Organization of public entities to attend to the judicialization of access to medications in the state of Santa Catarina, Brazil

Abstract

This study describes the organization of the State of Santa Catarina (SC), Brazil, to attend to the judicialization of access to medications from the early 2000s to 2018. Document analysis and interviews with representatives of the Executive, the Judiciary, the State Attorney General Office (PGE, Procuradoria Geral do Estado/SC), the Public Defender's Office of the State of SC and the Public Prosecutor's Office of the State of SC (MPSC, Ministério Público de SC) were performed. The Judiciary, the PGE/SC and the MPSC organized themselves to address the phenomenon. Initially, the State Health Secretariat did not have an organization to attend to the judicialization; with the increase in the number of lawsuits, it created sectors, routines and systems, and at the end of 2018 there was a specific Administrative Management and sector. The main measures used were: public hearing of the Federal Supreme Court, statements by the National Justice Council, Incident of Resolution of Repetitive Demands, State Monitoring and Resolution Committee for Health Care Demands in SC, Center for Repetitive Actions in Health Care, Multidisciplinary Judicial Support Commission and the Technical Support Center. The judicialization of access to medications in SC has not yet been resolved, since all the implemented measures have not prevented the increasing rise in expenses with lawsuits.

Key words Health's Judicialization, Access to medications, Executive, Judiciary, Public prosecutor's office
Introduction

The Brazilian Unified Health System (SUS, Sistema Único de Saúde) and its service providers are, for a considerable part of the Brazilian population, the only alternative to obtaining access to medical care and essential medications. Despite the public policies in the area of Pharmaceutical Assistance, such as the National Medication Policy and the National Pharmaceutical Assistance Policy, the adoption of the National List of Essential Medications (RENAMED, Relação Nacional de Medicamentos Essenciais) and the increase in investments, it is a fact that there are difficulties in accessing medications in the country. One of the consequences is the phenomenon known as judicialization of access to medication.

Based on the individual needs of citizens, who are often confronted with the technical criteria that define the best therapeutic offer, the Judiciary requires the Executive to provide medications, tending to disregard the SUS guidelines and the existence of public health policies (p. 169-170). It also ignores the potential risk that this citizen might be submitted to, especially when accepting experimental drugs, without registration with the National Health Surveillance Agency (ANVISA, Agência Nacional de Vigilância Sanitária) or those of questionable efficacy.

In a scope review, Vargas-Peláez et al. identified in the analyzed articles that the impacts at the beginning of the judicialization movement were positive, such as the guarantee of access to treatment for HIV/AIDS. Afterwards, the effects became negative, as there was an upsurge of lawsuits, with a predominance of individual ones. However, not all actions are abusive or misguided, as there are still rare diseases without standardized treatment in the SUS, or for other cases there are few alternatives, which, having already been used, have proven to be ineffective for the patient. In these situations, there are problems in the organization of pharmaceutical assistance, delays in the incorporation of new technologies and even in the updating of Clinical Protocols and Therapeutic Guidelines (CPTG) and RENAME. Therefore, judicialization seems to be the only possible access to medication.

For Schulze, the topic generates a lot of controversy. Some understand that judicialization is a form of access and others of inequality in public health (s/p).

In lawsuits involving the SUS, the main demand is for medication, dramatically impacting the budget of the Union, States and Municipalities. A study performed for the National Council of Justice showed that in the Courts of Justice of 17 Brazilian states, “Medical-Hospital Treatment and/or Medication Supply” is among the main issues in first instance cases involving health, and in the state of Santa Catarina the cases related to “Medication Supply” is the main type of lawsuit demand. Vieira pointed out that demands for medications in the SUS totaled 544,378 cases (24.4% of the total) until December 2018, a figure that may be underestimated, as the Judiciary also uses other classifications for this input in the processes. Additionally, through court decisions, the Ministry of Health expenditures on medication increased from R$422.6 million in 2012 to approximately R$1.0 billion in 2018.

In Santa Catarina (SC), lawsuits for medication requests started in 2000, which was granted. Costs with the purchase of medications through lawsuits went from just over R$38,000 in 2001 (seven cases), to an accumulated value close to R$ 1.1 billion in the period of 2010 to 2019, according to representatives of the Santa Catarina State Health Secretariat (SES/SC, Secretaria de Estado da Saúde de Santa Catarina) present at the Seminar “Judicialization of access to medications in Santa Catarina: Organization of actions related to Assistance to face legal actions” (Judicialização do acesso a medicamentos em Santa Catarina: Organização das ações relacionadas à Assistência para o enfrentamento das ações judiciais), held in December 2019 by professors from the Department of Pharmaceutical Sciences of Universidade Federal de Santa Catarina and by the SES/SC Legal Consultancy.

Based on an integrative review, it is observed that articles published between 2007 and 2017 that dealt with the judicialization of medications in Brazil, focused mainly on the legal actions themselves, analyzing costs and/or impacts, on the applicants’ profile or on the factors that lead to the judicialization. This work brings another perspective on the phenomenon, describing how in the State of Santa Catarina, Brazil, the Executive and Judiciary Powers and the Essential Functions of Justice (State Attorney General Office, Public Defender’s Office of the State of SC and Public Prosecutor’s Office of the State of SC) were organized to meet legal demands for access to medications.

Method

The research was based on document analysis and semi-structured interviews with representatives...
of the Executive, Judiciary, State Attorney General Office (PGE/SC, Procuradoria Geral do Estado de Santa Catarina) and Public Defender’s Office of the State of Santa Catarina (DP/SC, Defensoria Pública do Estado de Santa Catarina) and Public Prosecutor’s Office of the State of Santa Catarina (MPSC, Ministério Público de Santa Catarina). The documents were identified on the websites of the Government of Santa Catarina, SES/SC, PGE/SC, DP/SC, MPSC, Court of Justice of Santa Catarina (TJ/SC, Tribunal de Justiça de Santa Catarina), Federal Supreme Court (STF, Supremo Tribunal Federal), Superior Court of Justice (STJ, Superior Tribunal de Justiça) and National Council of Justice (CNJ, Conselho Nacional de Justiça). Term papers investigating judicialization in SC were also used as data sources.

Chart 1 lists the sectors, services and regions included in the survey, with a representative interviewed in each of them (total of ten interviewees). A script adapted from Vargas-Peláez et al. was used, in two versions (one for the Executive and PGE/SC and another for the Judiciary, DP/SC and MPSC), with the central questions: which, when and the results of the implemented measures, as well as the role of the Executive, PGE/SC, Judiciary, DP/SC and MPSC in the judicialization of access to medications in SC (in both scripts); on the judicialization in the organization chart of SES/SC and its evolution and flow since the 2000s (script of the Executive and PGE/SC); on the influence of the Judiciary, DP/SC and MPSC in the implementation of measures to respond to the judicialization of access to medications and the contribution of these measures (script of the Judiciary, DP/SC and MPSC). The interviews were carried out between October and November 2017, at the participants’ workplace (in this text under fake names), which were recorded, except in the case of the federal judge who chose to send responses by email. All respondents signed the Free and Informed Consent form.

The selected documents were classified and analyzed according to their content, interpreting, whenever possible, the importance of those at the national level for the SC context. The factually transcribed interviews were treated according to thematic content analysis, seeking to understand, from the perspective of the involved actors, the organization process in SC to address judicialization.

The research was approved in 2017 by the Ethics Committee for Research with Human Beings.

Results and discussion

National context

The Public Health Hearing, promoted in 2009 by the Federal Supreme Court (STF, Supremo Tribunal Federal), was mentioned by some of the interviewees. Chart 2 brings the main items

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<th>Organs</th>
<th>Sector / Service / Region of Jurisdiction</th>
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<tr>
<td>Executive power</td>
<td>Santa Catarina State Health Secretariat (SES/SC)</td>
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<td>Judicial power</td>
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Source: Authors elaboration.
**Chart 2.** Main measures to address the judicialization of health (national level and Santa Catarina).

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| Nacional  | Public Health Hearing          | STF    | 2009 | Current| Considering the case that generated the lawsuit, its analysis is guided by:  
  . Requirement of scientifically substantiated evidence  
  . Application of evidence-based medicine (EBM) and Clinical Protocols and Therapeutic Guidelines (CPTG) adopted by the Unified Health System  
  . Existence of public policy  
  . User health need  
  . Verification of drug registration  
  . The reservation of what is possible (scarcity of resources) does not eliminate the obligation of public entities to provide the requested service                                                                 | 14        |
| Recommendation n. 31 | CNJ | 2010 | Current | Recommendations to the Courts of Justice (State and Federal Regional):  
  . Establish accords until December 2010 for the technical support of physicians and pharmacists, in order to assist magistrates in decision-making (consideration of clinical issues)  
  . That magistrates: (a) instruct actions, whenever possible, with medical reports containing the description of the disease (including the International Classification of Diseases code), the prescription of drugs by generic name or active ingredient and with exact dose; (b) avoid authorization for the supply of medications without registration with the National Health Surveillance Agency (Anvisa, Agência Nacional de Vigilância Sanitária) or in an experimental phase; (c) listen to managers before considering urgent measures; among others  
  . Encourage visits by magistrates to instances of social control of the Unified Health System (SUS), as well as to SUS health services units  
  . Recommendations to the National School for the Training and Improvement of Magistrates (Escola Nacional de Formação e Aperfeiçoamento de Magistrados), National School for the Training and Improvement of Labor Magistrates (Escola Nacional de Formação e Aperfeiçoamento de Magistrados do Trabalho) and the Federal and State Magistrates Schools:  
  . Include health law legislation in training courses  
  . Encourage joint events (judges, members of the public prosecutor’s office and managers) of studies in the area of health, seeking dialogue on the subject | 15        |
| Resolution n. 107 – establishes the National Judiciary Forum (Health Forum) | CNJ | 2010 | Current | Responsibilities of the National Forum:  
  . Monitoring of lawsuits involving, for example, the supply of medications, products or supplies in general, treatments and provision of hospital beds  
  . Monitoring of lawsuits related to SUS  
  . Proposition of concrete and normative measures aimed at: (a) optimization of procedural routines, organization and structuring of specialized judicial units; (b) prevention of legal conflicts and the definition of strategies in matters of health law; among others  
  . Executive committees will be created at the National Forum The National Council of Justice, in order to ensure the proper performance of the National Forum's attributions, may sign terms of technical cooperation agreements or accords with public and private organs and entities, whose institutional activities are aimed at finding a solution to conflicts | 16        |
discussed at the Hearing. For Santos et al., it was a milestone in the relationship between the legal system and the political system regarding the Unified Health System (SUS) and the actions and services related to health in Brazil (p. 185). The arguments of the speeches given in this Hearing were confronted with the first decisions of the STF after the Public Hearing, and about 20% were considered by the magistrates in their decisions. It was expected that the definitions of the STF, an important milestone in the judicialization of health in Brazil, would standardize court decisions over time, especially given the fact that it was also recommended to the magistracy to be

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| National | I, II and III National Health Journey (or Right to Health Journeys) | CNJ  | 2014 | Current | - I Journey approved 45 statements, 14 of which were directly related to medications, including:  
  . The PCDT organizes the pharmaceutical provision, without limiting it – revoked at the III Journey  
  . The processing of lawsuits in which medications not registered by Anvisa, off-label and experimental drugs are required should be avoided by the courts – revoked in the III Journey  
  . Inclusion of the claimant in a service or program that already exists in the SUS when dealing with a drug, product or procedure already provided for in the official SUS lists or in PCDT – it was reworded in the III Journey  
  . Medical prescriptions must register the treatment or drug, using the Common Brazilian Denomination (CBD) or the Common International Denomination (CID), its active ingredient, followed, when relevant, by the reference name of the substance, posology, mode of administration and period of time of the treatment and, in case of prescription different from that expressly informed by its manufacturer, the technical justification |
|  | ) | | 2015 | | - II Journey approved 23 statements, eight of which involve medications, including:  
  . Judicial measures for access to medications and materials not registered by Anvisa or for off-label use should not be granted, except with proof of scientific evidence and urgent need – it was reworded in the III Journey  
  . Recommendation for the magistrate to inform the Municipal and State Health Councils when actions are taking place in the same District for access to medications, products or procedures already included in official lists  
  . Recommendation to verify whether the National Commission for the Incorporation of Technologies in the SUS (CONITEC, Comissão Nacional de Incorporação de Tecnologias) has analyzed the drug, product or procedure under judicial process  
  . Recommendation that the prescribing physician be notified in court when there is a prescription for a drug, product, orthosis, prostheses or procedures that are not included in official SUS lists or protocols, clarifying the pertinence and need for the prescription and signing a declaration of any conflict of interest |
| | ) | | 2019 | | - III Journey approved 35 new statements, reworded 29 statements and revoked 11 of the first two Journeys Among the new ones, 12 refer to medications, highlighting:  
  . Treatment abandonment occurs when the drug and other products have not been picked up for more than 03 (three) consecutive months, with the respondent being entitled to suspend the respective acquisitions, and the Court must be notified of the abandonment | 18 |
### Chart 2. Main measures to address the judicialization of health (national level and Santa Catarina).

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| National    | I, II and III National Health Journey (or Right to Health Journeys)       |              | 2019  | Current | - The judicial authority may determine the inclusion in the process of scientific evidence documents (technical note or opinion) available in e-NatJus (CNI) or in databases of the Technical Support Centers in Health (NATS, Núcleos de Assessoramento Técnico em Saúde) of each state, provided that related to the same drug, therapy or product required by the party.  
- In decisions that determine the supply of medication or services by more than one entity of the federation, it should be aimed, if possible, to individualize the acts that will be the responsibility of each entity.  
- The magistrate may order the defendant to deposit in court amounts that allow the plaintiff to purchase drugs or products granted by court decision, until the process of purchasing drugs for regular supply is completed, under penalty of confiscation of funds.  
- The issuing of a writ of mandamus regarding matters of public health will only be admitted when the drug, product, orthosis, prosthesis or procedure appears in the RENAME, RENASES or SUS protocol list. | 4, 21     |
| State       | Legal Actions Monitoring Center (NAAJ)                                   | SES/SC       | 2007  | Extinct | Assignments:  
- Clarifying questions from citizens, magistrates and members of the Essential Functions to Justice about the procedures for the acquisition and delivery of medications.  
- Analyze the standardization or not of the requested medications, indicating therapeutic alternatives or formulating technical opinions regarding those not standardized by SUS.  
- Register the processes in its own system.                                                                                      | 22        |
|             | Multidisciplinary Judicial Support Commission (COMAJ)                     | SES/SC       | 2011  | Current | Assignments:  
- Coordinate, guide and monitor compliance with court orders in the health area.  
- Receive and forward lawsuits and requests for administrative information about health care.  
- Carry out actions related to the reimbursement of amounts spent in legal proceedings involving the Federal Government and/or Municipalities.  
|             | State Monitoring and Resolution Committee for Health Care Demands in Santa Catarina (COMESC) | Several      | 2012  | Current | Approved 21 statements, 14 of which deal with medications, including:  
- Ordered actions with prescription and report of physician in practice in SUS.  
- Medical prescriptions must contain medication by CBD or CID, active ingredient, dose, route of administration, time of treatment.  
- Periodic presentation of medical prescriptions, every three months, or in a shorter period, in accordance with health legislation.  
- Existence of registration Anvisa.  
- Approved Recommendations, including:  
- Exhausting drug alternatives from standardized lists before opting for other drugs.  
- Compliance with decisions regarding deadlines, confiscation of values and fines.                                                                 | 27        |
|             | Legal Asset Management (GEJUD)                                          | SES/SC       | 2013  | Current | Activities:  
- Logistics for the storage and distribution of legalized medications and supplies                                                                                                                  | Study data|

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| State | Operational Support Center for Human Rights and the Third Sector (CDH) | MPSC | 2012 | Current | Assignments:  
. Defense of human rights, with emphasis on the right to health, education, protection of the elderly and people with disabilities, the control of psychiatric hospitalizations, the inspection of institutional acts and the management of third sector entities and residual issues of civil law | 28 |
|       | Technical Support Center for the Judiciary (NAT-JUS) | SES/SC | 2015 | Current | Assignments:  
. Advise magistrates: (a) with technical information on treatments recommended in the SUS and, in their absence, recommend a therapeutic alternative based on scientific evidence that justify or not the granting of the benefit; (b) in matters related to lawsuits seeking to provide health care, through the preparation of technical opinions  
. Propose the use of standardized medications in SUS, based on official lists and their respective updates, in addition to considerations issued in Opinions by Conitec  
. Suggest the search for the incorporation of new technologies together with Conitec | 23 |
|       | Decree n. 241 | SES/SC | 2015 | Current | Obligation of SC public servant prescribers:  
. Prescribe medication and request health tests and procedures in terms of public policies, from standardized lists and PCDT  
. Technically justify the prescription when there is a need for drugs not included in the lists | 24 |
|       | Center for Repetitive Actions in Health Care (NARAS) | PGE/SC | 2015 | Current | Assignments:  
. Representing the Public Treasury in the repetitive actions in health care attributed to the Central-Headquarters Execution Organ  
. Promote the standardization of the defense theses  
. Propose legal and administrative measures to prevent litigation  
. Create theses related to health  
. Articulate the dialogue with organs and authorities of the Executive and Judiciary Powers | 30 |
|       | Incident of Resolution of Repetitive Demands (IRDR) | TJ/SC | 2016 | Current | For the legal granting of standardized medication or treatment in the SUS, the following requirements are:  
. Need for the drug and adequacy to the existing disease, certified by a physician  
. Demonstration, in any way, of impossibility or impediment to obtain it through the administrative route  
For the judicial granting of a drug or procedure not standardized by SUS, the following requirements are:  
. Effective demonstration of financial insufficiency  
. Absence of public policy for the existing disease or its inefficiency, plus proof of the need for the drug sought by all means, including expert medical evaluation | 31 |

It continues.

guided by Recommendation n. 31 of the National Council of Justice (CNJ, Conselho Nacional de Justiça)\textsuperscript{14}. Recommendation n. 31/CNJ/2010\textsuperscript{15} established the adoption, by the Courts of Justice of the States and Federal Regional Courts, of measures to ensure greater efficiency in the solution of lawsuits involving health, subsidizing magistrates and other operators of law. Also in 2010, the CNJ created the National Judiciary Forum (Health Forum) through Ordinance n. 107/2010\textsuperscript{16}, for the monitoring and resolution of health care demands, coordinated by a National Executive Committee and constituted by State...
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<td>Ordinance n. 804</td>
<td>SES/SC</td>
<td>2017</td>
<td>Current</td>
<td>Responsibilities of the Health Managements (GERSA) in relation to lawsuits: . Monitoring, receiving, responding to inquiries, providing evidence of delivery and/or execution of services, carrying out exams, procedures, providing supplies and medications. Responsibilities of the Health Manager: . Carry out actions and supervise the technical team to work with the municipalities within its scope and being responsible for complying with state judicial demands, considering the decentralization of SUS. . Establish inventory control of lawsuit demands in the Management or in the municipalities covered by it. . Proceed with the return of medications, supplies or materials to the central administration, within 10 (ten) days, when 02 (two) months have passed without moving these products under their custody.</td>
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Committees17. As part of the Forum’s actions, the CNJ held in 2014, 2015 and 2019 the I, II and III National Health Journey (or Right to Health Journeys), respectively, to debate the problems of the judicialization of health and present and approve statements on the right to health18. Chart 2 lists the main aspects of the measures defined by the CNJ.

In 2015 the New Code of Civil Procedure created the Incident of Resolution of Repetitive Demands (IRDR, Incidente de Resolução de Demandas Repetitivas), which identifies processes in the first instance of jurisdiction when there are, simultaneously: I – effective repetition of lawsuits that contain controversy on the same issue of rights, only; II – Risk of offense to isonomy and legal certainty29 (s/p). This mechanism has been applied in SC as described below.

Santa Catarina context

Measures taken by the Executive Power

In the Executive, SES/SC is directly involved in judicialization. The Pharmaceutical Assistance Board (DIAF, Diretoria de Assistência Farmacêutica) was created in 2003 to meet the Basic Pharmaceutical Assistance, of Exceptional/High Cost Medications and Mental Health Programs, but it was also responsible for a period of time for the lawsuits involving medications and other products41.

Until 200613 the lawsuits were, in practice, first referred to the Legal Consultancy of SES/SC (COJUR-SES, Consultoria Jurídica da SES), linked to the office of the State Health Secretariat, whose function is to legally define parameters of conduct that assist the state manager in matters of health20. A copy of the court decision was sent to DIAF, which forwarded it to its Programming and Supply Management for registration and other referrals.

With the progressive increase in the number of cases, the organization and flow of judicialization underwent changes. Aiming to improve the organization of the filing of lawsuits, to achieve greater control and agility in complying with them, the Legal Actions Monitoring Center (NAAJ, Núcleo de Acompanhamento das Ações Judiciais) was created in July 2007, linked to the DIAF (see Chart 2 for the Center attributions). The NAAJ consisted of a multidisciplinary team (lawyers, pharmacists, physicians and administrative technicians), also including COJUR and DIAF, as they were already working in the area before the implementation of the Center21. The Center intermediated some achievements for SC, such as the “call of the Union to the processes”, that is, its co-responsibility in actions involving medications, thus avoiding the double supply of medications when the Union was a defendant together with the State21. It also implemented deals with the Union and Municipalities when they were defendants in the same actions, proposing, for example, reimbursement by the Union to the State of SC for half of the amounts used in oncological drugs and the accountability of Munici-
palties in meeting the demands involving basic drugs\textsuperscript{11}. Moreover, in a joint effort with the Judiciary, at least 1,360 injunctions were suspended, analyzing together the real situation of the concrete case\textsuperscript{11}.

Concomitantly with the creation of the NAAJ, as reported by interviewee Virginia, there was the implementation of a database on medications (Dadosmed), used by the SES/SC, PGE/SC, the Federal Public Defender’s Office and the MPSC. Therefore, the same tool could be used to defend or condemn the state. As of 2007, the user with a medical prescription called the SES/SC, through the Health Managements (GERSA, Gerências de Saúde) based in 16 municipalities in Santa Catarina, which guided the filling out of an application, containing the medical diagnosis and prescribed drugs. This was forwarded to the NAAJ, which after analyzing the requested medications, sent clarifications directly to the user’s address\textsuperscript{4}. According to Virginia, the process was lengthy, as there was only one sector to meet all the requests from the state. In 2010, the Center was dissolved, and its activities started to be carried out again by DIAF\textsuperscript{4} for around one year.

The decisions (injunctions) granted by the Judiciary against the State of SC began to be forwarded, as of 2011, to the newly created Multidisciplinary Judicial Support Commission (COMAJ, Comissão Multidisciplinar de Apoio Judicial)\textsuperscript{23}, which assumed virtually all the functions of the NAAJ, however linked to COJUR (COMAJ’s attributions are shown in Chart 2). For its performance, the existing database was restructured into SISCOMAJ. The creation of COMAJ, according to interviewee Matilde, was a consequence of the 2009 STF Public Hearing, mentioned above, and of the national judicialization scenario at that time.

In 2013, when the state administrative reform completely dissociated the judicialization from DIAF, the stages of programming and acquisition of judicialized medications were transferred to the Planning Management of Demand for Goods and Services (GPLAD, Gerência de Planejamento da Demanda de Bens e Serviços) and the organization of logistics to the Legal Asset Management (GEJUD, Gerência de Bens Judiciais) (Chart 2), allocating part of the DIAF staff in the new sector.

Created in 2015 by Ordinance n. 991/2015, in accordance with Recommendation n. 31/ CNJ/2010, and with an accord initiated in 2016\textsuperscript{23}, the Technical Support Center for the Judiciary (NAT-JUS, Núcleo de Apoio Técnico ao Judiciário), is a consultative body and has the purpose of advising the Judiciary in legal demands for the provision of health care (more details NAT-JUS activities in Chart 2). Interviewee Joaquina, when comparing the competences of COMAJ and NAT-JUS, commented that COMAJ keeps the post-judicialization and defense, providing information to the PGE, and the NAT keeps the earlier part, informing the magistrates. According to Joaquina, of the 112 Districts existing in the State Court until 2017, 12 of them were served by NAT-JUS, totaling 21 municipalities. In the case of the Federal Court, three subsections (Florianópolis, Criciúma and Itajaí) were assisted, covering 53 municipalities. Joaquina also explained that the judgment of the lawsuit goes to the magistrate and to the NAT at the same time, which has 72 hours to issue a technical instruction for the magistrate to make the decision. According to her, the magistrate’s decision is independent of the opinion of the NAT, that is, the magistrate can decide before the opinion is issued, but she emphasized that, in general, they were waiting for the answer. The answer is not simple, according to Joaquina, as it is analyzed individually so as not to generate bias, based on the concrete case. Between three and four referees meet and interpret the case, deciding which document will be prepared: Technical Note, Return Letter or Instruction Letter. She stressed that the Center does not dispute the diagnosis, and in imprecise situations, it is possible to return the lawsuit, requesting a better description of the case, so that the team can search the literature for evidence that justify or not the granting of the benefit. Joaquina pointed out some positive results in the Districts where the NAT-JUS operates, such as the reduction in the number of immediate granting of tutorships, the physicians withdrawal of the judicialization when they receive the Center explanations, the greater credibility of the pharmacist in issuing technical opinions and the extinction of expert medical evaluation in most cases (according to her, the magistrates reported that the technical documents prepared were excellent and, therefore, sufficient as an argument, without the need to pay for the costs of the expert evaluation).

The Judiciary guarantees the right to have access to medications but does not define the applicant’s counterpart. According to Virginia, many citizens did not even have a prescription for the withdrawal of their medications. Decree n. 241 of 2015\textsuperscript{24}, coming from SES/SC, was a measure to minimize the problems related to prescriptions (information about this Decree in Chart 2).
In 2016, SES/SC made another change, putting storage and distribution under the responsibility of a third-party company. Interviewee José said that GEJUD is part of the logistics of referral to the GERSA and/or Municipalities; the outsourced company separates and takes the medications to these places, which carry out the delivery of the medications. It is worth emphasizing that there was no computerized inventory control system in GERSA and Municipalities, a situation that persisted in the following years.

Ordinance n. 804 of August, 2017\textsuperscript{25}, another measure originating from the SES/SC in response to the judicialization, defined the responsibility of GERSA in monitoring and following-up the provided services, in compliance with court orders when the defendant is the State and its completion is centralized in the Managements, being the Regional Health Manager in charge, supported by the pharmacists allocated to its Management (see Chart 2 for more details). Interviewee Matilde understood that the accountability imposed by the Ordinance was of great relevance for the control and effective compliance with court decisions, optimizing resources, preventing the drug that is not being withdrawn from being purchased unnecessarily and sent monthly to the GERSA. For interviewee Virginia, the manager’s accountability was an achievement, as the manager is the state representative in that region.

Judicialization is not a government program, but it has taken on such proportions that it became institutionalized, such as the necessary restructuring measures for SES/SC to meet the legal actions. According to the interviews and document analysis, it is observed that specific sectors and services were created, mainly focused on the logistics of meeting the demands, but little has been invested in structure and human resources for this activity. Regarding human resources, new hirings were minimal, and most workers were relocated from other sectors or simply absorbed more of this activity, becoming overloaded. In GERSA, for example, the same team that attended to the Specialized Component of Pharmaceutical Assistance had to absorb the judicial activities. As a result, adequate controls were impaired (since there was no computerized inventory management system in the Managements), as well as the development of measures to reduce legal actions with Municipalities and prescribers.

One issue to be highlighted from the study data is that, although the citizen’s request was granted by the judge, it did not guarantee an improvement in their quality of life, as sporadic or consecutive shortage periods were frequent in the judicial assistance provided by the State. In these cases, the defendant could be fined\textsuperscript{26} or, according to interviewees Virginia and Iolanda, the applicant’s legal representative might request the confiscation of the value, either for the purchase of the judicialized product or to reimburse what was spent. However, as identified by the study, there were situations that, due to the long time generated by the bureaucracy to receive the amount, the applicant was without treatment at some point.

Another point to be highlighted is the drug abandonment by the applicant, which has generated a significant waste of public resources. In 2019, for example, this loss was of R$ 26,000,000.00 in drugs acquired through the courts, according to representatives of the SES/SC present at the Seminar “Judicialization of access to drugs in Santa Catarina: Organization of actions related to Assistance to face legal actions” (Judicialização do acesso a medicamentos em Santa Catarina: Organização das ações relacionadas à Assistência para o enfrentamento das ações judiciais), mentioned before.

\textbf{Other measures taken}

The State Monitoring and Resolution Committee for Health Care Demands in Santa Catarina (COMESC, Comitê Estadual de Monitoramento e Resolução das Demandas de Assistência da Saúde de Santa Catarina) was created in 2012, based on Resolution n. 107/2010 of CNJ\textsuperscript{27} which determined the creation of Executive Committees to coordinate and implement actions of a specific nature, considered relevant, making it possible to understand the operation of the Judiciary and the SUS. At COMESC, including members of several public organs of justice and health and civil society\textsuperscript{28}, statements and recommendations are issued that deal with common topics in lawsuits. Until April 2020, COMESC produced 21 statements\textsuperscript{29}, seeking to standardize procedures to be adopted by health and legal professionals, prioritizing health care and the organization of the SUS (see Chart 2 for more details on COMESC).

The MPSC has the institutional responsibility of manifesting itself in processes in which its participation is mandatory, and it must also protect unavailable individual rights, which include health. The MPSC in the health area has been supported, since 2012, by the Operational Support Center for Human Rights and the Third
As the demand for medications increased, the PGE/SC, which guides the public administration in complying with court decisions39, created in 2015 the Center for Repetitive Actions in Health Care (NARAS, Núcleo de Ações Repetitivas de Assistência à Saúde)30 (Chart 2), understood by some of the interviewees as a measure against judicialization. Until November 2017, the NARAS covered only the capital of Santa Catarina, with four prosecutors involved, when another eight linked to the Regional Prosecuting Offices were included. Interviewee Mariana, in November of the same year, reported that to date, the judicialization with NARAS has not been reduced much. For her, expanding the group to 12 attorneys dedicated entirely to lawsuits would greatly improve the situation, as they would standardize theses and fight in the courts, seeking through intense work with judges and courts to convince judges that it is not possible to give everything. Mariana commented that the analysis of what was being requested is done considering the applicant’s medication and illness. The PGE/SC informs, when possible, that for the disease being considered, the SUS provides medication and presents therapeutic alternatives. For Mariana, the PGE/SC [...] defends the system, tries to prevent the person from taking a drug other than one that the State could provide for free [...] tries to avoid draining health money.

According to informant Iolanda, decisions in relation to medications were modified due to the process of standardizing jurisprudence, adding that there was an IRDR judged in 2016 or 2015, which consolidated the understanding regarding the standardized ones, which would have unrestricted access, because they were inside a well-established, fixed public policy. Iolanda referred to thesis 1, signed by the Court of Justice of SC31, which deals specifically with “judicial concession of medication or treatment” (see Chart 2 for details). It is worth mentioning that in SC, until July 2020, the TJ/SC signed 21 theses of different contents based on the IRDR31. Other activities were carried out in SC to bring the Judiciary closer to the Executive, reported in the interviews, such as: (1) a course on pharmaceutical assistance with magistrates before taking over their Districts; (2) seminars and meetings between COMAJ and the Judiciary; (3) information exchange, through access to the data system for the PGE/SC, TJ/SC, MPSC and DP/SC and federal judges; (4) dialogues between judges and managers; (5) several events involving legal practitioners, public administrators and health professionals, aiming to clarify judicialization.

Judicialization flow

Until the beginning of 2015, the headquarters of SES/SC, in the capital of SC, continued to be the starting point of the judicialization, when the user’s request was then processed directly in GERSA32 (Figure 1), which must respond to citizens in up to 15 days, which streamlined the process.

According to recommendation of Statement n. 03 of the CNJ, the lawsuit is only acceptable upon proof of prior denial or unavailability of provision in [...] SUS [...]31. This document has been called a “negative certificate”, that is, a statement informing that the State does not provide the drug and its therapeutic alternatives, if any.

The citizens, with the medical prescription, the standard form developed by the District or by COMESC and the “negative certificate” of supply by the State and/or Municipality, activate the Judiciary (Figure 1). In order to do that, a lawyer is necessary. If you are unable to cover the costs of this professional, you can use the Free Legal Assistance provided by DP/SC33. Public defenders work to promote, whenever possible, the extra-judicial solution of disputes, trying to conciliate them before taking the appropriate action, which can be an individual or a collective/civil public lawsuit. Another representation option is the MPSC prosecutor.

According to Madalena, after defining the intermediary agent between the citizen and the judge and in possession of all the necessary documents, the lawsuit must be filed against some entity of the federation (Union, State and/or Municipality). If it is against the State and/or Municipality, the action will be filed in the State Court and if it is against the Union (alone or with other entities), it must be filed in the Federal Court, being judged in the first instance by a state or federal judge, respectively. Also, according to Madalena, it is the legal representative (lawyer, public defender or prosecutor) of the plaintiff who decides who will be the defendant or defendants, and may go against one, two or three entities of the federation.

Madalena stressed that even if the prosecutor were not the representative of the action, they need to manifest themselves, as they are the in-
Figure 1. Flowchart of the judicialization of access to medications in the State of Santa Catarina, 2018.

Legend:

Defesa do Estado de Santa Catarina (Defense of the State of Santa Catarina); Assessoria ao Judiciário (Support for the Judiciary).

Source: prepared by the authors, based on Ronsein4, Pereira11, documents and interviews.
spector of the law, since all lawsuits that deal with health have to go to the MPSC (Figure 1). The prosecutor analyzes the person’s lack of assets, whether the requested drug is or is not provided by the SUS, among other criteria. Also, according to Madalena, based on this finding, they [the prosecutor] will manifest in favor or against the provision of that treatment. The judge has a free decision, that is, they may be against the MP’s manifestation, since the decision will be taken after hearing the three instances: the plaintiff, the prosecutor and the defendant (or the defendants). When the State is the defendant in the lawsuit, the PGE/SC works as the defense (Figure 1).

As this is a health issue, a precautionary action is proposed with a preliminary injunction or interlocutory relief 26, due to the urgency. In this context, the first instance court judge must assess the merits of the lawsuit and issue a judgment, which may confirm the injunction or interlocutory relief or revoke the injunction 26. In case of rejection, the citizen has the right to appeal to the Court, using the appeal called “interlocutory appeal”, to insist on the request and obtain the medication. The Federal Regional Court (TRF, Tribunal Regional Federal) or the TJ/SC will consider the appeal if, respectively, the defendant is the Federal Government or the State and/or Municipality. The TRF or the TJ/SC can decide to maintain the injunction or to cancel it. This decision can be appealed again, this time to the STJ. If it constitutes an infringement against the Federal Constitution, an appeal to the STF 26 can be used (Figure 1).

Once the sentence is granted, the process is received by COMAJ, which forwards it to GP-LAD for programming and acquisition, subsequently forwarding it to GEJUD for storage and distribution logistics and, subsequently, the company transports it to GERSA and/or the Municipalities, which finally dispense it to citizens (Figure 1).

Conclusions

The judicialization of health has grown exponentially, forcing the State Executive, the Judiciary and the Essential Functions of Justice to (re)organize themselves to meet this demand.

In the Executive, the main changes took place in the SES/SC, with a restructuring that removed the court from DIAF in 2013, creating the GEJUD, specific for this demand. The NAAJ was also created, which was replaced by the COMAJ, with similar roles in judicialization cases. The database with information on medications was improved, with access to the Judiciary and other organs involved with judicialization. Another service implemented was the NAT-JUS, which has the strategic role of supplying magistrates with information and data based on scientific knowledge. Some regulations were approved, such as the Decree that obligates public servant physicians and dentists to prescribe medications from the official lists and the Ordinance that holds the Regional Health Manager accountable. Most of the changes adopted by the Executive, therefore, aimed to organize the work flow generated by the growing number of lawsuits.

In the Judiciary, the main contributions were the statements and recommendations of the Public Hearing, the Journeys on the Right to Health and the Health Forum, with the direct involvement of the STF and the CNJ, which had an impact on measures adopted in the state of SC (such as the NAT-JUS and COMESC, among others). It is also worth mentioning the IRDR provision of the Civil Lawsuit Code, absorbed by the TJ/SC.

Regarding the Essential Functions of Justice, the PGE/SC created the NARAS, consisting of prosecutors engaged in the dialogue with judges. The MPSC organized itself aiming to act upon receipt of the citizen’s request or at the time of acting as a legal supervisor, with the help of the Operational Support Center for Human Rights and the Third Sector.

This study indicated that the phenomenon of judicialization of access to medications in SC is yet to be resolved, because even with all the implemented measures, the expenses with lawsuits have continued to grow since the beginning of the 2000s. It is crucial, therefore, that public entities continue to improve their measures to better address the judicialization.
Collaborations

CR Caetano participated in the study design, data collection and analysis, drafting of the first version of the manuscript and final version review. FC Matheus worked on the review and final version of the manuscript. EE Diehl participated in the study design, data analysis and worked with the review and final version of the manuscript.

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