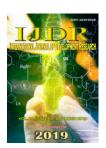


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# **JUDICIALIZATION OF MEDICINES IN BRAZIL: IMPACTS AND NUANCES ON SOCIETY**

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### **ABSTRACT**

This study presents the impacts and nuances on society regarding to the judicialization of medicines in Brazil. It is an bibliographical research, developed through the deductive method. The results were outlined in five guiding axes. The first "health, development and prevention" addresses the conjuncture between both; the second "State, Society and Health", in which the common good of society is provided by the State, the public interest converges with the interest of the majority. When conflicts emerge in this context, an intervention, the "judicialization of health" becomes essential, according to the axis discussed. The other axes "judicialization of medicines" and "impact of judicialization in the social sphere" discuss the complexity of the analysis proposed by the public authorities about what is the right to life and individual versus collective health. It is concluded that for the realization of the right to health it is necessary to implement public policies, in order to provide all citizens with equal treatment in meeting their demands.

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### INTRODUCTION

is a fundamental subjective public constitutionally guaranteed and linked to the dignity of the human person, it is up to the State to implement public policies that meet the needs of the hyposufficient, assuring them, in practice, the achievement of the right to integral health, as outlined in 196 of the Federal Constitution (BRAZIL, 1988). In this light, the Citizen Constitution promulgated in 1988 consecrated health as a right of all and the duty of the state, legally guaranteeing through social and economic policies equal access to actions and services and the reduction of the risk of disease among other diseases (BRAZIL, 1988). In the judiciary conception, there is usually an understanding of the right to health as an individual right and not as a collective one. In the understanding of (MARQUES, 2002), justice has acted mostly, due to those users who, by having more information and resources, are able to sue it when their rights

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are denied. It follows, however, that this kind of judicial conflict is different from that the judiciary has always been accustomed to judge, in which particular property is at stake, and the decision to adjudicate the conflicting property to one of the parties will only affect those individuals involved in the legal relationship. At this juncture, the judicialization of health phenomenon has become a challenge for all federative entities, considering that lawsuits are often brought in the face of the Union, State and Municipalities. Thus, the guarantee of the right to pharmaceutical assistance in the Brazilian legal system from the 1988 Constitution, gave rise to an increase in judicial demands for the enforcement of this right. This phenomenon has been called the judicialization of pharmaceutical care. In the case of individual lawsuits filed by SUS (Unified Health System) users for the medicines supply, publicly provided goods are at stake and, therefore, the decision on the award of the good, in this case the medicine, affect, albeit indirectly, the whole community. In this perspective, in the case of solutions involving public resources and social policies, it is necessary to adopt rational criteria and an analysis of the specific case,

and it is not possible to adopt a single solution for all situations in which the supply of medicines information is required (FERRAZ, VIEIRA, 2009). Thus, the judicialization sometimes favors those who can file their demands in the judiciary for access to medicines, procedures and services, as opposed to the citizen's right and the duty of State. This research is justified in the search for understanding the positivization of the right to health and public policies phenomenon, since the judiciary is now routinely assessing demands inherent to health services. In view of this, the intervention of the legal system regarding to access to medicines has been the object of much criticism, since in certain situations it safeguards the satisfaction of individual interests. Thus the problem in this study is built with the goal of understanding that after thirty years of following the Magna Carta, social development with a growing population and a significant increase in health demands, however, resources do not advance in the same proportion. In fact, the constitutional guarantee covers the citizen's right to receive medicines, including free of charge, provided that prescribed by a doctor to a person with a disease and without financial resources to pay for treatment (BRAZIL, 1988). Given the above, this article aims at presenting reflections inherent in the judicialization of medicines, from the perspective of societal analysis.

## **MATERIALS AND METHODS**

This work is characterized as exploratory and bibliographical research, of theoretical and methodological references about the judicialization of health in the field of medicines in light of societal analysis, supported by the deductive method. According to the classification proposed by Gil (2002, p. 44-45), "bibliographic research is developed based on material already prepared, consisting mainly of books and scientific articles". Thus, ita was selected bibliographic material relevant to the central theme of analysis: the judicialization of health in the field of medicines, configuring in dissemination works (scientific or technical works) and guidelines of the Ministry of Health and Justice, whose themes were very close to those developed in this research, aiming at the strengthening of certain concepts and understandings. This material supported the theoretical framework of the study that supports this research. De posse do arcabouço teórico, desenvolveu-se os resultados estruturados em cincoeixos norteadores: Saúde, desenvolvimento e prevenção, Estado, Sociedade e a Saúde; A judicialização da saúde no SUS; A judicialização de medicamentos e; Impacto da judicialização no âmbito social. With the theoretical framework, the results were developed structured in five guiding axes: Health, development and prevention; State, Society and Health; The judicialization of health in SUS; The judicialization of medicines; and, Impact of judicialization in the social field.

### RESULTS AND DISCUSSION

Health, development and prevention: The transformations that have taken place on the contemporary world scene over the last decades have happened along the lines of the so-called "globalization"; such transformations impact significantly in the health field. In Brazil, for example, about 60% of deaths are caused by large groups of cardiovascular diseases, neoplasms and external causes. Infectious diseases, in contrast, had their importance in mortality reduced from 45 to 7% in the same period (DUCHIADE, 1995). This scenario requires a

therapeutic model that considers individuals as social subjects, in which the development of a model would be crucial in order to spend more on coverage and effectiveness activities, based on the promotion and prevention of diseases; population aging is a factor that should increase the demand for health, considering that there will be more intensity in the use of services. For (Reichenheim, 1994), a vaccine costs less than an angioplasty; nor it is a matter of reproducing the old chorus of preventive medicine against healing, it is worth considering that the treatment of many diseases generally requires high cost and continuous medicines usage, in some cases also medical-hospital procedures. In this step, Michel Foucault (1999), French philosopher understands that discourse, even seemingly insignificant, can reveal its connection with desire and power, all of society discourse production is at the same time controlled, selected, organized and redistributed for a number of procedures designed to conjure its powers and dangers, to master its random event, to dodge its heavy and fearsome materiality. Such a pretense makes science not only an explanatory model and instrumental practice, but also an ideal of humanity's progress that is, the conception that humanity must progress upward in a given direction. Thus, starting from a modern episteme to analyze the ontological concept of disease and the production derived from the negative concept of health means to consider modernity as a relative principle, and not as a foundation or origin of this relationship between disease and health (FOUCAULT, 1970). The relationship between health and disease permeates because it is dualistic: the disease is configured, in the diagnosis about the patient-body, as lack of health; health, in turn, is the ideal of non-illness in the direction of which; the disease, as unhealthy, is denied by treatment. In Foucault's (1995) thought, the body becomes the surface of inscription of time and history, in such a way that the history of experience and the organization of time is also the history of what the body became by what was inscribed in it: "the body entirely marked by history and history ruining the body". From this perspective, disease and health are historical inscriptions on a body, progression to health, or regression to more disease.

So, the Health System starts to consider health in the limits between biological and social, as an expression of styles and life conditions, and because of this, health promotion comes to be a privileged strategy for investment in life, ways of life and life not exclusively in non-illness. Health promotion becomes at the same time broadening the scope of intervention and triggering new epistemological arrangements (PAIM, FILHO, 2000). In the same way, health is at the frontier between the biological and the social, in the expression of lifestyles, since they assume less precise limits in terms of definition and focus of intervention. In order to create new ethical, political and epistemological foundations for human development, it is necessary to establish and broaden dialogues that include and reflect on the uniqueness and contributions of Latin American, African and Asian countries in relation to the ongoing discussions on democracy and development alternatives in an increasingly globalized society in crisis (SANTOS, 2000). According to Santos (2007, 2008), the structural spaces and their unfolding, in the solidarity and emancipatory perspective proposed by Boaventura, are aligned with "promoting health with" and not "promoting health for". It corroborates the search for the expansion of democratic principles, among them qualifying participation, responsibility and solidarity. This search is evidenced by Bonaventura's project to analyze democratic participation experiences in countries without such

tradition and which enrich the debate precisely by realizing the emergence of anti-hegemonic knowledge and practices. Investing in the public health system, readjusting to the procedures of the (SUS), as well as the available medicines, is indispensable, in addition to investing in prevention, in order to try to absorb the demand of population growth and its consequent aging. Allied to this, having health also requires adequate food and housing, healthy working conditions, efficient basic sanitation, the possibility of leisure, information, which thus becomes a challenge in the current conjuncture.

State, Society and Health: Society is conceived by a group of individuals, who transfer part of their freedom to the state in order to receive protection. In this light, the state establishes laws for the protection of citizens and their property, as power is transferred by the people. For Hegel (2010), the state is what is in-itself and to-itself and, thus, has the effectiveness of its universality or full totality. As a moral sphere there is a relationship of rights and duties, where the individual receives advantages in that he has duties (obligations) to the State. In contemporary society, the common good is somehow provided by the state, where the public interest should not be far from the interest of the majority, but at the same time the interest of the majority cannot be detrimental to the minority, as it would not be the public interest and the public interest but an individual interest, so the expressions adopted to conceptualize society are multiple. Émile Durkheim (2002), suggested the observation of the various societies, not as belonging to an evolution, as distinct species of an organism whose observations and comparisons would lead us to know it. On the other hand, Auguste Comte (1978) did not attribute to the term "organism" its real value, since it was unsuccessful in clarifying where it came from or how this new being that it suggests was consolidated, since this is not an evolution of the individual as continuity. For the author, the State is a construct of social deliberation, which seeks to mediate individual and collective actions and ideas "it is from this conflict of social forces that individual freedoms are born" (DURKHEIM, 2002, p.88). As "every society is despotic, unless something external to it will contain its despotism" (DURKHEIM, 2002, p. 85), the state becomes necessary in modernity, in order to guarantee individual rights. In the book "The Rules of the Sociological Method" (DURKHEIM, 2007, p. 01) highlights the society as a social fact,

Every individual eats, drinks, sleeps, thinks, and society has every interest in having these functions performed regularly. Therefore, if these facts were social, sociology would have no object of its own, and its domain would be confused with that of biology and psychology. But in reality there is in every society a definite group of phenomena which are distinguished by definite characters from those which the other sciences of nature study. When I perform my duties as brother, husband, or citizen, when I perform the commitments I have made, I fulfill duties that are defined outside myself and my actions in law and custom. Even if they are in accordance with my own feelings and that I feel their reality inwardly, it is still objective: it was not I who made them, but received them by education. This is, therefore, an order of facts which have very special characteristics: they consist of ways of acting, thinking and feeling external to the individual, and which these facts impose on him.

In Bastos's observation (2002, p. 60), the state has an existential objective,

In the first analysis, the end of the state is the realization of the common good, but it should be warned that the teleological end of the state is still open to interpretation, as a portion of individuals who see in the state only a vehicle able of fulfilling their individual interests, completely disregarding the realization of the common good. Actually, the State is nothing more than a means for man to achieve his interests and develop, but the state must never be above the values of the human person, which must always be preserved.

In this respect, it can be said that the state aims at providing the common good, since it will govern on the basis of the general interest. To the extent that conflicts arise between social groups and individuals, the intervention of a then dominant will capable of preserving the order of society itself, becomes indispensable (BASTOS, 2002). The Modern State, from Weber's point of view (1999 p. 526), is a rational state that has a monopoly on the legitimate use of physical force within the territory it controls. Thus, endowed with legitimacy and legal domination, the state is the result of the development of capitalist society which, due to its complexity, demands rational and bureaucratic administration. That is, the state would be a "relationship of domination of men over men" (WEBER, 1999 p. 526). It is costly to demarcate what would be in the public interest, because every citizen in the society has their individual interests. Thus, the Federal Constitution established a framework of fundamental rights and guarantees, in which most will be contemplated with public and social policies. For Marshall (2002) the recognition of social rights would be an inevitable unfolding of the idea of citizenship that is based on the notion of equality between citizens and it political materializes in equal civil and (KERSTENETZKY, 2012). From this angle, it is necessary to include pharmaceutical assistance in the sphere of the social issue, considering that, once prescribed, in their absence, they directly affect the health of citizens. It is worth remembering that the State interference in the medicines industry with the insertion of generic medicines, made them more accessible, embodied in public policies. Currently, the medicines usage has become an indispensable practice in contributing to increase the quality and life expectancy of the population (PORTELA, LEAL, WERNER, SIMÃO, MEDEIROS, 2010), there is the understanding that ensuring access to the medicines considered essential and its rational usage are some of the aspects that contribute to the valorization and improvement of the Pharmaceutical Assistance service as a peculiar strategy of the Brazilian primary health care (PORTELA, LEAL, WERNER, SIMÃO, MEDEIROS, 2010). However, the number of lawsuits to force the State in the Public Administration to provide medicines, prostheses, supplies, surgeries, hospitalizations, and all kinds of healthrelated services is indeed increasing.

The judicialization of health in SUS: The Unified Health System (SUS) brings in its midst achievements and is configured as a regionalized and hierarchical network of actions and services, through which the Government implements its constitutional duty, and it is up to the Union, the States, the Federal District and the Towns, due to the Decentralization Principle, to perform services aimed at the health care of the population. However, often, the judicial

route is configured as a solution of access, within a reasonable time, of individuals to the SUS, regarding to care, procedures or medication. The criticism of the implementation of social rights by the intervention of the Judiciary finds its obstacle from the very positivization of article 196 contained in the Magna Carta, in which the realization of the right to health must be guaranteed by public policies and not by provision. judicial. Batista Júnior (2011), also retains this position, due to respect for the principle of separation of powers, and considers that social rights have a gradual effectiveness, depending on available resources. That is, although the judicialization is the result of important changes in Brazilian society under the Constitution, in a context of recognition of the protagonism of fundamental rights and the shortcomings of representative democracy, there are many controversies surrounding this phenomenon, especially in concerning the enforcement of the judicial decision on the scope of public policies. The characterization of judicialization, while situated in the midst of the changes brought about by the new constitutional law, is interpreted by Valle (2009, p. 97), in the following words:

The judicialization of politics – in this understanding of the options of the same nature, related to the prospective action of management – from the 1988 Constitution is manifested as a phenomenon characterized by the expansive presence of fundamental rights, their guarantees and institutions put at their service, expressing an advance of the egalitarian agenda in a context that has traditionally not known about the institutions of freedom.

In the same sense, art. 23, item II, of the Federal Constitution of 1988, states that health promotion is a material competence common to the three administrative spheres. Thus, all entities are jointly and severally responsible for health care and public assistance.

The judicialization of medicines: Regarding to the issue of access to medicines, many citizens nowadays, in certain situations, only have their own salary to pay for them. Due to lack of resources, SUS does not incorporate most of the modern and more expensive medicines. In addition, medicines that are part of the list, some of which should be available sometimes lack in Health Units and public hospitals. However, if the Standardization System of Procedures is necessary for the development of public health policy, it should be flexible to the point of respecting the particularities of each citizen, since it would be useless to provide the standard medication, if it does not present patient outcomes. The magistrates fulfilling their legal functions determine in a preliminary way, depending on the case, the obligation of the federative entity to provide the medicine or procedure to the citizen, but this is not a guarantee of effectiveness. In this perspective, the scenario permeates a collision of values or interests that opposes, on the one hand, the right to life and health and, on the other, the separation of powers, budgetary principles and the reserve of the possible. The reality, however, is more dramatic. What is at stake in the complex consideration here is the right to life and health of one versus the right to life and health of others. There is no legally easy or morally simple solution to this issue (BARROSO, 2008). The judicial response, in general, has been limited to determining whether health managers comply with the benefit claimed by the claimants, backed by an individual medical prescription. However, the required input or procedure is not always in accordance with Clinical

Protocols and Therapeutic Guidelines (PCDT) established by the SUS, or is included in the publicly funded drug lists (SANT'ANA, 2009). Destaca-se que após o início da vigência da Constituição Federal de 1988, mais especificamente em setembro do ano de 1990, houve a aprovação da Lei nº 8.080/90. Referida lei orgânica estrutura e operacionaliza o Sistema Único de Saúde (SUS). Em se tratando das atribuições do SUS, o artigo 6º da Lei em comento normatiza: "formulação da política de medicamentos, equipamentos, imunobiológicos e outros insumos de interesse para a saúde e a participação na sua produção" (BRASIL, 1990, p.01). It is noteworthy that after the beginning of the Federal Constitution of 1988, more specifically in September 1990, Law No. 8080/90 was approved. Said organic law structures and operationalizes the Unified Health System (SUS). Regarding to the attributions of the SUS, article 6 of the Law under review regulates: "formulation of the policy of medicines, equipment, immunobiologicals and other inputs of interest to health and participation in their production" (BRASIL, 1990, p. 01). Later the National Medicines Policy was implemented in the country, however, was not able to safeguard all rights to access to medicines to the population alone, as it demands legislative, financial and administrative efforts of the three entities of the federation, the community and partnerships with the private sector. It is assumed that the priorities and goals defined by each federative entity in the area of pharmaceutical care are linked to the existing financial possibilities. Thus, it is necessary to study in order to investigate, thus, the effectiveness of judicialization in the case of medicines, in order to evaluate whether the entry into court is able to satisfy access to medicines available under the SUS, as well as policies public policies, in an attempt to assess this access.

Impact of judicialization in the social field: The individualized legal demands related to medicines, procedures and health supplies are increasing. Comprehensively, health is mainly permeated by citizenship from the perspective of social justice, whose nature includes an individual and a collective dimension. Given the scenario of scarce resources, the State sometimes does not guarantee the effectiveness of a court decision in favor of a moderation between private issues to the detriment of the collective. Thus, such a restriction is called the "reserve of the possible", meeting demand would be limited by what an individual can reasonably demand from society, given the limited resources of the state (ALEXY, 2011). By means of the Annual Budget Law (LOA), the priorities inherent to the budget to be received by the federal government are defined. At the state and municipal levels, the actions must be outlined in their respective budget laws, including compliance with judicial determinations in health. The judiciary appreciates and judges each case uniquely, in many situations it does not have the exact knowledge of public accounting, however, depending on the decision, it will impact on the lives of many citizens and what would be an annual budget, can only meet an individual. In the opinion of Barroso (2008), concessional drug decisions without an effective observation of the demand may result in negative effects for the whole public health system, that is, it ends up causing dysfunction in the whole system. In view of this, it is concluded that the right to health as a Fundamental Social Law, affirmed in art. 60 of FF / 88, must be achieved through the State with the creation of public policies to guarantee better living conditions to all objectively. In this perspective, the state organization becomes indifferent in order to promote the right to health as a whole, in another band the important thing

is to be assured to the citizen, so that it does not configure itself omitted in the face of constitutionally guaranteed individual and collective issues.

#### **Final considerations**

The Federal Constitution allowed citizens to conquer fundamental rights, as well as instruments of equality and social justice. However, there are many struggles regarded to access to medicines and health services. It is therefore the duty of the State, in all its spheres, to guarantee its citizens the right to health. It appears that the right to life is the highest of any citizen, protected by the Federal Constitution and other laws, and may not be subject to regulatory and restrictive prescriptions, which are delayed in serious and irreparable damage to health, dignity and life. It is important that the judiciary guarantees access to medicines and health services, when they are not naturally dispensed with, on the grounds of noncompliance with what is constitutionally guaranteed. The consolidation of the SUS constituted major advances in the realization of the right to health in the country, even if in some situations it is ineffective, represented the individual's guarantee in order to have a comprehensive health care service. It is worth mentioning the lack of investments in the health sector, the growing increase with medicines, although some are generic in nature, makes the scenario alarming, favoring judicialization. In conclusion, in light of the foregoing considerations, for the realization of the right to health, it is necessary to carry out and execute public and social policies. in order to provide all citizens with equal treatment in meeting their demands, corollary to the right to life. Despite the existence of individual requests to the detriment of the collective, it should be analyzed that such care can compromise a whole network of public health services, given its distributive character. In this wake, the study sought to make considerations about health and society and their nuances.

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