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JOHN RAWLS' THEORY AND THE FAIRNESS OF SUPREME FEDERAL COURT DECISIONS IN HIGH-COST DRUG CLAIMS

Cristina Godoy Bernardo de Oliveira[1]
Luis Augusto Teixeira Morais[2]

ABSTRACT

Based on the Theory of Justice of John Rawls, this article analyses justice regarding the decisions of the Federal Supreme Court of Brazil (STF) related to public concessions of expensive medicines. This study focuses on constitutional principles like the universality and integrality in health care illuminated by the minimum existential and the reserve for contingencies. The study of the decisions of the Federal Supreme Court searched an equity approach and the consequences for the poor that depends on the public health system (SUS) to receive health care. Applying the analytical and synthetic methods, the analyses showed that the decisions are not fair in the same way John Rawls argues that because there is no protection of the minimum existential. Thus, there is a health injury to the poor that could be avoided by the theory of justice of John Rawls.

Keywords: Health Law. Judicial Decisions. John Rawls. Federal Supreme Court. Theory of Justice.

INTRODUCTION

The right to health and its availability by the State, as provided for in the Federal Constitution of 1988, has raised a series of debates about its legal limits. However, debates involving issues of justice seem to be impaired, despite the fact that public health is an area heavily permeated by such issues.

[1] Doutora em Filosofia do Direito pela Faculdade de Direito da Universidade de São Paulo (2011). Professora Doutora da Faculdade de Direito da Universidade de São Paulo - Campus Ribeirão Preto desde 2011. Pós-Doutorado em Filosofia do Direito pela Université Paris I - Panthéon/Sorbonne (Agosto/2014 - Dezembro/2015) com vínculo ao Instituto NoSoPhi. Academic Visitor da Faculty of Law - Oxford University onde está desenvolvendo o projeto de pesquisa concernente à Propriedade Intelectual (2015-2016). Faculdade de Direito de Ribeirão Preto da Universidade de São Paulo. São Paulo. Lattes: http://lattes.cnpq.br/9184220537466009 e-mail: cristinagodoy@usp.br

[2] Mestre em Direito pela Faculdade de Direito de Ribeirão Preto da Universidade de São Paulo (2019). Advogado. Faculdade de Direito de Ribeirão Preto da Universidade de São Paulo. São Paulo. Lattes:http://lattes.cnpq.br/9150996252519049 ORCID: https://orcid.org/0000-0003-0808-5187 e-mail: latmorais@gmail.com

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In this sense, a philosophical approach, with a political-normative perspective, can contribute to a deeper understanding of the subject, mainly to know how it is treated in the judicial sphere. Thus, there is practical relevance in philosophical formulations about justice and health.

Claims in the health area are demands of great importance for justice, among other reasons, because they are restricted by the scarcity of resources, and this has motivated several theories, notably utilitarian ones and those involved in the economic analysis of the right to seek arguments that may provide greater utility or greater efficiency.

Two arguments widely used by the Public Treasury in their defense in lawsuits of requests for social benefits by the State, especially those arising from the right to health, are the existential minimum and the reservation of the possible, which aim to limit state benefits to the most fundamental rights. and its economic-financial and budgetary capacity.

The utilitarian choice of these arguments is noticeable, given that there is the option of increasing the "happiness" of a greater number of individuals, even at the expense of the health of many others, which would result in a greater net balance of satisfaction, which it would be further increased by putting the brakes on a possible increase in taxation to fund greater public spending.

In the same sense of utilitarianism, for the consequentialist/efficientist current, the expenditure made by the State must be efficient in the sense of covering the greatest number of people, for example, in health treatment that covers more prevalent diseases and relatively easy to control it's cheap.

On the other hand, for John Rawls (2016), the utilitarian choice moves away from the arguments of justice, and therefore, proposes a theory that, primarily, takes into account justice as equity in the distribution of the result of social cooperation, as well as of the duties arising from it.

Therefore, it is necessary that there is equality in the enjoyment of freedoms, that opportunities are equitably distributed and that the most advantaged only benefit from an unequal distribution that favors them, if this benefit can raise the expectations of the less advantaged.

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It is quite difficult to assert the priority of equality in the enjoyment of fundamental freedoms, as Rawls (2016) does in *A Theory of Justice*, when minimal material conditions are not met. Thus, it is clear that fundamental freedoms cannot be exercised in the absence of a minimum of material guarantees to citizens.

From this perspective, Rawls in *Political Liberalism* asserts that there could be a principle prior to the principle of equality[3], which had the objective of providing citizens with a social minimum (RAWLS, 2011).

The social minimum, which is considered the most fundamental core of primary goods, must have its distribution governed by the principle of equality[4], that is, it must be distributed to everyone equally, as it must be composed of a quantity and a diversity of goods that guarantee a dignified existence for all. Only after this minimum level could differences begin to occur, but even so, respecting the limitations of the difference principle with regard to inequalities, they would have to raise the expectations of the less favored.

The Federal Constitution of 1988 granted some fundamental social rights such as the right to health, foreseen as a universal right, that is, the right of all citizens, regardless of their social and economic position. It can be understood that universality is in line with the principle of equality in the distribution of the social minimum in health, allowing universal access to goods that have the important function of guaranteeing the exercise and enjoyment of fundamental freedoms.

However, another principle of the right to health is comprehensiveness, which raises serious questions such as, to what extent is the State obligated to provide health treatments? Is the concept of integrality consistent with a social minimum that allows for the exercise of fundamental freedoms and a dignified life? In other words, what minimum health treatment guarantees the enjoyment and full exercise of the fundamental freedoms and dignity of the human person?

[3] Rawls (2016) maintains that people in the original position, limited by the veil of ignorance and a list of principles selected by formal conditions, would choose two principles: i) equal right to the most extensive system of basic freedoms that is compatible with a system of identical freedoms for all; ii) distribution of economic and social inequalities in a way that simultaneously: a) provides the maximum expected benefit to the least favored; and b) is linked to positions and positions open to all under conditions of equal opportunity.

[4] The Rawls principle establishes the principle of equality only with a view to distributing basic freedoms (civil and political freedoms, among others), however in later formulations the author goes on to argue that to enable the equal enjoyment of these freedoms, people must have minimum material conditions – the social minimum.

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It is understood that one of the great challenges of justice is to know the quantity and diversity of primary goods that make up the social minimum, and, specifically, in this work, in the context of health. In other words, finding out how many and which treatments make up the social minimum in health should be one of the questions to be answered, if this is possible.

For part of the literature, the constitutional interpretation that defends the integral health care of the citizen has generated a huge amount of processes related to requests for treatment, including specific medications and treatments not provided by the SUS (Unified Health System), such as those not manufactured in Brazil, not scientifically proven, not marketed or not registered with regulatory bodies, such as Anvisa - National Health Surveillance Agency (TORRES, 2001; LOPES, 2006; SARLET; FIGUEIREDO, 2007; WEICHERT, 2010; LIMA, 2013; LIMA, 2016).

Medical treatments that are outside the policies established by the SUS, when guaranteed by the courts throughout the country, according to authors such as Scaff (2013), Wang (2013), Lopes (2013), among others, create budgetary imbalances in Municipalities and States, who claim, in most defenses, that there is a reserve of the possible that limits the offer of treatments and that the existential minimum has been exceeded.

Thus, different interpretations of the Constitution emerge in an attempt to limit or expand the package of health services made available to citizens. However, for Castro (2012), once the existential minimum in health is identified, this right must be satisfied, with no further restriction being admitted, as this is a requirement of the legal system, according to the principle of social non-regression.

In view of this situation, this article aims, based on Rawls' (2016) theory of justice as equity, to verify: i) whether the existential minimum and the reserve of the possible are present in this theory and how they are presented; ii) what are the universality and integrality guaranteed by the Federal Constitution of 1988, how are they covered in SUS policies and if they fit the Rawlsian social minimum concept; iii) the role of the judiciary in matters relating to the right to health; iv) the capacity of John Rawls' theory of justice as equity to guide the judicial decision in health; v) the use and delimitation by the STF of the key concepts: existential minimum, reserve of the possible, universality and integrality; and, based on that: vi) analyze whether the award of health treatments by

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the Federal Supreme Court is fair, insofar as the arguments and motivations present in the decisions are in line with the principles of justice of John Rawls.

To meet these objectives, a theoretical-philosophical and normative study was used, through analyzes and dialogues between John Rawls and his main commentators and critics. The same analytical and dialogic technique was used in reading the authors who deal with the key concepts listed in the checkpoints and those who study the theme of public health in the Federal Constitution of 1988, both from a doctrinal and jurisprudential perspective.

After debugging the main reliefs of the theory of justice under analysis and the main concepts, conclusions and syntheses were reached that were later used to guide the qualitative analysis of the STF decisions, selected according to the method described in the item "Analyzed decisions: financial impacts generated and information on the incorporation by CONITEC".

These conclusions and summaries served as a specific lens to broaden the view on how the STF employs and delimits the key concepts, bring to light the main arguments or motivations of justice used in its decisions and, finally, verify if these arguments or motivations fall into the Rawlsian theory of justice, in view of the principle of equity that is seen in the care not to harm the less fortunate.

THE EXISTENTIAL MINIMUM, THE RESERVE OF THE POSSIBLE AND THE THEORY OF JUSTICE AS EQUITY

In general, the existential minimum is understood as the set of minimum material conditions that guarantee a dignified life, which provides the enjoyment and enjoyment of individual and political rights. On the other hand, the reserve of the possible is understood as the insufficiency of financial resources on the part of the State to meet all social demands, and less frequently, as the technical impossibility, for example, when it is intended to distribute in general and a drug in the experimental phase. The origin of both concepts goes back to the debates on social rights that took place in the German Constitutional Court in the 1950s.

The existential minimum must be understood as a limit imposed by economic rationality on the realization of social rights, a rationality that reduces them to their

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essentiality. Therefore, it can be said that the existential minimum stipulated by public policies, based on constitutional parameters, is defined by the reserve of the possible (budgetary, technical limitations, etc.) and cannot be, again, in the judicial sphere, limited or restricted by the same argument (reserve of the possible).

In his theory of justice as equity, Rawls (2016) aims to formulate a conception of social justice, based on the consensual choice of justice principles carried out in an original agreement that will become a standard for evaluating the distributive aspects of the basic structure of the society.

The author assumes that the parties to the original agreement have interests in primary social goods, which all human beings are supposed to rationally want. In this list of primary goods, there is an essential part, represented by basic needs, called the social minimum. Thus, food, housing, education and health constitute the social minimum. The other primary goods that go beyond it are necessary for the realization of each individual's life plans according to their personal conception of good (RAWLS, 2016).

The social minimum is essential for people to enjoy the same fundamental rights and freedoms, as it offers minimum material and social conditions for a dignified existence and also enables competition for equal opportunities in an equitable manner, and is therefore distributed according to the principle of equality. Thus, only after this point of minimum equality should the principle of difference be applied.

It can be said that the existential minimum and the reserve of the possible are present in Rawls' theory of justice as equity and that both serve to maintain social cooperation.

The existential minimum can be equated with the social minimum, which is governed by the principle of equality, since not guaranteeing it to everyone would be unfair, as, just as freedoms should not be distributed unequally, nor with a view to an improvement in distribution of wealth, the social minimum must not be unequally distributed, nor should it aim to improve the condition of the less fortunate. In other words, the social minimum guarantees equal enjoyment of freedoms.

Regarding the reserve of the possible, this is not so evident in the theory of justice as equity, but it can be understood as a principle that aims to prevent exaggeration in taxation, by limiting public spending to budgetary, economic and financial possibilities. As will be seen below, in the original position, citizens, covered by the veil

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of ignorance, do not know anything about their own condition of life: if they are poorer and very dependent on the distribution of the social minimum or if they are the main maintainers of the distribution system, what is essential for a non-egoistic choice.

Rawls' work can be understood as necessary to provide theoretical-philosophical support for the minimization of social rights, which came to be considered excessive after the various crises of capitalism. Thus, the concepts of social minimum and non-exaggeration in taxation are contextualized with the rationalization of the distribution of social rights, which are now considered only those fundamental to a decent life, among others, in the sense of the possibility of enjoying equal freedoms. .

The theory of justice proposed by Rawls is an attempt to supplant utilitarianism, which, for the author, provides fragile foundations for democratic institutions, since greater social well-being should not be based on individual sacrifices.

However, Rawls was not able, as he wished, to move so far away from utilitarianism, since, as he goes on to say, there are other consensuses that can surpass individual plans, such as social welfare, which cannot be understood in any other way, if not as the greatest common good, which depends on distribution to the benefit of some and to the detriment of others and requires distributive criteria centered on equity.

THE THEORY OF JUSTICE AS EQUITY AS A GUIDE FOR JUDICIAL DECISION

It is not surprising that utilitarian arguments, such as the existential minimum and the reserve of the possible, are present in Rawls's theory of justice as equity. However, Rawlsian utilitarianism is mitigated by the importance it gives to the protection of the less fortunate and by the establishment of an equal social minimum for all. use of equity of distribution, important for any kind of decision involving issues of justice.

Thus, it is argued that Rawls's theory of justice as equity, although focused on aspects of normative policy, can also be used as a guide for the judicial decision, as it has important moral guidelines - the principles of justice.

The theory of justice as equity changes the logic of the normative structure proposed by Hans Kelsen, offering another meaning to the "fundamental hypothetical norm", which is now understood as the set of principles of justice chosen in the original

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position, which should guide the Constitution, laws and norms in general, as well as the judicial decision, mischaracterizing the legal purism of the science of law, which is congruent with neoconstitutionalism and post-positivism.

In this way, the justice of the Constitution or any constitutional provision, law or even judicial decision can be verified through the mental simulation of the deliberations made in the original position, as it states Rawls (2011, p. 31-32) “we can [..] enter this position at any time simply by arguing in favor of principles of justice in line with the information restrictions that have been specified” (veil of ignorance). The important thing is to analyze the justice of the legal or judicial rule, according to the two principles of justice, by choosing the alternatives "least worst among the worst" (a principle that also links to the reserve of the possible and the existential minimum).

In this sense, we agree with one of Rawls' most famous critics, Michael Sandel (2005), that the choice of the principles of justice is not exactly an agreement between parties, but a kind of cognitivism, in which it is possible to find the principles of justice through reason.

Given the above, the objective of analyzing court decisions and verifying their adherence to the principles of justice chosen in the original position becomes possible, a choice that is understood as an exercise in autonomous reflection, as the one that analyzes compliance with the principles of justice must put itself in the place of the less fortunate.

THE UNIVERSALITY AND INTEGRALITY OF THE RIGHT TO HEALTH IN THE FEDERAL CONSTITUTION OF 1988

From the Federal Constitution of 1988, the right to health came to be provided for as a right governed by the principles of universality and integrality, consistent with the criteria established in the Health Reform, which took place in the 1980s, which was a kind of guide for the constitutionalization of the right to health in the country.

Universality is interpreted differently by the doctrine. A mainstream understands it as the access of any citizen, regardless of their socioeconomic status, to free state-sponsored health services (literality of the constitutional rule, interpretation of which it is shared) (SLAIBI, 2004; COHN, 2005; BOTAZZO, 2008). A second current argues that universality should be restricted to the State's ability to provide all citizens equally and

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simultaneously with the same free health services, and for that, these should be the most basic and least costly (LOPES, 2006; LEAL, 2008). Still other authors understand that access should not be universal, but directed only to the poorest (TORRES, 2001; LIMA FILHO, 2006; SARLET; FIGUEIREDO, 2007), which goes against the constitutional will and its semantic clarity.

As for comprehensiveness, there are also many disagreements regarding its interpretation, which ranges from the integral medicine movement and its criticism of the curricula that train doctors with fragmentary and reductionist attitudes, through the form of organization of services and health practices, in that the attempt to overcome the dissociation between public health and care (philanthropy) and, on the other hand, between individual health and collective health is discussed, until the interpretation that defends the end of the existing dichotomy between preventive and curative actions (BRITO-SILVA et al, 2012).

However, for part of the doctrine, among which Pinheiro (2007) and Aith (2010), comprehensiveness refers to access to the most complex, innovative and costly treatment, despite the resulting consequences, such as the depletion of public resources by few individuals, which leads to situations of injustice.

In this context, one could imagine that any health demand not included in the SUS policies should necessarily be met based on requests to the Judiciary. However, there is a need for objective criteria that can ensure citizens' access to treatments whose scientific efficacy is proven, among other prerequisites, those that enable the State to pay for them safely and with a view to the proper application of resources mainly in serving the less fortunate.

However, to reach these objective criteria, universality and completeness must be interpreted based on the principles of the existential/social minimum and the reserve of the possible, given that any interpretation that does not take into account these limits may be contrary to justice in the equal distribution of the right to health.

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UNIVERSALITY AND INTEGRALITY IN LIGHT OF THE SOCIAL MINIMUM AND THE RESERVE OF THE POSSIBLE

There are also great divergences in the interpretation of the existential/social minimum in health and whether this minimum can be restricted by the reserve of the possible, in view of the principles of integrality and universality, with authors such as Torres (2003), Sarlet and Figueiredo (2007) , among others, defend only collective health and medical emergencies as the existential minimum. Others, such as Barcellos (2013), argue that the existential minimum refers, in addition to collective health, to the basic level of individual health care.

A contrario sensu, it is argued that the existential/social minimum in health, necessary to ensure equal enjoyment and the full exercise of fundamental freedoms, as defined by Rawls, corresponds to integrality and universality, which are represented by the comprehensive Public Policies SUS universal service, both preventive and curative, at the three levels of complexity of care: basic, medium and high complexity, as well as the supply of drugs and treatments already incorporated, according to the National List of Essential Medicines (RENAME), the drug lists exceptional and the Clinical Protocols and Therapeutic Guidelines of the SUS, and the reservation of what is possible cannot limit the offer of these services to the citizen, who must have sufficient budget provision for their care, as it is characterized as a minimum established constitutionally and technically -scientific, and, therefore, it is part of the main objectives of the State, which must direct to provide sufficient resources to guarantee it, in view of the maintenance of social cooperation, and which is defined, preferably, within the scope of public policies.

Thus, once a certain therapeutic provision is incorporated by the body responsible for technical-scientific analyzes (National Commission for the Incorporation of Technologies of the SUS – CONITEC[5]), including through national public consultation

[5] The National Commission for the Incorporation of Technologies in the SUS (CONITEC), created by Law nº 12.401, of April 28, 2011, which provides for therapeutic care and the incorporation of health technology within the scope of the Unified Health System (SUS), is a permanent collegiate body, part of the regimental structure of the Ministry of Health, its objective is to advise the Ministry in the attributions related to the incorporation, exclusion or alteration by the SUS of health technologies, as well as in the constitution or alteration of clinical protocols and guidelines therapeutic (BRASIL et al, 2019, p. 5).

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procedures, this becomes part of the existential/social minimum, although there may be some ethical problems, since, in most cases, it is the person who provokes the public agency to incorporate a certain drug. pharmaceutical industry that produces it, since otherwise, it would have insurmountable difficulties in its commercialization, due to the extremely high cost of its products, inaccessible, even to people belonging to the most privileged classes of the population. However, even in view of such ethical problems, the technical-scientific criteria work to mitigate possible deviations.

THE CONSTITUTIONAL RIGHT TO HEALTH IN THE FACE OF RAWLS' THEORY

The right to health, provided for in the Federal Constitution of 1988, must be distributed equally (universality), that is, without taking into account the economic need of each individual or their social position, which is compatible with the application of the principle of equality in the distribution of the social minimum predicted by Rawls (2016).

It can be thought that, in the original position, the parties to the agreement, as unaware of their ability to fund the health treatments they might need with their own resources, would rationally opt for a universal health system that would include them, regardless of the financial condition that they might have. Under these conditions, one could imagine that the parties would choose to have access to any and all available treatments, as they might think that if they needed them, they should be fully attended to.

However, Rawls (2016) states that in the original position, the parties share undemanding conditions, that is, they would demand health care provided by the State and would require a comprehensive level of treatment, but using accessible technology with proven efficiency and effectiveness. One might even think that they would choose treatment for all health conditions, but whose technique/technology had an acceptable cost-benefit ratio, in view of the protection of the social minimum itself and the non-exaggeration of taxation, which serve to protect the social cooperation, as the veil of ignorance makes them unaware of their own economic and social position, that is, they would not know if they would be predominantly funders or dependent on the health system.

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This characteristic of the parties in the original position would cause treatments whose efficacy was not proven or with cost-effectiveness problems to be rejected, which is compatible with the criteria established by CONITEC for the incorporation of new medical technologies.

As the SUS policy itself goes beyond basic care and comprises medium and high complexity levels, as well as the supply of high-cost medicines incorporated according to technical-scientific criteria, they can be admitted as the existential minimum/ in health in Brazil, and that treatment that is not present in the protocols and drug lists must undergo technical studies of incorporation.

For example, a person who has not been successful with the most modern and expensive treatments present in the SUS lists and distributed free of charge, goes to the Judiciary to request a new drug, which has not yet been incorporated into the SUS and which is expensive. In this case, the judge must only award such medication if this decision does not harm the equal distribution of the social minimum. However, this condition will not be met, as a part of the SUS budget will be reallocated to comply with the court order and will inevitably violate the existential/social minimum.

In other words, as the SUS budget resources are only provided for the maintenance of the existential/social minimum, the reallocation of these resources to meet requests that exceed the expected minimum contributes to worsen the conditions of the less fortunate, as they become deprived of this Minimum. In view of the worsening conditions of the poor, who are those who depend exclusively on the SUS to obtain health care, no matter how basic, the award of treatments that are not provided for in SUS policies is unfair from a point of view. from John Rawls's theory of equity.

However, just as an argumentative exercise, suppose that the distribution of high-cost medicines by the Judiciary that are not included in the official SUS listings is financed without prejudice to the existential minimum by a budget previously allocated especially for this purpose. if: such a distribution could raise the expectations of the less favored (Rawlsian criterion of distribution governed by the principle of difference)? Would this award be fair?

If one thinks only of pure and simple raising of the expectations of the less favored or of disproportionate expectations, one can imagine that, for example, there could be cheaper medicines, because if the Government, the only one to be able to pay

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for high-cost treatments, with very few exceptions, if it managed to make the returns of the pharmaceutical industry over time, such drugs, among others, could be made cheaper and would reach more people.

On the other hand, the industry could be encouraged to continue investing in research into new drugs, which would possibly make it expand its operations, generate jobs and pay more taxes (perhaps not in Brazil). In this way, raising the expectations of the less fortunate would be met, however, what about the fairness of distribution?

It can be imagined that assigning a specific budget to the distribution by the Judiciary of high-cost medicines that are not incorporated into SUS policies could be a fair solution, as it maintains the social minimum in an integral way. However, the budget destined to health must be stipulated universally and globally, and any amount destined to health must be directed to the care of all and equally, which would not occur in this case, mainly because most actions that serve the adjudication of high-cost treatments is managed individually and many people do not even know that they can or are able to access the judiciary to get innovative medications or do not even have access to doctors who are so up-to-date in their prescriptions.

Thus, in view of a mere expectation of improvement of the less fortunate in view of a real decrease in their perspectives, given the budgetary commitment generated by an exclusionary allocation, which will privilege the few, and the failure to comply with the principle of universality in health, it appears that it appears that the adjudication of high-cost medications not provided for in SUS policies generates a much greater negative impact than any argument for the expectation of improvement of the less favored.

THE JUDICIALIZATION OF FUNDAMENTAL SOCIAL RIGHTS - THE RIGHT TO HEALTH

Syndication or the possibility of judicialization of fundamental social rights has specific and opposing currents that can be found both in the normative and political spheres.

In the normative scope, the division is between the currents that defend the possibility or not of the Judiciary Power applying constitutional norms on fundamental

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rights, directly, that is, prior to the existence of infra-constitutional laws, according to the characteristics of the standard (ACCA, 2009).

In the political sphere, the division is between the currents that defend or not the legitimacy of the Judiciary to intervene in political decisions and what degree of intervention is allowed (ACCA, 2009).

In the normative scope, Alexy's (2007) theory of constitutional rule is preponderant: the rule will be binding when its violation can be declared by a Constitutional Court, referring to an existential minimum, and it will not be binding when it has a programmatic statement, that is. it is, when it exposes claims to fundamental rights in imperfect norms[6].

In relation to the political sphere, the discussion on the possibility of intervention by the Judiciary in fundamental social rights is divided between those who i) admit judicial control only regarding the procedural aspects of Public Policies - procedural current[7]; or ii) admit full judicial control, both in relation to the procedural aspect and the material aspect of Public Policies - substantialist current[8].

Despite accepting the immediate applicability of the constitutional rule on fundamental social rights and full judicial control of Public Policies, the particularities involved in the right to health lead to the need for the treatments provided by the State to be defined according to technical-scientific criteria , which ends up limiting the accuracy of the evaluation by the Judiciary on requested therapy and not yet incorporated into SUS policies, despite any type of technical assistance, since the court decision is not appropriate to the adjudication of new health technologies, being that the limitations in this area do not occur only in the normative or political scope, but, above all, due to the need for decisions based on a scientific methodology, which are taken by CONITEC.

[6] In the same sense, Canotilho (2008) states that, in the field of minimum existential benefits of the right to life, the citizen has an original and definitive subjective right to these benefits, which corresponds to a correlative duty on the part of the State, that is, a legal-benefit position that is guaranteed by binding norms recognizing definitive subjective rights to benefits.

[7] According to Martins (2015), the proceduralist current, headed by Habermas, understands that the Constitution cannot be seen as a global legal order and suprapositive of values. Consequently, fundamental rights depend on the implementation of the respective Public Policies, and individual enjoyment arising from the court decision is prohibited, since it would offend the democratic procedure.

[8] The substantialist current, led by Cappelletti, defends the principled and guiding character of the Constitution, and the rules that define fundamental rights and guarantees have immediate application and are fully capable of being syndicated before the Judiciary, which can award them individually (MARTINS, 2015).

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Thus, we agree with Sarlet and Figueiredo (2007) on the technical limitation of the judicial decision, which must also be understood in the reserve of the possible and which limits the award of treatment not yet considered as a component of the existential minimum, which is the task of the SUS and its technical bodies, as the analysis of the reasonableness and adequacy of a given therapeutic provision, as well as its essentiality, is much more authoritative when performed through internationally endorsed technical-scientific methodologies than when performed by a judge or by a collegiate of magistrates, despite all evidence of necessity. The analysis of the effectiveness/efficiency of the requested treatment is more qualified under CONITEC, mainly due to greater public participation (public consultation) and the scope of the decision, which goes far beyond individual adjudication and becomes accessible to all they need it.

It could be questioned that, if there is no planned treatment for a given disease in the SUS, even with an important epidemiological representation and low cost, the judiciary could award this treatment, disregarding the need for technical studies to be carried out by the area of incorporation of new therapeutic, or even that collective actions have the same potential to cover all those who fit the species, in a similar way to public policies.

However, even managed by collective actions, considered fairer than individual adjudication due to its particular characteristics[9], the procedural deficit, especially in relation to technical-scientific aspects, deprives the Judiciary Power of the necessary legitimacy for the adjudication of a new therapeutic, regardless of its cost.

Thus, it is understood that the best thing to be done by the Judiciary in the face of a therapy that has not yet been incorporated, whose efficacy/efficiency and cost-effectiveness are unknown, is to urge the SUS to start the analysis of incorporation under an emergency regime, due to, for example, the number of cases on the same object or in view of the preponderance of the disease.

In short, the role of the Judiciary is to enforce public policy, that is, to ensure the distribution of the social minimum in health and to determine that incorporation studies

[9] In the field of health, collective actions provide procedural economy, greater access to justice, effectiveness of material rights and reduction of individual actions. They also allow for a more comprehensive discussion of public policies, providing a more realistic idea of the dimensions of the need and the amount of available resources. Added to this is the fact that the Brazilian Courts admit the legitimacy of the Public Prosecutor's Office in the filing of public civil action in defense of health, with the production of erga omnes effects, which privileges equality and universality (THIBAU; GAZZOLA, 2014).

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are started, respecting the final decision of CONITEC, even if it is understand why not recommend the incorporation of the drug, as the Judiciary is not competent for analyzes that require specific scientific criteria, even in view of possible technical assistance.

Given the arguments brought forward, it could be argued that the application of Rawls's theory of justice as equity to the analysis of the decision on the award of high-cost drugs would be innocuous, since, after all, this is a decision that belongs only to Organs technical bodies of the executive. However, this claim is not supported, as the theory under analysis serves as a basis for the rejection of requests for treatments not included in the SUS policies, above all, to avoid harm to the less fortunate.

On the other hand, due to the massive adjudication of high-cost medicines not incorporated by the SUS, verifying the existence or not of analyzes and reasons, by the STF, of principles related to equity and, above all, the consequences to the less favored, from the perspective of the existential/social minimum and the reserve of the possible, it is relevant, given the importance of using distributive justice criteria in the grounds of judicial decisions and the very serious consequences of not using such criteria.

DECISIONS ANALYZED: FINANCIAL IMPACTS GENERATED AND INFORMATION ON THE INCORPORATION BY CONITEC

From now on, the description of the method for collecting the analyzed decisions and their main information will be described.

Given the obvious time constraints, an attempt was made to answer questions relating to how the STF decides within the scope of the right to health, applying qualitative analysis to some of its most important decisions regarding requests for high-cost medications, from last 5 (five) years, from 05/24/2014 to 05/24/2019, and that have in their discussion the arguments of the existential minimum and the reserve of the possible or arguments that touch them.

To this end, two surveys were carried out on the website of the Supreme Court, at the website http://portal.stf.jus.br/.

In the first search, the "free search" field was filled in with the following search term: drug and high cost, in the "date" field, the above-mentioned dates were informed, in the "legislation" field the 1988 Federal Constitution and article 196 was informed, and, finally, all types of decision were selected.

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The research returned 4 (four) judgments, 103 (one hundred and three) monocratic decisions, 15 decisions of the presidency and 1 (one) General Repercussion. It is important to inform that, again, due to the time limitation, it was decided to include in the selective reading only the decisions that met the following criteria: that had one of the following expressions in the body of the decision text, using the tool for this purpose. "Adobe Acrobat Reader DC®" research: "existential minimum" or "possible reserve" or "budget" or "equity", and 3 judgments were included in the selective reading; 21 monocratic decisions; 9 decisions of the presidency; and a single decision that the research returned, which deals with the general repercussion of the theme "solidarity of federative entities in the cost of health treatments", according to Extraordinary Appeal 855,178 RG/SE, by Minister Luiz Fux, in which the Full Court established the thesis, on May 23, 2019, that federation entities are jointly and severally liable in the provision of healthcare demands, due to the decentralization and hierarchization provided for by the Constitution.

In a second search on the STF portal, the following search term was filled out in the "free search" field: drug and high cost and reservation of the possible and minimum existential, in the "date" field, the aforementioned dates were informed in the "field" legislation" no legislation was selected and, finally, all types of decision were selected.

The survey returned 11 (eleven) monocratic decisions and 3 (three) decisions of the presidency. In the decisions brought forward, there was a repetition of 5 (five) monocratic decisions and 1 (one) decision of the presidency present in the first survey.

From this second survey, 6 (six) monocratic decisions and 2 (two) decisions of the presidency were added for selective reading, which in fact were the same STP 101 ES (Suspension of Provisional Guardianship) and the first decision dealt with the denial of the injunction to suspend the provisional relief and the second decision confirmed the denial of suspension.

The subsequent selective reading sought to separate the decisions with the greatest impact from those that discussed requests for high-cost medicines from the perspective of the reserve of the possible, the existential minimum, equity, budgetary/financial limits or the themes that touched them.

Decisions of a strictly procedural nature were discarded, in which no points were discussed regarding the merits, as well as decisions whose object was not high-cost

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medicine and those in which there was no discussion regarding the high cost, the existential minimum and to the reservation of what is possible, regardless of whether in its budgetary-financial aspect or relating to the separation of powers.

From the selective reading, 10 decisions were chosen for in-depth analysis according to the theory of justice as equity by John Rawls, using analytical and synthetic methods.

Due to the relevance of the decisions, the following decisions were included: STP 24 MC/MG - Precautionary Measure in the Suspension of Provisional Guardianship, Rapporteur: Chief Justice, Judgment: 25/04/2018; STA 761/DF - Suspension of Early Guardianship, Rapporteur: Chief Justice, Judgment: 11/26/2014; and SS 4972/SP - Security Suspension, Rapporteur: Chief Justice, Judgment: 12/10/2014, resulting in 13 (thirteen) decisions for in-depth analysis.

It is important to note that of the 13 decisions studied, only one of them was a public civil action, that is, even when dealing with an issue that a priori affects the community, the number of public civil actions requesting treatment compared to individual actions is much inferior. We chose to list it, as it is a situation that illustrates how a collective action is treated differently in relation to individual cases, because given the impact of a decision that encompasses the collectivity, the judiciary starts to be much more careful when it comes to measure the economic consequences when deciding on costly treatments.

It is also noteworthy that the objective of the qualitative research on decisions was not to compare how the STF decides on each individual action listed, but to explore the fundamentals present in them and bring them to the fore. In this sense, it would be impoverishing for the work not to analyze the fundamentals of public civil action and compare them with those present in individual lawsuits, since issues of equity must be taken into account both in the decisions of individual lawsuits and collective lawsuits.

The thirteen decisions analyzed in depth were as follows, according to the judgment date:

1. Interlocutory Appeal in Extraordinary Appeal No. 818.572 / CE, Rapporteur Min. Dias Toffoli, First Panel, Judgment: 09/02/2014.

This is an Interlocutory Appeal in the Extraordinary Appeal filed by the State of Ceará and by the Union against a decision that denied the extraordinary appeal. The

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judgment was given by the 1st Panel, on September 2, 2014, unanimously and pursuant to the vote of the Rapporteur Minister Dias Toffoli, they dismissed the State of Ceará and understood that the Union's grievance had been harmed.

The appellants wanted to reverse the decision at the level of appeal, issued by the TRF of the 5th region, which upheld a first-degree sentence that awarded high-cost medicine.

The petitioner has Lung Neoplasia and requested the drug Tarceva 150 mg (erlotinib hydrochloride), whose price to the consumer is shown in the updated list of drug costs[10] was not found and the price for public purchases without ICMS is R$5,923.33 per month. The annual cost is R$ 71,079.96 calculated according to the sale price to the government (public purchases).

Ordinance No. 51, of November 7, 2013 made public the decision to incorporate erlotinib hydrochloride for the treatment of advanced or metastatic non-small cell lung cancer, according to the website http://conitec.gov.br/ images/Reports/Ordinance/2013/CP38a40-PT51.pdf, accessed on 06/17/2019.

The STF's decision to confirm the a quo decision favorable to the petitioner took place a little less than a year after its incorporation by SUS.

2. STA 761 / DF - Suspension of Early Guardianship, Rapporteur: Chief Justice Ricardo Lewandowski, Judgment: 11/26/2014.

This is a request for the Suspension of Early Protection filed by the Municipality of São Paulo, aiming to suspend the effects of the early protection granted by the Federal District Court of Justice, to provide the drug Soliris (Eculizumab) to patients with paroxysmal nocturnal Hemoglobinuria. Request for the suspension of the anticipation of guardianship rejected by the President of the STF, Minister Ricardo Lewandowski, on November 26, 2014.

The petitioner has paroxysmal nocturnal Hemoglobinuria and requests the drug Soliris (Eculizumab) 10 mg/ml, whose consumer price without incidence of IMCS is R$17,964.79 and the price for public purchases without incidence of ICMS is R$14,343. 09. The annual cost of R$172,117.08 was calculated according to the sale price to the government (public purchases).

[10] http://portal.anvisa.gov.br/documents/374947/2829072/LISTA_CONFORMIDADE_GOV_2019-06-06.pdf/6ef66980-f221-42f7-9c75-bd009afa7bf4 - listing updated on 06/06/2019, accessed on 06/17/2019.

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Ordinance No. 77 of December 14, 2018 made public the decision to incorporate eculizumab for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), according to the website http://conitec.gov.br/images/Relatorios/Portaria /2018/OrdinancesSCTIE_75a81_2018.pdf, accessed on 06/17/2019.

The STF's decision to maintain the a quo decision favorable to the petitioner took place approximately 4 years before its incorporation by SUS.

3. SS 4972 / SP - Security Suspension Rapporteur: Chief Justice Ricardo Lewandowski, Judgment: 12/10/2014.

This is a request for a Security Suspension filed by the Municipality of Santo André, aiming to suspend the effects of the interlocutory relief granted by the Court of Justice of the State of São Paulo, to provide the drug Aubagio 14 mg (teriflunomide) to patients with multiple sclerosis and diabetes. Request for suspension of security denied by the President of the STF, Minister Ricardo Lewandowiski, on December 10, 2014.

The applicant has multiple sclerosis and requests the drug Aubagio 14 mg (teriflunomide), whose consumer price without incidence of IMCS is R$ 4,669.41 and the price for public purchases without ICMS incidence is R$ 3,728.06 . The monthly treatment cost is R$3,728.06, while the annual cost is R$44,736.72, calculated according to the price of sale to the government (public purchases.

Ordinance No. 19 of April 19, 2017 made public the decision to incorporate teriflunomide for the treatment of relapsing-remitting multiple sclerosis, according to the website http://conitec.gov.br/images/Relatorios/Portaria/2017/ Ordinance SCTIE-17a19_2017.pdf, accessed on 06/17/2019.

The STF's decision to maintain the a quo decision favorable to the petitioner took place just over 3 years before the recommendation for incorporation by the SUS.

4. Interlocutory Appeal in the Suspension of Injunction No. 815 / SP, Rapporteur: Minister President Ricardo Lewandowski, Judgment: 05/07/2015 Plenary

This is an Interlocutory Appeal in the Suspension of the Injunction filed by the Municipality of São Paulo and the State of São Paulo against a decision that denied the Suspension of Provisional Guardianship - STP 815/SP. The judgment was given by the Supreme Court, on May 7, 2015, unanimously and pursuant to the vote of the Justice Rapporteur Ricardo Lewandowiski, dismissed.

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The applicant has Hepatitis C and requests the combined use of the medications: i) Sofosbuvir 400 mg, whose consumer price without incidence of IMCS is R$ 51,699.88 and the price for public purchases without ICMS incidence is R$ 41,277 .18; ii) Simeprevir 150 mg, whose consumer price without ICMS is R$ 30,727.23 and the price for public purchases without ICMS is R$ 24,532.62; and iii) Ribavirin 250 mg, whose consumer price without ICMS is R$ 81.35 and the price for public purchases without ICMS is R$ 64.95. The cost of monthly treatment is R$69,252.91 and the total cost of treatment (12 weeks) is R$207,758.73, calculated according to the sale price to the government (public purchases).

Ordinance No. 29, of June 22, 2015 made public the decision to incorporate the drugs Sofosbuvir, Daclatasvir and Simeprevir for the treatment of chronic viral hepatitis C, according to the website http://conitec.gov.br/images/Relatorios/ Ordinance/2015/PortariaSCTIE_29_2015.pdf, accessed on 06/17/2019.

The STF's decision to maintain the a quo decision favorable to the petitioner took place just over 1 month before its incorporation by SUS.

5. ARE 889216 / DF - Extraordinary Appeal with Interlocutory Appeal, Rapporteur: Justice Dias Toffoli, Judgment: 05/25/2015

This is an Extraordinary Appeal with an Interlocutory Appeal filed by the Union. In a monocratic decision, Minister Dias Toffoli, on May 25, 2015, granted the Interlocutory Appeal, but denied the matter of passive legitimacy.

The appellant wanted to reverse the decision rendered by the TRF of the 1st region, which did not admit an extraordinary appeal filed against the appellate decision that granted the supply of high-cost medicine.

The applicant has Fabry Disease and requests the drug Replagal 1 mg/ml (alphagalsidase), whose consumer price without incidence of IMCS is R$ 4,787.38 and the price for public purchases without ICMS incidence is R$ 3,822.24, with a monthly treatment cost of BRL 3,822.24, and its annual cost of BRL 45,866.88, calculated according to the sale price to the government (public purchases).

Ordinance No. 76 of December 14, 2018 made public the decision not to incorporate alpha-agalsidase and beta-agalsidase as enzyme replacement therapy in Fabry's disease, according to the website http://conitec.gov.br/images/ Reports/Ordinance/2018/OrdinancesSCTIE_75a81_2018.pdf, accessed on 06/17/2019.

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The STF's decision to maintain the a quo decision favorable to the petitioner took place almost 3 years before the decision not to be incorporated by SUS.

6. ARE 881471 / AL - Extraordinary Appeal with Interlocutory Appeal, Rapporteur: Min. Dias Toffoli, Judgment: 06/09/2015

This is an Extraordinary Appeal with an Interlocutory Appeal filed by the Municipality of Maceió. In a monocratic decision by Minister Dias Toffoli, on June 9, 2015, the extraordinary appeal was denied.

The appellant wanted to reverse the decision rendered by the Appeal Panel of the Judiciary Section of Alagoas, which did not admit an extraordinary appeal filed against the appellate decision that granted the supply of high-cost medication.

The applicant has breast cancer and requests the drug Femara 2.5 mg (letrozole), whose consumer price without incidence of IMCS was not available in the list and price for public purchases without incidence of ICMS is R$ 525.47 . The monthly treatment cost is R$ 525.47 and the annual cost is R$ 6,305.64, calculated according to the sale price to the government (public purchases).

Ordinance No. 22 of June 10, 2014 made public the decision to incorporate previous hormone therapy (preoperative, neoadjuvant) for breast cancer, which includes the drug in question, according to the website http://conitec.gov .br/images/Incorporados/Hormoniotherapy-Cmama-FINAL.pdf, accessed on 06/17/2019.

The STF's decision to maintain the a quo decision favorable to the petitioner took place one year after the decision to incorporate the drug by the SUS.

7. SS 5192 MC / GO - Precautionary Measure in the Suspension of Security Rapporteur: Justice President Cármen Lúcia, Judgment: 08/07/2017

This is a Precautionary Measure in the Security Suspension filed by the State of Goiás, aiming to suspend the effects of the preliminary injunction granted by the Rapporteur of the Writ of Mandamus in the Court of Justice of Goiás, which determined the supply to the smallest AVB of the drug Spinraza (nusinersena) . Injunction rejected by the President of the STF, Minister Carmen Lúcia, on August 7, 2017.

The applicant has Spinal Muscular Atrophy type I and requests the drug Spinraza (nusinersena), whose consumer price without incidence of IMCS is R$ 309,869.60 and price for public purchases without ICMS incidence of R$ 247,399.94. The monthly

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treatment cost is R$247,399.94 and the annual cost is R$2,968,799.28, calculated according to the price of sale to the government (public purchases).

Ordinance No. 24 of April 24, 2019 made public the decision to incorporate nusinersena for spinal muscular atrophy (SMA) 5q type I, according to the website http://conitec.gov.br/images/Relatorios/Portaria/ 2019/OrdinanceSCTIE-24.pdf, accessed on 06/17/2019.

The STF's decision to maintain the a quo decision favorable to the petitioner took place just over a year before its incorporation into the SUS.

8. ARE 1057975 / BA - Extraordinary Appeal with Interlocutory Appeal, Rapporteur: Justice Ricardo Lewandowski, Judgment: 10/05/2017

It is an Extraordinary Appeal with an Interlocutory Appeal filed by the Federal Government. In a monocratic decision by Minister Ricardo Lewandowiski, on October 5, 2017, he denied the extraordinary appeal.

The appellant wanted to reverse the decision rendered by the TRF of the 1st region, which did not admit an extraordinary appeal filed against the appellate decision that granted the supply of high-cost medicine.

The Applicant has type 1 Diabetes and requests insulin Novorapid 100U/ml (Asparte) - 2,000 U/ml per month, whose consumer price without ICMS incidence is R$ 147.34 and price for public purchases without ICMS incidence is R$ 117.64. The monthly treatment cost is R$2,352.80 and the annual cost is R$28,233.60, calculated according to the price of sale to the government (public purchases).

Ordinance No. 10, of February 21, 2017, made public the decision to incorporate fast-acting analogue insulin for the treatment of Type 1 Diabetes Mellitus, including Asparte insulin, according to the website http://conitec.gov.br/ images/Reports/Ordinance/2017/OrdinancesSCTIE-09e10_2017.pdf, accessed on 06/17/2019.

The STF's decision to maintain the a quo decision favorable to the petitioner took place about 8 months after the decision to incorporate the drug by the SUS.

9. SL 1141 / MS - Suspension of Injunction, Rapporteur: Justice President Cármen Lúcia, Judgment: 01/16/2018

This is a request for suspension of a preliminary injunction filed by Mato Grosso do Sul, aiming to suspend the effects of the interlocutory relief granted by the judgment

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of the First Court of the Judicial District of Aparecida do Taboado/MS in Action n. 0801678-42.2017.8.12.0024 and maintained by the Rapporteur of Interlocutory Appeal no. 2002007-44.2017.8.12.0900 in the Court of Justice of Mato Grosso do Sul, which determined Mato Grosso do Sul and the Municipality of Aparecida do Taboado to provide the minor TVB with the drug Spinraza (nusinersena). Suspension of the Injunction rejected by the President of the STF, Minister Carmen Lúcia, on January 16, 2018.

The STF's decision to maintain the a quo decision favorable to the petitioner took place just over a year before its incorporation into the SUS.

10. STP 24 MC / MG - Precautionary Measure in the Suspension of Provisional Guardianship Rapporteur: Justice President Cármen Lúcia, Judgment: 25/04/2018

This is a request for the Suspension of Provisional Guardianship, with a request for an injunction, filed by the Municipality of Montes Claros/MG, aiming to suspend the effects of the provisional relief granted by the Court of Justice of Minas Gerais, to provide the drug Spinraza to a minor bearer of Spinal Muscle Atrophy AME. Request for an injunction to suspend guardianship rejected by the President of the STF, Minister Carmen Lúcia, on April 25, 2018.

The STF's decision to maintain the a quo decision favorable to the petitioner took place just over a year before its incorporation into the SUS.

11. ARE 1121505 / RN - Extraordinary Appeal with Interlocutory Appeal, Rapporteur: Justice Ricardo Lewandowski, Judgment: 25/04/2018

This is an Extraordinary Appeal with an Interlocutory Appeal filed by the Union. In a monocratic judgment by Justice Ricardo Lewandowiski, on April 25, 2018, the extraordinary appeal was denied.

The appellant wanted to reverse the decision rendered by the TRF of the 5th region, which did not admit an extraordinary appeal filed against the appellate decision that granted the supply of high-cost medicine.

The petitioner has type 1 Diabetes Mellitus and requests Insulin (Glargin) Lantus. As the dosage and posology were not informed in the decision, nor did research in the original process return this information, only the average value of the drug in all its presentations is informed, ie Lantus Solostar 100 U/ml - 3 ml, Lantus 100 U/ml - 3 ml, Lantus 100 U/ml - 10 ml and Lantus 100 U/ml - 3 ml + applicator cannula. The average

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consumer price without ICMS is R$114.62 and the average price for public purchases without ICMS is R$91.50. It was not possible to calculate the cost of the monthly treatment, as well as the annual one.

Ordinance No. 19 of March 27, 2019 made public the decision to incorporate long-acting insulin analogue for the treatment of type I diabetes mellitus, http://conitec.gov.br/images/Relatorios/2019/Relatorio_Insulinas_Analogas_DM1.pdf , accessed on 06/17/2019.

The STF's decision to maintain the a quo decision favorable to the petitioner took place almost a year before its incorporation by SUS.

12. ARE 1121083 / RJ - Extraordinary Appeal with Interlocutory Appeal, Rapporteur: Justice Edson Fachin, Judgment: 04/30/2018

This is an Extraordinary Appeal with an Interlocutory Appeal filed by the State of Rio de Janeiro against a decision that denied the extraordinary appeal. In a monocratic decision by Justice Edson Fachin, on April 30, 2018, he denied the extraordinary appeal.

The appellant wanted to reverse the decision rendered by the Court of Justice of Rio de Janeiro, which did not admit an extraordinary appeal filed against the appellate decision that granted the supply of high-cost medication.

The applicant has Systemic Lupus Erythematosus and requests the drug Forteo (Teriparatide) 250 mcg/ml, dose: 20 mcg day, or 0.08 ml day for 18 months, whose price to the consumer without incidence of IMCS is R$ 2,150 .41 and the price for public purchases without ICMS is R$ 1,716.89. The monthly treatment cost is R$1,716.89 and the total cost of treatment for 18 months is R$30,904.02, calculated according to the sale price to the government (public purchases).

The STF's decision to maintain the a quo decision favorable to the petitioner was made without even submitting a proposal to incorporate the drug to CONITEC.

13. STP 101 / ES - Suspension of Provisional Guardianship Rapporteur: Chief Justice Dias Toffoli, Judgment: 04/03/2019

This is a request for the Suspension of Provisional Guardianship, with a request for an injunction, filed by the Union, aiming to suspend the effects of the provisional relief maintained by the 8th Specialized Panel of the Federal Regional Court of the 2nd Region and granted in a sentence by the Court of the 5th Federal Court of Judiciary Section of the State of Espírito Santo, in the records of public civil action No. 0007010-

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81.2013.4.02.5001, to provide long-acting insulin analogues to difficult-to-control diabetic patients. Request for Suspension of Guardianship granted by the President of the STF, Minister Dias Toffoli, on April 3, 2019.

As this decision is a public civil action, the calculation of the impact will be informed according to the report of incorporation of analogous insulins:

> Budget impact analysis: The defined daily dose established by WHO for all technologies (40 IU) was considered. The diffusion of technologies was estimated per month, using a logarithmic function, with a diffusion of 50% at the end of the five-year time horizon. Prices were obtained from the Integrated System of General Services Administration (SIASG). Two population scenarios were made, one based on epidemiological data and the other based on dispensing data from the SUS and the "Aqui Tem Farmácia Popular" program. In the first scenario, the incremental budget impact in relation to NPH human insulin varies between R$5.5 billion (Glargina Basaglar®) and R$18.8 billion (degludeca). In the second, the variation is between R$1.1 billion (Glargina Basaglar) and R$3.7 billion (degludeca). At the suggestion of the CONITEC plenary, a scenario was calculated based on data from a state that currently supplies long-acting insulin analogues. Data from the state of Paraná were used, extrapolated to other states through the rate of use of these drugs in the population and the differentiated diffusion of technologies in states that currently provide or do not provide such technologies. In this scenario, the estimated budget impact for the five-year time horizon was approximately R$863 million for glargine with applicator and R$2.0 billion for detemir with applicator (BRASIL; MINISTÉRIO DA SAÚDE; COMISSÃO NACIONAL DE INCORPORAÇÃO DE TECNOLOGIAS NO SUS, 2018).

In response to the court order, the Ministry of Health instituted an administrative proceeding aiming at the elaboration of the Clinical Protocol and Therapeutic Guidelines - PCDT that contemplated the use of long-acting insulin analogues for the treatment of type 1 Diabetes Mellitus, in patients for whom the disease it is unstable or difficult to control, however, the procedure resulted in a new Clinical Protocol and Therapeutic Guidelines for Diabetes Mellitus type 1 (Joint Ordinance No. 8, of 03/15/2018, of the Ministry of Health), in which the conclusion was maintained according to which:

> This PCDT does not recommend the use of long-acting insulin analogues instead of NPH insulin for patients with DM 1 in order to achieve better glycemic control or prevention of hypoglycemia, as there is no qualified evidence of safety or effectiveness to justify its recommendation. in specific subgroups of patients with DM 1, as recommended by the National Commission for the Incorporation of Technologies (50). (BRASIL et al., 2018).

However, the incorporation of an analogous long-acting insulin for the treatment of type I diabetes mellitus, within the scope of the Unified Health System - SUS, took

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place with Ordinance No. 19, of March 27, 2019 http://conitec.gov.br/images/Relatorios/2019/Relatorio_Insulinas_Analogas_DM1.pdf, accessed on 06/17/2019.

The STF's decision to reverse the a quo decision favorable to the petitioner took place seven days after the incorporation of the drug by the SUS, that is, the Court did not award a drug already incorporated.

RESULT OF THE STF DECISIONS ANALYZED

For the STF, the entire right to health corresponds to any and all health treatment requested, regardless of its cost, provided that it is registered with ANVISA (understanding recently signed, after the judgment of the merits of the general repercussion in RE 657,718, on 22/ 05/2019, Rapporteur Min. Marco Aurélio) and proven such need through a simple medical report.

It is noted that the concept of social/existential minimum is not used or taken into account by the STF in the assessments of requests for high-cost medications. In this sense Cunha Filho (2013) argues that the STF seems to understand that there is a context of unlimited resources, making it possible to award the most extensive health treatment to all who apply. This understanding is opposed to the theory of justice proposed by Rawls, as the author assumes an environment in which there is moderate scarcity of resources, the only possible scenario for the existence of objective circumstances of justice, that is, of resolvable conflicts of interest.

In this way, John Rawls defines the social/existential minimum as a sufficient level for people to be able to enjoy the same rights of freedom and which must be established based on criteria that recognize the scarcity of resources (compliance with the principle of non-exaggeration taxation). In the case of health treatments, it appears that Rawls would recommend that the social minimum in health should be defined by technicians capable of establishing the parameters of cost-effectiveness and effectiveness, as medicines that do not meet these criteria are not part of the social minimum.

Regarding the reservation of the possible, the STF qualifies it as an excuse of the executive power for not making the right to health effective or that the high cost of medicines is not capable of causing damage to the economic and budgetary order.

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Another fundamental that is repeated in the Federal Supreme Court is the supremacy of the guardianship of the low-income citizen, understood as that individual lacking the financial resources to pay for their own treatment. In AgR RE 818.572 CE, judged on 09/02/2014, the judgment of the 1st Panel, whose rapporteurship was the Minister Dias Toffoli, understands, unanimously, that needy people are those who can prove the impossibility of paying for the treatment with their own resources needy.

The need for proof of hyposufficiency, which is repeated in two other decisions analyzed: ARE 881471 / AL - Rapporteur: Min. Dias Toffoli Judgment: 06/09/2015; and ARE 1057975 / Ba Rapporteur(A): Min. Ricardo Lewandowski Judgment: 10/05/2017, it is not a constitutional interpretation in line with the principle of universality, which dispenses with any calculation of the citizen's low sufficiency to obtain medical treatments funded by the State. It is concluded that, for the STF, public health should be restricted to all those with low incomes, for whom universality would be valid.

However, when it comes to high-cost medications, proving hyposufficiency is quite easy, even for those who have high income and greater capacity to trigger the Judiciary Branch at the level of the High Court. In this sense, Cunha Filho (2013, p. 194) makes the following comment about the decisions of the Supreme Court in the field of health:

> [...] adheres to a kind of distorted equality theory, in which people who have the resources to file lawsuits benefit more than those who are beyond the reach of judicial instances.

It would be better for the STF ministers to analyze the situation of the less privileged in a non-casuistic way, but globally, in view of the award of high-cost treatments, considering the equal distribution of the social minimum, that is, that minimum level capable of enabling equal enjoyment of freedoms.

However, the STF does not speak a single line about the possible damages to the distribution of the social minimum in health, nor about the negative consequences to the less favored. Disregard of the social minimum undermines the guarantee that the State must provide for equality in the enjoyment of fundamental freedoms.

Of the 13 decisions analyzed, only STP 101/ES, derived from a collective action, had the drug adjudication suspended, which, ironically, had already been incorporated into SUS policies seven days before its judgment.

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Only one of the decisions analyzed had a drug request that has not been incorporated so far, and another with a recommendation not to incorporate it. These are, respectively, ARE 1121083/RJ and ARE 889216/DF. All other decisions were incorporated before or after the judgment.

The STF awarded drugs incorporated prior to the judgment date in only 3 cases (AgRg RE 818.572/CE, ARE 881471/AL and ARE 1057975/BA), however, the prior incorporation was not at least mentioned, and it appears that it was not there was a consultation with CONITEC about the incorporation of the requested medications.

However, the majority of drug adjudications took place prior to incorporation by CONITEC, that is, in 7 of the 13 decisions analyzed, or in approximately 54% of the cases.

The adjudication by the STF of drugs not incorporated by CONITEC, as seen above, puts at risk the distribution of the social minimum (treatments incorporated into the SUS), since the Judiciary, unable to meet the technical-scientific requirements that stipulate the effectiveness and cost -effectiveness of the requested treatment, reallocates the budget provided by the SUS to the detriment of the less fortunate.

The decisions selected in the last five years have not innovated in their motivations and fundamentals, and some positions are absolute and do not present any change.

The only decision that differed as to its grounds was the aforementioned Suspension of Provisional Guardianship (STP 101/ES), in which the President of the STF, Minister Dias Toffoli, on April 3, 2019, granted the suspension of the provisional guardianship in a public civil action, the only decision contrary to the supply of medications, even though the decision to suspend the provisional guardianship was given seven days after the incorporation of analogous insulins by CONITEC.

The request for Suspension of Provisional Guardianship (STP 101/ES), with an injunction, was filed by the Union, which aimed to suspend the effects of the provisional relief maintained by the 8th Specialized Panel of the Federal Regional Court of the 2nd Region and granted in a sentence by the 5th Court Federal Court of the Judiciary Section of the State of Espírito Santo, in the records of public civil action No. 0007010-81.2013.4.02.5001, to supply long-acting insulin analogues to difficult-to-control diabetic patients.

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The Magistrate of the original action, in the first degree, upheld the public civil action filed by the Federal Public Prosecutor's Office and granted, in the context of advance protection, access to insulin analogues for patients with unstable type 1 diabetes mellitus, ordering the SUS to implement a protocol incorporation of the drug and make the costing or distribution to the state health secretariats feasible.

Upon appeal in the TRF of the 2nd Region, a judgment was obtained in order to confirm the appealed decision, including maintaining the reach of the effects of the decision to the entire national territory, as it is a diffuse law.

The suspension of the provisional guardianship, however, seems to be inconsistent with criteria of justice, since in public civil action, of a collective nature, the anticipation of the guardianship is much fairer than the anticipation carried out within the scope of an individual action, because, it covers all those individuals who also need the requested medicine, including those who have difficulty in accessing justice, ensuring greater equity, which, despite being considered and praised by the Minister President, was not enough to convince him of the need for maintenance the anticipation of guardianship, unlike other requests for suspension in individual actions that were rejected, as in ARE 1121505/RN, in which an identical drug was awarded, the analogous insulin Glarina.

In his reasoning, the Minister affirms the potential impact of this type of (collective) action and the difficulty that, once a certain social right is provided, it is suspended, and thus, he sees that its impacts are more noticeable and that it is more prudent that its effects occur after the final decision, as the appealed decision enters the heart of public policy.

However, the decision of individual action also enters the "core of public policy", but this is not a problem, as the financial impact is disregarded, while in collective action this becomes a problem that should be avoided, given its scope . Amaral (2001) tries to explain this incongruity:

> Taken individually, there is no situation for which there are no resources. There is no treatment that supersedes the health budget or, even more, the budgets of the Union, each of the States, the Federal District or the vast majority of municipalities. Thus, focusing only on the individual case, seeing only the cost of five thousand reais a month for a cocktail of medicines, or one hundred and seventy thousand reais for a treatment abroad, there is no shortage of resources (AMARAL, 2001, p. 146).

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The decision to suspend the provisional guardianship ends up adhering to almost all defense theses, including those identical to those expended in individual actions, whose financial impact is also relevant.

Another issue that could be noticed is that, in individual actions, the involvement of the judge with the life of a particular person, who is often a child, with a name given in the records and whose life history becomes known, leads the judgment at a higher level of personal commitment of the judge. In class actions people are not individualized, the imminent risk of life does not have a clear owner. This seems to interfere with the judgment, as the impersonality of a class action provides the necessary distance for the judge.

Another relevant and clarifying judgment on how the STF decides was the Provisional Measure in the Security Suspension filed by the State of Goiás (SS 5192 MC/GO) aiming to suspend the effects of the preliminary injunction granted by the Court of Justice of Goiás, which determined the supply of the drug Spinraza (nusinersena) to a child. The request for suspension was rejected by the President of the STF, Minister Carmen Lúcia, on August 7, 2017.

In her arguments, the Minister President ignored the facts brought by the appellant, who alleged, among other things, the risk of damage to public order, health and economy, caused by the alarming cost of the drug, whose treatment would cost almost R$3,000. 0000.00 (three million reais) per semester, which would represent damage to the care of a huge contingent of people in need of SUS services, with prejudice to all public policies designed to care for thousands of people, and only the treatment of the petitioner would be equivalent to 17% of the annual budget allocated to the SAMU that serves the entire state, and more than 30% of everything that is spent with the Emergency Care Units in one year and that serve millions of people.

Minister Carmen Lúcia did not justify the absence of damage to public order and economy, using a mere affirmation of its absence. Again, when the issue involves individualized human life, the STF makes no effort to analyze harmful effects that are not related to reverse damage (risk of death or injury).

At no point does the decision even analyze the impact on public health in the State of Goiás due to the granting of the measure, as alleged by the Public Treasury. The public budget and its service to the less fortunate is also not even mentioned. The

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absolutism of the right to life is constant in drug claims trials; however, the Supreme disregards the other many lives that are put at risk due to its short-sighted attitude towards the global implications.

It all boils down to a case-by-case and individualized justice, that is, from the moment the name of the patient who needs the drug is known, there are no alternatives to maintaining, at any cost, that life, which was individualized, still that the award of treatment is no guarantee of survival. The invisible drama of the underprivileged is not taken seriously. The withdrawal of resources, already scarce, that could serve thousands of people whose only possibility of treatment is through the public health system, is a form of injustice that is not even addressed.

The requested drug, called Spinraza (nusinersena) for the treatment of Spinal Muscular Atrophy (SMA 5q) was recently incorporated into SUS protocols in March 2019[11]. Its extremely high cost was not an impediment to the adoption of this public policy, as it was demonstrated, according to scientific criteria, that the drug has concrete effects in improving the quality of life of patients and that it has a positive cost-effectiveness, which is perfectly consistent with the social minimum.

Despite the high financial impact brought by the incorporation of the drug, the technical-scientific criteria used are superior to those used in the distribution of the drug by the Judiciary, which is incapable of conducting a minimally scientific study. This, despite the possibility of using experts, which is unusual in decisions about drug distribution, and the parameters revolve around the law and ethics of preserving life and health, and, at least in the decisions analyzed , there is no analysis of the fairness of the distribution of high-cost medicines taking into account the situation of the poor.

CONCLUSION

From everything, it appears that the analyzed decisions of the Supreme Court are far from justice as equity proposed by Rawls, because, in view of the scarcity of resources, it does not privilege the social minimum and awards treatments that did not

[11] [...] Based on the available scientific evidence and on the cost of the treatment, nusinersena is considered to have plausible efficacy and safety results for the treatment of individuals with 5q SMA type I. For the other populations with 5q SMA, the evidence is more incipient (MINISTÉRIO DA SAÚDE, 2019, p. 9).

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have their cost-effectiveness and efficiency/effectiveness studied by the SUS in its procedures for incorporating technologies, which is quite harmful to the less fortunate.

Thus, it is possible to observe that the largest portion of the population, which does not have the financial capacity to pay for their most basic health treatments, is not protected by the State, noting an exclusion of these individuals, therefore, it becomes noticeable that the justice as equity in Rawls' thought is not effected by the decisions of the Supreme Court, which should refrain from adjudicating medicines not incorporated into the SUS by CONITEC.

In addition, it is not just an absence of fair treatment in the Rawlsinian sense, but also a disrespect for the Federal Constitution with regard to the principle of equality, the right to health, the principle of human dignity, the principle of universality of health and the principle of integrality. Thus, with the non-compliance with the Constitution, the State itself can be weakened, as its citizens cannot trust what is constitutionally guaranteed and protected.

Finally, it is important to emphasize that, through the analysis of the selected decisions, it can be noted that the Judiciary does not have a harmonious strategy to face the discussion concerning the right to health, the existential minimum and the reservation of what is possible, as it provides different results when it comes to individual actions compared to collective actions, since in these there is a little more rigor in the analysis of equity issues. It is not feasible to observe the realization of justice when there is the provision of therapeutic services for some people and not for others. This is an issue that must be debated in order to develop solutions to the inconsistencies pointed out in this article, guaranteeing the preservation of the constitutional principle of equality, which is the mainstay of the Democratic State of Law.

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