Ana Luiza Chieffi[I]

Rita de Cássia Barradas Barata[II]

Legal suits: pharmaceutical industry strategies to introduce new drugs in the Brazilian public healthcare system

ABSTRACT

OBJECTIVE: To assess the distribution rate of legal suits according to drug (manufacturer), prescribing physician, and attorney filing the lawsuit.

METHODS: A descriptive study was carried out to assess the lawsuits in the São Paulo State (Southeastern Brazil) courts registry in 2006, and amounts spent in complying with these lawsuits, and total costs with medication thus resulting.

RESULTS: In 2006, the São Paulo State Administration spent 65 million Brazilian reais in compliance with court decisions to provide medication to approximately 3,600 individuals. The total cost of the medication was 1.2 billion Brazilian reais. In the period studied, 2,927 lawsuits were examined. These lawsuits were filed by 565 legal professionals, among which 549 were attorneys engaged by private individuals (97.17% of the total legal professionals). The drugs scope of the lawsuits had been prescribed by 878 different physicians. By assessing the number of lawsuits filed per attorney, it was found that 35% of them were brought before the courts by 1% of them.

CONCLUSIONS: The data related to the lawsuits and to the medication classified according to manufacturer, show that a small number of attorneys is responsible for the largest number of lawsuits filed to obtain these drugs. The finding that more than 70% of the lawsuits filed for certain drugs are the responsibility of one single attorney, may suggest a close connection between this professional and the manufacturer.

DESCRIPTORS: Judicial Decisions. Drug Utilization, Legislation & Jurisprudence. Drug Costs. Drug Industry. National Drug Policy. Single Health System.

INTRODUCTION

Today, one of the greatest challenges faced by healthcare authorities is presented by the number of lawsuits seeking healthcare products, treatments and/or procedures not covered by the *Sistema Único de Saúde* (SUS – Brazilian Public Healthcare System). These lawsuits are aimed at meeting individual demands in detriment of comprehensive management and planning of healthcare issues for the collectivity, and thus disorganize the healthcare service.[a] The right to universal

[a] Conselho Nacional de Secretárias de Saúde. Assistência farmacêutica no SUS [internet]. Brasília; 2003 [citado 2007 mar 7]. (Coleção Conass Progestores: para entender a gestão do SUS, 7). Available at: http://www.conass.org.br/?page=publicacao_livro_textodetalha&cod_livro=2

[I] Secretaria de Estado da Saúde. São Paulo, SP, Brasil

[II] Departamento de Medicina Social. Faculdade de Ciências Médicas. Santa Casa de São Paulo. São Paulo, SP, Brasil

Correspondence:
Ana Luiza Chieffi
R. Eneás de Carvalho Aguiar, 188, 1º andar
Cerqueira Cesar
05403-000 São Paulo, SP, Brasil
E-mail: ana.chieffi@bol.com.br

Received: 8/9/2009
Approved: 12/4/2009

Article available from www.scielo.br/rsp

and equal access to healthcare actions and services is as important as full healthcare.[b] However, this right depends on, among other factors, resources being appropriately applied to healthcare policies. The current exponential growth of these lawsuits interferes in the continuity of public healthcare policies and hampers a planned allocation of resources.[c] The States have limited funds and misusing them adversely affects the population as a whole; therefore, it is up to the Executive Branch to define the priorities taking into account the population's healthcare needs.[8]

Many preliminary injunctions aim at providing high-cost prescribed medication, many of which have only recently been launched in other countries and are still not available in Brazil. Lobbying, carried out by the industry and by those who market pharmaceutical products, at associations of chronic disease patients and the intense advertising activities targeted at physicians results in both patients and prescribers believing that the use of new drugs is absolutely indispensable. As a rule, these products are extremely expensive, but they are not necessarily always more effective than other drugs available at a lower cost, and prescribed for the same condition.[1]

Obtaining innovative – new chemical identify – products, according to the Food and Drugs Administration (FDA), is rare in the market. In 2007, only 17 molecular entities were approved in the United States.[2] Between 1998 and 2002, 415 drug applications received the approval of the FDA, among these, only 133 (32%) were made up of new chemical entities. Out of the 133 total, only 58 were drugs that presented benefit somewhat superior to drugs in the same category, that is, 14% of the total. In the same period, 77% of the production resulted in "imitation" drugs, which are drugs classified by the FDA as being on the same level of other drugs already available in the market to treat the same condition.[1] In line with this, it can be noticed that the industry is not producing so many "new" drugs, and that the so-called "new" drug prescribed to a certain patient could be replaced by a similar therapy which would bring no disadvantage to the patient, and would cost less to both patient and the SUS.

A large number of lawsuits seek to obtain drugs not provided by the SUS, in other words, drugs not distributed to the Brazilian population by any of the pharmaceuticals assistance program. However, there are situations in which therapy for the condition, for which the medication is being sought, is provided for and regulated based on the offer of alternative therapies.[8]

In Brazil, a drug can only be marketed after being registered at and receiving the approval of the *Agência Nacional de Vigilância Sanitária* (Anvisa – National Agency for Public Health Surveillance). However, being approved does not mean a drug will be listed in the SUS pharmaceuticals assistance program. The government defines through its programs the drugs for treating conditions, based on scientifically accepted criteria, since these drugs will be used by thousands of Brazilians. Therefore, it is of utmost importance to provide to the population drugs that are safe, efficient and cost-effective.[8]

The principles of universality, comprehensiveness and equity that govern the SUS end up favoring industry strategies of opening up markets for their new products. When a drug is listed in a pharmaceuticals assistance program, it means that it has a permanent market in a country whose majority of the population cannot afford the costs of medical treatment. A universal public healthcare system, including every kind of healthcare service and aiming at meeting any and all needs in healthcare, guarantees a market for pharmaceuticals regardless of the prices of new drugs. If the industry depended on the income of individuals to enable such a market, this market would certainly be very much limited, due to the low income of most of the Brazilian population. However, when the purchaser is mainly the government (federal, state or city), this market is increased, thus enabling innovations be introduced systematically.

Interpreting the meaning of a universal right to healthcare and the responsibility of the state in ensuring it, in addition to interpreting the constitutional principles of universality and comprehensiveness have been used to justify lawsuits to obtain drugs and medical procedures which do not fall under the scope of SUS programs.[d]

The objective of the study was to assess the distribution rate of legal suits according to drug (manufacturer), prescribing physician, and attorney filing the lawsuit, in addition to identifying the trend in the inclusion of new drugs under the special drugs program as a result of the exponential growth of lawsuits.

METHODS

A descriptive study was carried out based on the São Paulo State Courts registry (SCJ - *Sistema de Controle Jurídico*) to follow up on the enforcement of court orders.

[b] Ministério Público Federal. Procuradoria Geral da República. Manual de atuação do Ministério Público Federal em defesa do direito à saúde [internet]. 2008 [citado 2008 maio 4]. Disponível em: http://pfdc.pgr.mpf.gov.br

[c] Barroso LR. Da falta de efetividade à judicialização à saúde, fornecimento gratuito de medicamentos e parâmetros para a atuação judicial. Migalhas de Peso [internet]. 2008 [citado 2008 fev 8]. Disponível em: http://www.migalhas.com.br/mostraarticuladas.aspx?cod=52582

[d] Santos L. SUS: contornos jurídicos da integralidade da atenção à saúde. Radis. 2006 [citado 2008 jul 25];(49). Disponível em: http://www.ensp.fiocruz.br/ radis/49/web-02.html

The survey covered the lawsuits entered into the system as of January 1 to December 31, 2006, and filed by patients that, in the course of the lawsuit, stated they resided in the city of São Paulo, Southeastern Brazil, and received medication through lawsuits filed against the State of São Paulo.

The data selected for analysis based on each lawsuit were: court filing number, lawyer, prescribing physician and medication sought after.

The SCJ was implemented in 2005 and as of then it has underwent updates aimed at improving its performance. Initially, much of data had to be entered into the system manually, and contained typing mistakes.

The SCJ is an electronic registry that was not organized as a database. As a result, it was necessary to standardize each and every one of the interest variables and to codify them based on the reports obtained from the system. Standardizing was carried out according to the name of lawyers, name of physicians and name of the active ingredient. After this stage, a file with this data was created for reference throughout the study.

The drugs that gave cause to more than 30 lawsuits were initially grouped according to active ingredients, totaling 21 items. When these drugs had the same active ingredient but were presented differently (for instance, insulin lispro 10ml cartridge and 3ml refill), the amount of requests were added together. For rituximab 100 and 500mg, it was decided to consider the amount of requests for the product that was requested in higher quantities, this is because these products are used together to make up the appropriate dosage.

To determine the size of the share of the market of a certain drug when it is included under a SUS program, the information used was the data on total expenditure of the São Paulo State with general and special drugs. Although the costs are borne by the São Paulo State, the Health Ministry allocates funds for special drugs. The legal costs connected to the lawsuits were also assessed.

To analyze the data, descriptive statistics were used to characterize the lawsuits according to the above aspects. EpiInfo, version 3.3.2, and Microsoft Office Excel® 2003 were used for data processing, thus enabling data analyses, tabulation, and building charts and tables.

The project was assessed and approved by the Ethics in Research Committee of the Santa Casa de Misericórdia of São Paulo, according to the norms of Resolution 196 of the National Health Council (Conselho Nacional de Saúde) (Project 262/07). The data used do not identify the complainants or the names of lawyers and prescribing physicians.

One last obstacle faced during this study was the lack of access to certain pieces of information because they were illegible or even unavailable in the course of the lawsuit.

During the course of this study, there was an increase in the number of patients requesting diabetes medication, who were already being provided with medication, but were not registered under the SCJ. In 2006, adalimumab and etanercept were included under the protocol of the Special Medication Program (*Programa de Medicamentos de Dispensação Excepcional*),[e] but since this only took place in the end of the year, they were treated as non-standardized medication.

RESULTS

Distribution of lawsuits according to filing legal professional

One way of investigating the possible creation of an "industry" of lawsuits is to assess the distribution of lawsuits aiming at identifying the dispersion or concentration of the legal professionals filing these suits.

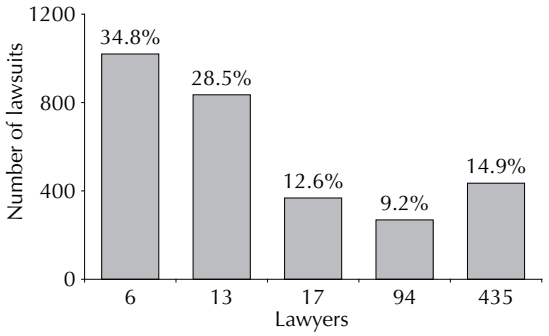
In the study period, 3,007 lawsuits concerning 2,712 patients were entered into the registry. Out of the total number of lawsuits, in 80 (3%) the name of the legal professional could not be retrieved in the SCJ, thus resulting in the study being carried out based on 2,927 lawsuits.

The 2,927 lawsuits were filed by 565 different legal professionals out of which nine were state prosecutors, seven were state attorneys and the remaining were lawyers engaged by the parties (549 corresponding to 97% of the filing legal professionals). The drugs sought after in the lawsuits were prescribed by 878 different physicians.

Out of the 565 legal professionals, six (1%) filed at least 105 and at the most 292 lawsuits each, which corresponds to 35% of the total number of lawsuits; whereas 435 legal professionals (77%) filed a single lawsuit, corresponding to 15% of the total (Figure 1).

While assessing the distribution rate of lawsuits, it was found that out of the six legal professionals responsible for filing the highest number of lawsuits against the State, four are State Attorneys. The São Paulo Legal Aid (*Defensoria do Estado*) was created in 2006 and aims at providing legal assistance to the needy population of the State of São Paulo. Before that the São Paulo State Attorney's Office had a team of professionals to provide legal services to citizens that could not afford to be represented at the Courts. During this study's

[e] Ministério da Saúde. Secretaria de Assistência à Saúde. Departamento de Sistemas e Redes. Protocolos clínicos e diretrizes terapêuticas: medicamentos excepcionais. Brasília; 2002.



Source: São Paulo State Court Registry, 2008.

Figure 1. Distribution of lawsuits per number of lawyers. City of São Paulo, Southeastern Brazil, 2006.

data gathering period, it was still the State Attorney's Office that filed suits against the State in the name of the needy population. Therefore, when examining the data concerning the legal professionals filing more than ten lawsuits against the State of São Paulo, these State Attorneys were not included, thus we were left with a total number of 32 legal professionals.

While assessing the complaints of lawyers who filed more than ten lawsuits against the State, 1,463 lawsuits were found. These were filed by 32 different lawyers and contained 578 drug items prescribed by 816 different physicians.

Out of the 816 physicians whose prescriptions provided grounds for the lawsuits, it was found that 77 had written more than ten prescriptions and out of these, 14 came up in more than 20 lawsuits and five in more than 30.

Most sought after drugs in lawsuits

Concerning the drugs sought after through legal proceedings, there were more than 30 requests for 21 drugs; seven of which were requested 80 times and five (24%) were regularly supplied by the SUS. Among the drugs with more than 80 requests, we found 86 requests for NPH insulin, 337 for special insulin (insulin glargine and insulin lispro), 121 for infliximab (Remicade®), 133 for etanercept (Enbrel®), and 249 for adalimumab (Humira®). It is worth noting that each lawsuit may contain a request for more than one drug (Table 1).

The data show that the distribution of lawsuits is considerably concentrated in terms of the medication sought after, prescribing physician, and legal professionals responsible for filing the cases.

Most lawsuits are aimed at obtaining expensive, sophisticated and newly marketed drugs and, therefore, aimed at drugs that have not accumulated a lot of experience in terms of usage. A small number of lawyers are associated to a large number of lawsuits suggesting they specialize in this kind of lawsuit. Only 36 lawyers were responsible for filing 76% of the cases (Figure 1). The same takes place among physicians, although at a smaller scale, due to the small number of physicians specialized in treaty this group of conditions, or because of the small number of professionals familiar with legal proceedings.

Concentration of lawsuits per lawyer according to drug and manufacturer

Once a concentration in the distribution of lawsuits in is established according to a limited number of lawyers, drugs and physicians, the next step was to investigate the features of this concentration (Table 2).

Out of the lawsuits analyzed, 1,309 sought to obtain the 14 drugs listed in Table 2. These lawsuits were filed by 31 different lawyers; however, 11 lawyers were responsible for filing 613 (47%) lawsuits.

Figure 2 shows the maximum concentration rate of lawsuits per lawyer according to medication sought. More than 70% of the lawsuits aimed at obtaining drugs such as palivizumab, rituximab, bevacizumab, and aripiprazole were filed by one single lawyer, and between 59% and 70% of the lawsuits requesting adalimumab, erlotinib, peginterferon and, etanercept were also filed by one single lawyer.

By analyzing the number of lawsuits filed per lawyer, it was found that 35% of them were lodged by 1% of the lawyers, thus revealing a concentration of the number of lawsuits in the hands of certain legal professionals (Figures 1 and 2). The data from the lawsuits show that a small number of lawyers are responsible for most lawsuits filed aimed at obtaining the above drugs (Figure 2).

Out of the 31 lawyers assessed, 21 filed lawsuits (60% or more) concerning one single drug; seven concentrated lawsuits aimed at two drugs and only four filed legal suits for three or more different drugs. The marked specialization connecting lawyer to product is noteworthy.

Santos & Gonçalves,[f] in a descriptive analysis of court orders against the Federal Government, between April 2005 and March 2006, found that "the flow of claimants suggests there is a scheme to sue the State, involving patient associations, lawyers, and possibly the pharmaceutical industry". The authors noted in their study that all the court orders examined (28) were obtained by privately hired lawyers and 21 of them were obtained by the same lawyer.

[f] Santos CC, Gonçalves AS. Análise descritiva de mandados judiciais impetrados contra a secretaria de saúde do Distrito Federal para fornecimento de medicamentos [dissertation] Fundação de Ensino e Pesquisa em Ciências da Saúde; 2006.

Table 1. Drugs causing more than 30 lawsuits filed by lawyers responsible for more than 10 lawsuits each. City of São Paulo, Southeastern Brazil, 2006.

Drug requested	Number of lawsuits
Rituximab 100 mg	33
Bevacizumab 400 mg	34
Acetylsalicyclic acid 100 mg[a]	35
Imatinib 100 mg	35
Peginterferon alpha-2a -180 mcg[a]	36
Rituximab 500	37
Teriparatide 750 mcg	38
Regular human insulin 100 UI/ml – 10 ml	38
Ribavirin 250 mg[a]	45
Insulin aspart 100 UI/ml (refil)	46
Aripiprazol 15 mg	55
Insulin glargine 100 UI/ml – 10 ml	59
Erlotinib 150 mg	59
Palivizumab 100 mg	70
Human insulin NPH 100 UI/ml - 10 ml[a]	86
Insulin lispro 100 UI/ml (refil)	98
Insulin glargine 100 UI/ml (refil)	109
Infliximab 100 mg[a]	121
Insulin lispro 100 UI/ml – 10 ml	130
Etanercept 25 mg	133
Adalimumab 40 mg	249

Source: São Paulo State Court Registry, 2008.
[a] Drugs supplied on a regular basis by the SUS through pharmaceutical assistance programs.

Therefore, in several analyses, a high concentration between lawyers and drugs can be found.

Concentration of number of lawsuits per prescribing physician according to drug and drug manufacturer

Figure 3 shows the maximum concentration rate of lawsuits per physician and prescribed medication: 66% of the 59 lawsuits aimed at obtaining erlotinib were prescribed by the same physician. For the remaining drugs, the concentration rate of lawsuits is less marked and less than 30%.

DISCUSSION

The costs of marketing and management in 2001 totaled in average 35% of the revenues of the pharmaceutical industry in the United States. The industry claims that marketing encompasses advertising to consumers, sales visits to physicians, free samples,[5] and adds in medical journals. However, in addition to the marketing mentioned by the industry, there is also marketing disguised as educational information.[1] In 2001, in the United States, the pharmaceutical industry funded more than 60% of continued medical education by sponsoring conferences and talks. This educational process has resulted in the pharmaceutical laboratories exerting influence in medical prescriptions, thus increasing their sales and fostering a kind of medical practice that makes intense use of medication. On many occasions the studies presented at these conferences describe successful usage of certain drugs, which fall outside the scope of FDA approval, aiming at widening their scope of application, thus increasing the number of prescriptions. Moreover, the costs with information are borne by the marketing budget of pharmaceutical companies, therefore, affecting the final purchase price of drugs.[1,7]

Specialists are paid by the pharmaceutical industry to give talks and presentations on their products, and the industry controls the number of prescriptions for a certain product before and after a certain presentation or talk in order to measure the return on investments.[6,7] A study carried out in the United States and published in 2008 reports the existence of conflict of interests among the authors of Clinical Trial Protocols and the pharmaceutical industry. Out of the 50 protocols examined, 83% of investigators were in conflict of interest with the industry since their studies were funded by the latter or by its profits.[3]

State cost of medication and State legal costs resulting from lawsuits seeking supply of medication

In 2006 the State of São Paulo, in complying with São Paulo State court decisions, spent 65 million Brazilian reais to provide medication for approximately 3,600 individuals.[g] In comparison, in the same year, to the Special Medication Program, 838 million reais were spent to provide medication for 380 thousand individuals. This means that for each patient seeking to obtain medication through a lawsuit, 18 thousand reais were spent, whereas, the cost per patient according to the Special Medication Program was 2.2 thousand reais.

In 2006, the total São Paulo State budget for healthcare was eight billion reais[h] (not including payroll). The São Paulo State spent 1.2 billion reais in drugs, out of which 827 million reais were spent with only 30 kinds of drugs, out of which 24 fell under the Special Medication Program, two were for hospital use (sodium

[g] Terrazas FV. O poder judiciário como voz institucional dos pobres: o caso das demandas judiciais por medicamentos [dissertação de mestrado]. São Paulo: Faculdade de Direito da Universidade de São Paulo; 2008.
[h] Secretaria de Economia e Planejamento do Estado de São Paulo. Planejamento e Orçamento[internet]. [cited 2008 Jul 9] Available at: http://www.planejamento.sp.gov.br/planorca/orca.aspx#

Table 2. Drug, number of lawsuits, lawyers, highest number of lawsuits per lawyer, physician, and highest number of lawsuits per physician. City of São Paulo, Southeastern Brazil, 2006.

Drug	Number of lawsuits	Number of lawyers	Highest number of lawsuits per lawyer	Number of physicians	Highest number of lawsuits per physician
Adalimumab	249	8	148 (59.4%)	73	15 (6.0%)
Insulin lispro	228	13	45(19.7%)	146	8 (3.5%)
Insulin glargine	168	14	38 (22.6%)	120	6 (3.5%)
Etanercept 25mg	133	10	81 (60.9%)	61	14 (10.5%)
Infliximab 100mg	121	6	40 (33.1%)	56	24 (19.8%)
Palivizumab	70	3	52 (74.3%)	35	5 (7.1%)
Erlotinib	59	7	41 (69.5%)	15	39 (66.1%)
Aripiprazole 15mg	55	4	42 (76.4%)	33	7 (12.7%)
Insulin aspart	46	11	15 (32.6%)	36	4 (8.7%)
Teriparatide	38	9	11(28.9%)	27	4 (10.5%)
Rituximab	37	6	27 (72.9%)	16	9 (24.3%)
Peginterferon alpha-2a	36	4	24 (66.7%)	19	6 (16.7%)
Imatinib	35	6	13 (37.1%)	21	8 (22.8%)
Bevacizumab	34	4	28 (82.4%)	18	9 (26.5%)

Source: São Paulo State Court Registry, 2008.

chloride 0.9% and imipenem + cilastatin sodium), and the others were: imatinib, adalimumab, etanercept, and special insulin (insulin lispro, glargine, humalog and detemir) supplied through court orders resulting from lawsuits.

The amount of resources spent in acquiring medication shows the importance of the role played by the number of lawsuits in government expenditure and in the profits of the pharmaceutical industry.

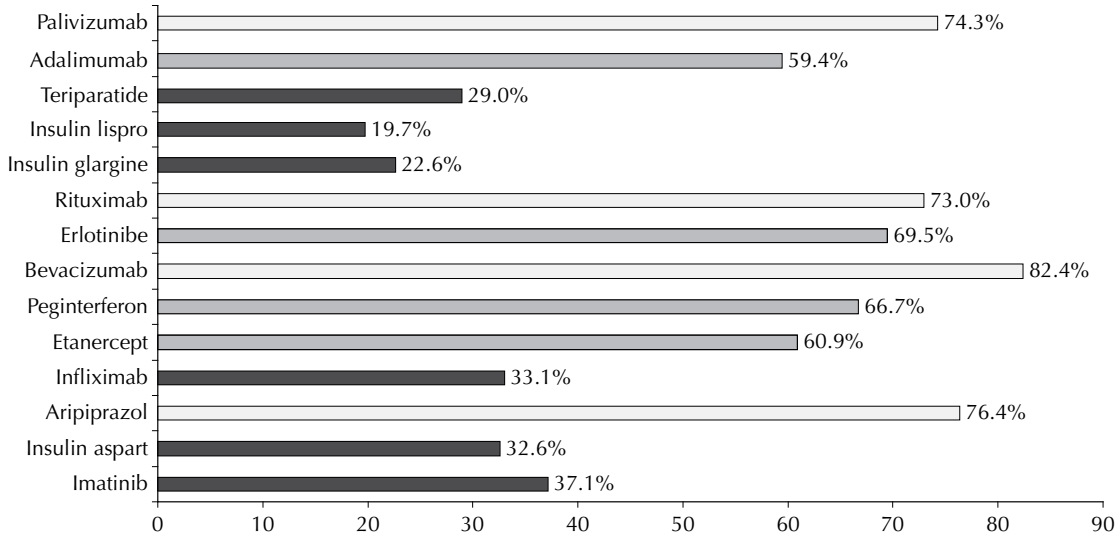
In the period between 2004 and 2006, the amount spent with adalimumab and etanercept which are indicated for treatment of auto-immune diseases such as rheumatoid arthritis, but have not yet been included under the protocol of the Special Medication Program, totaled approximately 111.2 million reais in order to comply with court orders. In the end of 2006, both drugs were incorporated by the Healthcare Ministry to the Special Medication Program,[i] and in the beginning of 2007 they were available at SUS pharmacies. As a result, there has been an increase in the use of such medication, which until then was only supplied via the courts.

In 2004, the State of São Paulo spent, approximately, four million reais in adalimumab, 21 million reais in 2005, and 39 million in 2006. In etanercept, the amount spent was 3.2 million reais in 2004, 15 million in 2005, and 29 million in 2006. It was noted that there was an increase in the number of lawsuits seeking to obtain these two drugs in the period prior to their being included under the SUS program.

In a study describing lawsuits aimed at supplying medication brought against the State of Rio de Janeiro, between 1991 and 2001, Messeder et al[4] found the appearance and later on the increase of requests for mesalazine, riluzole, peginterferon, sevelamer, levodopa+benserazide, rivastigmine, simvastatin, and infliximab as of 2001. These drugs were included in the end of 2002 under the Special Medication Program of the Brazilian Health Ministry.[j] The increase in the number of lawsuits requesting these products may suggest a strategy of the pharmaceutical industry to have these drugs introduced under the SUS protocols.

The drugs bevacizumab and erlotinib, used in the treatment of various kinds of cancer, in the period studied, were not available in the Brazilian market and, therefore, had to be imported by the State. Anvisa gave its approval to the registration of these drugs in 2006; however, they only became available in the Brazilian market in 2007.[k] After the request for registration is approved, it is still necessary for the purchase price to receive the approval of the Chamber for the Regulation of the Medication Market (Cmed - *Câmara de Regulação do Mercado de Medicamentos*), which is an entity within Anvisa. It is only after the price is registered with Cmed that a certain drug can be marketed in Brazil.

[i] Ministério da Saúde. Portaria nº 2.577, de 27 de outubro de 2006. Aprova o Componente de Medicamentos de Dispensação Excepcional. *Diario Oficial Uniao*. 13 nov 2006;seção 1:44.
[j] Ministério da Saúde. Portaria nº 1.318 de 23 de julho de 2002. Define para o Grupo 36 - Medicamentos, da Tabela Descritiva do Sistema de Informações Ambulatoriais do Sistema Único de Saúde - SIA/SUS. Diario Oficial União. 24 jul 2002;Seção 1:p. 68.
[k] Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Registro de medicamentos [internet]. 2008 [citado 2008 jul 9]. Available at: http://www7.anvisa.gov.br/datavisa/Consulta_Produto/consulta_medicamento.asp



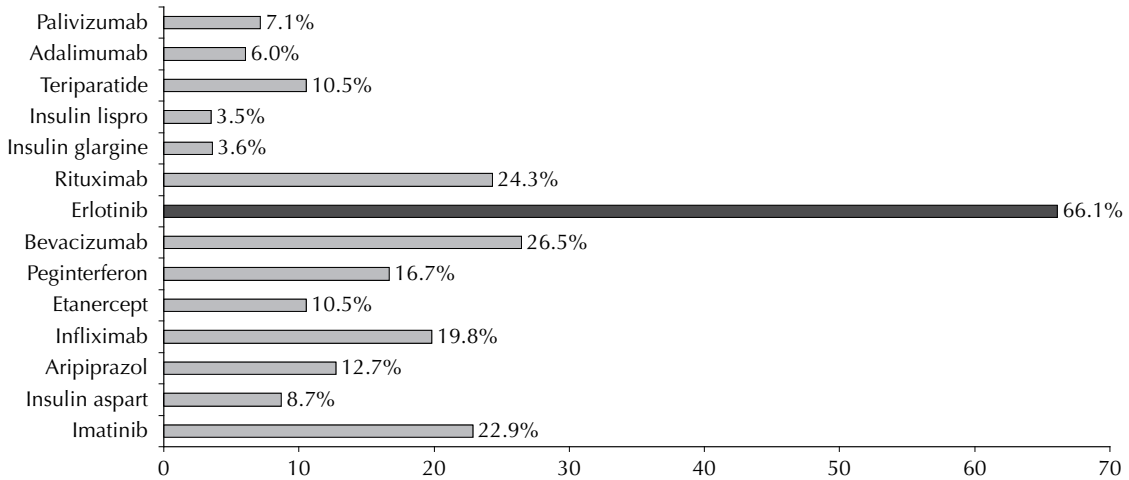
Source: São Paulo State Court Registry, 2008.

Figure 2. Highest concentration of lawsuits per lawyer according to drug prescribed. City of São Paulo, Southeastern Brazil, 2006.

The period of time between the registration of the drug and the registration of the price of the drug provides the industries with the possibility of purchasing this drug through legal procedures, which enables them to practice the price the industry itself establishes, since these drugs do not have counterparts and are manufactured by one single pharmaceutical laboratory. When a lawsuit is filed, SUS is legally bound to acquire the drugs and import them to Brazil without having the opportunity of negotiating the price.

This situation seems to corroborate the strategy of introducing "innovative" products. Initially, a product is launched at medical events, preferably at a talk or conference given by a renowned specialist. Following that, some physicians start prescribing the drug. Patients in turn are guided by their own physicians or by associations of patients who have the condition – associations which a frequently funded by the pharmaceutical industry – to seek a legal remedy in order to obtain the medication prescribed. This phenomenon repeats itself thus the number of claimants increase progressively.[1,7]

Although analyzing the features of the legal suits did not enable us to exhaust the complexity of the role these



Source: São Paulo State Court Registry, 2008.

Figure 3. Highest concentration of lawsuits per physician according to drug prescribed. City of São Paulo, Southeastern Brazil, 2006.

lawsuits may play in the strategy of introducing new drugs and opening markets to newly launched products by the pharmaceutical industry, the data revealed a high concentration in the distribution of lawsuits both in terms of the drugs sought after, and in terms of lawyers filing these suits and prescribing physicians.

REFERENCES

1. Angell M. A verdade sobre os laboratórios farmacêuticos: como somos enganados e o que podemos fazer a respeito. Rio de Janeiro: Record; 2007.
2. Fitzgerald GA. Drugs, industry and academia. *Science*. 2008;320(5883):1563. DOI:10.1126/science.1161006
3. Holloway RG, Mooney CJ, Getchius TS, Edlund WS, Miyasaki JO. Invited article: conflicts of interest for authors of American Academy of Neurology clinical practice guidelines. *Neurology*. 2008;71(1):57-63. DOI:10.1212/01.wnl.0000316319.19159.c3
4. Messeder A, Osório-de-Castro CGS, Luiza VL. Mandados judiciais como ferramenta para garantia do acesso a medicamentos no setor público: a experiência do Estado do Rio de Janeiro, Brasil. *Cad Saude Publica*. 2005;21(2):525-34. DOI:10.1590/S0102-311X2005000200019
5. Mohapatra PR. Interaction between medical practitioners & pharmaceutical industry. *Indian J Med Res*. 2008;127(1):93.
6. Moynihan R. Key opinion leaders. Independent experts or drug representatives in disguise? *BMJ*. 2008;336(7658):1402-3. DOI:10.1136/bmj.39575.675787.651
7. Petersen M. Our daily meds. New York: Sarah Crichton; 2008.
8. Vieira FS. Ações judiciais e direito à saúde: reflexão sobre a observância aos princípios do SUS. *Rev Saude Publica*. 2008;42(2):365-9. DOI: 10.1590/S0034-89102008005000010

The authors declare that there are no conflicts of interest.