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THE UTILIZATION OF CLINICAL PROTOCOLS AND THERAPEUTIC GUIDELINES AND THE RATIONALIZATION OF JUDICIALIZATION FOR THE RIGHT TO HEALTH

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ABSTRACT

The article analyzes the adoption of the Clinical Protocols and Therapeutic Guidelines (CPTGs) as an objective measure to be used by the courts in cases where the purpose is to offer positive benefits in terms of realization of the right to health. Such a benchmark can assist the judge in the task of deciding the legal situation of medication supplies, guaranteeing the prevalence of rationality as outlined in the formulation of related public policies and, consequently, the use of technical-political arguments in the distribution of healthcare goods and resources. However, this is not an absolute parameter, and the content of the CPTGs may be questioned, even judicially. With this, judicial action is used as an instrument of democratization and social control among public choices, which can impact health policy itself.

Keywords
Clinical Protocol; Judicialization; Right to Health; Therapeutic Guidelines.

SUMMARY

CONSTITUTIONAL, ADMINISTRATIVE AND CIVIL PROCEDURE. INTERLOCUTORY APPEAL. ORDINARY ACTION. INJUNCTIVE RELIEF. SUPPLY OF MEDICATION. NO RECOMMENDATION BY THE MINISTRY OF HEALTH FOR TREATMENT OF ILLNESS AFFECTING THE APPELLANT. IMPOSSIBILITY. LACK OF INDISPUTABLE PROOF OF VERIFICATION OF ALLEGATIONS. NEED FOR DISCOVERY/EVIDENCE. NOT MEETING THE REQUIREMENTS OF ART. 273 OF CPC. AGTR DENIED.1. 1. The appeal decision, issued via ordinary action, dismissed the application for injunctive relief, considering that there are various technical manifestations about the inappropriateness of the medication requested by the appellant for the disease that affects the appellant, including its adverse effects, explaining the reasons that led to the SUS not recommending the use of the drug for the treatment of disseminated melanoma. 2. The allegations presented in the case have not been able to invalidate the reasoning of the decision, in the sense that the requested medication (Ipilimumab) is not recommended by the Ministry of Health for patients with disseminated melanoma, which seems to be the case of the aggravating disease. 3. Demonstrated non-indication of the medication for the disease that affects the appellant, without any presentation of any argument against this contraindication, without verification of the verisimilitude of its allegations, preventing the granting of the injunctive relief. 4. If the indication of the medication requested for the disease affecting the appellant has not been proven, and a protracted delay is necessary, the application for injunctive relief must be rejected. 5. It is not for the courts to decide whether or not to administer a particular medication to the patient, since such a decision is of an eminently medical nature, and it is not incumbent upon the state judge to order State entities to provide a certain medication to the patient when the Ministry of Health advises against its administration 6. Appeal denied. (CASE NUMBER: 08002575420164050000, AG/SE, FEDERAL JUDGE MANOEL ERHARDT, 1st CHAMBER, JUDGMENT: 03/14/2016).

Introduction

The phenomenon of judicialization of social rights, during close to two decades, has led legal practitioners, social actors and the Public Administration itself to adapt the classic model of intersubjective rights for conflict resolution, generating a clear expansion of debates related to its implementation.

The 1988 Brazilian Constitution (CF/88) has expressly outlined the importance of society's participation in the construction of health policy[1], the creation of the system and the formation of the legal substrate of the so-called "participation of society in the production of Health Law"[2]. However, the concept of public

[1]For example, we can cite article 194, sole paragraph, item VII, which lists the democratic and decentralized character of the administration of social security subsystems, as well as article 198, item III, which establishes community participation as one of the guidelines of the Brazilian National Health System. BRASIL. *Constituição da República Federativa do Brasil de 1988*. Available at: <http://www.planalto.gov.br/ccivil_03/constituicao/constituicaocompilado.htm>. Date accessed: 31 May 2107.

[2]This expression was coined by *Fernando Aith*. AITH, Fernando. *Curso de direito sanitário*: a proteção do direito à saúde no Brasil. 1. ed. São Paulo: QuartierLatin, 2007. p. 155.

policy – understood as a program of governmental action constituted by a series of acts and cases that aim at execution of previously defined goals, united by a common purpose[3] – requires planning and rationality that judicialization cannot always offer.

This duality, evidenced after the promulgation of CF/88, when there was an increase in the range of social rights previously provided for in constitutional texts, placed demands of providing benefits on the Judiciary, turning this Power into an important *locus* for disputes of a distributive nature. The judicial action turned into a channel of popular participation, capable of correcting or readjusting the course of concrete policies. A series of questions has arisen from this situation, however, regarding limits of actuation of the judicial sphere, within the cycle of formation and implementation of public policies.

Beyond the issue of the limits of the Judiciary's action, there are great divergences regarding the range of the protection offered by the right to health in CF/88, especially in terms of content immediately demanded by the expression "full service care". Consequently, judicial actions at times interfere in the planning outlined by public administrators, in practice affecting the guarantee of right to health of the community.

Therefore, establishment of objective parameters for resolution of conflicts that involve the realization of public policies, frequently resulting from failures or insufficiencies in such policies themselves, is necessary. Hence, the action of law practitioners and of civil society is directed at demands, be they individual or collective, to not deny right to health, and to establish concrete parameters for administrative decision-making[4].

I. The use of clinical protocols as an objective parameter in the judicialization of medications

Although still incipient, there is increased concern by the Judiciary in having clear and objective parameters in the judicial concession of medications[5]. It is exactly in this context that we can place Appeal 08002575420164050000/SE, heard in the

[3]BUCCI, Maria Paula Dallari. O conceito de política pública em direito. In: BUCCI, Maria Paula Dallari (Org.). *Políticas públicas*: reflexões sobre o conceito jurídico. 1. ed. São Paulo: Saraiva, 2006. p. 39.

[4]Regarding the particularities of the judicialization of health and the attempt to create objective parameters, we recommend an interesting article by *Sueli Gandolfi Dallari*, who summarizes the entire problem. DALLARI, Sueli. Aspectos particulares da chamada judicialização da saúde. *Revista de Direito Sanitário*, Brasil, v. 14, n. 1, p. 77-81, June. 2013. Available at: <http://www.revistas.usp.br/rdisan/article/view/56624>. Date accessed: 31 May 2017. http://dx.doi.org/10.11606/issn.2316-9044.v14i1p77-81.

[5]Judge Gilmar Mendes, in Regimental Appeal in the Suspension of Injunctive Relief 175/CE, following Public Hearing n. 4, established a series of objective parameters for the concession of medications, in a whose vote that is worth reading. SUPREMO TRIBUNAL FEDERAL. *Agravo regimental na suspensão de tutela antecipada 175/CE*. Rel. Min. Gilmar Mendes. Tribunal Pleno, data do julgamento: 17/03/2010.

1st Chamber of Federal Regional Court of the 5th Region, by federal appellate judge Manoel Erhardt[6].

The appeal was interposed against the first decision, which refused a request for preventive injunction for the medication ipilimumab, as use of this product for treatment of disseminated melanoma (the disease suffered by the petitioner) was previously advised against.

Federal appellate judge Manoel Erhardt maintained the decision, making it clear in the summary of judgment that:

> 5. It is not the role of the Judiciary Power to decide on the administration or non-administration of a determined medication to a patient, such a decision being of eminently medical character, but it is also not the role of the State-judge to determine that the state entities supply a certain medication to the patient when the Ministry of Health advises against its usage[7].

As can be seen, the referred-to decision applies the impossibility of supplying a medication expressly advised against by competent authorities for a determined disease as an objective parameter, reinforcing the importance, in the protection of the right to health, of technical decisions regularly made by the organs for this purpose.

Law n. 8.080/1990[8], altered by Law n. 12.401/2011[9], establishes the observance of Clinical Protocols and Therapeutic Guidelines (CPTGs) as one of the objective parameters for the supply of medications by the Brazilian National Public Health System (known in Brazil as *SUS*) – as in article 19-M, line I, which restricts the content of "full therapeutic assistance."

Within the scope of incorporation, exclusion or alteration of new technologies in SUS, as well as in the creation and alteration of the CPTGs, article 19-Q of Law n. 8.080/1990 establishes that the National Commission for Incorporation of Technologies in SUS (known in Brazil as *Conitec*) is responsible for technically assisting the Ministry of Health in decision-making.

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[6]TRIBUNAL REGIONAL FEDERAL DA 5ª REGIÃO. *Agravo de Instrumento 08002575420164050000/SE*, Relator Desembargador Federal Manoel Erhardt, 1ª Turma, data do julgamento: 14/03/2016.

[7]Id. Ibid.

[8]BRASIL. *Federal Law. 8.080, of September 19, 1990*. Provides for the conditions for the promotion, protection and recovery of health, the organization and operation of the corresponding services and other measures. Available at: <http://www.planalto.gov.br/ccivil_03/leis/L8080.htm>. Date accessed: 31 May 2017.

[9]BRASIL. *Federal Law 12.401, of April 28, 2011.* Alters Law 8.080, of September 19, 1990, which provides for therapeutic assistance and the incorporation of technology in health within the scope of the Brazilian National Public Health System - SUS. Available at: <http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/lei/l12401.htm>. Date accessed: 31 May 2017.

The action of this Commission is based on two basic premises, expressly provided for in the 2nd paragraph of the above-mentioned article 19-Q: on one hand, scientific analysis based on evidence, seeking to determine the validity, accuracy, effectiveness and safety of the medication, product or procedure (line I); and, on the other, the evaluation of the relationship between cost and the technology's effectiveness, with assets that have already been incorporated into the public health system (line II) serving as the paradigm.

In the case of disseminated melanoma, the prohibition against the medication found in the court is related to CPTGs in oncology, with the absence of concrete evidence of the "global benefit in terms of survival" serving as the foundation[10].

Herein can be found the main the feature in adopting the parameter: the prohibition of the medication's use based on the global benefit in terms of survival, which considers not only the effectiveness of the medication, but also its cost-benefit.

In one of the studies used by Conitec to justify the non-usage of ipilimumab, researchers noticed that the global survival of the patients using that medication, along with decarbazina, (recommended by clinical protocols) was 11.2 months, while the global survival of patients using decarbazina along with a placebo was 9.1 months.[11]

Additionally, Technical Note n. 236/2013 of the Evaluation Center for Health Technologies, solicited in another case, noted a striking difference in cost of medications: while treatment with decarbazina costs R$5,518.80, while the cost of ipilimumab, in the specific case evaluated by the above-mentioned technical note, would be R$254,402.76[12].

The use of economic arguments in a broad sense (including the cost-benefit relationship) to justify the non-supply of medications is not usually accepted by courts, although they are considered by administrators in formulation of public policy[13].

In any case, it is certain that the use of clinical protocols as a parameter for judicialization does not remove the possibility of the magistrate, according to evidence presented in the proceedings and given the specificities of the specific case, to conclude that there is a need to supply a medication not provided for by public

[10]BRASIL. Ministério da Saúde. Secretaria de Atenção à Saúde. *Protocolos clínicos e diretrizes terapêuticas em Oncologia*. Brasília-DF: Ministério da Saúde, 2014. p. 221.

[11]ROBERT, Caroline; THOMAS, Luc, BONDARENKO, Igor et al. Ipilimumab plus Dacarbazine for Previously Untreated Metastatic Melanoma. *The New England Journal of Medication*, v. 326, n. 26, p. 2520, 2011. Available at: <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1104621>. Date accessed: 5 Sept. 2016.

[12]NÚCLEO DE AVALIAÇÃO DE TECNOLOGIAS EM SAÚDE. *Nota Técnica 236/2013*. Available at: <http://www.cnj.jus.br/files/conteudo/destaques/arquivo/2015/04/7013f6a5289dce21248b15af6931b120.pdf>. Date accessed: 4 Sept. 2016.

[13]The fact that economic arguments (for example, the cost of a particular medication) are part of the process of formulating a public policy does not mean that they have priority over other arguments, such as in the case of rare or neglected diseases, where there is obligation of State action.

policy[14],[15]. It is noted that, in examining the summary itself, that the appellate judge makes it clear that the party did not present arguments contrary to the advisement against the medication, or eventual side effects, which confirms the possibility of probative production in this sense.

This shows that the guidelines in the clinical protocols are not absolute; beforehand they may shed light on points of contention related to the facts of the demand and serve as parameters for the conflict's resolution – even if this creates situations that are not outlined in health policies' adopted instruments, but that should be taken into consideration.

II. Some impacts of the use of CPTGs as an objective parameter

The use of clinical protocols as an objective parameter to guide decisions in public health policies opens up the possibility of judicial questioning of policy contents, thereby making the very criteria within them used for the determination of prohibitions and instructions, subject to a greater social control.

The expanded interpretation of the content of the right to health – according to which the State must supply any medication judicially ruled, even in conflict with established public policy – therefore makes the role of the National List of Essential Medications (known in Brazil as *Rename)* and of the CTPGs relative. Such programs are the result of political choices through which concrete goals are established – in accordance with the means and resources made available to the public power – to achieve, progressively, the goal of universalization of access to medication. In this sense, they provide rationality to public health policies, even if it their contents may be questioned.

If there is no agreement as to the limits of the action of the Judiciary in control of public policies, the fact is that there are constitutional objective parameters[16], as well as the criteria embodied in the protocols, which have to be respected

[14] In this sense, we cite the Appellant's Appeal 08073709320154050000/SE, from the report of the federal judge himself Manoel Erhardt, in which medication is not provided for in public health policy because of the lack of effectiveness, in this case of five different chemotherapy programs. TRIBUNAL REGIONAL FEDERAL DA 5ª REGIÃO. *Agravo de Instrumento 08073709320154050000/SE*, Relator Desembargador Federal Manoel Erhardt, 1ª Turma, data do julgamento: 20/02/2016.

[15] According to Statement 61 of the II Jornada of Health Law of National Council of Justice, which amends Statement 4 of I Jornada: "Clinical Protocols and Therapeutic Guidelines (PCDT) are organizing elements of pharmaceutical supply, inputs and procedures, and are not limitations. Therefore, in the specific case, when all the therapeutic alternatives foreseen in the respective PCDT have already been exhausted or are unfeasible for the clinical condition of the SUS patient, according to the principle of art. 198, II of the CF, the courts can determine the supply, by the Brazilian National Public Health System, of the drug, input or procedure can be outside protocol." CONSELHO NACIONAL DE JUSTIÇA. *II Jornada de direito da saúde*. Available at: <http://www.cnj.jus.br/files/conteudo/destaques/arquivo/2015/05/96b5b10aec7e5954fcc1978473e4cd80.pdf>. Date accessed: 31 May 2017.

[16] DUARTE, Clarice Seixas. O duplo regime jurídico do direito à saúde na CF/88: direito fundamental de caráter social e direito público subjetivo. *Pensar*: revista de ciências jurídicas. Fortaleza, v. 17, n. 2, p. 437, 2012. Available at: <http://ojs.unifor.br/index.php/rpen/article/view/2311>. Date accessed: 5 Sept. 2016.

by the administrator and by the legislator, and that serve as factors in the interpretation of concrete demands brought by the Judiciary in this field. It is the case of the fundamental objectives for reducing social inequalities provided for in the 3rd article of CF/88; of the explicit administrative principles (article 37); of the priority of preventive health actions and of the necessary participation of society into the *SUS* (articles 198, II and III)[17]; among others.

Regarding this point, the Public Prosecutor and the Public Defender, which have become important actors in guaranteeing the diffuse and collective interests related to health – especially regarding vulnerable groups, such as elders, children, teenagers and indigenous people -, acquire a function even more relevant for the guarantee of the right to health, controlling its own public choices, especially from the instruments of collective guardianship.

Addressing the possibility of action of the Public Prosecutor in judicialization of public policies, *Hugo Nigro Mazzilli* states:

> The public civil action still serves for the Public Prosecutor to question public policies, when in the exercise of its functions in efforts so that the Public Powers and the services of public relevance observe the rights guaranteed in the Constitution. Certainly, the Public Prosecutor cannot ask the Judiciary Power to administrate in place of the administrator; however, it can judicially force application of principles of the Administration, which may be overlooked and, with that, restore legality. The Public Prosecutor may also not be moved by political-partisan criteria; however, its action has undeniable political character in the technical sense of the expression, meaning that the ministerial institution can legitimately question government acts that, among other hypotheses, harm the principle of legality, create corruption or abuse of power, or diverge from the principles of morality, efficiency and reasonability, among others, that must inform the Administration[18].

In fact, this model of control allows for correction of one of the main critiques of individual judicialization of healthcare: that supplying technologies not offered by SUS to those who appeal to the Judiciary would generate a situation of inequity in relation to those who submit to the choices made by the administrator/legislator through public policies. From the moment that public choice itself is judicially disputed in the collective scope, the decision will bring a response that is applicable on a large scale, driving eventual positive effects of demand by

[17]BRASIL. *Constituição da República Federativa do Brasil de 1988*, cit.
[18]MAZZILLI, Hugo Nigro. *A defesa dos interesses difusos em juízo*: meio ambiente, consumidor, patrimônio cultural, patrimônio público e outros interesses. 26. ed. rev., ampl. e atual. São Paulo: Saraiva, 2013. p. 141.

extending it to everyone who is in a similar situation (making the provision subject to judicial discussion).

From another perspective, another consequence of the adoption of CPTGs as an objective parameter is the deepening of the debate on use of public resources by the State, the cost-benefit of technologies and the appropriateness of the administrator's choices, avoiding that which *Canotilho* calls "fuzzy methodology", that is, one that does not take into consideration the complex factors related to the right being implemented[19].

As the WHO *World Health Report of 2010* warned, "Pooled funds will never be able to cover 100% of the population for 100% of the costs and 100% of needed services. Countries will still have to make hard choices about how best to use these funds."[20]

With the adoption of the CPTGs as a parameter – as in the analyzed decision – and with policy choices clarified by means of evidence–based technical justifications, there is greater security both for the administrator, who has the possibility of planning health policy, and for the social actors, who will have an objective, a technical reference that can be questioned (even judicially), and whose results can impact the (re)formulation of public health policy itself.

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[19]CANOTILHO, José Joaquim Gomes. *Estudos sobre direitos fundamentais*. 1. ed. Coimbra: Coimbra Ed., 2004. p. 100-101.

[20]ORGANIZAÇÃO MUNDIAL DA SAÚDE. *Relatório Mundial da Saúde 2010*: financiamento dos sistemas de saúde: o caminho para a cobertura universal, 2010. p. 2. Available at: <http://www.who.int/whr/2010/whr10_pt.pdf>. Date accessed: 5 Sept. 2016.

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