Tiago Lopes Coelho<sup>1</sup>

Felipe Ferré<sup>II,III</sup>

Orozimbo Henriques Campos Neto<sup>1</sup>

Francisco de Assis Acurcio

Mariângela Leal Cherchiglia<sup>IV</sup>

Eli Iola Gurgel Andrade<sup>IV</sup>

Programa de Pós-Graduação em Saúde Pública. Faculdade de Medicina. Universidade Federal de Minas Gerais. Belo Horizonte, MG, Brasil

- Programa de Pós-Graduação em Bioinformática. Universidade Federal de Minas Gerais. Belo Horizonte, MG, Brasil
- Departamento de Farmácia Social. Faculdade de Farmácia. Universidade Federal de Minas Gerais. Belo Horizonte, MG, Brasil
- <sup>IV</sup> Departamento de Medicina Preventiva e Social. Faculdade de Medicina. Universidade Federal de Minas Gerais. Belo Horizonte, MG, Brasil

#### Correspondence:

Tiago Lopes Coelho Rua Jornalista Juracy Manoel, 16 apto. 101 Silveira 31140-370 Belo Horizonte, MG, Brasil E-mail: tiago.lopesc@yahoo.com.br

Received: 12/5/2013 Approved: 4/8/2014

Article available from: www.scielo.br/rsp

# Legal and health variations in drug litigation injunctions granted in Minas Gerais

## Variáveis jurídicas e de saúde no deferimento de liminares por medicamentos em Minas Gerais

### ABSTRACT

**OBJECTIVE:** To investigate the factors related to the granting of preliminary court orders [injunctions] in drug litigations.

**METHODS:** A retrospective descriptive study of drug lawsuits in the State of Minas Gerais, Southeastern Brazil, was conducted from October 1999 to 2009. The database consists of 6,112 lawsuits, out of which 6,044 had motions for injunctions and 5,167 included the requisition of drugs. Those with more than one beneficiary were excluded, which totaled 5,072 examined suits. The variables for complete, partial, and suppressed motions were treated as dependent and assessed in relation to those that were independent – lawsuits (year, type, legal representation, defendant, court in which it was filed, adjudication time), drugs (level five of the anatomical therapeutic chemical classification), and diseases (chapter of the International Classification of Diseases). Statistical analyses were performed using the Chi-square test.

**RESULTS:** Out of the 5,072 lawsuits with injunctions, 4,184 (82.5%) had the injunctions granted. Granting varied from 95.8% of the total lawsuits in 2004 to 76.9% in 2008. Where there was legal representation, granting exceeded 80.0% and in lawsuits without representation, it did not exceed 66.9%. In public civil actions (89.1%), granting was higher relative to ordinary lawsuits (82.8%) and injunctions (80.1%). Federal courts granted only 68.6% of the injunctions, while the state courts granted 84.8%. Diseases of the digestive system and neoplasms received up to 87.0% in granting, while diseases of the nervous system, mental and behavioral disorders, and diseases of the skin and subcutaneous tissue received granting below 78.6% and showed a high proportion of suspended injunctions (10.9%). Injunctions involving paroxetine, somatropin, and ferrous sulfate drugs were all granted, while less than 54.0% of those involving escitalopram, sodium diclofenac, and nortriptyline were granted.

**CONCLUSIONS:** There are significant differences in the granting of injunctions, depending on the procedural and clinical variances. Important trends in the pattern of judicial action were observed, particularly, in the reduced granting [of injunctions] over the period.

DESCRIPTORS: Pharmaceutical Preparations, supply & distribution. Pharmaceutical Services, legislation & jurisprudence. Judicial Decisions. Patient Advocacy.

#### RESUMO

**OBJETIVO:** Investigar fatores relacionados ao deferimento de liminares por medicamentos.

**MÉTODOS:** Estudo descritivo retrospectivo dos processos judiciais por medicamentos em Minas Gerais, de outubro de 1999 a 2009. A base de dados, constituída por 6.112 ações judiciais, teve 6.044 com pedido de liminar e 5.167 com requisição de medicamentos. Foram excluídas as ações que continham mais de um beneficiário, totalizando 5.072 ações analisadas. As variáveis deferimento total, parcial e suspensão foram tratadas como dependentes e avaliadas em relação às independentes: processo (ano, tipo de ação, representação judicial, réu, justiça de ajuizamento, tempo de decisão judicial), medicamentos (nível 5 da *Anatomical Therapeutic Chemical*) e doença (por capítulo da Classificação Internacional de Doenças. As análises estatísticas foram realizadas pelo teste Qui-quadrado.

**RESULTADOS:** Dentre as 5.072 ações com liminares, 4.184 (82,5%) foram deferidas. O deferimento variou de 95,8% em 2004 a 76,9% em 2008. Quando houve representação judicial, o deferimento superou 80,0%; nas ações sem representação, não ultrapassou 66,9%. Nas ações civis públicas (89,1%) o deferimento foi superior ao verificado em ações ordinárias (82,8%) e nos mandados de segurança (80,1%). A Justiça Federal deferiu apenas 68,6% das liminares, contra 84,8% da Justiça Estadual. Doenças do aparelho digestivo e neoplasias apresentaram deferimento acima de 87,0%, enquanto doenças do sistema nervoso, transtornos mentais e comportamentais e doenças da pele e do tecido celular subcutâneo tiveram deferimento inferior a 78,6% e apresentaram elevada proporção de liminares suspensas (10,9%). Os fármacos paroxetina, somatropina e sulfato ferroso tiveram 100% de deferimento. Escitalopram, diclofenaco de sódio e nortriptilina obtiveram deferimento inferior a 54,0%.

**CONCLUSÕES:** Há diferença significativa no deferimento das liminares a partir de variáveis processuais e clínicas. Tendências importantes no padrão de atuação judicial foram observadas, particularmente a redução do deferimento ao longo do período.

DESCRITORES: Preparações Farmacêuticas, provisão & distribuição. Assistência Farmacêutica, legislação & jurisprudência. Decisões Judiciais. Defesa do Paciente.

#### INTRODUCTION

Defining the judiciary's role is one of the greatest challenges of democratic societies. It is a difficult and controversial task to identify the limits of judicial activity, especially in its control over political activity.<sup>2,5,7</sup> This task has become increasingly more intricate due to the proactiveness of the judiciary in guaranteeing the efficacy of social rights. This new position has expanded the horizons of judicial action, reconfigured relations between the different branches of government, and destabilized the structures that once served to steer the checks and balances system in the judiciary.<sup>12,a</sup>

Judicial proactivity in Brazil has gained prominence in the healthcare industry. Over 240,000 lawsuits for health benefits were in progress in 2011, which contributes to the exponential growth of expenditure and indicates that the judiciary is determined to play a prominent role in the process of guaranteeing the right to health.

Petitioning for medicines via the judiciary represents the principal means by which the constitutional right to health is exercised. Consequently, this method presents itself as one of the factors that can influence the interpretation of the National Policy on Drugs. The change in the performance of pharmaceutical assistance for the implementation of this policy was recently directed to the expanding of the concept of essential

<sup>&</sup>lt;sup>a</sup> Cappelletti M. Juízes legisladores? Porto Alegre: Fabris; 1993.

drugs, culminating in the inclusion of several drugs in the essential drugs list in force (RENAME – 2013) in order to universalize the availability of drugs according to growing demands.<sup>b,c,d</sup>

Because of this major role, several issues arise, which control the effects of judicial intervention. While the judiciary is appointed as the last resort for those who do not receive the necessary health care guaranteed by the State, judicial action often has negative effects on the development of the health system (e.g., irrational spending) and may eventually harm patients seeking legal protection (e.g., cases of lawsuits that determine the delivery of multiple drugs whose combined use results in drug interactions, causing adverse reactions and endangering patients' health).<sup>3,4,9,13</sup>

Injunction motions are among the key aspects of this phenomenon. Under Article 273 of the Code of Civil Procedure, this procedural tool seeks to anticipate the motion made in court, where delaying the verdict can jeopardize the right being claimed. Thus, the granting of injunction does not require a definitive proof of the existence of a right, but requires the plaintiff to prove that the delay in deciding endangers the right being claimed (*periculum in mora*).

In case of legalization of health, this application is very common, and most of the suits receive favorable decision. The high rate of granting has been problematized in several studies and concludes by questioning the limits to use such an instrument in suits, which seeks access to medicines.<sup>6,8</sup> It is important to acknowledge that injunctions may be essential to ensure a patient's right to an emergency situation. However, some features of this procedural tool – urgency, plausibility of the claims, and provisional decision – can be decisive in the disorganization of the health system and increasing the use of drugs without sufficiently documented scientific evidence.<sup>3</sup>

Despite emphasizing the injunction motions in investigations dealing with the legalization of health, especially with regard to the developments in drug policy management and to promote rational use of granting, one cannot find studies with a specific approach on the use of this procedural tool [injunction] in drug suits.<sup>e</sup> This absence precludes an understanding of the fundamentals that guide the magistrate in the decisionmaking process of the injunctions and prevents him/ her from reaching further clarity about the balanced use of such an instrument.

This study aims to investigate the factors related to granted injunctions in the health care industry.

#### METHODS

A retrospective descriptive study based on the data obtained from administrative files related to lawsuits for drugs in the state of Minas Gerais, Southeastern Brazil, was conducted from 1999 to 2009 October.

Data were collected from the personnel of the State Secretariat of Health of Minas Gerais, between February and November 2009, by researchers of the Grupo de Pesquisa em Economia da Saúde (GPES -Health Economics Research Group) of Universidade Federal de Minas Gerais (UFMG). A pretested questionnaire, on completed or ongoing court proceedings, was presented to the administrative personnel. The information obtained was stored in a database by using Microsoft Office Access 2007®, including 6,112 lawsuits in total. Among these, 6,044 had motions for injunction filed and 5,167 were petitions for drugs. Cases with more than one beneficiary were excluded because of the difficulty to establish unambiguous association in those with more than one patient, and consequently, several drugs. During screening, 5,072 cases (83.0% in total) were selected with reference to 6,237 diseases and 9,932 drugs.

Associations for the descriptive analysis were established using database management system (DBMS) MySQL 5.1.41, and the rest of the primary analyses were performed using Microsoft Office Excel 2007<sup>®</sup>.

The dichotomous variables related to total, partial, and suppressed injunctions were treated as dependent. Due to the unknown distribution of each variable, Pearson's Chi-squared test was performed with Yates continuity correction (p < 0.05), reporting only the statistically significant variables. Independent variables were described in terms of the distribution of relative and absolute frequency. Independent variables were the beneficiary (gender, legal representative), case (year, type of lawsuit, legal representation, defendant, type of court filed with, time of adjudication, the district of prosecution, judiciary department), drugs by chemical substance pursuant to level five of the Anatomical Therapeutic Chemical (ATC), disease (according

<sup>&</sup>lt;sup>b</sup> Ministério da Saúde. Secretaria de Políticas de Saúde. Departamento de Atenção Básica. Política nacional de medicamentos. Brasília (DF); 2001. <sup>c</sup> Decreto nº 7.508, de 28 de junho de 2011. Regulamenta a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a organização do Sistema Único de Saúde - SUS, o planejamento da saúde, a assistência à saúde e a articulação interfederativa, e dá outras providências. *Diario Oficial Uniao.* 29 Jun 2011:1.

<sup>&</sup>lt;sup>d</sup> Ministério da Saúde. Portaria nº 533, de 28 de março de 2012. Estabelece o elenco de medicamentos e insumos da Relação Nacional de Medicamentos Essenciais (RENAME) no âmbito do Sistema Único de Saúde (SUS). *Diario Oficial Uniao*. 29 Mar 2012.

<sup>&</sup>lt;sup>e</sup> Torres IDC. Judicialização do acesso a medicamentos no Brasil: uma revisão sistemática [MA dissertation]. Salvador: Universidade Federal da Bahia; 2013.

to chapter of the International Classification of Diseases – ICD-10), and medical document (prescription and/or medical report). Statistical analyses were performed using R project version 2.14.1 and OpenEpi version 3.01 software.

Ethical aspects and confidentiality of the study were guaranteed. This study was a part of the "Impacto das ações judiciais na política nacional de assistência farmacêutica: gestão da clínica e medicalização da justiça" (Impact of lawsuits on the national pharmaceutical care policy: clinical management and the medicalization of justice),<sup>f</sup> and the "Avaliação de cobertura, acesso e qualidade da assistência farmacêutica, garantidos pelas decisões judiciais em Minas Gerais" (Evaluation of the coverage, access, and quality of pharmaceutical care, guaranteed by the decisions of the courts in the State of Minas Gerais). The project was approved by the Ethics Committee of *Universidade Federal de Minas Gerais* (Opinion of the ETIC 292/08, dated September 24, 2008).

#### RESULTS

Table 1 shows the distribution of the proportion of injunction motions granted in the specified course of time, according to the procedural variables, judicial representation, type of claim, defendant, and court in which the claim was filed. Out of the 5,072 injunction motions selected, 4,052 (79.9%) were fully granted and 132 (2.6%) were partially granted, totaling 4,184 (82.5%). By excluding the initial years (1999-2002) because of less occurrence, the granting of injunctions varied from 95.8% in 2004 to 76.9% in 2008, considering that the defendant could seek to reverse the decision by filing an appeal with the court thereafter. Table 1 shows that by 2003, the appeals did not result in suspension and in 2007 - the year with the highest number of suspended injunctions - approximately 10.0% of the granted motions in the first instance were reversed by the Court. Although, the data analyzed show the number of suspended injunctions, but do not indicate the number of appeals filed thereafter.

Table 2 shows the proportion of granted injunctions in cases with and without representation by legal counsel. All cases without legal representation were found in ordinary lawsuits, representing 14.4% present in this type of lawsuit. The ability to appeal the judiciary independent of having an attorney is an exception in the Brazilian legal system, established in Article 9 of Law 9,099/95 as well as in Article 10 of Law 10,259/2001. In cases where legal representation was involved, the proportion of acceptance was above 80.0%, more than

the lawsuits filed without legal representation, which did not exceed 66.9% of the approvals. Despite lower acceptance rates, injunctions petitioned without the aid of a legal counsel, where they were granted, were in most cases confirmed after appeal. The cases in which there was legal representation, petitions made by public defenders achieved greater success (86.9% granted) and the acceptance rate of the injunctions requested by the center for legal assistance (84.6%) exceeded the motions moved by private attorneys (82.7%). The granting of injunctions filed in public civil actions (89.1%) was superior to those recorded for ordinary lawsuits (82.8%) and writs of mandamus (80.1%). However, the suspension of the injunctions in public civil action was 3.1% higher than that in ordinary actions, and 6.4% higher when compared with the writs of mandamus. The Federal Courts granted only 68.6% of the injunctions, whereas the State Courts granted 84.8%.

Table 3 shows the time required for a decision on a motion for injunction in the first instance. Out of 5,072 injunction motions, 48.2% were decided within a week and 70.0% within 30 days. The time between the date of the motion and decision interfered in the results of the injunction with proportionately greater acceptance for motions granted in very short period of time.

Although there were 6,237 diagnoses in total, covering 450 different diseases, most cases (85.9%) reported only one diagnosis, varying from one to twelve. As seen in Table 4, digestive system diseases and neoplasms showed a high rate of occurrence (over 87.0%) and diseases of the nervous system, mental and behavioral disorders, and diseases of the skin and subcutaneous tissue received granting below 78.6% and also showed a high proportion of suspended injunctions (10.9%). However, there was a similar proportion of suspended injunctions in the diseases related to blood and blood-forming organs as well as in some immune disorders (n = 48) that obtained 98.0% of acceptance. The diseases in Chapter XX of the ICD-10, referring to the external causes of morbidity and mortality (V01 to Y98), were not claimed. There was no significant difference between the approval process of cases involving just one disease and those with multiple illnesses.

The comparison of acceptance proportion from the area of filing (capital or inland) indicated greater acceptance in the counties of the capital. A difference in acceptance rates was also observed in different judicial sectors.<sup>g</sup> The analysis from the judicial sectors showed 20.8% variation among sectors, with Uberlândia recording the lowest percentage of acceptance (72.6%

<sup>&</sup>lt;sup>f</sup> Ministério da Ciência e Tecnologia; Conselho Nacional de Desenvolvimento Científico e Tecnológico; Ministério da Saúde. Edital MCT/ CNPq/MS-SCTIE-DECIT/CT-Saúde 33/2007. Brasília (DF); 2007.

<sup>&</sup>lt;sup>g</sup> O setor judiciário é uma divisão administrativa que consiste no agrupamento de comarcas de uma mesma região. Tribunal de Justiça de Minas Gerais [cited 2014 Mar 30]. Available from: http://tj-mg.justica.inf.br

Veer	Motion	Gra	nted	Partially	granted	То	tal	Suspe	ended
Year	N	n	%	n	%	n	%	n	%
1999ª	2	2	100.0	0	0.0	2	100.0	0	0.0
2000	8	6	75.0	0	0.0	6	75.0	0	0.0
2001	3	3	100.0	0	0.0	3	100.0	0	0.0
2002	6	5	83.3	0	0.0	5	83.3	0	0.0
2003	49	41	83.7	0	0.0	41	83.7	0	0.0
2004	121	115	95.0	1	0.8	116	95.8	4	3.4
2005	368	337	91.6	5	1.4	342	93.0	9	2.6
2006	770	669	86.9	16	2.1	685	89.0	39	5.7
2007	1,231	987	80.2	51	4.1	1,038	84.3	97	9.3
2008	1,534	1,138	74.2	41	2.7	1,179	76.9	100	8.5
2009 <sup>b</sup>	980	749	76.4	18	1.8	767	78.2	20	2.6
Total	5,072	4,052	79.9	132	2.6	4,184	82.5	271	5.3

Table 1. Annual distribution of granted injunctions. Minas Gerais, Southeastern Brazil, 1999-2009.

<sup>a</sup> October to December.

<sup>b</sup> January to October.

of 489 injunctions) and Divinópolis with the highest percentage of acceptance (93.4% of 274 injunctions).

Only one drug had been suits filed against in 68.9% of motions, while in 96.1% of cases, up to eight were filed suit against. A single case had up to 27 drugs filed suit against. Ultimately, 9,932 medicines representing 699 different drugs were recorded. The medicines with the highest numbers of lawsuits filed against were adalimumab (362, 83.7% of acceptance), etanercept (289, 77.2% of acceptance), and *suporte nutricional* (nutritional support – 237, 77.2% of acceptance). The drugs paroxetine (31), somatropin (26), and ferrous sulfate (19) received 100% acceptance. Escitalopram (28),

sodium diclofenac (23), and nortriptyline (18) received less than 54.0% of the suits accepted. The anatomical group P (antiparasitic products, insecticides, and repellents) had the lowest rate of acceptance (71.4%), but in none of the cases were the injunctions for this group of drugs suspended. The anatomical group H (systemic hormonal preparations, excluding sexual hormones and insulin) was not surpassed and had 85.7% of injunction motions granted preliminary. The presence of other items, along with drug petitions did not significantly alter the proportion of acceptances; however, they were 11.7% higher when the prescription was attached to the motion (n = 4,719), 5.6% higher with medical report attached (n = 4,051), and 2.7% higher in motions with a

Table 2. Distribution of	f granting according to	procedural variables. I	Minas Gerais, Southeast	ern Brazil, 1999-2009.
--------------------------	-------------------------	-------------------------	-------------------------	------------------------

Procedural variable	Motion	Gra	nted	Partially	Partially granted		tal	Suspended	
Procedural variable	N	n	%	n	%	n	%	n	%
Legal representative of the be	neficiary								
Legal attorney	2,807	2,273	81.0	48	1.7	2,321	82.7	162	7.0
Public defender	1,175	971	82.6	50	4.3	1,021	86.9	73	7.1
Center for legal Assistance	188	151	80.3	8	4.3	159	84.6	9	5.7
Without representation	511	324	63.4	18	3.5	342	66.9	4	1.1
Not informed	391	333	85.1	8	2.1	341	87.2	23	6.7
Claim filed									
Public civil action	284	242	85.2	11	3.9	253	89.1	26	10.3
Ordinary action	3,312	2,640	79.7	103	3.1	2,743	82.8	198	7.2
Writ of mandamus	1,443	1,139	78.9	18	1.2	1,157	80.1	45	3.9
Other	33	31	93.9	0	0.0	31	93.9	0	0.0
Defendant									
State only	3,528	2,890	81.9	72	2.0	2,962	83.9	209	7.1
More than one defendant	1,544	1,162	75.3	60	3.9	1,222	79.2	62	5.1
Filing court									
Federal	707	460	65.1	25	3.5	485	68.6	8	1.1
State	4,365	3,592	82.3	107	2.5	3,699	84.8	263	6.0
Total	5,072	4,052	79.9	132	2.6	4,184	82.5	271	5.3

Time	Мо	Motion		nted	Partially	/ granted	Total		
	n	%	n	%	n	%	n	%	
Up to 1 day	266	5.2	250	93.9	2	0.8	252	94.7	
Up to 1 week	2,180	43.0	1,950	89.4	3	0.1	1,953	89.5	
Up to 30 days	1,054	20.8	894	84.9	3	0.2	897	85.1	
Over 30 days	978	19.3	772	78.9	4	0.4	776	79.3	
Date unknown	594	11.7	186	31.2	120	20.3	306	51.5	
Total	5,072	100.0	4,052	100.0	132	100.0	4,184	100.0	

Table 3. Distribution of the granting of injunctions according to the time for decision. Minas Gerais, Southeastern Brazil, 1999-2009.

single drug. Among the drugs litigated against, 54.5% are standardized in the RENAME 2013 list of drugs, with the granting of injunctions in 81.1% of the cases. This finding did not differ significantly relative to drugs not listed in the RENAME.

#### DISCUSSION

Among all cases with injunctions, 4,184 out of 5,072 cases were granted. Granting varied from 95.8% in 2004 to 76.9% in 2008. The result of the injunctions varied according to the type of claim filed, with higher acceptance of public civil actions, and lower acceptance of cases with writ of Mandamus. Where there was legal representation, acceptance exceeded up to 80.0% and in cases without representation, it did not exceed more than 66.9%. The court also led to different results for injunction motions. Digestive system diseases and neoplasms showed up to 87.0% granting, while diseases of the nervous system, mental and behavioral disorders, and diseases of the skin and subcutaneous tissue, received granting less than 78.6% times and showed a high proportion of suspended injunctions (10.9%). As for the drugs, some were granted in all opportunities and others in only half of the cases.

The proportion of motions granted, which are verified in this study (82.5%), was below the results achieved by other studies because the literature does not report approval percentage of less than 90.0%, and in some cases, it reports 100% approval.<sup>1,8,9,11</sup> Data referring to the results of injunction motions indicate that the development of the phenomenon and the subsequent maturing of discussions resulted in a stricter judiciary – in Minas Gerais, between 2004 and 2008, the proportion of motions granted dropped from 95.8% to 76.9%, and the proportion of injunctions suspended after appeals filed increased. This maturing process was accompanied by a consensus on the need to create focused interagency structures in order to provide technical assistance to the magistrates, which, in turn, could constitute the basis for greater judicial rigor, pursuant to Recommendation 31 of the National Council of Justice (CNJ).<sup>h</sup> However, one still needs to perform specific tests to check whether the proportional decrease in the deferrals was the result of greater rigor, and if it was, would there be a relationship between greater rigor and imposition of more secure and cost-effective benefits.

In the case of Minas Gerais, the CNJ's recommendation encouraged the creation, in December 2010, of the State Executive Committee for Health,<sup>i</sup> which, in turn, developed partnership between the Court of Minas Gerais and the Center for Health Technology Assessment of UFMG's *Hospital das Clínicas*. Since 2010, this partnership has provided the magistrates the technical documentation to assist them in their decisions when assessing clinical issues presented in lawsuits involving health care. In 2014, the partnership also began to assist in actions involving supplementary health care.<sup>j</sup> Since the database of this study contained lawsuits from 1999 to 2009, the introduction of expert opinion in the evaluation of the actions did not contemplate a sensitive variable.

The time required to grant the injunctions is an important indicator to portray the extent to which health care claims are treated as emergencies by the judiciary. This study reinforces the results achieved by other studies by showing that, in most cases, the approval occurred within 30 days, and a considerable proportion of the motions were granted within a week.<sup>8,9,k</sup> However, we still need to investigate whether the perception of urgent health care assessed by the judiciary is supported by scientific standards, especially after the creation of institutional technical support structures. As for the relationship between the time and proportion of motions attended to, those that were decided in lesser

<sup>h</sup> Recomendação nº 31 de 30 de março de 2010. Recomenda aos Tribunais a adoção de medidas visando a melhor subsidiar os magistrados e demais operadores do direito, para assegurar maior eficiência na solução das demandas judiciais envolvendo a assistência à saúde. DJ. 7 Abr 2010:4-6.
<sup>1</sup> Tribunal de Justiça de Minas Gerais. Magistrado do TJ/MG integra Fórum Nacional do Judiciário para a Saúde. Minas Gerais; 2013 [cited 2014 Mar 30]. Available from: http://tj-mg.justica.inf.br/noticia/2013/10/magistrado-tjmg-integra-forum-nacional-judiciario-saude
<sup>1</sup> Tribunal de Justiça de Minas Gerais. Convênio vai orientar magistrados nas ações envolvendo saúde. Minas Gerais; 2014 [cited 2014 Mar 30]. Available from: http://www.tjmg.jus.br/portal/imprensa/noticias/convenio-vai-orientar-magistrados-nas-acces-envolvendo-saude-1.htm#.Uzi0mqhdU0g
<sup>k</sup> Camargo IA. Análise das demandas judiciais para o tratamento da artrite reumatoíde no Estado de São Paulo [MA dissertation]. Sorocaba: Universidade de Sorocaba; 2011.

Table 4. Distribution of the results of injunctions related to disease classified by WHO/ICD-10. Minas Gerais, Southeaster	n
Brazil, 1999-2009.	

Disease according to chapter of ICD-10	Motion	Gran	nted		Partially granted		tal	Suspended	
0	N	n	%	n	%	n	%	n	%
D50-D89 III Diseases of the blood and blood-forming organs, and certain immune disorders	48	44	91.7	3	6.3	47	98.0	5	10.4
XVI P00-P96 Certain conditions originating in the perinatal period	14	13	92.9	0	0.0	13	92.9	0	0.0
XI K00-K93 Diseases of the digestive system	323	284	87.9	5	1.5	289	89.4	8	2.5
XVII Q00-Q99 Congenital malformations, deformations and chromosomal abnormalities	60	50	83.3	3	5.0	53	88.3	2	3.3
II C00-D48 Neoplasms [Tumors]	495	428	86.5	3	0.6	431	87.1	30	6.1
XIX S00-T98 Injury, poisoning, and certain other consequences of external causes	53	39	73.6	7	13.2	46	86.8	9	17.0
X J00-J99 Diseases of the respiratory system	234	190	81.2	12	5.1	202	86.3	15	6.4
XIV N00-N99 Diseases of the genitourinary system	151	117	77.5	12	7.9	129	85.4	7	4.6
XV O00-O99 Pregnancy, childbirth, and puerperium	13	11	84.6	0	0.0	11	84.6	0	0.0
IX 100-199 Diseases of the circulatory system	626	481	76.8	38	6.1	519	82.9	23	3.7
III A00-B99 Certain infectious and parasitic diseases	174	142	81.6	2	1.1	144	82.7	11	6.3
IV E00-E90 Endocrine, nutritional, and metabolic diseases	680	543	79.9	19	2.8	562	82.7	35	5.1
XIII M00-M99 Diseases of the musculoskeletal system and connective tissue	887	714	80.5	18	2.0	732	82.5	62	7.0
VII H00-H59 Diseases of the eye and adnexa	139	111	79.9	1	0.7	112	80.6	6	4.3
VI G00-G99 Diseases of the nervous system	407	293	72.0	27	6.6	320	78.6	10	2.5
V F00-F99 Mental and behavioral disorders	481	363	75.5	9	1.9	372	77.4	20	4.2
XVIII R00-R99 Symptoms, signs, and abnormal clinical and laboratory findings not classified elsewhere	48	36	75.0	1	2.1	37	77.1	4	8.3
XXI Z00-Z99 Factors influencing health condition and contact with health services	30	23	76.7	0	0.0	23	76.7	0	0.0
VIII H60-H96 Diseases of the ear and mastoid process	4	3	75.0	0	0.0	3	75.0	0	0.0
XII L00-L99 Diseases of the skin and subcutaneous tissue	156	113	72.4	2	1.3	115	73.7	17	10.9
CID not specified or invalid	931	931	76.7	42	3.2	973	79.9	68	5.6
Total	6,237	4,929	79.0	204	3.3	5,133	82.3	333	5.3

periods showed the highest proportion of approvals. This finding indicates the need to verify the existence of the association between the time of acceptance and the effective provision of technical assistance.

The prevalence of chronic diseases observed is similar to the findings of other studies.<sup>8,13</sup> There was no uniformity of approval when cases were analyzed on the basis of the diagnosed diseases. The trend indicates that the court's decision is sensitive to the potential risk to the patient. The need for quicker treatment in order to achieve the best treatment or the possibility of a cure may have influenced the formation of an emergency; the diseases related to blood and blood-forming organs were superior in their approvals to cases involving chronic diseases or long-term treatments, such as skin diseases and mental disorders. It is conjectured that the financial impact of treatment may have touched the judges as well, since diseases, which initially do not involve emergencies, but then require very expensive treatment at later stages, showed approvals similar to those with imminent risk.

The comparison of approval proportions based on the type of action indicated a higher proportion of the granting of injunctions in public civil actions, contrary to expectations. Valle & Camargo<sup>10</sup> argue that the statements given at the public hearing held in

Table 5. Requested medication according to ATC/WHO Classification. Minas Gerais, Southeastern Brazil, 1999-2009.

Anatomical level	Motion	Granted		Partially granted		Total		Suspended by appeal to the Court	
	N	n	%	n	%	n	%	n	%
H – Systemic hormonal preparations, excluding sex hormones and insulin	328	269	82.0	12	3.7	281	85.7	17	5.2
J – General anti-infectives for systemic use	375	309	82.4	9	2.4	318	84.8	26	6.9
L – Antineoplastic and immunomodulating agents	1,800	1,494	83.0	23	1.3	1,517	84.3	131	7.3
B – Blood and blood-forming organs	579	444	76.7	42	7.3	486	84.0	26	4.5
R – Respiratory system	482	380	78.8	25	5.2	405	84.0	26	5.4
A – Digestive System and Metabolism	1,518	1,167	76.9	81	5.3	1,248	82.2	66	4.3
D – Dermatological Drugs	125	91	72.8	11	8.8	102	81.6	7	5.6
G – Urogenital system and sex hormones	279	214	76.7	10	3.6	224	80.3	12	4.3
V – Various	339	252	74.3	16	4.7	268	79.0	8	2.4
C – Cardiovascular system	1,467	1,003	68.4	154	10.5	115	78.9	72	4.9
N – Nervous System	1,935	1,383	71.5	115	5.9	1,498	77.4	80	4.1
S – Sense organs	215	156	72.6	4	1.9	160	74.5	6	2.8
M – Musculoskeletal System	333	213	64.0	30	9.0	243	73.0	27	8.1
P – Antiparasitic products, insecticides, and repellents	21	15	71.4	0	0.0	15	71.4	0	0.0
Not specified or invalid	136	89	65.4	4	2.9	93	68.3	4	2.9
Total	9,932	7,479	75.3	538	5.4	8,017	80.7	508	5.1

ATC: Anatomical Therapeutic Chemical; WHO: World Health Organization

2009 in the Supreme Court indicate a pattern by the judiciary toward the greater acceptance of individual claims, given that the financial impact of the judicial action would not be as evident as that in class actions. Even with 10.0% of the revoked injunctions, the public civil actions remained ahead of other types of actions in terms of acceptance proportion. However, in some cases, public civil actions are managed to ensure individual rights, and it would therefore not be appropriate to assume them to always be collective. As for this aspect, in spite of Law 7,347/1985 (regulates the public civil action), establishing that it should handle cases involving collective or diffuse interests, the courts, including the High Court of Justice (precedent: REsp 931,513/RS, REsp 819,010/SP and AgRg no REsp 1328270/MG), consolidated the possibility of using the action in drug claims for a single citizen, particularly in cases of "protection by the court of hyper-vulnerable interests" (REsp 931,513/RS).

The discrepancy in approval observed from the comparison between the lawsuits filed in Federal and State Courts indicate the need for studies that seek to identify, for each justice (State and Federal), the differences in training judges, especially with regard to health law or which propose to evaluate the distinctions related to the quality of the institutional structures created to provide technical support to the judges. The verification of the proportion of approvals based on the types of representation and the most successful motions made in proceedings with professional representation ratify the fact that the motions filed by lawyers favor approval. This situation questions the mechanisms established to facilitate access to justice, regardless of the representation by the legal professional given that, in principle, the use of such paths could not interfere with the patient's chance of success, especially in cases involving health emergencies. In this sense, one should investigate the specific aspects of the legal representative's performance that can interfere with the granting as well as clarify the reason or the reduced rate of successful cases with judicial representation with the courts of appeal.

Pepe et al<sup>8</sup> evaluated the decisions of court injunctions in the State of Rio de Janeiro, Southeastern Brazil. The authors suggested an almost absolute trend of acceptance in the actions that petitioned for drugs. In this study, we found a maximum approval of 85.7%, with less than 70.0% acceptance near or distant from an absolute granting for the same. Considering some diseases individually, approval is almost absolute; as is the case of diseases related to the blood and bloodforming organs as well as some immune disorders in which the proportion of granting reached 98.0%. These results suggest specific differences in the treatment of injunctions. The variation of acceptance in different anatomical groups of the ATC indicates that some treatments may influence the court's decision.

We observed the exploratory character of the statistical method chosen to establish the differences between the groups. Although the number of evaluated cases was lower in the early years and demanded correction of continuity, the approach to the whole period adds representativeness to the study of the phenomenon. Given the results, in-depth statistical analyses should be prepared to make specific comparisons and enable further knowledge on the elements that influence the outcome of judicial

#### REFERENCES

- 1. Delduque MC, Marques SB. A judicialização da política de assistência farmacêutica no distrito federal: diálogos entre a política e o direito. *Rev Eletrol Tempus Actas Saude Coletiva*. 2011;5(4):97-106.
- 2. Garapon A. O juiz e a democracia: o guardião das promessas. Rio de Janeiro: Revan; 2001.
- Macedo El, Lopes LC, Barberato-Filho S. Análise técnica para a tomada de decisão do fornecimento de medicamentos pela via judicial. *Rev Saude Publica*. 2011;45(4):706-13. DOI:10.1590/S0034-89102011005000044
- Marques SB, Dallari SG. Garantia do direito social à assistência farmacêutica no Estado de São Paulo. *Rev Saude Publica*. 2007;41(1):101-7. DOI:10.1590/S0034-89102007000100014
- Maus I. Judiciário como super-ego da sociedade: o papel da atividade jurisprudencial na 'sociedade órfã'. Novos Estud CEBRAP. 2000;58:185.
- Menicucci TMG, Machado JA. Judicialization of health policy in the definition of access to public goods: individual rights versus collective rights. *Braz Polit Sci Rev.* 2010;4(1):33-68.
- 7. Moro SF. Jurisdição constitucional como democracia. São Paulo: Editora Revista dos Tribunais; 2004.

decisions. Important trends in the standard of judicial performance were observed in procedural variables (court of filing, legal representation, time between motion and decision), clinical (disease and drug), and particularly with respect to the change in the performance standard in the study period. These results will allow us to obtain a fresh perspective of the legalization of health, as it is from the identification and understanding of the elements that determine judicial decisions that one can more clearly identify the extent to which judicial actions can help to expand the State's capacity to meet the real health care needs of the population.

- Pepe VLE, Ventura M, Sant'ana JMB, Figueiredo TA, Souza VR, Simas L, et al. Caracterização de demandas judiciais de fornecimento de medicamentos "essenciais" no Estado do Rio de Janeiro, Brasil. Cad Saude Publica. 2010;26(3):461-71. DOI:10.1590/S0102-311X2010000300004
- Sant'ana JMB, Pepe VLE, Figueiredo TA, Osorio-de-Castro CGS, Ventura M. Racionalidade terapêutica: elementos médico-sanitários nas demandas judiciais de medicamentos. *Rev Saude Publica*. 2011;45(4):714-21. DOI:10.1590/S0034-89102011005000042
- Valle GHM, Camargo JMP. A audiência pública sobre a judicialização da saúde e seus reflexos na jurisprudência do supremo tribunal federal. *Rev Direito Sanit*. 2011;11(3):13-31.
- Ventura M, Simas L, Pepe VLE, Schramm FR. Judicialização da saúde, acesso à justiça e a efetividade do direito à saúde. *Physis.* 2010;20(1):77-100. DOI:10.1590/S0103-73312010000100006
- Vianna WL. A judicialização da política e das relações sociais no Brasil. Rio de Janeiro: Revan; 1999.
- Vieira FS, Zucchi P. Distorções causadas pelas ações judiciais à política de medicamentos no Brasil. *Rev Saude Publica*. 2007;41(2):214-22. DOI:10.1590/S0034-89102007000200007

This study was supported by the *Conselho Nacional de Desenvolvimento Científico e Tecnológico* (CNPq – Process 551495/2007-3) and by the *Fundação de Apoio à Pesquisa de Minas Gerais* (FAPEMIG – Notice MS/CNPq/FAPEMIG/SES 09/2009, Process EFP-00001059).

The authors declare no conflict of interest.

816