

RESEARCH ARTICLE**Judicialization of Public Pharmaceutical Care Policies****Author**

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E-mail: fcarneirodebora@gmail.com**Abstract**

Judicial activism can be an important mechanism for citizens to protect their rights against legislative inertia and executive bureaucracy. However, when judges exceed decision-making power, a movement called judicial extremism, they generate legal uncertainty, as they do not have the expected legal basis for a court ruling, but only generic principles and moral values of the judge himself. The extremist judge, disrespects public policies, disrespects the public budget, disrespects the rights of the community, and imposes obligations on the Administration, without evaluating the consequences and without this generating effective social justice. In relation to public policies related to pharmaceutical assistance, judicial activism can help to correct management failures, but judicial extremism imposes on the Public Administration the supply of any medication, even if there is a therapeutic alternative available in public policy. This behavior has become widespread in Brazil and contaminates other countries with public health systems. The pharmaceutical industry gains the most, with marketing strategies or the creation of pseudo-differentiation between new pharmaceuticals and drugs, guarantee, with judicial decisions, an open consumer market, free from questioning and profitable. With the current global health crisis, information and misinformation about the disease and possible forms of treatment have enhanced the discussions and the role of tripartition of powers, collective and individual fundamental rights, economic groups, science, and assistance. A broad dialogue between the main actors in the process is needed so that fundamental rights are efficiently and guaranteed.

Keywords: judicial activism. judicial extremism. public policy. right to health, pharmaceutical assistance

1. Introduction

This article aims to discuss the judicialization of public pharmaceutical care policies, based on the role of the Judiciary in guaranteeing rights, the effects of the judicialization process and the role of the pharmaceutical industry in the continuity of lawsuits. Since society began to demand the material exercise of their rights from the public authorities, governments began to work with public policies. Such policies became judicialized, and this caused the expansion of a movement known as judicial activism.

The efficiency and effectiveness of public policies challenge governments because the needs of the population need to be met with managerial models that do not always guarantee sufficient dynamism for the execution of plans. Furthermore, political-ideological and industry pressures interfere in managers' choices. Managers are subject to pressure and their choices prioritize the individual needs of citizens rather than the needs of the collective.

The Welfare State wants to generate justice, allowing capitalist accumulation, but avoiding some negative impacts, such as social destabilization.¹ However, when it comes to the right to health, it must be considered that the needs for a hospital or a medication will always be greater than the financial resources. Thus, the choice of how to invest becomes tragic. Unfortunately, some judicial sentences have abandoned rationality, reasonableness and even consistency.

In this conflict between Executive and Judiciary, the Judiciary is taking advantage, especially when the discussion takes place in the Constitutional Court. The defense of an abstract principle is more important than politics and sometimes the law itself.

The scarcity of resources requires rational and efficient measures. Actions that should have been exceptions became the rule and the Judiciary began to act in a more creative and discretionary way, replacing the legislator, often without due concern with the results of such measures or with the budgetary impact of its decisions.² This impact was even more evident in this period of health emergency. In this way, judges, who are fascinated by their own decision-making power, they are changing what was known as judicial activism to judicial extremism.

This judicial extremism, in relation to public policy, is more than an expanded interpretation of rights, but the unreasonable expansion of the judge's discretion, who not only judges according to the laws, but creates the laws. It disregards the Executive and Legislative, the public budget and the very meaning of social rights. Instead of protecting fundamental rights, judicial extremism has become a source of injustice.

2. Fundamental social rights

The discussion about human rights is directly associated with the origin of the Modern State. After the legal organization of the States, these human rights were constitutionalized and came to be called fundamental rights.

The difference between fundamental rights and human rights is not just the name. Human rights are discussed at the international level, and they are addressed to the individual. Fundamental rights are human rights recognized by each State in its constitutions and they are addressed to the State.³

It is important to emphasize that human rights, in their formation, are based on natural law and, therefore, on moral aspects studied since the beginnings of philosophy. When natural law is replaced by human

voluntarism, reason begins to decree what is good or bad, right, or wrong. The law written in the legal system is now based on human arbitrariness, which varies from time to time.⁴ The declaration of rights depends on the political, social, economic, and cultural moment of each society, since fundamental rights represent the most political of legal texts.⁵

With Neoconstitutionalism, the separation of powers became fluid to accompany the social, economic, and political transformations of society.⁶⁻⁸ Thus, the Democratic Rule of Law became the Social Rule of Law, as it was not concerned with maintaining the freedoms of citizens, but with ensuring social rights,⁹ through state social benefits. It is impossible to acquire full citizenship, without conditions or mechanisms for the individual to be included in all aspects of social life.¹⁰

Social rights refer to the individual person, and the use of the term “social” refers to social justice,¹¹ with distribution and redistribution of rights through financial resources. The positive effectiveness of these rights is directly related to the idea of the State ensuring the exercise when the individual cannot do it alone.¹² The original purpose of social rights is to promote substantive equality.¹³

Considering the historical context, certain behaviors (or rights) are valued more than others, and in the conflict decision-making process. In the current jurisprudence of the Federal Supreme Court (STF) and the Superior Court of Justice (STJ) of Brazil, the right to health is something invested with a fundamentality that places it above other constitutional norms or principles and, therefore, is considered a right absolute fundamental.¹⁴ It is noteworthy that the force of the law depends more on its content (values and interests) than on its form (adaptation to the legal system).¹⁵

The judicialization of politics, derived from the axiological change of constitutionalism, from liberal to social democratic, is based on multiple factors, such as the centrality of the constitution and its normative force. From this protagonist, the Judiciary invoked strategic decisions on administrative aspects as if it were its competence,¹⁶ a phenomenon known as judicial activism.

From the judicialization of politics, it was possible to observe four consequences of the process¹⁷: (a) increase in the impact of judicial decisions on political and social processes; (b) increased resolution of political conflicts in the courts; (c) the construction of the State's legitimacy on the basis of legal concepts (valuing the rule of law and fundamental rights); and (d) the use of legal mechanisms to articulate, through legal demands, different economic, political and social interests.

3. Activism versus judicial extremism

According to Strapazon and Goldschmidt,¹⁸ the term judicial activism was created in the United States, at the time of the New Deal. The first public use of the term was attributed to the American historian and political analyst Arthur Meier Schlesinger Jr, who used it according to sociological theory, which defines activism as the militant behavior of a leadership that takes responsibility for organizing and mobilizing a group or the whole society, in defense of a progressive or conservative cause.

The concept has been present in English legal literature since the 19th century, as the innovative action of the Judiciary confronted the Legislature.¹⁸ Tocqueville (1835), studying the prison system in the United States, warned about the possibility of activism, when verifying that the power given to judges to determine which laws would or

would not be applied.¹⁹ Thus, there was a risk that judges would censure the legislator, while occupying the political scene.

American judicial activism has shown that interpretation can restrict rights (*Dred Scott v. Stanford*, 1857) or can expand them (*Brown v. Board of Education*, 1954). Unfortunately, this story repeats itself in Brazil, the STF decisions are creating categories of Brazilian citizens, depending on the amount of vaccine doses received (STF, ADPF n° 669; STF, ADPF n° 913).²⁰ The more activist or conservative posture of the judge or the Court depends on the case to be judged and the political-ideological position of its members.⁸

When activism emanates from the higher courts, it has an *erga omnes* effect. However, this liberality in the jurisdictional decision is not absolute and must have legality contours.²¹ The absence of such outlines can represent arbitrariness, an excess in the judge's performance that can be interpreted as interventionism.²²

Abuse of judgment represents judicial extremism.²³ The extremist is one who is at the extreme of an idea, without admitting possibilities and indifferent to debate. It does not assimilate arguments contrary to its own, it does not recognize mistakes and it is not willing to change. It does not need to be linked to fanaticism or violent acts, as violence is not expressed only in its physical context, but is related to behaviors that reject established rules, trying to create a model, in which the result is achieved immediately, instead of in ways gradual and declining partial results.

The extreme view relativizes the entire legal system based on the "judicial interpretation", as judges annul the Executive's actions and the Legislative's decisions, even when they do not infringe the Constitution. The problem is that they are contrary to the will of the judge, his convictions, or values.¹⁸ The

political debate is ignored by the verdict of a magistrate or even an unelected collegiate.

According to Sponholz,¹⁹ debates in the social environment can delay social transformations and, therefore, the Judiciary runs over them and determines change. Without debate, rejection by citizens is avoided. This judicial activity against the majority is not capable of instituting values in the social environment, but it imposes the terror derived from the power that the decision emanates from. It is noteworthy that "to choose" has a subjective character, while "to decide" is intersubjective, as the decision is something that depends on the construction of a consensus.²⁴ As decisions are based on a judge's voluntarism, based on his personal and moral convictions, the result is this lack of rationality, lack of standardization and lack of coherence.

Based on these decisions, there is a trivialization of court decisions, either due to their non-compliance, or due to the demobilization of social movements and organizations.²⁵ Social organizations lost their role in mobilizing and fighting for the realization or recognition of new rights because the Judiciary became the center of decision-making

4. Control of public pharmaceutical assistance policies by the Judiciary.

The transversality of the right to health, with other branches of Law and with the Health Sciences area itself, determines the need for discussions and improvement of actions, according to the particularities of each State. However, with globalization, pressure from international organizations and the pharmaceutical industry, the debate process is corrupted and the Judiciary, with its activism or extremism, destroys any argument.²³ The principle of integrality of Brazilian public health refers to the integration of actions for the

promotion, prevention, and recovery of health, but jurists distort the principle "everything for everyone", uncritically, with generic solutions and based on the general principles of Law and the judge's moral convictions and personal feelings.²⁶ Judicialization violates both the principle of completeness and the principle of equity²⁷ because it privileges a small group that has access to the Judiciary.²⁸

With the current health crisis, health decisions, previously determined in public policies of the Ministry of Health, were ignored, disregarded, or overruled by a single judge, who has no knowledge in the health area, based on biased journalistic articles. Even the concepts of "science" and "clinical research" were transformed until they lost their essence. The Judiciary has turned science into dogma and all questioning is being criminalized. The pandemic is not just a new virus, it is the scourge of scientific darkness in the Middle Ages, in the 21st century.

In relation to the health system, each country establishes access in accordance with its laws and the Constitution. Thus, the norms will define the population covered (universal or segmented); the sources and resources used in coverage (fees, contributions, direct payment, public or private resources), the coordination of the service and the levels of integration, the service network (public, private, philanthropic), the form of remuneration of professionals and the services offered (including pharmaceutical assistance).²⁹

In relation to public pharmaceutical care policies, the World Health Organization (WHO) recommends that, in relation to the selection of essential drugs, the list be established by each country, considering the therapeutic needs of the population. Essential drugs are defined as those that meet the population's priority health needs.³⁰ The guides also provide an improvement in the quality of care, by defining guidelines to ensure

safe, effective, and good quality medicines.²³ Improvement in care stems from the limitation of drugs without proven efficacy, which present greater risks than benefits or from duplication of drugs for the same clinical indication. The main objective of the policies is to ensure access and rational use of high-quality essential medicines.³¹

The pharmaceutical industry is for-profit and not concerned with promoting health. The trade in medicines for rare diseases or major pandemic emergencies has become very profitable. These are shorter clinical studies, lack of alternative treatment, less investment in marketing, government approval for marketing in less time and with little scientific evidence.³² In the case of alternative drug therapies for the treatment of COVID-19, pressure from media groups and large pharmaceutical companies has turned into an imperialist discourse, preventing doctors and researchers from all over the world from presenting their contributions.

The pharmaceutical industry is the most interested in the legalization processes of pharmaceutical assistance because it allows the availability of products that did not meet the requirements for entering the official lists.³³ Furthermore, gaps in legislation are used by the industry to profit even more.

For example, the registration of the drug in Brazil is requested by the manufacturer to the regulatory agency (Agência de Vigilância Sanitária -ANVISA). Once registered in the country, the drug will be evaluated and may be incorporated into the Ministry of Health's list of drugs (RENAME - national list of essential drugs) and the price may be discussed at the Drug Market Regulation Chamber (CMED). In a situation of judicialization of pharmaceutical assistance, if the State is condemned in the judicial process, the registration of the medication will be evaluated. If it is registered in another health agency in the world, but is not registered in

Brazil, the State is obliged to submit to the price and conditions required by the manufacturer. This was the case for eculizumab in Brazil. The pharmaceutical company only applied for registration in Brazil in 2015, the year in which patent protection ended. With the registration, the value of the drug dropped by 35%.³²

Another form of industry profit is the artificial creation of a difference between the drugs, when in fact there is an equivalence.³⁴ This practice, between bevacizumab and ranibizumab, resulted in a loss of € 45 million to Italian coffers. Pharmaceutical companies were fined € 90 million in 2014 by Italy's Competition and Market Assurance Authority (AGCM) and € 182.5 million by the European Court of Justice in 2018 for the same practices.

The intervention of the Judiciary Power is necessary when the Executive Power's inertia is demonstrated in the fulfillment of obligations or in the mismanagement of resources in public policies. However, poor management in issues such as basic sanitation is not evaluated, as it is easier to request pharmaceutical assistance or hospital care, maintaining the logic of individualism.^{35,36} From 2010 to 2018, the Ministry of Health spent around US\$1.5 billion on the purchase of legalized drugs.³⁷ This amount corresponds to 10% of the pharmaceutical assistance budget for the period. The British Judiciary also has problems with the judicialization of pharmaceutical care, but decisions are based on assumptions such as scarcity of resources and the difficulty of choosing between legitimate demands and that individual rights cannot be protected without considering their impact on meeting the needs of other users.³⁷

Vargas-Pelález et al,³⁸ through a systematic review, observed that in the processes of judicialization of health, the interpretation of the right to health is different

between Europe and Latin America. While in Europe judges prioritize the social over the individual, in Latin America judges tend to value the individual aspect, without considering the impacts on the health system or on the rest of the population. Countries with a liberal culture have health policies in a residual form and refer mainly to social assistance; countries with a conservative culture, health policies are based on rights and duties with the occupational state; and countries with a social democratic culture have a more interventionist health system with the aim of correcting inequities.²⁹ It's called distributive justice.

Finally, it is important to highlight that the correct interpretation of the right to health requires a deepening of issues related to constitutional, administrative and health law, with medical, social, and economic issues.³⁹

5. Conclusion

Judicial activism is an important mechanism within modern democracies. However, it must be considered that the practice of judicial activism must be reserved when they show disrespect for the Constitution. As soon as there is no constitutional disrespect, the court decisions that change public policies become extreme and can bring harmful consequences to the Institutions.

The guarantee of the right to health is a very special issue, as it is related to several other rights, in addition to causing significant impacts on economies. Pharmaceutical assistance, inserted in the universality and integrality of the right to health, does not refer only to the individual's right, but to the right of a community.

It is not possible to disrespect the infra-constitutional laws without questioning their constitutionality. It is not up to the Judiciary to disregard budget laws and the public budget itself, when these comply with

the constitution, but do not guarantee all individual desires.

Therefore, the dialogue between public managers and the Judiciary is essential, so that citizens receive from the State what is due to them, whether in pharmaceutical assistance or in relation to any other fundamental right.

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