DEBATE ARTICLE

DOI: http://dx.doi.org/10.12957/demetra.2014.10504

Profile of lawsuits over the access to food formulas forwarded to the brazilian ministry of health

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Abstract

Introduction: Health-related lawsuits against public agencies - including requests for industrialized food formulas - have increased exponentially in Brazil over the last few years. They pose a significant challenge to managers of Brazil's Unified Health System (SUS). As health and feeding are rights under the Federal Constitution, filing of lawsuits has become a challenge to be faced by the Government. *Objective*: To describe lawsuits over access to food formulas against the Ministry of Health in Brazil in 2013. *Methods*: Exploratory and descriptive study of lawsuits against the Ministry of Health in 2013. Descriptors included: gender, age and disease of those who requested formulas, region of origin, food formulas, legal representation, diagnostic confirmation and origin of prescription of food formulas. *Results*: Between 2007 and 2013, there was a growing number of lawsuits over industrialized nutritional formulas forwarded to the Ministry of Health. The analysis of 168 lawsuits filed in 2013, helped to identify the profile of complainants. Their ages range was below two years old and above 41 years old; 53% of them were male, and had mainly neurological diseases (39.3%) and endocrine, nutritional and metabolic diseases (33.9%). The majority of lawsuits was filed in the South (36.9%). Over half of nutritional formulas were prescribed by public health services (53.9%) and most of the lawsuits were represented Public Defenders (65.6%). There was a small number of cases that had diagnostic

confirmation (40.5%), especially when cases of allergies/food intolerance were identified. *Conclusion*: The analysis of the profile of lawsuits made in the present study raises issues rarely discussed in the area of food and nutrition; moreover, it provides information that may contribute to the organization of nutritional care in the Unified Health System (SUS).

Key words: Right to Health. Health Policy. Lawsuits. Food and Nutrition Programs and Policies.

Introduction

Lawsuits over health procedures and inputs against public agencies in Brazil have grown exponentially in recent years. This phenomenon, called "legalization of health" involves political, social, ethical and health-related aspects, in addition to legal issues and the management of public services, thus bringing significant changes to social and institutional relations.[1]

Although the legalization of health is a legitimate way of claiming rights, it undermines the rational allocation of public resources, leading to overlapping of individual rights over collective rights and increasing the unequal access to health.[1-5]

Food and nutrition are basic requirements for the promotion and protection of health; therefore, they are determinant and conditioning factors for good health.[6] The organization of nutritional care at SUS is guided by the National Policy on Food and Nutrition, which also advises that the epidemiological profile of a given territory should be the basis for setting priority actions. Malnutrition and obesity, as well as noncommunicable chronic diseases and special dietary needs, are considered as requirements for the organization of nutritional care.[7]

Some of these health problems associated with food and nutrition may require alternative diets, leading to the use of industrialized nutritional formulas.[8] These formulas are usually expensive and are not subsidized by SUS in particular, except in hospitals and for patients with phenylketonuria.[9-11] However, some states and municipalities have organized a network of health monitoring for individuals with special dietary needs, with clinical protocols and/or their own treatment guidelines, which may involve the supply of industrialized nutritional formulas.[12]

As health and nutrition are considered rights under the Federal Constitution, the request for nutritional formulas through lawsuits against the three spheres of SUS management has grown, and this is a problem for the Government, especially because unplanned allocation of public funds is necessary. The need for subsidies and the development of protocols that guide the prescription and administration of nutritional formulas and their provision by the Government, when necessary, are recurring demands in several areas of agreement and in regional and national conferences where management and social control of SUS are present.[13]

In the Federal Government, the Ministry of Health is the agency responsible for responding to lawsuits that request inputs and SUS-related procedures. These lawsuits are forwarded to technical areas by the Legal Counsel of the Ministry of Health (CONJUR-MS), the implementing agency of the Attorney General's Office,for a technical reportin order to support the defense of the Union The General Coordination of Food and Nutrition (CGAN), Department of Primary Care of the Health Care Division (DAB / SAS), is notified of lawsuits over procedures and procurement of inputs for Nutritional Therapy

There are several studies that discuss the legalization of health and check the profile of lawsuits,[14]; there are not, however, publications nationwide whose theme is the request of nutritional formulas to the Brazilian state.

Given the above, this article aims to describe lawsuits over the supply of industrialized nutritional formulas, received by the Ministry of Health and forwarded to CGAN/DAB/SAS for a technical report in 2013.

Methodology

It is exploratory and descriptive study with a quantitative approach, about lawsuits over industrialized nutritional formulas received by the Ministry of Health and forwarded to CGAN/DAB/SAS in 2013. This particular time period was chosen because information was better organized in the lawsuits forwarded.

As a complement, in order to monitor the progress of lawsuits, the number of technical reports published between 2007 and 2013 was identified. For the description of the profile of lawsuits received in 2013, the data were categorized into the following

variables: gender, age and disease of complainant, region, state and municipality of origin, requested nutritional formula, (public or private) legal representation; diagnostic confirmation (existence of tests or examinations proving the diagnosis of the disease) and origin of prescription of nutritional formula (service public or private health).

The variable "disease of complainant" was grouped into five categories, according to the International Classification of Primary Care (ICPC-2):[15] neoplasms; neurological diseases; diseases of the urinary tract; digestive diseases; and endocrine, nutritional and metabolic diseases. In addition, the "other" category was also created, given that the classification of these diseases according to ICPC-2 would involve the creation of groups with only one disease .

The nutritional formulas were grouped together, based on nutritional composition, purpose and target age: Formulas for Food Allergy; Pediatric Nutritional Formulas (breast milk substitutes); Pediatric Nutritional Formulas (Enteral nutrition and supplements); Modules & Supplements for Adults; Immunomodulatory and Adult-specific Formulas; and Standard formulas for Adults.

The data were consolidated in the*software* Excel® 2010. A descriptive analysis was performed using Epi-Info® version 7 for a description of frequencies for categorical variables.

Results

In 2007, 39 lawsuits were received with requests for nutritional formulas, while in 2013 the number of lawsuits was 168, which represents an increase of 4.3 times over the whole period (Figure 1).

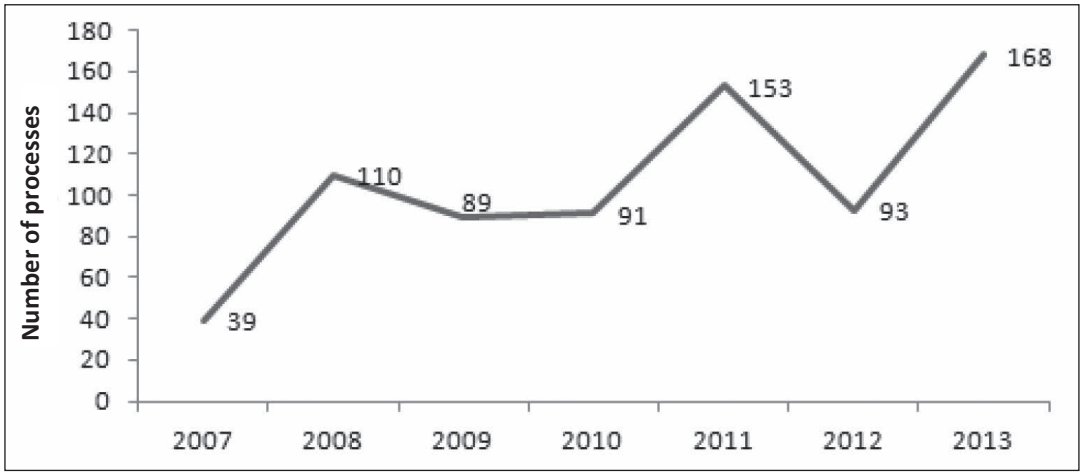

Figure 1. Increase in the number of lawsuits forwarded to the Ministry of Health with requests for nutritional formulas between 2007 and 2013. Brazil, 2014.

Detailed data of the lawsuits could be retrieved for 2013 only; 53.0% of complainants were men and 47.0% were women, aged between zero and 98 years old. However, they were predominantly children under two and adults above 41 years old (Table 1).

Most lawsuits were filed in the South (36.9%), Northeast (29.2%) and Southeast (26.8%) (Table 1). All the 168 lawsuits were from 63 municipalities; five of them accounted for 38.1% of the requests for nutritional formulas (data not shown), as can be seen in Table 1.

Table 1. Profile of lawsuits over nutritional formulas forwarded to the Ministry of Health in 2013. Brazil, 2014.

Gender	**N**	**%**
Male	88.0	52.4
Female	78.0	46.4
Not informed	2.0	1.2
Age (Years)		
0-| 2	57.0	33.9
2 -| 10	18.0	10.7
10-| 20	16.0	9.5
20- |40	8.0	4.8
41-| 65	23.0	13.7
>65 years	27.0	16.1
Not informed	19.0	11.3
Region		
South	62.0	36.9
Northeast	49.0	29.2
Southeast	45.0	26.8
Midwest	11.0	6.5
North	1.0	0.6
Complainant's disease		
Neurological diseases	66.0	39.3
Endocrine, nutritional and metabolic diseases	57.0	33.9
Neoplasms	22.0	13.1
Digestive diseases	10.0	6.0
Diseases of the urinary tract	8.0	4.8
Other	5.0	3.0

Requested formulas		
Standard for adults	69.0	41.1
Allergies	55.0	32.7
Pediatric - enteral nutrition and supplements	24.0	14.3
Immunomodulatory and adult-specific	11.0	6.6
Modules and supplements for adults	8.0	4.8
Pediatric - breastmilk substitutes	1.0	0.6
Existence of Diagnostic Confirmation		
No	100.0	59.5
Yes	68.0	40.5
Origin of prescription of nutritional formula		
Public health service	76.0	45.2
Private health service	65.0	38.7
Not informed	27.0	16.1
Legal representation of complainant		
Public	107.0	63.7
Private	56.0	33.3
Not informed	5.0	3.0

With regard to diseases/health problems of complainants, those related to the neurological system showed the highest prevalence (39.3%), followed by endocrine, nutritional and metabolic diseases (33.9%) and neoplasms (13.1%). It was found that 46 (80.7%) of the lawsuits over cases of endocrine, metabolic and nutritional disorders were related to allergies and food intolerance (data not shown).

Only 40.5% of lawsuits had diagnostic confirmation of complainants' diseases, and it was found that complainants with endocrine, nutritional and metabolic diseases were those that filed more lawsuits without documentation and proof of their disease. It is noteworthy that 40 (87.0%) out of the 46 complainants with food allergies and intolerance had no diagnostic confirmation (data not shown), (Table 2).

Table 2. Number and percentage of lawsuits according to disease of complainant and diagnostic confirmation. Brazil, 2014.

Disease	Existence of diagnostic confirmation			
	Yes		No	
	N	%	N	%
Neurological diseases	37.0	55.2	29.0	44.8
Endocrine, nutritional and metabolic diseases	9.0	33.3	48.0	66.7
Neoplasms	13.0	59.1	9.0	40.9
Digestive diseases	3.0	30.0	7.0	70.0
Diseases of the urinary tract	4.0	50.0	4.0	50.0
Other	2.0	40.0	3.0	60.0
Total	**68.0**	**40.5**	**100.0**	**59.5**

As for type of nutritional formulas requested, most lawsuits were filed over standard formulas for adults and formulas for food allergies, accounting for 69 (41.1%) and 55 (32.7%) lawsuits, respectively (Table 1).

More than half (53.9%) of prescriptions of nutritional formulas was issued by public health services, and most complainants were represented by Public Defenders (65.6%) (Table 1).

Discussion

Lawsuits over nutritional formulas increased more than fourfold between 2007 and 2013, confirming the growth trend of request for inputs through lawsuits in the health area as reported by other studies.[16,17]. This increase is due to the development of new technologies in health care, the pressure on the pharmaceutical industry on prescribers and users, greater understanding and enforceability of the population about their rights and greater access to the legal system.[4,14,18-21]

The fact that most lawsuits referred to patients younger than two and older than 40 years old, and the little difference between the percentage of lawsuits filed by men and women, were results also found by Machado *et al*.[22] and Diniz *et al*.,[17] who underwent profile analysis of lawsuits in Minas Gerais and the Federal District, respectively, that requested access to inputs and health services.

When the more prevalent diseases are taken into consideration, the fact hat most lawsuits referred to complainants at endpoints of the age range makes sense. As the population grows older, neurological diseases, which mainly affect elderly individuals and involve special dietary needs, are becoming increasingly prevalent.[23] In addition, allergies/food intolerance, which affect 0.3% to 7.5% of children under two years old worldwide and require use of nutritional formulas in this age group, account for over 80% of metabolic , endocrine and nutritional diseases in the present study.[24]

When analysis was performed by region, it was found that the South (36.9%), Northeast (29.2%) and Southeast (26.8%) had the highest number of lawsuits. This finding is in line with the analysis by Faleiros *et al*.[25] of 523 lawsuits with different demands received by the Ministry of Health between 2002 and 2005. They found that 84% of the lawsuits had been filed in the South and Southeast regions. Minas Gerais (26%) and Santa Catarina (22 %) were the states with the highest number of lawsuits.

In addition to the increase in lawsuits against the state in recent years,[4,17,19,28] studies have identified that most of the decisions of the Judiciary Power are favorable to complainants (up to 97.5% in some states).[17,26-30] The enforceability of the right to health is legitimate through court proceedings when the individual is unable to access inputs, actions and health services. However, studies have shown that the Judiciary Power has limited knowledge of technical issues and of the organization and management of SUS; its decisions are primarily based on the prescription of health professionals and the alleged urgent receipt of the input, without considering safety, effectiveness and cost-effectiveness of the product requested.

Decisions that are favorable to applicants, but made indiscriminately, compromise proper allocation of public resources and the organization of SUS.[19,31,32]

Apart from budgetary issues, studies have shown that most lawsuits require the supply of inputs on an individual basis. This may benefit individuals with fewer needs and reinforce social inequalities in health.[3,5,22,31,33,34] In this sense, some authors suggest that individuals who file lawsuits against the state may have better socioeconomic conditions,

as they often must bear the costs of legal representation and are assisted by private health services.[22,31] The analysis of this study identified results that do not confirm this assumption, since most lawsuits (65.6%) were represented by a Public Defender and more than half of nutritional formulas were prescribed by professionals in the public health system (53.9%).

However, a review by Brito[14] of 39 papers on the legalization of the right to health, published between 2001 and 2011, found that only in two out of the six studies with information on legal representation and origin of prescription, [35,36] more than half of prescriptions and legal representations had been made available by the public service.

Diagnosis and prescriptions should also be observed, as they may be mistaken. In the process of this analysis, there is a predominance of requests without diagnostic confirmation (59.5%). The requirement of diagnostic confirmation that can justify the request of industrial nutritional formulas, as well as proper prescription, should be essential for the Judiciary Power to make decisions.

The safety of individuals is at risk when prescriptions are written indiscriminately and do not represent their actual needs. Industrialized nutritional formulas, which must be used in acute and chronic situations in order to improve and/or maintain the nutritional status, require not only the diagnostic confirmation of the disease, but also the proper assessment of the nutritional status of the individual to justify the need for using them[37].

Some authors suggest that the high number of requests for the same input may induce its introduction into SUS.[4,40] However, the introduction of new technologies into the health system must occur through critical, technical review based on scientific evidence.

It is worth noting that there are alternatives to using industrialized nutritional formulas with people with special dietary needs. For example, using nutritional formulations prepared with food and excluding and replacing, in the diet, foods that trigger allergies and intolerance. These alternative therapies can be considered, provided that there is no nutritional loss for individuals clinically stable with capacity of digestion and absorption, with chronic diseases or under palliative treatment.[38,39]

In this context, it is necessary to note that there are economic interests involved, especially by those who produce new technologies in health care, including medications and nutritional formulas.[19,40] Analyses made by other researchers showed that the prescriptions usually refer to the trade name of inputs, when they should only indicate

their active ingredient or nutritional composition. The use of trade names makes it difficult for patients and the Government (when it is supposed to supply the input) to choose other options for formulas with similar composition, but equally effective and less costly.[3,19]

Several strategies are used by industries that produce these inputs to induce prescriptions by health professionals, such as visits to prescribers, funding for participation in events, sponsorship of professional associations, among others.[19,41-46] In this sense, it has also been observed that the pharmaceutical industry lobbies patient associations, which usually lack enough knowledge to assess the effectiveness of treatments, in order to motivate the filing of lawsuits against the State with request for its products.[19,31,47] Furthermore, studies show the predominance of a few lawyers and prescribers involved in many lawsuits, and this may be indicative of a conflict of interests.[22,33]

In addition to the the issues already discussed, legalization summarizes the right to health for the supply of inputs, regardless of its association with comprehensive care, which should include multidisciplinary monitoring and consider actions to promote health and prevent and treat diseases.[3,31].

This study has some limitations. The analysis was performed with lawsuits forwarded to CGAN/DAB/SAS for preparation of technical reports; however, others lawsuits may have been sent to other technical areas of the Ministry of Health, such as the General Coordination of Medium and High Complexity and Department of Pharmaceutical Care, and these were not considered in the evaluation.

CGAN/DAB/SAS does not receive feedback on the outcomes of lawsuits, and it was not possible to check the profile of the lawsuits forwarded between 2007 and 2012 because there was no systematic information available, precluding further analysis on the subject. Furthermore, the analysis was restricted to lawsuits received by the Ministry of Health, but states and municipalities also receive claims and, in most cases, bear these costs.

Moreover, this is the first systematic analysis of lawsuits received by the Ministry of Health that requested the provision of nutritional formulas. This study showed an overview of lawsuits at the national level, identifying characteristics of complainants by region, gender, age and diseases. It allows for analysis of other important issues for debate, such as the existence of diagnosis and the use of public health and legal services.

Final remarks

This study showed, by analyzing lawsuits that were forwarded to CGAN/DAB/SAS for technical reports, an increase in the number of lawsuits over nutritional formulas against the Ministry of Health

The analysis of the lawsuits of 2013 allowed the identification of the profile of complainants: aged at the endpoints of the age range, and having mainly neurological diseases and allergies/food intolerance. Moreover, it was observed that more than half of nutritional formulas were prescribed by private health services, while legal representation for the lawsuit was most often provided by a Public Defender. Another important factor identified was the low number of lawsuits that had diagnostic confirmation, especially when cases of allergies/food intolerance were observed.

The legalization of health appears as a problem for managers at SUS and it can increase existing inequalities. The Judiciary and the Executive Powers need to be co-articulated so that they can find solutions together to ensure the right to health without any harm to the management and organization of SUS. The Judiciary Power must have technical and political support as regards the main diseases that require nutritional formulas, diagnostics, need to use industrialized nutritional formulas, treatments and possible conflicts of interest.

The Executive Power is faced with some challenges to effectively ensure the right to health. It is necessary to have more awareness of individuals with special dietary needs at SUS, by developing clinical guidelines and treatment protocols as well as securing funding and supply of industrialized nutritional formulas when proven necessary. This organization should be made based on careful evaluations that consider the epidemiological profile of the population and the concepts of cost-benefit and cost-effectiveness, and they should also be evidence-based.

Further challenges are continuing education and training of health professionals involved in caring for people with special dietary needs that make ethical choices of the approach to be adopted, especially regarding the prescription of nutritional formulas.

Lawsuits over nutritional formulas may have negative implications for Brazil's Unified Health System (SUS), while they point out flaws in the organization of health care which are hindering comprehensive care provision to patients with special dietary needs. Acknowledgment of these flaws can inform decision making about strategies for improvement of public health policies. Thus, the analysis of the profile of these lawsuits made in this study promotes reflections seldom discussed in the area of food and nutrition, and presents information that may contribute to the organization of nutritional care at SUS.

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Received: April 14, 2014
Approved: May 5, 2014