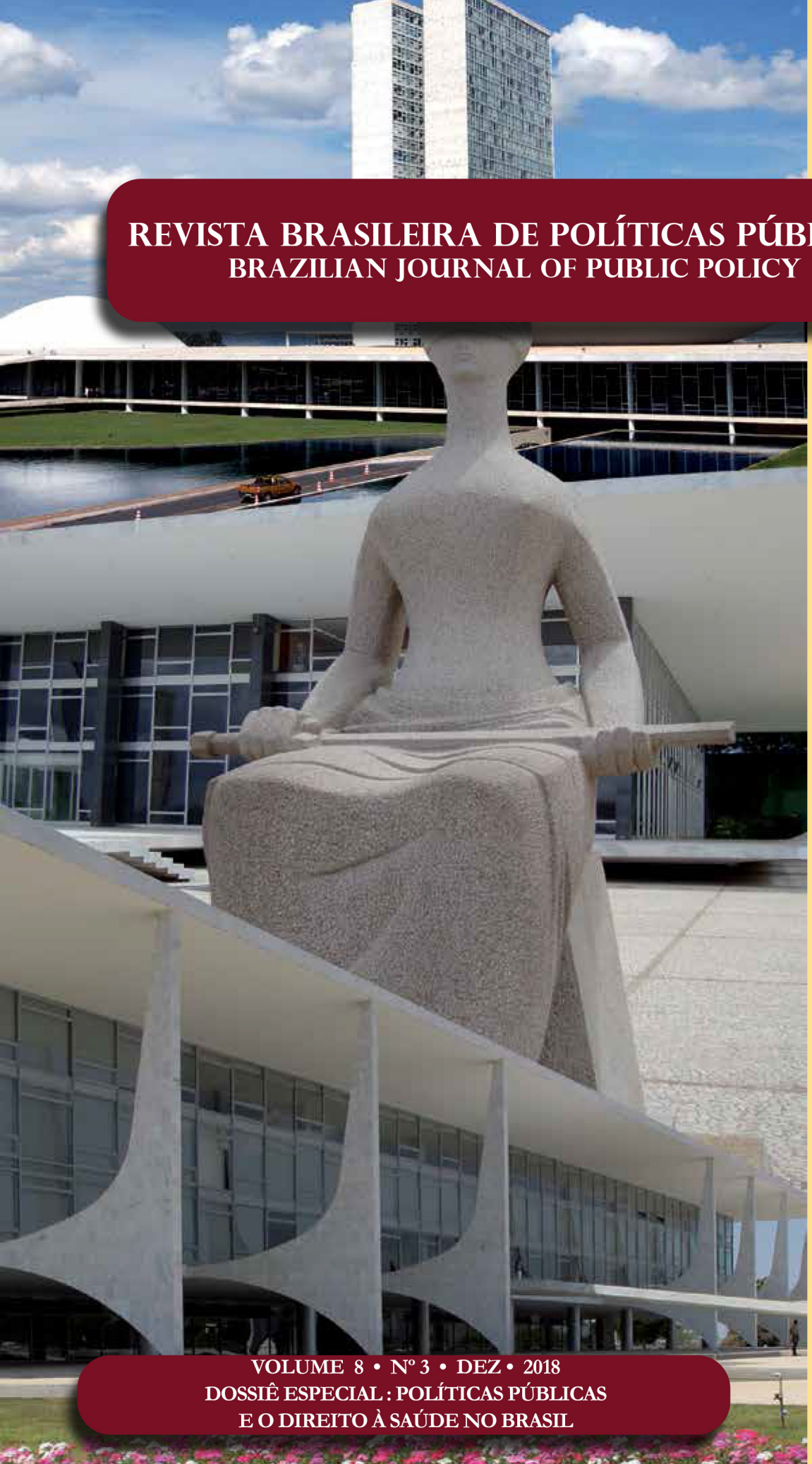

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The courts and the delivery of medicines by unified health system in Brazil: recent developments in a difficult relationship between judges and policy-makers

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Sumário

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The courts and the delivery of medicines by unified health system in Brazil: recent developments in a difficult relationship between judges and policy-makers*

Os tribunais e o fornecimento de medicamentos pelo sistema único de saúde no Brasil: evolução recente de uma difícil relação entre juízes e formuladores de políticas públicas

Eduardo Rocha Dias**

Gina Vidal Marcílio Pompeu***

Abstract

The aim of this study is to examine the dynamics in the relationship between the Legislative and the Judiciary in the implementation of the fundamental right to healthcare in Brazil, based on a documental and bibliographical analysis of lawsuits aimed at obtaining drugs not incorporated by the Unified Health System. The enshrinement by the Brazilian Constitution of 1988 of the right to healthcare as a duty of the State and a right of all, led to the modification of the performance of judges. From the position of self-restraint of the Judiciary on the subject, there was a growing intervention in public policies related to health. The Judiciary itself, from the Federal Supreme Court (public hearing) and the National Council of Justice (recommendations and resolutions), began to dictate guidelines aimed at rationalizing the performance of the judges. Nonetheless, the Legislative also triggered a reaction to the advancements of the Judiciary, through the editing of Law 12.401/2011 and the emphasis on the consensual solutions enshrined in the Code of Civil Proceedings of 2015 and Law 13.140/2015. Recent decisions issued by the Superior Court of Justice and the Federal Supreme Court point to the inflection in the position of the Judiciary. In this sense, it is necessary to emphasize the importance of recognizing the institutional limits for the actions of the Judiciary in the control of public policies related to health as well as the establishment of institutional dialogue between the Judiciary and the Administration to overcome mutual misunderstandings and incomprehension.

Key words: Fundamental right to healthcare; judicialization; medicines; relationship between Legislative and Judiciary.

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Resumo

Por meio deste estudo, pretende-se examinar a dinâmica na relação entre Poder Legislativo e Poder Judiciário na implementação do direito fundamental à saúde no Brasil, a partir de uma análise documental das ações judiciais que objetivam obter medicamentos não incorporados pelo Sistema Único de Saúde. A consagração, pela Constituição brasileira de 1988, do direito à saúde como dever do Estado e direito de todos, levou à modificação da atuação dos juízes no tocante a ações que visam determinar o fornecimento de medicamentos. Da posição de autocontenção do Judiciário no tocante ao tema, passou-se à crescente intervenção nas políticas públicas relacionadas à saúde, com impactos no orçamento destinado a atuações nesse campo. O próprio Poder Judiciário, a partir do Supremo Tribunal Federal (audiência pública) e do Conselho Nacional de Justiça (recomendações e resoluções), começou a ditar diretrizes visando racionalizar a atuação dos juízes. Não obstante, o Poder Legislativo também desencadeou uma reação ao avanço do Judiciário, por meio da edição da Lei 12.401/2011 e da ênfase às soluções consensuais consagradas pelo Código de Processo Civil de 2015 e pela Lei 13.140/2015. Recentes decisões do STJ e do STF apontam para a inflexão na posição do Judiciário, mais deferente em relação às disposições legislativas e, sobretudo, à atuação do Executivo. Nesse sentido, necessário destacar a importância do reconhecimento dos limites institucionais para a atuação do Judiciário no controle das políticas públicas relacionadas à saúde e do estabelecimento de diálogo institucional entre Judiciário e Administração para superar desconfianças e incompreensões recíprocas.

Palavras-chave: Direito fundamental à saúde. Judicialização. Medicamentos. Relacionamento entre Legislativo e Judiciário.

1. Introduction

The examination of the so-called judicialization of healthcare in Brazil, from the study of the evolution of judicial decisions concerning the delivery of medicines, allows interesting considerations regarding the relationship between Judiciary and Legislative, as well as the limits to the creative activity of the judge.

The right to healthcare, in spite of its terminological imprecision, as to the object and extent, was enshrined verbatim in arts. 6 and 196 of the Brazilian Constitution of 1988, which, over time, gives rise to different positions on the part of the subjects of subjective right, and on the functions of the State: executive, legislative and judicial.

At the outset, a more reticent position is identified regarding the granting of requests for the delivery of medicines; in a second moment, due to the constitutional order of immediate applicability of the constitutional precepts, the Judiciary, even through the action of the Federal Supreme Court, will intervene more vehemently, and in this bias determines the systematic granting of drugs, which generates greater impacts on the health budget in Brazil; the confrontation between the judiciary and the executive reveals itself and the resulting judicialization of politics. In the second decade of the 21st century, we identify the phase of rationality seeking in judicial intervention, a situation in which the courts seem to be at present.

This quest for greater rationality seems to be a result of factors of two orders, internal to the Judicial Branch itself, and to the Federal Supreme Court's actions, as well as external ones, materialized in the work of the Legislative. Among the first ones, reference should be made to the holding of a public hearing in 2009, in which the need to establish parameters for the Supreme Court's action in judicial actions involving the right to healthcare was discussed, as well as the work of the National Council of Justice, a Judiciary agency, chaired by the President of the Federal Supreme Court, issuing recommendations and resolutions on the subject.

On the other hand, the Legislative Branch has worked to establish criteria for the incorporation of new technologies, among which are inserted the medicines (Law 12401/04/2011), which undoubtedly becomes a matter that judges should consider in their decisions, and also in the search for dialogued and consensual solutions, which materialized mainly in the 2015 edition of the Code of Civil Proceedings and Law 13.140/06/2015. As will be seen, such diplomas favor the search for mediation and conciliation, among other fields, regarding the right to healthcare. The Judiciary, on the other hand, in the search for alternative solutions to conflict resolution, also favored this second group of measures.

To this end, this study initially deals with the right to healthcare, content and extent, and the evolution of judicial decisions regarding the granting of medicines, based on the way the Judiciary has positioned itself. It then examines the way in which the Legislature has reacted and how excesses identified in the work of the Judiciary have been subject to containment by legal measures. Finally, it seeks to assess the prospects for change in case law and what measures may contribute to more appropriate decisions. The constitutional parameters are analyzed in the field of the right to health, and if this discussion reveals the existence of fields where the Judiciary should be more deferential towards legislative and administrative choices, above all because it does not detain technical expertise and because its exaggerated intervention has the power to systemically affect public health by prioritizing individual interests to the detriment of collective interest.

2. Right to healthcare and evolution of judicial decisions.

Defining what health is, and specifically the right to healthcare, its object and extent, is not an easy task. If it is decided to depart from the concept contained in the 1946 Constitution of the World Health Organization[1], a difficulty further amplified. In fact, such a "state of complete well-being" seems unreal. At most, there is an ideal to be achieved, but in practice it demands multiple stages and modalities of action by public authorities and society. Such imprecision undoubtedly contributed to greater intervention by the Judiciary in the fulfillment of its content, through the determination of the delivery of medicines.

The interpretation of art. 196 of the Constitution, therefore, should consider two aspects which are more objective[2]: one that considers health as the effect of social and economic policies that avoid risks of aggravation (protection in a broad sense) and another that imposes the universal and equal access to actions and services that promote, protect and recover health. The first part requires the adoption by the State of public policies[3] that guarantee the conditions for a quality life (education, sanitation, transportation, among other dimensions); the second part covers access to services and actions that recover the health already affected by some disease and protect it in a strict sense, since in a broad sense protection is obtained through the conditions that ensure quality of life. One dimension is more preventive; the other, more curative.

Health protection and promotion translate, synthetically, the evolution of the legal protection of this legal asset from a phase in which one had health as an individual asset, involved in a doctor-patient relationship, to a phase in which one identifies in health a collective good. The public relevance of health as an asset was soon affirmed by the adoption of measures to combat epidemics, which had already arisen in the Roman Empire[4], and which constitute the embryo of the future sanitary administrative police, nowadays characterized as sanitary surveillance. Industrialization and the urbanization of societies have created other risks and turned a new role for the State into a necessity, this time as a provider of health services, initially

1 "Health is a state of complete physical, mental and social well-being, and it does not consist only in the absence of disease or infirmity ".

2 SANTOS, Lenir. *Judicialização da saúde e a incompreensão do SUS*. Judicialização da saúde no Brasil. Campinas: Saberes, 2014. p. 130.

3 NUNES, António José Avelãs; SCAFF, Fernando Facury. *Os tribunais e o direito à saúde*. Porto Alegre: Livraria do Advogado, 2011. p. 79.

4 ESTORNINHO, Maria João; MACIEIRINHA, Tiago. *Direito da saúde*. Lisbon: Universidade Católica, 2014. p. 10.

for workers who contributed to insurance or social security systems, or later, for the population as a whole, with the idea of universality.

Health as an integral care, inheriting such evolution, presupposes a set of services, goods and supplies that "have direct costs for the Unified Health System, with a network structure based in health regions, organized in levels of services of greater or lesser technological density built from primary health care".[5] Such a network imposes a division of competences and resources among the entities of the Federation, according to the needs and the economic and demographic conditions of each entity. The second part of the provision of art. 196 of the Constitution. That is, actions and services of promotion, protection (in the strict sense) and recovery of health. From the art. 6º of 8.080/09/1990, it can be affirmed that the scope of the Brazilian Unified Health System includes the so-called health surveillance (sanitary and epidemiological) and comprehensive therapeutic care, including pharmaceuticals. This does not neglect science and technology and the training of personnel[6]. Assistance is organized in a network, with different levels of complexity (primary, secondary and tertiary care).

This Unified Health System action is not exclusive, since art. 199 of the Constitution allows the participation of private initiative in the field of public health, by means of a contract or agreement (§1 of article 199), configuring complementary health, and also allowing the exploitation of health services for profit purposes (caption of article 199), being it, in this case, supplementary health. Even private (supplementary) health, however, has public relevance, in the form of art. 197 of the Constitution, and the State shall regulate, supervise and control it.

With respect to public health, which is the responsibility of the State, its organization is drawn in principle by art. 200 of the Constitution and implemented by legal instruments, such as Law 8.080/09/1990 and Complementary Law 141/01/2012. This last one, which deals with the minimum values to be applied annually, by the Federation, State, Federal District and Municipalities, with actions and health services, conceptuates, for financing purposes, such actions and services in its art. 3º. On the other hand, Decree 7.508/06/2011 defines health care as a set of services divided into increasing levels of attention and complexity, and also indicates the "entrance doors" in the Unified Health Systems, in the form of art. 9th: primary care, emergency and urgency care, psychosocial care, and special forms of open access.

In the form of art. 6, item I, paragraph "d", of Law 8.080/09/1990, it is included in the Unified Health System field of action the execution of actions of "comprehensive therapeutic care, including pharmaceuticals". This topic is where the judicialization is allowed with reference to the supply of medicines.

Health judicialization means the determination by judicial decisions of the provision of a particular benefit, of a particular treatment or medicine, by the public authorities and, in the case of supplementary health, by private health plans and health insurance.

Specifically with regard to the Ministry of Health's spending on the acquisition of medicines by virtue of judicial decisions, that is, without considering the impact for States and Municipalities and for the Federal District, it has gone from R$139.6million in 2010 to R$838.4million in 2014[7]. In 2015 the amount went to R$1.2 billion. By 2016, up to June, R$ 686.4 million had already been spent[8].

In the Brazilian case, the degree of intervention of the Judiciary leads to decisions that: a) do not, as a rule, consider the scientific efficacy of treatments and drugs sought in court[9]; b) do not analyze the cost-

5 SANTOS, Lenir. *Judicialização da saúde e a incompreensão do SUS*. Judicialização da saúde no Brasil. Campinas: Saberes, 2014. p. 132.

6 SANTOS, Lenir. *Judicialização da saúde e a incompreensão do SUS*. Judicialização da saúde no Brasil. Campinas: Saberes, 2014. p. 137.

7 According to the Ministry of Health as in a piece of News. Available at: <http://portalsaude.saude.gov.br/index.php/cidadao/principal/agencia-saude/20195-em-cinco-anos-mais-de-r-2-1-bilhoes-foram-gastos-com-acoes-judiciais>., Access on: 04 Dec. 2016.

8 Rare diseases affect 13 million Brazilians. Available at: <http://noticias.uol.com.br/saude/ultimas-noticias/estado/2016/06/13/doencas-raras-afetam-13-milhoes-de-brasileiros.htm>. Access on: 11 Nov. 2016.

9 DIAS, Eduardo Rocha; SILVA JÚNIOR, Geraldo Bezerra da. Evidence-based medicine in judicial decisions concerning right

-effectiveness of the measures sought; c) result in purchases made without bidding, due to the urgency generated by the judicial determination, and entail excessive expenses for the treasury; d) subtract high volumes from the public budget; e) benefit people without considering criteria of distributive justice, but only the success in having access to justice and obtaining favorable decisions, and f) disregard priorities and public policies drawn up by the bodies that are legitimized for this purpose[10].

The peculiarities of the Brazilian public health system, which is based on a division of competencies among the different federated entities, can also bring significant impacts to entities with smaller budgets, as is the case of Municipalities, given the recognition, through precedents, that plaintiffs can bring actions against any federated entity or against all of them, for being solidary[11].

It is true that there has been a change in judicial decisions, especially if considering the position of the Superior Court of Justice and the Federal Supreme Court[12]. If, in the first instance, decisions tended to deny the granting of medicines, there was an increase in favorable decisions initially linked to access to medicines for the treatment of HIV infection. The reference to the constitutional character of the right to healthcare and to the dignity of the human person has become the basis for concessive decisions and for the attainment of indices of claims exceeding 80%[13]. The work of the Judiciary, under the pretext of effecting social rights, ends up transforming them into individual rights, disregarding the budget and the care of the community[14].

It is worth remembering the hypothesis, referred to by José Augusto Dias de Castro[15], of a decision based solely on journalistic news, determining the supply of medicine which was still in the testing phase[16]. The Federal Supreme Court itself came to recognize the right to treatment abroad for retinitis pigmentosa despite the lack of scientific evidence of the efficacy of the therapy sought[17].

From 2009, the beginning of a trend alteration starts, motivated by factors of two orders.

Through the initiative of the Judiciary itself, the criteria for judicial intervention was discussed. It should

to healthcare. *Einstein*, São Paulo, v. 14, n. 1, Jan./Mar. 2016. p. 4.

10 WANG, Daniel. Courts as healthcare policy-makers: the problem, the responses to the problem and the problem in the responses. São Paulo Law School of Fundação Getúlio Vargas – Direito GV. Research Paper Series – Legal Studies. *Paper* n. 75, p. 3. In <http://bibliotecadigital.fgv.br/dspace/bitstream/handle/10438/11198/RPS_75_final.pdf?sequence=1>. Access on: 20 Apr. 2014.

11 In accordance with the precedents of the STF (SL 47 AgR, Tribunal Pleno, judged on 17-3-2010), of the STJ (*AgRg no REsp 1136549/RS,* judged on 8-6-2010) and the TNU (REQUEST 200481100052205, *DOU* 11-3-2011), the operation of the Unified Health System (SUS) is joint liability of the Union, the Member States and the Municipalities, so that any of these entities have legitimacy ad causam to appear in the passive demand pole that guarantees the access to the medication for people deprived of financial resources. This is because there is no constitutional provision that determines that a federated entity only has the duty to provide medicines, to the exclusion of others. Of all sorts of things, it can not be disregarded that the Constitution itself provides that it is for the law to dispose of the regulation and execution of health services (article 197) and that the respective actions and services are part of a regionalized, hierarchical and decentralized network (article 198 and its item I), which allows for the distribution of tasks among federated entities, including the supply of medicines.

12 BALESTRA NETO, Otávio. A jurisprudência dos tribunais superiores e o direito à saúde – evolução rumo à racionalidade. *Direito Sanitário magazine*, São Paulo, v. 16, n. 1, Mar./June 2015. p. 90-91.

13 WANG, Daniel. *Courts as healthcare policy-makers: the problem, the responses to the problem and the problem in the responses.* São Paulo Law School of Fundação Getúlio Vargas – Direito GV. Research Paper Series – Legal Studies. *Paper* n. 75, p. 20-21. In <http://bibliotecadigital.fgv.br/dspace/bitstream/handle/10438/11198/RPS_75_final.pdf?sequence=1>. Access on: 20 Apr. 2014.

14 SCAFF, Fernando Facury. *A efetivação dos direitos sociais no Brasil. Garantias constitucionais de financiamento e judicialização*. A Eficácia dos Direitos Sociais – I Jornada Internacional de Direito Constitucional Brasil/Espanha/Itália. São Paulo: Quartier Latin, 2010. p. 29-30.

15 A questão do direito fundamental à saúde sob a ótica da análise econômica do direito. *Direito Público da Economia magazin*e, year 6, n. 21, p. 149-158, jan./mar. 2008. p. 155.

16 In this case, it was ENBREL, which cost four thousand reais a box. Ordinance of the Ministry of Health recommended the use of another drug, Infliximab, whose effectiveness was best demonstrated. The case reached the Federal Supreme Court in Extraordinary Appeal 271.286, which, however, did not take into account the technical aspects, but only recognized the duty of the State to provide medicines to a person deprived of remedies when linking the right to health with the right to life.

17 RE 368564/DF, Rapporteur Ministro Marco Aurélio, 1ª Class, judged om 04/13/2011.

be highlighted the public hearing held in the Federal Supreme Court between April and May 2009, in which specialists from a wide range of areas were heard to obtain subsidies for the Court's actions in actions involving access to benefits in the health area.

As a result of the aforementioned public hearing, the National Council of Justice (CNJ) issued Recommendation 31 of March 30, 2010, urging State Courts of Justice and Federal Regional Courts to conclude agreements aimed at providing technical support from doctors and pharmacists to assist magistrates in the formation of a value judgment regarding the assessment of the clinical issues presented by the health action parties, observing the regional peculiarities. The courts were also requested, through their respective inspecting agencies, to direct the magistrates, among other measures, to seek to instruct the actions in which they act, as far as possible, with medical reports, with a description of the disease, including ICD, containing prescription of medicines, with generic name or active principle, products, orthoses, prostheses and supplies in general, with exact dosage, avoid authorizing the supply of medicines not yet registered by ANVISA, or in an experimental phase, excepting the ones expressly provided by law, listening, when possible, preferably by electronic means, the public managers, before the assessment of emergency measures.

It is curious to notice that many of such recommendations go as far as to urge judges to comply with the law, using prudence, dialogue between the parties involved, rationality, when determining the supply of a drug for example.

It is worth mentioning among the measures adopted by the CNJ that the National Forum of the Judiciary was set up to monitor and resolve demands for health care- the Health Forum, through Resolution 107 of April 6, 2010. The said Forum subsequently extended its area of operation to include supplementary health and legal actions involving consumer relations. Then, Recommendation 36, dated July 12, 2011, was issued specifically for the lawsuits involving supplementary health.

In the latter, it is also recommended that the Courts of Justice and the Federal Regional Courts conclude agreements aimed at providing technical support without burden to the Courts, composed of doctors and pharmacists, to assist magistrates "in forming a judgment on the value of assessment of the clinical issues presented by the parties ".

Secondly, in addition to the work of the Judiciary, it is worth recording the edition of Law 12.401/04/2011, which established criteria for the incorporation of new health technologies by the Unified Health System and clearer competences in this regard. It is to be hoped that such diploma will serve to instil greater deference from the Judiciary to administrative decisions, to help overcome the prevailing conception that the Judiciary may ignore the public policies drawn up by the legitimized bodies[18].

3. The actions of the Legislative and current trends in judicial decisions

Law 12.401/04/2011 inserted Chapter VIII in Title II of Law 8.080/1990, which refers to the conditions for promotion, protection and recovery of health and the organization and functioning of the corresponding services. According to article 19-Q of the law, the attributions to incorporate, exclude or change new drugs by the Unified Health System were disciplined as follows:

> Art. 19-Q. The incorporation, exclusion or modification by the Unified Health System of new medicines, products and procedures, as well as the constitution or modification of a clinical protocol or therapeutic guideline, are attributed by the Ministry of Health, assisted by the National Commission for

18 WANG, Daniel. Courts as healthcare policy-makers: the problem, the responses to the problem and the problem in the responses. São Paulo Law School of Fundação Getúlio Vargas – Direito GV. Research Paper Series – Legal Studies. *Paper* n. 75, p. 49-50. Available at: <http://bibliotecadigital.fgv.br/dspace/bitstream/handle/10438/11198/RPS_75_final.pdf?sequence=1>. Access on: 20 Apr. 2014.

the Incorporation of Technologies in the Unified Health System.

The National Commission for the Incorporation of Technologies to the Unified Health System (CONITEC) is responsible for preparing a report and deciding on the basis of "scientific evidence on the efficacy, accuracy, effectiveness and safety of the drug, product or procedure subject to the process, accepted by the body responsible for registration or authorization of use "(item I of § 2 of article 19-Q of Law 8.080/1990). The Commission will also take into account the "comparative economic evaluation of benefits and costs in relation to technologies already incorporated, including in regard to home, outpatient or hospital care, when appropriate" (item II of § 2 of article 19- Q of Law 8.080/09/1990).

The arts. 19-M, 19-N and 19-O, added by Law 12.401/04/2011, deal with the dispensation of drugs and products of health interest, which must observe therapeutic guidelines defined in clinical protocol for the disease or injury to be treated. By clinical protocol and therapeutic guideline it is understood, as foreseen in item II of art. 19-N of Law 8.080/1990, the:

> document which establishes criteria for the diagnosis of the disease or health problem; the recommended treatment, with medicines and other appropriate products, when appropriate; the recommended dosages; the mechanisms of clinical control; and the monitoring and verification of therapeutic results, to be followed by SUS managers.

As provided in art. 19-O of Law 8.080/1990, clinical protocols and therapeutic guidelines should:

> establish the medicines or products necessary in the different evolutionary stages of the disease or of the health problem they treat, as well as those indicated in cases of loss of efficacy and the appearance of intolerance or relevant adverse reaction caused by the first product, product or procedure choice.

The sole paragraph of art. 19-O of Law 8.080/1990 establishes that "if needed, the medicines or products will be evaluated for their efficacy, safety, effectiveness and cost-effectiveness for the different evolutionary stages of the disease or the health protocol".

In the absence of a clinical protocol or therapeutic guideline, dispensation will be performed, as provided in art. 19-P of Law 8.080/2011:

> I - based on the relations of medicines instituted by the federal manager of the Unified Health System, observing the competencies established in Law 8.080/1990, and the responsibility for the supply will be agreed in the Tripartite Interagency Committee;
>
> II - within the scope of each State and the Federal District, in a supplementary manner, based on the relations of medicines instituted by the state managers of the Unified Health System, and the responsibility for the supply will be agreed in the Bipartite Interagency Committee;
>
> III - in the scope of each Municipality, on an additional basis, based on the relations of medicines instituted by the municipal managers of Unified Health Sytem, and the responsibility for the supply will be agreed in the Municipal Health Council.

The provisions of the Code of Civil Proceedings of 2015 (Law 13.105/2015) and of Law 13.140/2015 seems to be of no minor importance, regarding the search for a consensual solution of conflicts, including in the scope of the public administration. It opens up a vast field to try to arrive at dialogued and consensual solutions, in which the administration can show the Judiciary its role and the alternatives available in the field of public health. It also allows the improvement of the state performance, informing the services and actions made available and allowing the citizen's service.

As Lenir Santos reminds us[19], the responsibilities of each member of the Brazilian Federation in terms of the provision of health services are due to the complexity of such services and the compatibility with socioeconomic, demographic and geographical levels. They must, together with society, set guidelines that guide the choices of therapies, since "there isn't money for everything". The Unified Health System can not

19 JUDICIALIZAÇÃO da saúde e a incompreensão do SUS. Judicialização da saúde no Brasil. Campinas: Saberes, 2014. p. 138.

be "a concession desk for procedures that are detached from guidelines essential to its systemic organization and sanitary security"[20]. Hence the role of the National Agency of Sanitary Surveillance - ANVISA, acting in the field of efficacy and safety of medicines, products and procedures, and the National Commission for the Incorporation of Technologies in Health - CONITEC, which should evaluate which drugs will be incorporated, as seen above, based on evidence-based criteria on efficacy, accuracy and safety, as well as the costs and benefits of the available alternatives.

It should be emphasized that the Unified Health System guarantees to the population, in what concerns health care, procedures and services contained in RENASES - List of Health Actions and Services and RENAME – National List of Essential Medicines, disciplined by arts. 21 to 29 of Decree 7.508/06/2011.

A decision of the Supreme Federal Court, in which the role of ANVISA was recognized, is the one pronounced in the case of synthetic phosphoethanolamine, known as the "cancer pill". This is ADI 5501, whereby the Brazilian Medical Association (AMB) questioned Law 13.269/04/2016, which authorized the dispensing of said substance without its efficacy and safety being certified by the entity authorized to do so, in the case the ANVISA. By a majority, the Supreme Federal Court understood that the legislative action violated the separation of powers, besides opening a dangerous precedent to the health protection of the population. The Rapporteur, Luís Roberto Barroso, alluded to the existence in the species of an "administrative reserve" and that the technical judgment of ANVISA was improperly replaced by a political judgment of the parliament.

In 2017, the Supreme Court of Justice, in deciding Special Appeal 1,663,141/SP, filed by a health plan operator in response to the decision that ordered the supply of imported medicine without registration with ANVISA, reversed prior ruling, deciding that there was a violation of both the Law 9,656/06/1998, whose art. 10, item V, makes it possible for health plans to exclude from their coverage the supply of imported non-nationalized drugs, as well as art. 12 of Law 6,360/1976, which establishes the need to register with the competent body of imported medicines. The decision is important because it may also reflect a change of understanding regarding the supply of medicines not registered in public health[21], imposing law enforcement and greater deference to ANVISA's actions.

Another important decision, issued in the judgment of Extraordinary Appeal 566471 and 657718, is related to the supply of high-cost medicines not registered in ANVISA nor made available by Unified Health System for the treatment or control of rare diseases. According to the World Health Organization (WHO), rare diseases are those that affect up to sixty-five per 100,000 people[22]. In Europe and the United States, studies indicate that between 6% and 8% of the population is affected by some rare disease. There are no comprehensive studies in Brazil[23]. In a population like the Brazilian one, this implies considering a universe of between thirteen and fifteen million people.

The trial was suspended on September 28, 2016 after three votes were issued. Initially, Minister Marco Aurélio proposed the following thesis at the trial: "recognition of the individual right to the provision by the State of a high-cost drug not included in a National Drug Policy or an Exceptional Dispensing Drug Program, in exceptional character, a constant list of the approved ones, depends on the demonstration of the indispensability - adequacy and necessity -, the impossibility of replacing the drug and the financial incapacity of the patient, and the lack of spontaneity to help from the members of the family in solidarity, respected the dispositions about alimony of articles 1,694 to 1,710 of the Civil Code, and the right of recourse is guaranteed[24]".

20 JUDICIALIZAÇÃO da saúde e a incompreensão do SUS. Judicialização da saúde no Brasil. Campinas: Saberes, 2014. p. 139.

21 SCHULZE, Clenio Jair. *STJ inaugura nova posição na judicialização da saúde*. Available at: <http://emporiododireito.com.br/stj-inaugura-nova-posicao-na-judicializacao-da-saude-por-clenio-jair-schulze/>. Access on: 4 Sept. 2017.

22 Ministry of Health launches clinical protocols for 12 rare diseases, Available at: <http://portalsaude.saude.gov.br/index.php/cidadao/principal/agencia-saude/18086-ministerio-da-saude-lanca-protocolos-clinicos-para-12-doencas-raras>. Access on: 11 Nov. 2016.

23 Information available at: <http://rederaras.org>. Access on: 11 Nov. 2016.

24 REQUEST for examination of case dockets postponed trial on access to high cost drugs by judicial process**"** Available at: <http://www.stf.jus.br/portal/cms/verNoticiaDetalhe.asp?idConteudo=326275> Access on: 11 Nov. 2016.

Subsequently, Minister Luís Roberto Barroso, after stating that the discussion of the subject should be subtracted from the Judiciary, which is not responsible for defining public health policies, but only intervening in extreme situations, affirmed that, as a rule, in case of unincorporated drugs, including high cost, the State can not be obliged to provide them. "There is no health system that can withstand a model in which all medicines, regardless of their cost and financial impact, must be offered by the State to all people," he added[25]. After, he proposed five cumulative criteria that must be observed by the Judiciary so that certain health benefits can be inferred:

> Financial inability to bear the corresponding cost; demonstration that the non-incorporation of the drug did not result from an express decision of the competent organs; inexistence of therapeutic substitute incorporated by the Unified Health System; evidence of efficacy of the medicinal product sought in the light of evidence-based medicine; since the responsibility for the final decision on the incorporation or non-incorporation of medicines is exclusive of this federative entity[26].

It must outlined that one unexpected consequence of excluding the rich from assistance is undermining the principle that Unified Health System should be universal. Although Constitution has that it is possible for the Legislative to be selective upon granting protection within the scope of social security rights, as can be seen in number 3 of the sole paragraph of article 194, denying access to category of persons may open the door to future exclusions of other categories thus affecting Unified Health System claim to universality.

Minister Luís Roberto Barroso also defended a dialogue between the Judiciary and people and organs endowed with knowledge in the area of health, either to verify, initially, the presence of the requirements for dispensing the drug, or, once determined its supply in the judicial process, in order to evaluate the possibility of its incorporation. Regarding medicines not registered with ANVISA, he proposed the following thesis with general repercussions:

> The State can not be required to supply experimental medicines without proven efficacy and safety under any circumstances. Regarding medicines not registered with Anvisa, but with proof of efficacy and safety, the State can only be obliged to provide them in the event of unreasonable delay of the agency in assessing the application for registration (term longer than 365 days), when three requirements are met: 1) the existence of an application for registration of the drug in Brazil; 2) the existence of registration of the drug in renowned regulatory agencies abroad; and 3) the inexistence of a therapeutic substitute with registration in Brazil. The actions that demand the supply of medicines without registration in Anvisa must necessarily be proposed to the Union[27].

Finally, Minister Edson Fachin considered that there is a subjective right to public health care policies, and there is a violation of individual rights due to failure, omission or delay in the provision, then suggesting that it is preferable to take collective actions, not individual ones, in the fulfillment of the right to healthcare, and that the management of individual actions should be exceptional, in addition to requiring a large probative output regarding the inefficacy of the existing public policy, also proposing criteria for the Judiciary to impose the provision or costing of medicines or health treatments:

> 1) necessary to demonstrate prior administrative application to the public network; 2) preferential prescription by a physician connected to the public network; 3) preferred designation of the drug by the Common Brazilian Denomination (DCB) and, in the absence of the DCB, the IND (International Common Denomination); 4) justification of the inadequacy or lack of medication/treatment dispensed in the public network; 5), and in case of refusal of dispensing in the public network, it is necessary to carry out a medical report indicating the necessity of the treatment, its effects, studies of evidence-based medicine and advantages for the patient, and compare with eventual drugs provided by the Unified Health System"[28].

25 REQUEST for examination of case dockets postponed trial on access to high cost drugs by judicial process" Available at: <http://www.stf.jus.br/portal/cms/verNoticiaDetalhe.asp?idConteudo=326275>. Access on: 11 Nov. 2016.

26 REQUEST for examination of case dockets postponed trial on access to high cost drugs by judicial process" Available at: <http://www.stf.jus.br/portal/cms/verNoticiaDetalhe.asp?idConteudo=326275>. Acesso em: 11 Nov. 2016.

27 REQUEST for examination of case dockets postponed trial on access to high cost drugs by judicial process" Available at: <http://www.stf.jus.br/portal/cms/verNoticiaDetalhe.asp?idConteudo=326275>. Acesso em: 11 Nov. 2016.

28 REQUEST for examination of case dockets postponed trial on access to high cost drugs by judicial process" Available at:

The Minister also stressed that the Judiciary should take a more deferential stance regarding the technical and democratic choices of the competent bodies, which must also be accountable for their actions and be transparent regarding the criteria adopted.

A concern with the respect for public policies and the criteria established by law and Administration for the registration and incorporation of new technologies has been expressed in the votes of the Ministers which have pronounced themselves until now, especially in the vote of Minister Luís Roberto Barroso. There is still a possibility of judicial intervention and the proposed criteria may actually lead to a replication, in the judicial sphere, of procedures that should be adopted in the administrative sphere, which is not reasonable, except in exceptional cases. The Judiciary does not have the structure, the expertise, does not involve the participation of all those interested in the public policy in question and does not appreciate problems of equity regarding the access to budget funds[29].

It is interesting to observe that the discussion undertaken here approaches the identification of limits to the institutional capacities of the Judiciary. Cass Sunstein and Adrian Vermeule[30] argue that the issue of interpretation in law, in particular the greater or lesser deference to the textual meanings of legal norms, must take into account institutional aspects. Among these aspects, they point out the reliability of the judges, especially if they have specific knowledge regarding the legislation they intend to apply, and the systemic effects that their decisions may entail. That is, can generalist judges adopt broader interpretations of texts on unknown specific subjects, such as those related to health, for example? Or is it better to adopt narrower, more formal interpretations? Can judges assess the consequences of their decisions on the health system and the budget? The paths indicated by the votes given above point to a possible reversal in the tendency to grant everything in the field of health judicialization from institutional elements as well.

It is commendable, on the other hand, the concern about a transparency of administrative procedures for registering and incorporating new drugs. This may lead to a type of judicial intervention, of a collective nature and no longer individual, that questions the public policy itself and includes the possibility of demanding the presentation of the criteria for the decision, which eventually determines that the matter is reviewed in the administrative level and which is concerned with equity in the distribution of public resources and with the scientific effectiveness of medicines and treatments.

Brazilian legislation, as in Law 12.401/04/2011, may fulfill in this field a pedagogical role, of reminding judges that they can not do everything and that there are technical aspects to be considered and that their decisions inevitably hide. A reserve of administration or greater deference to legislative and administrative decisions is thus affirmed, which can only be dismissed by the Judiciary in exceptional situations. The so-called Chevron doctrine, elaborated by the US Supreme Court, can still be invoked in this sense.

The concrete case which led to the affirmation of the Chevron doctrine involved the questioning of the legality of norms issued by the environmental protection agency of that country[31]. According to this doctrine, the Judiciary must maintain the interpretation of a law made by the agencies, by means of regulations, for example, unless such interpretation is inconsistent with clearly expressed parliamentary intent. For this reason, the Chevron doctrine implies respect or judicial deference to administrative interpretations (judicial deference), about which it is important to define not whether they are correct, but whether they are admis-

<http://www.stf.jus.br/portal/cms/verNoticiaDetalhe.asp?idConteudo=326275>. Acesso em: 11 Nov. 2016.

29 WANG, Daniel. Courts as healthcare policy-makers: the problem, the responses to the problem and the problem in the responses. São Paulo Law School of Fundação Getúlio Vargas – Direito GV. Research Paper Series – Legal Studies. Paper n. 75, p. 50. Request for examination of case dockets postponed trial on access to high cost drugs by judicial process" Available at: <http://www.stf.jus.br/portal/cms/verNoticiaDetalhe.asp?idConteudo=326275>. Acesso em: 11 Nov. 2016. <http://bibliotecadigital.fgv.br/dspace/bitstream/handle/10438/11198/RPS_75_final.pdf?sequence=1>. Access on: 20 Apr. 2014.

30 SUNSTEIN, Cass; VERMEULE, Adrian. *Interpretation and institutions.* University of Chicago Law School. Coase-Sandor Working Paper Series in Law and Economics, 2002, p. 48. Available at: < <http://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=1279&context=law_and_economics>. Access on: 4 Sept. 2017.

31 SCHWARTZ, Bernard. *Administrative law.* Boston: Little, Brown and Company, 1991. p. 701-702.

sible. That is, the Judiciary should not replace the interpretation adopted by the agency, unless it violates the law clearly. If it does not violate it, administrative interpretation must prevail.

Above all, it seems necessary to establish an institutional dialogue and affirmation of the powers of public officials, since sometimes not even the health professionals themselves seem to know the clinical protocols and the procedures they envisage, not demonstrating sensitivity to the aspect of cost and the effectiveness of treatments and impacts for the budget and society.

Such dialogue could take place in a consensual solution of litigation, such as mediation, transaction and other forms of amicable dispute settlement, encouraged by the 2015 Code of Civil Proceedings and Law 13.140/06/2015. Also through technical conciliation nuclei, which allow the intermediation between health plans or the Unified Health System and the Judiciary, already adopted in some Brazilian courts.

This bias reveals a mechanism whose study and application may prove interesting, for this purpose: the so-called meaningful engagement, developed by the Constitutional Court of South Africa[32]. It is a case law construction that seems to serve to respect the separation of powers and at the same time ensure the realization of fundamental rights that require allocation of resources from the budget. In the Olivia Road case of 2008, which resulted from a building eviction order issued by the city of Johannesburg to the detriment of more than 400 people for health and safety reasons, the Court determined that the city and the occupants should make a significant commitment to resolve the conflict in the light of the values of the Constitution, to guarantee living conditions for those living in the buildings, ensure health and safety, and report back to the Court later on the results of the compromise.

The main advantage in adopting such a commitment is the overcoming of a unilateral imposition by the Judiciary, which affects the budget, through a consensual and participatory solution, under the supervision of the Judiciary, with greater respect for the separation of powers[33]. There is already a Brazilian Senate bill (PLS 736, 2015) that seeks to include a significant commitment to the country's constitutional control system[34].

4. Conclusion

The analysis of the evolution of judicial decisions related to the topic of health judicialization shows an interesting dynamic. From a phase of self-restraint, a maximization of the Judiciary's action followed, in the context of the Brazilian Constitution of 1988 and the affirmation of new rights and promises that it had set up.

However, the excesses of this phase were noticed, due to the lack of consideration, among other aspects, of legal forecasts, limits of budgets and the consequences for the public health system of judicial intervention. Not to mention problems of equity in the care and distribution of public resources.

The fundamental right to healthcare, based on the general prediction of art. 196 of the Constitution and the consideration of human dignity, can not lead to granting extremely expensive or untested drugs and unproven results to all applicants, without considering the competence established by the Legislative

32 VIEIRA JUNIOR, Ronaldo Jorge Araújo. Separação de poderes, estado de coisas inconstitucional e compromisso significativo: novas balizas à atuação do Supremo Tribunal Federal. Senado Federal: Brasília, 2015, p. 29. Available at: <https://www12.senado.leg.br/publicacoes/estudos-legislativos/tipos-de-estudos/textos-para-discussao/td186>. Access on: 18 Dez. 2016.

33 VIEIRA JUNIOR, Ronaldo Jorge Araújo. Separação de poderes, estado de coisas inconstitucional e compromisso significativo: novas balizas à atuação do Supremo Tribunal Federal. Senado Federal: Brasília, 2015, p. 50. Available at: <https://www12.senado.leg.br/publicacoes/estudos-legislativos/tipos-de-estudos/textos-para-discussao/td186.>. Access on: 18 Dez. 2016.

34 VIEIRA JUNIOR, Ronaldo Jorge Araújo. Separação de poderes, estado de coisas inconstitucional e compromisso significativo: novas balizas à atuação do Supremo Tribunal Federal. Senado Federal: Brasília, 2015, p. 34. Available at: <https://www12.senado.leg.br/publicacoes/estudos-legislativos/tipos-de-estudos/textos-para-discussao/td186>. Access on: 18 Dez. 2016.

for technical instances, the cost of incorporation of new drugs and the scientific evidence regarding its effectiveness.

The problems caused by the excesses of the judicial intervention were faced by the Judiciary itself, and also by the Legislative, as highlighted in this work. It can even be said that the edition of Law 12.401/04/2011 has fulfilled the scope of reaffirming the technical competencies of the Executive, for example, regarding the incorporation of new technologies in health and the definition of clinical protocols. The legislator, therefore, may play an important role in reaffirming the Executive's technical competencies, and in a pedagogical way, set limits for judicial intervention.

The pendulum must return to the position of greater balance between individual interests and rights and collective needs, and it is necessary to consider the greater institutional expertise of the entities to whom the legislation gives competence, for example, to decide on the effectiveness and safety of new drugs, as is the case in Brazil, of ANVISA, as well as from the bodies that design and implement public health policies and the incorporation of new technologies.

It is reaffirmed that the judicialization may take a new course, no longer purely individual, but to consider the way in which these policies are exercised and the actions of the institutions which have to decide. In this sense, it is essential to have a permanent dialogue between the Judiciary and these bodies, in order to clarify the limits of their institutional capacities and to find consensual solutions, to remove obstacles, incomprehensions and mutual distrust. Dialogue, mediation, partnership and advice from scientists and technicians seem to be a timely way forward, with a view to realizing the right to healthcare without affecting budgets and the implementation of public policies in this area.

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