Revista Bioética
ISSN: 1983-8042
bioetica@portalmedico.org.br
Conselho Federal de Medicina
Brasil

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(Des)judicialização da saúde: mediação e diálogos interinstitucionais
Revista Bioética, vol. 25, núm. 2, 2017, pp. 290-300
Conselho Federal de Medicina
Brasília, Brasil

The de-judicialization of health: mediation and interinstitutional dialogues

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Abstract

Based on an examination of legislation, jurisprudence and doctrine, the usual path of requests for medicines in the Sistema Único de Saúde (Unified Health System) is analyzed, with a focus on requests falling outside the Relação Nacional de Medicamentos Essenciais (National List of Essential Medicines). The usual approach, where the only solution to a negative response is the filing of lawsuits, overloads the system, increasing complexity and causing iniquities. In this context, the present article aims to rethink this approach through non-judicial mechanisms of conflict resolution. Based on the premise that judicialization is neither born nor ends in the judiciary, measures to "de-judicialize" health are considered: the adoption of mediation chambers outside the protocols of the Unified Health System and prior to judicial demands; the reinforcement of interinstitutional dialogue between entities such as the Defensoria Pública (Public Defender's Office), the Ministério Público (Public Prosecutor's Office), the Secretaria de Saúde e Núcleos de Apoio Técnico dos tribunais (Health Department) and the Núcleos de Apoio Técnico (Technical Support Centers) of the Courts; and the expansion of non-judicial channels, facilitating access, reducing non-treatment expenditure, and improving public health.
Keywords: Judiciary. Public health. Judiacialization of health. Health care evaluation mechanisms.

Resumo

(Des)judicialização da saúde: mediação e diálogos interinstitucionais

Partindo do exame da legislação, jurisprudência e doutrina, analisa-se o trajeto usual dos pedidos de medicamentos no Sistema Único de Saúde, enfatizando-se solicitações fora da Relação Nacional de Medicamentos Essenciais. O roteiro usual pelo qual a única resposta às negativas é a propositura de ações judiciais onera o sistema, torna-o complexo e potencializa iniquidades. Nesse contexto, procura-se repensar essa sistemática partindo de mecanismos não judiciais de solução de conflitos. Com base na premissa de que judicialização não nasce no judiciário e nele não termina, consideram-se medidas para "desjudicializar" a saúde: adoção de câmaras de mediação além do protocolo do Sistema Único de Saúde e antes das demandas judiciais; reforço do diálogo interinstitucional entre entidades como Defensoria Pública, Ministério Público, Secretaria de Saúde e Núcleos de Apoio Técnico dos tribunais; ampliação das vias não judiciais, facilitando o acesso, reduzindo gastos não destinados ao tratamento e aprimorando a saúde pública.
Palavras-chave: Poder judiciário. Saúde pública. Judicialização da saúde. Mecanismos de avaliação da assistência à saúde.

Resumen

(Des)judicialización de la salud: mediación y diálogos interinstitucionales

A partir del examen de la legislación, la jurisprudencia y la doctrina, se analiza el trayecto usual de los pedidos de medicamentos en el Sistema Único de Salud, con énfasis en las solicitudes por fuera del Listado Nacional de Medicamentos Esenciales. El itinerario usual, a partir del cual la única respuesta a una negativa es la proposición de acciones judiciales, torna costoso al sistema, lo vuelve más complejo y potencia las inequidades. En este contexto, se procura repensar esta sistemática partiendo de mecanismos no judiciales de solución de conflictos. Asumiendo que la judicialización no comienza ni termina en el Poder Judicial, se consideran algunas medidas para "desjudicializar" la salud: la implementación de cámaras de mediación además del protocolo del Sistema Único de Salud, previo a las demandas judiciales; el reforzamiento del diálogo interinstitucional entre entidades como la Defensoría Pública, el Ministerio Público, la Secretaría de Salud y los Núcleos de Apoyo Técnico de los tribunales; y la ampliación de las vías no judiciales, para facilitar el acceso, reducir los costos en gastos no destinados al tratamiento y mejorar la salud pública.
Palabras clave: Poder judicial. Salud pública. Judicialización de la salud. Mecanismos de evaluación de la atención de salud.

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Declaram não haver conflito de interesse.

Creativity is intelligence having fun
Albert Einstein [1]

The usual route for the provision of medications implies, in practice, that the only alternative to the denial of a request is the judicial process. The present study seeks to analyze the legal structure that has led to this situation, and to identify strategies that can provide concrete alternatives to de-judicialization. It does not intend to rule out, in any way, the use of lawsuits to discuss access to health.

What is proposed is a rethink regarding the lack of alternatives to a system in which medications, which are not listed in the Relação Nacional de Medicamentos Essenciais - Rename (the National List of Essential Medicines), are necessarily denied by health agencies, without room to analyze the singularities of the therapeutic project in question.

This situation emerged from a wider process. The redemocratization of Brazil, which brought with it a resignification of the concept of citizenship, established a wider right to health in constitutional form. Furthermore, the resignification of the concepts of health and disease [2,3] brought new aspects to the debate about their meaning and reach. In this sense, the concept of health as *physical, mental and social well-being, not merely the absence of disease or infirmity* [4] is key, recommended in the Constitution of the World Health Organization, adopted in Brazil through Decreto 26.042/1948. [4]

In this sense, Article 196 of the Brazilian Federal Constitution [5] sets out what is determined in Article 25, item 1, of the *Universal Declaration on Human Rights* [6] in dealing with universal access to health. In fact, the Organic Health Law, Law 8.080/1990 [7], guarantees access to treatments, including the supply of medicines. Far from implying an absence of cost, the structuring of a system that is accessible to the user represents a significant portion of the budget. These transitions have also generated a change in people's view of the judiciary, giving it a prominent role in this transformation of access to health care and services, which has contributed to intensifying the phenomenon of the jurisdictional presence in health [8,9].

The theme raises numerous and necessary debates and follows diverse vectors, as has been described in diverse doctrinal writings [8] and reiterated judicial decisions. From the point of view of effectiveness and reality, the limits of the right to health are questioned, and require constant revision, whether due to the rapid modification of medical and pharmaceutical techniques or by the expansionary nature of fundamental rights [10]. These characteristics imply both the magnification and the perception that these tasks should be carried out gradually, as a continuous construction [11].

Among the most present discussions or arguments are: the impact of these demands on the public budget, disagreements over how to spend and manage resources, cost increases, the reservation of the possible [12-14], provisions for judicial measures and the existential minimum. As is said with simplicity but wisdom, *health is priceless, but has a cost*, which makes the debate about its extent a constant challenge. Thus, the expansive vocation of the right to health requires a constant rethinking of its meaning and limits.

In the operational field, there has been an increase in the rigor, scientificity and organization of the system, with the importance of the Comissão Nacional de Incorporação de Tecnologias - Conitec (National Commission for the Incorporation of Technologies) in the Sistema Único de Saúde - SUS (the Unified Health System), dealt with in Article 19-Q of the Organic Health Law [7]. Significant progress has been noted regarding the factual realization of access to health by judicial means, with the concreteness and timeliness of decisions favorable to the patient avoiding the loss of rights and ensuring effective protection [15]. Nevertheless, it is possible to perceive repeated excesses in the granting of such decisions, due to the lack of decision-making criteria (or the inattention in their application) [16], which compromise public property and the right to health itself [17].

Given this scenario, it is essential to examine the current procedure of access to the health system. In summary, there is an administrative request that culminates in the provision or refusal of the medicine or treatment, often based on the criteria of competence (the indication that another entity is responsible) or non-coverage under the standard protocol, without offering alternatives to the patient, even if falling within said protocol. It should not be forgotten that the patient and his/her family members may have little access to knowledge of the legal situation or bureaucratic procedures and even less so in relation to the clinical situation.

In order to rethink the system, judicial decisions, current legislation and doctrine were analyzed, seeking to explain how to promote (or deny) access and present alternatives. In summary, the study proposes a kind of escape from the judiciary through direct access, mediation and

interinstitutional dialogues. It seeks to avoid judicialization, especially in the following cases: 1) where the medicine is included in Rename (when approval is mandatory); 2) the cost of the treatment is low and its efficacy is easily demonstrated; 3) there is an alternative therapeutic option that fully meets the request of the patient, such as medicines with the same active principle (generic) that vary only with respect to their commercial name; 4) the use of the Núcleo de Apoio Técnico - NAT (Technical Support Center) of the courts or the database of the Conselho Nacional de Justiça - CNJ (National Justice Council) allows a resolution to be reached prior to legal action through the absolute adequacy of the request.

This adaptation may even include medications outside the standard list, respecting certain criteria, which may involve cost-effectiveness, the in-progress analysis by Conitec, recognition by the Agência Nacional de Vigilância Sanitária – Anvisa (Brazillian Health Regulatory Agency) or the lack of an alternative.

Now is the time to think about creative mechanisms that coherently allow access to health and the protection of the public, beyond the judiciary, through instruments of de-judicialization that harmonize individual and collective interests, protecting the budget, access and the necessary urgency of health care.

Essential medications and those not included in Rename

Obtaining medications under the SUS, as a general rule, presupposes a patient served by the public network with a prescription from a public health system professional. This is the rule, although it is often ignored by the judiciary in some districts, both in the federal and state courts. Despite the efforts to structure the system, the volume of health-related actions has increased. This challenge motivated the CNJ to organize so-called "Jornadas de Direito da Saúde" (Health Law Conferences), which sought, among other measures, to distance themselves both from a bureaucratic profile that envisioned an exuberant quantity of procedures and from the naive humanism that ignored the coda that *health is priceless, but has a cost*.

Exemplars of this maturation include: 1) the adoption of the requirement of the periodical renewal of the medical report of continuous treatments [18] based on the structural nature of the decisions that affect it, and the preference for medicines registered by Anvisa; 2) the exceptional character of drugs that are not part of the SUS protocol (non-protocolized); 3) the implementation of the NAT to assist magistrates through expertise in health.

However, these efforts have not completely resolved the issue, and the decision to seek legal redress remains focused on the refusal of the Ministry of Health and state and municipal health departments to provide certain specific drugs and treatments. Under the current regime, public health administrators cannot provide medicines outside the Rename protocol. This results in all situations without access to treatment being directed towards the judiciary, such as that of a patient who has exhausted the usual alternatives (either due to health limitations or through not employing them); citizens who have been denied procedures and medicines that appear in Rename; and completely unsuitable cases.

In other words, a system has been structured in which the judicial route becomes as natural as it is indispensable when faced with any denial, regardless of its nature or pertinence. If in the administrative sphere criticism is focused on limitations, in relation to the work of the judiciary the concern is very often based around the potentially excessive granting of permission, and the virtue of the middle ground has been the subject of intense debate. In fact, judicial decisions are often made so that laws and ordinances are overridden in order to benefit the specific need of a particular patient.

From the perspective of Arenhart [18], these challenges reach as far as the budget, with emphasis on non-compliance with the Law of Fiscal Responsibility, the underfunding of health, and confusion between the floor and ceiling of health contributions. In consideration of the precepts of equality, impersonality and even for organizational purposes, there is (or should be) a preference for dispensing drugs that are part of the SUS protocol. However, in view of the specialist nature of the right to health, the supply of drugs outside Rename has been judicially determined, in a subsidiary manner, where it is demonstrated that the protocol instituted by the SUS is inexistent, ineffective, incompatible or exhausted, in terms of the feasible and reasonable requirements of the patient.

Along these lines, Summary 101 of the Tribunal Regional Federal da 4ª Região (Federal Regional Court of the 4th Region), published in 2016, establishes that for the *judicial granting of health benefits not included*

 http://dx.doi.org/10.1590/1983-80422017252189

in a pre-established protocol, the prescription of the attending physician is not enough, and the production of evidence attesting to the appropriateness and necessity of the request is necessary [19]. Considering that the patient is obliged to demonstrate the insufficiency of the clinical protocols, the judicial decision must attenuate and justify the exceptionality. This is the meaning of the jurisprudence of the Supreme Federal Court, as illustrated, for brevity, in comparison with the following:

Regulatory appeal in extraordinary resource with appeal. Administrative. Provision of medication. Joint responsibility of federated entities. Reaffirmation of case-law under the system of general repercussion. RE 855.178-RG. Supply of medicine outside SUS list. Possibility. Offense to the principle of separation of powers. Non-occurrence. Regulatory appeal disproven [20].

In line with this, Statement 4 of the I CNJ Health Law Conference emphasized that *Protocolos Clínicos e Diretrizes Terapêuticas – PCDT (Clinical Protocols and Therapeutic Guidelines) are organizing, not limiting, elements of pharmaceutical delivery. Thus, in the specific case, when all the therapeutic alternatives foreseen in the respective PCDT have already been exhausted or are unfeasible to the clinical situation of the SUS user patient, according to the principle of art. 198, III, of the Federal Constitution, the supply by Sistema Único de Saúde – SUS (National Health System) of the non-protocolized drug can be judicially determined* [21].

This means that, in the current institutional configuration, the judicial route becomes the rule to obtaining medicines outside the protocols of the SUS, requiring the costly proceduralization of all involved: the judiciary, public health administrators and the patient, an economic and conjunctural effort of expressive complexity. The Judiciary assumes a new responsibility, that is, of structuring itself with technical personnel to provide opinions, expertise and analysis that will serve as a support to the decision. That is to say, not only the interpretation of the order, but the verification of certain concrete elements linked to the patient's profile and the treatment that is expected to be obtained.

In turn, the public health administration depends on a complex structure to acquire, store and make medicines available. It should also organize procedures for the application and effectuation of treatments. When it comes to medicines outside the protocol, the difficulty of operationalization is a challenge that cannot be overlooked. The patient must bear, in addition to the financial cost, the time burden required to obtain treatment, which is not always quick, even with the protection of the grant of judicial urgency. The current procedure entails the overlapping of assessments made independently and often devoid of dialogue.

Even when the patient possesses a report from a SUS professional, a new evaluation is made by the Secretaria de Saúde (Health Department), (before the denial), followed by the opinion of the NAT attached to the Court and a further expert opinion, all to achieve the same purpose for the same patient. The municipal, state and federal prosecutors, in turn, cannot simply agree to the requests, regardless of the patient's documents or even the costs of the drugs (unlike, for example, tax foreclosures whose low value allows the state to refrain from action), allocating resources, then, to (re)discussing the treatment.

This flagrantly bureaucratic *modus operandi* generates a waste of resources, a distrust of the system and the prescribing doctor and disregards the costs of the judicial action itself [22]. All the complex and official procedure for dispensing drugs and treatments through the judicial process generates substantial expenditure of time and financial costs absolutely disproportionate to the interest of the public and private individuals who need to settle their interests in litigation. This analysis becomes even more complex when it is noted that most of the claims are upheld [23]. In other words, it is vital to locate elements and modes of action that aim to access health services without having to move the entire machine of the judicial system - and the equally complex administrative system - created by resistance to the agreement between patient and public service.

The conflict of interest that arises from this impasse needs to be equilibrated to facilitate resolution for both sides. It is necessary to reflect on shared limits and possibilities aimed at the non-judicialization of health, and the possibility of decisions without the presence of the Judiciary. A joint approach is necessary, without unreasonable resistance, to reach an adequate, coherent and just route to the implementation of article 196 of the Constitution [5].

Proposals to tackle judicialization

Summarizing some essential points, the description of the current model allows us to observe a number of symptoms: 1) the prevalence of a judicial solution in the face of refusals, with a

large number of individual actions [9]; 2) high costs not related to structured treatments within the system; 3) the time burden on the availability of the drug or treatment; 4) insufficient dialogue between public and private entities and between different spheres of public administration; and 5) overlapping of independent medical assessments.

From this perspective, it is possible to think of adjustments that can contribute to improving the health system, which is already much more structured than it was during the drafting of the Organic Health Law. Four situations can be identified based on some of the objective suggestions expressed in this article. First, the need to consider that judicialization (here taken as the excessive flow towards the Judiciary) cannot be tackled only within the Judiciary, since judicial actions are a consequence, not the cause itself. On the other hand, as they say in the health area, they are side effects:

A strategy used by the Judiciary in some districts has been extrajudicial action, which extends the possibilities of its action and the realization of the right to health. This makes it possible to consider the idea of the juridification of social relations (conflicts are discussed from the legal point of view), without judicialization necessarily occurring (at best, it avoids bringing conflicts to the Judiciary). As a result of this action, a valorization of dialogue is observed, in order to generate effective actions in the referral and resolution of conflicts. In addition, it contributes decisively to the establishment of a judicial health policy [24].

Moreover, to think only of conciliation before or during the process, but effected within the scope of the judiciary, at a preliminary or post-trial stage, in a hearing for this purpose, for example, obviously does not avoid the activation of the legal machine that one wishes to keep on the sidelines of the discussion. In order to achieve the objective here proposed, the possibility of administrative spaces that specifically evaluate the concrete cases of patients and can assess the need (or not) to release treatments outside clinical protocols should be borne in mind.

These spaces for extrajudicial debate should preferably rely on the participation of the Public Prosecutor's Office, the Federal Public Defender's Office and the entities involved in the supply of procedures and drugs. This perspective is aligned with the national policy of encouraging self-determination, which is based on CNJ Resolution 125/2010 [25], whose purpose is to promote a fair legal order based on public policies for consensual solutions to conflicts. With the same intention, the Conselho Nacional do Ministério Público – CNMP (National Council of the Public Prosecutor's Office) issued CNMP Resolution 118/2014 [26].

Administrative mediation in the area of health has shown itself to be a viable and interesting alternative [27]. Even if, in the absence of resolution, the elements produced can form part of the judicial action. This is contrary to the usual procedure, in which the analysis of the Health Department does not properly integrate with the analysis of a legal judgment, except for the letter of refusal that does not always explain the issues, often concentrating only on the absence of the provision of the medicine within the clinical protocol.

An example is the "SUS Mediado" (Mediated SUS) project, launched in 2012 in Rio Grande do Norte, which brings together the Defensoria Pública Estadual (State Public Defender's Office), the Procuradoria Geral do Estado (State Attorney General's Office), the Secretaria de Saúde Estadual (State Health Department), the Defensoria Pública da União (Federal Public Defender's Office), the Procuradoria Geral do Município de Natal (Attorney General's Office of the Municipality of Natal) and the Secretaria de Saúde Municipal (Municipal Health Department). In short, the format of the project is that:

The mediation sessions for administrative resolution of the health issues covered by the program take place every Wednesday through a Conciliation Chamber, composed of a pharmacist, a doctor, a State Public Defender, a representative of the State and the Municipal Attorney General's Office and the person receiving care, who meet at the Headquarters of the Public Defender of the State with the primary purpose of solving the demand extrajudicially, guaranteeing the concrete realization of the right to health. Also, through this program, the citizen who has not had his or her case resolved in the extra-judicial sphere is ensured of the possibility of opposing through his own judicial action, through a State or Federal Public Defender, to bring his or her rights into effect [28].

Similarly, in 2013, in the Distrito Federal, the Câmara Permanente Distrital de Mediação em Saúde – Camedis (Permanent District Chamber of Health Mediation) was created to assist in the reduction of lawsuits. According to the Conselho Nacional de Secretários de Saúde (National Council of Health

 http://dx.doi.org/10.1590/1983-80422017252189

Secretaries), *the growth in the number of lawsuits filed within the scope of the* Secretaria de Estado de Saúde do Distrito Federal - *SES/DF* (the State Health Department of the Distrito Federal) *is approximately 30% each year* [29]. Joint Ordinance 1/2013 defines, in article 2, that the institutional mission of Camedis to find solutions to the demands for health products and services, with the purpose of avoiding lawsuits or proposing solutions to those in process [30].

From this agreement, it was defined that, before the request, the Health Department verifies if the medicine is included in the SUS protocol. If it does not appear, a therapeutic alternative is offered, which allows citizens to participate more actively in the decision-making process, letting them distance themselves from litigiousness, one of the obvious causes of judicialization. The culture of litigiousness is still highly present in Brasilia, as is, as a consequence, the adversarial model of the judicial process in the realization of the right to health.

However, the results already achieved allow us to understand Camedis as a promising out-of-court strategy. This Chamber focused on three major institutional measures for the realization of the right to health: to strengthen space for institutional dialogue starting with the District Committee; constitute a framework for the consensual resolution of conflicts in health; and empower citizens through consensual solutions [31].

In Rio de Janeiro, it was defined as a protocol that the Public Defender's Office, responsible for a significant portion of legal actions regarding medications in the state, should previously consult the state and municipal secretariats in an attempt to obtain such medications through the administrative route. If this is not feasible, legal action can be taken. In the same state, in agreement between the State and Municipal Health Departments and the Rio de Janeiro State Public Defender's Office - the body responsible for most of the medication requests in the state - established a flow that facilitated the supply of medicines. Based on this consensus, the procedure adopted was:

When the patient wishes to file a suit for medication or health supplies under state or municipal jurisdiction, the Office of the Public Defender's Office should request a medical report from the Unified Health System and before filing the action should send a letter to the federative entities questioning whether the requested item is available. If the state and/or municipality has the drug or supply, they should contact the patient and schedule its delivery, communicating the fact to the Public Defender's Office. Only in response to the negative response of public entities should legal action be proposed [32].

The rapprochement of entities is fundamental, and dialogue among administrators greatly facilitates the gradual change of public policies. These interfaces allow us to better understand and address the origins of the problem, including rethinking government strategies. It is even possible to take advantage of previous experience of cases in which drugs and treatments were later granted in court, with sufficient grounds, to change public policies. It is not a matter of supporting rampant judicial activism, but of re-establishing the dynamic character of checks and balances. It is a question of distinguishing activism from judicialization, due to their obvious philosophical peculiarities [32].

In this regard, Amaral [10] recommends that individual judicial demands be used to rationalize the system: *if the Judiciary, instead of replacing the decision of the public agent with its own, demands from the former the rapid justification of its choices and procedures and, by the end of this deadline, evaluates the reasons given, although not necessarily abiding by them, perhaps a great step is being taken towards a greater realization* [33].

The very possibility of procedural legal antecedents can serve as a valve to consider the procedures comprehensively, according to article 190 of the Código de Processo Civil – CPC (Civil Procedure Code) 34. On the feasibility of a legal transaction involving the Public Prosecutor's Office and the Fazenda Pública (Treasury), Statements 253 and 256 of the Permanent Forum of Civil Proceduralists is recommended reading [35].

Today, access to justice no longer follows the "quantitative" style, which originated in the "Florence Project" of 1973 under the guidance and leadership of Cappelletti [36], which sought to facilitate the judicialization of pretensions, preventing parties from failing to assert their access to the judiciary to secure their rights. This took place in the reforms of the CPC of the 1990s, and especially with the creation of the special courts.

The process should be instrumental, with it falling to the judge alone to consider the application of the (uniform) values of society, and perhaps even making alternative use of the law [37]. This led to flagrant exhaustion of the conditions of the judiciary to meet the minimum intentions within a suitable time and conditions. A potentially effective route, which is spelled out in the new CPC, is that of

"qualitative" access to justice [36] which considers not only the proper results of the process, but also the satisfaction of the claims through extrajudicial and consensual channels of action.

Secondly, based on the premise that judicialization does not begin or end with the judiciary, what can be called "inter-institutional dialogues" should be encouraged and put into practice. There is currently a chasm between the various spheres involved in the procedure: the patient must obtain a prescription from the SUS doctor, which is then considered by a doctor of the NAT. Next, the same is evaluated by an expert physician, and there is also the possibility of the prescription being conferred by more than one SUS doctor. The redirection of this model, in order to avoid overlapping of actions and to confer differentiated credibility to the doctor within the judicial sphere, seems to be more in line with constitutional precepts.

It is not only this. In the extra-judicial sphere, with the creation of mediation chambers and procedures, the theme will be treated in a multidisciplinary manner by the diverse framework of legal decisions that make up the SUS, with the possible participation of the Public Prosecutor's Office. The inter-institutionalization of the procedures, in relation to the (extrajudicial) consensual resolution of the conflicts, will give greater security to public entities and facilitate the access to health by the population. This will require goodwill and cooperation among those involved.

It is not coherent to imagine that the combination of efforts leads through different means to the best decision-making technique for the dispensation of health. Once several experts have evaluated the concrete situation, the result tends to be to use the best technical-scientific decision to adapt the treatment to the individual, allied to the reasonable cost that is bearable by the system, with the urgency depending on the peculiarities of each case.

Thirdly, the measures of access to health involving intellectual property law have not yet been sufficiently observed. It should be remembered that the law provides for possibilities such as compulsory licensing, that is, acquisition through payment, unfortunately confused with some form of expropriation, hence the frequent use of the term "patent infringement". Finally, as a fourth element for reflection, the question of the costs of public health provision in the current model is considered. With the increase resulting from judicialization, public entities have been obliged to create large and costly structures to comply with orders resulting from judicial decisions.

Budgets were utterly torn apart due to the impossibility of forecasting the amounts to be spent through these determinations arising from judicialization. The costs of legal actions are exorbitant at all levels, from the values of the health procedures themselves to amounts such as late fees, costs, lawyer payments and the other costs of legal action. Undoubtedly, it would be less costly to offset these expenses by converting part of the existing structure to the creation of centers for the consensual evaluation of public health action requirements.

Health expenditures, which are already high, should focus mainly on the costing of treatments, concentrating on investment directly linked to health and, where possible, prevention. It is also necessary to increase primary health care, as opposed to the judicial process.

In addition, it is necessary to consider the cost of the system in relation to the demand and the costs of judicialization themselves. Extra-judicialization therefore constitutes a relevant channel for reallocating resources. Reducing judicial litigation leads to the saving of public resources, concentrating expenditures on the real objectives of public policies (health), and promotes the most important matter: better care for people in need of health services.

Extrajudicial chambers for mediation of health procedures

Initially, four premises were briefly developed: avoid the judiciary; dialogue between SUS administrators; medication procurement techniques through compulsory licensing (which many insist on designating "patent infringement"); and consideration of structural costs.

From these, it may be possible to formulate a proposal for reflection on a possible method for structuring a consensual and out-of-court solution to conflicts involving public health at state and municipal levels. It is perfectly feasible to preemptively solve many of the issues that currently end up being handled by judicial measures based on the common effort of those involved in yielding, where appropriate, to obtain the relevant benefit intended. In this sense, Carlini suggests:

 http://dx.doi.org/10.1590/1983-80422017252189

Conflict resolution by non-judicial mechanisms can be interpreted as a sign of the maturity of an organized society, because it attaches importance to dialogue and the weighing of arguments rather than the search for a solution dictated by magistrates who will not always have the objective conditions to take into account the impact of their decision on the whole of the public or private society [38].

It is possible to discuss processes that reassess the possibility of administrative measures for health procedures not provided for in the SUS protocols. One of the tools is to structure "mediation chambers" and health procedures, composed of multidisciplinary teams, within the state and municipal structures. The participation of a representative of the Union - with the function of analyzing requirements regarding health actions that are outside the possibilities described in the clinical and therapeutic protocols of the SUS - should also be considered.

After the rejection of the administrative requests issued to the Secretaries of Health, the chambers will come into play. These entities will carefully analyze the procedures, evaluating the possibility of granting - independently of the judicial process - the health actions required and justifiably denied.

The rejections can be reanalyzed from criteria that are more legal than clinical (medical or pharmacological), objectively involving concrete cases. In other words, the time, money and other resources that would be applied to the work of legal proceedings will be substituted by probative production and the administrative decision will replace that would be reached in the courts. To do so, two operational measures must be adopted: 1) constitution of the chamber and its personnel structure; 2) details of procedures.

Establishment of the mediation chamber and health procedures

The creation of the chambers can happen in federal, state or municipal administrative spaces, according to the demands of each federative entity. The most appropriate approach is that these will be structured from the existing organization that manages the treatment of the results of the lawsuits, through the experience of the employees and the appropriate structural arrangement.

Equally propitious would be representatives of the State and Municipal Health Departments, the *State and the Municipal Attorney General's Office*, the Ministry of Health, the Advocacia-Geral da União - AGU (Brazilian Office of General Attorney), the Public Prosecutor's Office and the public defender's offices. In addition, of course, to experienced medical practitioners such as experts and representatives of the NAT.

It is not, therefore, intended to ignore the advances achieved, but to incorporate them, by considering whether the judicial route will be indispensable when the substantive discussion depends on medical aspects. Nevertheless, considering the equally practical interest of this trial, the easiest and most urgent approach could be the creation of these chambers by the states and municipalities within their judicial prosecutor offices, with the participation of qualified professionals from the Health Departments.

This is because the intention at this moment is more about the legal analysis of the feasibility of preventing litigation than the health specialties themselves. Thus, it seems coherent to suggest that the team formed for this purpose focuses on the legal technique, in the sense of analyzing compliance with the settled or majority decision criteria that have guided judicial actions in the granting of verdicts, reaching, in advance and preventatively, administrative measures that "save" those involved in typical litigation.

Standardization and detailing of procedures

The structuring of an extrajudicial system aims to overcome the "system of all or nothing", that is, where either the protocol of the SUS is followed or legal action is sought. If, on the one hand, the change of rationality is significant, its implementation does not require profound changes. The start of the path remains the same, beginning with the request for release of the treatment by the patient. What changes is the second step, where, faced with a negative response, the individual does not directly seek legal action. What is suggested is a complete chamber composed of representatives of all the public entities involved in public health measures.

This would assume the status of an extrajudicial assessment panel, which is responsible for analyzing the factual situation in the light of the needs and singularities of the patient, described in the medical record and prescription of a SUS health professional, or, if justified, by a private physician. The exceptional request - after the refusal of the Health Department - that authorized the procedure described herein being sought must be accompanied by all documents and elements that

serve as proof of the modification of the previous decision. In addition, they must follow NAT opinions, CNJ recommendations, health committees, settled jurisprudence (or known majority) of the courts, among others.

Upon such request and documentation, the collegiate shall defend or administratively revoke the exceptional request, by means of a reasoned decision. If it is considered pertinent, the interested patient will be allowed to produce other tests. If further opinion is required, the collegiate may refer the case to an official doctor for demonstration. Valuing extra-judicialization, let it be clear, does not contradict the constitutional right to a lawsuit. The development of mechanisms that facilitate the evaluation of singularities, without prejudice to the evaluation of medical foundations, does not make the judicial sphere indispensable.

Even if a lawsuit is subsequently lodged for the same reason, it will be based on the appropriate evidentiary content, falling within the due administrative procedure, which will allow a fair and technical debate within the judicial process. It is reasonable, however, and also advisable, that where possible the suggested chamber be created in state and municipal prosecutor departments, as these state representatives deal with judicialization and its results on a daily basis. The Chamber of Mediation and Health Procedures shall be created by law or substantiate its actions in existing law, due to the necessity of the handling and destination of public funds being specified in this normative structure.

Final considerations

The increasing volume of lawsuits in health is notorious. It is considered that part of the problem is in the way the system has been organized, adopting imperative treatment protocols, which, while on the one hand are fundamental to the organization of the system, on the other, drive judicial actions. In the administrative sphere, the system coexists in large part with the reduction of possibilities (the "administrative request, refusal, lawsuit" that no longer applies). In general, either the patient follows the usual protocol or cannot have their request met, even when the therapeutic alternative offered is not suitable due to being exhausted, inappropriate, insufficient or ineffective.

There are solutions to the judicialization of health, but they require the acceptance of criticism of the phenomenon in its multiple meanings in a constructive manner. The frequent argument regarding the separation of powers gives way to the appreciation of the "checks and balances" [39] and the dialogues between different entities, forming genuine service networks. The usual censorship of the Judiciary's interference in public policies is not resolved by the impossibility of access to the judicial sphere, but by the provision of real and concrete alternatives.

However, it is not intended here to deconstruct the existing system, nor to reject NAT or other current mechanisms. What is recommended is a new step that filters medication cases outside the protocol, but with lower costs and proven effectiveness. Recognition of the right to a given treatment, both at the administrative level and at the judicial level, depends on the specific situation of each patient. Emphasizing prescriptions, even outside the protocol, values fundamental filtering that, as shown, will not prevent access to judicial channels. On the contrary, it will make it more qualified.

It is also worth commenting on the important repercussions to the question of access to medical treatment in the higher courts. The First Section of the Superior Tribunal de Justiça - STJ (the Superior Justice Court), in assessing special appeal no. Resp 1657156/RJ, considered the need to apply the case to the system of special repeals [40], that is, to establish a solution that could be applied to several cases in which the same legal matter is discussed. In a matter of order presented at the trial session dated 05/24/2017 and published in the Diário de Justiça (the Justice Gazette) dated 05/31/2017, the topic to be debated was designated "The obligation of public power to provide medicines not incorporated in normative acts of the SUS" [41]. In addition, the national suspension of all outstanding cases, individual or collective, on the matter, was determined, except for urgent matters on the supply of medicines.

It is considered that the SUS protocol is preponderant in character, but it should not be taken as having a limiting role of access to health. Access outside the SUS protocol requires, in an essential manner, adequate proof of the need and specific justification of each clinical case, such as the hypothesis of the non-existence of a therapeutic alternative in the SUS, or the failure, incompatibility or impossibility of continuity of drug use adopted in public policies.

It is also important to emphasize that the Supremo Tribunal Federal - STF (Federal Supreme Court) is currently discussing the "duty of the state to

provide a high-cost drug to a person with a serious illness who does not have the financial conditions to purchase it." This is an equally central question [42]. Among other aspects, it is considered central to investigating the very meaning of high cost and its confrontation with other elements. This sets the challenge of the collation of multiple factors, including survival time, risks, presence of palliative character, the existence of alternatives and their effects (including collateral).

To conclude, it is useful to offer a simple recommendation: *the more the doctor justifies his opinion, the less medical the judge needs to be*. Challenges are set and traditional solutions should not be overlooked. One cannot deny the insufficiency of the current model, the potential for new solutions, the great possibilities of using (more) adequate forms of conflict resolution, and the need for a joint effort to adopt effective remedies for the realization of the right to health.

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Participation of the authors

The authors participated jointly in all the stages of the creation of the text, including its conception, bibliographic research, and the writing and revision of the article.

Recebido: 4.11.2016
Revisado: 10. 3.2017
Aprovado: 8. 4.2017