Lawsuits in health: an integrative review

ABSTRACT
Objective: To analyze the national and international scientific evidence available in the literature on types of judicialization of health lawsuits. Method: Integrative review, which selected primary studies in the PubMed, LILACS, Web of Science and Scopus databases, with the Descriptors: judicial decisions, health's judicialization, Saúde (in Portuguese), Health, and the keyword: Judicial Action. Results: 30 studies were selected. In Brazil, the majority were legal claims for medicines and the other for medical errors, requests for vaccines, supplies for diabetics, food compounds, surgical procedure, examinations, among others. In international studies, lawsuits were found for medication, benefit coverage and hospitalization for psychiatric treatment. Conclusion: It is evident that the most demanded type of lawsuit was access to the medication at an international level. It is still more noticeable the little discussion on this subject, demonstrating that judicialization of medicines can indicate a reality of Brazil.

Descriptors: Health's Judicialization; Judicial Decisions; Health; Right to Health; Public Health Policy.

RESUMO
Objetivo: Analisar as evidências científicas nacionais e internacionais disponíveis na literatura sobre os tipos de ações de judicialização da saúde. Método: Revisão integrativa, que selecionou estudos primários nas bases de dados PubMed, LILACS, Web of Science e Scopus, com os Descritores: decisões judiciais, judicialização da saúde, Saúde, Health, e a palavra-chave: Judicial Action. Resultados: Foram selecionados 30 estudos, sendo que no Brasil, a maioria se tratava de demandas judiciais por medicamentos e as demais por ações por erro médico, solicitação por vacinas, insumos para diabéticos, compostos alimentares, procedimento cirúrgico, exames, entre outras. Em estudos internacionais, foram encontradas ações por medicamentos, cobertura de benefícios e internação para tratamento psiquiátrico. Conclusão: Evidencia-se que o tipo de ação mais demandada foi o acesso ao medicamento a nível internacional. Ainda é mais perceptível a pouca discussão sobre essa temática, demonstrando que a judicialização de medicamentos pode indicar uma realidade característica do Brasil.

Descritores: Judicialização da Saúde; Decisões Judiciais; Saúde; Direito à Saúde; Política Pública de Saúde.

RESUMEN
Objetivo: Analizar las evidencias científicas nacionales e internacionales disponibles en la literatura sobre los tipos de acciones de judicialización de la salud. Método: Revisión integrativa, que seleccionó estudios primarios en las bases de datos PubMed, LILACS, Web of Science y Scopus, con los Descriptores: decisiones judiciales, judicialización de la salud, Salud, Health, y la palabra clave: Judicial Action. Resultados: Se seleccionaron 30 estudios, siendo que en Brasil, la mayoría se trataba de demandas judiciales por medicamentos y las demás por acciones por error médico, solicitud por vacunas, insumos para diabéticos, compuestos alimentares, procedimiento quirúrgico, exámenes, entre otras. En estudios internacionales, se encontraron acciones por medicamentos, cobertura de beneficios e internación para tratamiento psiquiátrico. Conclusión: Se evidencia que el tipo de acción más demandada fue el acceso al medicamento a nivel internacional. Es aún más perceptible la poca discusión sobre esta temática, demostrando que la judicialización de medicamentos puede indicar una realidad característica de Brasil.

Descritores: Judicialización de la Salud; Decisiones Judiciales; salud; Derecho a la Salud; Política Pública de Salud.
INTRODUCTION

The fact that the Constitution of the Federative Republic of Brazil of 1988\(^1\) in its art. 196, describes that “health is the right of all and the duty of the State, guaranteed by social and economic policies aimed at reducing the risk of diseases, and universal and equal access to lawsuits and services for their promotion, protection and recovery”, initiated a phenomenon that today is denominated “judicialization of health”. This phenomenon is interpreted as the cost of medical procedures, medications, treatments, hospitalizations, orthoses and prostheses by judicial means.

In Brazil, judicialization of health began in the 1990s, with a high demand for lawsuits by the Judiciary to ensure that managers of public health services provided antiretroviral medications. For the organization and regulation of the distribution of these medicines, the Política Pública de Distribuição Gratuita de Medicamentos (Public Policy for the Free Distribution of Medicines) was established through Law 9313/1996, which ensured free and universal distribution of antiretroviral agents. It was hoped that, with the implementation of this law, there would be a decrease in judicial demands which did not occur\(^2\)–\(^8\).

According to a study carried out by the Oswaldo Cruz Foundation - Fiocruz, “Judicialização da Política de Saúde nos Municípios Brasileiros: Um retrato nacional”, a profile of the judicialization was presented in the city of São Paulo, following a pattern presented in the national survey, where 65% relating to medicinal products\(^9\). This issue is of great relevance to public administration, since the number of lawsuits that are filed with the Municipalities, States or the Federation to grant health treatment is high, resulting in one more expense to the public sector to effect such payments\(^10\).

During the last decades, judicialization of health has grown in some Latin American countries, such as Colombia which, with the enactment of Law 100/1993, reformulated the health system with the objective of providing universal coverage\(^11\). In Colombia, 640,000 lawsuits were filed by patients between 1999 and 2008, one of the highest rates of judicialization of health. In Argentina, 72% of lawsuits are of individual demands for access to medicines\(^12\).

This study was carried out in the expectation of understanding aspects related to the increase of lawsuits for access to health services in Brazil; and, with this, to identify measures or alternatives to be adopted to reduce these lawsuits, as well as to identify gaps in knowledge on the subject.

OBJECTIVE

This study aims to analyze the national and international scientific evidence available in the literature on types of judicialization of health lawsuits.

METHOD

Study design

It is an integrative review, a method that aims to gather and synthesize the published studies, allowing general conclusions on a specific theme, and explanation of knowledge gaps\(^8\).

Methodological framework and stages

Evidence Based Practice is the methodological framework adopted. The study involved the following steps: elaboration of the research question, literature search of primary studies, data extraction, critical evaluation of the included primary studies, analysis and synthesis of results, and synthesis of the knowledge evidenced\(^8\).

1st Stage: Elaboration of the research question

The research question delimited for this study was: “What scientific evidence is available in the literature that analyze the types of judicialization of health lawsuits?”.

2nd Stage: Literature search of primary studies

The search for primary studies was conducted in September 2017, in the following databases with free access at the institution under study: National Library of Medicine National Institutes of Health (PubMed), Latin American & Caribbean Literature in Health Sciences (LILACS), Web of Science and Scopus.

The controlled descriptors were selected in the Descriptors in Health Science Descriptors (DeCS) and MeSH Database. Thus, in LILACS, the following descriptors were used: Judicial decisions, Health and Health's Judicialization. For Pubmed, Web of Science and Scopus were: Health and the uncontrolled delimited descriptor (keyword) was Judicial Action. In the Pubmed, Web of Science and Scopus databases, the terms were combined as follows: Health AND Judicial Action; and in LILACS: Judicial decisions OR Health's Judicialization AND Health.

3rd Stage: Data extraction

For data extraction, authors prepared and used a tool consisting of items related to identification of the article, objective and main results that answered the integrative review’s guiding question.

Criteria of inclusion and exclusion

The inclusion criteria were complete articles in Portuguese, English and/or Spanish, published between 2007 and 2017, available in full that addressed the theme “health lawsuits involving access to all types of health services”. Theses, dissertations, chapter books, theoretical articles, letter to the editor were excluded from the sample of this study.

Articles were searched between 2007 and 2017 in order to find the most recent publications related to the application of legislation, legal conduct and repercussions on the health service.

4th Stage: Critical evaluation of the included primary studies

Analyzes were performed independently by two reviewers, and the synthesis of the studies was presented in Charts 1 and 2.

5th Stage: Analysis and synthesis of results

A descriptive analysis of each study was carried out, presenting a synthesis of the main results of these studies in Charts 1 and 2.
6th Stage: Synthesis of the knowledge evidenced

To evaluate the studies regarding Levels of Evidence, the classification was used in seven levels, being considered as level 1 (stronger) the evidence from a systematic review or meta-analysis of randomized clinical trials; level 2, evidence from well-delineated randomized clinical trials; level 3, evidence from well-delineated clinical trials without randomization; level 4, evidence from well-delineated cohort and case-control studies; level 5, evidence from a systematic review of descriptive and qualitative studies; level 6, evidence from a single descriptive or qualitative study; and level 7 (weaker), evidence from expert opinion(10).

RESULTS

In the first analysis of the 512 studies, after reading the title and abstract, articles that did not address lawsuits in health and duplicate articles were excluded (n=414). In the second analysis, through reading in full (n=98), 53 studies that did not portray the subject and 18 that were theoretical articles, book chapter, theses and dissertations were excluded. Three studies that did not appear in the selection by the databases were included through manual search, resulting in 30 articles selected for this study (Figure 1).

The years with the greatest number of publications were 2012, 2013, 2014 and 2015 with four publications in each year and in 2016 five studies were published. Regarding the language, 24 were published in Brazilian Portuguese, four in English and two in Spanish.

Chart 1 - Synthesis of studies of lawsuits of demands for medications (n=21), 2007-2017

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<thead>
<tr>
<th>Article/Country</th>
<th>Objective</th>
<th>Main Results</th>
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<tr>
<td>(11) Biehl, J.; Socal, M.P; Amon J.J.</td>
<td>To evaluate the claims, offering empirical evidence that myth counters prevail and claim the heterogeneity of the phenomenon of judicialization.</td>
<td>Most applicants are, in fact, poor and older individuals who do not live in major metropolitan areas. They also depend on the State to provide their legal representation and most of the requested medicines were already on government forms.</td>
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<td>(12) Cabral, I.; Rezende, L.F.</td>
<td>To analyze individual lawsuits taken to guarantee access to medicines in the municipality of São João da Boa Vista.</td>
<td>Most of lawsuits were filed by women represented by private lawyers asking for medication.</td>
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<td>(13) Chieffi, A.L.; Barata, R.B.</td>
<td>To analyze the lawsuit used to obtain medicines through the Department of Health of São Paulo State.</td>
<td>Most of the litigation was filed by private lawyers, 47% had private network prescriptions and 73% of the cases were from patients with social vulnerability.</td>
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<td>(14) Chieffi, A.L.; Barata, R.C.B</td>
<td>To analyze the concentration in the distribution of lawsuits according to the medicine (manufacturer), prescribing doctor and soliciting attorney of the lawsuit.</td>
<td>1,309 lawsuits were for acquisition of 14 medications. Most cases were represented by private lawyers and 11 lawyers accounted for 613 (47%) cases.</td>
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<tr>
<td>(15) Coelho et al.</td>
<td>To investigate factors related to the deferral of injunctions by medications.</td>
<td>Of the 5,072 lawsuits with injunctions, 4,184 (82.5%) were deferred. The medications paroxetine, somatropin and ferrous sulfate were 100% deferred. Escitalopram, diclofenac sodium and nortriptyline obtained a reduction of less than 54.0%.</td>
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<tr>
<th>Article/Country</th>
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<td>[16] Leitão et al. Análise das demandas judiciais para aquisição de medicamentos no estado da Paraíba</td>
<td>To describe medical-scientific and health aspects of court injunctions for the supply of medicines to the Court of Paraíba against public agents.</td>
<td>Seventy-five claims were identified for different medications. The most frequent were the antineoplastic medications, followed by insulin and angiotensin II antagonists.</td>
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<td>Saúde e Sociedade. 2016; v. 25, p. 800-807. Brazil</td>
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<td>[17] Lopes et al. Medicamentos biológicos para o tratamento de psoríase em sistema público de saúde</td>
<td>To analyze the access and profile of use, by judicial means, of biological medicines for the treatment of psoriasis.</td>
<td>There was access by injunction (59.5%). 66% used the biological medication for 13 months, 26.6% abandoned treatment due to worsening of the condition, 20.5% had adverse effects and 13.8% did not have surgery, due to lack of efficacy.</td>
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<td>Rev de Saúde Pública. 2014 v. 48, n. 4, p. 651-661. Brazil</td>
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<td>[18] Machado et al Judicialização do acesso a medicamentos no Estado de Minas Gerais, Brasil</td>
<td>To analyze the profile of claimants and medications pleaded in lawsuits.</td>
<td>Most of applicants were women, aged 60 or over, retirees, pensioners and housewives. The most requested medications were immunosuppressants.</td>
</tr>
</tbody>
</table>
### Article/Country | Objective | Main Results
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[26] Sant’Ana et al. Rational therapeutics: health-related elements in lawsuits demanding medicines Rev de Saúde Pública. 2011; v. 45, n. 4, p. 714-721. | To characterize the main procedural, medical-scientific and health elements that support the decisions of the individual judicial demands for medicines considered essential. | All lawsuits contained prescriptions and medical certificates. The prescriptions were in discrepancy with the legislation. There were no medical examinations in any of the lawsuits and 7.4% consisted of complementary tests. |
[27] Silva, E.; de Almeida, K.C.; Pessoa, G.S.C. Análise do gasto com judicialização de medicamentos no Distrito Federal, Brasil Cadernos Ibero-Americanos de Direito Sanitário, 2017; 6(1), 112-126. | To analyze the profile of public health spending in the Federal District with non-standard medications occurs at this location. | Total expenses were 43.7 million reais. Among the medications with the highest expenditure, the recombinant factor IX (haemophilia treatment) was observed as the most responsible (22.53%). |
[28] Souza et al. Direito à saúde no tribunal de justiça: demanda por medicinações em oncologia Rev da Rede de Enfermagem do Nordeste. 2012; v. 13, n. 4. | To describe the demand for the right to health in the Court of Mato Grosso State on medicines for people with cancer. | There were 25 lawsuits for cancer medications, 32% cited the amount of medicine needed, 60% determined the medication delivery period, 16% brought the dosage and 4% contained the deadline to meet the demand determined by the judge. |
[29] Stamford, A.; Cavalcanti, M. Decisões judiciais sobre acesso aos medicamentos em Pernambuco Rev de Saúde Pública. 2012; v. 46, p. 791-799. | To analyze the decisions of the legal system on access of the population to medicines in the Sistema Único de Saúde (Brazilian Unified Health) System by judicial means regarding decision criteria and possible political and economic pressures. | The Federal Constitution and medical prescription were identified as a decision criterion in lawsuits. |
[30] Vieira, F.S.; Zucchi, P. Distorções causadas pelas ações judiciais à política de medicamentos no Brasil Rev de Saúde Pública. 2007; v. 41, p. 214-222. | To describe the effects of lawsuits that requires the supply of medications, in relation to aspects of the national medication policy. | The total expense was of 876 thousand reais (Brazilian currency) for items that are not part of the Municipal Relation of Essential Medicines. Of the total expenditure, 75% were allocated to the acquisition of antineoplastic agents and two of these medications were not registered in Brazil. |
[31] Wang et al. Os impactos da judicialização da saúde no município de São Paulo: gasto público e organização federativa Rev de Administração Pública-RAP. 2014; v. 48, n. 5. | To analyze the impact of health judicialization in the city of São Paulo. | Approximately 55% of health care expenditures are spent on the supply of State or Union medicines and 45% on non-contemplated SUS (Unified Health System) treatments. |

### Chart 2 - Synthesis of studies of lawsuits demands of surgical procedures, hospitalization in the Intensive Care Unit, medical error, consultations and examinations, surgical materials, home hospitalization, among others (n=9), 2007-2017

| Article/Country | Objective | Main Results |
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[32] Arruda Análise sobre a judicialização da saúde no estado de Mato Grosso no período de 2011-2012 Cad Ibero-Americanos de Direito Sanitário. 2017; v. 6, n. 1, p. 86-111. | To understand the phenomenon of the judicialization of access to public health in Mato Grosso State. | Population is more aware of their rights and requires it through judicial decisions. |
[33] Asensi et al. Judicialização, direito à saúde e prevenção Rev Eletron de Comun Inf Inov Saúde. 2015 jan-mar; 9(1). | To analyze the practice of preventive medicine, with regard to vaccination, resulting from the intervention of the Judiciary. | 110 cases were identified, 25 of which were about the supply of vaccines to specific individuals. They emphasized that they did not find lawsuits that sought to force the State to act in a preventive way. |
[34] Gomes O Erro médico sob o olhar do Judiciário: uma investigação no Tribunal de Justiça do Distrito Federal eTerritórios Cad. Ibero-Americanos de Direito Sanitário. 2017; v. 6, n. 1, p. 72-85. | To know judicial decisions from the Second Instance on medical errors. | It resulted in 202 civil cases, being the specialty with the largest number of cases in Gynecology/Obstetrics. |

To be continued
Twenty-seven studies were found in Brazil, where medication lawsuits were predominant (74%). Afterwards, there were studies (26%) that described requests for surgical procedures, hospitalization at the Intensive Care Unit, medical error, consultations and exams, home care, surgeries, food supplements, orthoses and prostheses, hospitalization for psychiatric treatment, SPA hospitalization, request for vaccines, supplies for diabetics, home hospitalization, demand for hospital transportation, among others.

In international studies, lawsuits were found for medications and hospital procedures in Minas Gerais State, Brazil, from 1999 to 2009. The most requested procedures were hospitalizations in common beds, Intensive Care Unit and surgeries of the circulatory system.

DISCUSSION

The public health system in Brazil comprises a set of lawsuits and services, however, it is noted that most of the studies published on the types of judicialization of health lawsuits deal with access to medicines.

Lawsuits for medicines have been taking place even after the creation in 1996 of public policy, which promises the free and universal dispensation of medications. From this perspective, it is worth mentioning that lawsuits also occur with medications contained in the Relação Nacional de Medicamentos Essenciais (RENAME - National Relation of Essential Medicines). This practice needs to be reviewed in light of the fact that most of lawsuits are accompanied by a medical professionals(19).

In this sense, 21 articles involved access to medications(11-31), in which six articles were required medications, such as Adalimumab and Etanercept(14'15'17'18'20'22'), indicated for the treatment...
of rheumatoid arthritis. Four articles demanded medications, such as Infliximab\textsuperscript{[14, 17, 20–22]}, also recommended for rheumatoid arthritis. Rituximab\textsuperscript{[16, 22, 25, 28],} was indicated for treatment of non-Hodgkin’s lymphoma. These medicines are present in RENAME, but the population has been finding difficulties in accessing these medicines, in which the pharmaceutical assistance policy presents flaws in the programming, acquisition and distribution of medications\textsuperscript{[18].}

On the other hand, requests for non-standard and high-cost medications can be influenced by the pharmaceutical industry in partnership with prescribing doctors. And the irrational and unnecessary use of new medications, often without scientific evidence, aiming at the future standardization of this technology, and may be a factor that promotes an increase in the demand for medicines and high expenses with judicialization\textsuperscript{[41].}

In order to standardize a new medication, it is necessary, in addition to the safety factors, effectiveness and effectiveness, that these are the best option in relation to the cost, because thus more people would have access\textsuperscript{[42].}

Judicialization of health does not only include access to medicines. One of the articles found in this review refers to civil and criminal cases on medical error, in which the specialty with the greatest number of cases was Gynecology/Obstetrics\textsuperscript{[34].} Braga, Vieira and Martins\textsuperscript{[43]} performed a study in which there was a tendency to increase lawsuits in the ophthalmological area, and a predominance of lawsuits in surgical ophthalmologic procedures.

In a recent study in the United States, medical errors are classified as the third leading cause of death, where data on mortality in the country were analyzed for eight years, noting that more than 250,000 deaths per year are attributed to errors\textsuperscript{[44].} However, the study detected little scientific publication on the judicialization of medical error.

It is noteworthy that the types of lawsuits outside Brazil were demands on coverage of benefits in Argentina, medicines, such as antiepileptics in Colombia and hospitalization for psychiatric treatment in Spain. Given the lack of world literature on the proposed theme, it is questioned whether health judicialization is a specific problem of greater transparency in Brazilian public health, or if the scarce publication is due to scientific omission, considering that nations worldwide are subject to such structural-political complications.

### Study limitations

The limitation of this study was that the selected databases were only those accessible to researchers of this study, and the extension of the search in other paid databases could contemplate other types of studies in other realities.

### Contributions for the area of Public Policy

The study contributes to the characterization of health judicial demands, enabling public managers to detect failures in distribution and acquisition of medicines, which can avoid lawsuits for standardized medications. On the other hand, the study boosts reflection on the scientific evidence of requests before lawsuits are judged through consultations with doctors, in order to avoid prescriptions of non-standardized technologies, especially in medicines, and can thus reduce the quantity of lawsuits in health.

### CONCLUSION

This integrative review found that access to the medication was the most obvious type of lawsuit. However, even with the increase in judicialization of health, what resulted in the main limitation of this study was the scarcity of literature on the subject. At the international level, the lack of discussion on the subject was even more evident, revealing that the judicialization of access to medicines may indicate a reality that is characteristic of Brazil. Thus, it is evident the need to produce new studies on the reason for requesting standardized medications through lawsuits. This indicates possible management failures in the acquisition and distribution of these medications and the reason for the medical prescription of non-standard medications, which may indicate a presumed lack of knowledge of prescribers about medications present in the SUS lists. This fact can also indicate the induction of prescription by the pharmaceutical industry, aiming at the inclusion of new medications.

### REFERENCES


44. Makary MA, Daniel M. Medical Error - the third leading cause of death in the US. BMJ [Internet]. 2016 [cited 2019 Mar 12];353:i2139. Available from: http://dx.doi.org/10.1136/bmj.i2139