ORIGINAL ARTICLE

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SUMMARY

The object of analysis of this article is the intertwining between the right to health in Brazil and the activation of the Supreme Federal Court (STF) as a guarantee of practical effectiveness, the judicialization of the policy, especially the granting of high-cost drugs. Before the right to health in Brazil, two Principles collide, that of the reservation of the possible and that of the existential minimum, which requires according to Barroso (2009) a weighting by the interpreter of the law on the reasonableness of specific cases. To verify, with regard to the right to health, we analyze some Judgments of the STF on the matter, which are on its website. We observed that there is in the decisions of the STF a preponderance of the reserve of the possible to the detriment of the existential minimum.

Keywords: Federal Constitution, Right to Health, High Cost Medicines, Principle of The

Reserve of the Possible.

INTRODUCTION

Our object of analysis is the intertwining between the right to health in Brazil and the activation of the Supreme Federal Court (STF) as a guarantee of practical effectiveness, the judicialization of politics. More specifically, it deals with the compulsory determination of the supply of high-cost drugs from the decisions given by the Supreme Court.

This theme is urgent, in particular, when the National Council of Justice (CNJ), through its “Justice in Numbers” 2018 (last report published on the CNJ website, but referring to the base year 2017), demonstrates that there were 1,346,931 lawsuits regarding the different nature of the right to health. According to Sarlet (2018, n.p.) “[...] the Union’s spending on lawsuits involving health benefits grew by 727% between 2010 and the end of 2016, when it reached R\$ 3.9 billion.” The year 2016 is emblematic, because it was the year in which the processing of Extraordinary Appeal (RE) 657718 began, with general repercussion recognized, of rapporteurship of Minister Marco Aurelio, which had its outcome on May 22, 2019.

The RE 657718, had as epicenter the judgment resulting from the supply of high-cost medicines by the government, especially those that were not on the list of the Unified Health System (SUS), as well as those that were not registered with the National Health Surveillance Agency (ANVISA). With the outcome in May 2019, the STF made some decisions regulating the compulsory granting of medicines.

The decisions were to appease the relationship between the right to health and the state budget. According to Minister Roberto Barroso “it is not about denying a fundamental right to health. It is a question of analyzing that state revenue, budget and allocation to public health are finite” (STF, 2019, n.p.). This decision is in line with the Principle of The Reserve of the Possible and with recent decisions on the Brazilian budget, in particular the approval in 2016 of the Proposed Constitutional Amendment 241, numbered in the Senate as 55, which provides for the freezing of public spending, which may collide with the Principle of Existential Minimum.

The decision was taken, by a majority of votes, in the judgment of Extraordinary Appeal (RE)

657718, with recognized general repercussion, of rapporteurship of Minister Marco Aurélio, and fixed the following thesis: 1 - the State cannot be obliged to provide experimental medicines; 2 - the absence of registration with Anvisa prevents, as a general rule, the supply of medicine by court decision; 3 - it is possible, exceptionally, the judicial grant of a medicinal product without health registration, in case of unreasonable mora of Anvisa in assessing the application (period longer than provided for in Law 13.411/2016), when three requirements are met, such as: I) the existence of an application for registration of the drug in Brazil, except in the case of orphan drugs for rare and ultra rare diseases; II) the existence of registration of the drug in renowned regulatory agencies abroad; III) the lack of a therapeutic substitute with registration in Brazil. Finally, the STF also decreed that, 4 - the actions that require the supply of medicines without registration in ANVISA must necessarily be proposed in the face of the Union (STF, 2019).

Thus, in detail, this article seeks to identify whether during the procedure of RE 657718 the Brazilian State already behaved in order to deny requests for compulsory granting of medicines that were not registered with ANVISA and/or were off the SUS list. The question is: the behavior of the STF in relation to the compulsory granting of medicines before the outcome of RE 657718 was against or in favor of the release of drugs that were off the List of the SUS and had no registration of ANVISA?

Our hypothesis is that the Principle of The Reserve of The Possible may have influenced the decisions of the Supreme Court regarding the granting of medicines considered high cost, in particular, those that do not fit the decision given in May 2019.

To verify the behavior of the STF in relation to the granting or not of drugs considered high cost, we observe the judgments that were delivered by the Supreme Court in the period from 2017 to 2018 (time interval between the beginning and the end of the Extraordinary Appeal already mentioned). These Judgments are available on the Website of the STF and were analyzed all that took place in this time interval, in all were 15.

Our main concern regarding the data contained in the Judgments was to analyze the response given by the STF. This information has given us the ability to analyze what has actually guided the supreme court's court decisions regarding the supply of high-cost medicines, as stated in our final considerations.

In this article, first, we will deal with the right to health, as well as its judicialization. Next, we will demonstrate the arguments surrounding the debate between the Existential Minimum Principle and the Principle of The Reserve of The Possible, to, thirdly, analyze the behavior of the STF from the Judgments contained in the Website of the STF.

RIGHT TO HEALTH IN BRAZIL: THE GRANTING OF MEDICINES AND THEIR JUDICIALIZATION

Brazil's health system is funded by a series of taxes at the Federal, State and Municipal levels. States receive money from the Federal Government, while municipalities receive funding from the Federal and State governments. In addition, *a priori*, the government has always committed to collect taxes, increase them and even take advantage of the state's oil revenues to finance the Unified Health System (SUS).

This effort reflects a long history of social and political commitments to provide public health services. After gaining independence from Portugal in 1822, Brazil saw the emergence of well-organized social movements advocating state intervention in health care.

Supported by taxes on personal income (Personal Income Tax) and Social Security, health authorities agreed with these movements in which medical care was a responsibility of the State and that everyone should contribute to the system. This policy survived democratic and authoritarian governments throughout the 20th century, lasting until the transition to democracy in 1988. It was also sustained with the help of proactive social health movements, such as the sanitists, composed of doctors, bureaucrats and politicians.

This idea of shared responsibility in the provision of health services was so popular that it became part of the 1988 constitution. Through the introduction of the SUS by the constitution, health care has become an official responsibility of the State and a Human Right, an issue on which liberals and conservatives could agree.

Thus, the right to health in Brazil is a social right, which is included as a constitutional precept, in particular, in Art. 6, in the wording attributed by Constitutional Amendment N°. 90/2015, which provides: "Social rights are education, health, food, work, housing, transportation, leisure, security, social security, protection of motherhood and childhood, assistance to the homeless, in the form of this Constitution" (BRASIL, 2019, n.p.). Thus, as a

social right it is up to the Brazilian State to act on social policies so that citizens are effectively served, especially with regard to health.

Health as a state duty that is done through social policies is based on the Federal Constitution of 1988, in Art. 196, which precedes:

health is the right of all and the duty of the State, guaranteed through social and economic policies aimed at reducing the risk of disease and other injuries and universal and equal access to actions and services for its promotion, protection and recovery (BRASIL, 2019, n.p.).

Thus, it is observed that health should be guaranteed as a social right through social policies and that it is the duty of the State.

According to Vasconcelos Filho (2010), the realization of social rights is directly related to the intervention of the State, especially through social policies. The right to health is an example of a social right with individual ownership, corresponding to its basic needs not only for physical existence, but for psychic and moral existence.

The two articles mentioned above, Art. 6th and Art. 196, guarantee brazilian citizens social rights and their effectiveness through social policies, a novelty and an advance, with regard to the expansion of democratic rights, in relation to the authoritarian regime previously established in Brazil between 1964 and 1988. Thus, it is up to citizens to enjoy such rights, especially the social right to health, which enables citizens to live a dignified and healthy life, in a thesis through the SUS.

The SUS is administered by the Federal, State and Municipal governments. Municipalities provide health services, states coordinate health actions, and the federal government regulates and finances the system. The SUS was a relevant step in the decentralization of health care in Brazil, as it also established the criteria for the distribution of resources between states and municipalities. In the 1990s, there was greater decentralization of health care, through the Basic Operational Standards (NOB-SUS). Since then, the financial burden of the direct provision of health goods and services has been largely transported by Brazilian states and municipalities (RIBEIRO, 2013). An example of the provision of public health

services, which makes the right to health fulfilled is the free distribution of medicines.

The National Drug Policy, created in 1998, dictates plans, programs and activities related to pharmaceutical assistance for all levels of government (federal, state and municipal). The policy followed a diagnosis of “unbalanced outpatient drug supply”, which was considered to have a negative impact on health care. The policy states that the Ministry of Health continuously updates the National List of Essential Medicines, which defines which drugs are provided free of charge in the public health system. These are those “considered basic and indispensable to address most of the population’s health problems (BRASIL, 2001).

Pharmaceutical assistance policy is also decentralized. The National List of medicines, which is based on the regional epidemiological profile, forms the basis for the organization of states and municipalities. The States and Municipalities are responsible for financing these drugs and also for the delivery of the medication included in the three lists (national, state and municipal).

Social rights, in particular, health rights are not done automatically. The effectiveness of social rights faces many challenges, in addition to the legality expressed in the Federal Constitution, there is, according to some studies, a reality that is distant from the “cold letter of the law”, that is, the distance between constitutional norm and effective practice is a Brazilian reality (RIBEIRO, 2013; VIEIRA, 2008; HOIRISCH, 2010; VALLE; CAMARGO, 2011). This distancing between norm and practice has gone against art. 5, in its item XXXV, where it predicts that: “the law will not exclude from the assessment of the judiciary injury or threat to law” (BRASIL, 2019, n.p.). Thus, the non-realization of social rights, especially that of health, which is our object of study, is conducive to undergoing a judicialization of the policy, which consists in provoking the judiciary to take a position to guarantee the law, in most cases, forcing the Union, States and Municipalities to comply with the legal texts.

In Brazil, the judicialization of health care is used to describe the judicial affirmation of the positive constitutional right to health by individuals who cannot obtain goods and services from the public health system. This level of judicialization of health care is only possible because the 1988 Constitution adopted a system of strong judicial review of individual rights. In addition to guaranteeing an individual right to health, the Federal Constitution also obliges the State to create and maintain a universal health system, the SUS (Law N°. 8080/1990).

In the vast majority of cases, the government is required to comply with court orders, even if they are not part of the administration's plan. This has two effects on the system: the impact of decisions on the allocation of budgetary resources in the public health system and on the management of pharmaceutical care itself. These effects fall mainly in the states and municipalities, because they are the providers of the main health goods and services ordered by the courts. In an attempt to regain control over budget expenditures and the management of pharmaceutical care, there have been reports of a wide variety of interventions in Brazil's health policy. The interventions arise, especially, from the decisions taken by the STF, in order to condition the behavior of Brazilian magistrates in relation to the granting of health rights, such as the case of medicines.

One such intervention is RE 657718, which began in 2016 and its outcome in 2019. The recommendations are in line with regulating, based on a General Repercussion, the behavior of magistrates with regard to the granting of high-cost medicines. In the end, the Judiciary, through the STF, implements a revenue for containment of public spending that meets the Principle of The Reserve of The Possible.

PRINCIPLE OF THE RESERVATION OF THE POSSIBLE: ITS INTERFERENCE IN THE RIGHT TO HEALTH (AN EXISTENTIAL MINIMUM)

The supply of high-cost medicines to Brazilian citizens lives up to a dichotomous analysis: one focused on the Principle of The Reserve of the Possible and the other in the perspective of the Existential Minimum Principle, which in turn meets the Principle of Dignity of the Human Person. One should ask about the possibility of solving the problems of reality to be faced, based on the weighting of the values or rights involved, based on the postulates of reasonableness and proportionality in the conjuncture of the Democratic State of Brazilian Law, as outlined by Alexy (2008).

The principles, according to Minister Barroso (2009, p. 8), "harbor a fundamental right, a value, an end. It happens that, in a pluralistic legal order, the Constitution houses principles that point in different directions, generating tensions and eventual collisions between them." Also according to the Minister of the Supreme Court, in these cases of collision we can not leave for the "all or nothing", but it is up to the interpreter of the law to analyze each case,

and thus act to the weighting between relevant principles and facts.

This discussion translates into an understanding of the magistrate in individualized cases or even in a modeling of the magistrate's decision in cases of General Repercussion, defined by a majority of the STF. The important thing in this thesis is that, according to Barroso (2009, p. 12),

Whenever the Constitution defines a fundamental right it becomes chargeable, including through legal action. It may occur from a fundamental right needs to be weighed with other fundamental rights or constitutional principles, a situation in which it should be applied to the greatest extent possible, taking into account the political and legal limits, preserved its essential core.

In accordance with the explanation of a possible collision of legal principles or norms, the legislator should consider a given reality. According to the thesis of Minister Barroso (2009), in the case of a decision on the granting of high-cost medicines, it is not only necessary to verify the effective proof of the hyposufficiency of the requesting citizen. It is also necessary to take into account the scarcity of public resources, that is, the interpreter of the law must act reasonably between the limits of the principles of the Reserve of the Possible and that of the Existential Minimum, which once again falls on the interpretation of the magistrate.

However, according to Farena (1997, p. 13):

Allegations of negative effect of a social right based on the argument of the reservation of the possible should always be examined with suspicion. It is not enough simply to claim that there is no financial possibility of complying with the court order; it must be demonstrated. What cannot be seen is that the evocation of the reservation of the possible becomes a true reason for an economic state, an economic AI-5 that actually operates as an anti-Constitution, against everything that the Charter enshrines in matters of social rights.

Thus, it is necessary to analyze how the interpreter of the law has behaved in the face of the needs of citizens who converge with fundamental rights. To identify this, an analysis will be carried out from the STF Judgments in the years 2017 and 2018, in matters dealing with the

compulsory granting of high-cost drugs.

STF RULING: AN ANALYSIS OF THE GRANTING OF HIGH-COST MEDICINES

After verifying that the State is responsible for the health of the Brazilian citizen as a fundamental right, that the right cannot always be enfixed as it is in the constitutional records (Reserve of The Possible), it is worth identifying how the STF acted in relation to its Judgments regarding the granting of high-cost drugs.

In 2017 and 2018, 15 judgments were counted. Of the 15 Judgments, only 03 had citizens as the requesting agent in search of their rights. Thus, the analysis of judgments that were incited by individuals was privileged.

Table 1 – Judgments x Rapporteur x Decision

Year	Judgment	Rapporteur	Decision
2017	ARE 968012 AgR / SP – SÃO PAULO	Min. Ricardo Lewandowski	He dismissed it. Absence of Proof of Hyposufficiency.
2017	ARE 1037265 A GR / RN	Min. Dias Toffoli	He dismissed it. Medicinal product in experimental phase and not available by SUS.
2017	ARE 1065116 A GR / PE	Min. Cármen Lúcia	Dismissed. The drug is not made available by SUS. There is a medicine of equal efficacy provided by SUS

Source: Data collected by the author on the Website of the STF

From the above in Table 1, we can observe that the STF approaches in the first Judgment of a decision based on criteria of the Existential Minimum Principle, in which there is a need to prove the hyposufficiency of the requesting agent citizen. The second and third Judgment are in line with our hypothesis, which discusses the Principle of The Reserve of the Possible, in which, decided by the STF, it denies the provision in case of drugs in the experimental phase and that is off the list, which also means not registering in ANVISA.

The Judgments of Pernambuco and Rio Grande do Norte do not present technical reports on the efficacy of the drug in the experimental phase, as well as does not consider the

Existential Minimum Principle (this in the case of nb). The Pernambuco also does not bring an efficacy report on the requested drug, as well as its technical comparison with that existing in the SUS list, nor does it bring a report of risk of life and/or health, that is, it does not consider the minimum existential and superlative the Principle of The Reserve of the Possible, even without presenting technical reports on public budgets.

FINAL CONSIDERATIONS

The decision of RE 657718 in May 2019 presents a list of requirements to grant a provision for the granting of high-cost medicines. In a thesis, the conclusion given by a majority of votes and General Repercussion aligns with the Principle of The Reserve of The Possible, which seeks to limit the expenditure of the public authorities on medicines.

Our study shows that even before the decision of RE 657718, from the analysis of three Judgments delivered by the STF between the years 2017 and 2018, the Judiciary, through its Supreme Court already had the understanding that now confirmed after a wait of more than two years. We also demonstrate that the STF has been guided by the Principle of The Reserve of The Possible, but without considering the weighting between the Existential Minimum Principle, as proposed by Alexy (2008) and Barroso (2009), because the Judgments do not bring in their budgetary evidence and or even the living conditions of the requesting agent citizen.

From this, our final considerations are in tune with the analyses of Farena (1997), who states that by privileging the reservation of the possible over the existential minimum, an Economic State is established and not guaranteeing social rights. This finding leads us to observe that the right to health, in this specific issue, studied here, is the result of the interpretation of judges and their collegiates and not of the law, as it is in the Constitution.

Finally, this investigative exercise alerts us to the need for our legislators to produce relative and more specific rules regarding the right to health, especially the granting of high-cost medicines. Otherwise, the judicialization of large-scale health will tend to be a constant in the Brazilian reality.

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