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Profile of legal claims for medicines in a large municipality in the state of Bahia

Perfil das demandas judiciais dos medicamentos em município de grande porte do estado da Bahia

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ABSTRACT
The phenomenon of judicialization of health to obtain assistance, care, procedures, health products and medicines is being incorporated into health care practices, based on the demands to obtain Fundamental Rights.

KEYWORDS: Judicialization of health, Medicines, Health.

1 INTRODUCTION

The phenomenon of judicialization of health to obtain assistance, care, procedures, health products and medicines is being incorporated into health care practices, based on the demands to obtain Fundamental Rights.

For Engelmann (2012, p89), the phenomenon of the judicialization of health is at the heart of the politics of contemporary Western democracies, which involves several problems to be explored by Political Science, permeated by the emergence of a "legal interpretation" of political life.

> The profiles of arguments present in the decisions show that the activism of the Judiciary is based on legal conceptions that oppose the "unity of the State" and the "interpretation of the Constitution" to the dynamics of public administrations. The phenomenon that can be called the "juridicization of politics" in Brazil involves several problems that need to be better explored by political science, among which we highlight the emergence of a "legal interpretation" of the dynamics of the execution of policies with strong public repercussions.

On the other hand, in European countries several forms of collective advocacy are also identified, linked to the defense of socially excluded groups (such as immigrants) or interest groups. Thus, the problem of judicialization with the emergence of lawsuits demanding public policies are recurrent in Western democracies.

Thus, the function of the Judiciary is to effect the right to health, when the Legislative and Executive Powers are not able, considering that their decisions should aim at the best for the whole society, but brings in legal activism the limits of the judiciary's performance, the concern with management, in the face of increasingly scarce resources, provoking a much deeper discussion about the observance and strengthening of the principles of the SUS, highlighting equity as a marker of decisions and impacts of legal action (FARIA, 2014).

The fundamental right to health is enshrined in the Brazilian Constitutional Charter, constituting part of the list of rights classified as fundamental social. However, despite being expressly provided for as a right of all and a duty of the State, the fact is that in various situations and for the most different justifications the State fails to fulfill its social role in guaranteeing and enforcing this fundamental right. (RODRIGUES, 2014). In this way, the State has the duty to provide services, that is, the duty to provide supplies, care, procedures and medicines that are necessary for full assistance

The Pharmaceutical Assistance Policy then emerges as one of the public policies that must manage and guarantee access to medication to fully assist the individual in accordance with the ordinary norm, Law No. 8080/90. to the health provided for in the constitutional norm.

Since Law No. 8080/90 (BRASIL, 1990), which guarantees comprehensive therapeutic assistance, including pharmaceutical care, in paragraph **d of item I of article 6**, the Brazilian State has been obliged, through public policies, to provide all medicines consumed by users of the Unified Health System - SUS and also by those who use private services.

Public policies such as the National Drug Policy (PNM) and the National Pharmaceutical Assistance Policy (PNAF) were presented as guarantees for this, but the accessibility of medicines was never consecrated as an irrefutable right, on the contrary, given the great demands and the high cost of the drug in the health care system, it is not always possible to comply with the dispensing of all the drugs prescribed in the thousands of health units and hospitals in the country. (BRASIL, 2014,2004,1998, 1996,1990).

To this end, pharmaceutical assistance at the municipal level has to guarantee the supply of medicines that comply with all the coverage of primary care and special programs of the Ministry of Health, requiring a direct articulation with the state and federal entities and as a way to ensure access and quality in pharmaceutical care requires an observance of the National List of Essential Medicines-RENAME and preferably organize a Municipal List of Medicines Essentials-REMUME, which portrays the epidemiological reality of each municipality.

From 1999 onwards, the attendance to the demand for medication was developed in the Clinical Protocols and Therapeutic Guidelines (PCDT) for each of the drugs considered to be of high cost, with an alleged intention to rationalize the prescriptions and dispensations. These

protocols aim to clearly establish the diagnostic criteria for each disease, the recommended treatment with the available drugs, the correct doses, the control mechanisms, the monitoring and verification of results, and the rationalization of prescription and supply. Observing the ethics and technical prescription, the PCDT also have the objective of creating mechanisms to guarantee the safe and effective prescription (CONASS, 2004, P. 55). reference

A document of the Pan American Health Organization (PAHO, 2009, p.9) presents the various aspects that constitute barriers to access to medicine, such as: *1. Research and development problems; 2- Availability Problems; 3-Limitations of health services; 4-Limitations in the supply system; 5- Limitations in Accessibility.*

In 2002, it was estimated that 70 million people did not have access to medicines in Brazil, which corresponded to approximately 41% of the Brazilian population that year. The challenges for the management of PA, caused by the phenomenon of judicialization of Health, have demanded a type of administrative and judicially differentiated action, in order to respond to court orders, avoid the growth of new demands as well as preserve the principles and guidelines of the Unified Health System (PEPE *et.al*., 2009; VIEIRA, ZUCCHI, 2007).

Citizens are an important part of this process and have sought, within the new social, democratic order and valuing social and individual rights, promoting the establishment of regulations and public policies that favor better
access conditions (BIEHL; PETRYNA,2016)

Henriques (2015) points out that fundamental rights differ from others precisely because they present characteristics in order to have as their purpose to protect the individual from provisions to the contrary, as well as to guarantee the exercise of these rights.

In particular, the lack of free access to medicines for the treatment of chronic diseases affects more intensely and frequently the most vulnerable population in poorer regions of the country, especially certain classes of drugs, such as some that act on the respiratory system, according to data from the National Survey on Access, Use and Promotion of the Rational Use of Medicines (PNAUM), developed in 2012 (AKERMAN; FREITAS, 2017)

In this environment, the citizen seeks the intervention of the Judiciary to determine the free supply of medicines in a variety of hypotheses with the objective of realizing the constitutional promise of universalized and integralized provision of the health service, seeking to find forms and instances of democratic control of technical standards compatible with the requirement of legal security proper to the Rule of Law.

Then, from the entry of the Judiciary in technical decisions, a conflict between legal rationality and technical rationality is fought, and legal rationality is incompetent to assess substantive issues (CASTRO, 2016), a situation already warned by Barata and Cheffi (2009), especially with regard to the compromise of equity in the SUS.

In the recent study by Oliveira and others (2018) on lawsuits in the State Department of Health of the state of Pernambuco, in 2016, 63.5% of the 2,560 lawsuits raised were for access to medicines, while access to the ICU represented 8.1% and to food 5.1%. The processes on the search for High Cost Drugs (48%) are more concentrated in metropolitan regions. The five most requested drugs were Cinacalcet - indicated in patients on dialysis in the treatment of Secondary Hyperparathyroidism (SHPT), chronic kidney disease (CKD) and Somatropin, Abiraterone, Insulin Glargine and Leuprorelin. These data point to an opportunity to better study the reality of judicialization for access to medicines throughout the country and to deepen investigations on its social determination.

Such studies are also justified due to the scarce literature having as object the phenomenon of judicialization. Thus, this article aims to analyze the judicialization of access to medicines in the SUS, in a municipal health network, in the years 2017, 2018 and 2019.

2 METHODOLOGY

Documentary research, with a quantitative-qualitative approach. The unit of analysis is a lawsuit, filed by the citizen against the municipal health department of the municipality of Feira de Santana-BA, with manifestation of the judicial system, demanding the supply of medicines that were requested, in the years 2017, 2018 and 2019.

It was chosen the municipality of Feira de Santana, second largest city in the State of Bahia, distant from the state capital by 108Km, connecting by BR 324. The municipality has an estimated population of 619,609 people and a population as of the 2010 census of 556,642. It has an HDI of 0.712. The Municipal Human Development Index (HDI-M) of Feira de Santana is considered high by the United Nations Development Program (UNDP) - its value is 0.712 (IBGE, 2010). Feira de Santana occupies the 1546th position, in relation to the 5,570 municipalities in Brazil. Infant mortality Infant Mortality [2017] 14.67 deaths per thousand live births.

With a population of 556,642 inhabitants, Feira de Santana (2020) has a basic network of: APS, in 2019, consisting of:

- 91 Family Health Units (FHU);
- 12 Basic Health Units (TRADITIONAL UBS);

- 120 Family Health Teams (FHT) with doctor, nurse, nursing technician, administrative assistant, general services and community health agents;
- 44 Oral Health Teams (eSB) with dentist and dental office assistant;
- 35 dentists who work in traditional UBS;
- 22 Extended Family Health Center Teams (eNASF)

To meet this network, the secretariat has a coordination of Pharmaceutical Services that guarantees the supply and dispensing of medicines in all units, even if it does not have a pharmacist in front of this exclusive activity of the pharmaceutical professional.

During the study period, 480 cases of judicialization of medicines for the municipality of Feira de Santana were registered with the State Attorney General's Office. These processes only appear in the PGE reports quantitatively, without definition of which drug, who was the petitioner and other important data for the study. And, because they also appeared in the data of the Health Department of the municipality, they were excluded from the study in order not to occur overlapping data and, also, because any type of analysis became impossible, given that there was no physical process. As there was no physical process, 100% had no record of the lawyer's name or resorted to the Public Defender's Office. Due to this situation, it was decided to use only the information from the Health Department of the municipality of Feira de Santana, which offered full conditions for the analysis of physical processes.

Thus, 173 cases were included in the studies, from July 2017 to August 2019 , and 87% of the processes allowed to obtain information about the drugs, the illness of the petitioner and their legal conduct. A similar study in the city of São Paulo presented similar results regarding the organization of processes (VIEIRA; ZUCCHI, 2006)

The data, therefore, are primary in nature, coming from 174 non-digitized processes. Initially, these cases should be collected in files of regional courts, in the State Attorney General's Office (PGE) of Bahia. There was no computerized system or database on Judicialization, even though it is one of the most important works of the PGE, given the number of judicialization processes and, also, access to the processes was not facilitated, so that only in the Coordination of Pharmaceutical Services of the municipality of Feira de Santana, the guidance was obtained to file a request for authorization with the coordination of continuing education of the secretariat. The request went through the Secretariat's Ethics Committee and was authorized. Upon returning to the Coordination, the latter directed that data collection be carried out at the Pharmaceutical Supply Center (CAF). In the Field Diary, the researcher reports

> the meeting of a jumble of messy folders and processes. I had to spend precise time sorting the folders, finding loose sheets of process to get the process complete, but all the work was rewarded with abundant material that met the needs of the research. I had to go back there several times to check data, number of processes and other information.

After exhaustive reading of the material, the following elements of interest for the analysis were identified: gender and age of the applicant; informed diseases, therapeutic classification of the requested drugs, origin of the prescription (SUS or private), type of legal representation, existence of RENAME and/or REMUME and registration with ANVISA.

The data were organized in tables, categorized and simple frequencies were calculated. For the category of drugs by type, the Anatomical Therapeutic Chemical Classification (ATC) was used. To apply the ATC classification, all medicinal products were identified by the respective IND International Non-proprietary Name (generic).

3 RESULTS AND DISCUSSION

The profile of the plaintiffs in the 174 cases analyzed was composed of 90 (51.7%) females and 84 (48.2%) males, showing a distribution more or less compatible with the distribution in the population of Feira de Santana, which remains stable at about XX/YY (Table 1).

Table 1. Profile of the applicants and origin of the prescriptions of lawsuits, against the Municipal Health Department of Feira de Santana-BA, 2017, 2018 and 2019

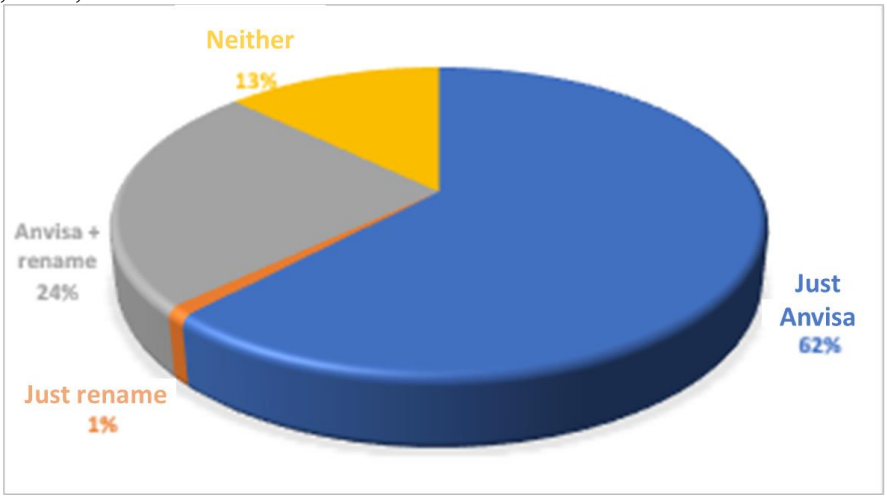
Variable	**n**	**%**
Gender		
Female	90	51,7
Male	84	48,2
Age Group (years)	**n**	**%**
Age 0-20	29	16,6
Age 21-40	57	32,7
Age 41-60	59	34
Age 61-80	25	14,3
Over 80	4	2,2
Origin of prescriptions*	**n**	**%**
SUS Services	166	95,4
Private services	8	4,5

It can be observed that the most demanding age group was the group of 41 to 60 years, with a total of 59 (34.0%) individuals. In the range of 0 to 20 years, all minors were legally represented by their parents. No parent appearing as a legal representative.

In the total of the processes analyzed, 306 different items were requested, with 20 cases containing medicines and non-medicines (medical-scientific and sanitary elements) and 133 processes where only medicines were requested. It was possible to identify that 86% of all drugs

were registered with ANVISA, and of these, 24% were also part of RENAME. Only 1% of the drugs were only in RENAME, while 13% were not in either of the two lists (Graph 1). It is important to emphasize that the management of pharmaceutical care must have the security of the records to enable the policy of standardization of medicines that will facilitate, in turn, the availability of the same in the network and better access to users (BRASIL, 1998).

Figure 1. Distribution of medicines required jududucially, by registration in ANVISA and inclusion in RENAME, Feira de Santana, Bahia, 2017-2019



A total of 133 drug items were requested, corresponding to 15 different types of drugs corresponding to 6 classes of the ATC (A, C, H, M, N, L). Of the total of 306 drugs, 7 (4.5%) were not available in the national market and 15 (9.8) belonged to Group 1 of the drugs of the Specialized Component, the one whose financing is under the exclusive responsibility of the Union. Group 1 consists of drugs that represent a high financial impact for the Specialized Component, those indicated for diseases with more complex treatment, for cases of refractoriness or intolerance to the first and/or second line of treatment, and for those that are included in productive development actions in the health industrial complex (BRASIL, 2017).

Drugs intended for diseases of the nervous system were the most judicialized, in a number of 30 (33%), followed by drugs for diseases of the cardio-vascular system 28 (20%) (Table 2).

Table 2. Distribution of medicines judicialized by ATC classification, in the municipality of Feira de Santana, Bahia, from 2017 to 2019

ATC Rating*		Drug	n	%
Letter	**Organic systems/ Therapeutic function**			
N	Nervous system	Valproic Acid, Agomelatine, Amitriptyline, Aripiprazole, Baclofen, Pyridostigmine, Carbamazepine, Cytolopram, Clonazepam, Lidocaine, Methylphenidate, Depakote Sodium, Diazepam, Phenobarbital, Gabapentin, Imipramine, Lacosamide, Oxcarbazepine, Risperidone, Sertraline, Tizanine, Tramadol, Trileptal, Codeine Phosphate, Zolpidem, Atropine, Paracetamol, Cecolote, Agomelatine, Riluzole	30	33
C	Cardiovascular system	Amiodarone, AAS, Candesartana, Benicar, Olmesartana, Clopidogrel, Cilostazol, Digoxin, Desmopressin Monocordyl Acetate, Losartana, Nebivolol, Prednisone, Propranolol, Metoprolol, Sinvastatin, Minoxidil, Solifenacin, Oxybutynin, Enoxaparin, Enalapril, Trimetazidine Dichloridate, Rivaroxabana, Cinacalcete, Cilostazol. Isosorbide, Cilexetila,Olmesartana	28	20
A	Gastrointestinal tract and metabolism	Sodium Alendronate, Calcitran, Rosuvastatin, Dipyrone, Domperidone, Lactulon, Sorbital, Omeprazole, Ondansentron, Ranitidine, Renalvit, Rifaximin, Sulfassalazine., Minilax. Insulin, Insulin Glargine, Insulin Glulisine, Mesalazine, Arcabose, Sitagliptin Phosphate, Vitamin Complex, Calcitrol, Glicazide, Adalimumabe, Aflibercepte, Diosmin, Calcium Dobesilate, L-OrnithineL-Aspartate	28	19
L	Antineoplastic and Immunomodulatory Agents	Cetuximabe, Tamoxifen, Doxazonine, Imatinibe, Rituximabe, Sorafenibe, Tacrolimus, Temodal, Infliximabe, Miclofenate Sodium, Mycophenolate Mofetil, Azathioprine, Ranibizumabe, Temozolomide, Ondasentron, Human Gamma Globulin, Rifaximin	17	11
H	Systemic hormonal drugs, excluding sex hormones and insulins	Aspride, Azathioprine, Metformin Hydrochloride, Cinacalcet, Deposteron, Glycazide, Insulins, Mimpara, Levothyroxine, Testosterone, Desmopressin Acetate	12	10
M	Musculoskeletal System	Trometamol, Lysine Clonixinate, Tizanidine, Calcitrol, Ardapol, Adalimumabe, Baclofen, Hydrocortison, Tacrolimus, Anlodipine Besylate, Ardapol, Pyridostigmine Bromete	12	7
D	Dermatological	Helioridal, Hixizine, Flutinol	3	

ATC1: Anatomical Therapeutic Chemical Classification
Source: Department of Health of the Municipality of Feira de Santana. Coordination of Pharmaceutical Services. Own elaboration.

Already, the most judicialized drug was ranibizumab indicated for the treatment of macular edema (usually from complications of diabetes mellitus), which appeared in 17 cases. The other 4 most demanded drugs were: imipramine; Insulin garglina, oxybutin; rivaroxaban

Of the antineoplastic drugs delivered by lawsuit, one of them was not registered in Brazil and was prescribed and judicially granted the right of use without having a record of clinical trials that confirm its efficacy. Sorafenib, indicated for renal cell carcinoma, is, at the time of writing

this article, under analysis by the National Commission of. Incorporation of Technologies in SUS (CONITEC).

Non-medicated materials and supplements and a diagnostic procedure, Magnetic Resonance Imaging, were required in a total of 65 items, the most frequent being disposable diapers and collecting bags (in 23 processes, each), followed by lancets and children's colostomy bags (12 processes, each). A request for milk and powdered food supplements in one of the processes draws attention (Table 3).

Table 3. Types of non-drug materials and supplements and diagnostic procedures demanded in lawsuits against the Municipal Health Department of Feira de Santana, Bahia, 2017-2019

Materials and procedures	n	%
Disposable diapers	25	38,5
Collector bag	7	10,7
Lancets	5	8,0
Children's colostomy bag	12	18,4
Urethral catheter	2	3,0
Colostomy barrier cream	3	5,0
Urethral catheter	3	5,0
Insulin Infusion Pump	2	3,0
Gazes	2	3,0
Micropore	2	3,0
Diagnostic procedure (magnetic resonance imaging)	1	1,5
Powdered milks and food supplements	1	1,5

Source: Department of Health of the Municipality of Feira de Santana. Coordination of Pharmaceutical Services. Own elaboration.

Another major difficulty of the research was to identify expenses related to the lawsuits. Most of the lawsuits did not record values of the judicially approved drugs.

From 2017 to 2019, federal transfers for Pharmaceutical Services in the municipality of Feira de Santana-Ba, according to data from the National Health Fund (FNS), totaled R$ 11,179,789.99 million. The values, deflated for December 2019, according to the National Consumer Price Index (IPCA) of the Brazilian Institute of Geography and Statistics (IBGE), went from R $ 3.78 million to R $ 3.64 million, making a reduction of around 4% (R $ 145 thousand).

It is important to note that in the triennium in evidence, health financing policies have changed considerably. There was a decrease in the number of financing blocks (which included the Pharmaceutical Services block), from Ordinance No. 3,992, of December 28, 2017 (BRASIL, 2017), to only two: the ASPS Costing Block and the Investment Block in the Public Health Services Network. In addition, in 2017, the effects of Constitutional Amendment No. 95/2016 (BRAZIL, 2016), considered one of the densest austerity measures adopted in the country for freezing spending on primary expenditures for 20 years, came into force. The budget of the

municipality deals in a general way with the forecasts for health, without detailing the items on health products, inputs and others. (BRAZIL, 2016, 2017).

4 DISCUSSION

Access to medication by judicial means, the well-known judicialization, has stimulated research without, however, achieving uniformity of actions and conclusions that guide management and magistrates for conduct that really achieves equality of care.

Marques (2008) emphasizes that, if, on the one hand, the positive health benefits by the State represent an advance in relation to the effective exercise of citizenship, on the other hand, the tension with managers who understand that the judiciary interferes and compromises what is planned in terms of budget and even in the execution of public policies is intensified.

Contradicting this discussion as an "imbroglio", Fleury (2012) presents arguments that judicial activism can save the SUS, to the extent that the danger of private management presents a successful management and hence destroy the guarantees to the universal right to health, but does not guarantee the justice of equality.

With regard to the discussion about whether there is a great articulation between doctors, lawyers, the pharmaceutical industry, this study did not find elements that supported statements about it. Most of the legal representations were made through the Public Defender's Office and the prescriptions mostly came from the public health service.

This impression from the analysis of the evidence discussed here is in accordance with a study by Orozimbo Campos et al. (2012), which showed that there was coherence in the relationships of the most demanded drugs with the diagnoses and the main medical specialties. Demonstrating prescription coherence, not necessarily rationality.

Finally, it can be observed that the way the municipality's care management favors the search for the judicial route to obtain the medicines. The lawsuits indicate disregard for the PNM and total disregard for RENAME, the statute of limitations was considered the most important and unique requirement for favorable judgment. And, for the secretariat, the sentence was unquestionable.

5 CONCLUSION

This study is a study, with simple statistics and, therefore, does not present a definitive conclusion, on the contrary it served as a stimulus for the researcher to continue the studies in the field of judicialization of health and especially in health equity. The difficulties of the study due

to the absence of systematization of information, either in the health department or in the organs of the Judiciary, did not weaken the spirit of organizing and doing the work, on the contrary, these conditions were considered opportunities for a better knowledge of the work scenario of pharmaceutical colleagues who without the security of job stability, Coming from a public tender, they shrink and do not find strength for the demands of improvements in the quality of work, leading to the compromise of care and pharmaceutical care.

Given this scenario, it is expected that the research will present proposals to public entities seeking new forms of management and especially outlining strategies that favor dialogue and *perhaps* a partnership with the Judiciary for the sake of drug users and the incessant search for equality and even better equity.

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