

Health Judicialization: Access to Medicinal Products Used in the Treatment of Autoimmune Diseases through the Judicial Power of the State of Amazonas

RÚBIA SILENE ALEGRE FERREIRA

Doutora em Economia – Universidade Católica de Brasília (UCB)
Docente do Curso de Direito, Centro Universitário do Norte – Uninorte

MATHEUS PIO TORRES

Bacharel em Direito – Centro Universitário do Norte – Uninorte

ALLAN CARLOS MOREIRA MAGALHÃES

Doutor em Direito Constitucional pela Universidade de Fortaleza (UNIFOR)
Docente do Curso de Direito, Centro Universitário do Norte – Uninorte

MARUCCIA MARIA DO P. S. ROBUSTELLI

Mestre em Sociologia - Universidade Federal do Amazonas (UFAM). Docente
do Curso de Direito, Centro Universitário do Norte – Uninorte

LUIZ CLÁUDIO PIRES COSTA

Mestre em Direito Ambiental – Universidade do Estado do Amazonas
Docente do Curso de Direito, Centro Universitário do Norte – Uninorte

Abstract

This work aims to highlight the most important legal aspects in the supply of medicines used in the treatment of autoimmune diseases granted by the 2nd Court of the Public Finance of the State of Amazonas (VFP-AM). In this work, the concept of the judicialization of health is demonstrated, as well as the definition of autoimmune diseases and the drugs used in the treatment, and finally; discusses the grounds of the judgments in which there was a concession by the 2nd Public Finance Court of the State of Amazonas to medicines for the treatment of autoimmune diseases. In order to respond to the proposed objectives, the theoretical framework from legal doctrine was used, as well as articles published in scientific journals, master's dissertations and doctoral theses. The results indicate that the difficulty of access to medicines by SUS, provoke legal demands before the 2nd VFP-AM, which grants and determines that the agency supplies the medicines, in order to respect

the constitutional rule of health protection, life and dignity of the human person.

Keywords: Judicialization, access, medication, treatment, autoimmune diseases, SUS.

INTRODUCTION

One of science's relentless pursuits has been to achieve longevity in order to reduce mortality. Over the years modern medicine has evolved to the present day, offering innovative ways to prolong the natural cycle and to cure or delay the diseases that haunt the human being. Thus, it is possible to age healthy and have more time to enjoy life.

Prophylaxis is the branch of medicine that consists of procedures and resources used to prevent and prevent human pathologies. The medicine is one of the most used and recommended resources by general medicine. The importance is given by the fact that with the evolution of medicines it was possible to fight previously fatal diseases such as polio, tuberculosis and to control autoimmune diseases such as lupus disease.

Drug costs are not low. Accessibility to medicines by the population is expensive, due to some factors, such as: the circumstance of diseases becoming more resistant, requiring the generation of new medicines; the increase in manufacturing costs; profit margin and tax incidence.

The 1988 Constitution attributes to the public power the duty to ensure the right to health for all, adopting the Unified Health System - SUS as a management tool. Despite the fact that every Brazilian has access to health in a public way, the state provision finds it difficult to comply with the provisions of CRFB / 88. Not all people get vital medicines through SUS, so few are able to buy due to the high price, leaving the search for judicial protection that protects the most valuable legal asset of the legal system, which is life. The Brazilian population has been growing, and consequently, the demands involving health cases also tend to increase.

Efficient public health provision is a legal imperative, given that health is a diffuse and collective right of second generation, and the State must ensure and properly manage public budgets for this purpose. Due to the inertia of the Executive Power to adequately provide a public health service, and the Legislative Power to supervise the acts of the Executive Power, judicialization is shown as a way to solve the problem, leading to a significant increase in judicial demands. facing this public area. The greatest legal benefit in this case is the categorical protection of the diffuse and collective right to health.

Thus, the objective of this research is based on highlighting the most important legal aspects in the supply of medicines used in the treatment of autoimmune diseases granted by the 2nd Court of the Public Finance of the State of Amazonas. In order to respond to the proposed objective, the theoretical framework from legal doctrine is used, as well as articles published in scientific journals, master's dissertations and doctoral theses.

This research is structured in three chapters as follows: the first section studies the concept of the judicialization of health. The second topic consists of the definition of autoimmune diseases and the drugs used in the treatment and the third topic analyzes the judgments in which there was a concession by the 2nd VFP to autoimmune diseases drugs and their applications. Finally, it weaves the conclusions.

THE CONCEPT OF HEALTH JUDICIALIZATION

The right to health

Before addressing the judicialization of health, it is important to have a sense of what health is and its relation to the legal system. According to Mapelli (2015, p.84 / 85) citing Dallari (2010), it is in the preamble to the WHO (World Health Organization) Constitution that health is seen as a fundamental right, and should be implemented in a broad way by the States through health and social policies, as well as where the definition of health is enshrined in both law and medical sciences, namely: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".

The right to health has historically undergone transformations until we reach the understanding we have today. In the past, in the periods of the Old Republic, health was seen as a gift that could be taken at any time by the State, without constitutional protection. Over the years, influences such as the Health Reform of the 1970s, which defended health as a fundamental and citizenship right, contributed to its constitutionalization.

Thus, according to the understanding of Asensi (2010):

The universalization of health was accompanied by its normative institutionalization, which enabled the crystallization of principles, norms and guidelines that would be developed in the following years, the most significant expression of which was the creation of the Unified Health System (SUS).

When inserted in the Federal Constitution of 1988, the right to health became more rigid and its process of alteration more difficult, recent decisions indicate that fundamental rights such as health cannot be abolished. The understanding that is made is that the positivist interpretation must be removed.

There are three points defended by Vieira (2014) that justify the right to health as a stone clause. First, because according to §2 of art. 5, of CRFB / 88, the individual rights and guarantees found in art. 5 of CRFB / 88, do not exclude others arising from the regime and principles adopted by the Constitution or international treaties signed by the Brazilian Republic. Thus, it is possible to have an individual right or guarantee outside of art. 5 of CRFB / 88 and that it is a stone clause, even if implicit, according to §4 of art. 60, CRFB / 88.

The second point is based on the fact that the right to health is directly correlated to the right to life, the most precious legal asset in the legal system, found in the caput of art. 5 of CRFB / 88, whose value is inviolable. In addition, the right to life is based on the radiating principle of human dignity, found in item III of art. 1, CRFB / 88.

Finally, thirdly, it stresses that social rights arose from the need to ensure true equality for all members of society. And equality, as the primary source of social rights, is also provided for in art. 5, “caput” of the Federal Constitution.

In view of the justifications pointed out, the conclusion reached is that health, despite being outside the list of individual rights and

guarantees of art. 5, of CRFB / 88, has the protection of a stone clause because it is, in the doctrinal understanding, directly related to the right to life and the principle of human dignity, which would be violated if the right to health was not protected.

Currently, health is found in Section II, articles 196 to 200, of the Federal Constitution of 1988, in which art. 196:

Art. 196. Health is the right of all and the duty of the State, guaranteed through social and economic policies aimed at reducing the risk of disease and other diseases and universal and equal access to actions and services for their promotion, protection and recovery.

From the above provision, it is understood that the State is the guardian of the right to health, and must adopt social and even economic policies to guarantee the regular exercise of this right. It happens that, like the other social rights, health finds it difficult to be protected, in the words of Asensi (2010):

The health budget is “in dispute” with the budget of other social rights, such as education, housing, work, leisure, etc. The demand for positive provision by the State within the scope of these rights gives rise to the need to define the budget, programs and implementation strategies for each of them, which can contribute to an asymmetry from the point of view of public policies and an imbalance of budgetary appropriation for every right.

In view of this understanding, the funds directed to health are not always sufficient, causing the absence of medications, long lines for surgeries and the lack of professionals to serve the most needy population. As a result of the lack of tutelage by the administrative authorities, society seeks support from the Judiciary, so that this social right is fully exercised, resulting in what is called “judicialization of health.”.

The paradox created is that instead of health being a public order problem, it should be a matter of economic development and public investment. For Vasconcelos and Maia (2012), human health is protected by the economic order, insofar as it considers dignified life for all, by ensuring the protection of consumers and the environment necessary for healthy quality of life. For without health there is no life and without life, there is no economy.

Thus, it is understood that health is a fundamental and citizenship right, inherent to the survival of human beings, classified as a diffuse and collective right and its holder being indeterminate, with the State having a duty to ensure this right and its efficiency. application in society.

Judicialization of Health

The Federal Constitution of 1988 determined that health is a right of every citizen and it is the duty of the State to provide it in full. However, the Government finds it difficult to respect this fundamental right, for example, some medicines for autoimmune diseases are not provided by SUS. In pursuit of the exercise of the right to health, citizens have sued the Public Entity before the Judiciary, which is sometimes granted the request for medical assistance, forcing SUS to provide these.

On the other hand, the State expresses itself against the insurgency of having to offer services that it cannot maintain, alleging the Principle of the Possible Reserve. This principle correlates with the fact that the provision of certain social rights requires budgetary resources and trained people to assist in the exercise of this right. In other words, there is a budget for each social right and an economic limitation for each state agency. Therefore, if the State has to supply more medicines or emergency surgeries, it will compromise another social benefit, such as education, for example.

On the one hand, we have the population demanding the exercise of the social right to health, and on the other, we have the State claiming “to do what can be done, without compromising other rights”. Thus, a balance must be sought so that more rights are not compromised.

Another factor to be explained, is the occurrence of legal rationality that prevails over political action and technical (medical) knowledge. When the magistrate issues a sentence, he uses all the legal instruments and apparatus to substantiate the decision, according to the principle of motivated free conviction of the judge, without ever ignoring the laws, summaries and the evidence of the process.

The question consists of the fact that the magistrates who deal with the theme “judicialization of health” do not have medical and technical knowledge, or are not familiar with the theme. Of course, the

NCPC provides ways for the court to request assistance for its conviction, such as expert evidence (art. 464 to art. 480, of the NCPC / 15) or the *amicus curiae* (art. 138, of the NCPC / 15), however, the full decision of the case would still be up to the court, which contains only legal knowledge.

Although the right to health is progressing slowly, it is being implemented through the judicialization of health. Its future is indeterminate like other social rights, as it is pending the resolution of conflicts and clarifications, where even the judge's sentence may not be synonymous with justice. According to Canotilho (2004):

the methodological burden of vagueness, indeterminacy and impressionism that the theory of science has been dubbing, in caricatural terms, under the designation of 'fuzzism' or 'fuzzy methodology' hangs over dogmatic and legal theory of economic, social and cultural rights. "[...] In all its radicalism, the censorship of fuzzysm thrown at lawyers basically means that they do not know what they are talking about when they address the complex problems of economic, social and cultural rights.

That is, even before the Judiciary, there are vague understandings about certain issues involving the right to health, such as access to medicines used in the treatment of autoimmune diseases, not provided by SUS. What should prevail is a balance between the different areas, be they: legal, political, technical (medical) or even social opinion, so that the provisions of art. 196 of CRFB / 88. In the words of Mendes (2017):

it seems sensible to conclude that concrete problems must be solved taking into account all perspectives that the issue of social rights involves. Weighting judgments are inevitable in this context fraught with complex conflicting relationships between public principles and guidelines or, in other words, between individual rights and collective goods.

While indeterminacy and vagueness persist, legal and social mechanisms must be implemented to fill in the gaps. Thus, each judicial demand must have a specific analysis according to the subject to be dealt with. Dallari (2017) shows the right to property as an example:

Take, for example, the most traditional civil law - the right to private property: in contemporary constitutional systems, it assumes that all property fulfills its social function. However, only the examination of each specific situation can determine whether that condition is being fulfilled.

The judicialization of health, seen as a juridical-social mechanism, has solidified the medical and sanitary provision expected from the State, however, only the judicial factor is not sufficient to fulfill this right. The fact is that, in complex societies, the contours of each and every right are only defined in each reality. It is clear that always from the constitutional and legal framework, but also from the implementation of public policy in accordance with the popular will. This is the meaning of the Democratic Rule of Law, (DALLARI, 2010).

The above statement guides the popular will as a question for the realization of rights. Thus, the Democratic State of Law, translated by the will of the people, results not only from the positive norm, but also from the reality of each citizen and from the expected fulfillment of individual and collective rights included in the Constitution.

DEFINITION OF AUTOIMMUNE DISEASES AND DRUGS USED IN TREATMENT.

Autoimmune diseases

Autoimmune diseases, “are a group of diseases that arise because the immune system attacks the body itself.”, (STAICHAK, 2017). Furthermore, the immune system is the set of cells, tissues, organs and molecules that humans and other living beings use to eliminate foreign agents or molecules, including cancer, in order to maintain the organism's homeostasis, according to Teva et al. (2009).

Delves (2017) argues that the immune system has the function of defending the body against foreign or dangerous invaders such as microorganisms (germs, bacteria, viruses and fungi), parasites, cancer cells and even transplanted organs and tissues. The defense of the human body must know how to distinguish between what belongs to the organism and what does not belong to the body itself - a substance identified as not proper and dangerous, whose technical definition is antigen. The autoimmune response is defined as the immune system's

response against an antigen belonging to the body itself, involving the action of T lymphocytes with production of inflammatory cytokines and B lymphocytes with production of autoantibodies, (STAICHAK, 2017).

There are several autoimmune diseases in the world. However, the most common are: severe disease: rheumatoid arthritis, Hashimoto's thyroiditis, type 1 diabetes mellitus, systemic lupus erythematosus (lupus) and vasculitis. In addition to those that act as if they were autoimmune: Addison's disease, polymyositis, Sjogren's syndrome, progressive systemic sclerosis, many cases of glomerulonephritis (kidney inflammation) and some cases of infertility, (DELVES, 2019).

Medicines used to treat autoimmune diseases

The drugs used to treat autoimmune diseases vary from disease to disease. Treatment generally uses corticosteroids (corticosteroids) that suppress the immune system and in some autoimmune diseases, plasmapheresis and intravenous immunoglobulin are used (DELVES, 2019). Corticosteroids are hormones produced by the human body, the main ones being produced by cortisol and aldosterone, which regulate various functions of the body, in addition, these hormones can be used as drugs helping to defend the body, (UFMG, 2015).

The treatment of Multiple Sclerosis is different. According to Bichuetti (2019) it is a disease where the immune system attacks myelin, using both immunomodulators and immunosuppressants. An immunomodulatory drug makes minor adjustments to the immune system, either by increasing or decreasing a substance or a change in the way a certain cell behaves. Thus, it is possible for a drug to attract T cells (type of white blood cell), distancing them from myelin. An immunosuppressive medication, on the other hand, dramatically reduces the activation or effectiveness of the entire immune system.

The indication between one and the other by the clinician will depend on factors such as the disease, the degree of attack, the patient's profile and availability in the SUS.

Access to medicines through SUS

Access to Brazilian health is expressed through the SUS - Unified Health System. In its eagerness to nationalize health, the constituent

power, through art. 198, of CRFB / 88, attributed to all federative entities the duty to ensure and provide complete care for the population:

Art. 198. Public health actions and services are part of a regionalized and hierarchical network and constitute a single system, organized according to the following guidelines:

Art.I - decentralization, with a single direction in each sphere of government;

II - comprehensive care, with priority for preventive activities, without prejudice to assistance services;

III - community participation. [...]

According to Fonseca (2014), "Before the creation of SUS, there was a health system that served, in the public sector, patients who were entitled to Assistance Institutes, which had already been centralized in the former National Institute of Medical Assistance and Social Security (INAMPS). So, whoever did not have the right and access to INAMPS, had to be assisted in another parallel system, which was the state and municipal public systems. The Unified Health System unified the population's access to all of this and, based on some principles, such as universality, made the system open to anyone, without the need to prove a link with any institution (BRASIL, 1990). "

Through SUS, it is possible to carry out tests with advanced equipment and geared towards medicine, surgeries that were not previously performed, clinical and specialized medical care, therapeutic treatments, in addition to the supply of pharmaceutical products through basic health posts.

The Ministry of Health has a portfolio entitled "Department of Pharmaceutical Assistance and Strategic Inputs", under the Secretariat of Science, Technology, Innovation and Strategic Inputs in Health (SCTIE), demonstrating the importance that the pharmaceutical sector has for the implementation of the right to health. The distribution of medicines by the Unified Health System is divided into three types of the Pharmaceutical Assistance Block, namely the Basic, Strategic and Specialized, as well as the Popular Pharmacy Program, which is different from the others in terms of financing and choosing which species the medicine will belong, considering that it is the joint responsibility of the three federative

entities, Union, states and municipalities to choose which of these three species the medicine will belong to, as well as who will finance it.

The distinction between the drugs allocated to each federative entity is important in view of the fact that it is a policy established by SUS, aiming to supply the drugs according to the patient's treatment. In addition, the citizen has an easier time knowing which entity is providing the medication, as well as how much money is being allocated.

The most important drugs supplied by SUS are listed in RENAME - National List of Essential Medicines. According to the Ministry of Health's website, folder entitled Pharmaceutical Assistance - About Pharmaceutical Assistance:

Rename is a guiding list and it is up to each municipality to establish its own list of medicines according to their epidemiological characteristics. It includes the medicines and supplies made available in the Unified Health System (SUS) and is divided into Basic Component of Pharmaceutical Assistance (CBAF), Strategic Component of Pharmaceutical Assistance (CESAF), Specialized Component of Pharmaceutical Assistance (CEAF), in addition to certain medications from hospital use.

It so happens that the State has difficulties in administering the pharmaceutical assistance policy, whose lack of planning and stock control causes the lack of medicines. The information presented above is important not only for the assertion of the principle of information and transparency, but it is also a key point that can contribute to a future judicial demand in case of denial of the medication by SUS.

We cannot forget that access to medicines through SUS is influenced by the global pharmaceutical market, in which the economic value is established by the private sector. As diseases become more resistant, prophylaxis is updated and forced to provide new means of combat. Thus, a race for scientific innovation and price increases begins.

On the one hand, there is the search for scientific innovation generating an increase in prices, and on the other hand, there is the public interest in seeking access to new technologies for medical friendliness. Therefore, the Brazilian State starts to regulate the incorporation of new pharmaceutical technologies, by means of Law

12,401, of 2011, which regulates the incorporation of technologies in the Unified Health System, in order to find a balance to provide the best benefit to the Lowest price.

Moving away from the concept that medicine is a social right, the understanding defended by Dallari (2010) is that it is both public and private:

In fact, the medicine is a hybrid object, at the same time a commodity and a sanitary one, making the right that deals with it purely classic contractual aspects, resulting from its market facet, others clearly associated with social rights, which imply discipline access to them as essential goods for health care, and others that are in strict dependence on economic-social and cultural development and that have been called for their trans-individual character, identifiable in the protection of traditional knowledge or in the assessment of risks and ethical benefits of clinical trials, for example. It is also necessary to remember that the right to medicine cannot be - under any circumstances - confused with the right to health, although it is part of the rights that concern health.

Despite not being equivalent to a social right, medicines are of paramount importance for humans, and are inherent to their survival. Its access by SUS, despite being often difficult, is perpetuated through the Judiciary, seeking to realize the right to health (art. 196, CRFB / 88) and the right to life (art. 5, caput, CRFB / 88). Thus, public authorities are responsible for providing an accessible and adequate distribution of medicines to the Brazilian population.

JUDGES FAVORABLE TO THE SUPPLY OF MEDICINES BY THE 2ND STICK OF THE PUBLIC FARM OF THE STATE OF AMAZONAS

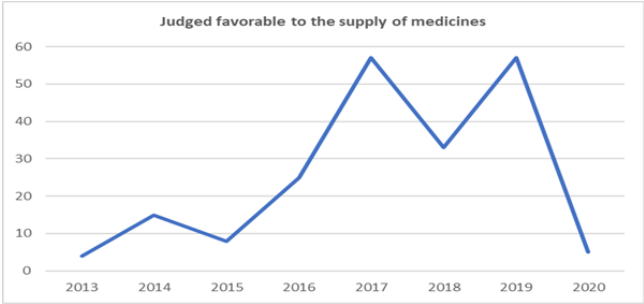
This section presents the results related to the granting of medicines resulting from lawsuits. The data were extracted from the database of the Court of Justice of Amazonas. The period covered corresponds to the period from 2013 to 20/02/2020. The access to the data was carried out by means of a search under the menu "supply of medicines". It resulted in 205 processes related to the selection, as shown in figure 1.

As evidenced by the demands for the supply of medicines, they are systematically made and the variations are in smaller volumes in the periods of 2013 and 2015. For 2013, three requests were found and in 2015 eight. The year 2014 is slightly larger (15) of this nature.

It is noticed that as the requests are granted by the Public Power, the volume increases. In 2016 there are 25 orders and in the next periods, 58 in 2017; 32 in 2018; 58 in 2019 and for 2020, until the date of 20/02/2020, six requests had already been answered.

The result by researched topic presented an average of 205 cases. In view of this, the process of selecting processes involving the theme of “drugs used in autoimmune diseases” was moved on.

Figure 1: Judged favorable to the supply of medicines



Source: Court of Justice of Amazonas (TJAM)

From this selection, 3 (three) processes of the 2nd VFP were chosen, which were: 0603175-06.2016.8.04.0001; 0623302-62.2016.8.04.0001 and 0609639-12.2017.8.04.0001, which we analyzed under the constitutional perspective of the right to health, raising 4 (four) north: the diagnosis of the disease with the explanation of the factual framework; the requested medication; the basis of the decision; and whether or not the medicine was granted.

Table 1: Autoimmune disease judges

<i>Process</i>	<i>Diagnosis</i>	<i>Drug</i>
0603175-06.2016.8.04.0001	Systemic lupus erythematosus	Rituximab - 500 mg, 02 (two) vials every 15 (fifteen) days.

Phatic framework

The factual picture begins with the diagnosis of the author of SYSTEMIC LUPUS ERYTHEMATOSUS, ICD 10 M32.1, 5 (five) years after the filing of the action, and was admitted to the Getúlio Vargas Hospital. He was advised to use the drug RITUXIMABE - 500 mg, 02 (two) vials every 15 (fifteen) days. The medicine was not supplied by the Health Department, on the grounds that it was not in stock and that there was no provision for purchasing the medicine. The request for advance protection for the supply of the medication was granted, in civil duty. The State in dispute challenged the plaintiff's request based on the lack of reference to the documents attached to the disease, which is LÚPUS. The absence of the reference could not be ignored, since according to a technical note attached to the process, there was no evidence in the literature to indicate RITUXIMABE for the treatment of SYSTEMIC LUPUS ERYTHEMATOSUS. The Prosecutor's Office reported that Rituximab was used to treat Rheumatoid Arthritis, but not for Lupus Erythematosus. The granting of a fine and the granting of legal fees were also contested. The Public Ministry, in support of the Federal Constitution, was in favor of granting the drug to the applicant.

Basis for the decision

Analyzing the weighting of values, the arguments raised in the context of the Contestation are not able to remove the duty to provide the medical assistance intended by the Claimant. High cost claims and principled analyzes of the Right to Health are not capable of removing the subjective right of the citizen to have dignified and humanitarian treatment, under penalty of serious violation of the dignity of the human person, a major principle that should serve as a guide to any constitutional interpretation. (0603175-06.2016.8.04.0001, Judging Judge: Leoney Figliuolo Harraquian, District: Manaus / AM; Judgment date: 8/15/2016; Publication date: 8/22/2016).

<i>Concession</i>	The request for advance protection for the supply of the medication was granted, in civil duty.
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Source: Court of Justice of Amazonas (TJAM)

<i>Process</i>	<i>Diagnosis</i>	<i>Drug</i>
0623302-62.2016.8.04.0001	Systemic lupus erythematosus	Mycophenolate Mofetil and Rituximab

Phatic framework

The author was diagnosed with LUPUS (Systemic Lupus Erythematosus). He needed the administration of the drugs MYCOPHENOLATE OF MOFETILE and RITUXIMABE. Because it is hyposufficient and due to the high value of the drugs, the applicant sought care at SUSAM seeking assistance. Initially, MICOFENOLATO DE MOFETILA was granted, however, since its last visit to CEMA - Central de Medicines, was informed of the lack of the medicine and that the State of Amazonas would no longer provide the same. As for RITUXIMABE, there was a refusal on the part of CEMA, claiming that the medication would not be available for its diagnosis, according to Ordinance No. 1554/13 of the Ministry of Health. State to supply the drugs MICOFENOLATO DE MOFETILA and RITUXIMABE, due to severe illness and inability to afford the cost of treatment. Fine of 10 thousand reais per day of non-compliance. The contested State alleged the principle of the Reserve of the Possible, stating that the resources of the Public Power are limited and social demands are unlimited. The imposition of the decision would be a tragic choice, since prioritizing the provision of certain services would result in the detriment of others. In addition to alleging the Judicialization of the subject and the limit of the Judiciary Power to intervene in the decisions of the Executive Power, with respect to the principle of harmonization of powers, as the granting of advance protection could be interpreted as judicial activism. The defense also emphasizes the lack of specific knowledge of the subject on the part of the Judiciary, considering that even with a technical opinion, the sentence could not compete with that of the Public Administration.

Basis for the decision

The court based its decision on art. 196, caput, of the CF, emphasizing that health is the right of all and the duty of the State. "In effect, the constitutional rule allows us to conclude that universal access to health is achieved through two aspects: one of a diffuse nature, attributed to the regulation of efficient public policies and to the state

Rúbia Silene Alegre Ferreira, Matheus Pio Torres, Allan Carlos Moreira Magalhães, Maruccia Maria do P. S. Robustelli, Luiz Cláudio Pires Costa- **Health Judicialization: Access to Medicinal Products Used in the Treatment of Autoimmune Diseases through the Judicial Power of the State of Amazonas**

and operational organization that translates into the distribution of the most diverse specialties medical; and another one of an individual nature, related to the possibility of vindicating from the Public Power the provision of specific health services, related to the ideal patrimony of each individual, which arises in view of the need to protect constitutionally protected values, such as life, physical integrity and the dignity of the human person. (0623302-62.2016.8.04.0001, Judging Judge: Leoney Figliuolo Harraquian, District: Manaus / AM; Judgment date: 11/14/2017; Publication date: 11/23/2017) ”.	
Concession	The judge of the 2nd VFP, confirmed the anticipation of the effects of the provisional emergency relief and upheld the request for an obligation to make, ensuring the supply of the medications requested in the treatment.

Source: Court of Justice of Amazonas (TJAM)

Process	Diagnosis	Drug
0609639-12.2017.8.04.0001	Systemic lupus erythematosus	Rituximab (Mabthera) 4 vials of 500 mg - 2 vials every 15 days

Phatic framework

The applicant has had SYSTEMIC LUPUS ERYTHEMATOSUS (ICD M32.1), since 2006, with ACR criteria: photosensitivity, malar rash, alopecia, arthritis, leukopenia, lupus nephritis and FAN + 1: 640 fine speckled nuclear, together with the medical report. She underwent treatment, using monthly cyclophosphamide and corticosteroid therapy, suffering from renal changes refractory to treatment, requesting the urgent release of the drug RITUXIMABE (Mabthera) to prevent the progression of the disease to chronic dialysis renal failure. The dosage applied in the first month would be 4 bottles of 500 mg - 2 bottles every 15 days. The drug was approved by ANVISA - National Health Surveillance Agency - and is used in the treatment of people affected by LUPUS who are refractory or intolerant to conventional regimes, as in this case. The author points out that the bottle costs an average of 7 (seven) thousand reais, and in her case would be 4 (four) bottles, that is, around 28 (twenty-eight) thousand reais. Being the same hyposufficient, she would not be able to afford the treatment. After the price estimate, the applicant sought SUS - Unified Health System - in search of the medication, through SUSAM - Amazonas State Health Secretariat. However, the administrative procedure has been stalled for more than 1 (one) month, resulting in a lawsuit. In defense, the State of Amazonas claimed its passive illegitimacy, considering that the drug belongs to SUS 1st Group, whose acquisition is financed and acquired directly by the Union and distributed by the States, and thus the dispensation is directly linked to the Clinical Protocols and to CEAF - Pharmaceutical Assistance Specialized Component. Thus, it would not be up to the State of Amazonas to supply the aforementioned medicine.

Basis for the decision

The judge based her decision on the medical report presented, dated two months ago on January 19, 2017, with the administrative request occurring on January 30, 2017, de-characterizing the urgency, as well as the protection sought to prevent the evolution of the disease and not the result of death. The records were sent to the 2nd VFP.

Concession	Understanding the judgment that the documents attached to the case records are sufficient to prove the requirements pointed out by the defendant and prevailing the right sustained by the plaintiff, the anticipated guardianship granted and the action upheld was confirmed to condemn the State of Amazonas in the obligation to do, the which you should continue to supply the medicine.
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Fonte: Tribunal de Justiça do Amazonas (TJAM)

The results of the analysis of the cases indicate a negative result from public health agencies when it comes to the access to medicines used to treat autoimmune diseases, mainly to the drug rituximab, used to treat autoimmune disease lupus, causing demands before the Judiciary. After analyzing the processes, the 2nd Public Finance Court of the State of Amazonas, appears to be affiliated with the State Government's thesis on the granting of medicines to claimants whose requests are denied by SUS, SUSAM and CEMA.

The Judicialization of Health has proved to be an effective alternative in the application of the right to health, however, it is not

enough to reverse the national health crisis. Other solutions must be applied with the cooperation of all the organs of the three branches, the economy, in addition to popular opinion and professional understanding of public health.

CONCLUSIONS

Life is one of the most gracious gifts that human beings have. Their livelihood is inherent to several factors, including health conservation. Throughout the century, technological innovations collaborated for medical knowledge, creating more effective medicines. However, the state provision is flawed, making judicial invocation pertinent.

Health was established in the 1988 Constitution. Access to services for health promotion, protection and recovery is universal and equal. Thus, it is a right for all, characterized as a diffuse and social right, and all federal entities are responsible for providing it through social and economic policies that aim to reduce the risks of diseases and injuries. However, the State does not always fulfill its duty, resulting in judicial demands brought by citizens who seek judicial protection to have their right to health effective.

Among the judicial demands, we highlight those that are filed seeking the granting of medicines used in the treatment of autoimmune diseases such as Lupus. Autoimmune diseases are those in which the immune system is attacked by agents of the body itself, that is, protective cells attack themselves and destroy other cells. Treatment usually occurs with corticosteroids, immunosuppressants and immunomodulators. Nevertheless, some of these medications are costly and limited, resulting in a lack of stock in SUS - Sistema Único de Saúde, which consequently leads to requests for the granting of medications before the Public Finance Court.

The studies of the three judges of the 2nd Public Finance Court demonstrate that despite the State making praiseworthy arguments, there is nothing to justify the lack of efficient provision of public health care, in which the judgment of this registry joined the thesis on the granting of medicines by from federative entities to people who have their requests denied by SUS, considering that health is a diffuse and individual right.

Diffuse right in the sense that it is up to the State to provide it to any and all indeterminate citizens, and individual right insofar as it is possible to claim from the State a specific health service inherent to the injury suffered by the individual. Since this protection arises from other protected legal assets such as life and physical integrity, protected by the principle of human dignity.

The legal system is seen as a support for public health provision. However, overloading the Judiciary with the judicialization of health is not a plausible solution. Joint efforts from administrative, political, legal and technical knowledge spheres, as well as new studies and data tend to contribute to better health delivery.

REFERÊNCIAS

ASENSI, Felipe Dutra. *Indo além da judicialização: O Ministério Público e a saúde no Brasil*. Rio de Janeiro: Escola de Direito do Rio de Janeiro da Fundação Getúlio Vargas, Centro de Justiça e Sociedade, 2010.

BICHUETTI, Denis Bernardi. *Conheça melhor o seu remédio: imunomoduladores e imunossuppressores, o que são?* 2019. Disponível em: <<https://amigosmultiplos.org.br/noticia/conheca-melhor-o-seu-remedio-imunomoduladores-e-imunossuppressores-o-que-sao/>>. Acesso em: 12 nov. 2019.

BRASIL. AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA - ANVISA. *Consultas / Consulta Genérica / Consulta Genérica*. Disponível em: <<https://consultas.anvisa.gov.br/#/genericos/q/?nomeProduto=MICOFENOLATO%20DE%20MOFETILA>>. Acesso em: 12 nov. 2019.

BRASIL. AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA - ANVISA. *Consultas / Medicamentos / Medicamentos*. Disponível em: <<https://consultas.anvisa.gov.br/#/medicamentos/25351198997201791/?classeTerapeutica=L01XC02>>. Acesso em: 12 nov. 2019.

BRASIL. MINISTÉRIO DA SAÚDE. *Sobre a Assistência Farmacêutica*. Disponível em: <<http://saude.gov.br/assistencia-farmaceutica/sobre-a-assistencia-farmaceutica>>. Acesso em: 12 nov. 2019.

BRASIL. Superior Tribunal de Justiça - Stj. Agresp nº 200601317493. Relator: Ministro Luiz Fux. *Diário de Justiça Eletrônico* - Stj. Brasília, 27 nov. 2006.

BRASIL. Tjam. 0623302-62.2016.8.04.0001 nº 02. Impetrante: Mariele Simone Lopes Araújo. Impetrado(a): Estado do Amazonas. Relator: Juiz Leoney Figliuolo Harraquian. Manaus, AM, 14 de novembro de 2017. *Diário da Justiça Eletrônico*. Manaus, 23 nov. 2017.

BRASIL. Tjam. Processo: 0603175-06.2016.8.04.0001 nº 01. Requerente: Patrícia Batista Gomes. Requerido: Estado do Amazonas. Relator: Juiz Leoney Figliuolo Harraquian. Manaus, 15 de agosto de 2016. *Diário da Justiça Eletrônico*. Manaus, 22 ago. 2016.

BRASIL. Tjam. Processo: 0609639-12.2017.8.04.0001 nº 03. REQUERENTE: VALDENIRA MARTINS BRASIL. REQUERIDO: ESTADO DO AMAPÁ. Relator: Juiz Leoney Figliuolo Harraquian. Manaus, AM, 02 de setembro de 2019. *Diário da Justiça Eletrônico*. Manaus, 05 set. 2019.

BRASIL. Tjrs. Apelação Cível nº 70063659031. Apelante: Estado Do Rio Grande Do Sul. Apelado: Neusa Maria De Carli. Relator: Laura Louzada Jaccottet. Tenente Portela, RS, 22 de abril de 2015. *Diário de Justiça Eletrônico*. Tenente Portela.

CANOTILHO, J. J. Gomes. *Estudos sobre direitos fundamentais*. Coimbra: Coimbra Editora. 2004. pp. 100/101. (Texto Metodologia Fuzzy e os camaleões normativos na problemática actual dos direitos económicos, sociais e culturais – pp. 97/114).

DALLARI SG, Nunes Júnior VS. *Direito Sanitário*, 2010, p. 8.

DALLARI, Sueli Gandolfu. *O Sistema Único de Saúde*. Enciclopédia jurídica da PUC-SP. 1. ed. São Paulo: Pontifícia Universidade Católica de São Paulo, 2017. Disponível em: <https://enciclopediajuridica.pucsp.br/verbete/172/edicao-1/o-sistema-unico-de-saude>.

DELVES, Peter J. *Considerações gerais sobre o sistema imunológico*. 2017. Disponível em: <<https://www.msmanuals.com/pt-br/casa/doen%C3%A7as-imunol%C3%B3gicas/biologia-do-sistema-imunol%C3%B3gico/considera%C3%A7%C3%B5es-gerais-sobre-o-sistema-imunol%C3%B3gico>>. Acesso em: 12 nov. 2019.

DELVES, Peter J. *Doenças autoimunes*. 2019. Por Peter J. Delves, PhD, University College London, London, UK. Disponível em: <<https://www.msmanuals.com/pt-br/casa/doen%C3%A7as-imunol%C3%B3gicas/rea%C3%A7%C3%B5es-al%C3%A9rgicas-e-outras-doen%C3%A7as-relacionadas-%C3%A0-hipersensibilidade/doen%C3%A7as-autoimunes>>. Acesso em: 12 nov. 2019.

FONSECA, Karla Cristina Rocha. *Ações para aumentar o nível de informação da população sobre o papel da estratégia saúde da família*. Montes Claros – MG, 2014. Trabalho de Conclusão do Curso de Especialização em Atenção Básica em Saúde da Família - UFMG.

MAPELLI Júnior, Reynaldo. *Judicialização da saúde e políticas públicas: assistência farmacêutica, integralidade e regime jurídico do SUS*. São Paulo, 2015. Tese de doutorado – Faculdade de Medicina da Universidade de São Paulo. Programa de Radiologia.

MENDES, Gilmar Ferreira, 2017, Série IDP - *Curso de direito constitucional*, 12ª edição, 12th edição, São Paulo. Disponível em: Minha Biblioteca.

STAICHAK, Rodrigo Luiz. et FILHO, Carlos Rory Pucci. Et MANSANI, Fabiana Postiglione. Folder de conscientização sobre doenças autoimunes – liga acadêmica da autoimunidade – disponível em <https://sites.uepg.br/conex/anais/anais_2017/assets/uploads/trabalhos/07262017_130738_5978c4da09fa2.pdf> data: 15 de Outubro de 2019.

TEVA, Antonio et al. *Conceitos e Métodos para a Formação de Profissionais em Laboratórios de Saúde* - Volume 4. Rio de Janeiro: Epsjv, 2009. Disponível em: <http://www.fiocruz.br/ioc/media/ConceitosMetodos_volum4.pdf>. Acesso em: 12 nov. 2019.

UFMG, *Observatório da Saúde da Criança e do Adolescente* -. Corticoides: Cartilha. 2015. Disponível em: <<https://site.medicina.ufmg.br/observaped/wp-content/uploads/sites/37/2015/08/Cartilha-Corticoide-final.pdf>>. Acesso em: 12 nov. 2019.

Rúbia Silene Alegre Ferreira, Matheus Pio Torres, Allan Carlos Moreira Magalhães, Maruccia Maria do P. S. Robustelli, Luiz Cláudio Pires Costa- **Health Judicialization: Access to Medicinal Products Used in the Treatment of Autoimmune Diseases through the Judicial Power of the State of Amazonas**

VASCONCELOS Arthur; MAIA, Maurilio Casas. *O direito à Saúde*. Revista Direito e Desenvolvimento, João Pessoa – a. 3, n. 6, p.65 - 81 jul/dez., 2012.

VIEIRA, Evelise Pedroso Teixeira Prado. *O direito à saúde como cláusula pétrea e o conteúdo deste direito: medicamentos e tratamentos médicos* – Artigo disponível em conteudojuridico.com.br: Julho/2014.