

The treatment of rare diseases in Brazil: the judicialization and the Health Economic-Industrial Complex

O tratamento de doenças raras no Brasil: a judicialização e o Complexo Econômico-Industrial da Saúde

Pedro Ivo Martins Caruso D'Ippolito¹, Carlos Augusto Grabois Gadelha²

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ABSTRACT This study presents the panorama of the treatment of rare diseases in Brazil, focusing on issues related to judicialization and the Health Economic-Industrial Complex. The legal and economic structures pertinent to the theme are analyzed, questioning the absence of articulated national solutions, which makes judicialization for the treatment of rare diseases the solution – inefficient and unsatisfactory, it is said – for complying with the device. Health as a right. In this context, strategies are debated to mitigate technological and economic dependence in order to sustain universal, integral, and equitable access to health. Methodologically, the perspective of the work is primarily theoretical, exploratory and based on documentary information and academic literature on the subject, going through the administrative rules, court decisions and explanatory texts on the subject in its legal, economic, and institutional dimension. In conclusion, it can be noticed that health spending can compromise a significant portion of the national budget, given the importation of medicines and other treatments. Therefore, the interaction between the Judiciary and the Executive branch and its technical executive bodies is urgently measured to provide a sanitary and economic rationality to the system, to ensure universal, equitable, and integral access to care for rare diseases.

KEYWORDS Human rights. Rare diseases. Health's judicialization. National Science, Technology and Innovation Policy. Access to essential medicines.

RESUMO *Este estudo apresenta o panorama do tratamento de doenças raras no Brasil, enfocando questões relacionadas à judicialização e ao Complexo Econômico-Industrial da Saúde. São analisadas as estruturas jurídicas e econômicas pertinentes ao tema, questionando a ausência de soluções nacionais articuladas, o que torna a judicialização para o tratamento de doenças raras a solução – ineficiente e insatisfatória, segundo se diz – para o cumprimento do dispositivo. Saúde como um direito. Nesse contexto, são debatidas estratégias para mitigar a dependência tecnológica e econômica, a fim de sustentar o acesso universal, integral e equitativo à saúde. Metodologicamente, a perspectiva do trabalho é primariamente teórica, exploratória e baseada em informações documentais e literatura acadêmica sobre o assunto, passando pelas normas administrativas, decisões judiciais e textos explicativos sobre o assunto em sua dimensão jurídica, econômica e institucional. Concluindo, percebe-se que os gastos com saúde podem comprometer uma parcela significativa do orçamento nacional, dada a importação de medicamentos e outros tratamentos. Portanto, a interação entre o judiciário e o poder executivo e seus órgãos técnicos executivos é mensurada com urgência para fornecer uma racionalidade sanitária e econômica ao sistema, para garantir acesso universal, equitativo e integral ao atendimento de doenças raras.*

PALAVRAS-CHAVE *Direitos humanos. Doenças raras. Judicialização da saúde. Política Nacional de Ciência, Tecnologia e Inovação. Acesso a medicamentos essenciais e tecnologias em saúde.*

¹Tribunal de Justiça do Estado do Rio de Janeiro (TJRJ) – Rio de Janeiro (RJ), Brasil.
pidippolito@gmail.com

²Fundação Oswaldo Cruz (Fiocruz), Escola Nacional de Saúde Pública Sergio Arouca (Ensp), Departamento de Administração e Planejamento em Saúde (Daps) – Rio de Janeiro (RJ), Brasil.



Presentation

This paper analyzes issues related to rare diseases and their relationships with universal and comprehensive access to health. It investigates the way in which, in the logic of public health, the treatment for rare diseases can be guaranteed, even by the action of the Judicial Branch.

According to Ordinance n° 199/2014 of the Ministry of Health¹, which establishes the National Policy for the Comprehensive Care of People with Rare Diseases, such diseases are those that affect up to 65 people per 100 thousand individuals. There are, likewise, other parameters for characterizing a disease as rare.

We will consider here the diseases whose treatments are based on external dependence, that is, that depend on imports. The study of the Health Economic-Industrial Complex (HEIC) becomes relevant, most importantly due to the production and commercialization of medicines².

The issue becomes relevant in the face of increasingly frequent cases, of judicialization of requests for the provision of treatment of rare diseases. According to the Ministry of Health³, approximately, 60 thousand actions are being processed in the three spheres of government, which generates expenses outside the financial programming of over R\$ 500 million per year.

Rare diseases embody a very intense responsibility for the Unified Health System (SUS), as they represent increasingly higher expenditures. There is, therefore, a clash between universal access to health and the budgetary capacity of public entities. According to information from the Ministry of Health⁴, spending on lawsuits jumped from R\$ 139.6 million in 2010 to R\$ 1.2 billion in 2015, largely involving demands related to rare diseases.

Nevertheless, it is considered whether such liability should burden upon health plans, which could assume, at least in part, rare disease treatments of their clients.

Thus, the paper aims to present three perspectives that involve the theme regarding

the treatment of rare diseases: i) legal: the legislative framework that would justify the actions of the Public Power and private entities; ii) system organization: the way in which the different public and private spheres are organized; iii) HEIC, specifically with regard to the production and supply of medicines.

Methodology

The perspective of the work is, primarily, theoretical, exploratory and based on documentary information and academic literature on the subject, going through the administrative rules, court decisions and explanatory texts on the subject in its legal, economic and institutional dimension. A broad survey of the legal and normative apparatus was made, such as ordinances and resolutions of public bodies, court decisions – of the Federal Supreme Court (STF), Superior Court of Justice and the Court of Justice of the State of Rio de Janeiro – and explanatory texts on the theme.

Thus, in summary, the achievement of this article involved the following methodological procedures: i) legal and institutional documentary research; ii) survey and incorporation of legal basis theories about the right to health to the proposed theme; iii) academic background: theoretical literature on HEIC and access to medicines; iv) exploratory survey of alternatives to ensure universal, equitable and integral access through efficient institutional arrangements for care related to rare diseases.

Legal aspect

This topic addresses the question of the legal delineation of the right to appropriate treatment of rare diseases. This is a projection of the fundamental right to health, given that the Constitution of the Federative Republic of Brazil (CRFB)⁵ itself is positive. However, for a better understanding of the scope of such a statement, it is imperative to forcibly discuss the theme of fundamental rights.

For purposes of systematization of the theme, fundamental rights are seen from generational perspectives.

However, the idea of generations of rights does not result in the rejection of the former with the advent of the latter. Rights of the first generation, based on the ideals of the XVIII century liberal revolutions, are shaped by the idea of abstention of the State, germinating the duty of nonintervention in aspects of the private life of individuals. They are inherent to individual freedoms, grounding the rights to property, conscience, gathering and the inviolability of domicile. However, the recognition of only formal equality between people has resulted in increased social inequalities. In this context of refutation of the absenteeism nuance of the State, the so-called second generation fundamental rights are increased, characterized, primarily, by benefits to be met, such as health, education and social security, establishing minimum conditions for access to essential goods. Achieving social justice becomes the scope for recognizing this generation of rights. For this purpose, greater State intervention in the economy is required, with the aim of correcting serious asymmetries in access to essential goods and means of production. The CRFB⁵, for example, provides for an extensive list of social rights, enshrining in its art. 196, universal access to health.

Thus, if fundamental rights of the first generation are qualified by the deprivation of state action, the second rights are related to positive benefits from the Public Power.

Subsequently, due to the advent of, mainly, the phenomenon of globalization, the so-called third generation fundamental rights arise, characterized by metaindividuality and congregation of interests, such as the environment, administrative probity, healthiness of the economic and consumerist order, among others.

Since the creation of the United Nations, in 1945, but, especially, since the 1980s, in view of the significant concentration of income in the central countries, there has been discussion

about the so-called right to development, raised by some scholars, to the fourth generation of fundamental rights. Effectively, the United Nations General Assembly, in 1986, promulgated the Declaration on the Right to Development⁶.

According to art. 1, paragraph 1 of the Resolution⁶,

[...] the right to development is an inalienable human right, by virtue of which every human person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realized.

Thus, the right to development represents, in short, the equality of economic and social opportunities relative to States and people, in order to increase welfare and seek a more equitable distribution of the resources generated. CRFB⁵ provides, in various devices, for the right to development. For example, art. 3, I establishes as objective of the Republic the construction of a free, fair and solidary society.

In this context, CRFB⁵ provides for the fundamental right to development, which not only results in economic growth, but mainly in access to knowledge and welfare of the entire population. In this respect, is part of the role of the State the scientific and technological development.

Thus, CRFB⁵ itself devoted a chapter to science and technology, further refined by Constitutional Amendment n° 85/2015⁵, which has inserted the idea of innovation. According to art. 218 of the CRFB⁵, “The State will promote and encourage scientific development, research, scientific and technological training and innovation”. In addition, paragraph 1 of the provision states that

basic and technological scientific research will receive priority treatment from the State, in view of the public good and the progress of science, technology and innovation⁵.

With the generations introduced, it is noteworthy that there is no discussion about the fundamental nature of the right to health. However, a qualitative analysis of such a right is necessary, especially in relation to its extension and coverage.

Therefore, the study of so-called 'social rights', which can be classified as species of fundamental rights, characterized by a provision bias on the part of the Public Power, gains relevance. They are, therefore, fundamental rights of the second generation.

The CRFB⁵, provides for an extensive list of installment rights, establishing in its art. 6, that

social rights include education, health, food, work, housing, transportation, leisure, security, social security, protection of motherhood and childhood, assistance to the helpless, in accordance with this Constitution⁵.

Indeed, in the Brazilian constitutional system, all legal discipline concerning fundamental rights, such as their immediate applicability, fully affects social rights.

Compared to other countries, the legal treatment of social rights in Brazil emerges as a unique reality. Thus,

[...] in countries such as Germany, France, Portugal, Spain and Italy (and this profile can be extended to the vast majority of European countries), this has prevented, by and large and save exceptions, the admission of a direct applicability of the constitutional norms of social rights, which - at least as a rule! - makes them required, under the condition of subjective rights, only in the form and according to the limits of ordinary conforming legislation⁷⁽⁶⁴⁰⁾.

Despite the conceptual divergences, according to art. 196 of CRFB⁵,

health is the right of everyone and the duty of the State, guaranteed by social and economic policies aimed at reducing the risk of disease

and other grievances and equal access to actions and services for its promotion, protection and recovery.

Aware of the varied social rights provided for in CRFB⁵, the health aspect gains prominence. Art. 196 of the CRFB is the starting point of the normative treatment of the right to health. Posteriorly,

[...] the Constitution refers the regulation of health actions and services to the legislator (art. 197), in addition to creating and setting guidelines for the unified health system (art. 198), enabling the participation (at a complementary level) of private initiative in the provision of health care (art. 199), as well as establishing, by way of example, the attributions (under the law) that fall under the unified health system⁷⁽⁶⁷⁶⁾.

By mentioning that health is a right of all and a duty of the State, the Political Letter⁵ establishes to the citizen a subjective public right, that is independent of legislative interposition. In fact, given the plexus of obligations arising from the constitutional norm, for better health care, it is necessary to formulate public and economic policies that streamline the allocation of limited budget resources. In addition, the responsibility for such a budget organization rests with the Executive Branch, so that any judicial intervention should be punctual.

On the other hand, for the purpose of organizing and structuring health benefits, CRFB⁵ has devised a basic model, covering all federative entities, without forgetting popular participation, in accordance with its art. 198

Another theme of relevance to the present study concerns the connection between the principle of separation of powers and fundamental rights. It is mentioned that it would not be up to the Judiciary to determine the adoption of public policies by the Executive, this, rather, the administrative vector of the State, with the technical-scientific knowledge necessary for the efficient allocation of resources.

Nevertheless, despite the criticisms pointed out, there is an increase in the so-called judicialization, and the judicial decisions that determine the implementation of measures by the Executive are not uncommon.

However, in relation to the right to health, the STF has jurisprudence in the sense that, once the administrative malpractice has been verified, it is up to the judiciary to correct it.

In this vein, the STF has already stated in the sense that:

[...] the subjective public right to health represents an unavailable legal prerogative assured to most people by the Constitution of the Republic (art. 196). [...] The right to health - in addition to qualifying as a fundamental right for all people - represents an inseparable constitutional consequence of the right to life⁸.

Consequently, it is not fundamental rights that must bow to the separation of powers. On the contrary, since the very dispersion of state attributions strives for the attainment of fundamental rights. The Major Law⁵ is not, therefore, an innocuous idea, which is why it demands the implementation and effectiveness of its rules.

Continuing, after considering the possibility of acting in the Judicial Branch, the analysis of the argument regarding the possible reserve remains.

The reserve for contingencies is limited, notably, to the financial barrier of the State for the realization of installment rights. It is a theme related to resource scarcity and 'tragic choices'. One must not neglect that the implementation of public policies requires the expenditure of financial resources by the State. Thus, it is questioned whether the Public Power should assure, and to what extent, all sorts of social rights, despite possible contingencies with budgetary resources.

In fact, one should not lose sight of the economic and financial reality of various entities of our federation. Indeed, in the Brazilian State, there are not enough resources to satisfy all the needs of the population.

In such cases, an inversion of the probative burden could be considered, so that it would be up to the public body to demonstrate its financial impossibility. Thus, having proved that it is not feasible to assume expenses with certain social rights, without prejudice to their basic functioning, the federative entity could exempt itself from this responsibility.

Nevertheless, circumventing these situations, in the specific case of health, which is relevant to the present study, CRFB⁵ itself presents the solution, by providing for solidarity among all entities of the federation in offering the appropriate treatment. Thus, regardless of the existence of previous adjustments between the federative entities regarding the supply of medicines, for example, their joint and several liability should not be ruled out, and the individual can sue against any of them.

On the other hand, given their constitutional scope, fundamental rights have horizontal effectiveness and must be observed even by individuals; and not only so-called first generation rights: second generation rights, as well, can be imposed on private agents.

According to Nelson Rosenvald,

the principle of solidarity is the mainstay of the constitutionality of norms that impose restrictions on private autonomy to the point of providing positive benefits from economic agents⁹⁽¹²³⁾.

It should be registered that CRFB⁵ itself, in its art. 3, I and III, establishes as the fundamental objective of the Republic the construction of a free, fair and solidary society, with a view to eradicating poverty and social and regional inequalities. Thus, private individuals are also passive subjects of fundamental rights, including social rights. It is not argued that the State has the original responsibility for the provision of social rights. However, private individuals are not given immunity from the duty of social solidarity.

However, still according to Rosenthal⁹⁽¹²⁵⁾, “in order to avoid the demagoguery that converts solidarity into tyranny, culminating in making economic activity unfeasible”, two criteria are required to impose social benefits on private agents: i) “the existence of any legal relationship maintained by the parties”⁹⁽¹²⁵⁾; and ii) “the object of the demand is imbued with the existential minimum, understood as an essential good for the achievement of elementary parameters of a dignified life”⁹⁽¹²⁵⁾.

For example, the statement n° 302 of the precedent of the prevailing jurisprudence of the Superior Court of Justice¹⁰, which states that “the contractual clause of health insurance that limits the hospitalization of the insured” is abusive.

Decomposing the sumular entry, one observes the fulfillment of the two conditions. First, there must be prior legal relationship between the insured and the health plan. Therefore, the private entity is not required to cover the hospitalization of anyone and everyone; only from their customers. Likewise, there must be a connection with the right limited to the existential minimum – in this case, limitation to the length of hospital stay. Thus, the health plan should not be imposed, for example, the offer of merely aesthetic procedures.

Notwithstanding, the criticism asserts the insecurity generated by this judicial interposition, with repercussions in the economic and legal field, especially in the case of activities intensely regulated by the Public Power.

Regarding health insurance contracts, a theme that is relevant to the present work, it should be noted that:

[...] health insurance companies are managed on the basis of the mutualism assumption, that is, the contribution of a group of people, in fixed amounts that must be paid within a previously fixed period of time and strictly in compliance with the commitment, so that a common fund can be constituted from which the necessary amounts will be

extracted for the payment of the expenses that each of the payers will have during the term of the contract¹¹⁽³⁷⁾.

One should not lose sight of the fact that, despite providing fundamental rights, judicial decisions imposing treatments that are not based on scientific evidence, together with their unpredictability, may unjustifiably burden health plans, with the possibility of deleterious effects for all sorts of users.

Thus, a careful prudence should be adopted when imposing on individuals the observance of any social right, and not just a right to health. This is because it cannot be forgotten that private economic activities may become unfeasible if they absorb, without the synallagmatic counter-payment, all sorts of social demands.

Service structure

This topic expatiates on the organization of the health system around the treatment of rare diseases, presenting the government agencies that act in the sector. In light of arts. 196 and following of the CRFB⁵, the responsibility for guaranteeing the right to health rests with all the entities of the federation.

However, as a way to rationalize care, avoiding waste, overlap and, mainly, gaps, was issued by the Ministry of Health, Ordinance n° 199/2014¹, which

establishes the National Policy for the Comprehensive Care of People with Rare Diseases, approves the Guidelines for Comprehensive Care of People with Rare Diseases within the SUS and establishes financial incentives for funding.

Among the objectives of the National Policy for the Comprehensive Care of People with Rare Diseases, provided for in art. 5 of the mentioned Ordinance, are

I - guarantee the universality, comprehensiveness and equity of health actions and services

in relation to people with rare diseases, with consequent reduction of morbidity and mortality, [as well as] V - guarantee people with rare diseases, in a timely manner, access to available diagnostic and therapeutic means according to their needs¹.

As principles of the National Policy, it is noteworthy that the Ordinance, in its article 6th, establishes

IV - guarantee of access and quality of services, offering comprehensive care and multiprofessional care, [besides] VI - incorporation and use of technologies that [...] should be the result of the recommendations formulated from the process of assessment and approval by the National Commission for incorporation of Health Technologies in SUS (Conitec) [...]¹.

It goes without saying, therefore, that the State has assumed responsibility for full, universal and equitable care in the field of rare diseases seeking to ensure quality services and multiprofessional care, taking into account the parameters dictated by Conitec.

However, regarding the incorporation of technologies and medicines, the Brazilian Health Regulatory Agency (Anvisa) assumes special importance. Created by Law n° 9.782/1999¹², Anvisa has the institutional aim to, according to art. 6,

[...] promote the protection of the health of the population through the sanitary control of the production and commercialization of products and services subject to sanitary surveillance, including environments, processes, inputs and technologies related to them, as well as port, airport and border control.

Without prejudice, according to art. 7 of Law n° 9.782/1999¹², is the responsibility of Anvisa

[...] to authorize the operation of companies that manufacture, distribute and import the

products mentioned in article 8 of this Law and the marketing of medicines.

In turn, art. 8 provides that

is the responsibility of the Agency, in accordance with the legislation in force, to regulate, control and monitor products and services involving public health risks, [such as] medicinal products for human use, their active substances and other inputs, processes and technology¹².

In turn, Conitec is an organ of the structure of the Ministry of Health created by Law n° 12.401/2011 and regulated by Decree n° 7.646/2011¹³. According to art. 2 of said Decree,

[...] Conitec, a permanent collegiate body, that is part of the regimental structure of the Ministry of Health, aims to advise the Ministry of Health in the attributions related to the incorporation, exclusion or alteration by SUS of health technologies, as well as the constitution or alteration of clinical protocols and therapeutic guidelines¹³.

Among its main attributions, it is worth mentioning that, under the terms of art. 4 of Decree n° 7.646/2011, it is the responsibility of Conitec to issue reports on “the incorporation, exclusion or alteration by SUS of health technologies”¹³, as well as “propose the updating of the National List of Essential Medicines – Rename”¹³.

The composition of Conitec¹³ is governed by art. 7 of said Decree, which will be 13 full members, appointed by the Ministry of Health, National Supplementary Health Agency (ANS), Anvisa, National Health Council (CNS), National Council of State Health Secretaries (Conass), National Council of Municipal Health Secretaries (Conasems) and the Federal Medicine Council (CFM)¹³.

For what is relevant to our work, Conitec¹³ plays the role of selecting technologies in the health area that will be incorporated or

excluded within the scope of SUS. It can, therefore, be perceived that the Commission is a specialized body with high technical knowledge. However, it should not be neglected that there is a deficit of popular representativeness in the composition of Conitec¹³, contrary to the constitutional provision itself, by which the participation of the community is a guideline of the SUS (art. 198, III of CRFB).

Moreover, given its importance in the organizational structure of SUS, the independent character of Conitec¹³ should be reinforced, thus, considering its scope to the category of Regulatory Agency. As such, the Commission would have a juridical nature of autarky, a legal entity governed by public law with its own personality, in order to enjoy technical and budgetary autonomy, in addition to the fixed mandates of its leaders, which could not be relieved *ad nutum*.

Therefore, Conitec's decisions would be, even more, entered with autonomy, regardless of the pressures of public and private actors, acting as free as possible of conflict of interest, with the intention of being incorporated, or not, such a particular technology. Indeed, a greater representation of civil society in the Commission's board of directors – including, for example, the association of rare disease sufferers and members of the Academy – would be a welcome measure as a way of balancing forces in deliberations.

Thus, Conitec could, for example, be a judicial decision-making body on the request to provide certain rare disease treatments, given the necessary expertise.

Health Economic-Industrial Complex

This topic discusses the scenario of technology production for therapies against rare diseases, debating about the economy that can be generated from the increase of national productive capacity.

Thus, in relation to the treatment of rare diseases, the performance of the Brazilian State may occur, briefly, through public

procurement; production of medicines in public laboratories; research and innovation; and technological incorporation.

Indeed, the study of HEIC is imperative, considering that the existence of a national technological and productive base is an essential factor to enable universal access to treatments that require long-term stable care, according to precise clinical protocols^{2,14}.

HEIC encompasses the economic activities related, alongside the health services segment, with the following industries: i) chemical and biotechnological, such as pharmaceuticals, vaccines, blood products, among others; ii) mechanical, electronic and material based, such as those related to medical equipment and materials¹⁴.

On the point, it should be emphasized that:

[...] the characterization of HEIC starts from a systemic understanding of health, which recognizes not only the demand of society for goods and services but also the productive base responsible for its supply. The set of these productive and technological activities, which maintain intersectoral relations of purchase and sale of goods and services and (or) knowledge and technologies, configure the productive base of health. The dynamics between industrial segments and health care services imply a systemic relationship between certain industrial sectors and social services, establishing what is currently known as the health complex or the economic-industrial health care complex¹⁵⁽²²⁾.

In this vein, given the scope of HEIC, which involves conditions that range from scientific research to commercialization activities, to delineate the present work, we will consider the production and commercialization aspect of medicines to treat rare diseases.

Therefore, fundamentals related to the productive and innovation base will be sought so that SUS advances in technological incorporation in an organized and comprehensive manner, without departing from a rational

and systemic approach. This is because a fragmented and alternative incorporation, such as the one resulting from judicialization, in which the general and relevant aspects of care policy are not weighed, has deleterious effects on the budget, which may limit the long-term development of the health care system.

Consequently,

[...] for the Brazilian health system to meet the demand of the population, it is necessary to expand the health production base and to consolidate a dynamic of innovation endogenous to the Country¹⁵⁽²³⁾.

In view of this, without prejudice to the inherent generation of technology, income and jobs, HEIC must, as clearly stated in its concept, be guided by the social demand for health. Thus, the formulation of public policies should be the north for the functioning of the system, bringing together the economic and technological aspects with the fulfillment of social demands.

Otherwise, the State plays a relevant role, since it harmonizes the actors involved, as well as directing and inducing public and private activities, with a view to achieving the widest possible public policies. There are very important activities for society that cannot be dependent on private economic contingencies, so that it is imperative to exude not only State regulation, but, also the provision by state entities themselves.

In the Brazilian case, according to the World Health Organization (WHO)¹⁶, in 2012, annual public spending on health was below the world average, reaching ten times lower compared to developed countries – US\$ 512 per citizen versus US\$ 615,00.

Furthermore, according to WHO¹⁶, in our Country, private spending is higher than that of public spending – in the proportion of 57% to 43% of total health expenditure approximately. By way of comparison, countries such as the United Kingdom, Cuba, Japan, Italy, Germany and Spain have a public share of over 70%.

It should also be underlined that, in 2015, total health spending reached almost 10% of GDP in Brazil, whereas in developed countries the average is 16%. In the specific case of public spending, the level reached is 3.8% of Gross Domestic Product (GDP), which is well below the minimum level of any other universal system in the world (in all cases, over 6.5% of GDP)¹⁷.

It is perceived, therefore, compared to other States, that there is scope for growth in public investment in health in Brazil, which would allow not only the development of public policies for direct care of users of the system, but also the stimulation of activities, research, technological development and production, essential for the stability of rare disease treatment.

The theme was addressed when the Constitutional Amendment n° 85/2015⁵ was enacted, which, in relation to the right to health, changed art. 200, V of the CRFB, emphasizing that it is the SUS's task “to increase, in its area of activity, scientific and technological development and innovation”⁵. As seen above, in developed countries, there is a greater abundance of investments, mainly of public origin, in the health sector, which results in greater stimulation to research and development activities.

Thus, one should not lose sight of the economic dimension of health when formulating public policies, departing from the idea that the respective expenses inexorably result in expenses. On the other hand, since they play a role in generating knowledge, income and jobs.

To better clarify the above, it must be emphasized that

[...] it is considered that science, technology and innovation in health are strategic activities not only for their role in knowledge generation – especially in the context of the 3rd Technological Revolution – but also for their interface with the dynamization of productive segments with potential for generation of investments, employment and income. On the

other hand, the recognition of the economic dimension of health, not restricted to the perspective of spending, opens opportunities for inserting the area in broader development strategies. For example, the implantation or expansion of a pharmaceutical plant, the stimulation of phytoderivatives, the participation of health in centers and poles for the generation and diffusion of innovations, the installation of a referral hospital unit in a specific region, among others, are possibilities that open paths to strengthen health as a strategic area of development¹⁸⁽⁵⁹⁾.

Likewise, it should be noted that the State, as a consumer, plays a relevant role in the health market, given its demand for products and services, boosting productive and innovative development. Thus, this is an example of indirect State action in the economic domain, through the promotion of investments in the areas of services and production of goods.

Notwithstanding, in addition to acting as a buyer of products and services for their universal availability to the population, the State has a primary role in regulating the health market, especially in relation to supplementary health activities.

Indeed, one could consider an irreconcilable dichotomy between the economic and social dimensions of health. Nevertheless, in close analysis, there is, therefore, no antinomy between such realities. This is because, for health services to be offered to the population with quality, it is essential to invest in the national productive base, especially through the State, which, as seen, compared to other countries, still spends little in the area. It is up to the Public Power, therefore, to reconcile access to the comprehensive health system with the economic logic inherent to the agents of the productive sector.

Concluding the present work, the theme of judicialization must be exposed. The term judicialization of health refers, in general terms, to an everyday reality in the Brazilian courts, where lawsuits are proposed for the purpose

of obtaining some service or product in the health area, against the State or complementary health entities, such as hospital admissions, specific treatments, medications etc.

According to data from the National Council of Justice, in 2016, more than 1.3 million lawsuits were processed, throughout Brazil, in which health related issues were discussed. Such massification of judicial demands has consequences for the dynamization of HEIC, as it may curb the development of national technologies.

This reality stems, inexorably, from the constitutional treatment of so-called social rights, including health, since they can be claimed in view of the State. Consequently, the role of the Judiciary in enforcing health rights is increasing, given its power of coercion in relation to public administrators.

Likewise, one should not forget the deleterious effects of the so-called judicialization of health, especially in relation to the aspect of citizens' rights and the concrete economic and budgetary basis. Without an institutional organization that covers everything from rational and systemic access to health to technological and productive development, the State, condemned to the immediate provision of a certain health product or service, ends up not organizing itself for the purpose of efficiently guaranteeing access and stimulating national production and technology.

Effectively,

[...] operating without great power to manage purchases and within a monopolized market, SUS does not achieve economies of scale that would be expected under other circumstances. In a centralized purchasing system it is expected that the purchase of a larger volume of a medicine is related to a greater bargaining power and a series of savings that together reduce final prices¹⁹⁽⁴⁸³⁾.

Consequently, as a corollary of the judicialization of health issues, the incorporation of new technologies is more fragmented and

disaggregated, unaware of a systemic and programmed view, which leads to increased costs, inefficiency of scale and resource allocation, as well as decreased procurement management capacity.

Final considerations

By way of conclusion, it should be noted that the right to health is a fundamental right, as provided for in the CRFB text and in international treaties. One should not lose sight of the fact that health spending can commit a significant portion of the national budget, especially due to the importation of medicines and other treatments. However, the study of HEIC, in its aspects of innovation and productive development, has as its ultimate goal the structural guarantee of access on an integral basis, including the reduction of costs on a stable basis, given that the production of technology in the Country reduces dependence and the risk of fluctuations in supply and prices, increasing access and rational treatment of rare diseases in Brazil. HEIC is the productive and technological counterpart of the right to health and comprehensiveness, being inseparable from the right to treat rare diseases.

It was intended to register that the

judicialization of health is a reality that, although mitigable, is unaffordable, especially if the Executive Branch does not qualify its structuring and does not provide technical support for decision-making by the Judiciary.

Thus, the interaction of the Judiciary with the Executive Branch and the technical executive bodies becomes urgent, in order to articulate the organization of the health system and its productive and technological base, which would, in many cases, prevent the rendering of judicial decisions determining the provision of inappropriate medicines or treatments to this group of diseases. Only with this systemic view and organization of the State, in addition to the participation of civil society, will it be possible to guarantee access, overcoming the false dichotomy between the right to health and the concrete actions for its realization.

Collaborators

D'Ippolito PIMC (0000-0002-1659-5948)* contributed to the general conception, information gathering, bibliography and writing. Gadelha CAG (0000-0002-9148-8819)* contributed to the general design, structure and revision of the final writing. ■

*Orcid (Open Researcher and Contributor ID).

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