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Right to health litigations: a discussion on the observance of the principles of Brazil's Health System

ABSTRACT

The paper reflects upon the legal interpretations of the right to health and its consequences. In order to exemplify the complexity of the theme and its emotional appeal, it analyzes the Supreme Court's decision in a public litigation against the State of Alagoas demanding that medication be supplied. Different interpretations, by both judges and health professionals, of the notion of integral health care, one of the principles of Brazil's Health System, are examined. It is held that scarcity of resources must be taken into consideration when drawing up public policies that aim to allocate funding efficiently and in a manner that is compatible with the principals of the health system. Finally, the impact of judicial decisions concerning medication not offered by the system and the behavior of the Brazilian judiciary with this respect are discussed.

DESCRIPTORS: Single Health System. Right To Health. Judicial Decisions. National Drug Policy. Equity in Health.

INTRODUCTION

A Ruling of the *Supremo Tribunal Federal* (STF –Federal Supreme Court), in February 2007[a] stimulated much debate in the press. The court suspended a motion *in limine* or a preliminary motion that determined that the State of Alagoas had to acquire medicine not supplied by Brazilian Health System (*Sistema Único de Saúde* – SUS), to patients who had had renal transplants as well as to those who suffered from chronic renal disease. This generated declarations from several patients' associations, which alleged that this ruling limited citizens' rights to health and to integral therapeutic assistance. In this context, the lists of medicines supplied by SUS to its diverse health programs were accused of being restrictive.

Within this debate and from the perspective of the individual, overruling a judicial action that demands that a certain pharmaceutical product be supplied by the State resounds as inhumane. Even the Justice of the Supreme Court retracted from her own ruling according to which only those medicines listed in SUS's programs had to be supplied by the State. Later, in two decisions suspending the Writ (3158 and 3205) against the States of Amazonas and Rio Grande do Norte respectively, she held that both States should be obliged to supply medicines to patients suffering from severe diseases.[b]

[a] Supremo Tribunal Federal. Suspensão de Tutela Antecipada nº 91 de 26 de fevereiro de 2007. Diário de Justiça nº 43 March 5th 2007 [accessed on: 8/11/2007]. Available from: http://www.stf.gov.br/portal/jurisprudencia/listarJurisprudenciaDetalhe.asp?s1=000002928&base=basePresidencia

[b] Supremo Tribunal Federal. TV Justiça. Rio Grande do Norte e Amazonas devem fornecer medicamentos a duas portadoras de doenças graves. Brasília; 2007 [accessed on 8/11/2007] Available from: http://www.tvjustica.gov.br/maisnoticias.php?id_noticias=3632

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Thus, we are confronted with a complicated situation in which the right to go against such motions is annulled by these rulings. Motions are currently deferred, in most cases, with an *in limine* court order. Although the other party – the Executive Branch – is heard *a posteriori*, what matters is that this occurs after the fact, and so, even if, in the end, the court comes to the conclusion that the demand was not justified, public resources invested in the case were already squandered.

This situation stimulates a reflection on the meaning of social justice and right to health. It also brings forth the need to recuperate the ideals of universal, equal, and integral health care defended by the *Movimento de Reforma Sanitária* [Health Care Reform Movement] transformed into the guiding principles of SUS and incorporated into the Federal Constitution and the *Lei Orgânica da Saúde* (The National Health Code).

Integral health care according to two distinct perspectives: SUS *versus* the courts

An important consideration is that in many of the judicial actions what is demanded is that the plaintiff be granted access to a specific pharmaceutical product that has not been incorporated in the list of medicines supplied by SUS, even if the treatment for this disease is contemplated by the health care system that provides other alternative therapeutics.[2,3] This situation calls to question several issues. The fact that the State defines which medicines are to be employed in the treatment of diseases in its programs of pharmaceutical assistance, based upon accepted scientific criteria, does not imply in an omission with respect to its recognition of the right to health. Rather it reveals the States' commitment to the formulation of appropriate public policies that constitute the means set forth by the Constitution to guarantee that this right be recognized. In so doing, it must consider the essential health needs of the population and establish policies that can be financed by the State, with society's cooperation. In this sense, it is the State's duty to prevent access to health care services from becoming an additional factor that contributes towards further increasing rather than diminishing pre-existing inequities among the population.

Analyzing right to health litigations from this perspective, it can be verified that what is at stake is the demand for medicines that do not comply with the criteria established by the State. The latter, in turn, is driven by the duty to preserve the collective interest and to delimit its options guided by the principles of universal and equitable health care, considering its budgetary constraints. Considering limitations imposed by scarce resources, it is the State's obligation to define priorities in expenditures according to its financial capacity and the health needs of the population. Technical criteria must be observed in order to guarantee a more effective health policy and more efficient expenditures. Mechanisms of social control should be employed to assure the observance of SUS's principles and the options made are maximizing the results in terms of access to health services and actions and improvement of the population's state of health.

However, this does not seem to be the understanding of the Judicial Branch with respect to this issue. Integral health care, according to the courts, is more associated to the notion of consumption, as indicated by the deferral of motions without any restrictions that take into consideration existing public policies with respect to the diseases at hand. According to this conception, right to health is limited to access to medicines, reducing it to curative and palliative actions, thus disconsidering the fundamental character of promotion and prevention of diseases and disorders. From this point of view, the existence of a market with its supplies of more than 16 thousand pharmaceutical specialties is confounded with the existence of SUS, which should be held responsible for providing treatment to the population at all levels of complexity of health care.

Within the SUS, integral care is clearly defined. It signifies that all the means necessary should be employed in order to provide care, such as medical assistance, exams, hospital stay, treatment, amongst others. It implies in guaranteeing access to different types of means of procuring health, according to the level of complexity of the health care required, that is, exams for primary care as well as for secondary and tertiary care; providing access to medicine for both out-patient and in-patient services.

The need to define and implement policies in order to guarantee the right to health

It should be recalled, with this respect, that Article 196 of the Federal Constitution stipulates that the right to health will be guaranteed by means of economic and social policies.[a] In other words, the Constitution itself recognizes that in order to guarantee the right to health much more than the assuring the access to services is required. Policies that make it possible for individuals to have adequate housing, basic sanitation, employment, income, leisure and education are necessary. Considering that the scarcity of resources is a reality, it becomes evident that it is not possible to do without policies when the objective is to guarantee the observance of the principles of universal, integral, equal and equitable access to health care.

[a] Brasil. Constituição da República Federativa do Brasil: Texto constitucional promulgado em 5 de outubro de 1988, com as alterações adotadas pelas Emendas Constitucionais nº 1/1992 a nº 53/2006. Brasília; 2007.

For example, an hypothetic situation which the calculation is simple: the prevalence of chronic viral hepatitis C in Brazil, estimated at 1% of the population.[a] In June, 2006 the Brazilian population, according to the *Instituto Brasileiro de Geografia e Estatística* (IBGE – Brazilian Institute of Geography and Statistics), was composed of 186,770,562 people. Therefore, according to the calculation made above approximately 1,867,706 of them have the hepatitis C virus. Supposing that SUS provided treatment for up to 25% (466.927) of these people, with pegylated interferon. Since this treatment consists of an application of 180 mcg of this medicine, once a week for 48 weeks and that the price of one syringe with 180 mcg of this drug costs R$ 1,107.49,[b] the estimated cost of the treatment would be 24.8 billion reais.

If the aforementioned situation had occurred, the above value would correspond to 64% of the total budget spent by the *Ministério da Saúde* (Health Department) in the year 2006 (38.8 billion reais).[c] That is, two thirds of the federal health budget would have been spent in providing this single pharmaceutical product to one fourth of the estimated population that has the disease. This means that it is necessary to employ adequate criteria in order to properly allocate health resources and not that patients with chronic viral hepatitis C should not be treated. That is why policies are important, for given the financial constraints of the State, it is necessary to determine which health actions and services will be undertaken, in observance of the constitutional principles and SUS. In this respect, the existence of clear criteria to determine whether or not new technology will be incorporated, is of fundamental importance, and once incorporated, the establishment of other criteria establishing the rational use of this technology is indispensable.

It may be argued that health care resources are insufficient and that it is necessary to increase funding for this sector. There are no doubts about this. However, limits always exist. In 2006, Brazil's Gross Internal Product (GIP) increased, according to the IBGE, in 3.7%; however, expenditures with medicines of the *Ministério da Saúde* increased 26% and there was an increase of 7,5% in expenditures with health in general.[d] Increasing health resources may imply in having to spend less in other areas, such as education, housing, employment generating policies, income redistribution, among others.

The issue which is frequently raised and that constitutes a fallacy is that the refusal to supply a specific pharmaceutical product does not imply lack of recognition of a citizen's right to health.

The fact that a pharmaceutical product is registered in the country does not, in and of itself, imply that it has been automatically incorporated into the Brazilian Health System. It must be kept in mind that no national health system provides citizens with all medicines available in its internal market. The costs of treatment are prohibitive and even the universal health systems of developed countries encounter difficulties in guaranteeing funding.

In the United Kingdom, where the model of health care is focused on primary care, expenditures with medicines at this level of complexity increased 10% between 2001 and 2002. Four therapeutic classes were responsible for 25% of this increase: antidyslipidemics (33%); antihypertensives (18%); antipsychotics (32%) and hypoglycemiants (23%). The principal reasons for these increases were associated to the expansion of the recommendation of their use and the inclusion of new drugs.[1]

In Brazil, a new medicine is registered when its efficacy and security has been corroborated by the producer, through the presentation of results from clinical trials. This measure attempts to guarantee that medicines made available to the public are capable of doing what they offer to do and that there action does not do harm to human beings. Besides the technical justification, when drugs are analyzed from the perspective of a national policy, the possibility of registering several pharmaceutical products utilized for the same therapeutic indications is intended to minimize the possible effects of market flaws, increasing the supply of similar therapeutic alternatives, reinforcing competition and, thus, regulating prices.[e]

This measure does not necessarily imply that these products will be incorporated in the public health system. When a medicine is incorporated into the *SUS*, its use is immediately massified; its potential consumers are millions of Brazilians. From this perspective, the State's responsibility is amplified.

[a] Ministério da Saúde. Programa Nacional de Hepatites Virais. Protocolo Clínico e Diretrizes Terapêuticas. Hepatite Viral Crônica C. Interferon-alfa, Interferon-alfa Peguilado,Ribavirina.Brasília; 2002 [accessed on 8/11/07]. Available from: http://www.emv.fmb.unesp.br/docs/protocolo_hepC.pdf [Série C. Projetos, Programas e Relatórios]

[b] Associação Brasileira do Comércio Farmacêutico. Revista ABCFarma. Preço fábrica para ICMS de 18%. [accessed on 1/6/2006] Available from: http://www.abcfarma.org.br/home/revista/edicao/198/

[c] Value obtained by utilizing the system Siga Brasil do Senado Federal. Valor total liquidado pelo Fundo Nacional de Saúde - 2006. [accessed on 8/11/2007] Available in: http://www.senado.gov.br/sf/orcamento/siga/siga.asp

[d] Value obtained by utilizing the system Siga Brasil do Senado Federal. Valores liquidados pelo Fundo Nacional de Saúde - 2006: total e com ações do orçamento da União que financiam a aquisição de medicamentos. [accessed on 8/11/2007] Available from: http://www.senado.gov.br/sf/orcamento/siga/siga.asp

[e] Agência Nacional de Vigilância Sanitária. Como a Anvisa avalia o registro de medicamentos novos no Brasil. Brasília; 2005 [accessed on 8/11/2007] Available fron: http://www.anvisa.gov.br/medicamentos/registro/registro_novos.htm

According to the aims of the Federal Constitution and the directives of the system, the population should be provided with medicines that are secure (are known not to cause harm), efficacious (do what they propose to do), effective (do what they propose to do when utilized by people under realistic conditions and not in the homogeneous groups utilized in the clinical trials) and cost-effective (among the available alternatives, do what they propose to do for people under realistic conditions at the lowest cost possible)

It must also be considered that the cost of incorporating medicines should be tolerable to society, taking into consideration the need to attend to the set of diseases and disorders that assail the Brazilian population as a whole.

These are the criteria that guide SUS's decision as whether or not to incorporate a pharmaceutical product. The existence of such parameters is indispensable for the rationalization of the use of such products from the point of view of therapeutics as well as public resources. This is not a panacea of present times. This decision-making process is upheld by recommendations of the World Health Organization since 1975, when it published the first Model List of Essential Medicines.

In this respect, SUS has its own List – the *Relação Nacional de Medicamentos Essenciais* (RENAME[a] – The National List of Essential Medicines), that directs the supply of medicines for the treatment of the major health problems of the population[3] Medicines for the treatment of rarer diseases are indicated in the *Programa de Medicamentos de Dispensação em Caráter Excepcional*[b] (Program for the Exceptional Supply of Medicines).

Judicial actions that disconsider policies

The utilization of mechanisms that diverge from the Brazilian Health System in order to gain access to medicines has generated setbacks to equity in health.[3] Attending to these demands is another problem. The large quantity of cases throws public finances into disorder because the State ends up being inefficient, loosing its purchasing power. Furthermore, providing medicine in an indiscriminate manner has resulted privileges for those segments of the sick population who have greater financial resources with which to pay lawyers, or who have greater access to information, in detriment to those segments with less resources and thus in greater need.[c]

The existence of limits with respect to the State's capacity to pay can be easily verified, through the hypothetical example, aforementioned, of pegylated interferon. In this case, it becomes evident that social rights and among these the right to health exist within a perspective of social efficacy, being contingent on reservations with respect to what is possible. The increasing number of judicial rulings determining that medicines be provided cause distortions, for supplying these drugs is not a financial expenditure linked to the budget, antecipated when formulating policies and planning the health care programs.[d]

Besides, as Santos[e] points out, integral health assistance should be guaranteed to every person who seeks diagnosis and treatment in SUS's health care services, according to its technical and administrative norms, its principles and its directives. Santos states that the incorporation of technologies in public health should be base don what is considered necessary, opportune, reasonable, convenient and essential in order to guarantee collective and individual health and not because it exists in the marketplace.

Thus, intervention on the part of the Judiciary Branch with respect to the issue of providing medicines, undertaken without observing the consolidated norms that discipline access to health, compromises the efforts of the Executive Branch and the legal organization of Brazilian Health System.

As to the specific case analyzed by the *Supremo Tribunal Federal* (Brazilian Supreme Court) in February 2007, the initial petition listed 17 medicines and referred to the obligation of the State of Alagoas of furnishing these particular drugs as well as all others that should by chance be demanded. However, these 17 pharmaceutical products have already been incorporated within SUS's list of medicines, and are supplied at both ambulatory and hospital care.

Thus, it seems logical to recognize that it is correct to defer such a motion if the 17 products included in the public health policy were not available to those in need of them and to judge which administrative sphere of competence is responsible for this failure to recognize the right to health. However, it would not be judicious if the petition were deferred in full, for the effect of this would be to oblige SUS to provide whatever product offered by the market that be demanded through the judicial system.

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[a] Ministério da Saúde. Relação Nacional de Medicamentos Essenciais: Rename. Brasília; 2007.
[b] Ministério da Saúde. Medicamentos de dispensação excepcional. Brasília; 2006 [accessed on 8/11/2007]. Available in: http://portal.saude.gov.br/portal/arquivos/pdf/texto_excepcionais.pdf
[c] Interview with Professor Elival da Silva Ramos – Associate Professor of Faculdade de Direito da USP (Law School of the University of São Paulo) *J CREMESP.* 2005[accessed on 08/11/07];(214). Available in: http://www.cremesp.org.br/?siteAcao=Jornal&id=517
[d] Nogueira RWL. Saúde, medicamentos, desenvolvimento social e princípios orçamentários. *Jus Navigandi.* 2004 [accessed on 8/11/2007];9(542). Available from: http://jus2.uol.com.br/doutrina/texto.asp?id=6127
[e] Santos L. Saúde: conceito e atribuições do Sistema Único de Saúde. *Jus Navigandi.* 2005 [accessed on 1/17/2006];9(821). Available from: http://jus2.uol.com.br/doutrina/texto.asp?id=7378

FINAL CONSIDERATIONS

It must be recognized that society cannot abdicate of the Judiciary Branch as a means of guaranteeing its rights. However, it is necessary to point out the paradoxes that are involved in the judicial actions that demand the acquisition of medicine by the State. The Judiciary Branch determines that medicines included in the policies, but often denied to citizens inasmuch as they are not available at the systems' basic health units, should be supplied and these demands are pertinent. However, the Judiciary Branch also determines that pharmaceutical products not included in the health policies and programs be supplied even if those policies establish that other medicines or therapeutic approaches be utilized in these cases.

This reveals that the criteria "existence of a public policy" in general is not being observed by the Judiciary Branch when it decides whether or not a judicial action should be deferred. Furthermore, what is explicated thereby is that the right to health is confounded with the supply of any medicine available in the market without observing technical issues and the entire apparatus developed by the State for treating the sick. For this reason it is extremely urgent for the Judiciary Branch to recognize that there are no means of guaranteeing the right to health as established by the Federal Constitution other than those determined by policies.

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