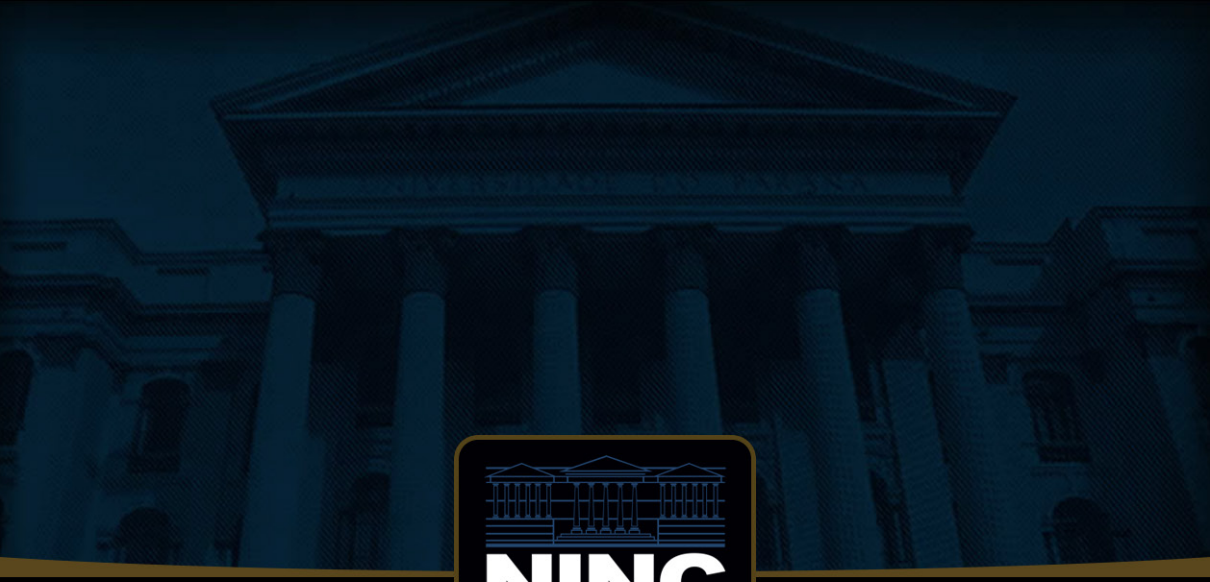

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JOURNAL OF CONSTITUTIONAL RESEARCH

VOL. 12 | N. 1 | JANEIRO/ABRIL 2025 | ISSN 2359-5639

Articles

Revista de Investigações Constitucionais
ISSN 2359-5639
DOI: 10.5380/rinc.v12i1.96212

Judicialization of Health Rights in Colombia and Brazil: A Comparative Analysis of Courts' Approaches to Experimental, Excluded and Included Medicaments and Technologies

Judicialização dos Direitos à Saúde na Colômbia e no Brasil: Uma Análise Comparativa das Abordagens dos Tribunais em Relação a Medicamentos e Tecnologias Experimentais, Excluídos e Incluídos

RODOLFO GUTIÉRREZ SILVA [I, *]

[I] Universidad Cooperativa de Colombia (Santa Marta, Colombia)
rodolfo.gutierrez47@gmail.com
https://orcid.org/0000-0002-9248-3374

Recebido/Received: 21.07.2024 / 21 July 2024
Aprovado/Approved: 28.12.2024 / 28 December 2024

Abstract

The judicialization of health rights in Colombia and Brazil has significantly influenced health policies and resource allocation. This article compares the judicialization of health rights in these countries, focusing on courts' approaches to experimental, excluded, and included medicaments and technologies. Using a qualitative and comparative methodology, the study reviews literature and jurisprudence to examine legal frameworks, judicial precedents, and empirical evidence. The analysis addresses four areas: the general context of judicialization, court considerations for experimental technologies, services and medicaments not included in the basic health plan, and those included. In Colombia, courts follow a "negative list" framework, granting access to most health services unless explicitly excluded. Brazilian courts, guided by constitutional mandates, often favor patient

Resumo

A judicialização dos direitos à saúde na Colômbia e no Brasil influenciou significativamente as políticas de saúde e a alocação de recursos. Este artigo compara a judicialização dos direitos à saúde nesses países, focando nas abordagens dos tribunais em relação a medicamentos e tecnologias experimentais, excluídos e incluídos. Utilizando uma metodologia qualitativa e comparativa, o estudo revisa literatura e jurisprudência para examinar marcos legais, precedentes judiciais e evidências empíricas. A análise aborda quatro áreas: o contexto geral da judicialização, considerações dos tribunais sobre tecnologias experimentais, serviços e medicamentos não incluídos no plano básico de saúde, e aqueles incluídos no plano. Na Colômbia, os tribunais seguem um modelo de "lista negativa", garantindo acesso à maioria dos serviços de saúde, a menos que explicitamente excluídos. Os tribunais brasileiros, guiados por mandatos

Como citar esse artigo/*How to cite this article*: GUTIÉRREZ SILVA, Rodolfo. Judicialization of Health Rights in Colombia and Brazil: A Comparative Analysis of Courts' Approaches to Experimental, Excluded and Included Medicaments and Technologies. **Revista de Investigações Constitucionais**, Curitiba, vol. 12, n. 1, e505, jan./abr. 2025. DOI: 10.5380/rinc.v12i1.96212.

* Professor Faculty of Law, Universidad Cooperativa de Colombia, Santa Marta, Colombia. Doctor of Law (Dr. Iur.), (Magna Cum Laude), University of Hamburg, Germany, LLM Master of Laws, University of London, Birbeck, UK. BSc Social Policy and Sociology, London Metropolitan University.

access, relying on public health institutions' technical assessments. The study concludes that judicialization has advanced health rights but also posed challenges to health system sustainability, equity, and balancing individual rights with public health. Addressing these challenges requires strengthening health technology assessment processes, fostering inter-institutional dialogue, and implementing systemic reforms for equitable access. Additionally, internal judicial reforms and external health system and policy reforms are essential for a sustainable and equitable system, emphasizing interdisciplinary dialogue, data transparency, and clarity in normative and political premises.

Keywords: Judicialization of health rights; medicaments; courts; health; health technology assessment (HTA).

constitucionais, frequentemente favorecem o acesso dos pacientes, baseando-se em avaliações técnicas de instituições públicas de saúde. O estudo conclui que a judicialização avançou os direitos à saúde, mas também apresentou desafios à sustentabilidade do sistema de saúde, à equidade e ao equilíbrio entre direitos individuais e saúde pública. Abordar esses desafios requer o fortalecimento dos processos de avaliação de tecnologias em saúde, o fomento ao diálogo interinstitucional e a implementação de reformas sistêmicas para garantir acesso equitativo. Além disso, reformas judiciais internas e reformas externas do sistema de saúde e políticas são essenciais para um sistema mais sustentável e equitativo, enfatizando o diálogo interdisciplinar, a transparência de dados e a clareza nas premissas normativas e políticas.

Palavras-chave: *Judicialização dos direitos à saúde; medicamentos; tribunais; saúde; avaliação de tecnologias em saúde (ATS)*

CONTENTS

1. INTRODUCTION

The Judicialization of the Right to health is a widespread phenomenon driven by barriers to accessing essential medicines and healthcare services[1] as well as a combination of different factors such as strong constitutional protections[2], social inequalities[3],

[1] BIEHL, João; AMON, Joseph J.; SOCAL, Mariana P.; PETRYNA, Adriana. Between the court and the clinic: lawsuits for medicines and the right to health in Brazil. **Health and Human Rights,** vol. 14, n. 1, p. 1-17, jun. 2012; VARGAS-PELAEZ, Claudia M.; MATTOZO ROVER, Marina R. M.; SOARES, Luciano; BLATT, Carine R.; MANTEL-TEEUWISSE, Aukje K.; ROSSI, Francisco A.; RESTREPO, Luis G.; LATORRE, María C.; LÓPEZ, Julian J.; BÜRGIN, María T.; SILVA, Consuelo; NAIR LEITE, Silvana; ROCHA FARIAS, Mareni. Judicialization of access to medicines in four Latin American countries: a comparative qualitative analysis. **International Journal for Equity in Health**, vol. 18, p. 1-14, jun. 2019; VARGAS-PELÁEZ, Claudia M.; MATTOZO ROVER, Marina R.; NAIR LEITE, Silvana; ROSSI BUENAVENTURA, Francisco; ROCHA FARIAS, Mareni. Right to health, essential medicines, and lawsuits for access to medicines – A scoping study. **Social Science & Medicine**, vol. 121, p. 48-55, nov. 2014.

[2] BIEHL, João. The pharmaceuticalization and judicialization of health. On the Interface of Medical Capitalism and Magical Legalism in Brazil. **Osiris,** Chicago, vol. 36, n. 1, p. 309-327, 2021.

[3] YAMIN, Alicia Ely. The Right to Health in Latin America: The Challenges of Constructing Fair Limits. **University of Pennsylvania Journal of International Law**, vol. 40, p. 695-724, 2018.

failures in political and health systems[4], and the impact of neoliberal policies[5]. This process has significant implications for health system sustainability, resource allocation[6], Democratic legitimacy, and the balance of power between the judiciary and other branches of government.

Previous research has highlighted Judicial Intervention as a Democratic Tool, for instance, in Colombia, litigation has been a peaceful and democratic method to enforce the right to health, leading to significant structural reforms[7] while in Brazil, studies has focused on inequities in health access, for example, the focus on individualized claims for advanced treatments benefits those who can access the judiciary, thus worsening overall health[8]. Similarly, the judicialization of health in Brazil has significant budgetary implications, with a substantial portion of health resources being allocated to comply with court orders for specific treatments, often at the expense of the broader population[9]. The literature also has researched the institutional responses, for instance, Brazil has seen various institutional responses to mitigate the negative impacts of judicialization, including public hearings by the Supreme Federal Court, recommendations by the National Council of Justice, and the creation of a health technology assessment system through Federal Law 12.401/11[10]. In the literature there are many studies on the topic of the judicialization of health rights. However, studies that compare different countries and evaluate court´s approaches to experimental, excluded and included technologies, medicaments and services are missing. Comparing the judicialization of health rights in Brazil and Colombia holds significance for several reasons. It can shed light on the reasons behind this trend and its impact on healthcare systems. Understanding the successes and shortcomings in each country can also guide reforms within the justice system. Additionally, courts in Colombia and Brazil can serve as examples for nations facing challenges.

This article aims to provide a comparative analysis of the judicialization of health rights in Colombia and Brazil, focusing on the courts' approaches to experimental,

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4 LAMPREA, Everaldo. The judicialization of health care: A global south perspective. **Annual Review of Law and Social Science**, vol. 13, n. 1, p. 431-449, oct. 2017.

5 ABADÍA-BARRERO, César Ernesto. Neoliberal justice and the transformation of the moral: the privatization of the right to health care in colombia. **Medical Anthropology Quarterly,** vol. 30, n. 1, p. 62-79, 2016.

6 LAMPREA, Everaldo. The judicialization of health care: A global south perspective. **Annual Review of Law and Social Science**, vol. 13, n. 1, p. 431-449, oct. 2017.

7 ARRIETA-GÓMEZ, Aquiles Ignacio. Realizing the Fundamental Right to Health through Litigation: The Colombian Case. **Health and Human Rights**, vol. 20, n. 1, p. 133-145, jun. 2018.

8 FERRAZ, Octavio L.M. The right to health in the courts of Brazil: worsening health inequities? **Health and Human Rights,** vol. 11, n. 2, p. 33-45, 2009.

9 VIEIRA, Fabiola Sulpino. Judicialization and right to health in Brazil: a trajectory of matches and mismatches. **Revista de Saúde Pública**, vol. 57, p. 1, 2023.

10 D'ÁVILA, Luciana Souza; ANDRADE, Eli Iola Gurgel; AITH, Fernando Mussa Abujamra. Consecuencias políticas e institucionales de la judicialización de la salud en Brasil y Colombia: un análisis comparado. **Revista Derecho y Salud,** vol. 4, n. 4, p. 64-75, 2020.

excluded, and included medicaments and technologies. The analysis will be structured as follows: First, it will examine the general context of the judicialization process of the right to health in Colombia and Brazil. Second, it will analyze the elements considered by courts in relation to experimental technologies, medicaments and treatments (Phase I – III) and without registration (Phase IV). Third, it will explore the elements considered by courts in relation to services and medicaments with registry and non-incorporated into the basic plan of health. Fourth, it will discuss the elements considered by courts in relation to services and medicaments incorporated into the basic plan of health. Finally, it will highlight the challenges facing courts in the recognition of experimental, excluded and included medicaments and technologies in Brazil and Colombia.

2. METHODOLOGY

A qualitative and comparative study examined Colombia and Brazil's courts' approaches to experimental, excluded, and included drugs and technologies. Figure 1 shows the study methodology:

- **Analysis of the general context:** The general context of the judicialization process of the right to health in Colombia and Brazil was analyzed.
- **Analysis of elements considered by courts in relation to experimental technologies, medicaments, and treatments (Phase I - III) and without registration (Phase IV):** A jurisprudential analysis was conducted in Colombia and Brazil, examining 5 emerging categories: Legal Framework and Precedents, Scientific Evidence, Public Authority Approval, Financial Considerations, and Impact of Court Decisions.
- **Analysis of elements considered by courts in relation to services and medicaments with registration and not incorporated into the basic health plan:** A jurisprudential analysis was carried out in both countries, evaluating the same 5 emerging categories mentioned in point 2.
- **Analysis of elements considered by courts in relation to services and medicaments incorporated into the basic health plan:** A jurisprudential analysis was conducted in Colombia and Brazil, examining 2 emerging categories: Legal Framework and Precedents, and Implicit and Explicit Inclusion Model.
- **Synthesis, analysis of common patterns and themes, differences, and recommendations:** Based on the analyses carried out in points 2, 3, and 4, patterns, common themes, and differences were identified in the approaches of the courts in Colombia and Brazil regarding the judicialization of health rights in relation to experimental, excluded, and included medicaments and technologies. The conclusions and recommendations are based on a critical

synthesis of the analyzed evidence, including the jurisprudential analysis in both countries, with the objective of improving the understanding of the judicialization of health rights and its impact on access to medicaments and technologies in Colombia and Brazil.

The process of literature review and jurisprudential analysis at all stages also included a process of identification, screening, eligibility, and inclusion. This methodology led to an analytical framework that showcases the complexities of the judicialization of health rights in Colombia and Brazil, comparing the courts' approaches to experimental, excluded, and included medicaments and technologies, and the challenges they face in their recognition, based on a comprehensive jurisprudential analysis in both countries.

3. GENERAL CONTEXT OF THE JUDICIALIZATION PROCESS OF THE RIGHT TO HEALTH IN COLOMBIA AND BRAZIL

There has been an uptick in health rights litigation and other initiatives since the 1990s, reflecting a growing awareness of the importance of human rights in healthcare[11]. For instance, the Ministry of Health and Social protection of Colombia reported that between 2000 and 2021 around 2,419,480 tutelas were filed. The number of tutelas (legal claims) filed for health rights in Colombia is expected to increase significantly due to various challenges the health system is currently facing. One major issue is the fragmentation and disintegration of the system, with many key health promoting entities (EPS) such as *Sanitas, Compensar, Coomeva, Medimás, Convida and Comfamiliar Huila* undergoing liquidation, voluntary withdrawal or intervention procedures by the National Health Superintendent (*Superintendencia Nacional de Salud*) due to financial insolvency, mismanagement and failure to provide adequate services to their members. In recent years, the government has intervened or liquidated several of the largest Health Promoting Entities in Colombia, such as *Saludcoop, Cafesalud, Medimás,* and now *Sanitas* and *Nueva EPS*, affecting millions of users who have faced uncertainty and interruptions in their health services

In Brazil, on the other hand, cases during the period 2014-2019 ranged between 702,739 and 1,293,625, an average of 117,123 – 215,604 a year[12]. While the health

[11] FLOOD, Colleen M.; GROSS, Aeyal. Conclusion: contexts for the promise and peril of the right to health. In: FLOOD, Colleen M.; GROSS, Aeyal (Ed.). **The right to health at the public/private divide: A global comparative study.** Cambridge: Cambridge University Press, 2014. p. 451-480.

[12] FERRAZ, Octavio Luiz Motta. **Health as a human right: the politics and judicialisation of health in Brazil**. Cambridge: Cambridge University Press, 2020. p.9

system in Colombia is based on Social Security[13], the system in Brazil is mainly public[14]. Indeed, Health-care litigation has increased notoriously in the last 20 years due to different factors and there is still a debate between those who believe judges should intervene and those who do not. Many countries have adopted different strategies in order to reduce the high level of judicialization by creating HTA [Health Technology Assessment] agencies[15]. Indeed, countries such as Brazil new settlement chambers (*Cámaras de Conciliacao de Litigios de Saude*) and centers for technical advice for judges (*Nucleo de Assistencia Tecnica -NAT*) has been created[16]. In the case of Colombia, in 2023 the Colombian Constitutional Court acquired a new power that would allow it to suspend, exceptionally, the effects of laws that are under review for unconstitutionality, this could affect any reform of law in relation to the health sector. Most of the remedies are individuals rather than structural. Litigation continues to be persistent, reactive and repetitive.

Without any doubt, the right to health has progressed in the last decades, both countries have implemented policies and programmes of health in order to protect accessibility. Coverage and public spending have increased, and some countries have undertaken drastic reforms in order to improve the quality of services. However, there are still many gaps in order to ensure equity. Due to the high level of violations of the right to health Courts have been reacting by particularly solving problems related to different type of cases. However, when deciding cases in relation to the Right to Health Courts have been profoundly immersed in structural imbalances of political, social, and legal types.

4. ELEMENTS CONSIDERED BY COURTS IN RELATION TO EXPERIMENTAL TECHNOLOGIES, MEDICAMENTS AND TREATMENTS (PHASE I – III) AND WITHOUT REGISTRATION (PHASE IV)

Generally speaking, in many countries in Latin America patients with life-threatening illness might access experimental technologies and treatments without registration through different mechanisms such as the "Right to try", Clinical trials, Compassionate use, Special authorizations and in Emergency situations (such as pandemics).

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13 GUERRERO, Ramiro; GALLEGO, Ana Isabel; BECERRIL-MONTEKIO, Victor; VÁSQUEZ, Johanna. The health system of Colombia. **Salud Pública de México**, vol. 53, supl. 2, p. 144-155, 2011.

14 BECERRIL MONTEKIO, Víctor; MEDINA, Guadalupe; AQUINO, Rosana. Sistema de salud de Brasil. **Salud Pública de México,** Cuernavaca, vol. 53, supl. 2, p. 120-131, 2011.

15 WANG, Daniel; DE VASCONCELOS, Natália Pires; POIRIER, Mathieu J. P.; CHIEFFI, Ana; MÔNACO, Cauê; SRITHARAN, Lathika; VAN KATWYK, Susan Rogers; HOFFMAN, Steven J. Health technology assessment and judicial deference to priority-setting decisions in healthcare: Quasi-experimental analysis of right-to-health litigation in Brazil. **Social Science & Medicine**, vol. 265, p. 113401, nov. 2020.

16 RIBEIRO, Leandro Molhano; HARTMANN, Ivar Alberto. Judicialization of the right to health and institutional changes in Brazil. **Revista de Investigações Constitucionais,** vol. 3, n. 3, p. 35-52, sep./dec. 2016.

The Constitutional Court of Colombia has issued many judgements in relation to these types of medicaments, particularly, by establishing some precedents, however, generally speaking, the Court has decided to exclude them, since there is not enough evidence in relation to the security and efficacy[17]. For the Colombian Court the fact that a public authority has not approved a medicament does not automatically entail that it is experimental. An experimental medicament depends on the "best available evidence"[18]. Indeed, in Judgement T-027/2015[19] the Court acknowledged the importance of the scientific community. The court has established a particular rule that allows a patient to claim medicines without the approval of a public authority and the treating physician is responsible to determine whether there is sufficient scientific evidence to provide a medicine without approval by the health authority[20]. The accreditation of a medicine as a therapeutic alternative can occur through the acceptance of the scientific community or the issuance of registration by the National Institute of Drug and Food Surveillance *Invima*, however, at the end is the treating physician who determine whether or not there is sufficient evidence. Similarly, in judgment T-1330/05[21] the Court established that in certain events the absolute prohibition of experimental interventions may be disproportionate and therefore violate the right to health. The Court has introduced the "Right to Try" in its jurisprudence specifically for cases of patients in a vegetative state persistent or minimally aware conscious state. Some commentators are interpreting the right to try as a right[22]. In Judgement T-243 of 2015[23], the Court has also acknowledged that Colombian citizens might access medicaments without a registry provided that it was ordered by the treating physician unless there is an alternative measure, namely, it is possible to substitute it for another with the same active ingredient affecting the patient´s health and the other medicaments with a valid registration,

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17 COLOMBIAN CONSTITUTIONAL COURT, Judgment T-302/2014, Magistrado Ponente: Luis Guillermo Guerrero Pérez. Available at: <https://www.corteconstitucional.gov.co/relatoria/2014/T-302-14.htm> Accessed on: 14 abr. 2024

18 COLOMBIAN CONSTITUTIONAL COURT, Judgment T-418/2011, Magistrado Ponente: María Victoria Calle Correa. Available at: <https://www.corteconstitucional.gov.co/relatoria/2011/t-418-11.htm> Accessed on: 1 nov. 2023

19 COLOMBIAN CONSTITUTIONAL COURT, Judgment T-027/2015, Magistrado Ponente: Luis Guillermo Pérez. Available at: < https://www.corteconstitucional.gov.co/relatoria/2015/t-027-15.htm> Accessed on: 1 nov. 2023

20 COLOMBIAN CONSTITUTIONAL COURT, Judgement T-302/2014, Magistrado Ponente: Luis Guillermo Guerrero Pérez. Available at: <https://www.corteconstitucional.gov.co/relatoria/2014/T-302-14.htm> Accessed on: 14 abr. 2024

21 COLOMBIAN CONSTITUTIONAL COURT, Judgment T-1330/05, Magistrado Ponente: Humberto Antonio Sierra Porto. Available at: <https://www.corteconstitucional.gov.co/relatoria/2005/T-1330-05.htm> Accessed on: 1 mar. 2024.

22 DUQUE GIRALDO, Mateo. Propuestas para una adecuada recepción del derecho a acceder a tratamientos y medicamentos experimentales: caso Estados Unidos-Colombia. **Díkaion,** Chía, vol. 29, n. 2, p. 411-440, jul./dec. 2020

23 COLOMBIAN CONSTITUTIONAL COURT, Judgment T-243/15, Magistrado Ponente: Jorge Ivan Palacio. Available at: < https://www.corteconstitucional.gov.co/relatoria/2015/t-243-15.htm> Accessed on: 1 mar. 2024.

whose active ingredient is the same, are effectively available on the Colombian market. Similarly in Judgement T-057/2015[24] the court stated that when examining the viability of ordering, by way of amparo the provision of a treatment, procedure or medicine of an experimental nature it must be reviewed whether there is no valid substitute in the Plan of health. Therefore, in practice, despite experimental medicaments are not covered by the Basic plan of health, the Colombian Court could guarantee them in certain situations.

In Brazil, the intervention of judges in experimental medicaments have involved particularly high-cost medicaments. Courts have been granting high-cost medicines and have to deal with a conflict of principles such as the "reserve of the possible" and the "existential minimum"[25]. Many claims have been litigated, for instance, by seeking treatments for patients with rare diseases[26]. For some authors, this intervention might have an impact on the financial sustainability[27] since most of the claims are driven by private interests and urban elites. However, for other authors, most of the claims are from poor people living outside of metropolitan areas[28] and many of them are older people[29]. Although individuals are also accessing unregistered medicaments through the courts[30] however, in Brazil, the Supreme Federal Court in Extraordinary appeal RE657.718 /MG declared that the State cannot be obligated to provide experimental drugs[31]. It has established that Courts should order drugs without registry only on an exceptional basis, namely when there is a delay of *Anvisa*, and three additional requirements are met: i) Existence of a request for registration in *Anvisa,* ii) Existence of registration in renowned regulatory agencies, iii) Absence of therapeutic substitute.

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[24] COLOMBIAN CONSTITUTIONAL COURT, Judgment T-057/15, Magistrado Ponente: Martha Victoria Sáchica Méndez. Available at: <https://www.corteconstitucional.gov.co/relatoria/2015/t-057-15.htm> Accessed on: 15 mar. 2024.

[25] MACÊDO, Karla Vanessa. Derecho a la salud: La judicialización de la concesión de medicamentos de alto costo. **Revista Científica Multidisciplinar Núcleo do Conhecimento**, vol. 7, p. 5-16, dec. 2020.

[26] CATAMA, Julie; MONSORES, Natan. Judicialización de la salud: una cuestión de necesidad en las enfermedades raras. **Revista Brasileira de Bioética, Brasília,** vol. 15, p. 1-18, jun. 2019.

[27] DE MIRANDA SILVESTRE, Roberta; DE ALMEIDA LOPES FERNÁNDEZ, Gustavo Andrey. Health judicialization: case study on judicial demands. **Revista de Enfermagem UFPE,** vol. 13, n. 3, p. 863-874, mar. 2019.

[28] BIEHL, João; SOCAL, Mariana P.; AMON, Joseph J. The Judicialization of Health and the Quest for State Accountability: Evidence from 1,262 Lawsuits for Access to Medicines in Southern Brazil. **Health and Human Rights,** vol. 18, n. 1, p. 209-220, 2016.

[29] ABOU SALHA, Leila; COSTA REIS, Flávia; MOREIRA GONÇALVES, Roberta; DA SILVA LIMA, Jordão Horácio; ABOU SALHA, Nádia; PEREIRA PINTO, Rooney; DE MENEZES, José Elmo; PEREZ OLIVEIRA, Eduardo; LOPES FERREIRA, Pedro; BARBOSA, Maria Alves. Judicialization of health: profile of demands for oncological medicines in a state in the central region of Brazil. **International Journal for Equity in Health**, vol. 21, p. 1-15, aug. 2022.

[30] DA SILVA, Ricardo Eccard; DA COSTA LIMA, Elisangela; NOVAES, Maria Rita C.G.; OSORIO-DE-CASTRO, Claudia G. S. The high "cost" of experimental drugs obtained through health litigation in brazil. **Frontiers in Pharmacology**, vol. 11, p. 1-7, may 2020.

[31] FEDERAL SUPREME COURT OF BRAZIL Extraordinary appeal 657.718 /219. 2019. Available at: <https://redir.stf.jus.br/paginadorpub/paginador.jsp?docTP=TP&docID=754312026> Accessed on: 15 mar. 2024

TABLE 1. CRITERIA CONSIDERED BY COURTS FOR EXPERIMENTAL TECHNOLOGIES, MEDICAMENTS AND TREATMENTS IN COLOMBIA AND BRAZIL

Criteria/Elements	Colombia	Brazil
Legal Framework and Precedents	Allows access under specific conditions (Judgements T-027/2015, T-1330/05, T-243/2015, T-057/2015). Balances scientific evidence and physician judgment.	Sets conditions: Anvisa registration request, renowned agency approval, and no substitutes (RE657718/MG).
Scientific Evidence	Emphasizes "best available evidence" and scientific community acceptance.	Focuses on regulatory approval and therapeutic alternatives.
Public Authority Approval	Physician's assessment crucial; lack of approval doesn't mean experimental.	Critical; specific criteria for ordering unregistered drugs.
Financial Considerations	Ensures access even if not in the Basic Health Plan.	High-cost medications often involved; concerns about financial sustainability.
Impact of Court Decisions	Balances rights and evidence, influencing health policy.	Significant policy implications, especially financial sustainability.

Source: Author´s own elaboration

5. ELEMENTS CONSIDERED BY COURTS IN RELATION TO SERVICES AND MEDICAMENTS WITH REGISTRY AND NON-INCORPORATED INTO THE BASIC PLAN OF HEALTH

The Colombian Health System transitioned from having a positive list or mandatory health plan to a negative list of exclusions. The court's general position regarding this negative list is that it operates on the premise that "everything is included unless it is expressly excluded". Indeed, the Constitutional Court of Colombia has been very active in fulfilling the right to the highest attainable level of health. The Right to health has been recognized as a fundamental right in art. 1 of Statutory Law 1751 of 2015, therefore any individuals can sue for services and medicaments even if they are not included in the mandatory health plan[32]. The health System of Colombia has included a basic plan of health that covers different treatments, technologies and medicines and art. 15 of Law 1751 of 2015 has established some exclusions. However, the Court might guarantee the right to an excluded treatment, medicine, or technology in exceptional cases when the following requirements are cumulatively met 1) absence of a therapeutic alternative in the benefits plan, 2) prescription by the treating physician 3) patient´s financial inability to bear the cost and 4) existence of a threat or violation to life or

[32] CARDENAS RAMÍREZ, Elena. Alcances del derecho a la salud en colombia: una revisión constitucional, legal y jurisprudencial. **Revista de Derecho**, vol. 40, p. 199-226, jul./dic. 2013.

physical integrity of the patient[33]. The Colombian court has also established some limits and restrictions on Intra-urban transportation, accommodation, and food for the patient and their companion, Provision of extrahospital doctors: caregiver, home care, and nursing services, dental treatments, access to fertility treatments, sexual reaffirmation processes, and technologies such as wet wipes and access to health for foreigners. In judgement SU-508 of 2020 the Court stated that if there is not medical prescription the judge has 2 options: 1) Judges might grant the health service or technology provided that the order is conditioned upon subsequent ratification by the treating practitioner, and 2) When there is "a reasonable indication of health impairment", the Court may protect the right in its diagnostic facet. Although art. 15 of Statutory Law 1751 of 2015 prohibits those public resources be used for financing cosmetic treatments, the Colombian Court upheld a ruling ordering psychosocial assessment for plastic surgery[34]. While Inter-municipal transport is included in the plan of health, however, Intra-urban transport for the patient is conditioned on medical prescription. However, even if there is no prescription, a study on the economic conditions as well as on the health conditions of the patients must be undertaken. Similarly, although the Basic plan of health does not include transport for the patient´s companion, the right should be granted provided that there is a medical prescription, and if such prescription is not available a study on the economic conditions as well as on the health conditions of the patient must also be undertaken.[35] In the case of the caregiver service the Court has sustained that is exceptional and the Health Promoting entity must grant this right when two conditions are met 1) when there is medical certainty about the patient´s need to receive this service; and 2) when such aid cannot be assumed by the patient´s family because it is materially impossible[36]. At the same time, the court has set an important precedent regarding subjects of special constitutional protection such as drug dependents, people with HIV/AIDS, and people with cancer. Simultaneously, many cases have been resolved in relation to exemptions from payments and co-payments

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[33] COLOMBIAN CONSTITUTIONAL COURT, Judgement SU 508/2020 ¶ 146. Magistrado Ponente: Alberto Rojas Ríos and José Fernando Reyes Cuartas. Available at: <https://www.corteconstitucional.gov.co/relatoria/2020/SU508-20.htm> Accessed on: 18 feb. 2024

[34] COLOMBIAN CONSTITUTIONAL COURT, "Court upheld ruling ordering psychological assessment for plastic surgery". 4 abr. 2024. Available at: <https://www.corteconstitucional.gov.co/noticia.php?Corte-confirma-fallo-que-ordena-valoraci%C3%B3n-psicol%C3%B3gica-para-realizaci%C3%B3n-de-cirug%C3%A-Da-pl%C3%A1stica-9489> Accessed on: 1 apr. 2024

[35] COLOMBIAN CONSTITUTIONAL COURT, Judgement T-459/22 ¶ 71, 72 and 73. Magistrado Ponente: Diana Fajardo Rivera. Available at: <https://www.corteconstitucional.gov.co/relatoria/2022/T-459-22.htm> Accessed on: 1 feb. 2024

[36] COLOMBIAN CONSTITUTIONAL COURT, Judgement T-015-21. Magistrado Ponente: Diana Fajardo Rivera. Available at: <https://www.corteconstitucional.gov.co/relatoria/2021/T-015-21.htm> Accessed on: 15 mar. 2024

In relation to Brazil, some authors are keen to suggests that Courts take into account the satisfaction of all health needs with the most advanced treatment available, irrespective of its costs[37]. Extraordinary appeal RE 566.471[38] has also establish that Courts in Brazil can order medicines not incorporated into SUS on an exceptional basis when the following cumulative requirements are met: administrative denial, illegality or delay in incorporation by CONITEC, impossibility of substitution, proof of efficacy based on high-level scientific evidence, demonstrated clinical indispensability, and patient´s financial inability to afford the medication.

TABLE 2. CRITERIA CONSIDERED BY COURTS FOR SERVICES AND MEDICAMENTS WITH REGISTRATION AND NOT INCORPORATED INTO THE BASIC HEALTH PLAN IN COLOMBIA AND BRAZIL

Criteria/Elements	Colombia	Brazil
Legal Framework and Precedents	Negative list of exclusions; "everything included unless excluded" (Statutory Law 1751 of 2015). Courts can guarantee excluded treatments in exceptional cases.	RE 566.471 established that absence of inclusion in SUS lists generally prevents judicial provisions. Exceptions allowed only when specific cumulative requirements are met.
Scientific Evidence	Required to validate treatments; limits on exclusions when no alternatives exist or not ordered by a physician.	Requires high level scientific evidence through ramdomized clinical trials, systematic review or meta-analysis. Must prove clinical indispensability through detailed medical report.
Public Authority Approval	Physician's order is crucial; considers financial capacity and threat to life or physical integrity. Courts can also protect diagnostic rights.	Requires analysis of CONITEC´s non-incorporation act or administrative denial. Courts must consult NATJUS for technical assessment before decisions.
Financial Considerations	Ensures access to treatments not in the Basic Health Plan, considering patient's economic conditions.	Orders treatments based on proof of financial incapacity and cost considerations.
Impact of Court Decisions	Ensures access to necessary treatments, setting limits and exceptions. Courts can order services even without explicit inclusion if health needs demonstrated.	Significant policy implications, focusing on financial sustainability and public institutions' roles. Courts must notify competent bodies to evaluate possible incorporation into SUS when granting medications.

Source: Author´s own elaboration

[37] FERRAZ, Octavio Luiz M.. The right to health in the courts of Brazil: worsening health inequities? **Health and Human Rights**, vol. 11, n. 2, p. 33-45, 2009.

[38] FEDERAL SUPREME COURT OF BRAZIL Extraordinary appeal RE 566.471. 26 sep. 2024. Available at: <https://portal.stf.jus.br/processos/detalhe.asp?incidente=2565078> Accessed on: 25 dec. 2024

6. Elements considered by Courts in relation to Services and Medicaments incorporated into the basic plan of health

It is well known the elements that courts take into account when reviewing health-related cases including existing constitutional and legal frameworks, Courts play a very crucial role in the recognition of medicaments and services already included in the plan of health. This includes the application of law and existing regulations, commitments and obligations as well as an evaluation of the evidence. A significant portion of the cases litigated in the Courts of the 2 countries are related to services and medicaments already included in the basic plan of health. This means that any citizen is constitutionally entitled to these technologies or services, however, due to different factors patients are not able to access it.

In the case of Brazil, Courts take into account the constitutional right as recognised in the Brasilian constitution of 1998, Since Health Rights litigation in Brazil has increased, this has led to the development of new strategies among several stakeholders in order to improve decision making based on evidence. Therefore, new institutions[39] that supports staff as well as databases such as e-NatJus that centralizes technical reports have been created. Brazilian courts evaluate whether the health service of medicament claimed are fundamental in order to guarantee the right of individuals. However, judges tend to interpret the right to health as established in article 6 and 196 of the constitution of Brazil irrespective of their costs[40]. This perspective assumes that the interpretation of judges is favouring the elites. Thus, generating inequalities in access. In addition to that, the existence of a report from CONITEC did have an influence in the decision-making process, thus for the Courts did continue deciding cases in favour of patients despite the report recommended against the funding of such treatments[41].

On the other hand, Courts started recognizing that some fundamental rights were interconnected with other rights such as the right to health. Then the court decided to use the principle of vital minimum in order to recognize the dignity of the person and in 1998 the Court acknowledged that fundamental rights are accepted by consensus because of their connection to dignity[42]. Judges tend to interpret the

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39 Núcleo de Avaliação de Tecnologias de Saúde (NATS) and CONITEC a HTA (Health Technology Assessment body)

40 FERRAZ, Octavio Luiz M. The right to health in the courts of Brazil: worsening health inequities? **Health and Human Rights**, vol. 11, n. 2, p. 33-45, 2009.

41 WANG, Daniel; DE VASCONCELOS, Natália Pires; POIRIER, Mathieu J. P.; CHIEFFI, Ana; MÔNACO, Cauê; SRITHARAN, Lathika; VAN KATWYK, Susan Rogers; HOFFMAN, Steven J. Health technology assessment and judicial deference to priority-setting decisions in healthcare: Quasi-experimental analysis of right-to-health litigation in Brazil. **Social Science & Medicine**, vol. 265, p. 113401, nov. 2020.

42 COLOMBIAN CONSTITUTIONAL COURT, Foro Conmemoración de los 30 años de la acción de tutela en Colombia. 2022. Available at: <https://youtu.be/eS5FrFpSoQo> Accessed on: 10 feb. 2024.

right to health as established in commitments and obligations and existing legislation such as Art. 49 of the Constitution and precedents. As previously mentioned, the Colombian court through art. 15 of Law 1751 of 2015 adopted an "express exclusion model" according to which the patient is entitled to receive all health services and technologies except those that are expressly excluded. Similarly, the court has established two models in relation to inclusions. Health services and medicaments might be explicitly included or implicitly included. Through the *Implicit inclusion rule* the court recognize those medicaments, technologies and services that are not expressly excluded in the list of exclusions. The court has applied these rules for ordering diapers, wheelchairs, pressure sore creams, gloves, and catheters[43]. Among those explicitly included are those medications, technologies, and services financed with UPC (Capitated Payment Unit) resources. The court has established that reconstructive or functional surgeries and bariatric surgeries are included, this includes Gastric bypass (Roux-en-Y), Biliopancreatic diversion with duodenal switch, Sleeve gastrectomy. Similarly, the court has established inter-municipal transport and nursing services as included in the Basic Health Plan. In order to access implicit and explicitly included services and medicaments the patient must show the prescription from the treating physician. The negation of these services constitutes a violation of the right to health. However, judges in Colombia are able to grant medicaments even if the patient does not provide a medical prescription, particularly when there is a "*notorious fact*" that the patient needs the medicament or service or when there is "*reasonable evidence*" that the lack of such service or technology might affect the health of the patient. The Court in those particular cases is able to protect the right in its diagnostic aspect and order the health promoting entity to issue a concept that demonstrates whether the patient requires the medicament or service. Thus, in Judgement T-394 of 2021 the Court stated that Health promoting entities must guarantee the right to diagnosis regardless of whether or not a medical prescription is required to provide health services.

[43] COLOMBIAN CONSTITUTIONAL COURT, Judgement T-050/23. Magistrado Ponente: Paola Andrea Meneses Mosquera. Available at: <https://www.corteconstitucional.gov.co/relatoria/2023/T-050-23.htm> Accessed on: 1 apr. 2024

TABLE 3. ELEMENTS CONSIDERED BY COURTS IN COLOMBIA AND BRAZIL FOR SERVICES AND MEDICAMENTS INCORPORATED INTO THE BASIC PLAN OF HEALTH

Criteria/Elements	Colombia	Brazil
Legal Framework and Precedents	Statutory Law 1751 of 2015: Negative list of exclusions ("everything included unless excluded"). Courts apply laws, regulations, and evidence to ensure access.	Constitutional right to health (Articles 6 and 196). Courts rely on laws, obligations, and technical reports (e.g., CONITEC, e-NatJus) for decision-making.
Implicit and Explicit Inclusion Model	Implicit inclusion: Services and medicaments not expressly excluded are included. Explicit inclusion: Services and medicaments financed with UPC resources, including surgeries like gastric bypass and inter-municipal transport.	Courts ensure treatments based on technical reports, often favoring fundamental health rights irrespective of cost. Decisions are influenced by technical assessments and cost considerations, but courts may prioritize constitutional health rights.

Source: Author´s own elaboration

7. CHALLENGES FACING COURTS IN THE RECOGNITION OF EXPERIMENTAL, EXCLUDED AND INCLUDED MEDICAMENTS AND TECHNOLOGIES IN BRAZIL AND COLOMBIA

Health services and medications are regulated by courts in Brazil and Colombia, creating a complex situation. Scientific evidence, legal frameworks, public authority interaction, and financial sustainability must be balanced in both countries to recognize experimental, excluded, and included treatments and technologies.

In Colombia, courts interpret the statutory framework (Law 1751 of 2015) based on a "negative list" of exclusions, where all health services and medicaments are presumptively included unless explicitly excluded. The Constitutional Court has been proactive in ensuring access even to excluded treatments in exceptional cases, relying on criteria like lack of alternatives, physician recommendations, and threats to life or physical integrity. For experimental treatments, the court allows access under certain conditions based on "best available evidence" and scientific community acceptance, balancing physician judgment with the evidence. However, lack of regulatory approval does not automatically make a treatment experimental. In contrast, Brazil's legal framework is anchored in Articles 6 and 196 of the 1988 Constitution, which guarantee the right to health. The Supreme Federal Court has tried to limit this, stating that courts should only order unregistered drugs in exceptional cases when there is a delay by the regulatory agency ANVISA, a registration request exists, the drug is approved by renowned regulatory agencies, and no therapeutic substitute exists. However, critics suggest that

courts still tend to rule in favor of patients in most cases, even against recommendations by the health technology assessment body CONITEC. This has significant financial sustainability implications. This approach underscores the reliance on institutional authority and technical assessments, as seen in the landmark decision RE 657718/MG, which sets strict criteria for the provision of experimental drugs without HTA (Health Technology Assessment). In terms of access to incorporated services and medicaments, the Colombian system uses both implicit inclusion (all services not expressly excluded) and explicit inclusion (services financed by the UPC). Courts ensure access to necessary treatments like diapers and wheelchairs not expressly excluded. In Brazil, courts ensure treatments based on technical reports, often favoring fundamental health rights irrespective of cost, though they consider technical and cost factors.

The impact of court decisions is substantial in both countries in terms of health system sustainability and the roles of public institutions. Courts struggle to balance individual rights with evidence, costs and institutional authority in a context of imperfect regulatory frameworks and resource constraints. Developing transparent, participatory HTA processes to inform coverage decisions, while allowing flexibility in exceptional cases, remains an ongoing challenge that will shape the future of right to health litigation.

Brazilian and Colombian courts have limited the right to health due to separation of powers, financial sustainability, and democratic legitimacy. Despite these restrictions, thousands of repeated health claims are filed annually. This might be because courts are not fully considering the structural causes of this litigation. In some cases, Courts have examined health case context and structure, however, to advance health rights judicialization and universal health coverage, courts must consider structural causes and adopt a rights-based approach to health policy.

Brazilian courts often face conflicts between the "reserve of the possible" and the "existential minimum" (mínimo existencial). In high-cost medication cases, courts must weigh treatment necessity and cost. Rural and economically disadvantaged people might be disadvantaged by judicial decisions that favor those with better access. These issues require major judicial and health system reforms in both nations. First and foremost, HTA must be strengthened in Brazil. Public, participatory HTA frameworks can rigorously evaluate experimental treatments before court approval. Consequently, treatment safety and efficacy improve as judicial legitimacy and consistency improve. In contrast, Colombian courts should prioritise transparency and consistency over HTA. By establishing clear experimental treatment approval guidelines will ensure judicial consistency and fairness.

This high level of litigation may continue because many courts are not fully considering the structural causes. Many individual claims are commonly addressed without fully considering the context and systemic issues that is driving health rights

judicialization. Therefore, focusing on symptoms rather than causes is leading to repeated claims. Indeed, a few Brazilian and Colombian courts have examined health litigation's context and structural factors. In order to reduce this high level of litigation. Therefore, Courts should take into account the possibility of ordering more structural injunctions and consistently adopt a rights-based structural approach to health-related cases.

Internal judicial reforms and external health system and policy reforms are needed to address the complexities of health court adjudication in Brazil and Colombia. Internally, courts should consider structural injunctions, as Colombia's Judgment T-760 showed, and systemic factors like health system maturity in case evaluations. Increased partnerships with public health institutions and stakeholders could help courts understand health technology, resource constraints, and healthcare context. The external aspects of healthcare reform should address market deficiencies, bureaucratic and technocratic aspects, government responsiveness to vulnerable populations, incentives, state planning and supervision, and professional working conditions and skills. These reforms help courts make better decisions, protect the right to health, and create a more sustainable and equitable health system. To overcome health litigation polarization, normative and political premises must be clarified, empirical data gaps addressed, and interdisciplinary dialogue fostered.

8. CONCLUSION

The judicialization of health rights in Colombia and Brazil has greatly improved access to medicines, technologies, and health services. Courts in both nations have interpreted laws, evaluated scientific evidence, and balanced individual rights and public health. Lack of alternatives, physician recommendations, and threats to life or physical integrity have led the Colombian Constitutional Court to guarantee access to health services and medications, even those not covered by the basic health plan. Under certain conditions, the court has allowed experimental treatments, emphasizing the importance of best evidence and scientific community acceptance. In contrast, Brazil's Supreme Federal Court has imposed more stringent criteria for access to healthcare and medications, partly in response to criticism that courts prioritize patient´s rights over financial sustainability and institutional authority. Despite these measures, the Brazilian judiciary continues to face challenges in balancing individual rights with the broader implications for the health system´s sustainability.

Both countries struggle with court decisions affecting health system sustainability and public institution roles. In imperfect regulatory frameworks and resource constraints, courts must balance individual rights, evidence, costs, and institutional authority. The article suggests addressing these complexities with internal judicial reforms

like structural injunctions and systemic factors and external health system and policy reforms. These reforms should address market deficiencies, government responsiveness to vulnerable populations, state planning and supervision, and professional working conditions and skills. Health rights judicialization in Colombia and Brazil has shown how courts ensure medication and service access. It has also shown the challenges of balancing individual rights with public health and the need for comprehensive health system reforms to make it more sustainable and equitable. To achieve universal health coverage and protect citizens' health rights, both countries must foster interdisciplinary dialogue, address data gaps, and clarify normative and political premises.

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