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Essays

Niklas Luhmann's Systems Theory and the challenges involved for legally achieving the of right to health in regard to medicines

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Abstract
This essay deals with some of the limits and risks related to the essential performance of the judiciary in the control of the public medicine supply in defence of the right to health and dignity of the human being. This question relates to the necessity of making explicit legal decisions and submitting them to evaluations based on latent economic interests and diverging social expectations in regard to the interpretation of the Fundamental Right to Health, considered here from a re-reading of Niklas Luhmann's Systems Theory, adjusted to the historical evolution of Brazilian social systems and to the identification of the 1988 Federal Constitution as a point of convergence of their comunications processes, not restricted, in any way, by judical and political systems. From this perspective, new ways must be sought to support judicial proceedings in which the duty of the state to supply medicines in defense of the concrete rights and dignity of human beings and advances in social rights is established as well to reduce the risks of possible attacks by the pharmaceutical industry and the mass medication of modern society.

Keywords
Access to justice, social systems, right to health, medicines, dignity of the human being

Introduction

This study rediscusses some issues related to jurisdictional procedure in the control/imposition of the supply of medicines by the State in defence of the Right to Health and the dignity of the human being from LUHMANN's Theory of Systems 1998).

Under a revisited luhmannian systemic perspective (CRUZ, 2007), certain functional limits of the law and some of the contingencies resulting from the collision of various operational logics between the systems involved in these legal-health litigations are approached here.

Among these different systemic logics related to the matter at issue, political, economic, health, legal and psychic order must be considered, in this last hypothesis, taking into account the interest of the human being whose Right to Health is, in principle, connected with the use of the petitioned medicines in a given, concrete case, subject to judicial evaluation.

In other words, this work looks to consider how some expectations of individuals of the health system – while Science and public health practice - and certain latent demands of the economic system regarding public

health services and pharmaceutical assistance, whether on a collective scale (public policies), or from an the individual perspective, are (or should be) received and processed within the legal system through its jurisdictional bodies, from the perspective of a constitutional interpretation, principles, and the evolutionary logic of fundamental social rights.

Therefore some epistemological problems linked to the evolution of social systems will need to be initially considered, with special attention to the ones that the Brazilian legal system with its methodological impasses and internal disputes has been experiencing.

These are related to the fact that social reality has assumed an increasing degree of complexity and intensification in the social conflicts characterised, in general terms, by an undetermined amount of actions, activities, selections of meaning and relations to power that tend to increase with the passing of time, as the world itself becomes increasingly more complex, unpredictable, and contingential.

Paradoxically, this considerable increase in complexity has been accompanied by a continuous formation and differentiation process of meaning systems, amongst which the legal system, whose function has been to try and organise part of this complexity in the course of this historical process and reduce this contingency present in the ample possibility of relations and meanings (LUHMANN, 1998, p.50).

In this context, the misalignment that occurs between the positivist-legalist rationality of the law and antagonistic expectations of other social systems, and of society as a whole, in relation to the operation of the legal system and its organisational structures, such as the judiciary, as well as its answers to the small part of the social conflicts that get to be institutionalised through lawsuits - many of which are not only incomprehensible, but also responsible for decisions below the normative expectations generalised by the Federal Constitution of 1988, stands out.

An approach to this delicate issue should, furthermore, consider the risks and ambiguity which may possibly be incurred in this necessary jurisdictional procedure due to possible economic and communications distortions of the drug industry and of a society that is increasingly "medicalised", in the most severe Foucaultian sense of the term (SCHWARTZ, 2004; ANGELL, 2007; BARROS, 2004; FOUCAULT, 1974).

Summarising the question, the central dispute of this essay can thus be stated as: how to compatibilise protection to human dignity in a concrete way in respect to public policies of medicines, taking into account the possible commercial attacks on the part of the drug industry and the undefined medicalisation of society without, however, denying the great social advances resulting from jurisdictional procedure that have achieved part of the right to health through judicially granting access to medicines?

It is, therefore, using this approach that it is intended to discuss the achievement of the right to health through access to justice and of its accomplishing "production of individually and socially just results" (CAPELLETTI et al., 1988, p.8), even in its curative branch, in which a great part of the judicial demands for medicines lie.

The Law and the essential expected norms for the functioning of society

Among the various social and legal theories, equally possible and serving as approaches, the choice of the systemic vision of law and society of LUHMANN (1998; 1989; 1983) in order to theoretically base the development of the present essay is justified by its explanatory potential for understanding the interdisciplinary dimension of the right to health and its constitutional interpretation, especially in relation to the structural couplings between the legal system and the health system, once such a theory is reinterpreted from the set of luhmannian works, from the peculiarities of the Brazilian society and from the historical development of the national legal health subsystem (CRUZ, 2007).

Thus it is possible to incorporate, to understand the aforementioned legal health subsystem, its complex operational growth that cannot disconsider the expectations and operation of the health system, much less the end function of programs constituted for the implementation of basic social rights related to health.

In a brief synthesis, the theory of the systems at issue, developed in the field of social sciences as self-referencing communication systems by LUHMANN (1998), can be understood as an extension, duly adaptated, of systemic thought originating in other scientific areas, more specifically, in the domain of biology, from the study of cognition processes and of the emphasis on the concept of living organisms as integrated wholes, with the neurophysiological studies of MATURANA et al. (1980; 2005) supporting it.

The systemic or autopoietic vision of law has been, as an alternative to the scientific stalemate that dominated the legal theories, divided between its consideration as a closed or practically independent normative system and its sociological criticism as a conditioned decision-making sphere. Both would be insufficient to explain the role and inter-relations developed by the legal system in modern society and direct their interpretation, in view of the new limits and functions that are placed on it, based on the high degree of complexity in social relations that conditions their regulation (LUHMANN, 1983; TEUBNER, 1989; BÜLLESBACH, 2002; CAMPILONGO, 2002).

The extreme formalism, both theoretical and practical, to which the law was relegated and greatly conditioned by legal scientific positivism, caused it to be partitioned into an artificially constructed space and, isolated from reality itself, regarded as "be", on which this precise normative system, which "should be", should incite and exert its social regulation.

In this way, from the law's internal point of view, such a theoretical and practical approach has consoli-

dated itself as a mere closed system, reduced to a formal relationship between hierarchically organised norms, considered as valid simply by the observance of legislative procedures, without the analysis of their material content nor their adaptation to the more elevated, constitutionally guaranteed, societal values and principles.

In general lines, the study health law, as well as related constitutional law, has highlighted the considerable insufficiency of the traditional positivist scientific model that, well or badly, at least in the legal field, was especially influenced by the "Pure Theory of the Law" of KELSEN (1999) who ended up not only conditioning his study in the field of application of the law itself to an exaggerated degree of formalism and abstraction, insufficient for its explanation,but also in part of the social phenomenon which is inoperative in view of the internal systemic conflicts among its legal principles (GRAU, 2002, p.31).

Here it is fundamental, however, to make a clear distinction between the criticism of positivism - as a scientific analytical model of law and social sciences, under the axiom of the valorative neutrality and the search for "natural laws of social life and of social science based on a model from the natural sciences " (LOWY, the 2003, p.18-19) - and the consideration, in itself, of modern law as positive law, not ignored by systemic theory, but that considers such "positivity", in the sense of the contingency of its structures, to be related to its continuous adaptation to society's transformations and its complexity in the historical context, in opposition to perennial natural law (LUHMANN, 1983, p.225; CANARIS, 1996, p. 27-30).

Therefore, especially in the field of legal health systems, the aforementioned luhmannian systemic theory is defended by SCHWARTZ (2004) as an indispensable theoretical structure for repositioning law in view of increasing social complexity, as in that related to the increase in health risks resulting from it and the necessity of facing the new challenges imposed on the decisions regarding this legal subsystem in order to strengthen the constitutional principle-based nature of health protection.

However, while it includes systems, the relation between law and other social systems occurs in an indirect way through communications, understood under the luhmannian perspective of the term, as not restricted to the "traditional metaphor of 'transmission'".

Communications referred to here must be considered, however in a more general sense, as in the synthesis of a constituted communication process that consists of three inseperable stages: information, participation, and understanding, which are the product of meaning selection carried out, not by separate individuals, but from within the interior of the social system itself. (LUHMANN, 1998, p.141).

Hence, according to GRAU (2002, p.56), it can be said that the law "not only has a language, but is a language, inasmuch as it instruments a modality of communication among men, either to order conflict situations, or to instrumentalise policies".

Thus, it is fundamental to recognise its specific function, rationality, and codes, according to which the legal system perceives and re-elaborates part of the influences and external demands of other social systems, "selecting its specificity, bringing it to its recursively hermetic interior, where the question will be (re)processed in its autoreferential and autopoietic clausural logic", as explained by SCHWARTZ (2004, p.29) in his study regarding the *legal treatment of risk in the right to health*.

In brief, it can be said that the function of law consists in undertaking the diffusion and maintenance of minimal expectations (normative) that each system, whether social or psychic, may nourish in relation to the others (LUHMANN, 1983, p.237).

The term *normative,* by being related to *expectation*, does not refer to the dichotomy between "must be" and "be", crystallised in criticized scientific legal positivism, not even its classic distinction between "*acquired right*" and "*right expectation*", so often used incorrectly to corroborate attacks on the rights and fundamental social guarantees from the constitutional "reforms" to the Social Security system recently established by the Federal Constitution of 1988.

In systemic language, the "*normative expectations*" cited here may be taken as part of the law itself, as rules of law; they are in the form of rules or principles, given that the *normative* term that characterises *expectation* is opposed not to "be", but to the "cognitive", in its functional rather than its semantic meaning. Hence why, according to LUHMANN (1983, p.57):

> All expectation is phatic, either in its satisfaction or disappointment the phatic covers the normative. The conventional contraposition of the phatic to the normative must, therefore, be abandoned. It is an erroneous conceptual construction, as in the case of wanting to compare being human and women; one conceptual manoeuvre that in this case is harmful to women, and in this case to must be. The opposite adapted to the normative is not phatic, but rather cognitive. It is only possible for it to coherently opt between these two orientations in respect to the treatment of disappointments, and not between the phatic and the normative.

The distinction between normative and cognitive expectations "is not defined in semantic or pragmatic terms, nor referenced to the fundamental affirmative systems or to the contradiction between informative and directive affirmations - but rather on functional terms, in view of the solution of one certain problem" (LUHMANN, 1983, p.56).

It refers, therefore, to the type of anticipation that will be produced by systems of meaning, whether psychic or social, for the absorption of frustrations in view of the uncertain and various possibilities of meaning that the phenomenal world presents to them.

In this context there are two possibilities: (i) the adaptation of the expectation to the situation that it is contrary to or (ii) its maintenance despite its frustration, in conflict situations, hence why the expression "counterfeit maintenance of normative expectations" (LUHMANN, 1983. p.114-115; 1998, p.90).

While cognitive expectations, once not met, characterise a "not always aware willingness of assimilation in terms of learning ", the normative expectations, on the contrary, "are characterised by the determination to not assimilate disappointment", that is, the latter are maintained as expectations despite a situation that opposes them (LUHMANN, 1998, p.56).

The normatisation of expectations through law initially operates in the temporal dimension of meaning. The norm, in this theoretical context, according to the synthesis of VILLAS BÔAS FILHO (2006, p.150), "would thus be a way of temporal structuring of expectations, which would consist of fixing a given expectation as a norm and, by means of absorption mechanisms of the frustrations, neutralizing it against the behaviours which deviate from it".

Thus the normativity of law can be understood, in general terms, as a species of contraphatic stability.

In their turn, besides normatised, in order to fulfill its social systems integrating function and the reduction of the complexity and contingency concerning the difficulty of observation and understanding of the functioning of such systems, such expectations must be socially generalised.

Within its possibilities, it is up to the law to exert the cited generalisation in line with expectations, partially influencing the communicative processes of the other systems that depend on the cited normative expectations for their stabilisation and functioning. The correction of the resulting external factors of the conflicts of meaning would, therefore, be complementary and only one of the ways of maintaining such normative expectations in society.

However, due to societal evolution and the level of functional differentiation of its social subsystems, the constitution starts to assume, through its normative programs and principles, a generalising role in such normative expectations, no longer limited to the strictly legal positivism of law.

The Federal Constitution of 1988 and the legal health system

The Constitution of the Federative Republic of Brazil of 1988, under a new systemic reading, must be interpreted as the "point of convergence of the communicational processes of Brazilian society in the sense of the most profound way of institutionalizing normative expectations" (CRUZ, 2007, p.257).

Such a constitutional function is essential for the consolidation of symbolically generalised means of communication from which society's complex expectations, normatised in constitutional programs, principles and rules, become autonomous in concrete cases, for example, litigation involving the supply of medicines to be discussed here, allowing for the stability and functioning of various social systems, such as the economic system itself, scientific systems, and not only national legal and political systems.

From the legal system's internal point of view, such conclusive programs and constitutional principles interact in their selective information processes in their systemic cognitive opening to the environment as they define the possible meanings of feelings about the legal/non-legal binary codes. Guaranteeing, thus, a minimum coherence with the self-referability of the legal system, exerting internal control of its communicational operations, its directioning and the conditions under which such processes can and must occur. A constitutional interpretation allows the evolution of law itsefl as legislative production is demonstrated to be incapable of meeting this generalization of expectations and the partial uniformisation of the meanings attributed by increasingly specialised social systems, whose symbolically generalised means of communications would not be captured by traditional legislative process.

Contrary to the neoliberal self-regulation advocates' controversial, and some times badly- intentioned, interpretations of the luhmannian theory systems, contradictorily associated to the Theory of the *Communicative Act* and the belief in HABERMAS's consensus (2001, 1997), it is indeed possible, from the re-reading of LUHMANN (1983; 1990a; 1992; 1998), to sustain and better understand in which conditions there is an interdependence among social systems, individuals, and the Law, as well as the primordial function of the latter, especially from the Constitution, in the contra-factual maintenance of these normative expectations in relation to all other social systems (CRUZ, 2007).

In this sense, it is possible to recontextualise, initially, the legal system and, immediately after that, the Constitution itself. According to LUHMANN (1983, p.227):

> [...] By becoming potentially conflicting, they [social systems] must be regulated in great detail. In general terms, the functional differentiation brings about an increase in problems and internal conflicts in society and, in this way, an increase in decision-making burdens in all generalisations. Increasingly, society's partial systems become more reciprocally dependent: the economy depends on the assurance of policies and parametral decisions; policy, economic success; science, financing and planning capacity of policies; the economy, scientific research; family, the economic result of full employment policy programs; politics, socialisation through the family; and so on. At the same time partial systems, in order to be able to exert their constant and reliable function, have to be protected against fluctuations in other spheres by their uncontrollableness. The dependencies and reciprocal independencies of the partial systems grow simultaneously. [...] This way, the necessity of availabilities and securities increase, which has to be met, although one's liberty means another's insecurity [...] The consequential problems of functional differentiation are transparent here, as well as in other cases, in the various levels of law, in the fact that already familiar ideas become questionable and insecure; cracks appear in the dogmatic systems.

Therefore, if on the one hand society's functional differentiation process implies through the fact that none of its emerging systems are able to reclaim supremacy over the others, not even an intention to replace them

in their respective functions, on the other hand, the interdependence between them is not extinguished and, especially, the systemic function of law (LUHMANN, 1992, p.1434-1435).

In other words, considering the luhmannian theory and the highlighted increase of current society's complexity, regulation by law does not lose its meaning and functionality in the context of self-referential social systems, despite the impossibility of completely directing the internal communicational processes of the other autopoietic systems.

Therefore, the Constitution, even under a systemic perspective, is not restricted to the "mechanism of structural coupling [only] between law and politics", as was understood for example, by (CAMPILONGO, 2002, p.98).

Contrary to this understanding, the Constitution, as a "political unit of a nation" (BERCOVICI, 2005, p.9), is not limited to the legal and political systems, but indeed assumes "the best place for the occurrence of the structural coupling between the legal system and society's other functionally differentiated subsystems" (SCHWARTZ, 2004, p.117).

It is noted here, that the term "politics", in order to refer to the Constitution, must be considered in its broadest meaning, related to the social whole, and not only in one of its more restricted meanings with which this term is used in the luhmannian theory to specify politics' social subsystem (HESPANHA, 1999, p.60).

In the case of Brazil, this position is reinforced considering the historical confluence of society that mobilised various social systems around the redemocratisation of the country at the end of the 80s, thus forming a singular structural coupling between these systems of which the Federal Constitution of 1988 is the fruit.

As inferred, the formation of social movements around health and its onslaught with the defenders, for example, of the biomedical and privatised health system then in force, formed a network of new communicational processes in Brazilian society, not restricted to health reform, in a way that the Constitutional Assembly of 1987 cannot be reduced, in any way, to a simple manifestation of the political system, or of a formal exercise of original constituent power (CRUZ, 2007).

Regarding the referred to singular structural coupling between various social subsystems, in the country's historical redemocratisation process, it resulted in a new formation of social communicational processes through the generalisation of new common normative expectations, institutionalised and maximized at the constitutional level.

There is, therefore, the normative force of the Constitution in the binding and obligatory sense of its provisions as it represents this maximum normatisation of the expectations with which they operate society's various systems.

Consequently, it can be affirmed that the Brazilian Federal Constitution of 1988 manifests "the new media, symbolically generalised, on which they come to rely on social systems, not only legal and political, but also economic, scientific, educational and familiar, among others, in its internal communicational processes, delimiting its new borders and its autopoieses" (CRUZ, 2007, p.267).

In this new historical and constitutional context, social security, in which the health system is inserted, can be understood as the result of this broad and democratic communicational process. Its institutionalisation in 1988 would represent for Brazil, as well synthesizes BOSCHETTI (2003, p.71-72), "which meant *sécurité sociale* for the French or *social security* for the English in the 1940's: a movement of reorganisation of existing policies already under new bases and principles, with expansion, however with the introduction of new rights, too ".

Therefore, in what concerns the health system, it is seen that its normative expectations and the very redefinition of the Brazilian State's functions in the matter of public health policies assumed by the Constitution of 1988 result, from the systemic point of view, in a long reordering period of the communicational processes and of the inter-relations of various social systems, marked by the generalisation of expectations around the redemocratisation and reduction of the country's social inequalities, having a concrete impact in the new interactions among several social players in their striving to make a fairer and more solidary society come true.

Such striving and sets of ideas were a large part of the tensions between the health reform movement and the economic and political systems, in clashes for the redefinition in an organisational form of the Brazilian health system that could oppose the, until then, effective, essentially therapeutic and commercial, biomedical model (CRUZ, 2007, p.249).

Although it is not the objective of this essay to deepen the discussion about the conceptualisation of the biomedical model, here it is necessary to clarify that the references made to it relate to PAIM's description (1997, p.20) regarding the flexnerian paradigm in favour of the hegemonic biomedical model, fought against by health reform in the 1980's, that, in general lines, reduces the health system to the set of health care assistance establishments, centred on diagnosis and on allopathic medicine.

This way we have, in general, a model that can be understood as the practise of sovereign, in which mechanical devices, biologists, individualistic principles, specialization and technology are hegemonic. It would not be excessive to relate it to the influx of economic and logical demands on this model to the conform to health systems centred in this flexnerian paradigm, in which, according to SANTOS (2005, p.73), the "health professionals involved in this dimension continue reproducing the orthodox capitalist model, in which health and medicines are considered exchange products, merchandise for intense commercial exploitation".

Opposing this way of conceiving and organising the national health system, the Constitution of 1988

determines, therefore, the formation of the new Brazilian health system organization

The normative expectations in relation to health have become, since 1988, guaranteed in various constitutional rulings, from which are may highlighted here, in principle, its articles 6, 194, and 196.

The insertion of health at the constitutional level among the social rights that compose Basic Rights and Guarantees of the Federative Republic of Brazil (Title II, Chapter II, art.6), as well as in the "integrated set of initiative actions of public authorities and society", that compose the Social Security (Title VIII, Chapter II, art.194), is of paramount importance for the following discussion concerning the supply of medicines through appealing to the judiciary.

Regarding article 196 of the Federal Constitution of 1988, there are still some considerations to be made. According to the aforementioned constitutional provision, we have:

> Art.196, Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and egalitarian access to actions and services for its promotion, protection, and recovery. (BRAZIL, 1988).

In these terms, the health system and the other social systems which compose the Brazilian society redefine their responsibilities and those of the State itself in the organisation of the national health system.

Society commits itself to making possible social and economic policies with the objective of reducing "the risks of illness and other harms" in a preventive dimension, which cannot be met simply through the maintenance of a private and discriminatory, curative-medical assistance system, like the one that had developed until 1988.

To that end, " universal and egalitarian access to actions and services for its promotion, protection, and recovery" must guarantee to all, whether or not they are Brazilian citizens, the right not only to be taken care of by curative assistance services by the Unified Health System (SUS), but also to be covered by other public policies and actions aimed at the prevention and promotion of their health in general way.

Health promotion must be understood not only as the cure and prevention of illnesses, but in a more comprehensive and interdisciplinary way, related to the guarantee of quality of life while intrinsically linked to health. It is presented, therefore, as "a process that is built and modified, subject to influence from all other social systems" (SCHWARTZ, 2004, p.102).

In other words, the systemic operations related to health, independently of their origin and by extension, must come from a minimum conformation to the constitutional norms, while normative expectations are guaranteed by the Constitution and, thus, shared by all social systems.

The indefinite medicalisation of society and the economic policies of medicine

Notwithstanding such considerations and the expansion of the normative expectations that the law must maintain in relation to health, and even though there persists of a medical-curative assistance subsystem, and public responsibility for it , it is undeniable, with its due adequacy to the new social values and the public relevance and expansion of its protection network in the sense of universal access and integrality of its services, that it is looking to overcome the previous essentially biomedical, authoritarian, and private system.

It is especially regarding this last perspective of the right to health that a large part of the claims, in respect to the expansion of pharmaceutical assistance for meeting concrete situations, in principle, apparently not covered by public medicine policies, are concentrated.

The problematic nature of such claims must consider some economic and political expectations that are, many times, latent and that are not duly considered in these legal conflicts regarding the definition of meanings, through which, even if from this perspective of assistance, the normative force of the right to health must be contraphatically maintained as a concrete case.

Given the format of the Brazilian health system and the persistent influence of a biomedical model in the organisation of Brazilian health, it would even be possible to say that a large part of the "litigation" concerning the supply of certain medicines not only have economic and political repercussions, but also congregate in themselves, in their own initial conformation, disputes and tensions which are not simply health expectations, even though not always clearly manifest (ANGELL, 2007; CRUZ, 2007; BARROS, 2004; FOUCAULT, 1974).

Such results from the complexity and interdependence of the social systems, that in the case of the definition of public health meanings end up producing questions of a mixed nature, and not only health, but also politics and, above all, economic ones, are increasingly more related to the definition of meanings that must assume state contributions for the fulfilment of this specific source of the right to health.

Such inter-relations among the health system and the economic and policy systems can be better understood by considering the "indefinite medicalisation" of society and "medicine's political economy ", described by FOUCAULT (1974) in order to characterise the "current crisis of Medicine".

The aforementioned process of indefinite medicalisation can be understood, in a general way, as the expansion of medicine and its field of operation, in a broad sense, as an authority act, beyond its traditional domain centred in the patient-disease relation, no longer being restricted to patients' demands (FOUCAULT, 1974, p.12).

Thus not only modern medicine but public health policies themselves started being granted authoritarian

powers with normalising functions, not restricted to the existence of disease or the patient demands, since everything "that assures the individual's health, whether the quality of the waters, the accommodation system or urbanistic regimen, is today a domain of the medical intervention" (FOUCAULT, 1974, p.13).

In this sense, FOUCAULT (1974, p.13) highlights the rise, in the twentieth century, of doctors' role in regulating society through the normalisation of behaviours, replacing the codified system of laws directed by the lawmakers in seventeenth and eighteenth centuries by the "perpetual distinction between the normal and abnormal person, and the perpetual task of reproducing the normative system".

This expansion of the interventive domain of health practices that are no longer restricted to sick people and illnesses would result from its "epistemological unblocking ", which occurred at the end of the eighteenth century, in the context of social medicine's development. It would have been thanks to the attention to other things and not just patients, as it is clearly inferred in the French urban social medicine model, in which medicine ceases being essentially clinical and begins being social, which allowed it to become free, since then, from the "scientific and therapeutical stagnation in which it was" (FOUCAULT, 1974, p.14).

Also according to FOUCAULT (1974, p.18), the new and considerable economic role of medicine is aligned with this emerging paradigm, thanks to the possible insertion of the body in the market, no longer restricted to its identification as a productive force, but fundamentally through the consumption of health, mediated by Medicine.

Since the eighteenth century, with the development of social medicine, health was already related to economic problems, aiming, through medicine, at responding to commercial needs, to the aforementioned political arithmetics of the national states in a consolidation phase and, later, to capitalistic demands regarding the maintenance and reproduction of the work force. (FOUCAULT, 1979, p.84; ROSEN, 1979, p.47; 1994, p.98).

In its turn, this "political economy of Medicine" regards the new and principal economic role assumed by modern medicine, no longer restricted to the aforementioned functions, but rather related to the direct production of wealth with the introduction of health itself in the market, as an object of consumption. According to FOUCAULT (1974, p.18):

> Currently, medicine finds the economy through an alternative route. Not simply because it is capable of reproducing the work force, but because it is directly able to produce wealth, as health is the object of desire for some and of profit for others. Health, as the object of consumption, as it can be produced by some - pharmaceutical laboratories, physicians, etc. - and consumed by others - the potential or current patients – became an important economic object, entered the market.

The insertion of the body in the market, mediated by medicine, is, therefore, highlighted, initially as a salaried work force and, later, through consumption of health, which, as a consequence, would have allowed for several "disfunctions in the health system and contemporary medicine" (FOUCAULT, 1974, p.19).

In this context, contrary to what it may seem, doctors would not be the only or the most benefitted by this indefinite social process of medicalisation, but rather the pharmaceutical industry. As FOUCAULT (1974) warned, the "pharmaceutical monopolies" are the ones that would keep the profits generated by disease and health, being supported even by the collective financing of this health system. Such a situation, however, persists up until today (ANGELL, 2007, p.207-229; BARROS, 2004, p.119).

Hence why, still according to FOUCAULT (1974, p.21), the doctor's practice and knowledge could be repositioned as a simple intermediary between the pharmaceutical industry and the customers' demands, the doctors being mere "distributors of therapies and medicines".

In this respect, the Folha de São Paulo's article of September 3rd, 2005 could also be cited, under the heading "Supervised Prescription" ("Receita Vigiada"), which reported the pressure exerted by the laboratories' in their advertising to people, in their possession of copies of prescriptions supplied by pharmacies, and in regard to health professionals, thus controlling the prescription of branded products represented by them. Such a mechanism would be used to verify if doctors benefited by certain "favours" from the laboratories would be, in fact, "partners" of the pharmaceutical industry (COLLUCCI, 2005).

However, despite initial advances in technology resulting from this commercialism and the new economic and political roles of medicine, and, in a broader sense, public health itself in the 1970s, FOUCAULT (1974, p.19) called attention to a strong stagnation phase of such medicine in regard to public health, no longer responding to the expected and so advertised, even today, advance of health welfare.

Also, the relationship between living standards and consumption level is different, as in terms of health, no significant improvement of its indicators is seen as medical consumption increases. This asymmetry can be demonstrated by relating the consumption of services and health products to the alterations in living standards. Studies in this direction pointed to the fact that "the environmental variables, especially food consumption, education, family income, are factors that have much more influence than medical consumption" (FOUCAULT, 1974, p.19).

According to FOUCAULT (1974, p.20), this absence of a direct relation between the growth in medical consumption and living standards would reveal the following economic paradox: "a growth in the consumption that is not followed by any positive phenomenon on the side of health, morbidity, and mortality".

This exaggeration between the expectations of society in relation to "health consumption" and its repercussion in the real improvement of health conditions

currently persists despite the supposed advancements of the pharmaceutical industry and its apparent engagement in the development of new medicines that would justify, in theory, its high product prices, as well as its excessive profits.

In this sense, there are several works that question the methods of the big private pharmaceutical laboratories to keep their high profitability in a global market whose total estimate of medicine sales to citizens subject to medical prescription was around 400 billion dollars globally in 2002 (ANGELL, 2007, p.21; BIRTH, 2005; BARROS, 2004).

Amongst these studies, for the following discussion concerning the concession of medications by the Brazilian judiciary, here it is necessary to point out ANGELL's (2007) survey to demonstrate the real "creative" and "innovative" dimension of the pharmaceutical laboratories, despite their official discourse, from the systematisation of data supplied by the US Food and Drug Administration (FDA), responsible for the registration of new medicines in the USA. According to a meticulous survey by the aforementioned author:

> Of 78 medicines approved by the FDA in 2002, only 17 contained new active principles, and only seven of them had been classified by the FDA as improvements in relation to older medicines. The other 71 medicines approved in that year were variations of old medicines or had not been considered better than medicines already on sale. In other words, they were drug "imitations"". [...] Moreover, from these seven, not one came from an American pharmaceutical laboratory of importance. (ANGELL, 2007, p.32-33).

This small number of really innovative medicines, according to the FDA's official classification, in comparison to the large amount of "new" products launched annually with heavy investments in marketing and advertising, were not, however, an isolated fact of 2002.

From the examination of medicines registered in the aforementioned US agency, between 1998 and 2002, ANGELL (2007, p.71-72) could find that throughout this period, 415 new medicines had been approved, amongst which only 133, that is, 32 %, had been considered as "new molecular entities", the others only being variants of already existing medicines. Nevertheless, of these 133 medicines, only 58, or 14% of the total, were finally considered as possibly innovative medicines in the sense of representing significant progress in relation to already commercialised medicines.

That is so because, as the aforementioned author explains, for the FDA, even "totally new molecules may not be better than an already existing medicine for the same condition". Therefore, according to criteria of the aforementioned US agency, not all these "new molecular entities" get to be classified as drugs for "priority inspection", however those medicines "with probability of representing a 'significant improvement, in comparison with commercialised products, regarding the treatment, diagnosis or prevention of an illness'" (ANGELL, 2007, p.70-71).

The relevance of these figures and the disproportion between the sum of annually registered medicines by the FDA and the lower percentage (inferior to 15%) that it considers as innovative requires the dissemination of these data and the attempt to insert these criteria of distinctions between "new medicines" annually produced in the merit of the judicial proceedings regarding the request of the inclusion of new medicines in the list of those supplied by the SUS or of its supply directly by the State to certain patients, removing, as a judicial criterion for assessing the innovative nature of the petitioned medicine, the simple argument that the drug at issue was approved for commercialisation by the FDA in the USA, or in any other foreign state agency or national register.

As it will be treated in the following and conclusive topic, the risk resulting from these economic interests opposed to the constitutional purpose of the health system must start to be considered, without, however, hindering, per se, the appeal to the judiciary and its effective control over public authorities in the sense of assuring the effectivation of the basic right to health, however under the individual perspective of the supply of medicines.

Access to Justice and the effectivation of the Right to Health

The judiciary not only performs an essential systemic function for law but also for society as a whole, for, through its decision-making process, it contributes to the explanation of which expectations have a normative nature and, consequently, exert their coercive force in order to contrafactually keep such expectations in such a way as to readapt the behaviours deviating from them.

In this sense, according to the luhmannian functionalist perspective, SCHWARTZ (2004, p.131) affirms: "an intense actuation of the judiciary in the achievement of basic rights must be understood as a decision-making criterion to base the autopoietic and organisational dynamics of the legal system".

More than rediscussing the new challenges of the judiciary, due to its role in the achievement of social rights (CAPPELLETTI, 1993), and the fundamental character of the right to health (CRUZ, 2007), presupposes in this work, that from such considerations is pointed out the duty of the state to enable the titular individuals of the public subjective right to health all legal means and resources for the protection of this right (SCHWARTZ, 2004, p.135).

Therefore, in what concerns the centrality of the public policies for its accomplishment in general and collective terms, it is essential to making it concrete in a global perspective of health promotion and prevention, nevertheless, it is consolidated, correspondingly, in an understanding, according to which:

> With the normative, doctrinal and jurisprudential recognition that health is a *basic right of man*, we have it that the constitutional norms referring to health are norms of *immediate applicability* and *complete effectiveness*, characterists recognised by the highest Brazilian judiciary

> court – The Supreme Federal Court (Supremo Tribunal Federal - STF) -, which is responsible for the precipituous safeguarding of the Constitution. (SCHWARTZ, 2004, p. 136-137).

In other words, access to justice with the possibility, for example, of petitioning for the supply of certain medicines against the state, in itself is a key element for the delineating process of the meanings of the legal health system and for the effective and adequate control of public policies (or not) that have been implemented for the purposes constitutionally elected by the Brazilian society.

This is not to say that each and every petition for medicines taken into jurisdictional consideration must be accepted so as to modify the course of the state's operation. In the same way, however conversely, we can not remove, not even in matters related to public health policies, the Constitutional Right of Action, not being possible to readily deny the appeal to the judiciary in situations in which the individual feels threatened or violated in their health related rights.

In the specific case of legal actions involving the supply of medicine, the overcoming of the communicational stalemate among involved agents, patients as plaintiffs, public powers as defendants and, mainly, judges, must be searched for; each one provided with a specific logic and language, most of the times incompressible to the others that participate in this communicational process, in a broad sense, and not simply a "legal" one (CRUZ, 2007).

The difficulty faced by the judge must be considered. He must, in judging a concrete case, measure the assault to human dignity, which can only be individually analysed – since that is the dimension already given by the doctrine in this legal concept (SARLET, 2007). It is not possible to want a merely quantitative and hypothetical evaluation - for example, the decision could end up saving only one life to the detriment to thousands of other lives that could be saved with the use of the state treasury involved in one public health policy. This type of mensuration is equivocal and utilitarian. Life is life: whether one, or a thousand. The dignity of a human being does not allow this confrontation.

However, nothing prevents, on the contrary everything recommends, that the involved public authority demonstrate in court, for example, that the given medicine does not need to be replaced by another not included in the SUS' list – in case the effect of both are the same for the hypothesis in litigation. In the same way that the defendant makes evident the ease of obtaining, observing the administrative structure, the medicine in a health center close to the author - without, of course, being hindered by excessive bureaucracy. Or also, that it proves that the involved entity in the petition of new medicines does not defend the real interests of the population, but possible spurious interests of certain economic groups with dubious interests, trying to improperly include imitation medicines, as if they were innovative, in a public listing - in this case, if, it is inclusive and demonstrated, it would be necessary to take serious measures of a criminal nature.

In conclusion, what can not be admitted is that an existing inversion in the filing of a petition and the absence of a proper defence by the public authority invalidates the search for legal protection. A serious judiciary, in its turn, must always be attentive to its local reality, without, however, mingling with one or another group of power - whether public or private.

Finally, we should not believe that that the judges are making public policies in these cases, but only applying constitutional norms. And, by doing so, must act with the necessary prudence, without, however, accepting generic arguments (such as the reserve of the possible funding), in general, which can not be demonstrated in procedural court records. The search by everyone, including the judiciary, is for a system that increasingly encourages the dignity of the human being.

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