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# Legal decisions on access to medicines in Pernambuco, Northeastern Brazil

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## ABSTRACT

**OBJECTIVE:** To analyze decisions from the legal system concerning the population's access to medicines within the Brazilian Public Health System through judicial channels, with regard to decision-making criteria and possible political and economic pressure.

**METHODS:** This was a descriptive retrospective study on documents with a quantitative and qualitative approach. Data were gathered from the State of Pernambuco Superintendency for Pharmaceutical Care, and the data sources used were 105 lawsuits and administrative reports between January and June 2009. It was ascertained which medications have a patent or patent request in the database of the Brazilian Patent Office (INPI), in order to identify the frequency with which patents feature in lawsuits. The data obtained were classified according to Anatomical and Therapeutic Chemical System. To analyze the judicial decisions, the theory of autopoietic social systems was used.

**RESULTS:** There were lawsuits involving 134 medications, with an estimated value of R\$ 4.5 million for attending the treatments requested. 70.9% of the medications had a patent or a patent request and they were concentrated in three therapeutic classes: antineoplastic and immunomodulating agents; digestive tract and metabolism; and sensory organs. Six central ideas within judges' decision-making criteria were identified (the federal constitution and medical prescriptions), along with pressure between the legal, economic and political systems concerning access to medications.

**CONCLUSIONS:** The analysis on judicial decisions based on the theory of autopoietic social systems made it possible to identify mutual stimulation (dependency) between the legal system and other social systems in relation to the issue of citizens' access to medications. This dependency was represented by the federal constitution and intellectual property. The federal constitution and medical prescription were identified as decision-making criteria in lawsuits. Intellectual property represented possible political and economic pressure, especially in cases of launching medications into the market.

**DESCRIPTORS:** Pharmaceutical Services. Judicial Decisions. Intellectual Property of Pharmaceutic Products and Process. Equity in Access. Health Law.

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## INTRODUCTION

The International Covenant on Economic, Social and Cultural Rights, of 1966, recognized the right of every person to enjoy the highest level of health and highlighted the population's access to medication through referring to its participation in scientific progress and its benefits.<sup>a</sup> Although late, the publication of the Alma-Ata Declaration, in 1978, was the first international mention of the importance of medications that are essential to primary healthcare.<sup>b</sup>

When countries in Latin America and Central America recognized this right in their federal constitutions, they began to face a frequent problem: the rising number of lawsuits against governments, demanding that medications that were not in the list of essential medications for the public health systems should be supplied.<sup>7</sup>

The number of lawsuits against local governments can reach close to seven thousand per year in Brazil, representing annual expenditures of up to R\$ 60.4 million (\$ 60.4 million).<sup>3,4,11,21</sup> Concession of medications is considered to be a means of judicialization of health-care policy.<sup>5</sup> Researchers have suggested that judicial decisions do not take into account the possibility that there may be influences external to the political system capable of interfering in the incorporation of therapeutic innovations within the Brazilian National Health System (Sistema Único de Saúde, SUS), such as pressure from the pharmaceutical industry or from doctor and patient associations.<sup>5,13,21</sup>

The objective of this study was to analyze decisions from the legal system concerning the population's access to medications within SUS through judicial channels, with regard to decision-making criteria and possible political and economic pressure.

## METHODS

This was a descriptive retrospective study on documents with a quantitative and qualitative approach. Cost reports (spreadsheets with estimated total values of the annual acquisition of each medication and the total number of registered patients for each medication) and interlocutory decisions from 105 lawsuits that demanded that medications should be supplied by the Pernambuco State Health Department, between January and June 2009, were analyzed.

A form was used to gather the variables of the cost report in the quantitative stage: commercial name of the medication, common designation of the drug in Brazil, name of the producing laboratory, total acquisition cost

of each medication, and total number of registered patients for each medication.

The medications were classified in accordance with the Anatomical and Therapeutic Chemical System of the World Health Organization. It was ascertained which medications have a patent or patent application in the database of the Brazilian Industrial Property Office (Instituto Nacional de Propriedade Industrial, INPI).

The data were analyzed using the Excel® software, version 2007, and the variables were presented as simple frequencies.

The interlocutory decisions of the magistrates of the Pernambuco Court of Justice were analyzed qualitatively from a simple random sample, using the criterion of sampling until saturation.<sup>5</sup> The technique of collective subject discourse, similar to what was described in the study of Marques & Dallari,<sup>12</sup> was used to organize and tabulate the qualitative data. The main arguments mentioned by the magistrates were transcribed from each interlocutory decision. Key expressions were extracted and, from the similarity between them, a synthesis of the discourse was produced, from which the central ideas were identified.<sup>9</sup>

## Theoretical Framework

The Luhmann<sup>10</sup> theory of autopoietic social systems was used to identify the decision criteria and describe the relationship between law, politics and economy.

This theory has three theoretical contributions: shape theory, differentiation theory and evolution theory.<sup>10</sup> The present study does not intend to detail these contributions, but a few concepts need to be outlined in order to understand its application to health issues, which may be communicated in political, economic, juridical or scientific shape.

The Luhmann social theory takes communication (selection process through differentiation) to be the minimum unit, or cell, of society. Another theoretical basis is *autopoiesis*: production (*poiesis*) by itself (*auto*). Even though this concept has its origin in biology, Luhmann made the required adaptation of *autopoiesis* to the theory of society by identifying communication as the social element responsible for producing and reproducing society.<sup>10</sup>

According to Luhmann, the elements (communications) are created within autopoietic social systems,

<sup>a</sup> United Nations. International Covenant on Economic, Social and Cultural Rights. Geneva;1996 [cited 2011 Jun 22]. Available from: <http://www2.ohchr.org/english/law/pdf/cescr.pdf>

<sup>b</sup> Ministério da Saúde. Secretaria de Políticas de Saúde. Projeto Promoção da Saúde. Declaração de Alma-Ata. In: Conferência Internacional sobre cuidados primários de saúde; 2001; Brasília, BR. p.15.

and establish connections among themselves through operational closure. This closure enables recursive (cyclic) production of sense, i.e. the communication acts on itself (self-referential network). Thus, communications are not imported from the environment (surroundings). On the contrary, they are processed (produced) inside the social system, according to their own criteria.<sup>8,10</sup>

However, social systems do not ignore stimuli from the surroundings, but create reciprocal dependence between the social system and its environment. This relationship of dependence is called structural linkage and, through it, social systems choose the communication stimuli that come from the environment.<sup>8,10</sup>

As some communications reach a high level of complexity, social systems with specific functions are formed, for instance the legal system. In accordance with the specific function of each social system, there is an exclusive binary language code that allows each system to autopoietically choose the communication stimuli from the surroundings. Each binary code has a positive and a negative version. For instance, the legal system operates with the code of legal/illegal language, and the political system with a can/cannot code. Thus, the code leaves the communication stimuli susceptible to acceptance or rejection. As a result, the meaning will be maintained or changed within the social system, thus allowing its autopoiesis (Figure 1).<sup>8,10</sup>

Operationally closed social systems do not import elements straight from the environment. However, they are cognitively open to the environment, and observe (hetero-reference) without risking their own identity.<sup>8,10</sup>

Social evolution depends on communicative performance. Moreover, action by organizations within the social system is the *sine qua non* condition for attaining this evolution, since only organizations are capable of communicating with their surroundings. For these organizations, communication of decisions is the operational baseline.<sup>10</sup>

**RESULTS**

The lawsuits analyzed reached around R\$ 4.5 million during the year; 70.9% of the medications had a patent in Brazil or a patent request in the INPI, thus characterizing market monopoly. Among these medications, 73.7% were concentrated in three therapeutic classes (Table 1), which represented 77.7% of the financial resources directed towards addressing these lawsuits (Table 2).

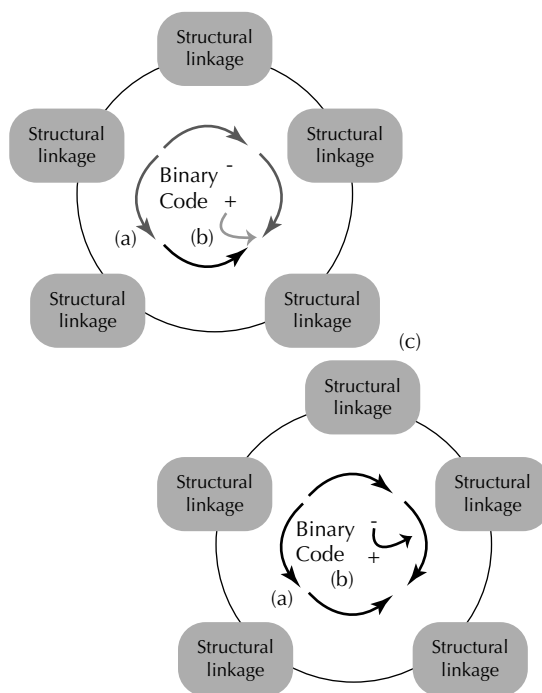
Eight pharmaceutical companies were the manufacturers of 80% of the medications with a patent or a patent request in the INPI; 90.95% of the financial resources of the Pernambuco State Health Department

for the acquisition of these medications related to seven pharmaceutical laboratories.

The mean acquisition value of each medication for annual treatments belonging to the classes of antineoplastic and immunomodulatory agents ranged from R\$ 37,000 to R\$ 193,000. The values in the sensory organs class ranged from R\$ 18,000 to R\$ 30,000.

Fifty interlocutory decisions were analyzed by 35 magistrates: 20 judges and 15 appeal judges of the Pernambuco Courts of Justice in the judicial districts of the state capital and the interior of the state.

Six discourse syntheses were produced and their respective central ideas were identified through the magistrates' decision criteria, as follows: 1: Insufficient financial resources in the public budget cannot be used as an argument by the State to justify non-implementation of actions and health services required by citizens; 2: The health of human beings is their greatest asset and deserves protection from the State through implementation of public policies capable of ensuring



(a) Circularity of the communication elements, creating a recursive self-referential network; (b) Direction determined from the binary code. Maintenance of the direction is represented in the circularity of the elements by a dark shade. Change in the direction is represented in the circularity of the elements by a light shade; (c) Structural linkage, allowing reciprocal stimuli between different social systems.

**Figure 1.** Communication process based on Niklas Luhmann's concept of autopoiesis and structural linkage of the autopoietic social systems.

**Table 1.** Medications with a patent or patent application in the Brazilian Intellectual Property Office (INPI) in the lawsuits of the Pernambuco Court of Justice, according to the anatomical-therapeutic class. Pernambuco, 2009.

Anatomical-therapeutic class	Medication	Frequency %	Medications with a patent or patent application in the INPI	Frequency of patents in the class %
Antineoplastic and immunomodulatory agents	45	33.6	42	93.3
Digestive tract and metabolism	23	17.2	16	69.6
Sensory organs (ophthalmological products)	12	9.0	12	100.0
Central nervous system	14	10.4	3	21.4
Blood and hematopoietic organs	6	4.5	5	83.3
General anti-infectants for systemic use	6	4.5	5	83.3
Cardiovascular system	6	4.5	1	16.7
Respiratory	5	3.7	3	60.0
Hormones for systemic use, except sexual hormones	5	3.7	3	60.0
Genitourinary system	5	3.7	3	60.0
Musculoskeletal system	3	2.2	2	66.7
Vitamin	3	2.2	0	0.0
Anti-parasitic products	1	0.7	0	0.0
Total	134	100.0	95	70.9

Source: Pernambuco State Health Department, 2009

enough protection for human beings; 3: Access to high-cost medications for treating chronic diseases in citizens who do not have financial conditions allowing them to purchase such medications is the State's duty; 4: The public authority has the obligation to promote universal, comprehensive and free access to each and every treatment prescribed by a doctor, using all available technological means; 5: The State has a duty to provide medication prescribed by a trained doctor, and whether it was previously included in the government's list of medications is irrelevant; 6: The State can suggest an alternative to the medication prescribed by a doctor, as long as there is documental proof of the equivalence of its effectiveness.

## DISCUSSION

The results reflected similarities with the global market for medication sales in the United States, in which the therapeutic classes of antineoplastic and immunomodulatory agents were among the ten most sold medications. Three medications in this therapeutic class appeared in the global ranking of the ten most sold products.<sup>c</sup>

Other studies have also found this therapeutic class to be among the classes most demanded judicially.<sup>11,21</sup>

The estimated values of the annual treatments of the therapeutic classes most demanded judicially were burdensome. Comparison between these values and the gross domestic product (GDP) per capita of Brazil (almost R\$ 17,500 in 2010)<sup>d</sup> and the average monthly income of Brazilian families (R\$ 2,763.47),<sup>e</sup> corroborates the arguments of the legal decisions concerning the insufficiency of purchasing power among the population for buying these medications. The majority of the Brazilian population cannot afford these costly treatments without resorting to SUS. However, it is necessary to analyze this situation of high prices, which may be associated with the patents of the medications. Among the medications demanded judicially, 70.9% had a patent or a patent request in the INPI.

As also stated by Reis & Bermudez,<sup>15</sup> the present study allowed the observation that just a few companies concentrate the majority of the billing relating to active pharmaceutical agents in Brazil. There is a monopoly of production and trading of medications

<sup>c</sup> IPPharm Exec. We leap tall buildings to bring you the definitive guide to the world's top pharma companies. Pharm Exec. 2009 May [cited 2011 Jul 22]:68-79. Available from: <http://pharmexec.findpharma.com/pharmexec/data/articlestandard//pharmexec/352009/621548/article.pdf>

<sup>d</sup> Instituto de Pesquisa Econômica e Aplicada. Brasil chega a PIB per capita de US\$ 10 mil em 2010. E agora? Brasília; 2010 [cited 2011 Jul 23]. Available from: [http://www.ipea.gov.br/portal/index.php?option=com\\_content&view=article&id=2036&Itemid=75](http://www.ipea.gov.br/portal/index.php?option=com_content&view=article&id=2036&Itemid=75)

<sup>e</sup> Instituto Brasileiro de Geografia e Estatística. Pesquisa de Orçamento Familiar (POF) 2008/2009 mostra desigualdades e transformações no orçamento das famílias brasileiras. Brasília; 2010 [cited 2011 Jul 10]. Available from: [http://www.ibge.gov.br/home/presidencia/noticias/noticia\\_visualiza.php?id\\_noticia=1648&id\\_pagina=1](http://www.ibge.gov.br/home/presidencia/noticias/noticia_visualiza.php?id_noticia=1648&id_pagina=1)

**Table 2.** Estimated expenditure on acquisition of medications with a patent or patent application in the Brazilian Industrial Property Office (INPI) in the lawsuits of the Pernambuco Court of Justice, according to the anatomical-therapeutic class and pharmaceutical company holding the patent or patent application. Pernambuco, 2009.

Pharmaceutical company holding the patent or patent application in the INPI	Expenditure on acquisition of antineoplastic and immunomodulatory agents (R\$)	Expenditure on acquisition of medications for the digestive tract and metabolism (R\$)	Expenditure on acquisition of medications for sensory organs (ophthalmological) (R\$)	Total
Roche	734,099.10	-	-	734,099.10
Pfizer	643,193.32	-	712.80	643,906.12
Bristol-Myers	557,613.00	-	-	557,613.00
Jonhson & Jonhson	444,116.40	-	-	444,116.40
Novartis	85,068.00	83,422.80	258,276.19	426,766.99
Merck	238,791.05	-	-	238,791.05
Abbott	159,620.16	-	-	159,620.16
Genzyme	143,368.92	-	-	143,368.92
Wyeth	75,362.40	-	-	75,362.40
Bayer	70,262.40	-	-	70,262.40
Sanofi-Aventis	-	8,913.66	-	8,913.66
Novo Nordisk	-	2,115.00	-	2,115.00
Eli Lilly	-	946.40	-	946.40
Total	3,151,494.75	95,397.86	258,988.99	3,505,881.60

Source : Pernambuco State Health Department, 2009

and a market oligopoly of beneficial items that are essential for human health. In this context, a debate on the intellectual property of products and pharmaceutical processes is justified.

Luhmann<sup>10</sup> stated that property is valued in term of money and is present in all economic transactions, and that it can only be properly understood from an overall social perspective, as a mechanism of structural linkage. According to Tachinardi,<sup>19</sup> intellectual property protection is a mechanism of power and an instrument for controlling the market so as to reduce the uncertainties of innovators, i.e. moving towards a political and economic focus rather than a legal focus. Behind the discourse stating that the objective of intellectual property is to stimulate invention, there is a real economic objective: financial appropriation of scientific knowledge. Proner<sup>14</sup> stated that technological dependence is a factor of economic and political subordination, and that, when allied with science, it creates an unquestionable source of power.

In this situation of judicialization of health policy and intellectual property, one relevant issue is the second-order effects of judicial decisions, given that the decisions set precedents and affect the expectations of private agents, with positive or negative consequences for society. The juridical system needs to consider the possibility that its decisions may bring predictability from an economic viewpoint. The procedural-constitutional system is leading towards greater linkage of Brazilian

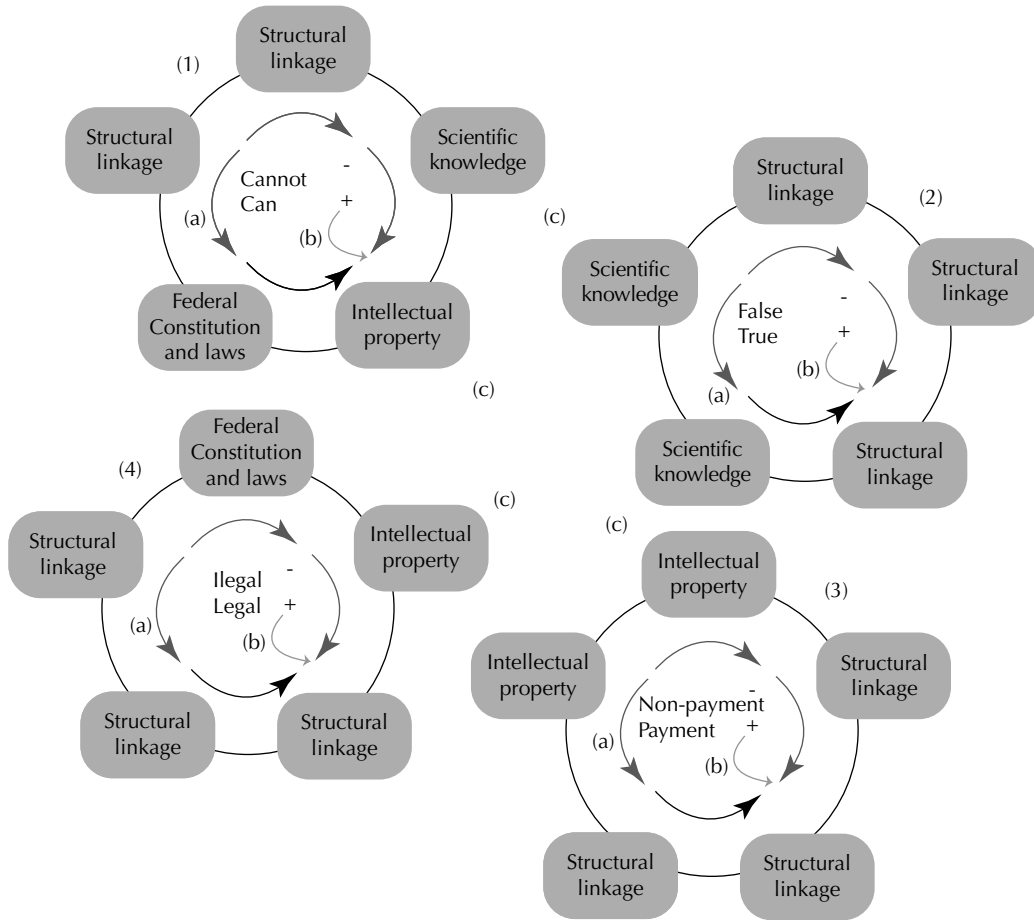
judges to the precedents of higher courts, such as the mechanism of binding precedents.<sup>20</sup>

The operations of the legal system were seen to be recursive. Many decisions referred to others from state courts, the Federal Court or from the Federal Supreme Court. In addition, precedent no. 18 of the Pernambuco Court of Justice itself was referred to on many occasions: "The State has a duty to provide medications that are essential for treating serious illnesses, for needy citizens, without charging them, even if such medications are not present on the official list".

The judicial system kept its exclusiveness through its recursiveness of communication. The operations came from previous decisions from other courts – the Brazilian Federal Constitution (articles 5 and 196) – and decisions from other courts, thereby creating the conditions for the subsequent operation.<sup>17</sup>

Wang<sup>22</sup> stated that all the decisions from the Federal Supreme Court that were analyzed granted the medication requested and that references to precedents from the court's own decisions were frequently made, as observed in the present study.

The Constitution was the judges' decision-making criterion (central ideas 1, 2 and 3), and this has already been observed in an international study concerning this issue.<sup>6</sup> Based on the theoretical framework used in the present study, the Constitution was a relevant structural linkage. The Constitution is an operative precondition



(1) Political system. 2) Scientific System. (3) Economic system. (4) Legal system. (a) Circularity of the communication elements, creating the recursive self-referential network. (b) Direction created from the binary code with positive and negative versions. (c) Structural linkages (Federal Constitution and laws, intellectual property and scientific knowledge), allowing reciprocal stimuli between these social systems.

**Figure 2.** Structural linkages between the political system and the scientific, legal and economic systems in the decision-making process. Pernambuco, 2009

for the political system, i.e. a preset means for decision-making that brings legitimacy. For the judicial system, it played the role of assuring normative expectations, thus increasing the possibility of implementation of the public policies announced in its text.<sup>17</sup>

Through this, it was possible to demonstrate the relationships between access to medications, the law, politics and the economy. The legal system rejected the communication from the political system regarding the limited financial resources of the health budget (central ideas 1 and 2). In the light of the theory of autopoietic social systems,<sup>10</sup> it was observed that the legal system, which operated with the exclusive binary code of 'legal/illegal' in relation to its surroundings, was selective. No cognitive opening<sup>10</sup> of this social system in the communication process relating to the limited financial resources for implementing the right to health

was observed. Such a cognitive opening is important because it influences the implementation of the right to health, especially regarding access to medications.<sup>7</sup>

On the other hand, there was a cognitive opening of the legal system in relation to central idea 6, with acceptance of the communication about selection of medications through pharmaceutical attendance (an organization in the political system). However, central idea 5 indicated the opposite, i.e. rejection of the same communication. This mutual dependency (structural linkage) between the two social systems for achieving the right of access to medications increased the risk that one system might interfere with the other.<sup>10</sup>

Another decision criterion of the legal system was medical prescription, which was present in central ideas 4 and 5 and has been reported in other studies.<sup>6g</sup> This

criterion allowed observance of the structural linkage between the decisions of the legal, economic, scientific and political systems.

Pharmaceutical attendance needs to select communications from the economic and scientific systems, considering the great quantity of medications available and the low therapeutic gain from those released on the market.<sup>1</sup>

On the other hand, a decision by this organization not to include a medication released onto the market, in the SUS list, may stimulate the legal and economic systems. This will be stimulated to a greater degree if medications under patent protection are involved. This may involve use of means of dissemination<sup>10</sup> (advertising) and symbolically generalized means of communication<sup>10</sup> (the power of doctors and of patients' associations),<sup>4g</sup> in order to increase the chances of communication acceptance.<sup>8</sup> Communication about new medications on the market is capable of reciprocally stimulating social systems via structural linkage. The decisions of the legal system can influence the decisions of pharmaceutical attendance regarding inclusion or non-inclusion of a new medication in the SUS list via structural linkage (Figure 2).

Cruz & Correia<sup>5</sup> warned that there was a need to take into consideration the risks and mistakes that jurisdictional action might cause, as a result of possible communicational distortions of the pharmaceutical industry. Such distortions can be noticed in the analysis performed by Barros,<sup>1</sup> in which regression of the therapeutic gain of the 1,284 medications released onto the market between 1990 and 2004 was observed. The therapeutic gain decreased from 31% to 23% over this period, according to an evaluation by the United States Food and Drug Administration (FDA).

Serra-Sastre & McGuire<sup>18</sup> stated that the demand for healthcare services is a reflection from doctors' decisions, not from the final consumer's decision, because of the asymmetry of information in the doctor-patient relationship. The dissemination of medications on the market is proportionally related to medical prescriptions for the new medications, for patients.

Analysis on the dissemination of new medication should be made from two aggregation levels: the market and the individual perspective of the decision-maker. At the individual level, the focus is on comprehension of the decision-maker's behavior. In countries that have public health systems, the price of medication will probably not be a relevant variable to be considered by the doctor at the time of making the prescription (decision process), since acquisition of the medication will be the government's

responsibility. However, the market demand will be affected by the prices of the products, which are targets of negotiation between the manufacturer and the government. The price is a relevant variable for the market, but not for the individual decision.<sup>18</sup>

Berndt et al<sup>2</sup> observed the degree of influence that widespread use of a medication has on doctors, through safety and effectiveness information. The fact that a medication is widely used on the market may suggest that it has greater effectiveness and low side effects and risks. Despite the availability of alternatives on the market, use of a certain medication may predominate, and not necessarily the most effective or safest one. As more people start to use the new product, communication increases, which accelerates the pace at which other people start to know about the existence of the medication.

The dissemination rates for medication brands depends indirectly on the attributes of the medication and directly on the previous sales of the therapeutic class, which reflects the learning and communication between doctors and patients. The accumulated sales on the market may affect the demand, from perception of the quality attributes of the product (effectiveness and safety), thus accelerating its dissemination rate.<sup>2</sup>

Experimentation and learning are central elements driven by the doctor's experience in both of these diffusion models. The characteristic attribute of the diffusion process is the combination of many pressures acting together, especially at the information level. The demand for new medications remains underexplored due to the diversity of pressures and interests that interact on the market.<sup>18</sup>

Regarding these pressures, the present study highlighted that intellectual property is the structural linkage that allowed reciprocal stimulations between different social systems involved in access to medications. The quality of patents needs to be evaluated and improved based on determining higher requirements for novelty and non-obviousness. Governments need to ensure prior opposition, such that applications that do not meet the rigor of these requirements will not be granted.<sup>16</sup>

The analysis on the juridical decisions, based on Luhmann's theory of social systems made it possible to identify the mutual stimulations (dependencies) between the legal system, and its surroundings concerning access to medication through SUS. These structural linkages (dependencies) were represented by the Federal Constitution and by intellectual property. It can be suggested that the legal system should use

<sup>1</sup> Scheffer MC. Aids, tecnologia e acesso sustentável a medicamentos: a incorporação dos anti-retrovirais no Sistema Único de Saúde [doctoral thesis]. São Paulo: Faculdade de Medicina da USP; 2008 [cited 2011 Jun 20]. Available at: <http://www.teses.usp.br/teses/disponiveis/5/5137/tde-08072008-133201/pt-br.php>

<sup>8</sup> Bomfim RLD. Agenda única de saúde: a busca do acesso universal e a garantia do direito à saúde [doctoral thesis]. Rio de Janeiro: UERJ; 2008 [cited 2011 Jun 20]. Available at: <http://www.tesesims.uerj.br/lildbi/docsonline/get.php?id=533>

the “therapeutic gain” of the medication as a decision-making criterion, in replacement for the medical prescription, so as to ensure scientifically proven benefits from treatments for citizens and mitigate the judicialization of health policy.

The theory of autopoietic social systems allows multiple descriptions of society from different observers and do not aim to determine any causal relationship.<sup>10</sup> The limitation of the present study is that it did not allow definition of the cause of judicialization of health policy.

More studies will be necessary in order to better comprehend the manner of dissemination and the demand for new medications, as well as access to them through SUS.

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