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Article

Reflections on the ambivalent nature of judicialization in health: Challenge to guarantee comprehensiveness and equity in the SUS

Reflexões sobre o caráter ambivalente da judicialização na saúde: Desafio para garantia da integralidade e equidade no SUS

Reflexiones sobre el carácter ambivalente de la judicialización en salud: Desafío para garantizar integralidad y equidad em el SUS

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Abstract

In Brazil, the right to health became universal and comprehensive, as per the constitutional provision. However, the judicial route began to be used to guarantee access to health treatments in response to the population's needs, without the use of much technical rigor. **Objective:** to review the literature on the positive and negative points found in the Judicialization of health. **Methodology:** a survey was carried out in the Virtual Health Library Database, with studies between 2010 and 2021. 59 articles were found, applying the inclusion criteria for this study, we selected 39 for analysis. After in-depth reading of the articles, themes organized into the following categories were chosen: medicines and treatments standardized by the SUS; medicines and treatments not standardized by the SUS; and interference from pharmaceutical industries and interinstitutional dialogues. **Results:** Most articles identified positive and negative points of the Judicialization of health or mentioned the existence of the contradiction regarding this subject. The studies showed that part of the Judicialization results from failures in the management itself. Therefore, a conflict can be seen in the dichotomy between the right to health effectively guaranteed and the structure and capacity of the system to achieve it. **Conclusion:** The entities involved in the Judicialization of health must dialogue with each other, in order to understand the phenomenon and face the challenges. It is necessary to recognize legal demands as a provocative source for improving SUS management, always aiming to provide better service to users, thus promoting equity and efficiency in spending public money.
Keywords: Legal Actions; Judicialization; Unified Health System; Comprehensive Health; Equity.

Resumo

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No Brasil, o direito à saúde passou a ser universal e integral conforme previsão constitucional. No entanto, a via judicial passou a ser utilizada para garantia do acesso a tratamentos de saúde frente à necessidade da população, sem o emprego de muito rigor técnico. **Objetivo:** revisar a literatura sobre os pontos positivos e negativos encontrados na judicialização da saúde. **Metodologia:** realizou-se um levantamento na Base de Dados da Biblioteca Virtual em Saúde, com estudos entre 2010 e 2021. Foram encontrados 59 artigos, aplicando os critérios de inclusão para esse estudo, selecionamos 39 para análise. Após aprofundada leitura dos artigos, foram eleitos os temas organizados nas seguintes categorias: medicamentos e tratamentos padronizados pelo Sistema Único de Saúde; medicamentos e tratamentos não padronizados pelo Sistema Único de Saúde; e interferência das indústrias farmacêuticas e diálogos interinstitucionais. **Resultados:** A maioria dos artigos identificaram pontos positivos e negativos da judicialização da saúde ou mencionaram a existência da contradição que versa esse assunto. Os estudos apontaram que parte da judicialização decorre de falhas da própria gestão. Percebe-se, assim, um conflito presente na dicotomia entre o direito à saúde efetivamente garantido e a estruturação e capacidade do sistema para a sua realização. **Conclusão:** Os entes envolvidos na judicialização da saúde devem dialogar entre si, no intuito de compreender o fenômeno e enfrentar os desafios. É necessário reconhecer as demandas judiciais como fonte provocadora para a melhoria da gestão do Sistema Único de Saúde, visando sempre ao melhor atendimento aos usuários, promovendo assim a equidade com eficiência no gasto de dinheiro público.
Palavras-chave: Ações Judiciais; Judicialização; Sistema Único de Saúde; Integralidade em Saúde; Equidade.

Resumen

En Brasil, el derecho a la salud pasó a ser universal e integral, según disposición constitucional. Sin embargo, se empezó a utilizar la vía judicial para garantizar el acceso a tratamientos de salud que respondieran a las necesidades de la población, sin el uso de mucho rigor técnico. **Objetivo:** revisar la literatura sobre los puntos positivos y negativos encontrados en la Judicialización de la salud. **Metodología:** se realizó una encuesta en la Base de Datos de la Biblioteca Virtual en Salud, con estudios entre 2010 y 2021. Se encontraron 59 artículos, aplicando los criterios de inclusión de este estudio, se seleccionaron 39 para el análisis. Después de la lectura en profundidad de los artículos, se eligieron temas organizados en las siguientes categorías: medicamentos y tratamientos estandarizados por el SUS; medicamentos y tratamientos no estandarizados por el SUS; y la interferencia de las industrias farmacéuticas y los diálogos interinstitucionales. **Resultados:** La mayoría de los artículos identificaron puntos positivos y negativos de la Judicialización de la salud o mencionaron la existencia de la contradicción respecto a este tema. Los estudios demostraron que parte de la Judicialización resulta de fallas en la propia gestión. Por lo tanto, se puede ver un conflicto en la dicotomía entre el derecho a la salud efectivamente garantizado y la estructura y capacidad del sistema para lograrlo. **Conclusión:** Las entidades involucradas en la Judicialización de la salud deben dialogar entre sí, para comprender el fenómeno y afrontar los desafíos. Es necesario reconocer las demandas legales como una fuente de provocación para mejorar la gestión del SUS, siempre con el objetivo de brindar un mejor servicio a los usuarios, promoviendo así la equidad y la eficiencia en el gasto del dinero público.
Palabras clave: Acciones Legales; Judicialización; Sistema Único de Salud; Integral en Salud; Equidad.

Introduction

Lawsuits for the supply of medicines, supplies, surgical procedures, Intensive Care Center (ICU) beds, prostheses, among other health treatments, within the scope of the Unified Health

System (SUS), have increased greatly in recent years, causing various impacts on administrative management, resources and the health of users, constituting a challenge that is difficult to solve [1].

The phenomenon of the judicialization of health, as it has come to be known [2], has been the subject of constant study. For Asensi, judicialization would be "the emergence of the role of the Judiciary in the realization of rights, mainly of a social and collective nature. In this sense, citizens turn to the Judiciary as a strategy for mobilizing resources and arguments to defend and win rights"[3, p.40].

In this scenario, we find the protection of the right to health, with its main pillars: integrality, universality and equity in relation to the protection, promotion and recovery of the user's health, confronted with budgetary and financial limits and the very organization of management to carry out public health policies.

While the 1988 Constitution recognized health as a social right, it also made it possible for citizens to access the Judiciary in search of their rights. Art. 5, XXXV of the Federal Constitution states that "the law shall not exclude any injury or threat to the right from the appreciation of the Judiciary"[4]. As a result, lawsuits involving health have become increasingly frequent.

In this vein, and given the intertwining of the relationship between the Judiciary and the SUS, another challenge is the need for technical knowledge on both sides to deal with this phenomenon[5] . According to the authors Silva and Schulman[6] and Paim et al.[7] , most of the time, lawsuits protect individual rights, which differs from public policies, which are designed and implemented with the collective interest in mind.

This debate leads us to reflect on the ambivalent nature of judicialization which, on the one hand, represents a means of seeing the constitutionally guaranteed right to health fulfilled and the hope of obtaining the treatment so desired; however, on the other hand, when judicial decisions are put into effect, they can lead to the disruption of an entire management system that has a planned budget and scarce resources.

The benefits achieved by judicialization include the realization of access to the right to health, even if reduced to mere treatment, the policies implemented for the treatment of Acquired Immunodeficiency Syndrome (HIV/AIDS), the revision of official lists, pressure for the incorporation of new technologies, and the pointing out and identification of deficiencies and failures within the system itself and in existing public policies, which contributes to the improvement of the system as a whole.

However, judicialization has a cost, and resources are scarce. In addition, public health in Brazil is underfunded, which certainly contributes to the problems of lack of care faced by the SUS and which lead to judicialization, thus establishing an endless cycle[8,9]. The phenomenon of judicialization, therefore, can interfere with the use of health resources and disorganize the management of the system[9]. In addition, the disorderly distribution of medicines and treatments not only affects a very small number of users, but also undermines existing policies in favor of the community[10,11].

This being the case, the phenomenon of judicialization is characterized by ambivalence, which can transmute into favorable or unfavorable, good or bad, depending on the scenario.

With the aim of analyzing the discussions on the ambivalent nature of the judicialization of health in Brazil in the context of the "*Sistema Único de Saúde*" (SUS – Unified Health System), a search was carried out for scientific articles published between 2010 and 2021.

Methodology

For this study, a bibliographic review was carried out, the aim of which is to find out about the different forms of scientific contribution that have been made on a particular subject or phenomenon[12] . To this end, the database of the "*Base de Dados da Biblioteca Virtual em Saúde*" (BVS – Virtual Health Library) was searched, as it is available online and free of charge. The BVS Portal was launched in 2008 to integrate networks of health information sources and strengthen their visibility[13].

The time frame for the survey was between 2010 and 2021, with the aim of researching the last few years of health judicialization in Brazil. The following words were used as descriptors of interest: "lawsuits and judicialization and the single health system".

For the inclusion criteria in this study, only articles in Portuguese were selected, which were in the period delimited by the search, obtained in full and free of charge. Exclusion criteria were articles whose virtual addresses could not be found and duplicates.

The initial search gave us 59 articles, of which 20 were excluded because they didn't fit the criteria. For our final analysis, 39 articles were selected.

The material was analyzed using the following categories:

(Category 1) Medicines and treatments standardized by SUS;

(Category 2) Medicines and treatments not standardized by SUS and interference from the pharmaceutical industry;

(Category 3) Inter-institutional dialogues.

This study uses the term "official lists" to refer to lists that contain a list selected for supply by the SUS, such as the National List of Essential Medicines (Rename), the State List of Essential Medicines (Resme) and the Municipal List of Essential Medicines (Remume).

Table 01 describes the articles with the respective categories covered and presents the discussion on the ambivalent nature of judicialization - indicated by the letter (A). It should be noted that some articles fall into more than one category, depending on their central themes and related topics.

Table 01. Description of the studies found and category.

Nº	Year	Authors	Title	Categories			(A)
				(1)	(2)	(3)	
1	2010	Pandolfo M, Delduque MC, Amaral RG[14]	Legal and health aspects that condition the use of the judicial route for access to medicines in Brazil.	x	x		x
2	2010	Borges DCL, Uga MAD[15]	Conflicts and impasses in the judicialization of obtaining medicines: first instance decisions in individual actions against the State of Rio de Janeiro, Brazil, in 2005.	x	x		x
3	2011	Sant'ana JMB et al.[16]	Essentiality and pharmaceutical assistance: considerations on access to medicines through lawsuits	x	x	x	x

			in Brazil.				
4	2011	Machado MAA et al.[10]	Judicialization of access to medicines in the state of Minas Gerais, Brazil.	x	x		x
5	2011	Santos J, Bliacheriene AC, Ueta J[17]	The judicial route for access to medicines and the balance between the needs and desires of users of the Health System and the industry.	x	x	x	x
6	2012	Campos Neto et al.[18]	Doctors, lawyers and the pharmaceutical industry in the judicialization of health in Minas Gerais, Brazil.	x	x	x	x
7	2013	Boing A et al.[19]	Judicialization of access to medicines in Santa Catarina: a challenge for health system anagement.	x	x		x
8	2013	Barreto JL et al.[20]	Profile of legal claims for medicines in municipalities in the state of Bahia.	x	x	x	x
9	2014	Leitão LCA et al.[21]	Judicialization of health in guaranteeing access to medication.	x	x	x	x
10	2014	Gomes FFC et al.[22]	Access to medium and high complexity procedures in the Unified Health System: a question of judicialization.	x	x		x
11	2014	Oliveira RG, Souza AIS[23]	The profile of legal claims for the right to public health in the municipality of Leopoldina-MG.	x	x		x
12	2015	Lima J, Kolling AF[24]	Analogous insulins: SUS responsibility and judicialization.	x			---
13	2015	Honorato S[25]	Judicialization of the Pharmaceutical Assistance Policy: Discussion on the Causes of Claim in the Federal District.	x	x		---
14	2015	Balestra Neto O[26]	The jurisprudence of the Supreme Courts and the right to health - Evolution towards rationality.			x	x
15	2015	Asensi F et al.[27]	Judicialization, the right to health and prevention.			x	---
16	2016	Costa PHS[28]	Rare neuromuscular diseases: a portrait of judicialization in the Federal Regional Court of the 1st Region	x	x		x
17	2016	Catanheide ID, Lisboa ESS, Luis EPF[29]	Characteristics of the judicialization of access to	x	x		---

			medicines in Brazil: a systematic review.				
18	2016	Asensi F, Pinheiro R[30]	Judicialization of health and institutional dialogue: the experience of Lages (State of Santa Catarina).			x	x
19	2017	Verbicaro LP, Santos ACV[31]	The need for parameters for the realization of the right to health: the judicialization of access to growth hormone in the state of Pará.	x	x		x
20	2017	Paim LFNA et al.[7]	What is the cost of brand name prescriptions in the judicialization of access to medicines?	x	x		x
21	2017	Silva AB, Schulman G[6]	(De)judicialization of health: mediation and inter-institutional dialogues.	x	x	x	x
22	2017	Silva HP, Pimenta KKP[32]	The work of lawyers and non-governmental organizations in the judicialization of public health in Brazil: who is it aimed at?		x	x	---
23	2017	Toma TS et al.[33]	Strategies for dealing with drug lawsuits in the state of São Paulo.			x	---
24	2018	Cordeiro MF[34]	Judicialization of Health: arguments used in lawsuits against the Unified Health System, in the Court of Justice of the Federal District and Territories, by the procedural actors.	x			x
25	2018	Santos ECB et al.[35]	Judicialization of Health: access to treatment for users with diabetes mellitus.		x	x	x
26	2018	Campos Neto OH, Gonçalves LAO, Andrande EIG[36]	The judicialization of Health in the perception of prescribing physicians.		x		---
27	2018	Souza KAO, Souza LEPF, Lisboa ES[7]	Legal actions and the incorporation of medicines into the SUS: the role of Conitec.	x	x	x	x
28	2019	Stédile LO[37]	There is a way out of the judicialization of pharmaceutical care in the Unified Health System.	x	x	x	x

29	2019	Nardi MRC et al.[38]	The Federal Supreme Court and judicial blockades of health actions: a critical perspective and the need to organize the system.			x	x
30	2019	Batistella PMF et al.[39]	Judicialization in health in a large municipality.	x	x		x
31	2019	De Carli P, Naundorf B[11]	The application of the principle of solidarity in the judicialization of health based on the principles of the SUS, the "*Supremo Tribunal Federal*" (STF - Federal Supreme Court) understanding and the trajectory of Rio Grande do Sul.		x		x
32	2019	Simone AL, Melo DO[41]	Economic impact of lawsuits for the supply of medicines in the state of São Paulo.		x		---
33	2019	Paixão ALS[42]	Reflections on the judicialization of the right to health and its implications for the SUS.			x	
34	2020	Araújo IC de S, Machado FR de S[45]	Judicialization of health in Manaus: an analysis of lawsuits between 2013 and 2017.		x	x	x
35	2020	Oliveira, YMC[46]	Analysis of legal claims for medicines in the state of Rio Grande do Norte.	x	x		x
36	2020	Freitas BC de, Fonseca EP da, Queluz D de PP[47]	Judicialization of health in the public and private health systems: a systematic review.	x	x		x
37	2021	Oliveira YM da C, Braga BSF, Farias AD, Vasconcelos CM de, Ferreira MAF[48]	Judicialization in access to medicines: analysis of lawsuits in the state of Rio Grande do Norte, Brazil.	x	x		x
38	2021	Coelho TL, Lopes L de MN, Campos Neto OH, Figueiredo TP de, Andrade EIG[49]	Intellectual property in the judicialization of pharmaceutical care: a structural demand in defense of the Unified Health System.		x	x	x
39	2021	Vasconcelos NP de[50]	Between justice and management: inter-institutional collaboration in the Judicialization of health.			x	

Source: Prepared by the authors based on the results found in the BVS.

Results and discussions

For the analysis, we present the discussion of the categories organized according to the correlated themes found in the studies.

Category (1) - Judicialization of medicines and treatments that are on the official lists standardized by SUS.

Initially, it is worth noting that the studies researched showed that the growth in the phenomenon of Judicialization stems from the difficulty in complying with public health policies, under the terms of art. 196 of the Federal Constitution of 1988. In agreement with this, Andrade[51] states that the realization of the right to health by the state, as well as other social rights, takes place through public policies, the drafting and implementation of which depend, for their success, on the excellence of the management of the health system

In 28 studies, judicialization was found for medicines included in the official SUS standardized lists. However, the legitimacy of the interest of those who resort to the courts is undeniable, since the product should be offered normally to the population, in a timely manner and in adequate quantity.

> The growing number of requests for medicines included in programs and in Rename may demonstrate some possible problems, such as: (i) **lack of medicines in the basic network; (ii) bureaucracy to be able to participate in programs; (iii) lack of knowledge on the part of the prescriber of existing government programs; and (iv) failure of the requesting individual to fit into the clinical protocols**[19, p.92] . (Emphasis added and translated by the translator)

Therefore, it is necessary to check for flaws in the system, from the purchasing process, administrative flows, stock disorganization, failures in the management of pharmaceutical assistance or even in the logistics of drug distribution. It is unacceptable to have constant interruptions in the supply of medicines provided for in public health policies. This shows a lack of planning and management difficulties.

Barreto et al.[20] and Boing et al.[14] agree that excessive bureaucracy, which is almost always demanded of patients, also ends up delaying access to treatment, which motivates patients to go to court. Barreto et al.[20] cite that for medicines in the specialized component, specifically, judicialization can reveal an escape from the bureaucracy that exists in this program.

Another reason for the cases of judicialization of medicines on the official lists, noted in the articles studied, was the lack of knowledge of these lists by patients and even by the prescribers themselves, as mentioned above by Boing et al.[19] and reported by Machado et al.[10] in these terms:

> Other reasons for requesting drugs that are part of the SUS programs may be that they are not available in pharmacies due to failures in the management of pharmaceutical care and the lack of knowledge of the official lists of drugs in the public system on the part of prescribers and requesters[10, p. 595] (translated by the translator).

This demonstrates the need for programs offered by the SUS and official lists of medicines to be widely publicized and accessible to the population and prescribers. This alignment between prescription and availability can prevent legal claims through access to alternatives available on official lists[23] .

Honorato[25] draws attention to the strong presence of judicialization of antineoplastic drugs[3] , since there are numerous public policies and even Specialized Centers for cancer treatment, which again demonstrates the lack of supply of these drugs due to a lack of organization of the system itself or the Judiciary's ignorance of the legislation and therapies offered by the SUS.

With regard to the judicialization of procedures, despite the high percentage of procedures covered by the SUS, Gomes et al.[22] clarify that the object of the action would not be to carry out the procedure itself, but to guarantee access to care, which is often hampered by the lack of vacancies, diagnosis time and other system management problems. According to these authors, in this case, the solution would involve "the need to reprogram the number of beds, intensify the management of existing beds and, above all, develop policies that encourage de-hospitalization and ensure the effectiveness of primary care"[22, p. 40] , as well as increasing the number of doctors and reducing the waiting time between making an appointment and having a consultation or surgery.

It is clear, therefore, that judicialization can be an ally of the SUS, insofar as it signals deficiencies and stimulates reflection on the need to review procedures and flows that are generating failures within the system itself and identifies deficiencies in existing public policies, which should be strengthened in order to reduce the judicialization of programs already included in the SUS.

According to the authors De Carli; Naundorf[10] judicialization will only have positive effects if it helps to order the system and enforce compliance with constitutional provisions and existing public policies. In this respect, it can be seen that this type of judicialization is welcome for the health system, as it is a way for the population to claim their rights, demanding that public bodies take measures to ensure that these technologies or health services are offered to patients and that they correct the flaws found in the health system[8] .

Category (2) - Judicialization of medicines and treatments that are not on the official lists standardized by SUS and the interference of the pharmaceutical industries

With regard to lawsuits claiming medicines and procedures that are not part of the SUS programs, *ab initio*, it is important to clarify, as already demonstrated in the STF's current understanding[53] , that the fact that the treatment is not on the system's official lists does not exclude the user's right to treatment, nor even exempt the state from having to fulfill its constitutional obligation of access to health.

As stated in the studies found, it is necessary to clarify that a single solution cannot be adopted for all situations in which the right to health is required, given the peculiarities of each specific case. It is also noted that the request for non-standardized medicines on the SUS lists may indicate care gaps, which occur when goods and services are not offered by the system, or that there has been a delay by the system in incorporating new technologies[14] . Therefore, it is necessary to recognize that these demands may reveal epidemiological needs that are not prevalent in society or patients who have not adapted to the existing treatment.

On the other hand, the Brazilian health system does not have infinite resources to provide all users with public health actions and services available on the market. In this way, expenses that are

[3] A drug that inhibits the development of malignant cells. There are several groups or types of antineoplastic drugs (cytostatic chemotherapy and hormones) and physical methods of antineoplastic treatment (radiation, cryotherapy, LASER, etc.)[52] .

not provided for in a budget, with prior planning, can jeopardize the actions of public health policies[47].

It should also be noted that judicial requests are often made on the grounds that the medicines offered by the SUS do not have the desired therapeutic efficacy. However, the difference is often only the brand name or the name of the manufacturer, and the medicine requested has exactly the same active ingredient as the medicine offered by the SUS[5].

Thus, in order to contain and rationalize judicialization, according to the STF[53], the obligation of the public authorities to provide treatments that are not on the official lists of the system depends on certain requirements, such as the indispensability of the medicine, its scientific proof and the ineffectiveness of those on the official lists of the system. This is because, as Borges and Uga rightly point out[15]:

> The fact that the right to health is constitutionally guaranteed through a public and universal health system does not mean that all services, medicines and treatments on the market should be made available by the system. **The provision of goods and services in the system requires the use of financial resources limited to the budget and it is therefore up to the executive branch to rationalize existing resources in order to promote the right to health in the most effective way**[15, p. 62] . (Emphasis added and translated by the translator)

In order to promote health more effectively and according to the studies analyzed on this subject, it is imperative to clarify that when selecting the procedures and medicines that will be provided in the system, the government uses various criteria, such as cost/benefit, dose/effectiveness, risk/benefit and effectiveness/efficacy[15].

At this point, it should also be clarified that, in order to regularize the incorporation of technologies into the SUS, the Comissão Nacional de Incorporação de Tecnologias (CONITEC - National Commission for the Incorporation of Technologies) was set up in 2011, with the aim of advising the Ministry of Health on matters relating to the incorporation, exclusion or alteration of health technologies by the SUS, as well as the creation or alteration of clinical protocols and therapeutic guidelines[8].

When incorporating a technology, not only should its clinical benefit be investigated, but a cost-effectiveness analysis should be carried out, which "is a form of complete economic evaluation in which both the costs and the consequences (outcomes) of health programs or treatments are examined"[43, p. 1] , which demonstrates the importance of studies to be carried out from this perspective, comparing new technologies with drugs that have already been incorporated.

On the other hand, judicialization can be an ally of the SUS, as it stimulates reflection on the need for new and updated public policies. On the other hand, the authors Souza et al.,[8] reveal that the increase in demand for new drugs can be understood as an action by the pharmaceutical industry to ensure that they are more standardized in the SUS and conclude that the judicialization of health, by interfering too much in health policies, has become pressure for the public administration to review existing protocols and draw up new ones, including new technologies.

In the same vein, Araújo's study[44, p. 283] reveals that "the volume of resources spent on the acquisition of medicines through the courts makes up a significant part of the pharmaceutical industry's profits and serves as a strategy for introducing new medicines and making the market for new drugs viable"; and that the relationships between the prescribing doctor, the lawyer and the

pharmaceutical industry, presenting important evidence that judicialization was at the service of the pharmaceutical industry.

Nevertheless, it is undeniable that this pressure mechanism can have positive effects, since it induces the updating of programs/protocols that need to keep up with the development of new knowledge about therapeutic practices. However, by incorporating them under pressure, there is a risk of doing so in a way that disregards criteria such as efficacy, safety and the population's health priorities, as well as being a strategy for the pharmaceutical industry to get its product approved.

With regard to the pharmaceutical industry, it was noted that its relationship with prescribing doctors should be guided by ethics and professionalism, with the aim of protecting patients' health. However, in several articles, the authors found evidence that their main interest was linked to the marketing of high-cost medicines[39, 31, 35, 16, 47, 48, 49] .

In this sense, it was described by the authors Campos et al.[36], see:

> These shady interests have been denounced in the literature and are related to the marketing of high-cost medicines, which are inaccessible to a significant portion of the population. Carvalho[45] points out that the legal field is one of the new avenues discovered by industries for these professionals to act on their behalf, arguing in defense of the universal right to health and new drugs and medical procedures[36, p. 789] (translated by the translator).

Batistella et al.[40] report that the pharmaceutical industry has used strategies to convince patients and prescribers with drug proposals that are not capable of bringing any benefit to their health, or even compromising it even more.

Boing et al.,[19, p. 93] present the data that "[...] between 1998 and 2002, 415 new drugs were approved by the Food and Drug Administration (FDA), but only 14% were truly innovative, that is, they showed significant advances". Thus, through advertising and marketing, the pharmaceutical industry is able to influence and condition the behavior of patients and health professionals, despite the fact that innovative drugs often don't have significant improvements compared to those already on the market[19 .

Campos, Gonçalves and Andrade[36] present an in-depth analysis of the relationship between industries and patients and prescribing doctors in an attempt to convince them to use medicines and/or equipment that are not yet on the official lists standardized in the public health system:

> In addition to advertising strategies through the media, the interviewees also reported harassment from the industry when it approaches medical students during their undergraduate and residency programs, using strategies that camouflage their interests by linking them to philanthropic actions. There is a practice in various regions of Brazil in which pharmaceutical companies support community experiments that bring together children and young people with diabetes, with a view to introducing new equipment such as insulin pumps. At medical congresses, industry interventions are identified. The interviewees recount their participation in these events and describe the clashes between representatives that materialize in the speakers' lectures. They recorded moments in which doubts about the adverse effects of new drugs were dismissed on the basis of science[36, p. 173] (translated by the translator),

Toma et al.[33] call for greater participation by the Federal Council of Medicine in actions aimed at curbing the prescription of medicines that have no scientific evidence, or that have not been considered in relation to the alternatives available, taking into account safety and cost-effectiveness, especially with regard to prescribers linked to the SUS itself, who cannot go against what the system offers without due justification.

Nardi et al.[38] argue that the excessive number of lawsuits disorganizes the public health system because, by migrating existing resources to comply with judicial orders, it hinders the performance of public policies organized within the scope of administrative management for collective care, since the cost of administrative compliance is significantly lower than judicial acquisition, and this divergence in values implies a reduction in investment in the field of health.

Thus, it can be said that it is more opportune and feasible to program the purchase of certain medicines than to comply with court injunctions, given that the government, by programming the purchase of medicines, is able to estimate consumption and cost, buy in larger quantities and/or at a greater discount, whereas court injunctions are not programmed by the state; it should also be noted that when funds are blocked to comply with court actions, the resources blocked from the federal entity are infinitely greater than those that would be used to purchase through a bidding process[35, 37].

In the case of municipalities, especially small ones, which have a much smaller budget than the states and the federal government, the effects of lawsuits are even more significant in terms of compromising the public budget and, therefore, the resources needed to carry out other public policies in the health sector. Thus, the occurrence of a single lawsuit is sometimes enough to compromise their budget, jeopardizing basic investments in health.

In view of this, we can conclude that the excess of new technologies, with no real therapeutic gains, included in the market by the pharmaceutical industries, increase the costs of medicines, directly impacting the resources of the states which, faced with the imposition of the Judiciary, are forced to provide medicines, including those with no proven efficacy and more expensive than similar ones already offered in public policies, disrupting the entire planning of the health system and potentially posing a risk to the patient of the appearance of unexpected adverse events.

Access outside the protocols requires proof of real need and justification for each clinical case, such as: the lack of a therapeutic alternative in the SUS or the impossibility of using the medicine on the official lists. We are not advocating preventing these drugs from being supplied, but the lawsuit must include a comparative study with the reference drug, in order to prove its necessity.

It should be remembered that the Brazilian health system must offer adequate health treatment to the population, not the best and most expensive that exists, given that the Public Administration must aim to guarantee quality at the lowest cost, as advocated by the principle of efficiency in article 5 of Law nº 14.133 of 2021.

Furthermore, lawsuits cannot be considered as the main deliberative instrument in the management of the SUS, but it should not be forgotten that they are admitted as an important element in the decision making of managers. They often act to improve access to medicines within the SUS, and can express legitimate claims and ways of acting by citizens and institutions, as well as helping to formulate political and social strategies that improve the health and justice systems with a view to making the right to health effective.

Thus, it can be seen that if the judiciary is provoked properly, it can be an instrument for shaping public policy[2] .

Category (3) - Inter-institutional dialogues

Another symptom of judicialization found in the analysis of the articles was the lack of dialogue between the public entities involved in an attempt to minimize judicialization. The coordination of the entities involved is a necessary measure, considering that judges do not have the expertise to analyze and decide on demands related to the right to health.

According to Asensi and Pinheiro[30] , greater interaction between institutions through dialogue, especially between the Judiciary and the Executive, with the aim of promoting projects to share experiences and challenges, standardize procedures and agree on strategies, can reduce judicialization.

In this sense, for a better understanding of this issue, the discussion must involve magistrates, other legal operators, managers, the technical areas involved, health professionals and the patients themselves, in order to prevent the excessive judicialization of health from promoting inequality and the fragility of public health policies, to the obvious detriment of the guarantee of social rights to the community.

In this context, Balestra Neto[9] reports that since 2010, initiatives have been set up to resolve demands related to the right to health. Among the measures, we highlight the signing of an agreement with the "*Conselho Nacional de Justiça*" (CNJ – National Council of Justice), in order to obtain technical support in the lawsuits. This support for the judiciary, which ensures greater efficiency in resolving actions relating to the right to health, was also found in the articles by Chrispim et al.[44] and Silva and Schulman[6] , which report on the so-called "*Núcleos de Apoio Técnico à Justiça*" (NAT-jus - Technical Support Centers for Justice).

Other examples include the partnership between CONITEC and the CNJ, which made the channel available: conitec@saude.gov.br, in order to clarify questions from magistrates about the incorporation of medicines, products or procedures into the SUS. As well as the availability of factsheets on health technologies on the website www.conitec.gov.br, aimed at supporting magistrates' decisions on medicines, incorporation, cost of treatment, alternatives available on the SUS and the availability or otherwise of Clinical Protocols and Therapeutic Guidelines for the related situation[8] .

At this point, it should be pointed out that medical reports cannot be the only evidence for judges to base their decisions on, since, it should be repeated, the judiciary has no technical knowledge of the medicines and treatments provided by SUS, which leads them, in the vast majority of cases, to make decisions based solely on the urgency of the requests and the state's duty to provide them.

This is why technical support is so important, as it aims to help the judge analyze medical reports in order to make decisions involving health claims.

According to Balestra Neto[26], the National Judicial Forum for "monitoring and resolving health care demands" was also created, with the aim of proposing procedural routines aimed at organizing specialized judicial units and normative measures for the prevention of judicial conflicts and the definition of strategies related to health law[26] .

In the meantime, research has also shown that specialized courts are being set up to process and judge lawsuits that have as their object the right to health, with guidance and technical support, facilitating the direct communication channel between legal and health bodies, in order to harmonize conduct, aiming to bring legal and health bodies closer together[32, 33, 34].

According to Asensi and Pinheiro[30], it has been shown that training the actors involved, through seminars and meetings, initiates and completes this dialog between the institutions, facilitating collaboration between the actors and consolidating mutual support, even during political transitions. Thus, interaction between institutions is fundamental.

Another solution was pointed out by the authors Silva and Schulman[6], namely mediation, spaces for dialog that are created with the aim of avoiding lawsuits or proposing solutions to ongoing lawsuits:

> As a result of the agreement, it was decided that, before a claim is made, the Health Department will check whether the drug is part of the SUS protocol. If it isn't, a therapeutic alternative is offered, which demonstrates the citizen's more active participation in the decision-making process, enabling them to distance themselves from litigation, one of the obvious causes of Judicialization[6, p. 294] (translated by the translator).

A similar measure was mentioned by Toma et al.[33] , who reported on the experience in São Paulo, with the Pharmaceutical Screening project in the "*Juizado Especial da Fazenda Pública"* (JEFAZ - Special Public Treasury Court), which aims to carry out a prior analysis of the case, by SES-SP technicians at the Special Public Treasury Courts, in order to identify other means for the patient than judicialization. When appropriate and possible, the patient is reintegrated into the SUS and given guidance on official programs and their protocols.

In the same article, Toma et al.[33] also report that, in 2009, the SES-SP launched a way of requesting medicines, called administrative care, after frustrating the alternatives available in the system, a multidisciplinary team evaluates the doctor's request and, if appropriate, issues an authorization for exceptional supply.

All these measures are successful strategies already used by other federal entities and adopted by institutions, bringing the field of law and health closer together in an attempt to reduce legal decisions that lack technical rigor.

In this way, it is understood that judicialization cannot be tackled only within the judiciary or the executive, since dialogue between the participants, including users of the system, facilitates understanding and combating problems, minimizing judicialization and even helping to change public policies, but it depends on the goodwill of those involved[50] .

In view of what was found in the categories, the studies show that judicialization is positive when there is an insufficiency in the system, in terms of treatments already standardized in the official SUS lists. This is mainly due to management errors, such as stock control, logistics in the distribution of medicines or lack of proper planning.

Judicialization has also proved positive when there are care gaps, which occur when goods and services are not offered by the system, and when there is a delay in the system incorporating new technologies.

In cases where the treatment requested is not included in public policies, there is a need to check for similar therapeutic alternatives that are on the official SUS lists. Otherwise, access outside the protocols requires scientific proof and justification for each clinical case, so that there is no rampant judicialization of health without analysis of technical criteria, which ends up disorganizing

all the planning that has been done, the existing resources and the public policies that have been drawn up.

In addition, it was noticed that the Judiciary, by ensuring access to products without much technical rigor in terms of therapeutic efficacy, ends up favoring, even if unconsciously, only the profits of the pharmaceutical industries. This issue was raised a lot[39, 31, 35, 16, 7 ,4, 46, 48] in the studies analyzed, since the participation of the pharmaceutical industry has sometimes been shown to be positive, by pressuring entities to incorporate new and efficient technologies into the official SUS lists, and sometimes negative, when it commercializes health, acting in collusion with doctors to prescribe technologies without proven efficacy.

It should also be noted that judicialization has shown some obstacles, such as the lack of technical knowledge of legal operators in relation to treatments, which makes it essential to provide technical support to the judiciary quickly and effectively.

Likewise, the lack of knowledge of the entities involved in judicialization about the official lists and the programs offered by the system was evident, which reveals that there should be greater dialogue between the entities involved, in an attempt to reduce legal decisions without technical rigor and for the official lists to become more accessible to society as a whole.

Finally, it should be noted that excessive judicialization reveals a reduction in investment in public health policies, given that resources are scarce and there is a need for allocative choices by the administration.

Final considerations

The analysis presents the positive and negative points of the Judicialization of health, demonstrating the contradiction in the subject, given that judicialization is born as the prerogative of the population to resort to the Judiciary to guarantee the entire set of basic rights that make up the core of health and that must be provided by the State, at the same time as resources are limited.

There is a need to improve the SUS in order to avoid problems in the health system that lead to a lack of standardized treatments, improving administrative procedures and preventing users from having to use the judiciary to realize their right to health. Much of the judicialized demand could be avoided if the SUS guidelines were taken into account and complied with.

But it must be clear that, even with more funding, the administration will always have to live with a budget limit that will force it to make choices. It is the executive branch's duty to make them in a way that promotes equity, efficiency and collective well-being.

Another aspect observed was that judicial decisions handed down without verifying the similar therapeutic alternatives available in the SUS or justifying the treatment requested with a technical/scientific basis, leads to the disorganization of health policies, because judicial intervention often removes resources from some to allocate to others, leading the state to adjust its budget, reallocate resources, and other projects and public policies are jeopardized, postponed or even eliminated.

Thus, formal recognition of the right to health based on existing legal norms is not enough. Based on the current interpretation of the Supreme Court, the state has an obligation to make the right to health effective. However, it is necessary to verify certain premises, such as the existence of

a state policy that covers the health provision requested or whether there is scientific evidence about the treatments requested in order to grant the injunctions.

Judicialization also has a perverse face, which privileges a small part of the population over the rest. It can be seen that judicialization carried out in the wrong way has a direct impact on the public budget, management and planning.

Thus, this study helps to understand the ambivalent nature of the judicialization of health, which can be beneficial to users when it drives the solution of problems in the system, the incorporation of new technologies, etc. On the other hand, these achievements should not obscure the fact that the excess of lawsuits, especially when they are used and decided without technical rigor, distort health resources, disorganize the system and cause resources from public policies for the whole community to be reallocated to cover the costs of judicialization.

In addition to this study, it was also identified that the entities involved in the judicialization of health should talk to each other in order to understand the phenomenon and combat the problems encountered, seeking knowledge about the existing treatments available in the SUS and even helping to change public policies.

Finally, it should be clarified that the considerations made in this article are not intended to reduce in importance the prerogative of the population to resort to the judiciary to guarantee their rights, but to emphasize the need for improvements in the management of the SUS, together with articulation with the judiciary, always aiming for the best patient care with efficiency in the spending of public money.

Conflict of interest
The authors declare that there is no conflict of interest.

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