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ARTICLE

Judicialization, public budgets, and access to medicines in Brazil: a documentary analysis from law and economics

Judicialização, orçamento público e acesso a medicamentos no Brasil: análise documental sob a perspectiva do Direito e Economia

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Abstract

Objective: To examine how Brazilian law reconciles the individual right to medicines, evidence-based health policy, and the distributive consequences of judicial decisions. Method: A qualitative legal-documentary analysis was conducted using purposive sampling. The corpus comprised the Federal Constitution, Laws No. 8,080/1990, 12,401/2011, 13,655/2018, and Complementary Law No. 101/2000; National Council of Justice documents; and the Federal Supreme Court decisions in General Repercussion Themes 6 and 1,234, consolidated in 2024. Documents were coded according to entitlement, institutional competence, evidence, opportunity cost, federal allocation, and implementation. Law and Economics was used as an analytical lens, without reducing fundamental rights to monetary calculation. Results: The 2024 precedents preserve exceptional judicial protection while imposing evidentiary requirements, deference to health-technology assessment, allocation rules among federal entities, and information-sharing mechanisms. This design can reduce inconsistent orders and transaction costs, but access may be restricted if technical evidence is interpreted mechanically or if administrative procedures remain slow. Conclusion: Legitimate adjudication should combine rights protection, reasoned scrutiny of administrative decisions, scientific evidence, budget transparency, and attention to distributive effects. The best institutional response is not unrestricted judicial intervention or absolute deference, but structured dialogue capable of correcting exceptional failures without dismantling universal policy.

Resumo

Objetivo: examinar como o direito brasileiro concilia o direito individual a medicamentos, a política de saúde baseada em evidências e as consequências distributivas das decisões judiciais. Método: realizou-se análise jurídico-documental qualitativa com amostragem intencional. O corpus foi composto pela Constituição Federal, pelas Leis nº 8.080/1990, 12.401/2011 e 13.655/2018, pela Lei Complementar nº 101/2000, por documentos do Conselho Nacional de Justiça e pelas decisões do Supremo Tribunal Federal nos Temas 6 e 1.234 da repercussão geral, consolidadas em 2024. Os documentos foram codificados segundo direito, competência institucional, evidência, custo de oportunidade, repartição federativa e implementação. Utilizou-se Direito e Economia como lente analítica, sem reduzir direitos fundamentais ao cálculo monetário. Resultados: os precedentes de 2024 preservam a tutela judicial excepcional, mas estabelecem requisitos probatórios, deferência à avaliação de tecnologias em saúde, regras de responsabilidade entre entes federativos e mecanismos de compartilhamento de informações. O desenho pode reduzir decisões contraditórias e custos de transação, porém poderá restringir o acesso se a evidência técnica for aplicada mecanicamente ou se os procedimentos administrativos permanecerem lentos. Conclusão: a adjudicação legítima deve combinar proteção de direitos, controle fundamentado das decisões administrativas, evidência científica, transparência orçamentária e atenção aos efeitos distributivos. A melhor resposta institucional não é a intervenção judicial irrestrita nem a deferência absoluta, mas o diálogo estruturado capaz de corrigir falhas excepcionais sem desorganizar a política universal.

1. Introduction

The judicialization of public policy exposes a structural dilemma of constitutional democracies. Courts are expected to protect enforceable rights, especially when delay threatens life or irreparable harm. At the same time, public policies distribute scarce personnel, technologies, and budgets across a population. A decision that produces an immediate benefit for one claimant may alter priorities, purchasing arrangements, and resources available to unidentified users. The legal problem is therefore inseparable from institutional design and distributive economics.

In Brazil, health is a constitutional right and a duty of the State. The Unified Health System (SUS) must provide universal and comprehensive care, while pharmaceutical policy relies on clinical protocols, regulatory approval, price rules, and health-technology assessment. Litigation frequently arises when a prescribed medicine is absent from public lists, has been rejected or not yet assessed, is indicated for a different purpose, or is not registered by the national regulator. These cases combine urgency with uncertainty.

Conventional descriptions often oppose the “right to life” to the “reserve of the possible.” This binary formulation is inadequate. Rights require institutions, budgets, evidence, and fair procedures; budgets, in turn, are legal instruments for realizing rights rather than excuses for noncompliance. Law and Economics contributes by identifying incentives, information asymmetries, opportunity costs, transaction costs, and distributional effects. Its role is analytical: it cannot assign the value of a life or replace constitutional commitments.

In 2024, the Federal Supreme Court (STF) completed major judgments in General Repercussion Themes 6 and 1,234. Theme 6 established criteria for exceptional judicial supply of medicines not incorporated into SUS. Theme 1,234 addressed jurisdiction, federal responsibilities, financing, and implementation. Binding Precedents 60 and 61 extended standardization. Together, these instruments constitute a new governance architecture for pharmaceutical litigation.

This article asks how the 2024 framework reconciles individual protection, administrative expertise, and collective resource allocation. Its objective is to interpret the relevant legal documents through Public Policy, Law and Economics, identifying advances, risks, and conditions for legitimate implementation.

2. Method

The study adopted qualitative legal-documentary analysis. Unlike a literature review, the unit of analysis was the normative and institutional document. Purposive sampling selected texts with direct authority over the right to health, pharmaceutical incorporation, fiscal governance, judicial reasoning, or implementation of health litigation. The temporal endpoint was December 2025, although the central precedents were completed in 2024.

The primary corpus comprised the Federal Constitution; Law No. 8,080/1990; Complementary Law No. 101/2000; Law No. 12,401/2011; Law No. 13,655/2018; National Council of Justice instruments concerning technical support; STF Themes 6 and 1,234; and Binding Precedents 60 and 61. Institutional news and explanatory documents were used only to clarify procedural history and implementation, not as substitutes for authoritative texts.

Analysis proceeded in four stages. First, each document was read to identify the right, duty, decision-maker, procedure, evidence standard, and remedy. Second, provisions were coded under six categories: entitlement; institutional competence; scientific evidence; opportunity cost; federative allocation; and implementation. Third, relationships and tensions among documents were mapped. Fourth, the results were interpreted using concepts of information asymmetry, incentives, transaction costs, externalities, and distributive efficiency.

Efficiency was not treated as simple expenditure minimization. The relevant standard was institutional efficiency consistent with constitutional rights: producing timely, equitable, evidence-based protection with the lowest avoidable administrative and social cost. No personal data or human participants were used; ethics committee approval was therefore unnecessary.

Table 1. Legal-documentary corpus and analytical function.

1	Federal Constitution (1988)	Constitutional	Arts. 6, 196–200	Universal right; State duty; SUS organization
2	Law No. 8,080/1990	Statutory	SUS organization and pharmaceutical care	Defines public responsibilities and comprehensive care
3	Complementary Law No. 101/2000	Fiscal	Planning, expenditure, accountability	Makes budget consequences and fiscal transparency legally relevant
4	Law No. 12,401/2011	Health policy	Technology incorporation and clinical protocols	Institutionalizes evidence and health-technology assessment
5	Law No. 13,655/2018	Administrative law	Consequences of public decisions	Requires attention to practical consequences and alternatives

6	CNJ Recommendation No. 31/2010 and NatJus policy	Judicial governance	Technical support for health cases	Reduces information asymmetry through expert evidence
7	STF Theme 6 / RE 566,471 (2024)	Judicial precedent	Non-incorporated high-cost medicines	Creates cumulative requirements for exceptional supply
8	STF Theme 1,234 / RE 1,366,243 (2024)	Judicial precedent	Jurisdiction, federal responsibility, reimbursement	Coordinates litigation, financing, and intergovernmental duties
9	Binding Precedents 60 and 61 (2024)	Binding precedent	Non-incorporated and unregistered medicines	Standardizes adjudication across the judiciary

Source: Prepared by the author(s) from official legal and institutional documents.

3. Results

3.1 From an individual claim to a governance problem

The Constitution and Law No. 8,080/1990 establish a strong entitlement, but they do not imply that every prescription automatically becomes a public obligation. Law No. 12,401/2011 created a procedure for incorporating technologies into SUS, linking collective coverage to evidence of efficacy, safety, effectiveness, and economic evaluation. The procedure responds to information asymmetry: prescribers and patients may know the clinical history, whereas regulators compare evidence, alternatives, prices, and population impact.

Judicial litigation can correct administrative omission, unreasonable delay, discrimination, or an exceptional mismatch between general policy and an individual clinical condition. It can also bypass comparative assessment. When courts decide with incomplete information, a high-cost order may be paid outside negotiated procurement and without evaluating a therapeutic substitute. The externality falls on the health budget and on users who are not represented in the lawsuit.

This does not make judicialization inherently inefficient. Litigation can reveal unmet needs, force transparency, and stimulate policy revision. The relevant distinction is between corrective adjudication and routine substitution of the policy process. A governance framework should preserve the former while reducing incentives for strategic bypass, contradictory orders, and fragmented purchasing.

3.2 Theme 6: exceptional protection and evidentiary burden

Theme 6 concerns high-cost medicines that are not incorporated into SUS. The 2024 thesis rejects both automatic supply and an absolute prohibition. Exceptional judicial provision depends on cumulative requirements, including the claimant's inability to pay, absence of an adequate incorporated substitute, scientific support, and scrutiny of the administrative non-incorporation or omission. The judge must engage with technical evidence rather than rely solely on an individual prescription.

From a Law and Economics perspective, cumulative requirements change incentives. They discourage claims supported only by asymmetric information and reduce the probability that promotional or low-quality evidence determines public

expenditure. Requiring analysis of alternatives directs attention to incremental benefit, not merely to whether a medicine can produce some effect. Requiring review of the administrative process also preserves investment in health-technology assessment.

The model nevertheless carries risks. Evidentiary burdens can become access barriers for poor claimants who lack expert support. Scientific uncertainty is common in rare diseases, and absence of large trials does not necessarily mean absence of benefit. Courts and technical centers must therefore distinguish lack of evidence from evidence of ineffectiveness. Legal aid, independent expertise, expedited procedures, and reasoned treatment of uncertainty are essential.

3.3 Theme 1,234: federal coordination and transaction costs

Theme 1,234 addresses who should respond to claims, which court has jurisdiction, how costs are allocated, and how decisions connect to public policy. These questions appear procedural, but they shape access and expenditure. Unclear responsibility produces duplicated defenses, jurisdictional disputes, delayed treatment, and uncertain reimbursement. Each is a transaction cost generated by fragmented federalism.

The 2024 arrangement seeks to standardize competence and direct financial responsibility according to the medicine and its incorporation status, while promoting a national platform and shared information. Better coordination can prevent the claimant from bearing the burden of identifying the correct public entity and can reduce repeated collection of the same clinical and administrative information.

The economic gain depends on implementation. A platform that merely adds documentation may increase rather than reduce costs. Interoperability, current price data, clear deadlines, privacy safeguards, and automatic reimbursement rules are necessary. Coordination must also prevent cost shifting, in which one level of government delays action expecting another to finance the order.

3.4 Budget impact, equality, and the invisible patient

Opportunity cost is central because the health budget is finite even when the constitutional right is universal. The cost of a judicial order is not simply its invoice; it includes emergency procurement, logistics, monitoring, and the value of services displaced. Courts rarely see the unidentified patients affected by reallocation. This "invisible patient" problem creates a representational imbalance between a concrete claimant and diffuse beneficiaries of public programs.

Budget impact cannot, however, operate as a generic defense. Public authorities possess the relevant financial information and must demonstrate consequences with transparent data. Law No. 13,655/2018 reinforces attention to practical consequences and alternatives in public decision-making. A reasoned decision should compare clinical benefit, available substitutes, urgency, price, population implications, and the quality of the incorporation process.

Equality also requires more than identical treatment. People with rare diseases or atypical clinical responses may be excluded by rules designed for the majority. Exceptional relief is therefore compatible with collective policy when it is based on relevant difference, reliable evidence, and a procedure capable of learning from repeated cases. Recurring successful claims should trigger reassessment by the competent health-technology body.

4. Discussion

The documentary analysis indicates a transition from atomized litigation toward structured judicial governance. The STF did not eliminate individual enforcement; it conditioned intervention on evidence, institutional review, and federative coordination. This approach is compatible with separation of powers when courts verify legality, procedural quality, rationality, and exceptional harm without assuming permanent management of pharmaceutical policy.

The framework can improve consistency and reduce transaction costs, but formal standardization is insufficient. NatJus technical opinions must be independent, timely, transparent, and sensitive to the individual record. Health authorities must decide incorporation requests within reasonable periods and publish understandable reasons. Public defenders and claimants require access to technical assistance. Without these conditions, deference may protect administrative inertia rather than expertise.

A Law and Economics approach also recommends feedback. Judicial data should identify recurrent medicines, diseases, prescribers, geographic clusters, approval rates, prices, and time to decision. Aggregated patterns can reveal supply failures, off-label demand, unequal legal representation, or outdated protocols. Feedback converts litigation costs into information for policy improvement.

Procurement incentives deserve attention. Individual orders may weaken bargaining power and produce purchases at higher prices. Centralized acquisition, price ceilings, risk-sharing agreements, and reimbursement protocols can reduce costs after a judicial determination. Yet confidential commercial arrangements must not prevent public accountability for value and budget impact.

The central normative conclusion is that neither maximalist intervention nor blanket restraint is adequate. Unrestricted intervention may undermine equal priority-setting; absolute deference may leave serious administrative failures uncorrected. Structured dialogue offers a middle path: courts demand evidence and reasons, administrators retain technical functions, federal entities coordinate financing, and repeated cases return information to the policy cycle.

4.1 Analytical framework for judicial decisions

A defensible decision can follow six questions. First, is there urgent and serious harm? Second, is the medicine registered and supported by reliable evidence for the relevant condition? Third, does SUS offer an effective alternative for this patient? Fourth, was the administrative incorporation or denial procedure timely, transparent, and rational? Fifth, what are the price, procurement, and distributive consequences, supported by public data? Sixth, which remedy protects the claimant while preserving coordination—for example, expedited administrative reassessment, temporary supply, monitoring, or centralized purchase?

This sequence does not turn judges into economists or physicians. It organizes the information needed for legal proportionality and makes the opportunity cost visible without allowing cost alone to decide. It also clarifies the burden of production: claimants establish clinical need and inability to pay, while government provides policy records, alternatives, prices, and budget evidence.

5. Conclusion

The 2024 STF precedents represent an important redesign of pharmaceutical judicialization in Brazil. Themes 6 and 1,234 preserve exceptional access while

strengthening evidence, administrative review, federal coordination, and implementation. In economic terms, the framework can reduce information asymmetry, inconsistent incentives, fragmented procurement, and procedural transaction costs.

Its legitimacy will depend on practice. Evidentiary requirements must not exclude vulnerable claimants; technical bodies must be independent and timely; budget arguments must be demonstrated rather than asserted; and digital coordination must simplify access. Courts should protect against exceptional failure while respecting a transparent and scientifically grounded policy process.

Public Policy, Law and Economics converge on a shared institutional objective: rights that are individually enforceable, collectively sustainable, and fairly distributed. The most efficient policy is not necessarily the least expensive, but the one that uses transparent procedures and reliable evidence to maximize constitutional protection across present and future patients.

Declarations

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Conflict of interest: The author(s) declare no financial, personal, or institutional conflicts of interest.

Data availability: The documentary corpus consists of publicly available legal and institutional documents cited in the article.

Use of generative artificial intelligence: The author(s) must insert a declaration that truthfully reflects the preparation of the final manuscript.

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