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Health as an enforceable positive right: the Brazilian Supreme Federal Court's case law on the access to medicines*

Abstract

This paper aims to present and discuss how the right to health has been considered a fundamental right and duty in the Brazilian constitutional order, in particular as a positive enforceable entitlement. The main purpose is to analyze – in light of the example of medicines – the role of the Brazilian Supreme Federal Court regarding the effectiveness of the right to health, and to present a discussion about proper criteria to justify judicial decisions in this domain.
Keywords: *Fundamental rights. Right to health. Brazilian Supreme Federal Court. Medicines.*

Résumé

Le présent article a pour objectif la présentation et l'examen de la manière dont le droit à la santé a été considéré comme un droit et un devoir fondamental dans l'ordre constitutionnel Brésilien, ainsi que sa condition de droit subjectif de nature positive et opposable. Il s'agit, en particulier, d'analyser le rôle du Suprême Tribunal Fédéral Brésilien en ce qui concerne l'efficacité du droit à la santé et d'examiner – en utilisant l'example des medicaménts – le probléme de la création e développement des critères plus clairs et précis pour justifier les décisions de la Justice dans ce domaine.
Mots-clés: *Droits foundamentaux. Droit à la santé. Tribunal Federal Suprême Brésilien. Médicaments.*

Zusammenfassung

Dieser Aufsatz beabsichtigt die Vorstellung und Analyse des Prozesses der Anerkennung des Rechts auf Gesundheit als Grundrecht und Pflicht des Staates in der brasilianischen Verfassungsordnung, vor allem aber seine Stellung als subjektives und gerichtlich durchsetzbares Leistungsrecht. Insbesondere handelt es sich um eine Analyse – unter Berücksichtigung des Beispiels der Ansprüche auf Medikamente – der Rolle des brasilianischen Obersten Bundesgerichtshof hinsichtlich der Effektivität des

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Rechts auf Gesundheit und der Diskussion um die Problematik der Definition und Entwicklung passender Kriterien zur Begründung der Gerichtsentscheidungen in diesem Bereich.
Schlüsselwörter: *Grundrechte. Recht auf Gesundheit. Oberster Brasilianischer Gerichtshof. Medikamente.*

A. Some preliminary remarks

The Brazilian legal system has established an intricate and diversified framework of norms concerning the protection of health in its varied dimensions, both at the level of the Federal Constitution of 1988 (henceforth BFC) and statutory law, including a dense and complex system of administrative normative acts. Besides this, a huge (and increasing) number of judicial decisions must be considered if one wants to understand and have a more precise comprehension and overview of the Brazilian health system.

Since our goal is not the presentation and analysis of the Brazilian health care system as such, but the more specific – but directly related – aspect that the right to health (and the corresponding duties and obligations) has been recognized as a subjective judicially enforceable (individual and collective) right, we will not elaborate on the health care system as a whole to any great extent. However, as it is important for the readers to understand not only why but also how the right to health is considered a subjective positive right, we will provide some information about the Brazilian health system relating to its malfunctioning and lack of effectiveness.

The *Sistema Único de Saúde – SUS* – Unified Health System (henceforth SUS) was conceived as a universal, public and national system, structured to provide complete coverage through a network of decentralized actions and services, organized in a hierarchical order of increasing complexity. Therefore, talking about health in Brazil means talking also about the SUS, its guiding principles and goals, funding, and the relations between public and private healthcare providers. Besides that – as already mentioned – one cannot understand the health system in Brazil without looking at its case law, especially as Brazilian courts – especially the Superior Tribunal de Justiça (STJ)[1] and the Supreme Federal Court – *Supremo Tribunal Federal* (henceforth STF)[2] – have played an essential role in making social rights in general and the right to health in particular both enforceable and effective.

The first consideration to be made is that before the promulgation of the BFC the right to health was not recognized and protected as a fundamental constitutional right. Moreover, during this time even the Brazilian health system did not have a universal and complete set of health care services. On the level of legislation, healthcare was part of welfare law, being accessed and provided according to the individual belon-

1 The STJ is a Superior Federal Court that has the competence of ensuring the application and authority of federal law by all Brazilian courts and judges (excluding labor law, electoral law and military law) both at state and federal levels. Besides this, the STJ has the competence to establish and to guarantee the uniformity and coherence of national Law, representing a kind of third level (that in general doesn't examine facts as such) of Jurisdiction.

2 The STF is the highest Court in Brazil and was created in 1891, based on the example of the US Supreme Court, acting also as a constitutional court.

ging to a professional group, as an employee, a retiree or a pensioner. There was a great fragmentation in healthcare provision, giving rise to all kinds of problems, including: a lack of uniformity in the extension of coverage, access to assistance restricted to regular employees (with the exclusion of large groups of people, such as rural and domestic workers), and a confusing assignment of competences among authorities responsible for actions related to healthcare.

These problems led to a situation of great social exclusion and can be considered as one of the causes connecting the claims for a fundamental right to health and a universal and more equitable healthcare system to a general vindication of social rights and corresponding public policies, a goal that was incorporated by the so-called Movement for Sanitary Reform (*Movimento da Reforma Sanitária*). The latter offered an appropriate arena to discuss ways of ensuring health as a right of an emancipatory citizenship and developing proposals towards the establishment of a universal, public and national healthcare system. The culmination of this social movement was the 8th National Conference on Health (*8ª Conferência Nacional de Saúde*), held in Brasília in 1986, when Brazil had already taken its first steps toward democratization. During the work of the National Constituent Assembly (*Assembleia Nacional Constituinte*), which was installed in February 1987, the recognition and strong protection of a right to health and the creation of a universal system were intensively debated and finally incorporated in the Brazilian constitutional system.

As a result of this debate and social pressure, the right to health, as a fundamental social right, was finally explicitly recognized in Article 6 of the BFC, along with the rights to education, food, work, housing, transportation, leisure, security, social welfare protection of motherhood and childhood, and assistance for destitute people. Besides this, Articles 196 to 200 laid down the main rules according to which the Brazilian health system should be structured, prescribing its scope, principles, funding, areas of competence, and the relation between the SUS and private health insurance providers.

The major guidelines that should be mentioned are the following: *a)* health as a social fundamental right and a state duty; *b)* universal and equal access to healthcare and health protection in general; *c)* healthcare as part of the entire social security system (health, social insurance – pensions, etc. and social assistance); *d)* healthcare provided by a decentralized and regionalized system, although planned and enforced under the single direction of the federal Ministry of Health, with emphasis on the so-called "municipalization", that is, a delegation of competences and responsibilities to Municipalities; *e)* healthcare actions and services organized in a hierarchical order of increasing complexity, also taking into account the epidemiological profiles of population groups; *f)* the adoption of a broad concept of health, including not only curative measures, but also the prevention of diseases and promotion of health, with an explicit preference afforded to preventive care; *g)* social control, achieved by the individuals' direct participation in the process of planning and supervising public health policies, also including the foundation of health councils at the national, state and municipal levels.[3]

3 See: *Lobato/Burlandy*, The context and process of health care reform in Brazil, in: Fleury/Belmartino/Baris, Reshaping health care in Latin America. A comparative analysis of health

These constitutional guidelines are direct and superior binding norms (principles, duties and rules – substantial and procedural), which must be followed, regulated and implemented by all state powers and actors. However, as it happens not only in Brazil, the normative framework have not always become a reality for everyone. In fact, several problems and malfunctions in diverse fields have been registered and are the reasons for the significant lack of effectiveness of the whole system.[4]

That aforementioned situation and the circumstances that health, according to the BFC, is a constitutional fundamental right, besides the great empowerment of the judiciary, the judicial system as a whole, a broad access to the judiciary and legal aid (access to justice) and the concept that the right to health protection is a subjective enforceable right, have led to an increasing process of litigation and even – according to some –strong judicial activism.

In this paper, we aim to show in what sense the right to health has been conceived, recognized and protected as a fundamental subjective (enforceable) right, how judges and courts are deciding on this matter. More than this, we will point out some of the major challenges and perspectives related to the recognition and protection of the right to health by the judiciary, focusing on the case law of the STF about access to medication.

In order to achieve our goal, we start with some remarks on the right to health as a fundamental enforceable right in the Brazilian constitutional system (2) and the most important aspects related to its judicial enforcement in Brazil, especially regarding the precedents of the STF, as the highest Brazilian court and guardian of the BFC (3) before concluding with some final considerations (4).

B. Health as a fundamental enforceable right in the Brazilian constitutional system

One of the most remarkable characteristics of the BFC is the large spectrum of rights and guarantees explicitly enumerated, with special regard to articles 5 to 17, where, respectively, individual rights (Art. 5), social rights (Art. 6), the fundamental rights of employees (Art. 7-9) and political rights (Art. 14-17) are recognized. Besides, there are also significant rights recognized in other constitutional provisions, such as those concerning the protection of the environment (Art. 225), and even implicit rights, deduced from the constitutional principles and the so-called enumerated fundamental rights. International human rights treaties, if ratified and approved by the National

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care reform in Argentina, Brazil, and Mexico, 2000. For broader, deeper and updated overview see, among others, *Figueiredo*, Direito à Saúde. Leis 8.080/90 e 8.142/90. arts. 6º e 196 a 200 da Constituição Federal, 2018.

4 To illustrate the statement, the lack of effectiveness can be explained by mentioning the common long queues for access to medical care, services, medication, medical examinations, hospital beds, intensive care, surgical proceedings, along with the bad and even desperate conditions for patients and medical staff, waste of huge amounts of public resources, the high cost of medication and other services and benefits, in most cases much higher than in USA and Europe.

Congress, are also part of the constitutional rights catalogue, but – in general – these do not have the formal superior normative rank that the constitution has.[5]

Of major importance for this paper regarding the role played by the right to health itself, but mainly concerning its judicial enforcement, is the fact that under the BFC, as mentioned, the right to health became a fundamental right, a circumstance that can be considered as a kind of Copernican turn. This can be traced back to the concept of fundamental rights adopted and developed by the German Basic Law (*Grundgesetz*) of 1949 and reinforced by the decisions of the German Federal Constitutional Court thereafter. According to this concept, fundamental rights are not merely constitutional rights, but constitutional rights whit a qualified (in the sense of a stronger) regime in terms of their normative value and protection.

Briefly, when the BFC shifted to the terminology *fundamental rights*, this was not only a matter of words but a question of what kind of constitutional rights should be recognized and protected, in order to ensure their real normative strength and social effectiveness. In this sense, fundamentality is an attribute recognized not in all rights, even if enshrined in the constitutional text, but rather it results from a combination of substantial and formal arguments.

The so-called substantial fundamentality concerns the special relevance afforded by society to certain values, interests and goods, which justifies a normative regime of reinforced protection. In other words, fundamental rights are – according to this concept – rights (legal entitlements) recognized by a specific constitutional system and attributed to human persons, granted by a set of substantial and procedural guarantees some of which are mentioned explicitly and others implicitly in the constitution. Even the variety of concepts and the way each constitution designs its own substantial and formal fundamental rights regime points to the notion that fundamental rights are, above all, a kind of trump against the majorities.[6]

In the case of Brazil, the specificities of constitutional law can ensure an accurate understanding of what fundamental rights are and how they have been protected. As already seen, the fundamentality of a constitutional right is associated with the set of guarantees that constitute a kind of qualified – in a stronger sense – regime of normativity and protection. This is precisely the case also with regards the right to health.

Starting with its fundamentality in a substantial sense, since health is a condition for life and, therefore, for the fruition and exercise of other rights, fundamental or not, it

5 According to the current – majority – position of the STF, while international treaties approved by Congress in accordance with the procedure prescribed in Article 5, § 3 of the BFC (3/5 of the votes of the Senate and the Chamber of Deputies in two separate voting turns) have the same normative value as constitutional amendments (this is the case of the UN-Convention about rights of people with disabilities), all other human rights treaties have a so-called supralegal status, for they are below the constitution but prevail in relation to any other normative act (for instance, both the UN-Covenant for Civil and Political Rights and the Covenant for Economy, Social and Cultural Rights and the American Human Rights Convention).

6 See Alexy, Theorie der Grundrechte, 2004, S. 407. ("Grundrechte des Grundgesetzes sind Positionen, die vom Standpunkt des Verfassungsrechts aus so wichtig sind, dass ihre Gewährung oder Nichtgewährung nicht der einfachen parlamentarischen Mehrheit überlasse werden kann"). With a particular reference to social rights see, Novais, Direitos Sociais. Teoria Jurídica dos Direitos Sociais enquanto Direitos Fundamentais, 2010, S. 319ff.

is not difficult to recognize the material fundamentality of health protection and promotion, not only as an individual right, but also as a public interest. Health is connected to the enjoyment of a good quality of life, which is also the goal of other rights and values, such as human dignity, liberty and autonomy, environmental protection, property, housing and food, work and social security, etc. This interdependence reveals a convergence across the normative regime of fundamental rights and human rights in general, supporting the arguments in favor of their broader effectiveness as a whole.[7]

According to the BFC, formal fundamentality is founded on three main arguments. The first can be designated as a topological argument and derives from the idea that, because Article 6 is inserted in Title II of the Constitution, which is dedicated to the "fundamental rights and guarantees", health and all the other social rights comprised in Article 6 must be considered fundamental rights.

The second argument is based on the clause of direct applicability, settled by Article 5 § 1 of the BFC, which stipulates that provisions defining fundamental rights and guarantees are immediately applicable and enforceable. However, it should be considered that this clause does not preclude legal conformation; instead, what it ensures is the recognition of a direct efficacy of the norms of fundamental rights and guarantees, as a *prima facie* presumption of effects that do not depend on subsequent regulation. Besides – also due to Article 5 § 1 – fundamental rights norms bind directly all state actors and, according to the case and circumstances, even private actors.[8]

The formal fundamentality (or fundamentality in a formal sense) represents and is also defined by the level of protection of fundamental rights against the intervention of the legislative branch of state powers. In the BFC, despite the absence of specific prescriptions about their limitation, fundamental rights, including social rights, are in general conceived as substantial limits to the power of constitutional amendment.[9] As stated by Article 60 § 4 of the BFC, the National Congress (even following the procedural requirements) cannot even deliberate on constitutional amendment bills that tend to abolish "individual rights and guarantees" (Article 60, § 4, IV).

On the other hand, even being directly prescribed by the BFC, there is a fourth pillar to be added to the definition of the constitutional regime of fundamental rights in a broad sense.

While not being exactly a specific guarantee involving more protection as such, Article 5 § 2 states that the explicit catalogue of fundamental rights does not exclude other rights and guarantees derived from the regime and other principles adopted by

7 *Loureiro*, "Direito à (protecção da) saúde", in: Estudos em Homenagem ao Professor Doutor Marcello Caetano, 2006, S. 657–692.

8 *Sarlet*, A eficácia dos direitos fundamentais, Uma teoria geral dos direitos fundamentais na perspectiva constitucional, 2018. S. 265ff.

9 It is important to mention, to be precise, that this concept represents the (still) dominant position in the legal literature, but the critique is getting stronger and a considerable amount of legal scholars are rejecting (in a more or less restrictive approach) the idea that all fundamental rights, especially some social and labor rights, deserve this stronger protection. It must be said, however, that, concerning the right to health (at least its essential aspects as a fundamental right directly connected to human dignity and the right to life), its condition as a substantial limit to the power of constitutional amendment isn't disputed.

the Constitution or contained in international treaties ratified by the Federative Republic of Brazil. This clause is a strong argument allowing the attribution of fundamentality to rights enshrined in other chapters of the BFC, for instance, the taxpayer's rights and guarantees (Article 150), several provisions (rights, principles, rules, duties) related to all social rights recognized in Article 6 (for the purpose of this paper, mainly the right to health and the Unified Health System – SUS – as such, Articles 196-200), the right to a healthy environment (Article 225), the right of children and elderly people and a series of cultural rights, among others.

But the quality of fundamentality and the corresponding qualified constitutional regime – although in general terms they have not been disputed as such – are largely controversial with regards to many aspects. In order to offer a very simple overview, one can roughly divide the controversy in two representative groups that support quite diverse conceptions of fundamental rights and their protection.[10]

First, even those who accept the fact that all rights enshrined as such (the rights contained in Part II – Fundamental rights and guarantees) are plain fundamental rights both in a substantial and formal sense may not always share the same opinion about the intensity of normativity and protection, considering that each guarantee must be interpreted and applied according to the function and content of the right.[11] A second position recognizes that civil, political, social, cultural, economic and environmental rights are fundamental rights but the plain regime of formal fundamentality – particularly the strong protection against constitutional amendments – in general does not include at least part of those rights, mainly in the domain of social rights.[12]

The most significant issue in this context is to find out to what extent the constitutional regime of fundamentality applies to the right to health. Here, in spite of the controversy on how each social right is shaped and protected at the constitutional level, the right to health (along with the right to education) has assumed a kind of preferred position among other social rights, not only due to its dense regulation in the BFC but also because of its primary importance for individual and collective life and human dignity and social, economic, political and cultural development. In this perspective, it can be added that this preferred position is even strengthened due to the circumstance that both health and education are the only areas provided with constitutionally-imposed minimum public financial resources, an aspect that impacts directly on the controversy about the limits of judicial enforcement of subjective positive rights.

According to the former considerations, the fact that the right to health is a fundamental right, submitted to the strong legal regime of fundamental rights in general, is surely a feature that distinguishes the right to health in Brazil and its normative efficacy in comparison with several other countries, because not all constitutional states attribute fundamentality to the right to health, the main consequence of which is its weaker protection directly deduced from the Constitution itself.

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10 It should be underlined that the classification in two groups is merely a way to show what is at stake and to offer a brief overview of the major conceptions and their internal common ground. Obviously even at the level of each group one can find several peculiarities.

11 *Sarlet*, A eficácia dos direitos fundamentais, Uma teoria geral dos direitos fundamentais na perspectiva constitucional, 2018, S. 282-297.

12 *Brandão*, Direitos Fundamentais, Democracia e Cláusulas Pétreas, 2008.

In France, for instance, there is no provision about a right to health, but only two indirect references: first, the protection of health is part of the Preamble of the Constitution of 1946; second, the right of everyone "to live in a balanced environment which shows due respect for health"[13] is contained in the Charter of the Environment of 2004. Both texts are considered part of the French Constitution of 1958, being part of its "constitutionality block". In turn, although the protection of health is recognized as a right in Spain, as it is included in "the guiding principles for social and economic policies" (Spanish Constitution of 1978, art. 43), it is not among "the fundamental rights and public liberties" or even "the rights and duties of all citizens" (Spanish Constitution, arts. 15-29 and 30-37, respectively). Moreover, Article 43 also assigns to legislation the competence to establish rights and duties for all in the matter of health. In Portugal, the Constitution created two different regimes of juridical efficacy and protection. There is the "regime for rights, liberties and guarantees", which is applicable to classical individual rights and social liberties by ensuring special protection and a presumption of direct applicability, at least in general terms (Portuguese Constitution of 1976, art. 17 and arts. 24-57). On the other hand, the regime designed for economic, social and cultural rights, among which is the right to health (Portuguese Constitution of 1976, arts. 58-79 and, specifically, art. 64), is less rigid and focuses on the prescription of general principles, as well as organizational and promotional tasks for the state.

These examples, on the other hand, are helpful when it comes to highlighting the peculiar constitutional regime of the right to health in the BFC. In sum, when interpreted in a systematic way, Articles 6 and 196 to 200, as already examined, stipulate that: *a)* health is a fundamental and social right; *b)* health is a universal right, which means that every individual has the right to health; *c)* the individual right does not exclude complementary collective and public dimensions of the right to health; *d)* health is safeguarded as an object of public relevance; *e)* the content of the right to health comprehends prevention and curative assistance; *f)* health must be organized and provided through the *SUS*, whose main structure is also instituted and regulated by the Constitution; *g)* the constitutional framework of the right to health includes a catalogue of legislative and administrative competences, *h)* the right to health and the corresponding constitutional principle and rules are directly binding and applicable norms; *i)* the right to health constitutes a limit to the power of constitutional amendment; *j)* health is also a state goal and duty, for which the constitution establishes a set of tasks and duties of respect, protection and promotion.

Despite the strong constitutional regulation, the actual content of the right to health as a fundamental right (both negative and positive) and its limits are only partially defined by the BFC, including a set of legislation and public policies and – in this context – the priority of the legislative and executive branches of the state in regulating and implementing these aspects.

Concerning the role played by the judiciary, which is the focus of this paper, the broad access to the judicial system, the functional and administrative independence,

13 Art. 1, French Charter for the Environment, 2004. For the Preamble of the Constitution of 1946, see: <http://www.conseil-constitutionnel.fr/conseil-constitutionnel/english/constitution/preamble-to-the-constitution-of-27-october-1946.105306.html>.

the wide set of competences (including the protection of fundamental rights by each judge and court) and the strong position occupied by the STF as the ultimate guardian of the BFC have led to a significant increase in the number of lawsuits related to the enforcement of the right to health as a subjective right, but also concerning the malfunctioning of the health system (public and private) as such.

To offer a more accurate overview, in the following section we present and discuss the STF case law related to the recognition and enforcement of a subjective positive right to access to medication, considering the current debate on the criteria that should be taken into account by all judicial actors when deciding such cases.

C. The right to health as a subjective positive right – the STF and the controversy about access to medicines through the judiciary

Regarding case law on the right to health in Brazil, major – but also controversial – developments can be mentioned, with special attention to the large number of decisions by the STF but also by the *Superior Tribunal de Justiça* (STJ) upholding lower court decisions that forced the government, in the different spheres of the Federation, to supply a variety of different health goods and services.

To illustrate this evolution, we present some information about the number of lawsuits filed against the government at the three levels of the federation (federal union, states and municipalities). Since the 1990 s, when the first cases recognizing the right to health as an enforceable positive right were decided by the STF and the STJ, the number of lawsuits has since increased significantly in quantity and variety, in the spheres of both state and federal courts.

According to the Justice in Numbers Report ("*Relatório Justiça em Números*") of the National Council of Justice,[14] 1,346,931 lawsuits directly related to the right to health were handled by the Brazilian Judiciary in 2016, comprising specifically the granting of demands for medications. This equates to an increase in 1,300% over the last seven years.

In addition, according to the aforementioned report, from 2010 to 2016 the federal union spent around R$ 4.5 billion Brazilian reais (about USD 1.200 billion) to comply with legal orders to purchase medicines, diet products, food supplements, besides legal deposits to cover several other benefits and services. It was even expected that by the end of 2017 the expenditures of the states, municipalities and union would reach the figure of R$ 7 billion. Needless to say, these circumstances reveal that the actions of the judiciary are particularly controversial regarding the acknowledgment of subjective rights to concrete health services and/or benefits, including, among many others, the dispensation of any kind of medical procedures and examinations, but mainly medicines.[15]

In this context, it is easy to understand why there is criticism (even though to a large extent misplaced) of exacerbated judicial activism and a strong process of judicia-

14 *Brasil*, Conselho Nacional de Justiça. Justiça em números 2017, Ano-base 2016.

15 According to the report, the number of lawsuits discussing the access to medicines was 312.147 in 2016, about 25% of the total.

lization of health policies. Nonetheless, the malfunctions of the public health system are significant in terms of meeting the demands in this area, but quite different due to regional inequalities, among other factors.

Even though this aspect will not be developed further in this paper, it should be underscored that most lawsuits involving health services and benefits provided by the government, within the sphere of the SUS (in other words, complaints addressing the public sector), aim at goods and services already provided for in the existing public policies. In other words, what is in fact at stake on the whole is not an intervention in a public policy as such, but merely the review of the implementation of concrete legal obligations.

Having said this, it should be clarified that the most controversial issue is, in fact, whether and – in the case of a positive answer – to what extent state actors can be forced by the Judiciary to provide services and benefits not directly covered by the existing public policies, mainly when it comes to assure access to rare and highly expensive medicines.

Here – regardless of increasing criticism and resistance in academic and political spheres – the STF still upholds its case law which recognizes that the right to health is also a positive right directly derived from the BFC. In other words, the definition of the content of the right to health as a positive right, despite the priority of the legislator and the administrative branch of government, cannot be completely excluded from judicial review and intervention. As a fundamental right, the right to health and other social rights and fundamental rights in general are – using the famous image of Ronald Dworkin as already mentioned – a kind of trump against majorities.[16]

Considering the most recent case law of the STF (and the STJ), these guidelines have been maintained, but the debate on the criteria that should be observed by judges and courts to justify the recognition or denial of a subjective positive right is still intense and in the last ten years some important developments can be seen. While many of these apply to the right to health in general, some address specific services and benefits. This is the case of the right to access medicines. For the sake of a better understanding of what is at stake here, we present and discuss some precedents of the STF.

One of the most important cases decided in recent years was judged on May 19, 2016, involving the declaration of unconstitutionality of Federal Statute no. 13,279/2016, that authorized the distribution of a drug called synthetic phosphoethalonamine to patients with a diagnosis of malignant neoplasia, despite the lack of conclusive studies regarding its side effects for human beings and the absence of the regular allowance from the Federal Government's National Agency of Sanitary Surveillance (*Agência Nacional de Vigilância Sanitária*, ANVISA, the Brazilian equivalent of the US Food and Drug Administration – FDA).[17] The STF stated, complying with its former case law, that the dispensation of the drug would not be admissible, since registration was a condition for monitoring the safety, efficacy and therapeutic quality of the product, without which it is presumed to be inadequate.

16 With a particular reference to social rights as trumps against majorities see *Novais*, Direitos Sociais. Teoria Jurídica dos Direitos Sociais enquanto Direitos Fundamentais, 2010, S. 319ff.

17 STF. Direct Action for the Declaration of Unconstitutionality 5,501 MC/DF, Judge-Rapporteur *Marco Aurelio Mello*, judged on May 19, 2016.

Besides, it should be added that although the STF is still issuing decisions granting access to drugs and medical treatments, the duty of the state to provide drugs is connected to the constitutional responsibility of caring for the quality and safety of the products circulating in the national territory, i.e. to the state's prohibitive action to prevent access to certain substances that have not undergone a strict scientific analysis observing the corresponding substantial and procedural requirements. This, however, does not mean that – also according to the current case law of the STF and STJ – the state cannot, under any circumstances, be compelled to supply drugs that are not on lists organized by the Ministry of Health and even those not approved by ANVISA.

On the contrary, the precedents of both courts, especially since the decision taken by the STF on March 10, 2010[18] (STA/175),make clear that the state can be obliged to provide for medicines that are not on the official list of the Ministery of Health, even when these drugs have not been approved by the ANVISA.

With this decision, the STF, upholding a lower court judgment granting access to an expensive medication for the treatment of a rare disease, established – in the sense of a guiding criterion – a distinction between what it called a new drug – not yet approved by ANVISA but already released for sale by the appropriate sanitary surveillance agency in the drug's country of origin – and an experimental medicine that is still at the stage of research and testing but has not yet been officially released for distribution.

However, considering that the lawsuits demanding health benefits or services from the government are not limited to supplying drugs and also taking into account that a set of criteria has been established that is being used by judges and courts (based on the binding case law of the superior courts) to justify both the granting of requests formulated in the lawsuits and denying them, one finds that over the years there was a consolidation of several of the guidelines and criteria adopted in the abovementioned decision in 2010, but that additional criteria have also been discussed and used.

These criteria, in turn, although partly suggested or at least supported by the specialized legal literature, have also been the subject of major criticism, be it because of a certain criterion or due to the way in which there have been applied by courts in different cases. The purpose of establishing binding criteria is to rationalize and uniformize, at least in terms of a general rule, the decision process in this matter. Moreover, this also involves an attempt to at least significantly reduce the levels of legal insecurity and lack of predictability and, thus, to enable prior and adequate planning by public officials.

For this reason, before discussing more recent developments, a list of the main criteria acknowledged and already consolidated in case law should be constructed, regarding the judicial decision involving health benefits or services.

(1) The right to health, as a subjective right, is simultaneously individual and collective, so that individual lawsuits are admissible.

18 STA – Suspensão de Tutela Antecipada. An explanation for non-Brazilian readers: the – free translation! – Suspension of a Preliminary Injunction is a kind of remedy addressing the STF with the purpose of obtaining the suspension of a decision taken by lower courts that granted some provisional and anticipatory remedy against the State that may significantly affect the public interest, such as budget-related issues.

(2) The judicial imposition on the government of benefits or services that are not provided for in law or in the public policies that have already been implemented – in this case of the SUS – should be an exception.
(3) The government's responsibility and its status as a legitimate party for a lawsuit is solidary, so that the case may be – in general – directed against any of the members of the Federation, specifically, the Union, the States, the Municipalities and the Federal District.[19]
(4) Whereas a private person must demonstrate the need for a benefit or service, the State must prove that there are real obstacles to supplying it, including the objection of insufficient resources (financial, human, logistic).
(5) If the benefit or service claimed is denied and this creates a situation of real risk to the life or human dignity, in other words, to the plaintiff's existential minimum[20] even the objection of the lack of financial conditions should be set aside.
(6) The non-satisfaction by the state of the so-called existential minimum involves a violation of its duty of protection within the sphere of social rights, especially here of the right to health, according to the constitutional (implicit) prohibition of insufficient protection.

It should be underlined that the mentioned criteria, as far as they are not limited to the access to medicines, have been used in other cases related to the right to health. These include lawsuits aiming at social benefits in education (especially in the case of access to daycare centers maintained in public establishments and of the right to mandatory and free basic education), as well as cases related to environment protection, basic sanitation, and the protection of children and elderly people.

But even though the criteria listed above are still used as guidelines by judges and courts, in the domain of the right to health, their application and justification in concrete cases ultimately led to new decisions by the STJ and STF on the topic, aiming to eventually correct or substitute some of the criteria or even add new ones.

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19 It is important to note that lawsuits against the States and Municipalities are judged by the state courts and cases related to the Union by the federal courts.

20 The so-called existential minimum (*mínimo existencial* in Portuguese) is a constitutional category imported mainly from German constitutional and social law (*Existenzminimum*). Even though it does not have the same content in different constitutional and legal orders, the existential minimum in Brazil (as well as in Germany) has been considered an implicit fundamental social right, including the physiological minimum (state benefits and services to grand the biological survival of an individual) and the social and cultural minimum, directly based on the human dignity and the fundamental right to a free development of personality, both illuminated by the social state principle. In Brazil, an additional argument supporting this concept of the existential minimum is that Article 170 from the BFC, directly based (and even almost written in the same way) on the Weimar Constitution of 1919, establishes that the aim of the constitutional economic order is to grant a life with dignity to everyone. In the literature see, for Brazil, among others, *Leal*, "Menschenwürde" und "Existenzminimum" in der Rechtssprechung des brasilianischen Supremo Tribunal Federal im Kontext der Verrechtlichung von Recht und Politik, and Sarlet, Menschenwürde und soziale Grundrechte in der brasilianischen Verfassung am Beispiel des Existenzminimums, both in: Kirste/ Gonzaga de Souza/ Sarlet (Hrsg.), Menschenwürde im 21. Jahrhundert. Untersuchungen zu den philosophischen, völker-und verfassungsrechtlichen Grundlagen in Brasilien, Deutschland und Österreich, 2018, p. 143-174 and 174-198.

In this perspective, we should highlight a recent decision of the STJ[21] in a case involving repeated lawsuits in which criteria were defined to acknowledge the obligation of the State to supply drugs that were not provided for by the SUS, i.e. they had not been included in the respective lists.

According to the Court, the criteria that should guide all courts decisions are:

1. a well-founded and detailed medical report, issued by the physician in charge of the patient, stating that it is essential or necessary to benefit from that drug and also that the drugs supplied by the SUS are ineffective for the treatment of their illness;
2. Financial incapacity of the patient to bear the cost of the prescribed drug;
3. The drug must be registered at the ANVISA;

Due to the type of appeal in the sphere in which the trial was held, the decision establishes a guideline to be followed by the whole Judiciary.

The discussion about the criteria to acknowledge subjective rights for the provision of drugs vis-à-vis the government has once again became prominent. It should be noted that the STF acknowledged the General Repercussion of the matter, be it about supplying drugs that were not on the lists of the SUS, or about supplying drugs that have not been registered at the ANVISA, mainly highly expensive and rare medicines.[22]

The judgment of the respective Extraordinary Appeals, no. 566,471 and no. 657,718, was finally ended in May 23, 2019. The thesis for the General Repercussion has been elaborated upon as follows:

> In no case can the State be obliged to supply experimental drugs without proven efficacy and safety. On the other hand, for drugs that have not been registered at the National Agency of Sanitary Surveillance, but whose efficacy and safety have been proved, the State can only be obliged to supply them if there is an unreasonable delay of the agency in deciding on the request for registration (a period of more than 365 days), when three requirements are met: (1) there is a request for registration of the medication in Brazil; (2) the existence of a registration of the drugs at well-known regulatory agencies abroad; and 3) the lack of a therapeutic substitute registered in Brazil. The lawsuits that demand the supply of medications that have not been registered at the ANVISA must necessarily be filed against the Union, considering the direct interest of a federal agency and the federal government.

Based on this statement, the cases related to the subject finally began to be decided on by the STF in June 2018, but only three opinions have been delivered up to this moment, while the final decision is still pending. For this reason, although here we cannot elaborate on the analysis of those opinions, their chief importance for the current controversy on the limits of judicial adjudication of the right to health is difficult to deny.

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21 STJ, Special Appeal no. 1,657, Judge-Rapporteur *Benedito Gonçalves*, judged on April 25, 2018.

22 The General Repercussion Incident (*Incidente de Repercussão Geral*) is a special institute demanding from the STF, after some debate and dissensus at the ordinary courts level, a qualified majority decision in order to create a binding precedent in this subject.

It is important to note that both cases, corresponding to two different Extraordinary Appeals (*Recursos Extraordinários*),[23] were decided simultaneously to avoid contradictions.

While in RE 566.471/RN, what was at stake is the state's obligation to provide for expensive medicines not included in the national drugs and medicines policies for people with low income, in RE 657.718/MG, what was decided on is the possibility to oblige the state to offer medication not already approved by the ANVISA.

In the first case, Justice Marco Aurélio stated that state actors could only be compelled to dispense drugs if fulfilling three conditions: a) the demonstration that the medicine is compulsory, in terms of its efficacy and safety, for the survival and improvement of the plaintiff's quality of life; b) the inexistence of an equivalent drug contained in the lists of the SUS; c) the proof of the lack of financial conditions of the sick person and/or their family to purchase the medicine.

Justice Roberto Barroso, in his concurring opinion, advocated the observance of six criteria and preconditions, namely: a) demonstration of the financial impossibility to pay the costs of the lawsuit; b) proof that the non-incorporation of the drug was not directly decided by the competent state actors; c) inexistence of a therapeutic substitute already contained in the list of the SUS; e) demonstration that the required drug's efficacy is based on medical evidences; e) the case must be addressed to the Federal Union, which makes the final decision about the drug's incorporation by the SUS; f) existence of a previous institutional dialogue between the Judiciary and other state and/or public entities or persons with technical expertise in the sphere of health, mainly with SUS experts.

Concerning the state's obligation to deliver drugs that have not been approved by the ANVISA, Justice Marco Aurélio's opinion supported the current case law of the STF recognizing that the state can be obliged to hand out a drug not already registered at the ANVISA, but only if (a) the drug can be regularly imported and no similar national medication is available and if this drug has been allowed by the official agency in the country of origin, and (b) it is demonstrated the drug is indispensable to preserve the person's life and health;

Justice Barroso, in turn, stated that, as an exception, the Judiciary can compel the government agencies to provide drugs in these circumstances, but only: (a) in case of a non-reasonable delay of the ANVISA's registration process; (b) if the drug's registration has been submitted to renown regulatory agencies abroad and (c) in the absence of a therapeutic equivalent approved by the ANVISA. Finally, as in the former judgment, Justice Barroso mentioned the need for a procedural requirement, namely, that this kind of case must be filed against the Federal Union.

Having a more restrictive position, Justice Edson Fachin, while concurring in general with Justice Barroso, argued that the State can only be forced to dispense drugs not approved by the ANVISA when the violation of the corresponding legal procedure is

23 The so-called *Recurso Extraordinário* (Extraordinary Appeal – free translation) is a kind of remedy with a function similar to the writ of certiorari in de American constitutional tradition, allowing the STF (and the US Supreme Court) to strike down (or uphold) decisions from lower courts – through judicial review – involving the application/interpretation of the BFC and the US Constitution.

demonstrated. The other Justices in general agreed whith the criteria proposed by Justice Barroso

It should be added, at this point, that in general the Court is upholding the precedent of STA-AgR (*Suspensão de Tutela Antecipada em Agravo Regimental*) 175/2010 regarding the difference between new and experimental drugs, in the sense that only the dispensation of the former can be exceptionally imposed on the State. To note, according to the court's former unanimous decision, new drugs are those not already approved by the ANVISA but allowed by the sanitary agency of the country of origin, while experimental drugs are those not even submitted to the regular experimental procedures granting their safety and efficacy.

To summarize, the BFC, in its ruling from May 23, 2019, although recognizing that as a general rule only the State can be obliged through a judicial decision to dispensate rare and very expensive medicines not included in already existing public policies, there are some exceptions. In the case that a drug has not been approved by the ANVISA the following criteria bust be fulfilled and demonstrated by the plaintiff: a) a considerable delay of the administrative procedure at ANVISA (more than 365 days); b) The existence of a registration request, that can be disconsidered in case of rare or very rare drugs; c) The medicine must be approved by a renowned foreign sanitary regulatory agency; d) The inexistence of a similarly effective medicine in Brazil for the case.

D. Final remarks

The example of the right to health demonstrates that in the BFC social rights achieved the status of fundamental rights, implying a qualified regime of normativity and protection. Differently from most constitutions, social rights became – in the same way as civil and political rights – a kind of trump against majorities, as they have been recognized as subjective positive enforceable entitlements. In this sense, the status of social rights under the BFC can be considered – along with Colombia and a few other countries – as a kind of Brazilian exceptionalism.

As a consequence, and considering the considerable empowerment of the Judiciary in Brazil, along with a huge increase in the guarantees and instruments to ensure the constitutional supremacy through judges and courts (including the expansion of access to judicial protection), the systematic malfunctioning and significant lack of effectiveness of the SUS has led to an impressive number of lawsuits demanding from the state the fulfillment of its duties of protection and the conditions for a life with dignity.

To illustrate this scenario, and taking into consideration a recent reportage published in 2018 by the internet provider UOL, based on official data and information, among the ten major problems of the Brazilian Health System (SUS), we can mentioned the following: a) the insufficient number of physicians (on average 17.6 for every 10,000 individuals); b) the long waiting time for a medical consultation and proceedings in general (since 1988 about 90 million people have been included in the SUS); c) the lack of hospital beds (from 2010 to 2015 there has been a reduction of 23,565 beds); d) the bad conditions of the emergency services; e) the lack of resources for

health (in 2018 only 3.6% of the federal budget was allocated to the SUS, while the global average according to the World Health Organization was 11.7%;[24]

Although the main part of these lawsuits is related to the implementation of already existing public policies, a considerable number of cases focus on the dispensation of benefits and drugs not included in any public policy and legislation, and even those without being approved by ANVISA. In this sense, as already seen, the Brazilian judiciary has been very open regarding the recognition and enforcement of subjective positive rights, contributing to the increase of litigation in this domain.

One of the major problems in this context is the still existing lack of consistent criteria and guidelines that could be used by the courts when deciding on this subject, creating a considerable level of legal uncertainty, besides an increasing tension between the Judiciary and other state powers.

For instance, this is the case of the statement that the right to life and the existential minimum are a kind of untouchable core of the right to health, in the sense that any related health service or good cannot be denied by the State in any circumstance. If a real threat to the right to life is indeed easier to demonstrate, the concept of an existential minimum, directly based on the human dignity principle, is by far more vulnerable to manipulation.

The major challenge, however, is how to achieve a proper balancing between the need for protection and promotion of the right to health – which is causing more and more litigation – and the State's duties to protect and implement other relevant fundamental rights, including social rights.

In this sense, this kind of litigation has been criticized relating to the level of judicial control of public policies and its implementatioj. The recent evolution of this process, however, as already mentioned, shows that the judiciary (mainly the STF) is creating and establishing a quite consistent and productive set of criteria, leading to a more rational, predictable and coherent judicial protection of social rights in general and the right to health in particular.

Another (at least partial) conclusion is that, although the focus is not only on a subjective right to medication, drugs still represent, in proportional terms, the majority of cases brought to the judiciary, revealing the need for – along with some general criteria – specific guidelines, such as the difference between new and experimental medicines, and the new criteria formulated by the STF in its recent ruling.

Another tendency worth mentioning is the relativization of the doctrine that access to the SUS is completely free of charge, because the STF's case law – supported by part of the legal literature – increasingly requires (and not only in the case of medicines) proof of both medical and financial need.[25]

Since it is not possible to conclude this paper with definitive statements, it should be said that the dynamics of the litigation related to the right to health in Brazil demonstrates to what extent a constitutional framework that creates and ensures both

24 *Sobrinho*, Falta de médicos e de remédios: 10 grandes problemas da saúde brasileira, in: UOL Newsletter "Boletim Ciência e Saúde", 2008.

25 For the legal literature see *Figueiredo*, Direito Fundamental à Saúde, Parâmetros para a sua eficácia e efetividade, 2007, S. 165ff.

broad access to justice and a strong and independent position of courts can be a catalyst of different phenomena, in a positive and negative sense.

The huge increase of lawsuits against the state is obviously challenging for the judiciary. Nonetheless the recognition of enforceable subjective rights, precisely the right to health, became an important mean to fight the lack of efficiency in the Brazilian health system. However, the expectation that individual legal action could solve the problem as such, cannot be met.

Maybe the most important aspect to consider is the long-standing experience of bad governance in certain areas and the fact that voting rights and elections have thus far not been able to contribute to substantial change. In this sense, the judicial enforcement of health rights has at least a considerable symbolic effect and also represents a kind of direct participation of the people in the decision-making process in the area of public policies, although it is not the appropriate way to achieve fulfillment of constitutional goals and duties by the State.

Whether the old and new criteria that have been adopted by the STF will be a more consistent and reliable way for judges and courts to enforce the right to health remains uncertain. On the other hand, they illuminate the effort made by the higher Courts (STJ and STF) to better organize and regulate the judicial interference in public policies. The fact is that the more consistent the criteria are, the greater the possibility to reduce the quantity of litigation and make judicial decisions more clear, transparent and controllable.

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