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Doctors, lawyers and pharmaceutical industry on health lawsuits in Minas Gerais, Southeastern Brazil

ABSTRACT

OBJECTIVE: To describe the relationship between the prescribing physician, lawyer and pharmaceutical industry in lawsuits against the state.

METHODS: Retrospective descriptive study based on data from administrative files, relating to lawsuits involving medicine demands, in the State of Minas Gerais, from October 1999 to October 2009. The variables studied were: gender, age, beneficiaries' illness, type of medical care (public or private), prescriber, type of legal representation and requested medication. A descriptive analysis of the variables with the distribution of frequencies was carried out.

RESULTS: A total of 2,412 lawsuits were analyzed with 2,880 medicine requests, including 18 different drugs, 12 of them provided through Pharmaceutical Policies of the Brazilian National Health System (SUS). The most frequent medicines requested were adalimumab, etanercept, infliximab, insulin glargine and tiotropium bromide. The main diseases were rheumatoid arthritis, ankylosing spondylitis, diabetes mellitus and chronic obstructive pulmonary disease. Private lawyers and doctors were predominant. The results revealed the association between doctors and law offices on drug requests. Among the lawsuits filed by the office A, 43.6% had a single prescriber of adalimumab, while 29 doctors were responsible for 40.2% of the same drug prescriptions. A single doctor was responsible for 16.5% of the adalimumab prescriptions, being requested through lawsuits filed by a single private law office in 44.8% of legal proceedings.

CONCLUSIONS: A greater representation of doctors and lawyers from the private sector can hinder equity in health. The results revealed the association between doctors and law offices on drug requests. This is an indication that justice and medical practice have been used, at certain times, to serve the interests of the pharmaceutical industry.

DESCRIPTORS: Health lawsuits and access to health . Equity in health. Pharmaceutical industry. Incorporation of medicines. Lawsuit officials. Doctors.

INTRODUCTION

New medicines are often launched on the market at higher prices than existing ones without adding any therapeutic benefits to patients. According to Vidotti et al[12] (2008), of the 109 medicines registered in the National Health Surveillance Agency (ANVISA) in Brazil, between 2000 and 2004, approximately 40% showed no innovation in relation to the previously available drugs, according to classification by the Food and Drug Administration (FDA). None were included

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in the National List of Essential Medicines (Rename); therefore, they did not meet the most important health needs of the population, as defined by the World Health Organization (WHO). Less than 10% of these drugs were intended for conditions considered strategic by the Brazilian Ministry of Health (MS), such as diabetes, tuberculosis and hypertension, and no drug was released for Hansen's disease.[13,a]

The high costs of new drugs impact the Pharmaceutical Assistance (AF) program of the Brazilian National Health System (SUS), as the lawsuits filed by the patients lead to the free supply of these drugs under the claim of constitutional right to health. The Judiciary contributes to the introduction to the market of medicines not previously standardized by the SUS or belonging to the Specialized Component Pharmaceutical Assistance program (high-cost drugs) for health conditions not governed by guidelines or protocols. On the other hand, requests related to medicaments belonging to other AF/SUS programs are motivated by supply-line problems, such as insufficient quantity procurement or failure to meet delivery schedule.[5,7,9,10,14]

Studies carried out in São Paulo and Minas Gerais in 2006 showed a high number of judicial claims requesting adalimumab and etanercept (then not yet incorporated into the SUS list) from a small group of prescribers and lawyers. Such results suggest inappropriate relationships between these professionals and the pharmaceutical companies, mischaracterizing the guarantee to the right to health as the overriding motivation in these lawsuits.[6]

The present study aims to describe the relationship between prescribers, lawyers and the pharmaceutical industry in lawsuits against the state.

METHODS

A retrospective descriptive study was carried out based on data contained in administrative files relating to legal proceedings involving medicament demands in Minas Gerais, filed between October 1999 and October 2009.

Data were collected at the Minas Gerais State Health Secretary (SES-MG) between February and November 2009 by the Health Economics Research Group (GPES/UFMG). A pre-tested form was applied to the administrative files of completed or ongoing legal proceedings. The information obtained was stored in a database using Microsoft® Office Access 2007.

The variables analyzed were: beneficiary (gender, age, city of residence), legal representative (lawyer, prosecutor, public defender), care (prescriber, medical specialty, type of healthcare provided, healthcare center, diagnosis according to the International Classification of Diseases – ICD-10), medicament (as classified by the Anatomical Therapeutic Chemical Code – ATC) and pharmaceutical company. The beneficiary's age was calculated based on the initial petition and birth dates.

From the 6,112 filed lawsuits, those requesting medicines containing drugs included in more than 100 cases were selected, which represented 18 items (47.1% of cases). These drugs were described according to chemical substance (ATC level 5) and grouped into their various presentations. However, only individual cases were considered, i.e., those representing a single applicant and involving a single law office, prescriber and medicament request, as it was not possible to establish a relation between a specific medicine/disease and an individual patient in collective lawsuits. Therefore, medicines whose drugs were requested in less than 100 lawsuits were included in the analysis.

The relationships between doctors, lawyers and the pharmaceutical industry were established by crossing between "name of the doctor," "law office", "active ingredient" and "pharmaceutical company". In the analysis, the following were considered as law offices: federal and state public defenders, municipal legal assistance services, legal assistance centers at law faculties and private law offices. These differences are pointed out in the results. Medical specialties and type of healthcare provider (SUS or the private sector) were also associated with the doctors and identified from the prescription recorded in the database.

The descriptive data analysis was conducted with the table presentation of the frequency distribution (relative and absolute) of selected variables. In addition to Microsoft Office Excel® 2007, the MySQL 5.1.41 software program was used to manage the database.

The ethical aspects and confidentiality of the study were guaranteed. This study is part of the project "Impact of lawsuits on the national policy of pharmaceutical assistance: clinical management and medicalization of justice", from Universidade de Minas Gerais,[b] with the approval of the Research Ethics Committee of the university (COEP) (Resolution No. ETIC 292/08).

RESULTS

The 6,112 lawsuits covered 10,078 medicament requests, including 802 different drugs. By applying the selection criteria, 2,412 lawsuits were analyzed,

[a] Organización Mundial de la Salud. Selección de medicamentos esenciales. Ginebra; 2002. (Perspectivas políticas de la OMS sobre medicamentos, 4). Available from: http://whqlibdoc.who.int/hq/2002/WHO_EDM_2002.2_spa.pdf

[b] Project developed by Grupo de Pesquisa em Economia da Saúde from Faculdade de Medicina in Universidade de Minas Gerais and supported by Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq).

totaling 2,880 medicaments which included 18 different pharmacological agents.

Most plaintiffs were female, with a slight predominance of over 40-year-olds (Table 1).

The most common diseases and medications included rheumatoid arthritis and ankylosing spondylitis (adalimumab, etanercept and infliximab), diabetes *mellitus* (insulin glargine) and other chronic obstructive pulmonary diseases (tiotropium bromide) (Tables 1 and 2).

Private lawyers and doctors from the private healthcare system were predominant (Table 1). However, there were also requests from the Public Defender's Office of Minas Gerais (DPMG) for the 18 medicaments studied here. In actions involving four of these drugs (tiotropium bromide, clopidogrel, losartan and simvastatin), the largest legal representation was made by the DPMG. There were 152 lawsuits filed by the DPMG for these four drugs, equivalent to 33.6% of the DPMG lawsuits and 6.3% of the total selected in this study (Table 2).

The medical specialties most common in the lawsuits were: rheumatology (17.9%), endocrinology (6.2%), cardiology (5.4%), psychiatry (4.5%), pneumology (3.6%) and oncology (2.5%).

There was a concentration of the same doctors and lawyers in the applications of the most demanded drugs (Table 2).

The four legal representatives responsible for the largest number of lawsuits brought 687 actions (61.8%): DPMG with 359; office A, 165; office B, 87; office C, 76. There was a concentration of requests for one or two drugs by the three law offices. Office A had 160 requests for adalimumab; office B, 59 for etanercept; and office C, 28 for adalimumab and 36 for etanercept. The three doctors with the highest number of prescriptions were linked to 126 applications (10.9%): doctor X was responsible for 76; doctor Y, 25; and doctor Z, 25. Regarding the results related to the law offices, the most common medicaments were adalimumab and etanercept. Doctor X issued 59 prescriptions for adalimumab and 17 for etanercept;

Table 1. Beneficiary frequency distribution according to the variables of the legal proceeding database. Minas Gerais, Southeastern Brazil, from 1999 to 2009.

Variable	All lawsuits (n)	%	Selected lawsuits (n)	%
Gender				
Female	3,682	53.9	1,613	56.3
Male	3,143	46.1	1,251	43.7
Total	6,825	100.0	2,864	100.0
Age (years)				
0 to 19	709	28.5	295	26.5
20 to 39	507	20.4	260	23.4
40 to 59	643	25.8	306	27.5
60 and over	631	25.3	252	22.6
Total	2,490	100.0	1,113	100.0
Diagnosis				
M05 Rheumatoid arthritis	363	35.3	331	38.4
E10 Diabetes *mellitus* type 1	285	27.7	207	24.0
J44 Other chronic obstructive pulmonary disease	231	22.4	178	20.6
M45 Ankylosing spondylitis	150	14.6	147	17.0
Total	1,029	100.0	863	100.0
Type of healthcare				
Private	3,621	84.9	1,715	87.5
Public	646	15.1	245	12.5
Total	4,267	100.0	1,960	100.0
Legal representative				
Lawyer	3,867	62.1	1,964	70.2
Public defender	1,472	23.6	504	18.0
Legal assistance center	231	3.7	69	2.5
No representation	662	10.6	260	9.3
Total	6,232	100.0	2,797	100.0

Table 2. Medicaments, doctors, law offices and the respective maximum number of lawsuits.[a] Minas Gerais, Southeastern Brazil, from 1999 to 2009.

Medicament	Lawsuits	Doctors	Maximum number of lawsuits per doctor	%	Law offices	Maximum number of lawsuits per law office	%
Adalimumab	357	54	59	16.5	20	160	44.8
Etanercept	286	72	17	5.9	17	59	20.6
Ursodeoxycholic acid	148	59	8	5.4	23	31	20.9
Infliximab	139	51	8	5.8	15	45	32.4
Insulin glargine	132	66	9	6.8	20	27	20.5
Tiotropium bromide	121	51	8	6.6	10	51[b]	42.1
Sildenafil	117	41	17	14.5	10	26	22.2
Clopidogrel	114	39	10	8.8	10	73[b]	64.0
Aripiprazole	112	29	8	7.1	11	20	17.9
Mycophenolate mofetil	108	53	5	4.6	16	34	31.5
Rituximab	79	32	4	5.1	17	16	20.3
Insulin aspart	77	32	6	7.8	10	15	19.5
Temozolomide	55	28	6	10.9	11	15	27.3
Clonazepam	52	22	2	3.8	11	9	17.3
Omeprazole	43	19	1	2.3	7	11	25.6
Losartan	43	21	1	2.3	4	20[b]	46.5
Acetylsalicylic acid	32	16	1	3.1	8	9	28.1
Simvastatin	27	9	1	3.7	5	8[b]	29.6
Total	2042	694	-	-	229	-	-

[a] Only the lawsuits involving a single law office, a prescriber and a request for medicament were considered.
[b] Cases in which the Public Defender's Office of Minas Gerais was predominant in the legal proceedings.

doctor Y, 21 and 2, respectively; and doctor Z, 9 and 15, respectively. The three doctors were rheumatologists, worked in the private sector and the medicaments were prescribed to treat rheumatoid arthritis.

A relationship between the doctors and the law offices was observed in the requests for medicaments Among the lawsuits represented by office A, 43.6% had doctor X as the prescriber to adalimumab (Abbott), and 29 doctors were responsible for 40.2% of the requests for this drug. Doctor X was also the main prescriber in the lawsuits involving etanercept, which were filed by offices B and C. At office B, doctor X was involved in 9.0% of the lawsuits, and at office C, in 12.3%.

DISCUSSION

Twelve of the drugs included in the lawsuits are provided by the SUS Pharmaceutical Assistance program, including insulin glargine and sildenafil 20 mg, standardized in Minas Gerais for type I diabetes *mellitus* and pulmonary arterial hypertension in 2005 and 2009, respectively. Sildenafil is part of the Specialized Component list of the Pharmaceutical Assistance program since March 2010. At the time of the study, it had been standardized only in Minas Gerais. Some drugs were not standardized at the time of the lawsuits, which led to judicialization. Some drugs included on official lists at the time of the lawsuits had their availability restricted as a result of failures in the Pharmaceutical Assistance program due to shortages or logistical problems, which led to legal aid.

Beneficiaries in the 0-19 and 40-59 age groups were the majority. Type 1 diabetes can be predominantly associated with the first age group, while rheumatoid arthritis and obstructive pulmonary diseases are more linked to the second group[3]. Information regarding to age has considerable limitations, because the birth date or the date of the application were not reported in 61.5% of cases.

A relation between the most requested medicaments with the diagnoses and the key medical specialties was observed in the lawsuits. This shows prescription consistency, not necessarily rationality, because many drugs are not the first line of treatment, such as monoclonal antibodies (adalimumab and etanercept) for rheumatoid arthritis.[c] Currently, there are five classes of drugs: analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, disease-modifying

[c] Ministério da Saúde (BR), Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Portaria SCTIE nº 66 de 6 de novembro de 2006. Aprova o protocolo clínico e diretrizes terapêuticas – artrite reumatóide Brasília (DF); 2006 [cited 2011 Jul 14]. Available from: http://portal.saude.gov.br/portal/arquivos/pdf/pcdt_artrite_reumatoide_2006.pdf

drugs and anti-citokyne agents, called monoclonal antibodies. These drug classes are available through the SUS, either by the municipal or state entity. Not using a protocol- defined therapeutic sequence can be considered as irrational, in pharmacological and economic terms, as adalimumab and etanercept are expensive drugs. But the therapy may vary according to patient characteristics and response to previous treatment regimes. Thus, where using the first or second-line treatment was not possible, after the available pharmacological alternatives were tested, the use of monoclonal antibodies could be advised.

Messeder et al[9] (2005) showed that there was an increase in the request of mesalazine, riluzole, peginterferon, sevelamer, levodopa + benserazide, rivastigmine, simvastatin and infliximab in the State of Rio de Janeiro, in 2001. These drugs were added to the Exceptional Dispensation Medicaments Program (current Specialized Component list of the Pharmaceutical Assistance) at the end of 2002. Similarly, the increase in the number of lawsuits for adalimumab in Minas Gerais can be observed, especially in 2006, when it was incorporated into the Exceptional Dispensation Medicaments Program. The increase in demand for these new drugs may reflect the performance of the pharmaceutical industry towards including their products in the SUS list. On the other hand, it may be the answer to an unmet demand for healthcare.

Doctors from the private sector predominated amongst those responsible for prescriptions that led to the judicialization of medicaments in Minas Gerais, which also happened in Santa Catarina, but contrasted with what was seen in the State of Rio de Janeiro and in São Paulo city, where doctors from the SUS were the majority.[9-11,13] Chieffi & Barata[5] (2009) observed similar values for residents of São Paulo city: 48.0% of attendances through the SUS and 47.0% through private healthcare.

Private lawyers prevailed in lawsuits filed in Minas Gerais, a situation observed in different parts of the cuntry.[5,8,10,13] However, the Public Defender's Office of Minas Gerais was responsible for most cases related to four of the 18 drugs most in demand, which is similar to the findings by Messeder et al (2005) and Sant'ana (2011).[9,11,d] A low frequency of legal proceedings filed by free legal assistance centers linked to law faculties was observed. This trend, also observed in other studies, indicates that people with lower income have not often accessed the courts to receive medicaments This is probably due to the low supply of this type of assistance, which also happens in the Public Defender's Offices. Long waiting lines are often common and a reason for discouraging those needing the free assistance.[8-10]

The lawsuits represent a diversion of substantial resources for the fulfillment of court injunctions, to the detriment of other actions and health services that the state provides. Information released by the Minas Gerais State Health Secretary (SES-MG) shows an unusual increase of more than 28,333% in spending on medicament lawsuits from 2002 (R$ 164,325.00) to June 2011 (R$ 46,362,563.00). To readjust the budget with this new situation, other public health projects are postponed.[1]

A small number of lawyers and doctors were associated with numerous lawsuits, as seen most notably but not exclusively, in relation to adalimumab in Minas Gerais. Chieffi & Barata[6] (2010) showed that 1 % of lawyers represented 35 % of the lawsuits in São Paulo, a single doctor prescribed erlotinib in 66% of lawsuits related to this medicament and a single lawyer filed 82 % of the lawsuits requesting bevacizumab .

The results suggest a relationship between law office A and doctor X, which may indicate a "partnership" between these professionals and the pharmaceutical company that produces adalimumab. A single doctor linked to office A was responsible for approximately 44% of prescriptions in 117 lawsuits; 34 doctors were related to the rest of the legal proceedings. No clear relationship was identified between these actors and offices B and C, since the medicament requests were distributed by a larger number of doctors. These results corroborate Chieffi & Barata[6] (2010), who reported a higher number of doctors and lawyers in the judicialization of new and more expensive drugs (Table 2).

When implementing the Policy of Pharmaceutical Assistance, it is necessary to discuss if other interests than those of the population, who need and are entitled to a pharmaceutical service of high quality, permeates the relationship between the pharmaceutical industry and the health professionals, whose actions should be guided by ethics and the pursuit of the patients well-being. These hidden interests are denounced in the literature, and are related to the commercialization of high-cost medicaments inaccessible to a significant proportion of the population.[2,6,8] Carvalho[4] (2005) pointed out that the court is one of the new routes discovered by the industry for these professionals to act on its behalf, with the argument of defending the universal right to health, and the right to new medicines and medical procedures. New technologies are often consumed by the pressure of the constitutional law and emotional appeal to the Judicial System.

This study is limited by obtaining incomplete or inconsistent data from a secondary administrative source, whose original purpose is not research. This may affect the extrapolation of information.

However, despite this analysis on the relationship between doctors, lawyers and medicament supply not

[d] Romero LC. Judicialização das políticas de assistência farmacêutica: o caso do Distrito Federal. Brasília (DF): Consultoria Legislativa do Senado Federal; 2008. (Texto para discussão, 41). [cited 2011 Aug 2]. Available from: http://www.senado.gov.br/conteg/textos-discussao.htm

allowing the complex exploration of the role of litigation as a strategy for introducing new medicines in the SUS, the data show a large concentration of the distribution of processes between a few doctors and law offices. This may be an indication that Justice and medicine have been used to serve the interests of the pharmaceutical industry.

The greater representation of doctors from the private sector and private lawyers can impair equity, because most patients who have access to the Judiciary and, therefore, to the drugs financed by the SUS, pay for medical and legal services. Obtaining drugs through the courts can favor citizens who have more financial resources to pay lawyers, or greater access to information, to the detriment of those who have no such option for socioeconomic reasons.[14,e]

Nevertheless, the consequences of judiciary actions must not only be seen in this perspective. There are assistance gaps and difficulties in accessing federal health policies that gain greater visibility with the lawsuits, which generate the necessary debate and contribute towards the achievement of solutions.

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