, may occur due to lack of legitimacy or weak control systems and/or in the notion of legal ambiguity(Edelman, 2016). In addition to this survey of scientific connections, at the end, we discuss the possible and institutional voids in this case and their unfolding, considering the dynamics between regulators and regulated, private initiative and public service, and the view and urgency of users, discussing institutions and legitimacy.

We hope, therefore, to offer an investigative path for the future incorporation of empirical data, aware of the relevance, social adherence, and field perspectives that the theme offers.

2. Theoretical reflections: The judicialization of health as a trigger for institutional voids

We begin with a rather simplistic reflection, with an exercise of literal interpretation of the law. Assuming that the understanding of universal access to health is taken in an unrestricted and unanimous sense, there would be no need for judicialization. Nor would it be feasible to deny judicial demands for access to treatments and medications. On the other hand, if the non-release of the cancer pill were unquestionable, given the legality and due competence of the prohibition, the medicine could never be produced in the laboratory of the largest public university in the country.

These reflections, of a purely hypothetical and highly simplistic nature, serve only to highlight that the law does not operate in an absolute and detached manner from social reality. Therefore, even regulatory and coercive aspects of institutions (Scott, 2008), are subject to social agreements around them. Thus, "legitimacy is the generalized perception or premise that an entity's actions are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions" (Deephouse & Suchman, 1995, p. 574, authors' translation).

It is understood, therefore, that even though there is a notion of formal legality, a legal aspect that provides conditions for an organization to operate "within the law", we comprehend that the situation of the cancer pill can be understood from the viewpoint of social legality, this being a component of the social structure, with a high connection in the process of social acceptance of the meaning of a law at the same time that it permeates the processes of social meaning of the letter of the law (Ewick & Silbey, 2002).

The partnership of Sociology of Law with Organizational Studies brought some important concepts to discuss the law as a social construct. This interconnection incisively points out that legal aspects cannot be viewed as mere formalities, nor that laws are processes exogenous to the environment of organizations. In this sense, Edelman (2016) evokes the idea of law endogeneity, claiming that the process of creating and maintaining a law is closely linked to the way the actors involved in the process, whether legislators or those regulated by the law, negotiate the meanings and contours of that law.

Accepting, therefore, that there is room for negotiation of the meanings of the law in this process that is understood as endogenous, the notion of legal ambiguity may help in the understanding that we propose. Sociology of Law understands that it is inadequate to say that the law "is", or to understand the law as a totally objective reality. Here it is understood that:

> 'the law' is in reality a jumble of conflicting principles, imperfect analogies, and ambiguous generalizations. In this way, lawyers, judges, regulators, and the target population negotiate the meaning of the law in each application, seeking a workable consensus rather than a logical certainty. (Suchman & Edelman, 1996, p. 932, authors' translation)

The excerpt transcribed above values the endogenous character of the law when there are different actors or organizations talking about its content. The issue of conflicting principles, for example, leads to the need for a viable consensus, which characterizes the dynamics of the cancer pill case. Thus, the concept of endogeneity of the law converges with the highlighted empirical scenario.

Having briefly explained the notions of legality, including within its social spectrum, and of legal endogeneity and ambiguity, we will now discuss the judicialization of health. We have seen a great increase in lawsuits as a resource for people to have their right to health guaranteed. This phenomenon has therefore been called the judicialization of health (Machado & Dain, 2012). The mandates of safety have been frequent when it comes to issues relating to health, and in this process the citizen seeks help in the courts so that something that is constitutionally guaranteed to him is fulfilled (Machado & Dain, 2012).

Therefore, it is known that the judicialization of health care is a reality in Brazil (Machado & Dain, 2012; Daniel Wei Liang Wang, 2015), however, the scientific productions around the theme are concentrated much more in the areas of health or law. In the area of Public and Business Administration, Accounting and Tourism we find only eight, four of which repeat authors (using the Spell indexer, a database that seeks to bring together the national production from the areas mentioned). Those studies deal with the budgetary mismatch that such court decisions bring to the public coffers (Daniel Wei L Wang, Vasconcelos, Oliveira, & Terrazas, 2014), similarly to Wang and colleagues (2014), but with the creation of a financial indicator (Scheren, Wernke, & Zanin, 2018), the regressive effects that end up benefiting most evidently those who are already socially favored (Daniel Wei Liang Wang, 2015), the main characteristics of the demands coming from judicialization (Scheren, Wernke, & Zanin, 2017), a research action aiming to provide a basis for improvement in the design of public policies (Oliveira, Ribeiro, Tavares, & Ferreira Neto, 2009), the role of judicialization of health and the judiciary (Lopes & Mello, 2018), the limits of the universality of the right to access and integrality of care given that judicialization strongly impacts displacing the public budget (Dresch, 2015).

Finally, Machado and Dain (2012) analyze a Public Hearing (PA) convened by the Supreme Federal Court (STF) to hear society regarding health-related issues:

> What was at stake in this PA was, among other things, the **legitimacy** or not of the Judiciary to act in the area of health. Perhaps there is **an expectation, certainly naive, of some managers to try to limit the role of the Judiciary** in this area, not only by retraction of the Judiciary, but also by the expansion of the powers of the Executive (…) Also of note is the expectation that the current stage of judicialization of health in Brazil will have a pedagogical effect on managers (…) In this way, judicialization would be treated more as an indicator of health conditions rather than as a problem in itself. (Machado & Dain, 2012, p. 1034, emphasis added)

A broader survey of data on the judicialization of health (without reducing it only to Administration and related areas) has shown that, in academia, the judicialization of health is already present mainly in the issue of effectiveness and efficiency of Public Administration, including its impact on planning, management (Pepe, Figueiredo, Simas, Osorio-de-castro, & Ventura, 2010) and budget execution (Daniel Wei L Wang et al., 2014) of federal entities.

From the perspective of social dynamics, of the complexity of purposes and institutional clashes, some studies value the discussion on the universalization of health care (Diniz, Machado, & Penalva, 2014), right to social justice (Ventura, Simas, Pepe, & Schramm, 2010) as well as the notorious interest of pharmaceutical groups, in association with doctors and lawyers already familiar with the system (Campos Neto et al., 2012).

Pharmaceutical assistance is, in fact, one of the cores of the judicialization of health, including for scientific studies. According to Diniz, Carvalho and Penalva (2014), pharmaceutical assistance figures as the second most frequent plea in the Federal District, behind it only the access to intensive care units. However, the focus is usually placed on access to high-cost medications, some of foreign origin, which are excluded from the lists of the single system, under the allegation of financial hyposufficiency.

For Machado it is clear that the terms and studies on the judicialization of health care need advancement, but according to his survey, research revolves around two currents:

> The term, however, lacks a better definition that would allow a more precise identification of the depth of this phenomenon in Brazil. It is initially divided into two currents of thought: one that sees in the political activism of the judiciary a hindrance to the development of citizenship and another that attributes to this phenomenon a form of amplification of citizenship itself. (Machado, 2015, p. 73)

We argue that a third way, which can encompass both currents of thought, is possible. Beyond the consequences of the development or not of citizenship, the judicialization of health can be understood as one of the triggers for institutional clashes. Thus, we come to position these ideas as elements that foster the institutional voids approach.

In 1997, Khanna and Palepu coin the term "institutional void" to designate the absence of specialized intermediaries, lack of enforcement mechanisms and the lack of sophistication of regulatory systems, something so frequent in emerging markets, especially the case of underdeveloped and/or developing countries (Khanna, Palepu, & Sinha, 2005). These authors, however, are more concerned

with developing possible strategies so that organizations immersed in these markets with voids are able to cope and grow even under these adverse conditions.

Changing the focus of analysis, Rodrigues (2013) is more concerned with understanding the operation and impacts of these institutional voids, highlighting how they occur, which laws or lack thereof and in which area they impact certain markets, how public policies — even if supported by the legal system — lose their ability to act in the absence of enforcement mechanisms, and so on. Thus, they arise as 'gaps' between rules/standards and their compliance, and may occur due to lack of legitimacy or weak control systems (Rodrigues, 2013). And it is in this alignment that we proceed with this study, but claiming that these 'spaces' for unexpected actions and that generate conflicts in the market not only occur due to lack of regulation and legitimacy questionings, of the act or of the actor themselves. The interpretation of laws and the social understanding of the scope and action of such regulations provide conditions for conflicts between various actors, showing that legal ambiguity can be, in itself, a kind of catalyst for an institutional void, as much as the lack of enforcement mechanisms, the absence of intermediary specialists and sophisticated regulatory systems.

So, we want to discuss the performance of a legally supported organization, both its existence and its competencies, which has one of its acts — also legally supported — strongly questioned by society. This issue challenges both the legitimacy of the act and the social acceptance of the organization itself, and is based on the complexity of the network of relationships, meanings, and interpretations given by organizations and social actors.

3. Data collection and method

We undertook a secondary data research of a longitudinal nature, especially between the years 2015 to 2018, to understand the events we reported in the previous section. Given the poignancy of the topic, and the possibilities of changes in interpretation, we make use of a tracking tool for any fresh news involving the term "phosphoethanolamine" on the internet, considering that its content becomes part of the documental body under analysis.

Among the documents are: legal content (e.g., laws, bills, discussions in the House of Representatives and courts) and media material. From the House of Representatives, there are 247 documents that relate to the term "phosphoethanolamine", and most of them are concentrated in the year 2016 (124 documents in 2016, 94 documents in 2015, 26 documents in 2017 and only 3 in 2018). In these documents, there are propositions, 5 of which are draft bills. They are divided as follows: 34 in 2015, 30 in 2016, 18 in 2017 and 2 in 2018. From ANVISA, there are technical notes and material that discuss the regulation and legality for manufac-

turing, distribution and consumption of medicinal drugs in Brazil. In the media material, we have from official media news to material published in social media channels, such as Facebook, Instagram and Youtube.

In parallel, we conducted a survey of articles in two scientific research indexes: Spell and Google Scholar, searching for studies on health judicialization. Spell for indexing articles on Public and Business Administration, and Google Scholar for a more comprehensive overview of the poignancy of the theme in other areas.

We obtained the following relevant results: there are only 8 articles indexed in Spell, while Google Scholar found — in the most diverse areas — more than three thousand citing the term. In the analysis, we could see that two major areas deal with the subject: health and law.

For the analysis, we employed a qualitative logic, with guiding topics, which Maxwell (2005) calls organizing topics, the codifications also occur in an inductive manner at first, organizing the codes around themes that arise in induction and also in these organizing topics (in a more deductive logic). Miles and colleagues suggest that the analysis should happen in orders, so we have this more inductive phase and in the following cycles the codes are grouped, culminating in a group of categories that explain the phenomenon studied, answering the research question in a structured way (Miles, Huberman, & Saldaña, 2014). The execution took place with the help of the qualitative research software NVivo.

4. Longitudinal empirical approach: A national remedy, a people's right

One of the most instigating points of the case is precisely to understand how a drug banned by ANVISA would be under production by the USP laboratory. In temporal terms, even during the course of the pill production at USP, coordinated by Professor Gilberto Orivaldo Chierice, ANVISA issued a technical note in 2015, stating that the production did not follow the legal requirements.

In summary, the aforementioned technical note claimed that Law no. 5991/1973 understands a drug as "every pharmaceutical product, technically obtained or prepared, with prophylactic, curative, palliative ends or for diagnostic purposes. Thus, any product, regardless of nature (plant, animal, mineral or synthetic) that has therapeutic claims, **should be considered a medicine and needs registration to be manufactured and marketed**" (ANVISA, 2015, p. 1, emphasis added). In 1999, when ANVISA is created, it becomes responsible for drug registration in the country and uses Law 6360/1976 as a basis, which anticipates the administrative and technical-scientific evaluation of the drug to be registered.

Thus, (i) there is no indication by ANVISA of a 2014 ordinance on the impossibility of manufacturing and marketing of the drug, i.e., prior to that production.

The agency states that the law is from 1976; (ii) However, ANVISA reports that it has no application for the registration of Phosphoethanolamine:

> At ANVISA there is **no registration granted** or registration application for drugs with the active substance phosphoethanolamine. In this context, we emphasize that **there is also no ongoing evaluation of projects containing phosphoethanolamine for the purpose of clinical research involving humans**. (ANVISA, 2015, p. 3, emphasis added)

(iii) the law determines that for a drug to be released, it needs to comply with non-clinical study reports (not conducted on human beings) and reports of clinical studies I, II and III, these ones being conducted on human beings and that each phase of these needs to be approved by competent bodies, these being the Ethics and Research Committee (CEP), the National Commission on Ethics and Research (CONEP) and ANVISA (ANVISA, 2015).

That being said, we have an institution legitimized and instituted by law that is responsible for releasing the manufacturing and the marketing of drug interactions in the country – ANVISA. It states that the drug produced by USP has no registration as belonging to non-clinical or clinical phases and perhaps for distribution to the population. Even so, it seems that USP — also a legitimate university and protected by law as a scientific research center — supplied the substance without registration, stopping to do so at some point. When this kind of cleaving occurs, the Brazilian judicial system is triggered and starts ordering the university to produce and deliver the drug.

The contradictions and complexity of the case are fostered by the unique popular notoriety; a part of Brazilian society has risen up in favor of the "medicine that cures cancer". There are demonstrations on social networks, petitions, and public demonstrations. Among these, there are those who claim that the drug is not released due to capitalist interests, of the big pharmaceutical industries, of doctors who would be out of work if cancer was cured, and that the "chemotherapy industry" is very interested in keeping its business alive and profitable, highlighting what we point out as the conciliation of public interest with private initiative.

Google Trends (Google, 2018) presented a report on the evolution of searches on its search engine for the search term "phosphoethanolamine" starting in 2004 up until 2018. The results indicate that until 2014 the number of searches for the term is practically equal to zero, while in 2015 there is a sudden increase in this search, as can be seen in Figure 1.

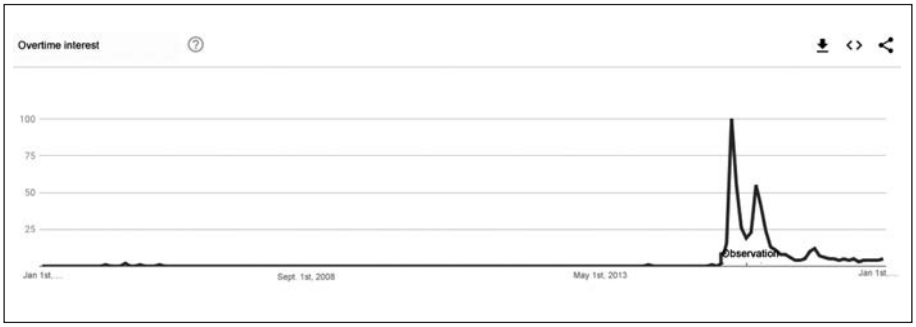

FIGURE 1. Evolution of searches on Google for the search term "phosphoethanolamine"
Fonte: Google (2018).

The 5 most frequent terms in related queries, according to the same report, are: (i) synthetic phosphoethanolamine, (ii) cancer phosphoethanolamine, (iii) buy phosphoethanolamine, (iv) usp phosphoethanolamine and (v) usp (the terms appear without accent and without capitalization because they were copied exactly as spelled in the report). Terms 6, 7 and 8 concern how to obtain, how to buy and how to access phosphoethanolamine. All terms are flagged as "sudden increase" searches in the report.

This popular motion seems to have caught the attention of parliamentarians who inserted the issue of phosphoethanolamine in the discussion agendas in Brasilia, such as the Committees of Consumer Law 78/2015 and 84/2015 (Brasil, 2015). The Ministry of Science, Technology and Information announced that it would release ten million reais for the study of the drug (Escobar, 2015).

As of the year 2016, discussions on the topic follow two main paths: on one side, legislators who start making large-scale propositions (84 from 2015 to 2018) within the House of Representatives, culminating in draft bills (5) and, finally, in Law 13269 of April 13, 2016 — the Cancer Pill Law that authorizes the use of synthetic phosphoethanolamine by patients diagnosed with malignant neoplasia (Brasil, 2016), and on the other side the "science", which, with the money allocated, started to conduct tests independent of the USP to investigate the efficacy of the drug.

Some segments of society are against it, endorsing the arguments made by the Brazilian Society of Clinical Oncology, for example:

> The legislators' decision demoralizes the Ministry of Health, Anvisa, science, and the country. It is a measure based on public and not technical pressure.

> We will continue fighting for patients to have better health and not to put lives at risk," says Gustavo Fernandes, president of the Brazilian Society of Clinical Oncology (SBOC). (Felix & Castro, 2016)

The legal validity of the law, or the formal legality, lasted less than two months. The Supreme Federal Court (STF), by a majority vote, granted an injunction to suspend the efficacy of the law, until the trial of the Direct Action of Unconstitutionality (ADIN) 5051/2016 opened by the Brazilian Medical Association, claiming that such law hurts the principle of the right to health and the right to safety and to life (STF, 2016).

> The rapporteur pointed out that the State's duty to provide medicines to the population is contrasted with the constitutional responsibility to ensure the quality and safety of the products in circulation. **The National Congress**, for the minister, by allowing the distribution of medication without prior control of sanitary viability by Anvisa, failed **to comply with the constitutional duty to protect the health of the population**. "The right to health will not be fully accomplished without the State fulfilling its obligation to ensure the quality of the drugs distributed to individuals by means of rigorous scientific screening, capable of ruling out deception, charlatanism and harmful effects to the human being."
> On this point, according to the rapporteur, there is offense to the postulate of separation of powers, since it is **not up to the National Congress** to enable the distribution of any medicine, but to Anvisa. The minister points out that the approval of the product by the agency is a condition for industrialization, marketing and importation for commercial purposes, according to Article 12 of Law 6360/1976. "In the absence of registration, the inadequacy is presumed." (STF, 2016, emphasis added)

In 2017, tests continue to be conducted and the previews are not encouraging for the cancer pill advocates. However, patients continue to file lawsuits and organize forums and marches on the issue, the illegal trade of the substance takes hold and a Parliamentary Commission of Inquiry is set up to discuss the issue and possible failures in clinical trials. In 2018, the CPI concludes that there was a failure at testing level and the judiciary has denied appeals for the release of the applicant's exclusive use (data from the news tracking that has been conducted since 2017).

From that moment on, when ANVISA takes a position and informs (in fact, reiterates that its regulations also apply to this case) that the cancer pill is not authorized to be produced and used, the courts no longer rely only on favoring the citizen having guaranteed access to health. They heretofore place this individual right within a broader issue, that of the legality of an institution, with legitimacy to

regulate on specific issues. More than that, they not only directly touch on their legitimacy to do so, but they call into question what an agency has already regulated.

The tone of a portion of society also went in this direction. Something like "it is absurd to have to follow so many rules when there is a medicine that will save so many people". And, of course, where there is some kind of social interest, there is often an electoral-political interest: legislative power comes into play.

Now, if the problem is that some kind of law prevents society from having what it wants and what it understands it needs, let it be through another law that this is done. The House of Representatives moves and positions itself, essentially, on the side of those who consider that the pill should subvert the rules, because it is an extremely delicate case, of such complexity that it gains special contours that would guarantee it such treatment. Thus, after much discussion, a law is presented, overriding the others:

> LAW NO. 13269, OF APRIL 13, 2016
>
> Cancer Pill Law
>
> SUMMARY: Authorizes the use of synthetic phosphoethanolamine by patients diagnosed with malignant neoplasia (Brasil, 2016)

In a synthetic way, we present three figures to help in the understanding of this process that we are analyzing. Figure 2 represents the most common process. There is Actor 1, legally established to regulate a specific issue, in this case ANVISA, regulating production and distribution of medicines in the country. There is also Actor 2, which could be any pharmaceutical industry, producing medicines according to what Actor 1 has regulated. These drugs produced by Actor 2 are, therefore, distributed to the population and, when it comes to issues in which the government is the provider of this "health guarantee", it is the government that pays, through the Executive.

In Figure 3 we try to represent the process by which this phenomenon of health judicialization occurs. In it, the link is broken in the supply of medicines to the population, because the Executive refuses payment and, therefore, there is no distribution. In this case, a new actor enters the process, which we are naming Actor 4 — the judiciary. By means of a lawsuit, those who consider that they should receive the medicine, request the courts to determine that the payment be (re) established and the flow returns to "regular flow".

Finally, in Figure 4, we seek to represent how this process of the cancer pill occurred, showing that other obstacles were present, besides the phenomenon of judicialization of law. In this flow, there is also a break in the production stage of the drug, that is, not only did citizens not have access to the drug and, therefore,

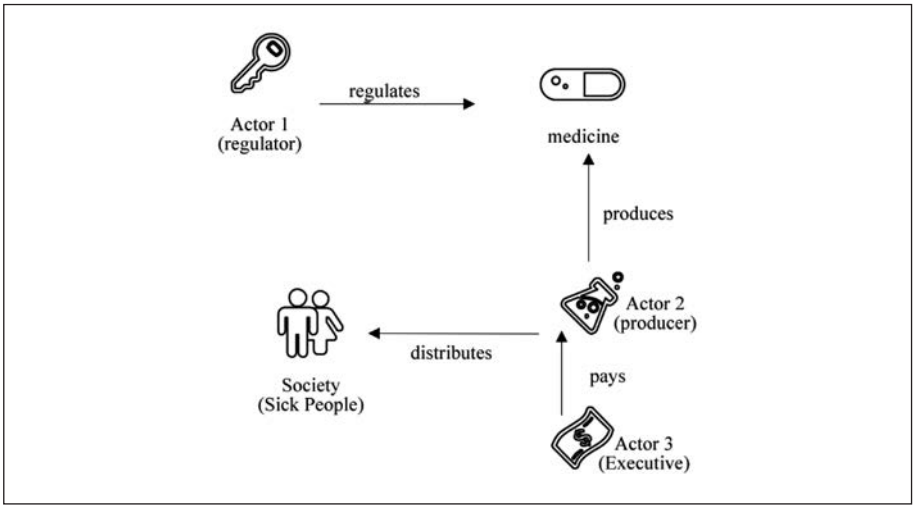

FIGURE 2. Regular Flow of Medicine Distribution by the Government

resorted to the courts to have this procedure determined. Here, the cycle is interrupted earlier, already in the production process, due to the finding of a legal irregularity. Thus, in addition to the process of judicialization of health, there is also the entry of a new actor, which we are numbering as Actor 5 — the legislative. In this flow, the House of Representatives enacts a law that determines that the pill should be produced and distributed, even though it seriously violates the regulations in force for all other drugs in the country. In this way, the production and distribution of the cancer pill would be reinstated, closing all the links again.

Given this analysis, we list relevant points: (i) First, by placing ANVISA under scrutiny as a social actor, one has no elements to say that this is not an organization seen as legitimate by society, besides having legal backing for action, but it insurges a social expectation of subjection of the agency's action to the user's interest. That is, ANVISA should release that which may be a solution for the patient. (ii) by viewing the players involved in the process, including legislative, executive and judicial entities, it is shown that the clashes also occur strongly also within the Public Administration itself, with the possibility of adoption of conflicting postures by different government players. In (iii) third, the fact that the drug was produced by USP even in light of the validity of the technical note weakens the control and regulation structure and strengthens the image of curing elixir for the cancer pill.

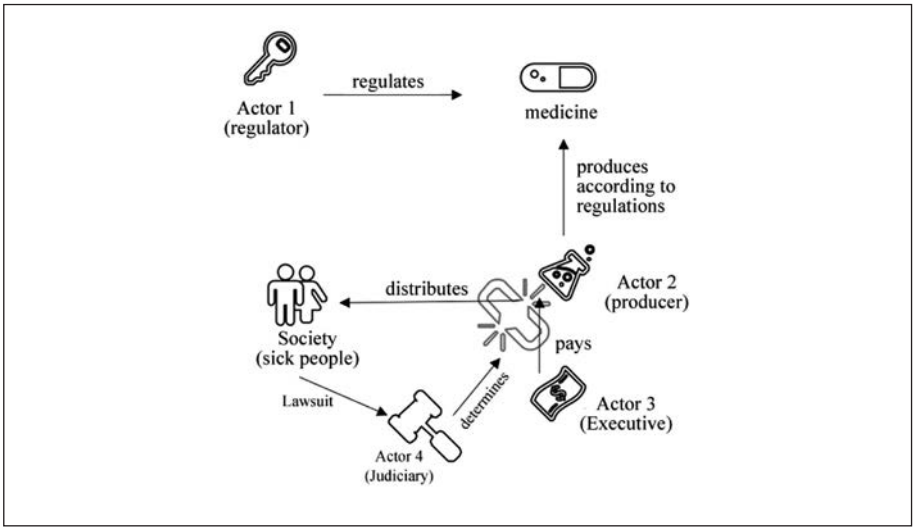

FIGURE 3. Flow of the Judicialization of Health Care

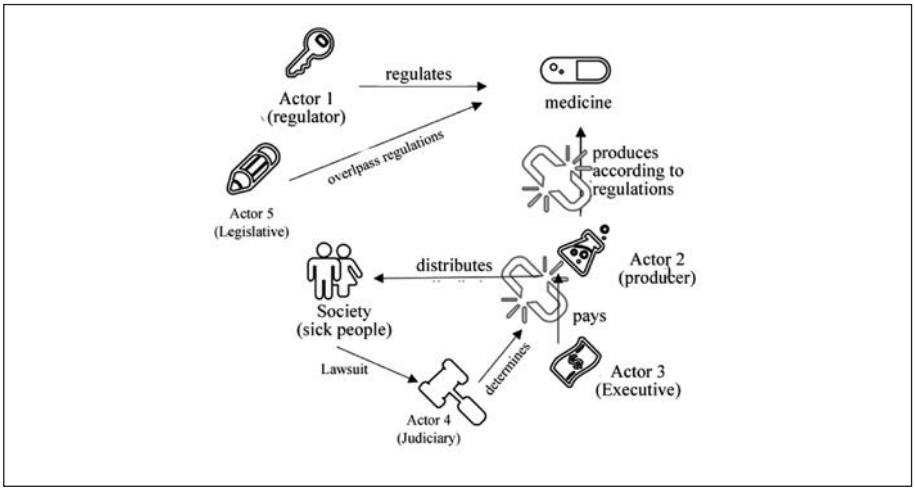

FIGURE 4. Flow of Overlapping Powers

We also draw attention to the understanding that the idea of judicialization of health is also not sufficient for the discussion of this case. Although we see this process occurring, it is merely one more element of this complex web of clashes.

Putting aside discussions about the use and effectiveness of the drug, it is notorious that the cancer pill, even without scientific proof, was (is) a lifeline of hope for cancer patients and their families. This social sentiment was the great driver of this scenario, in which divergences and voids were highlighted. Thus, we understand as the main antitheses (a) the coexistence between the production of the drug and the prohibition by ANVISA (b) the perception that a non-legalized drug can be seen as legitimate by society (c) the need for legislative and judicial discussion of a topic for which there is already a legitimate decision by the competent authority, see ANVISA's technical note and ordinance (d) the notoriety of the power of the citizen over the law, in an example of the inversion of the mandatary condition in which the law acts as social control over the citizen.

5. Conclusions and recommendations

The survey, therefore, corroborates our initial impressions and adds new angles to the case. The case of the "cancer pill" has peculiarities of great relevance to the Academy. First, it is a low-cost medicine, produced nationally. Second, the plea for the release of the production of a certain drug is recessive. The common case is the request for access to a certain high-cost drug, but not the social uprising for the release of the pill.

We tried to portray, through our longitudinal analysis and by researching the term on the internet, the progression of the fame of the pill, resulting in the spread of requests and also the warrants were already arriving before the prohibitive manifestation of ANVISA. So, when in 2014 the Sanitary Surveillance Agency had its say on the matter, regulating that even experimental medicines need registrations to be used and distributed to patients, there is a clear impediment to the cancer pill.

Notwithstanding the clash of liberation versus prohibition, the popular scope of the issue is a key point to be addressed, and operates as a driving mechanism for the institutional clashes that underpin this dynamic. It is not restricted to discussing laws for the mere sake of discussion, but to understanding representative facts of the social negotiation of the law, which is in line with Edelman's understanding (1992, 2016).

One of the points we highlight is legal endogeneity (Edelman, 2016; Edelman, Uggen, & Erlanger, 1999) the professions, and legal institutions. It suggests that organizations and the professions strive to construct rational responses to law, enabled by "rational myths" or stories about appropriate solutions that are themselves modeled after the public legal order. Courts, in turn, recognize and legitimate organizational structures that mimic the legal form, thus conferring legal and market benefits upon organizational structures that began as gestures of compliance. Thus, market rationality can follow from rationalized myths: the professions pro-

mote a particular compliance strategy, organizations adopt this strategy to reduce costs and symbolize compliance, and courts adjust judicial constructions of fairness to include these emerging organizational practices. To illustrate this model, a case study of equal employment opportunity (EEO. This feature, fine-tuned with the mobilization of the phenomenon and with the scope of this discussion, shows that law, when it aims to establish regulation of individual, every day, pragmatic behavior, is potentially subject to becoming an amalgamation of formal and popular legal meaning (Nelken, 2004; Sherwin, 2004).

We understand that the judicialization of health care, regardless of whether this is a mechanism that leads to budgetary chaos in public administration or an urgent manifestation to guarantee and defend citizens' rights, can be seen as a trigger for institutional conflicts. The concept of institutional voids finds ground in this sedimentation of legal and formal meaning. This new path leaves lapses in interpretation, conclusions pending, unspoken situations, appreciated only in concrete cases. In the meantime, institutional gaps are deepened.

There is an awkwardness between the content of the laws and the social acceptance of what they prescribe. This is true also between the limits of the scope and influence of the organizations' actions on some issues, both legal and of legitimacy. The Cancer Pill case triggered a war that pointed out the social and organizational discomfort with the issues of legality vs. legitimacy, competencies guaranteed by law vs. acceptance of this scope. We find it appropriate to continue the discussion, deepening the issue with more delimited theoretical ties to provide gains in understanding of these socio-legal and socio-organizational processes.

In any case, a cold view on the subject should be avoided. The problem cannot be understood by merely focusing on the abstract case. In this case, it is understood that any medicine produced and commercialized in Brazil must go through defined protocols, informed and inspected by ANVISA. Understanding of the problem occurs in the concrete case: when the possibility of solving a dramatic disease emerges, in a simple and inexpensive way.

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