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ACCOUNTABILITY FOR REASONABLENESS IN HEALTH CARE LITIGATION: A PROPOSAL FOR A PROCEDURAL ENFORCEMENT

Accountability para a razoabilidade nos litígios de saúde: uma proposta de controle procedimental

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ABSTRACT

The article examined the procedural criterion based on "accountability for reasonableness" as an auxiliary method to the jurisdictional control in health care litigation, especially given the creation of the National Commission for Health Technology Incorporation in the Brazilian National Health System. It was studied how the influx of pragmatism in the courts works suggests a diverse judicial model for the implementation of the right to health in an attempt de-judicialize the debate and the decrease the risks to equity in the distribution of resources. Empirical data collected through literature review were used to analyze the concrete performance of the Commission. It was concluded that the greater jurisdictional control over the administrator's decision-making procedure regarding the inclusion of medicines in public lists may be a pragmatic judicial stance to produce better results, by requiring the public administration to account for their actions and to demonstrate the reasons for the allocated decisions on pharmaceutical assistance, as well as stimulating social participation in the procedure.

Keywords

Accountability for Reasonableness; Constitutional Law; Health Care Litigation.

RESUMO

O artigo examinou o critério procedimental baseado na *accountability* para a razoabilidade *(accountability for reasonableness*) como um método auxiliar ao controle jurisdicional nos litígios de saúde, sobretudo diante da criação da Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde. Estudou-se como o influxo do pragmatismo na atuação das cortes sugere um modelo judicial diverso para a concretização do direito à saúde, na tentativa de desjudicializar o debate e diminuir os riscos à equidade na distribuição dos recursos. Utilizaram-se dados empíricos colhidos por meio de revisão bibliográfica para análise da atuação concreta da Comissão. Concluiu-se que o maior controle jurisdicional do procedimento de tomada de decisão do administrador acerca da inclusão de medicamento nas listas públicas pode ser uma postura judicial pragmática tendente a produzir melhores resultados, ao exigir que a administração pública preste contas de sua atuação e demonstre as razões das decisões alocativas na assistência farmacêutica, bem como ao estimular a participação social no procedimento.

Palavras-Chave

Accountability for Reasonableness; Direito Constitucional; Litígios de Saúde.

Introduction

Life is priceless. The guarantee of the constitutional right to health by the State must take into account an ideal distribution of public resources that allows maximizing the health protection of the entire population. For this task, it is up to the State to define priorities and elaborate a difficult calculation in relation to the allocation of resources.

Of the total deaths occurred in Brazil annually, about 70% are related to chronic non-communicable diseases: cardiovascular diseases, respiratory diseases, cancer and diabetes. A considerable portion of these deaths is premature, that is, it affects people aged 30 to 69 years and could have been avoided.

These diseases have a great socioeconomic impact, divided between the health system, society and families, and create a vicious circle with poverty. Its preponderance in causes of mortality constitutes the health problem of greatest magnitude in the country, and its confrontation has become a priority at the national level. From 2000 to 2014, the biggest decreases in premature mortality rates occurred in the Southeast and South (-5.6%) and the smallest, in the Northeast (-1.9%). For diabetes, the premature mortality rate increased in the North[1].

In 2014, of the total spent by the Ministry of Health to comply with court orders, 55% (R$ 381 million) referred to two medications: Soliris® and Naglazyme®, both demanded for the treatment of patients with rare diseases and not included in the drug lists of the Brazilian National Health System (SUS) nor in the Clinical Protocols and Therapeutic Guidelines (PCDT). These are the drugs that generated the highest cost for the Ministry of Health that year, intended to treat only 382 patients; the average annual cost per patient was R$ 941,541.19 in the case of Soliris®, and R$ 1,081,594.78 in the case of Naglazyme® (item 4.1, Case 009.253/2015-7, Judgment 1787/2017, rapporteur of Bruno Dantas, session of August 16, 2017, plenary session of the Federal Court of Accounts)[2].

The data cited are examples of the contrasting situations that health authorities have to deal with when formulating pharmaceutical assistance policy. How to provide the treatment for cardiovascular diseases and diabetes, which prematurely kill thousands of individuals, and, at the same time, for rare diseases that require expensive drugs, which is inaccessible by the patients' own means? Inevitably, the finitude of resources requires that tragic choices be made.

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[1]MINISTÉRIO DA SAÚDE. *Saúde Brasil 2015/2016*: uma análise da situação de saúde e da epidemia pelo vírus Zika e por outras doenças transmitidas pelo Aedes aegypti. Brasília-DF: Ministério da Saúde, 2017. p. 119-125.

[2]AUMENTAM os gastos públicos com judicialização da saúde. Tribunal de Contas da União, 23 out. 2017. Available at: http://portal.tcu.gov.br/imprensa/noticias/aumentam-os-gastos-publicos-com-judicializacao-da-saude.htm. Acesso em: 14 Oct. 2020.

It is not considered, in this regard, weighting between the right to health and the public budget, as they are not in the same hierarchy. It is about the need to prioritize, requiring that the real costs and possibilities of implementation be considered, as well as the effectiveness and security of the treatment, for an equitable allocation of resources.

In Brazil, however, jurisprudence in general has given little importance to the decision-making procedure of administrative authorities. In this scenario, it would be appropriate to consider another judicial model for the implementation of the right to health, in an attempt to gradually reduce judicialization in the country and to reduce the risks to equity in the distribution of scarce resources of a health system that belongs to all, litigants or not? Or, instead, the solution would be to maintain the current judicial interpretation and restructure the Judiciary in order to prepare it to receive an increasing number of demands? In our view, the latter does not seem to be the most appropriate solution to this challenge. We, therefore, dedicate ourselves to answering the first question.

We emphasize how the influx of pragmatism in the performance of judges and courts in the effectiveness of the right to health imposes a different attitude to that prevailing in national jurisprudence, in an attempt to obtain less unequal and more universal practical results and to de-judicialize the debate. To this end, a good tool for the judge is the adoption of the procedural criteria based on accountability for reasonableness, approached as an auxiliary method in jurisdictional control that favors interventions over the administrator's decision-making procedure on the inclusion of medicines in public lists, especially in view of the creation of the National Commission for Technology Incorporation at SUS (Conitec).

I. The influx of legal pragmatism in health care litigation

The result of the most recent audit carried out by the Federal Court of Accounts (TCU), completed in 2017, revealed that annual expenditures only by the federal government with judicial process related to health reached R$ 1 billion in 2015, which is equivalent to an increase of more than 1,300% since 2008, when it was R$ 70 million. Among the demands in 2015, 80% corresponded to the supply of medicines (item 7.2, Case 009.253/2015-7, Judgment 1787/2017, rapporteur of Bruno Dantas, session of August 16, 2017, plenary session of the Federal Court of Accounts)[3].

Empirical data from national and regional studies demonstrate that most of the demands have not aimed at providing basic health to the most needy

[3]AUMENTAM os gastos públicos com judicialização da saúde, *cit*.

population[4]: the aim is to obtain newer and more expensive drugs compared to those dispensed by SUS, make use drugs outside the prediction of the clinical protocol and, in both cases, it is not uncommon to disregard the safety and efficacy of drugs and the cost-effectiveness of their dispensing. Furthermore, the studies indicate a concentration of lawsuits in the most developed states in the country.

However, the analysis of the jurisprudence of the Federal Supreme Court (STF) on health in the period from 2000 to 2017 shows that the judicial debate is still centered, for the most part, on the collision between the right to life and health and the financial and secondary interest of the State, giving less weight - or even completely disregarding - to the context, the financial and organizational impacts on the health system and the litigants who claim medicines, as well as the scarcity of resources and the reasons of the health authorities in the administrative procedures for drugs evaluation[5].

The demands for pharmaceutical assistance not foreseen in the SUS lists or in the clinical protocols filed by private individuals in the face of federative entities involve scarcity of public resources, controversies about the setting of health priorities and issues of distributive justice. Therefore, they represent difficult cases, which generate impacts on the entire health system and which require a differentiated decision-making strategy, more committed to reality and to the practical results of decisions. From this scenario, this research valued the pragmatism, due to the importance it gives to the context and the consequences of the interpretation and application of the law. It is not the central object of our study to discuss in depth philosophical or theoretical issues related to the subject. We only intend to apply a pragmatic approach to health care litigation and, for this, there is no need for an unconditional adherence to the proposals of pragmatism.

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[4]For a detailed analysis of the demands, see: TAUK, Caroline Somesom. Expectativa e realidade: uma análise pragmática dos litígios de saúde. *Revista Brasileira de Direito Público*. Belo Horizonte, v.18, n.68, jan./mar. 2020. Available at: https://dspace.almg.gov.br/handle/11037/37383;CHIEFFI, Ana Luiza; BARRADAS, Rita De Cassia Barata; GOLBAUM, Moisés. Legal access to medications: a threat to Brazil's public health system? *Health Serv. Res.*, v.17, n. 499, p. 1-12, 2017. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5517947/. Acesso em: 09 Oct. 2018. https://doi.org/10.1186/s12913-017-2430-x; VIEIRA, Fabiola Sulpino; ZUCCHI, Paola. Distorções causadas pelas ações judiciais a política de medicamentos no Brasil. *Rev. de Saúde Pública,* vol. 41, n.2, p. 215-222, 2007. Available at: http://www.scielo.br/pdf/rsp/v41n2/5587.pdf. Acesso em: 09 Oct. 2018. http://dx.doi.org/10.1590/S0034-89102007000200007; FERRAZ, Octavio Luiz Motta. Harming the poor through social rights litigation: lessons from Brazil. *Texas Law Review*, v. 89, p. 1642-1668, 2011. Available at: https://texaslawreview.org/wp-content/uploads/2015/08/Ferraz-89-TLR-1643.pdf e MACHADO, Marina Amaral de Avila *et al.* Judicialização do acesso a medicamentos no Estado de Minas Gerais, Brasil. *Rev. Saúde Pública*, v. 45, n. 3, p. 590-598, 2011. Available at: https://www.scielo.br/pdf/rsp/v45n3/2403.pdf.

[5]This is what is verified in the following judgments, to name a few: AgR no RE 232335, de 25/08/2000, Rel. Min. Celso de Mello; ADPF 45, de 04/05/2004, Rel. Min. Celso de Mello; STAs 175 e 178, de 2009, Rel. Min. Gilmar Mendes; ARE 685230 AgR, de 05/03/2013, Rel. Min. Celso de Mello, ARE 744170 AgR, de 26/11/2013, Rel. Min. Marco Aurélio, ARE 812424 AgR, de 05/08/2014, Rel. Min, Celso de Mello, AI 824946 ED, de 25/06/2013, Rel. Min. Dias Toffoli e ARE 926469 AgR, de 07/06/2016, Rel. Min. Roberto Barroso. Disponível em: www.stf.jus.br. Acesso em: 09 out. 2018.

The philosophical current of pragmatism was well synthesized by Thamy Pogrebinschi, who, from the works of the first classical pragmatists (Charles S. Peirce and William James, members of the so-called Metaphysical Club, and also John Dewey), identified a common nucleus in the movement conceived for them. Thus, the matrix of pragmatism was formulated, composed of three main ideas: antifundationalism, consequentialism and contextualism.

Antifundationalism is characterized by rejection of metaphysical propositions. It presupposes that there are no absolute and finished truths, maintaining that the traditional concepts of certainty, reality and truth, elaborated along the lines of traditional metaphysics, must be submitted to a new method. In the pragmatist method, the meaning of each concept will depend on its practical consequences[6].

The second element of the philosophical matrix of pragmatism, the consequentialism, also called instrumentalism, refers to the concern for the future, that is, the prospective view of pragmatism. It is by anticipating the future consequences that one can know which of them is better and more useful. For pragmatism, all propositions are hypothetical and must be tested by deducing their consequences[7].

Finally, contextualism determines that philosophical investigations must be made from their specific contexts, highlighting the relationship between philosophical ideas, social life and the culture of the society from which the ideas originated. Discuss about culture of a society means to discuss the political, religious and scientific beliefs that make up the experience. The main constituent element of the experience is the practice, which refers directly to the formulation of the pragmatist concept of action. Therefore, experience and practice are valued[8].

The three characteristics of the pragmatic matrix are interrelated in the conclusion of José Vicente Santos de Mendonça: "[...] if there are no foundations that justify or validate concepts and theories, one must appreciate from their consequences, which only acquire meaning within the context in which they are inserted"[9].

Dealing with pragmatism in the field of law, Richard Posner points out that there is, in fact, a pragmatic mood that branched into a philosophy of pragmatism and into an everyday practice of pragmatism[10]. Looking at its consequences is the first aspect to understand what Posner's everyday pragmatism is. To this, the author adds (i) the disbelief in concepts regarded as certain and immutable and (ii) the use of several theories for the proper understanding of law, as well as (iii) the need for

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[6]POGREBINSCHI, Thamy. *Pragmatismo*: teoria social e política. Rio de Janeiro: Relume Demará, 2005, p.31.
[7]*Id. Ibid.,* p. 39; 47.
[8]*Id. Ibid.,* p. 49.
[9]MENDONÇA, José Vicente Santos de. *Direito constitucional econômico*: a intervenção do Estado na economia à luz da razão pública e do pragmatismo. Belo Horizonte: Forum, 2014. p. 38.
[10]POSNER, Richard. A. *Law, pragmatism and democracy*. Cambridge: Harvard University Press, 2003. p. 26.

its conformity with human and social needs[11]. In fact, these three elements refer, respectively, to the three elements of the pragmatic matrix: consequentialism, anti-fundationalism and contextualism.

In short, a pragmatic approach seeks to understand the right to health in the concrete context in which it is inserted, with the vision aimed at seeking solutions to practical questions. Against this background, the stage opens for the debate of another judicial model for the implementation of the right to health, in an attempt to de-judicialize conflicts and reduce the risks to equity in the distribution of resources.

II. The judicial implementation of the right to health: the individual and procedural models

The Federal Constitution of 1988 (CF/88) consolidated a theory of fundamental rights centered on the dignity of the human person. This theory must be understood with attention to the reality in which it will be applied. It is the conclusion of Ana Paula de Barcellos:

> There is no right without reality. It is reality what the right intends to transform and it is from it that right extracts the new needs and demands to be regulated; it is the reality that confronts the interpreter with the most intricate problems and drives him to work; it is from reality that the right cannot go beyond a certain limit, under pain of losing contact and walking alone and without meaning, unable to bring it closer to the law. The right, therefore, is a truism, is an instrument, it is a means, not an end in itself[12].

Regarding fundamental rights, there is much debate about the syndicability of social rights, including the right to health. In fact, judicial intervention in the right to health - the so-called judicialization of health - faces several criticisms[13]. However, the judicial action in the implementation of the right to health in Brazil is an undeniable reality, due to the normativity and effectiveness of constitutional provisions. For this reason and for the purposes of our study, we start from the

[11] POSNER, Richard. A what has pragmatism to offer law. *Southern California Law Review*, v. 63, n. 1660, 1989-1990. Available at: https://pdfs.semanticscholar.org/4880/3eecdcb20b0bbd1510890fdc6b9369ad48b2.pdf.

[12] BARCELLOS, Ana Paula de. *A eficácia jurídica dos princípios constitucionais*: o princípio da dignidade da pessoa humana. 2. ed. Rio de Janeiro: Renovar, 2008. p. 5.

[13] For an objective survey of the various criticisms, see: BARROSO, Luís Roberto. Da falta de efetividade à judicialização excessiva: direito à saúde, fornecimento gratuito de medicamentos e parâmetros para a atuação judicial. *Jurisp. Mineira*, Belo Horizonte, ano 60, n. 188, p. 44-46, jan./mar. 2009; e BARCELLOS, Ana Paula de. Constitucionalização das políticas públicas em matéria de direitos fundamentais: o controle político-social e o controle jurídico no espaço democrático. *In*: SARLET, Ingo Wolfgang; TIMM, Luciano Benetti (Orgs.). *Direitos fundamentais, orçamento e reserva do possível*. Porto Alegre: Livraria do Advogado, 2008.

premise that the syndicability of social rights is possible and, more than that, fundamental to ensure that public policies comply with the Constitution and the laws.

However, such premise does not put an end to the discussions. How should the Judiciary intervene? It is at this point that the models of jurisdictional control vary the most among countries. In Brazil, the majority jurisprudence has widely accepted the granting of medicines by **individual**, with the use of **strong remedies**, determining to the public authority the fulfilment of the exact required provision, by supplying the medicine in a short time, under penalty of a fine or other enforcement measure[14].

Courts in some other countries adopt the **procedural** model, following an approach based on the reasonableness of the administrative decision-making procedure. This is the case of the Constitutional Court of South Africa, which requires the government to justify its actions in order to verify whether it has proceeded reasonably towards the implementation of social and economic rights. The doctrine and the Constitutional Court south African raise three questions regarding the interpretation of social rights: the separation of powers, the vagueness of the rules that deal with those rights and the costs for their implementation. The emblematic case of South African jurisprudence is called "*Soobramoney versus Minister of Health, Kwazulu-Natal*" [1998 (1) SA 765 (CC)] "[15].

In the scenario of greater or lesser judicial intervention in the consolidation of rights, the dilemma proposed by Frank Michelman and studied by Octavio Ferraz[16]arises: given the vagueness of the content of social rights and the existence of reasonable disagreement about it, the Judiciary must exercise caution when replace the interpretation made by elected officials with their own interpretation of the content of the rights, reason why the use of strong judicial remedies to impose their interpretation attracts the charge of "usurpation"; however, given the general view that courts are guardians of fundamental rights, abstaining from the use of strong remedies when judging social rights may imply "abdication".

A strongly respectful model can pave the way for a total disregard for social rights by health authorities, especially in countries with high levels of corruption and non-compliance with the constitutional duties of the State, such as Brazil and South Africa, as highlighted by Ferraz. In contrast, allowing the courts to completely

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[14] FERRAZ, Octavio Luiz Motta. Between usurpation and abdication? The right to health in the Courts of Brazil and South Africa. *University of Warwick School of Law,* 2009. p. 12. Available at: http://ssrn.com/abstract=1458299. Acesso em: 09 Oct. 2018. http://dx.doi.org/10.2139/ssrn.1458299.

[15] EBADOLAHI, Mitra. Using Structural Interdicts and the South African Human Rights Commission to Achieve Judicial Enforcement of Economic and Social Rights in South Africa. *New York University Law Review*, v. 83, n. 5, p. 1580-1582, 2008. Available at: https://www.nyulawreview.org/wp-content/uploads/2018/08/NYULawReview-83-5-Ebadolahi.pdf.

[16] FERRAZ, Octavio Luiz Motta. Between usurpation and abdication? The right to health in the Courts of Brazil and South Africa, *cit.,* p. 6.

disregard the priority and allocation decisions made by elected officials and experts may also not be the best way out.

Specifically dealing with the setting of health priorities, the North American professors Norman Daniels and James Sabin[17] propose a theory, called accountability for reasonableness, which seeks to verify how health priorities are established by public authorities in order to ensure that health care in based on fair procedures leading to fundamental administrative choice, publicly accepted and that respect equity, increasing the legitimacy of the results. It takes care of procedural criteria for setting priorities by the public administration that can also be used by judicial bodies, in the form of a procedural control, but with its own characteristics.

And why, based on pragmatism, is it suggested to adopt accountability for reasonableness how an auxiliary method in the jurisdictional controls prevalent today? Pragmatist judge is more open to accepting contributions from other fields of knowledge than other judges[18]. In addition, he has a prospective view, anticipating the consequences and searching for the best possible result for society[19]. In this regard the adoption of the procedural criteria of Daniels and Sabin seems to be a pragmatic strategy of the judge, who, instead of limiting the discussion to the content of public health policies, is concerned about the requirements to be met in the procedure for setting priorities in order to a distribution of resources aimed a fair allocation, which produces desirable results for all, litigants or not.

III. The accountability for reasonableness

According to Norman Daniels and James Sabin, the legitimacy of limits and priorities in health care involves not only who has the moral authority to establish them, but how those limits and priorities are established. This is the main model of procedural justice for health systems applied according to the priority setting[20].

For Syrret, the allocation of decision-making causes legitimacy problems. Since choices are made in situations of scarcity, moral disagreements and conflicts arise over the choice of priorities, which can result in both resistance and distrust of society. In response, the legitimacy of public authorities can be claimed in two ways: based on their expertise, which is based on the body's ability to understand and fulfill its task, or on the use of a fair procedure, which is based on the existence

[17] DANIELS, Norman; SABIN, James E. *Setting limits fairly*: can we learn to share medical resources? New York, NY: Oxford University Press, 2002; e DANIELS, Norman. Accountability for reasonableness: establishing a fair process for priority setting is easier than agreeing on principles. *BMJ*, v. 321, n. 7272, p. 1300-1301, 25, Nov.2000. https://doi.org 10.1136/bmj.321.7272.1300.

[18] POSNER, Richard. A. *Law, pragmatism and democracy, cit.,* p. 76-77.

[19] POGREBINSCHI, Thamy. *Pragmatismo*: teoria social e política. Rio de Janeiro: Relume Demará, 2005. p. 39 e 47.

[20] FRIEDMAN, Alex. Beyond accountability for reasonableness. *Bioethics,* v. 22, n. 2, p. 102, 2008. http://dx.doi.org/10.1111/j.1467-8519.2007.00605.x.

of a connection between process equity, legitimacy and public acceptance of decisions, regardless of any substantive results. The accountability for reasonableness is based on the second form[21].

The proposed fair process aims at the implementation of public accountability, aimed at the organizations that allocate resources for the satisfaction of health needs, and has as fundamental elements the transparency of the decision bases, the use of reasons that everyone should accept as relevant to the satisfaction of health needs and the possibility of reviewing these decisions[22]. The main idea that supports this theory is that fair and reasonable people (fair-minded) are able to agree on the reasons for setting priorities when they realize that it has gone with justice and equity to meet everyone's health needs..

The authors clarify the notion of accountability for reasonableness by establishing four conditions[23]: (i) advertising condition, according to which the reasons for important decisions setting limits for health needs must be accessible to the public; (ii) a condition of relevance, which determines that the reasons for these decisions must constitute a reasonable explanation of how value is sought for money (value for money) in order to meet the various health care needs of a given population, considering the resources constraints; (iii) review condition, which requires mechanisms to review and improve public policies in the face of new evidence or arguments brought; and (iv) regulatory condition, which provides for public regulation of the decision-making procedure to ensure that all previous conditions are observed. This is a democratic approach: the observance of these conditions would remove the decisions on health needs from the "black box" and it would become them accessible to society, connecting them to an "ampler deliberative and educational process democratic"[24].

In this way, the accountability for reasonableness intends to collaborate to educate decision-makers about the indispensable aspects related to a fair decision, as well as to facilitate and stimulate social learning on the establishment of health priorities and the limits of budgetary resources, allowing a public deliberation process.

Finally, we highlight two relevant criticisms of Daniels and Sabin's theory[25]. The first concerns popular participation in the procedure, stating that the advertising

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[21] SYRETT, Keith. Health technology appraisal and the courts: accountability for reasonableness and the judicial model of procedural justice. *Health Economics, Policy and Law*, n. 6, p. 471, 2010. https://doi.org/10.1017/S174413311000022.

[22] DANIELS, Norman; SABIN, James E. *op. cit,* p. 45-46.

[23] *Id., loc. cit.*

[24] DANIELS, Norman. *Just health*: meeting health needs fairly. Cambridge: Cambridge University Press, 2008. p. 119.

[25] RID, Annette. Justice and procedure: how does "Accountability for Reasonableness" Result in fair limit-setting decisions? *Journal of Medical Ethics*, v. 35, n. 1, p. 15-16, Feb. 2009. http://dx.doi.org/10.1136/jme.2008.024430.

condition needs to be better specified. In fact, such condition presupposes that the public is aware of the setting of budget limits and priorities; however, this does not always occur. It is important that there is active communication about allocation decisions, through newsletters, web pages discussion or public events, for example, to obtain effective publicity and even to allow people to appeal the decision. The second criticism states that accountability for reasonableness is not inclusive enough, because the mechanisms of public representation are limited. It is therefore proposed to expand the mechanisms of stakeholder involvement, by encouraging participation in debates on funding priorities, the formation of associations, etc., in order to seek fair consideration of everyone's claims.

IV. How to apply the theory in court?

What is the reflection of the adoption of the theory of accountability for reasonableness in the role of the Judiciary in health processes? Greater jurisdictional control over the administrator's decision-making procedure, regarding the inclusion of medicines in public lists, favors interventions more procedural than substantive.

The role of judicial bodies based on the "theory on the screen" can be discussed as an alternative to the dilemma between usurpation, resulting from the use of strong judicial remedies in individual demands, and abdication, resulting from the use of procedural control along the lines of South Africa, bringing a vision with other nuances to the judicial intervention.

It is expected that the result of the judicial adoption of this model will be a more respectful stance to complex technical decisions or to the formulation of public policies taken by competent bodies, at the same time that the administration is charged with accountability for its performance. This stance aims to encourage health authorities to exercise caution in the decision-making procedure and to improve it whenever the courts indicate flaws in it and cancel their choices.

That way, the judicial bodies would ensure compliance with the regulatory condition provided by Daniels and Sabin. In the words of Daniel Wang,

> Thus, if courts control the quality of the decision-making process (whether it is open, transparent, based on acceptable evidence, reasons and principles that are accepted by fair-minded people and with opportunities for interested parties to challenge the decision) instead of allocating scarce resources themselves by deciding whether an individual claimant should have access to a treatment, they force health authorities to ration explicitly and by doing it in this way create incentives for fair decisions. Being able to articulate the reasons for their decision becomes a strategy for the authorities, by which to defend their decisions in litigation. The courts, therefore, meet with the

> "regulatory principle" in Daniels and Sabin's theory: ensure that the other conditions of **accountability for reasonableness** are met[26] (free translation).

Finally, a remark for comparative study purpose: the jurisprudence of England, the cradle of the public and universal health system model, is a recurring example of the application of accountability for reasonableness although the judges do not express reference to the theory. From the 1990s, with the judgment of the "*Child B*"[27]case, the English courts began to demand explicit reasons from the authorities to support their decisions, which should be the result of a public and transparent procedure taking into account the context of the individual case. This judicial stance culminated in the creation, in 1999, of the so-called today as National Institute for Health and Care Excellence (NICE), inspired by the idea of accountability for reasonableness. Among others, NICE has the function of evaluating the use of new technologies, based on a clinical and cost-effectiveness analysis.

V. Application of the theory in Brazil

If the application of the theory of accountability for reasonableness by the Judiciary requires, on the one hand, that the judicial bodies be informed about how the allocation decisions of resources was made and about the reasons for choosing priorities, on the other, it requires that the health authorities, in turn, give importance to the decision-making procedure and regulate it - after all, if there is no attention from the public administration in this regard, there is no reason to defend a judicial control over the procedure.

In this scenario, it is questioned what would be the practical mechanisms of a possible application of the theory in Brazil. It is precisely at this point that the

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[26] In the original: "*Thus, if courts control the quality of the decision-making process (whether it is open, transparent, based on acceptable evidence, reasons and principles that are accepted by fair-minded people and with opportunities for interested parties to challenge the decision) instead of allocating scarce resources themselves by deciding whether an individual claimant should have access to a treatment, they force health authorities to ration explicitly and by doing it in this way create incentives for fair decisions. Being able to articulate the reasons for their decision becomes a strategy for authorities by which to defend their decisions in litigation. Courts, therefore, meet the 'regulatory principle' in Daniels and Sabin's theory: they ensure the other conditions for accountability for reasonableness are fulfilled*". WANG, Daniel Wei Liang. *Can litigation promote fairness in healthcare*?: the judicial review of rationing decisions in Brazil and England. 2013. Tese (Doutorado) - Department of Law. The London School of Economics and Political Science, London, 2013. p. 18.

[27] The leading case "*R. versus Cambridge Health Authority, ex parte B* ([1995] 2 All ER 129, [1995] 1 WLR 898)]" discussed an administrative decision that refused to fund leukemia treatment for a girl of 10 years old. The case is emblematic because Justice Laws, one of the members of the High Court, seemed to meet the conditions of accountability for reasonableness by requiring health authorities to explain the priorities that led them to deny the cost of treatment and to defend judicial deference, provided there was transparency as to the reasons for setting priorities.

study of the National Commission for Technology Incorporation at SUS (Conitec), created by Law no. 12,401/2011[28].

With the proposal, it is expected that jurisdictional control will not be concurrent, but cooperative, helping to materialize social law and, therefore, tending to produce a more desirable result than the current form of control.

For Schapiro,

> Whether in the case of telecommunications or health, distrust of the proper functioning of other powers and their control mechanisms can be a device that encourages and justifies judicial activism. The point is that this activism can work in a competitive or cooperative way. In other legal systems, such as the English, faced with situations like this, the Judiciary's position is not to subrogate itself in the position of public manager, substantively choosing the form of allocation of public resource, but rather requiring the Executive to prove the reasonableness of your choice (WANG, 2013, p. 115-172). Following this path, liberal control does not act in a predatory way for the consistency of political choices, but in a cooperative way with the strengthening of republican control. By charging the Executive with the choice criteria, instead of providing individual lawsuits, the Judiciary encourages an improvement in impact analyzes and consistency of administrative choices[29].

Furthermore, the adoption of the method studied here may stimulate the phenomenon called institutional dialogues - an expression that comes from Canadian doctrine, by studying the provisions of the Canadian Charter of Rights from 1982 that allow the decision's modification, by Parliament, of the Supreme Court and facilitate the dialogue between the judicial body and the Legislative[30]. Thus, eventual judicial decisions on health care litigation, instead of closing the debate, would have the power to open the channels of dialogue between the Judiciary, Conitec and society to define the content of the right to health provided for in the Constitution.

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[28] BRASIL. *Lei n. 12.401, de 28 de abril de 2011.* Altera a Lei n. 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde - SUS. Available at: http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2011/Lei/L12401.htm. Acesso em: 30 Aug. 2020

[29] SCHAPIRO, Mario G. Discricionariedade desenvolvimentista e controles democráticos: uma tipologia dos desajustes. *Revista Direito GV*, v. 12, n. 2, p. 337, maio/ago. 2016. Available at: https://www.scielo.br/pdf/rdgv/v12n2/1808-2432-rdgv-12-2-0311.pdf.

[30] HOGG, Peter W.; BUSHELL, Alison A. The Charter dialogue between courts and legislatures (or perhaps the charter isn't such a bad thing after all). *Osgoode Hall Law Journal*, v. 35, n. 1, p. 75, 1997. https://digitalcommons.osgoode.yorku.ca/cgi/viewcontent.cgi?article=1612&context=ohlj&httpsredir=1&referer=.; e BRANDÃO, Rodrigo. *Supremacia judicial versus diálogos constitucionais:* a quem cabe a última palavra sobre o sentido da Constituição? Rio de Janeiro: Lumen Iuris, 2012. p. 273-274 e 286.

A final comment on the mention of the theme by the Brazilian Judiciary. In the Extraordinary Appeal (RE) 566471, the STF recognized the general repercussion of the controversy over the obligation for the government to supply high-cost medication. The ministers Luís Roberto Barroso and Alexandre de Moraes set out in their theses, as a requirement for the judicial supply of the drug, the proof that the failure to incorporate the drug claimed in SUS did not result from an express decision of the competent bodies. Barroso also demands the "establishment of an institutional dialogue between the Judiciary and entities with technical expertise in the health field"[31]. It is perceived, in this point, an appreciation of Conitec's attributions and of what was decided in the administrative procedure.

Similarly, in RE 657718, in which the STF recognized the general repercussion on the subject of the obligation of the State to pay for medicine not registered with the National Health Surveillance Agency (Anvisa), the vote of Minister Edson Fachin proposed the thesis that it is possible for the State to provide, as a general rule, the prohibition of dispensing, paying or reimbursing medicines without registration[32]. The vote states that, in the field of health care policies, the control of administrative decisions can be identified with accountability for reasonableness of Norman Daniels, implying a "more respectful stance to the technical or democratic choices made by competent bodies, without the administration or the regulatory entities failing to render account for their performance", and recognizing that it is possible to carry out control through the reasons presented in a given public policy.

1. The National Commission for Technology Incorporation at SUS

The creation of the National Commission for Technology Incorporation at SUS (Conitec), a national institution that is closest to the English NICE, represents a legislative reaction to the increasing demand for medicines not covered by SUS and makes it clear that health authorities are responsible for provide reasons for those affected by their decisions, accessible to the whole of society, with the intention of reducing court interference. Bill no. 338/2007[33] and n. 219/2007[34], originated in the Senate and which, jointly assessed by the National Congress, were converted into Law no. 12,401/2011, justify the growing disputes of drug users not contemplated in the tables of the Ministry of Health and the need for a solution to this impasse.

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[31] SUPREMO TRIBUNAL FEDERAL – STF. RE 566471. Available at: http://portal.stf.jus.br/processos/detalhe.asp?incidente=2565078. Acesso em: 14 out. 2020. Nota da autora: está pendente a fixação da tese.

[32] SUPREMO TRIBUNAL FEDERAL – STF. Recurso Extraordinário RE 657718. Available at: http://portal.stf.jus.br/processos/detalhe.asp?incidente=4143144. Acesso em: 30 ago. 2020. Nota da autora: julgamento concluído com fixação de tese.

[33] BRASIL. Senado Federal. *Projeto de Lei do Senado n. 338, de 2007*. Available at: https://www25.senado.leg.br/web/atividade/materias/-/materia/81517. Acesso em: 30 Agu. 2020.

[34] BRASIL. Senado Federal. *Projeto de Lei do Senado n. 219, de 2007*. Available at: https://www25.senado.leg.br/web/atividade/materias/-/materia/80822. Acesso em: 30 Agu. 2020.

The former Commission on Technology Incorporation of the Ministry of Health (CITEC) was the body that initiated the institutionalization of the technology incorporation process at SUS. Conitec replaced CITEC and is responsible for advising the Ministry of Health on the incorporation and exclusion of new drugs, products and procedures, the constitution or amendment of Clinical Protocols and Therapeutic Guidelines (PCDT) and the updating of the National List of Essential Medicines (Rename) and the National List of Health Actions and Services (Renases) (Law n. 8.080/1990, art. 19-Q, *caput*)[35].

Among the various objectives of the new body, the three most relevant for facing judicialization stand out: (i) to qualify the decision-making process in the evaluation of health technologies, seeking the promotion and health protection of the Brazilian population, the better allocation of available resources and the reduction of regional inequalities; (ii) to contribute to the qualification of judicial decisions and to the reduction of the judicialization of the right to health in the country; (iii) and to give visibility to the process of management and incorporation of health technologies.

Law no. 12,401/2011 also provided for the legal procedure on which the Commission's acts are based. Social participation in the decision-making process is strengthened by public consultations and hearings. The procedure is provided for Articles 19-Q and 19-R of Law no. 8.080/1990 and Decree 7.646 / 2011[36].

There are also two other legal changes that have a great impact from the perspective of the plaintiffs: the establishment of a period of 180 days for finalizing the analysis of the proposal, which can be extended, at most, for another 90 days, and the mandatory opening administrative process for the incorporation of medicines, instituted by private individual, legal entity or by the Ministry of Health. The end of the period without the completion of the procedure, however, does not require the dispensing of the medicine or product.

In the reports on new technologies it issues, Conitec considers the scientific evidence on its effectiveness, efficiency and safety, as well as the comparative economic evaluation of the benefits and costs in relation to the technologies already incorporated. The reports are available on the website of the Ministry of Health and can be a useful tool both for the interested population and for the magistrates who

[35] BRASIL. *Lei n. 8.080 de 19 de setembro de 1990*. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. Available at: http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2011/Lei/L12401.htm. Acesso em: 13 Jan. 2019.

[36] BRASIL. *Decreto n. 7.646, de 21 de dezembro de 2011.* Dispõe sobre a Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde e sobre o processo administrativo para incorporação, exclusão e alteração de tecnologias em saúde pelo Sistema Único de Saúde - SUS, e dá outras providências. Available at: http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2011/Decreto/D7646.htm. Acesso em: 30 Aug. 2020.

appreciate demands on the subject. The aim is to facilitate the transparency of the procedure. Transparency encourages society' learning about health priorization and the limits of budgetary resources, as well as approximating the important - and inevitable - decision to choose the best model of technology use and allocation of resources for a health system that belongs to all.

The legitimacy of administrative choices is strengthened the more these choices are opened to participation and popular control and technically based. By implementing these ideals, the new procedure provided for by Law no. 12,401/2011, at least potentially, intends to strengthen the legitimacy of Conitec's acts and, therefore, to stimulate judicial deference. To conclude, mention the lessons of Daniel Wang, for whom the Daniels and Sabins's theory "has emerged in Brazil as the right response to the increase in health care litigation, although its effectiveness is not guaranteed since it depends on courts accepting the legitimacy of the new health technology assessment system"[37] (free translation).

Finally, an elementary remark is necessary. Any analysis of Conitec's actions cannot disregard the risk of "capture" by the pharmaceutical industries and private interests[38]. This aspect shows that the adoption of the judicial stance regarding the Commission's choices must pay attention to the varied circumstances of the administrative procedure, including those related to the risk of capture of public officials.

2. Conitec's performance: an empirical analysis

It is necessary to verify concretely, in the light of pragmatism, what the results arising from Conitec's performance have been. Therefore, based on empirical data collected through bibliographic review, the context in which the demands against the Commission are inserted will be examined - what is required and by whom, if there is social participation and if it is able to influence the result of the final decision and whether there is an analysis of scientific and economic factors - and the consequences of its recommendations in relation to the incorporation, alteration or exclusion of medicines - what is the total number of incorporations and which technologies.

The assessment focuses on the quality of the decision-making procedure, seeking to analyze: (i) whether the technical basis was based on scientific evidence and on the comparative economic assessment of the benefits and costs in relation to the technologies

[37] In the original: "*In sum, a rationing scheme along the lines of what was suggested by Daniels & Sabin idea of accountability for reasonableness has emerged in Brazil as the right response to the increase in health care litigation, although its effectiveness is not guaranteed since it depends on courts accepting the legitimacy of the new health technology assessment system*". WANG, Daniel Wei Liang. *op. cit.,* p. 110.

[38] KOMESAR, Neil. *Imperfect alternatives*: choosing institutions in law, economics, and public policy. Chicago: The University of Chicago Press, 1994. p. 128. On the subject, check out also: JORDÃO, Eduardo. *Controle Judicial de uma administração pública complexa*: a experiência estrangeira na adaptação da intensidade do controle. São Paulo: Malheiros Editores; SBDP, 2016.

already incorporated, as well as on clear criteria (which is equivalent to compliance with the condition of relevance); (ii) if the reasons were accessible to society and if there was a public consultation, providing a dialogue with civil society, with federal entities and with the professional body involved with medical procedures (publicity condition); and (iii) whether the review of the decision was made viable (review condition).

According to a study based on public data on the Conitec page[39] conducted by Rosângela Caetano et al.[40] (experts not members of the commission) on the demands submitted between January 1, 2012 and June 30, 2016, the total number of submissions received has increased to 485, 92.2% of which refer to requests for incorporation of new technologies. The majority of demands for technologies are still related to medicines (62.1%), with 52.2% of all medicine submissions coming from internal demands, originating from departments and bodies of the Ministry of Health, from municipalities linked to the Ministry and state and municipal health departments. With regard to external demands, including manufacturers, medical societies, health and teaching and research institutions, bodies of the Judiciary, patient associations and patient or their family members/caregivers, 40.9% were an initiative of the pharmaceutical industry. Comparing the origins of the demands, the internal ones related to medicines were more successful, corresponding to 82.8% of the requests that received a favorable inclusion decision.

It is worth highlighting the conclusion of the research by Pereira *et al.*, in which the health technology assessment criteria considered in 16 countries were identified to support recommendations on the introduction of new technologies in their health systems. The survey evaluated 12 reports prepared by Conitec and concluded that all recommendation reports presented and considered relevant "evidence of efficacy/safety and security of the evaluated technology, economic evaluation and budgetary impact studies and the benefits of incorporating a specific technology" in the health system, as in the other countries studied[41].

A more recent study by Yuba et al.[42] analyzed 199 recommendation reports from Conitec issued between July 2012 and December 2016. The study confirmed

[39] COMISSÃO NACIONAL DE INCORPORAÇÃO DE TECNOLOGIAS NO SISTEMA ÚNICO DE SAÚDE – CONITEC. Disponível em: http://conitec.gov.br.

[40] CAETANO, Rosângela; SILVA, Rondineli Mendes da; PEDRO, Érica Militão; OLIVEIRA, Ione Ayala Gualandi de Oliveira, BIZ, Aline Navega; SANTANA, Pamela. Incorporação de novos medicamentos pela Comissão Nacional de Incorporação de Tecnologias do SUS, 2012 a junho de 2016. *Rev. Ciência e Saúde Coletiva*, v. 22, n. 8, p. 2516, 2017. Available at: https://www.scielo.br/pdf/csc/v22n8/1413-8123-csc-22-08-2513.pdf. https://doi.org/10.1590/1413-81232017228.02002017.

[41] PEREIRA, Viviane Cássia; SALOMON, Flávia Cristina Ribeiro; SOUZA, Andrea Brígida de. Critérios para decisões sobre incorporação de tecnologias em saúde no Brasil e no mundo. *Revista Eletrônica Gestão & Saúde*, v. 6, v. 4, p. 3088, out. 2015. Available at: file:///C:/Users/Samsung/AppData/Local/Temp/3313-Texto%20do%20artigo-5844-1-10-20170920.pdf.

[42] YUBA, Tania Yuka; NOVAES, Hillegonda Maria Dutilh; SOÁREZ, Patrícia Coelho de. Challenges to decision-making processes in the national HTA agency in Brazil: operational procedures, evidence use and Recommendations. *Health Res. Policy and Syst.*, v. 16, n. 1, p. 5, May 2018. https://doi.org/10.1186/s12961-018-0319-8.

that, of this total, most (117) were due to internal demands. Nevertheless, regarding these internal demands, the recommendation to incorporate the new technology was made in 83 reports (70.9%), of which only eight (9.6%) included a complete health technology assessment. The authors considered as complete the evaluation of health technology that met the following criteria: description of the technology and its current uses; safety and effectiveness assessment; cost-effectiveness analysis; financial impact information and systematic review[43]. Among the external demands, the incorporation of the new technology was made in 13 reports (17.3%), but ten of them (76.9%) included that complete assessment. Based on this finding, the study points out differences between internal and external demands in relation to the evidence used in the reports, as well as some non-conformity between the characteristics of the evidence used in the reports and those considered as mandatory in Conitec's internal regulations.

Regarding the recommendation phase of Conitec, the study by Rosângela Caetano et al., which covered 201 reports dated from January 2012 to June 2016, identified that about 70% (139) were subject to public consultation, while 62 included simplified processes[44]. Indeed, the number of public consultations and contributions has increased since the creation of Conitec. By October 2014, 97 public consultations had been carried out and more than 5,000 contributions had been received, more than half not from specialists, but from people who use the SUS, such as patients and family members, with most of the contributions concentrated in the states of the South and Southeast. As of July 2015, the total number of published public consultations was 123, with over 16,000 contributions on the technologies analyzed[45].

In fact, in the period from 2012 to 2016, 18.8% of the preliminary recommendations for not incorporating the medicines initially made by the Commission were modified after the public consultation. The changes were motivated by the presentation of new evidence of safety and effectiveness, new economic and budgetary impact assessments and proposals to reduce prices[46].

From January 2012 to July 2015, 132 new technologies were incorporated into SUS based on the recommendations of Conitec, increasing to 314 by September 2020[47].

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[43] *Id. Ibid.,* p.3.

[44] CAETANO, Rosângela; SILVA, Rondineli Mendes da; PEDRO, Érica Militão; OLIVEIRA, Ione Ayala Gualandi de Oliveira, BIZ, Aline Navega; SANTANA, Pamela. *op. cit.*, p. 2516.

[45] RABELO, Roberta Buarque; PETRAMALE, Clarice Alegre; SILVEIRA, Lívia Costa da; SANTOS, Vania Cristina Canuto; GONÇALVES, Helcio Caixeta. A comissão nacional de incorporação de tecnologias no SUS: um balanço dos primeiros anos de atuação. *Revista Eletrônica Gestão & Saúde*, v. 6, n. 4, p. 3236-3237, out. 2015. Available at: https://periodicos.unb.br/index.php/rgs/article/view/3326/3012.

[46] CAETANO, Rosângela; SILVA, Rondineli Mendes da; PEDRO, Érica Militão; OLIVEIRA, Ione Ayala Gualandi de Oliveira, BIZ, Aline Navega; SANTANA, Pamela. *op. cit.*, p. 2521.

[47] Information extracted from the commission's website. COMISSÃO NACIONAL DE INCORPORAÇÃO DE TECNOLOGIAS NO SISTEMA ÚNICO DE SAÚDE – CONITEC. Disponível em: http://conitec.gov.br. Acesso em: 14 out 2020.

Regarding the deadline for completing the procedure, specifically regarding the submissions related to medicines made from January 2012 to June 2016, of the 301 demands, 287 (95.3%) were concluded, leaving only 14 without a final decision. During this period, the average time for issuing recommendations from the Commission was 134 days[48].

Finally, studies indicate that institutional dialogue between health authorities and public bodies dealing with legal disputes is taking place, albeit incipient. In the period from January 2012 to August 2014, Conitec answered 701 questions regarding the incorporation of technologies at SUS, formulated mainly by the Judiciary and the Public Prosecutor's Office, in addition to making an electronic mail channel available for direct dialogue and more agile with magistrates[49].

Naturally, it cannot be generally stated that Conitec's administrative procedure fulfills the conditions of the accountability for reasonableness theory, which would be an unacceptable idealization of the body. It is only suggested, based on the data above, that the Commission demonstrates that it is acting in an attempt to materialize the provisions of Law no. 12,401/2011, through a procedure based on technical-scientific and transparent foundations. The punctual examination of each demand submitted to it will allow a more secure conclusion. As the study by Yuba et al. concludes, Conitec is a very recent body and has contributed with many advances in the incorporation of technologies, although it still goes through an implementation process[50], reinforcing the need for judicial control of the procedure.

Two final remarks are timely. The medicines intended in the lawsuits of greater economic weight for the health system are, for the most part, not subject to prior submission to the appreciation of Conitec with a view to incorporation. Of the 25 medicines whose lawsuits most consumed Union resources from 2012 to 2014, 20 of them were never submitted to the Commission's evaluation at any time. The five that had their claims submitted did not result in incorporation, for different reasons[51]: From this, it is concluded, on the one hand, that the increase in the judicialization of health has different causes, which cannot be seen only as a result of the technology assessment process established for the country, and, on the other, that a greater use of Commission services by society, industries and public bodies, transferring the discussion about the incorporation of technologies to it, could be a way to help in the reduction of lawsuits.

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[48] CAETANO, Rosângela; SILVA, Rondineli Mendes da; PEDRO, Érica Militão; OLIVEIRA, Ione Ayala Gualandi de Oliveira, BIZ, Aline Navega; SANTANA, Pamela. *op. cit.*, p. 2516.

[49] MINISTÉRIO DA SAÚDE. *Balanço Conitec*: 2012-2014. Brasília-DF: Ministério da Saúde, 2014. p. 37. Disponível em: www.conitec.gov.br. Acesso em: 09 out. 2018.

[50] YUBA, Tania Yuka; NOVAES, Hillegonda Maria Dutilh; SOÁREZ, Patrícia Coelho de. *op. cit.*, p. 8.

[51] For the list and reasons, see: COMISSÃO NACIONAL DE INCORPORAÇÃO DE TECNOLOGIAS NO SISTEMA ÚNICO DE SAÚDE – CONITEC. *Nota de esclarecimento à Interfarma*. Available at: http://conitec.gov.br/images/pdf/Esclarecimentos_Interfarma.pdf. Acesso em: 14 Oct. 2020. p. 7-8.

The second observation concerns the study by Daniel Wang on the effects of the creation of the English NICE in relation to judicialization. The author made some observations[52]. (i) Before the existence of NICE, patients took actions based on the general duty of management to provide comprehensive health care. After NICE, disputes requests were restricted to new and more expensive medicines or tried to prove that the treatment restriction provided for by NICE would not apply to the case, since there was an exception to the signed guidance. (ii) In cases where a NICE guideline that did not recommend the required treatment was challenged, the requests were based on procedural issues, such as the lack of transparency or expertise of the institution's specialists. As these issues are more sophisticated and complex, the demands were filed by pharmaceutical companies or patient associations. (iii) There was a change in the burden of proof. Before NICE, the authorities tried to discharge the burden of proving that there were reasons for not fulfilling the duty of health care in some cases. With the creation of NICE, in situations where there was already an orientation from it, the courts considered that the reasons provided by the administration, in principle, were legitimate and transferred the burden of proof, in most cases, to the plaintiff.

VI. Some parameters of judicial application of accountability for reasonableness

In the light of pragmatism and its attitude committed to reality, and based on the theory of accountability for reasonableness, we address some minimum parameters for the judicial application of the procedural control dealt with.

Regarding the demands for medicines not included in the SUS list or for use outside the scope of the clinical protocols and in which Conitec decided against incorporation, the judges and courts must, as a rule, defer to the technical decision and reject the request.

Using the theory of accountability for reasonableness, it is suggested to the Judiciary, exceptionally, to examine, if any, challenges about the quality of the decision-making procedure, transferring the burden of proof to the plaintiff who, normally, does not it will be an individual, given the complexity of the issue. Cite the example in which it is intended to demonstrate that the restriction of treatment provided by Conitec would not apply to the case. In this hypothesis, it is up to the judge to verify: (i) if the technical reasoning was based on scientific evidence and on the cost-effectiveness assessment, if there was production of evidence compatible with the complexity of the case and if the reasons for the decision were clearly indicated, they are accepted by reasonable people and lead to the conclusion reached by the health authority; (ii) whether the reasons were accessible to society and whether

[52] WANG, Daniel Wei Liang. *op. cit.,* p. 216-220.

public consultation was permitted; and (iii) whether the appeal or the review of the decision was provided. The judicial presentation of the Conitec report can be useful to allow this verification.

Once the conditions are met, the application is rejected. If any of the conditions are not fulfilled, the jurisdictional control is authorized to request the health authorities' opinion on aspects that were not considered or to annul the administrative decision.

In relation to the demands in which there was no appreciation of the incorporation, as in cases of new and more expensive medicines, it is suggested, as a requirement for urgent or definitive judicial protection, the prior summons of Conitec for an administrative procedure to be carried out, although simplified, observing conditions (i), (ii) and (iii) above, within a reasonable time, allowing the scientific community to appreciate the issue. In order to grant the request, a positive conclusion from Conitec is required based on scientific evidence and the cost-effectiveness assessment, since the appreciation within the individual demand must have the possibility of being universalized. Only exceptional cases would allow the judge to decide differently from that conclusion.

Thus, the argumentative burden of the author increases to justify that his situation receives a different treatment in relation to other SUS users. It should be noted that, contrary to what occurs in a significant part of the current judicial demands, the argumentative burden is not limited to the presentation of a prescription or the report of the applicant's doctor stating the need for the medicine and the lack of available and adequate therapeutic substitute for your treatment. It is necessary to present more robust technical foundations that support the request and the assessment of the administrative procedure.

Conclusion

Let's go back to the examples in the Introduction. In a scenario of scarcity of resources, who should decide between increasing health care to prevent the premature death of patients with diseases such as diabetes and providing treatment for rare diseases with expensive medicines that can also compromise the lives of patients? Will it still be possible to universalize health provision, granting it to all the needy, litigants or not? These are issues involving distributive justice considerations that do not have their own *locus* in the Judiciary.

Under this perspective, the proposal of the accountability procedural criteria for reasonableness is a pragmatic strategy that intends to equip the judges with the means to face the problems resulting from excessive judicialization, with the adoption of a contextual, empiricist and attentive to the practical results stance.

This is not intended, it is good to clarify, an abstention by the Judiciary in the implementation of the right to health - the studied procedural control does not reduce it to this role. In comparison with the prevailing model, the proposal has the virtue of requiring that public administration be accountable for its performance and demonstrates the reasons for allocation decisions in pharmaceutical care. In this way, jurisdictional control would prove to be cooperative and tending to de-judicialize the debate.

As is supposed, the proposal is not a panacea for reducing the judicialization of health; it is just another alternative that deserves to be discussed. There is no easy solution to a difficult problem, and different results - perhaps better - will not be achieved if alternative hypotheses are not tested. It was right who said that "insanity is to keep doing the same thing and expect different results"[53].

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[53] Unknown author, although the phrase is attributed, without proof, to Albert Einstein.

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