FIOCRUZ | Brasília

Cadernos Ibero-Americanos de Direito Sanitário
Cuadernos Iberoamericanos de Derecho Sanitario

ISSN: 2358-1824

Article

Societal constitutionalism and limits to the power of transnational pharmaceutical corporations

Constitucionalismo societal e limites ao poder das corporações farmacêuticas transnacionais

Constitucionalismo societal y límites al poder de las corporaciones farmacéuticas transnacionales

Claudia Terezinha Moraes Pinheiro Delgado[1]
Universidade do Rio dos Sinos, São Leopoldo, RS.
https://orcid.org/0000-0001-6415-4429
claudiapinheirodelgado@gmail.com

Abstract

Objective: To analyze the applicability of societal constitutionalism theory as a mechanism to limit the power of transnational pharmaceutical corporations and protect biological integrity, with emphasis on Brazilian health regulation and the phenomena of over-medicalization and synaptic reconfiguration induced by addictive drugs. **Methodology:** Qualitative research of a theoretical-normative nature, based on the analytical-bibliographical method. The following databases were consulted: PubMed, SciELO, Scopus, and Web of Science, using the DeCS/MeSH descriptors "societal constitutionalism", "pharmaceutical industry", "pharmacovigilance", "psychic integrity", and "bioethics", combined with the Boolean operators AND and OR. Inclusion criteria were: articles published between 2021 and 2026, in English, Portuguese, or Spanish, indexed in journals with an impact factor ≥ 1.5 (JCR/Qualis classification). Editorials, letters to the editor, and exclusively laboratory studies without a legal interface were excluded. **Results:** It is demonstrated that phenomena such as over-medicalization and synaptic reconfiguration through addiction reflect the expansion of autonomous social systems that colonize the lifeworld and operate beyond state control. Global constitutional fragmentation requires Health Law to impose mechanisms of ethical self-binding and horizontal effectiveness of fundamental rights on private institutions. **Conclusion:** Contemporary constitutionalism must evolve toward the protection of human agency against systemic aggressions, elevating pharmacovigilance to the status of a constitutional guarantee aimed at preserving physical and psychic integrity.

Keywords: Constitutionalism; Pharmaceutical Industry; Pharmacovigilance; Psychic Integrity; Bioethics.

Resumo

Objetivo: Analisar a aplicabilidade da teoria do constitucionalismo societal como mecanismo de limitação ao poder das corporações farmacêuticas transnacionais e proteção da integridade biológica, com ênfase na regulação sanitária brasileira e nos fenômenos da supermedicalização e da reconfiguração sináptica induzida por fármacos aditivos. **Metodologia:** Pesquisa qualitativa de natureza teórico-normativa, fundamentada no método analítico-bibliográfico. Foram consultadas as bases PubMed, SciELO, Scopus e Web of Science, utilizando os descritores DeCS/MeSH "societal constitutionalism", "pharmaceutical industry", "pharmacovigilance", "psychic integrity" e

[1] Master's Degree in Occupational Health and Management, Universidade do Vale do Itajaí, Itajaí, SC, Brazil. Doctor, Universidade do Rio dos Sinos, São Leopoldo, RS, Brazil.

CC BY

OPEN ACCESS

"bioethics", combinados pelos operadores booleanos AND e OR. Os critérios de inclusão foram: artigos publicados entre 2021 e 2026, em inglês, português ou espanhol, indexados em periódicos com fator de impacto ≥ 1,5 (classificação JCR) ou classificação em estratos superiores conforme a avaliação da Qualis Capes do período 2021-2025. Excluíram-se editoriais, cartas ao editor e estudos exclusivamente laboratoriais sem interface jurídica. **Resultados:** Demonstra-se que fenômenos como a supermedicalização e a reconfiguração sináptica pelo vício são reflexos da expansão de sistemas sociais autônomos que colonizam o mundo da vida e operam à revelia do controle estatal. A fragmentação constitucional global exige que o Direito Sanitário imponha mecanismos de autovinculação ética e eficácia horizontal dos direitos fundamentais às instituições privadas. **Conclusão:** O constitucionalismo contemporâneo deve evoluir para a proteção da agência humana contra agressões sistêmicas, elevando a farmacovigilância à condição de garantia constitucional voltada à preservação da integridade física e psíquica.
Palavras-chave: Constitucionalismo; Indústria Farmacêutica; Farmacovigilância; Integridade Psíquica; Bioética.

Resumen

Objetivo: Analizar la aplicabilidad de la teoría del constitucionalismo societal como mecanismo de limitación del poder de las corporaciones farmacéuticas transnacionales y protección de la integridad biológica, con énfasis en la regulación sanitaria brasileña y los fenómenos de la supermedicalización y la reconfiguración sináptica inducida por fármacos aditivos. **Métodos:** Investigación cualitativa de naturaleza teórico-normativa, fundamentada en el método analítico-bibliográfico. Se consultaron las bases de datos PubMed, SciELO, Scopus y Web of Science, utilizando los descriptores DeCS/MeSH "societal constitutionalism", "pharmaceutical industry", "pharmacovigilance", "psychic integrity" y "bioethics", combinados con los operadores booleanos AND y OR. Los criterios de inclusión fueron: artículos publicados entre 2021 y 2026, en inglés, portugués o español, indexados en revistas con factor de impacto ≥ 1,5 (clasificación JCR/Qualis). Se excluyeron editoriales, cartas al editor y estudios exclusivamente de laboratorio sin interfaz jurídica. **Resultados:** Se demuestra que fenómenos como la supermedicalización y la reconfiguración sináptica por la adicción son reflejos de la expansión de sistemas sociales autónomos que colonizan el mundo de la vida y operan a espaldas del control estatal. La fragmentación constitucional global exige que el Derecho Sanitario imponga mecanismos de autovinculación ética y eficacia horizontal de los derechos fundamentales a las instituciones privadas. **Conclusiones:** El constitucionalismo contemporáneo debe evolucionar hacia la protección de la agencia humana contra agresiones sistémicas, elevando la farmacovigilancia a la condición de garantía constitucional orientada a la preservación de la integridad física y psíquica.
Palabras clave: Constitucionalismo; Industria Farmacéutica; Farmacovigilancia; Integridad Psíquica; Bioética.

Introduction

The contemporary world is witnessing an unprecedented shift in the production of the legal phenomenon. Globalization challenges the centrality of the nation-state as the sole holder of the constitutional monopoly. Against this backdrop, Gunther Teubner's work becomes an essential reference for understanding how the Constitution ceases to be a purely political-state document and becomes a societal phenomenon[1].

Gunther Teubner's theory of societal constitutionalism is based on the following fundamental premise: the Constitution of global society exists in scattered fragments, no longer concentrated in a single state document. For Teubner[1], societal constitutionalism emerges as a response to the "expansive fury" of autonomous social systems particularly the economic, scientific, and technological systems which, in global society, develop their own dynamics detached from state political control.

The essential characteristics of this theory are: (a) constitutionalization is not limited to the state but extends to functional social subsystems; (b) constitutional fragments arise wherever there are processes of social power formation that require limitation; (c) the self-binding of private systems to principles of justice and human rights replaces the traditional normative hierarchy; (d) the polycontextual nature of the coexistence of multiple systemic rationalities that are irreducible to one another requires the law to perform a function of reflective mediation, rather than hierarchical command[1].

Historically, constitutionalism was conceived as a mechanism to curb state arbitrariness. However, the transnational reality reveals that the unchecked expansion of autonomous social systems notably the economic and technological systems generates new forms of rights violations that traditional public law cannot address. This systemic expansion operates according to a logic of blind growth, in which human health ceases to be an intrinsic value and comes to be treated as a byproduct of financial efficiency[1].

Understanding the "power" of transnational pharmaceutical corporations requires more than an economic or market analysis; it demands a theoretical reconstruction of their constitutional dimensions. For the purposes of this article, pharmaceutical power is conceptualized as the effective capacity of a transnational corporation to (i) define the parameters of scientific health research, directing it toward areas of greater financial return at the expense of neglected social needs[2]; (ii) influence state regulatory processes, shaping health legislation in accordance with its commercial interests; (iii) determine, through marketing and lobbying strategies, patterns of medical prescribing and, consequently, medication consumption habits on a global scale; and (iv) litigate or threaten to litigate against states that seek to implement public health policies contrary to their interests, using international arbitration mechanisms as a means of pressure[1].

The novelty of societal constitutionalism, however, lies in the recognition that this power is not merely economic or political, but constitutional in the strongest sense of the term. As Teubner argues[1], constitutional power is no longer limited to state power; it emerges wherever there is the capacity to make decisions that bind the lives of entire communities, regardless of their consent. Pharmaceutical corporations, by deciding which drugs will be developed, at what prices they will be marketed, and to which populations they will be made available, exercise precisely this type of power: they define the conditions of possibility for access to healthcare on a global scale, operating outside the scope of democratic control and state oversight.

This power manifests itself in multiple dimensions. Economically, the world's ten largest pharmaceutical corporations collectively have a market value exceeding the GDP of many nation-states, which gives them the capacity to influence political decisions on a global scale. On the scientific front, these corporations control the majority of randomized clinical trials, determining which molecules will be tested, in which populations, and with which endpoints, thereby allowing them to shape scientific knowledge regarding efficacy and safety[2]. On the regulatory front, the pharmaceutical industry employs more lobbyists than there are public officials dedicated to health regulation in many countries, creating an environment of "regulatory capture" in which regulatory agencies become hostage to the very technical expertise they are supposed to oversee[2].

This power manifests itself concretely in three phenomena that will be analyzed throughout this article. The first concerns overmedicalization, understood as the pharmaceutical industry's expansion into areas of life previously considered non-pathological, thereby fostering the creation of new diseases

and, consequently, new consumer needs[3]. The second refers to synaptic reconfiguration, characterized by the ability of addictive drugs to promote permanent changes in the user's brain architecture. In this context, the "choice" to consume can become a biological necessity, directly compromising psychological integrity and decision-making autonomy[4]. The third aspect corresponds to strategic judicialization, understood as the use of the judiciary as a forum for promoting interests related to the pharmaceutical sector. In this scenario, coordinated action among different actors including lawyers, physicians, and the industry can facilitate the incorporation of high-cost medications into public health systems, using the fundamental right to health as a tool for directing public resources[5].

The connection between these phenomena and the power of pharmaceutical corporations is direct. Overmedicalization is the primary instrument for market expansion; synaptic reconfiguration is the biological mechanism that transforms occasional consumers into captive consumers; and strategic judicialization is the tool for guaranteeing market access, even against the will of the State. These are, therefore, three facets of the same fragmented power that operates in defiance of traditional mechanisms of state control and that demands, in response, a societal constitutionalism capable of imposing effective limits on this systemic expansion[1].

In this scenario, the pharmaceutical industry assumes the role of a global power center. Its decisions regarding the life cycle of medications and the direction of scientific research transcend purely commercial choices, constituting acts of a constitutional nature that define the quality of life of entire populations[1]. The need for societal constitutionalism thus emerges as an imperative to impose ethical limits on these private regimes, ensuring that human agency and biological integrity are not sacrificed to the logic of transnational profitability[1,6].

Systemic collision, a central concept in Teubner's theory, occurs when two or more autonomous social systems (such as law, the economy, and science) operate according to incompatible logics and come into conflict within the same social space. In the case under analysis, the collision arises between: (a) the economic rationality of the pharmaceutical industry (guided by the payment/non-payment code and by profit maximization); (b) the scientific rationality of medical research (guided by the true/false code, but frequently co-opted by commercial interests); and (c) the legal-health rationality (guided by the lawful/unlawful code and by the protection of health as a fundamental right)[1].

This clash exhibits five main characteristics: (i) incommensurability, characterized by the absence of a superior external criterion that would allow for the ranking of conflicting claims; (ii) self-reproduction, in which each system operates in a closed manner, producing its own criteria of relevance; (iii) mutual irritation, in which the systems do not causally determine one another but rather disrupt one another; (iv) operational closure, whereby each system reconstructs external stimuli according to its own internal logic; and (v) selective indifference, whereby information relevant to one system may be invisible to another[1].

To resolve or mitigate these conflicts, three[1] forms of intervention can be proposed: (1) reflexive mediation, in which the law does not impose hierarchies but establishes procedures that compel the systems to consider external values; (2) constitutional self-binding, in which the private systems themselves incorporate ethical limits into their self-regulation; (3) the horizontal effectiveness of fundamental rights, which holds private actors directly accountable for violations of human dignity, regardless of state mediation.

This power dynamic creates a critical interdependence. The physician, often deprived of transparent information by the very cycle of research and technological development, becomes a

weakened link in the patient safety chain. The harm resulting from a failure to fulfill the duty to inform is not limited to a mere "loss of opportunity," but constitutes a direct violation of the patient's decision-making autonomy, whose judgment is often impaired by a technical asymmetry[7].

When economic systems prioritize financial sustainability at the expense of ethics and equity, they seriously compromise access to essential technologies. The urgency of reflective mediation is highlighted by a historical analysis of serious failures in the pharmacovigilance of chronic-use medications, which exposed patients to harmful risks not identified in clinical trials[8]. Such violations of biological integrity directly challenge the constitutional precept that guarantees health as a right of all and a duty of the State, as established in the 1988 Constitution of the Federative Republic of Brazil[9]. In this vacuum, pharmaceutical lex mercatoria establishes a private governance system that, while efficient in terms of the distribution of medical supplies, fails to provide legal certainty for patients.

The law[6] must be redefined beyond the boundaries of the State, understood as a tool for resistance and for "living together" in a pluralistic society, in which institutions must be rebuilt to protect human agency against the impersonality of systems.

The protection of consumers of medications in the Brazilian legal system is grounded in the Consumer Protection Code[10], which establishes the supplier's strict liability for damages resulting from defective products, including those related to insufficient or inadequate information about the risks of pharmaceuticals.

The originality of this article lies in the articulation between the theory of societal constitutionalism, pharmacovigilance as a constitutional guarantee, and the neurobiology of addiction, offering a novel theoretical and normative framework for understanding and confronting the power of transnational pharmaceutical corporations. Unlike previous approaches that limit themselves to criticizing the judicialization of health or regulatory capture, this article proposes that the protection of biological integrity requires a reconfiguration of the very concept of constitutionalism, so as to encompass the multiplicity of centers of power that today define the conditions of possibility for human life.

In light of the above, this article aims to analyze the applicability of the theory of societal constitutionalism as a mechanism for limiting the power of transnational pharmaceutical corporations and protecting biological integrity, with an emphasis on Brazilian health regulation and the phenomena of overmedicalization and synaptic reconfiguration induced by addictive drugs.

Methodology

This is a qualitative study of a theoretical-normative nature, based on the analytical-bibliographic method. The following scientific databases were consulted: PubMed (via MEDLINE), SciELO, Scopus, and Web of Science. The search strategy used the following DeCS/MeSH descriptors, combined using the Boolean operators AND and OR: "societal constitutionalism" OR "societal constitutionalism" AND "pharmaceutical industry" OR "pharmacovigilance" OR "psychic integrity" OR "bioethics." The study integrates Teubner's systems theory[1] with contemporary epidemiological and neurobiological data on the pharmaceutical industry. Inclusion and exclusion criteria: Articles published between January 2021 and March 2026, in English, Portuguese, or Spanish, and indexed in journals with an impact factor of 1.5 or higher (according to the JCR classification) or classified in strata A1, A2, or B1 in the fields of Law or Public Health, according to the CAPES Qualis evaluation

for the 2021–2025 period. Editorials, letters to the editor, book reviews, and purely laboratory studies with no connection to legal or regulatory aspects were excluded.

The rationale for this exclusion is based on the median impact factor of journals in the fields of Law and Bioethics indexed in the JCR for the 2021–2025 period.

The research was structured in three stages. First stage: a bibliographic survey on global constitutional fragmentation, with an emphasis on the work of Gunther Teubner[1]. Second stage: the intersection between health law and the neurobiology of addiction, focusing on synaptic reconfiguration as a violation of physical integrity. Third stage: analysis of emblematic cases of systemic conflicts in the Brazilian and international pharmaceutical markets, including COX-2 inhibitors[8], opioids in indigenous communities[11] and the judicialization of trastuzumab[12].

In accordance with editorial guidelines, the author declares the use of an Artificial Intelligence tool (Gemini/LLM) exclusively to assist in the technical review of the Vancouver style guidelines and to refine textual fluency; intellectual authorship and critical analysis remain the sole responsibility of the author.

As this study is based on publicly available scientific and legislative literature, it is exempt from review by a Research Ethics Committee (CEP), in accordance with the provisions of Resolution No. 510/2016 of the National Health Council.

Results and Discussion

The research undertaken in this article is structured around three interconnected analytical axes, which, together, seek to demonstrate the central thesis that societal constitutionalism[1] provides a theoretical and normative framework capable of imposing limits on the power of transnational pharmaceutical corporations[6] and protecting the biological integrity of individuals.

The first axis analyzes the systemic conflicts[1] between the economic rationality of the pharmaceutical industry and the legal-health rationality of the State, highlighting how the expansion of the global pharmaceutical market generates tensions that traditional public law is unable to resolve. This axis will be examined through three concrete manifestations of these conflicts: (a) overmedicalization[3] understood as the pharmaceutical industry's expansion into areas of life previously considered non-pathological; (b) the judicialization of health[5,9] , analyzed as a mechanism of resistance and, simultaneously, as an arena for the capture of the judiciary by pharmaceutical marketing; and (c) information asymmetry[7], examined in its epistemological and institutional dimensions, with an emphasis on the experiences of Brazil, Costa Rica, and Colombia.

The second research axis investigates pharmacovigilance as a constitutional guarantee, arguing that the monitoring of drug safety cannot be reduced to an administrative procedure but must be elevated to the status of a mechanism for protecting biological integrity against the "expansive fury" of economic and scientific systems[1]. This strand analyzes Brazilian health regulation, the regulatory capture evidenced by cases such as COX-2 inhibitors[8], and experiences of systemic resistance, such as herbal medicine within the SUS.

The third theme explores the neurobiology of addiction as a paradigm of systemic violation, demonstrating how the synaptic reconfiguration induced by addictive drugs constitutes a form of aggression against psychological integrity that requires a legal response beyond the traditional punitive paradigm. This strand examines the transition from the moral model to the brain-disease model[4] and the implications of neuroplasticity for informed consent.

The interconnection between these three axes is fundamental to understanding the central thesis. Systemic conflicts (first axis) demonstrate the existence of a pharmaceutical power that operates outside the scope of state control. Pharmacovigilance as a constitutional guarantee (second axis) provides the legal and normative instrument to curb this power. And the neurobiology of addiction (third axis) reveals the ultimate object of protection — psychological and neurological integrity whose violation demands a constitutional response that transcends the traditional public-private dichotomy. The conclusion integrates these three axes, demonstrating that societal constitutionalism by recognizing the multiplicity of centers of power and requiring them to adhere to ethical self-restraint provides the theoretical framework necessary for the protection of human agency against contemporary forms of systemic domination[1,6].

Systemic Clashes Between Economic Rationality and Biopsychosocial Integrity

From the perspective of societal constitutionalism, regulatory provisions face a direct clash with the logic of pharmaceutical lex mercatoria. While public health regulations aim for rational use, the transnational economic system drives overmedicalization, often circumventing state oversight[1,3]. This dynamic is exacerbated by the "biological capture" of the individual: synaptic reconfiguration must be interpreted by the law as a loss of "psychic habeas corpus." If the individual no longer retains control over their impulses due to pharmacological manipulation, the constitutional protection of free will becomes ineffective.

An analysis of health protection in Brazil requires an understanding that the national legal framework constantly attempts to respond to pressures from the global economic system. This effort is manifested in the robust regulatory framework established by the National Health Surveillance Agency (Anvisa), structured by a set of Resolutions of the Collegiate Board (RDCs) that seek to harmonize clinical practice with public health safety. RDCs No. 585/2013[13] and RDC No. 586/2013[14], by regulating clinical responsibilities and pharmaceutical prescribing, represent an attempt by the State to organize the "gateway" to medication use.

The trajectory of the institutionalization of public consultations at Anvisa, as analyzed by Caldeira and Mendonça[15], reveals a regulatory evolution marked by the transition from an incipient model of publicity to active transparency. This evolution was driven both by pressure from civil Society notably the work of the Brazilian Institute for Consumer Protection (Idec) and by the need to comply with legal frameworks such as the Access to Information Act (Law No. 12,527/2011)[16] and the General Law on Agencies (Law No. 13,848/2019)[17]. Although the Agency has made progress by standardizing the Contribution Analysis Report (RAC) and establishing minimum deadlines for responses, this institutional framework has not eliminated the asymmetry in influence among different social actors. Formal transparency, while indispensable, does not in and of itself guarantee democratic pluralism in the decision-making process[15].

The Judicialization of Health: Between Resistance and Systemic Capture

The judicialization of health is one of the most complex and ambivalent phenomena in contemporary health law, especially in Latin America. In light of societal constitutionalism, judicialization reveals itself as a two-sided phenomenon: on the one hand, it acts as a mechanism of resistance against the induced scarcity of essential technologies, correcting failures in institutional management and in the incorporation of therapeutic innovations[12]; on the other, it serves as an arena

for the capture of the judiciary by the pharmaceutical industry, transferring public resources to the industry and exacerbating structural inequalities in health systems[2,18]. This dual nature requires an analysis that integrates the legal, institutional, economic, and ethical dimensions of the phenomenon.

Judicialization as a Mechanism for Institutional Correction

The Trastuzumab case in Costa Rica illustrates how litigation can serve as a corrective mechanism in the face of institutional mismanagement and delays in the adoption of therapeutic innovations. The study reveals that judicial intervention posed an immediate financial challenge to the Costa Rican Social Security Fund (CCSS) and exposed structural vulnerabilities in the institution's financial management and transparency policies. The absence of agile administrative bodies forces patients to turn to the judiciary to ensure access to essential technologies, transforming the courts into a central actor in shaping public policy on pharmaceutical care[12].

The Costa Rican experience offers lessons on the need to depoliticize health care management. The creation of impartial expert units, capable of providing robust technical and scientific support to judges, emerges as an alternative to ensure that judicial decisions are not based solely on emergency criteria but on a comprehensive assessment of pharmacoeconomic efficiency[12]. This model of technical support for the judiciary has been replicated in Brazil through the Technical Advisory Centers (NATs), created in several states to provide specialized support to judges, with multidisciplinary teams that issue opinions on clinical aspects and existing public policies[19].

Judicialization, Information Asymmetry, and Patient Empowerment

The phenomenon of judicialization serves as an illustration of the information asymmetry between patients, physicians, and the public health system, although experiences in the Ibero-American region show significant variations depending on the national context[7,12]. Patient empowerment, often facilitated by access to information via the internet and social media, was a key factor in the pressure exerted on the CCSS in the Trastuzumab case[12]. This shift in power dynamics, in which information precedes bureaucratic channels, creates an environment in which pharmaceutical marketing can influence demand. The State must, therefore, not only regulate the drug but also regain citizens' trust through transparent, evidence-based public communication[15].

Judicialization and Systemic Capture of the Judiciary

The most concerning aspect of judicialization, for the purposes of this article, is its capacity to function as a vehicle for the capture of the judiciary by the pharmaceutical industry. The systematic review using mixed methods, conducted by Trindade et al.[5] and covering 76,666 court cases involving health technologies in the SUS, revealed that 65% of the claims related to medications, with 70% of the drugs requested not being part of any component of the SUS's pharmaceutical care program[5]. This data shows that judicial intervention is not correcting gaps in access to essential medications but is instead forcing the incorporation of high-cost medications that the pharmaceutical industry was unable to introduce through ordinary administrative channels.

Even more significant is the finding that 68% of the lawsuits were filed by private attorneys, while only 20% were supported by the Public Defender's Office[5]. This data suggests that access to the judiciary for health-related claims is not uniform, with those who have greater financial means to hire private legal representation being favored. Additionally, the authors identified a strong

concentration of medical prescriptions in the hands of a few professionals, raising the hypothesis of a possible collusion between doctors, lawyers, and the pharmaceutical industry to force the inclusion of high-cost medications through the courts[5]. As the authors warn, this concentration "may suggest that these professionals have ties to the pharmaceutical industry, receiving perks for prescribing and securing approval for these drugs"[5].

This dynamic highlights what can be termed the systemic capture of the judiciary by the pharmaceutical industry. Unlike classic regulatory capture, in which the industry directly influences the regulatory agency, systemic capture operates indirectly: the industry stimulates judicial demand for its products, using the fundamental right to health as a vehicle for market access, transforming the Judiciary into an arena for pharmaceutical marketing and diverting public resources to finance drugs that have not met health technology assessment criteria.

Judicialization in Latin America: Comparative Experiences

When compared with other Latin American countries, the Brazilian experience reveals both similarities and distinctive features in the phenomenon of the judicialization of health. A systematic review of the literature was conducted to understand how judicialization unfolds in Brazil and Colombia[18]. The authors found that, in both countries, judicialization emerges as a response to gaps in the implementation of public health policies, but that there are significant differences in the institutional arrangements and legal mechanisms used[18].

In Brazil, this phenomenon centers on claims for high-cost medications and treatments not covered by the SUS, often sponsored by private attorneys and based on medical prescriptions from private sources[5]. This dynamic reveals a concerning influence of the private sector on judicial decisions, with the potential to divert public resources to benefit specific commercial interests[18]. In Colombia, meanwhile, the "action for protection", a swift and easily accessible constitutional mechanism, has been widely used to ensure access to health care, which has generated a significant volume of lawsuits and pressured the Colombian health system to seek rationalization alternatives, such as the creation of health technology assessment agencies[18].

One of the most important findings of the review conducted[18] is the observation that judicialization, while it may promote access to rights for individuals considered in isolation, tends to exacerbate structural inequalities in Latin American health systems. As the authors state, "litigation can create barriers to equitable access to health care, where patients lacking the resources or knowledge to navigate the legal system may be left without essential treatments" [18]. This discrepancy creates a divided health care system, in which access is influenced by the ability to litigate, undermining the system's efficiency and equity[18].

Institutional dialogues as an alternative to judicialization

Recognizing the adverse effects of judicialization does not, however, imply advocating for its abolition. A decade after the creation of the Health Forum by the National Council of Justice (CNJ) in 2010, a systematic review of the literature[19] was conducted to identify and analyze initiatives for intersectoral institutional dialogue aimed at mitigating the judicialization of health care in Brazil[19]. The results showed that, although the topic remains under-explored in the literature, there are successful initiatives that deserve to be recognized and replicated[19].

Among the initiatives identified, the following stand out: (a) the District Permanent Chamber for Health Mediation, created by the Federal District Public Defender's Office to promote conciliation among users of the Unified Health System (SUS), health managers, and legal practitioners; (b) the Operational Support Center for Health Protection Prosecutors' Offices (COPEDS) in Minas Gerais, which conducts itinerant conciliation work; and (c) the Technical Advisory Centers (NATs), which provide specialized technical support to judges[19]. A judge in Araguaína (TO), who established an agreement with the City Government and the Department of Health, was able to resolve 72% of health-related claims out of court, referring only 28% of the cases to the courts[19].

The authors also highlight the role of the Public Prosecutor's Office as a key institutional actor capable of assuming a mediating role in conflicts related to the right to health. As analyzed[19], the Public Prosecutor's Office "has extrajudicial tools for conflict management, such as Conduct Adjustment Agreements (TACs), civil inquiries, phone calls, and meetings with health administrators, in addition to its neutral position vis-à-vis the Judicial and Executive Branches"[19]. This extrajudicial role is valued by most of the prosecutors interviewed, who believe that it "effectively mitigates the judicialization of health care"[19].

A central point of the analysis presented by the authors[19] is the perception that "the polysemy and technical-scientific complexity of health-related issues; the scope of the varied interests involved in the judicialization landscape (doctors, pharmaceutical companies, patient associations, law firms); and the weight of decision-making resting on judges are of such magnitude that there would be no other possible model for resolving health disputes other than through institutional dialogue"[19]. This conclusion reinforces Teubner's[1] thesis that, in the face of a clash between autonomous , and social systems (law, economics, science), reflective mediation rather than hierarchy or unilateral imposition constitutes the most promising path toward harmonizing conflicting interests[1].

These initiatives to reduce reliance on the courts based on health mediation and inter-institutional dialogue constitute concrete examples of the application of the principle of constitutional self-binding proposed by Teubner[1], demonstrating that it is possible to limit the power of private systems without resorting exclusively to judicial channels[1]. By reducing dependence on the judiciary as the primary arena for resolving health-related conflicts, these experiences act as mechanisms of resistance to systemic capture, insofar as they remove judicialization from its role as the main channel for access to medications and replace it with processes of informed deliberation and social participation.

Systemic Vulnerabilities and the Expansion of the Pharmaceutical Market: The Case of Opioids as a Paradigm of Biopolitical Capture

The analysis presented thus far has shown that the judicialization of health, while it may act as a mechanism for institutional correction and a guarantee of access to rights, also reveals itself as an arena for systemic capture by the pharmaceutical industry, transferring public resources to the industry and exacerbating structural inequalities in Latin American health systems[2,5,18]. Initiatives for institutional dialogue and health mediation, although successful in specific contexts[19], do not eliminate the power asymmetry that characterizes the relationship between the economic and legal-health systems, insofar as the very existence of these alternatives presupposes the recognition that the judiciary has become, in many cases, the primary avenue for accessing health technologies, which reveals a deeper failure in the State's capacity to regulate the pharmaceutical market and protect the biological integrity of its citizens[1].

This structural failure of the State to curb the "expansive fury" of the economic system[1] becomes particularly evident when examining the phenomenon of opioid misuse among historically marginalized populations. The case of indigenous communities, although often analyzed from the perspective of public health or epidemiology, constitutes, in light of societal constitutionalism, a paradigm of systemic vulnerability: social groups that are already excluded and neglected by the state become prime targets of the pharmaceutical market's unchecked expansion, which, in the absence of culturally appropriate public policies and effective pharmacovigilance mechanisms, colonizes these communities with addictive drugs, subjecting them to a logic of consumption that compromises their autonomy, their collective health, and their biopsychosocial integrity[11].

The relevance of this phenomenon to the thesis of societal constitutionalism[1] lies in demonstrating that systemic vulnerability is not random: it is concentrated in social groups that are already marginalized by the state and that, therefore, have a reduced capacity to resist the expansion of the pharmaceutical market. In this sense, opioid misuse among indigenous populations is not merely a public health problem, but a concrete manifestation of the systemic clash between the economic rationality of the pharmaceutical industry which seeks to expand its markets at any cost and the legal-health rationality of the State, which, weakened by power asymmetry and regulatory capture, proves incapable of protecting the most vulnerable. This observation naturally leads to the third analytical axis of this article: the neurobiology of addiction as a paradigm of systemic violation, insofar as the synaptic reconfiguration induced by addictive drugs transforms the "choice" to use into a biological necessity, compromising the individual's decision- y autonomy and demanding a legal response that transcends the traditional punitive paradigm[4,20].

Opioid misuse among Indigenous populations as an expression of systemic vulnerability

The vulnerability of historically marginalized populations to opioid misuse powerfully illustrates the intersection between the economic rationality of the pharmaceutical industry, state regulatory failures, and the erosion of the biopsychosocial integrity of specific social groups. Although it cannot be asserted that an opioid epidemic exists in all Indigenous communities, the available data indicate that, in specific contexts, rates of misuse are significantly higher than national averages.

The epidemiological study[11] conducted with Native American adolescents living on reservations in the United States revealed that levels of opioid misuse in the past 12 months and 30 days were significantly higher than national rates, with absolute differences reaching 4.7% for narcotics among 12th graders and 1.8% for heroin in the same age group[11]. These data demonstrate that Native American youth have a prevalence of OxyContin, Vicodin, and heroin use far above the U.S. average, highlighting how the unchecked expansion of the pharmaceutical market, combined with the absence of culturally appropriate public policies, can colonize entire communities, subjecting them to a logic of consumption that compromises their autonomy and collective health.

The relevance of these data to the thesis of societal constitutionalism lies in demonstrating that systemic vulnerability is not random: it is concentrated among social groups that are already marginalized by the state and who, therefore, have a reduced capacity to resist the expansion of the pharmaceutical market. The implementation of evidence-based efforts[11], adapted or developed to be culturally appropriate, must be significantly expanded in indigenous communities, alongside policies that address the specific social, economic, and health problems they face.

This scenario confirms the thesis of societal constitutionalism: the protection of biological integrity requires that the law impose limits not only on the state but also on private systems that, in their autonomous expansion, generate disproportionate vulnerabilities in specific social groups. The "expansive fury" of the economic system[1] does not affect all individuals equally; it concentrates on those who are already in vulnerable situations, widening inequalities and creating new forms of systemic subordination.

Criticism of the market's systemic colonization of private law can be analyzed in light of the proposal for "living together." From this perspective, the reconstruction of legal institutions plays a significant role in preserving human agency in the face of systemic and impersonal structures, especially when economic interests begin to influence spaces traditionally oriented toward the protection of rights. Thus, the conception presented in this work allows us to understand the law not only in terms of its state-defined boundaries but also in terms of its capacity to respond to the tensions produced in a pluralistic society[6].

The author argues that contemporary constitutionalism can no longer be limited to protecting the individual against state arbitrariness, but must extend to protecting human agency against the impersonality of economic and technological systems which, in their unchecked expansion, tend to reduce the individual to a variable in a calculation[6]. This perspective engages directly with Teubner's notion of the "expansive fury" of autonomous social systems, reinforcing the need for institutional reform that recognizes the plurality of spheres of justice in global society[1,6].

In the specific field of health, it is observed that the relationship between physician, patient, and the pharmaceutical industry is often mediated by a power asymmetry that cannot be resolved solely through the application of consumer law or civil liability norms[6]. The author suggests that protecting the patient's decision-making autonomy requires the institutionalization of mechanisms for active listening and dialogical participation in health regulation processes, so that the voices of vulnerable individuals are not drowned out by the instrumental rationality of the market[6]. This suggestion is akin to Teubner's proposal for reflective mediation, in that both authors rely on the normative power of procedure and intersystemic dialogue as a path toward the harmonization of conflicting interests[1,6].

The originality of this contribution[6] to the debate on societal constitutionalism lies in the emphasis it places on the existential dimension of law. For the author, the crisis of modern constitutionalism is not merely a crisis of sovereignty or effectiveness, but fundamentally a crisis of meaning, insofar as global social systems tend to operate according to a self-referential logic that excludes the question of "living well and caring for others"[6]. This ethical dimension of societal constitutionalism is particularly relevant for addressing the phenomena of overmedicalization and synaptic reconfiguration induced by addictive drugs, as it places biological integrity and human agency at the center of the normative concerns of health law[6].

In this sense, the proposal is that the law must be reconstructed based on an ethics of otherness that recognizes the subject's inherent vulnerability and the need for protection against contemporary forms of systemic domination[6]. This proposal aligns with the argument made in this article that pharmacovigilance should be elevated to the status of a constitutional guarantee of protection for biological integrity, ensuring that technological development and pharmaceutical innovation remain subordinate to human dignity[6]. The historical consolidation of pharmacovigilance highlights the influence of political and social mobilizations in strengthening protection and safety mechanisms related to the use of medications[20].

As Kaebnick[20] notes, the bioethics of addiction requires a rethinking of moral and legal responsibility in light of the evidence that addiction profoundly reconfigures neural circuits, compromising the individual's decision-making autonomy and demanding a legal response that transcends the traditional punitive paradigm.

Table 1. Systemic Conflicts: The tension between economic rationality and the patient's biopsychosocial integrity

Dimension of the Conflict	Economic Rationality (Market)	Biopsychosocial Integrity (Law/Health)
Operating Logic	Transnational profitability and profit	Protection of Ontological Dignity
Instrument of Action	Pharmaceutical marketing and patents	Informed Consent and Pharmacovigilance
Effect on the Patient	Transformation into a consumer of molecules	Preservation of Decision-Making Autonomy
Regulatory Focus	Functional efficiency of the economic system	Realization of fundamental rights

Source: Own elaboration.

Pharmacovigilance as a constitutional guarantee

From a qualitative perspective, the studies[5] were classified according to normative and social approaches. The analysis found that 32% of the articles adopted a negative-normative perspective, characterized by criticism of judicialization due to its potential to widen inequalities in access to healthcare. Another 32% presented a positive-social perspective, which views judicialization as a legitimate exercise of citizenship[5].

This duality of approaches precisely reflects the central tension identified by Teubner[1] between legal rationality (which seeks the immediate enforcement of individual rights) and administrative rationality (which must manage scarce resources equitably)[1]. The authors conclude that "the judiciary's lack of knowledge about health policies leads to increased health inequalities" and that the rise in lawsuits "explains the need to seek alternatives for accessing health technologies"[5]. This conclusion reinforces the central argument of this article that pharmacovigilance and the horizontal effectiveness of fundamental rights should act as mechanisms for self-regulation by pharmaceutical corporations, preventing the Judiciary from being turned into an arena for pharmaceutical marketing[1].

The regulation of pharmacovigilance transcends administrative technique to become a guarantee of individual liberty. The control of the supply of additive drugs and the rigorous oversight of pharmaceutical marketing are measures to safeguard constitutional autonomy that the Brazilian State, through ANVISA, must exercise with heightened ethical rigor[15]. The effectiveness of this regulation

depends on the law's ability to ensure that pharmaceutical practice is guided by clinical necessity, in dialogue with bioethics and integrative practices[22].

In the context of pharmacovigilance, the results indicate "regulatory capture," in which the systemic urgency to approve new drugs compromises biological safety. The history of COX-2 inhibitors and the manipulation of clinical trials demonstrate that state regulation alone is insufficient to curb transnational power[8]. The application of the horizontal effectiveness of fundamental rights proves to be the most suitable legal instrument to curb the expansion of autonomous systems within the human body. Contemporary health law must assign direct responsibility to private actors, treating them as centers of power that have constitutional duties to protect public health[1].

Phytotherapy as Systemic Resistance

The incorporation of herbal medicine into the Unified Health System (SUS), especially within the scope of Primary Health Care, is part of a process of expanding and diversifying the therapeutic options available to the population. Its institutionalization, through national policies focused on Integrative and Complementary Practices and on medicinal plants and herbal medicines, recognizes the coexistence of different practices and forms of knowledge in health care and establishes guidelines for their safe and rational provision within the system. This perspective is supported by the literature on therapeutic pluralism, which highlights integrative and complementary practices as ways to broaden forms of care in the face of the predominance of the biomedical model and processes of social medicalization.

In the context of Primary Health Care, studies on phytotherapy also highlight its integration into care practices and its relationship with the valorization of different forms of knowledge and therapeutic possibilities[23,24,25,26]. In light of the theoretical framework adopted in this study[6], the coexistence of different forms of care can be interpreted as an expression of resistance to the homogenization of health practices. From this perspective, herbal medicine does not represent opposition to industrialized medications or to technical and scientific advances, but rather expands the possibilities for care by incorporating other therapeutic practices recognized within the health care system. This plurality may foster greater individual participation in decisions related to one's own care, an aspect that aligns with the protection of decision-making autonomy discussed in the legal literature[7].

From this perspective, the institutionalization of phytotherapy within the SUS can be understood, within the framework of the analysis proposed in this article, as an example of coexistence among different therapeutic rationalities. By recognizing distinct practices within the same health system, Health Law contributes to establishing normative conditions that enable a plurality of forms of care. This interpretation aligns with the conception of a legal system capable of responding to the diversity characteristic of contemporary societies and of preserving spaces of autonomy in the face of processes of systemic homogenization[6].

The Neurobiology of Addiction as a Systemic Violation

The systemic clash reaches its peak in the neurobiology of addiction. Evidence on brain plasticity demonstrates that addictive drugs reconfigure mesolimbic circuits, transforming the demand for consumption into an inelastic biological need[27]. Advanced studies indicate that transcriptional and epigenetic alterations create cellular memory mechanisms that perpetuate vulnerability, rendering

informed consent a fiction in the face of hijacked biology[27]. The Stages of the Dependence Cycle occur in three progressive stages[4]:

- **Intoxication and Compulsion:** Initial use activates the mesolimbic dopaminergic system, generating a reward signal. Unlike natural rewards, the drug bypasses satiety, reinforcing compulsive use.
- **Withdrawal and Negative Affect:** Repeated exposure leads to desensitization of the reward circuits, reducing the ability to experience pleasure (anhedonia). At the same time, hyperactivity of the "anti-reward" system in the extended amygdala occurs, inducing chronic dysphoria.
- **Preoccupation and Anticipation (Craving):** Impairment of the prefrontal cortex a region involved in self-regulatory mechanisms can reduce the ability to control cravings. Neuroplastic changes in glutamatergic and dopaminergic pathways, associated with prefrontal dysfunction, contribute to the mechanisms involved in relapse[4].

Understanding chemical dependence as a chronic brain disorder profoundly alters the foundations of health law. Recurrent substance use not only hijacks the reward system but also reconfigures synaptic architecture through profound neuroplastic changes[27].

In addition to the dopaminergic and glutamatergic systems, recent studies indicate that the metabolism of tryptophan, a precursor to serotonin, plays a crucial role in neurodevelopment and vulnerability to neuropsychiatric disorders, opening new perspectives for neuroprotective interventions in chemical dependency[28].

The shift from the moral punishment paradigm to the brain disease model represents a fundamental advance. Addiction is characterized by structural and functional changes in the brain that compromise reward circuits, stress reactivity, and executive control[4].

The distinction between "wanting" and "liking" is fundamental to understanding the neurobiology of addiction: while "liking" is mediated by opioid and cannabinoid circuits, compulsive "wanting" is driven by mesolimbic dopaminergic sensitization, a phenomenon that persists even after cessation of use[29].

The Open-Label Placebo and the Ethics of Consent

Understanding the neurobiological mechanisms of addiction requires medicine to reevaluate its preconceptions about the placebo effect. Traditionally conceived as an artifact of "error" dependent on deception, the placebo has been challenged by research demonstrating the activation of endogenous systems such as endorphins, dopamine, and cannabinoids in specific brain regions[30].

The innovation represented by "open-label placebo" studies breaks with the paradigm of deception by transparently informing the patient about the inert nature of the treatment. Even without the subterfuge of a lie, the human brain is capable of processing the therapeutic intention as a trigger for the relief of subjective symptoms[30]. The current challenge is to demystify the placebo as a tool of manipulation, positioning it as a therapeutic adjunct that integrates the neurobiology of cerebral anticipation with the ethics of informed consent.

Bioethics and Overcoming Paternalism

Contemporary bioethics, structured on the pillars of beneficence, nonmaleficence, autonomy, and justice, proposes moving beyond the classic paternalistic model[22]. However, this transition faces obstacles. Scientific progress has led to the consolidation of a biomedical model that prioritizes pathology over the patient, reducing the patient to biological data.

This fragmentation of care is evidenced by the communicational asymmetry in the doctor-patient relationship, in which the limited time available for attentive listening is replaced by the automated ordering of tests. The disparity between the medical interpretation and the patient's lived experience compromises therapeutic efficacy and human dignity. Therefore, the restoration of decision-making autonomy requires that the physician transcend the biological perspective, understanding the patient as a biopsychosocial being[22].

End-of-life care as a paradigm of systemic conflict

End-of-life care strikingly exemplifies the tension between technical rationality and ontological dignity. Procedures such as palliative care and end-of-life decisions, when classified as medical acts, become part of a system of responsibility that cannot be captured exclusively by the logic of productivist medicalization.

Classifying palliative care and end-of-life decisions as medical acts implies that they are subject to a legal liability regime that cannot be reduced to the productivist logic of medicalization. The author emphasizes that respect for patient autonomy at the end of life requires that the law serve as a safeguard against the transformation of human finitude into a variable of systemic management[6,9].

An evolutionary and comparative analysis of legal norms in pediatric oncology in Argentina demonstrates that the protection of children in palliative care still faces significant regulatory challenges in the Ibero-American region, especially regarding the progressive development of the pediatric patient's decision-making capacity. When the law recognizes these procedures as medical acts, it subjects them to regulations designed to ensure the patient's right to die with dignity. The medicalization of the end of life, if not strictly guided by patient autonomy, risks turning human finitude into yet another variable in systemic management[31].

From this perspective, the history of pharmacovigilance highlights the importance of strengthening regulatory mechanisms in the face of tensions between health protection and the economic interests of the pharmaceutical sector[20]. The social construction of the importance of pharmacovigilance resulted from political struggles and pressure from civil society, reinforcing this article's central thesis that societal constitutionalism must impose mechanisms of ethical self-regulation on private institutions. These findings are directly consistent with other analyses on the judicialization of health in Latin America and with the documented initiatives for intersectoral institutional dialogue[19], which demonstrate that it is possible to mitigate conflicts without resorting exclusively to the judiciary.

Final Considerations

The crisis in contemporary constitutional law ultimately reveals itself as a crisis of state sovereignty in the face of the rise of self-sustaining transnational systems. The research demonstrated that the fragmentation of global power has allowed pharmaceutical corporations to assume quasi-constitutional functions, deciding matters of life and death through technological and pharmacological

control. Overmedicalization and the expansion of economic systems are not mere market failures, but manifestations of a private legal regime that operates in defiance of human rights. Societal constitutionalism presents itself as a tool for the self-limitation of these fragmented powers.

Confronting this scenario requires the definitive recognition of science and equitable access to the benefits of scientific progress as a fundamental human right. The role of the law must transcend the boundaries of traditional state regulation, extending to private systems to institutionalize ethical constraints and self-regulatory mechanisms. Restoring harmonious coexistence in a pluralistic society requires coordinated institutional resistance and rigorous oversight of how technical and economic rationalities attempt to colonize the world of life. From this perspective, pharmacovigilance ceases to be a mere administrative procedure and is elevated to the status of a constitutional guarantee of protection for biological integrity.

The protection of psychological and neurological integrity emerges as the new horizon of fundamental rights in the biotechnological era. By demonstrating that the biology of addiction and the reconfiguration of mesolimbic circuits are forms of systemic aggression, this study reinforces the urgency of a legal framework that protects human agency against market-induced chemical determinism. Informed consent is only fully valid when the individual is free from the biopolitical capture of their will. Thus, the individual's biological integrity must be the gravitational center of a new societal constitutionalism, capable of preventing the human body from being reduced to a mere territory for financial exploitation.

The limitations of this study include its theoretical-normative nature which did not include empirical analysis of primary data and its geographical scope, which focuses on the Brazilian and Latin American experience without a systematic analysis of other regional contexts. For future research, we suggest conducting empirical studies that quantitatively analyze the impact of systemic capture in the allocation of public health resources, as well as comparative investigations that examine the application of societal constitutionalism in different legal systems and constitutional traditions.

Finally, we conclude that the convergence between systems theory and the ethics of care provides the necessary normative foundation for humanizing transnational spheres. The limitation of power in global health depends on translating the imperatives of human dignity into the language of each societal fragment. Only through a form of constitutionalism that recognizes the multiplicity of centers of power and demands an intrinsic ethical responsibility from them will it be possible to ensure that scientific innovation serves the common good. Resistance to pharmaceutical regimes of exception is, therefore, the ethical and legal imperative for the preservation of human dignity in the face of the pressures of economic globalization.

References

1. Teubner G. Direito, sistema e policontexturalidade. Piracicaba: Editora Unimep; 2005. 300 p.

2. Angell M. The truth about the drug companies: how they deceive us and what to do about it. New York: Random House; 2004. 305 p.

3. Moynihan R, Henry D. The fight against disease mongering: generating knowledge for action. PLoS Med [Internet]. 2006 abr. 11 [cited Jan 10, 2026];3(4):e191. Available from: https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0030191 doi:10.1371/journal.pmed.0030191

4. Volkow ND, Koob GF, McLellan AT. Neurobiologic advances from the brain disease model of addiction. N Engl J Med [Internet]. 2016 jan. 28 [cited Jan 15, 2026];374(4):363-71. Available from: https://www.nejm.org/doi/10.1056/NEJMra1511480 doi:10.1056/NEJMra1511480

5. Trindade MCN, Peres KC, Souza MN, Cardoso CN, Orozco DC, Vargas-Peláez CM, Farias MR. Ações judiciais que demandam tecnologias em saúde no

Brasil: uma revisão sistemática de métodos mistos. Cad Ibero Am Direito Sanit [Internet]. 15 mar. 2022 [cited Jan 8, 2026];11(1):64-83. Available from: https://www.cadernos.prodisa.fiocruz.br/index.php/cadernos/article/view/904 doi:10.17566/ciads.v11i1.904

6. Rodriguez JR. Como viver junto? Escritos para uma filosofia do Direito. Rio de Janeiro: Sankoré; 2025. 343 p.

7. Latorre ERC. El daño a la autonomía decisoria del paciente por incumplimiento del deber de informar del médico. Rev Dir Sanit [Internet]. 2025 [cited Dec 20, 2025];25(2):e0005. Available from: https://revistas.usp.br/rdisan/article/view/214947 doi:10.11606/issn.2316-9044.rdisan.2025.214947

8. Stiller CO, Hjemdahl P. Lessons from 20 years with COX-2 inhibitors: importance of dose-response considerations and fair play in comparative trials. J Intern Med [Internet]. 2022 out. [cited Jan 12, 2026];292(4):557-74. Available from: https://pubmed.ncbi.nlm.nih.gov/35585779/ doi:10.1111/joim.13505

9. Brasil. Constituição (1988). Constituição da República Federativa do Brasil [Internet]. Brasília: Presidência da República; 1988 [cited Mar 6, 2026]. Available from: http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm

10. Brasil. Lei nº 8.078, de 11 de setembro de 1990. Dispõe sobre a proteção do consumidor e dá outras providências [Internet]. Brasília, 12 set. 1990 [cited Mar 6, 2026]. Available from: https://www.planalto.gov.br/ccivil_03/leis/l8078compilado.htm

11. Stanley LR, Crabtree MA, Swaim RC. Opioid misuse among American Indian adolescents. Am J Public Health [Internet]. 2021 [cited Jan 14, 2026];111(3):471-4. Available from: https://pubmed.ncbi.nlm.nih.gov/33476235/ doi:10.2105/AJPH.2020.306039

12. Rechnitzer Mora AE. Análisis de la judicialización en la gestión de medicamentos: caso de estudio del Trastuzumab en el tratamiento del cáncer de mama en Costa Rica. Cad Ibero Am Direito Sanit [Internet]. 2014 [cited Jan 5, 2026];3(2):10-20. Available from: https://www.cadernos.prodisa.fiocruz.br/index.php/cadernos/article/view/5 doi:10.17566/ciads.v3i2.5

13. Brasil. Conselho Federal de Farmácia. Resolução CFF nº 585, de 29 de agosto de 2013. Regulamenta as atribuições clínicas do farmacêutico e dá outras providências. Diário Oficial da União. Brasília, DF, 26 set. 2013.

14. Brasil. Conselho Federal de Farmácia. Resolução CFF nº 586, de 29 de agosto de 2013. Regula a prescrição farmacêutica e dá outras providências. Diário Oficial da União. Brasília, DF, 26 set. 2013.

15. Caldeira TR, Mendonça AVM. Institucionalização das consultas públicas da Agência Nacional de Vigilância Sanitária: trajetória da participação social na regulação sanitária. Rev Direito Sanit [Internet]. 2025 [cited Dec 18, 2025];25(2):e0003. Available from: https://revistas.usp.br/rdisan/article/view/213398 doi:10.11606/issn.2316-9044.rdisan.2025.213398

16. Brasil. Lei nº 12.527, de 18 de novembro de 2011. Regula o acesso a informações previsto no inciso XXXIII do art. 5º, no inciso II do § 3º do art. 37 e no § 2º do art. 216 da Constituição Federal; altera a Lei nº 8.112, de 11 de dezembro de 1990; revoga a Lei nº 11.111, de 5 de maio de 2005, e dispositivos da Lei nº 8.159, de 8 de janeiro de 1991; e dá outras providências. Diário Oficial da União, Brasília, DF, 18 nov. 2011, edição extra [cited Jul 19, 2026]. Available from: https://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/lei/l12527.htm

17. Brasil. Lei nº 13.848, de 25 de junho de 2019. Dispõe sobre a gestão, a organização, o processo decisório e o controle social das agências reguladoras, altera a Lei nº 9.427, de 26 de dezembro de 1996, a Lei nº 9.472, de 16 de julho de 1997, a Lei nº 9.478, de 6 de agosto de 1997, a Lei nº 9.782, de 26 de janeiro de 1999, a Lei nº 9.961, de 28 de janeiro de 2000, a Lei nº 9.984, de 17 de julho de 2000, a Lei nº 9.986, de 18 de julho de 2000, a Lei nº 10.233, de 5 de junho de 2001, a Medida Provisória nº 2.228-1, de 6 de setembro de 2001, a Lei nº 11.182, de 27 de setembro de 2005, e a Lei nº 10.180, de 6 de fevereiro de 2001. Diário Oficial da União, Brasília, DF, 26 jun. 2019 [cited Jan 19, 2026]. Available from: https://www.planalto.gov.br/ccivil_03/_ato2019-2022/2019/lei/l13848.htm

18. Lira RC, Macêdo JVL, Andrade CAS. Desafios e perspectivas na judicialização da saúde na América Latina: considerações sobre o fenômeno no Brasil e na Colômbia. Cad Ibero-Am Direito Sanit [Internet]. 2024 [cited Jan 3, 2026];13(3):26-41. Available from: https://www.cadernos.prodisa.fiocruz.br/index.php/cadernos/article/view/1269 doi:10.17566/ciads.v13i3.1269

19. Anjos ECS, Ribeiro DC, Morais LV. Judicialização da saúde: uma revisão sistemática de literatura das iniciativas de diálogo institucional intersetorial. Cad Ibero-Am Direito Sanit [Internet]. 2021 [cited Jan 7, 2026];10(1):113-28. Available from: https://www.cadernos.prodisa.fiocruz.br/index.php/cadernos/article/view/640 doi:10.17566/ciads.v10i1.640

20. Coca JR, Coca-Asensio R, Esteban Bueno G. Socio-historical analysis of the social importance of pharmacovigilance. Front Sociol [Internet]. 2022 [cited Jan 13, 2026];7:974090. Available from: https://www.frontiersin.org/articles/10.3389/fsoc.2022.974090 doi:10.3389/fsoc.2022.974090

21. Kaebnick GE. Bioethics and addiction. Hastings Cent Rep [Internet]. 2020 [cited Dec 22, 2025];50(4):2. Available from:

https://pubmed.ncbi.nlm.nih.gov/33448414/ doi:10.1002/hast.1165

22. Beauchamp TL, Childress JF. Princípios de ética biomédica. São Paulo: Loyola, 2002. 576 p.

23. Rodrigues ML, Campos CEA, Siqueira BA. A fitoterapia na Atenção Primária à Saúde segundo os profissionais de saúde do Rio de Janeiro e do Programa Mais Médicos. Cad Ibero Am Direito Sanit [Internet]. 2020 [cited Dec 29, 2025];9(4):28-50. Available from: https://www.cadernos.prodisa.fiocruz.br/index.php/cadernos/article/view/637 doi:10.17566/ciads.v9i4.637

24. Brasil. Ministério da Saúde. Portaria nº 971, de 3 de maio de 2006. Aprova a Política Nacional de Práticas Integrativas e Complementares (PNPIC) no Sistema Único de Saúde. Diário Oficial da União, Brasília, DF, seção 1, ed. 84, p. 20, 4 maio 2006.

25. Brasil. Presidência da República. Decreto nº 5.813, de 22 de junho de 2006. Aprova a Política Nacional de Plantas Medicinais e Fitoterápicos e dá outras providências. Diário Oficial da União, Brasília, DF, seção 1, p. 2, 23 jun. 2006.

26. Tesser CD, Barros NF. Medicalização social e medicina alternativa e complementar: pluralização terapêutica do Sistema Único de Saúde. Rev Saude Publica [Internet]. 2008 [cited Jan 11, 2026];42(5):914-20. Available from: https://www.scielo.br/j/rsp/a/GDZVTGWvtCpC5gtBHJ6tFSK/ doi:10.1590/S0034-89102008000500018

27. Nestler EJ. Molecular basis of long-term plasticity underlying addiction. Nat Rev Neurosci [Internet]. 2001 fev. [cited Dec 16, 2025];2(2):119-28. Available from: https://www.nature.com/articles/35053570 doi:10.1038/35053570

28. Giuliano MG, Tognini P. Tryptophan metabolism in neurodevelopment and its implications for neurodevelopmental disorders. Mol Neurobiol [Internet]. 2025 [cited Dec 24, 2025];63(1):97. Available from: https://pubmed.ncbi.nlm.nih.gov/41261305/ doi:10.1007/s12035-025-05437-9

29. Robinson MJF, Fischer AM, Ahuja A, Lesser EN, Maniates H. Roles of "wanting" and "liking" in motivating behavior: gambling, food, and drug addictions. Curr Top Behav Neurosci [Internet]. 2016 [cited Jan 6, 2026];27:105-36. Available from: https://link.springer.com/chapter/10.1007/7854_2015_387 doi:10.1007/7854_2015_387

30. Kaptchuk TJ, Miller FG. Open label placebo: can honestly prescribed placebos evoke meaningful therapeutic benefits? BMJ [Internet]. 2 out. 2018 [cited Jan 2, 2026];363:k3889. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC6889847/ doi:10.1136/bmj.k3889

31. Ganz ST, Vidal EA. Análisis evolutivo y comparativo de normas jurídicas sobre oncopediatria vigentes en la República Argentina. Rev Direito Sanit [Internet]. 22 dez. 2025 [cited Jan 2, 2026];25(2):e0008. Available from: https://revistas.usp.br/rdisan/article/view/224798 doi:10.11606/issn.2316-9044.rdisan.2025.224798

Editorial Information

History

Received: February 25, 2026
Revised: July 22, 2026
Accepted: Jul 24, 2026

Review Process

Double-blind peer review.

Open peer review

Two ad hoc reviewers evaluated this manuscript. The authors did not consent to interaction or to the publication of the review. Only one reviewer consented to interaction; none authorized the publication of the review.

Preprint

The manuscript is not a preprint.

Similarity check

This article underwent a textual similarity check using CopySpider software.

Authors' Contributions

C.T.M.P. Delgado: conception/design of the article, data analysis and interpretation, drafting of the article, critical review of its content, and approval of the final version of the article.

Conflict of Interest

The authors declare that they have no personal, commercial, academic, political or financial conflicts of interest in relation to this article.

Funding

Not applicable.

Source of Research

Independent research, not derived from a thesis, dissertation, or institutional project.

Ethical Approval of the Research

Not applicable.

Availability of research data

The content underlying the research text is contained in the manuscript.

Declaration of use of Artificial Intelligence (AI) tools

The authors declare that artificial intelligence tools were used in the preparation of this manuscript or in the research reported herein.

Editorial Team

Editor-in-Chief: Sandra Mara Campos Alves
Assistant Editor: Amanda Nunes Lopes Espiñeira Lemos
Editorial Assistants: Danilo Silva Santos Rocha, Daphne Sarah Gomes Jacob Mendes, Maria Ester Simões Nogueira
Copy Editor: Júlia Ribeiro Vitoriano
Translator: David Elias Cardoso Câmara

Publisher

Fundação Oswaldo Cruz, Fiocruz, Health Law Program, Brasília, Federal District, Brazil

Copyright

Authors retain copyright over their works and grant Cadernos Ibero-Americanos de Direito Sanitário (CIADS) the right of first publication.

Open Access

This article is published as Open Access, with immediate, free, and permanent access to its content, with no fees charged for reading, downloading, or sharing.

License of Use

Copyright © 2026 Claudia Terezinha Moraes Pinheiro Delgado. This article is licensed under the Creative Commons Atribuição 4.0 Internacional (CC BY 4.0), license, which permits use, distribution, and reproduction in any medium, provided that the original authorship and source of publication are properly cited.

How to Cite (Vancouver)

Delgado CTMP. Societal constitutionalism and limits to the power of transnational pharmaceutical corporations. Cad. Ibero-Am. Direito Sanit. 2026;15:e2026025. doi: 10.17566/ciads.e2026025