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Article

Direct Action of Unconstitutionality nº 5.779: the preponderance of the effectiveness of the right to health over the hierarchy of legal norms

Ação Direta de Inconstitucionalidade nº 5.779: a preponderância da efetividade do direito à saúde sobre a hierarquia das normas jurídicas

Acción Dereca de Insconstitucionalidad nº 5.779: la preponderancia de la efectividad del derecho a la salud sobre la jerarquía de las normas jurídicas

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Abstract

Objective: To reflect on whether the hierarchy of legal norms should be used as an infallible method of solution even when an apparent conflict between legal norms involving health law can be better resolved through a technical decision by the competent regulatory agency. **Methodology:** data was collected. In particular, Collegiate Board Resolution nº 52/2011, Law nº 13.454/2017 and Direct Action Unconditionally 5.779-Federal District. Specialized legal doctrine was sought on the central and peripheral themes. The data collected was analyzed using the critical-narrative review technique. **Results:** In Brazil, the adoption of regulatory agencies as normative agents and regulators of economic activities has made it possible to make decisions based less on political criteria than on technical criteria. The legislator, anchored in political criteria, according to the judiciary, cannot go beyond technical criteria. **Conclusion:** the judgment in Direct Action Unconditionally 5.779-Federal District shows that today's concept and the legal nature of the right to health impose new legal paradigms that validate the role of regulatory agencies (making technical decisions in favor of maximum effectiveness of the right to health), even to the detriment of politically legitimized decisions by the legislature. The formal paradigm cannot prevent the materialization of the right.
Keywords: Commercialization of Medicines; Hermeneutics; Legal Norms; Risk to Human Health. Health Surveillance.

Resumo

Objetivo: refletir se a hierarquia das normas jurídicas deve ser usada como método de solução infalível mesmo quando um conflito aparente entre normas jurídicas que envolva o direito à saúde e, sobretudo, a sua efetividade, puder ser melhor resolvido mediante decisão técnica do órgão regulador competente.

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Metodologia: estudo descritivo de abordagem qualitativa e análise documental. Foram analisadas as Resolução de Diretoria Colegiada nº 52/2011, Lei nº 13.454/2017 e Ação Direta de Inconstitucionalidade nº 5.779-DF. Buscou-se doutrina jurídica especializada sobre os temas central e periféricos. Para análise dos dados utilizou-se a técnica da revisão crítico-narrativa. **Resultados:** no Brasil, a adoção das agências reguladoras como agente normativo e regulador de atividades econômicas viabilizou a tomada de decisões pautadas menos em critérios políticos que em critérios técnicos. O legislador, ancorado em critérios políticos, segundo o entendimento do Judiciário, não pode ultrapassar os critérios técnicos. **Conclusão:** do julgamento da Ação Direta de Inconstitucionalidade nº 5.779 se extrai que o conceito hodierno e a natureza jurídica do direito à saúde impõem novos paradigmas jurídicos que validam o papel das agências reguladoras (tomada de decisões técnicas em prol da máxima efetividade do direito à saúde), ainda que em detrimento de decisões do legislador, legitimadas politicamente. O paradigma formal não pode obstar a materialização do direito.
Palavras-chave: Comercialização de Medicamentos; Hermenêutica; Normas Jurídicas; Risco à Saúde Humana; Vigilância Sanitária.

Resumen

Objetivo: reflexionar si la jerarquía de las normas jurídicas debe utilizarse como método infalible de solución, incluso cuando un conflicto aparente entre normas jurídicas que impliquen al Derecho sanitario pueda resolverse mejor mediante una decisión técnica del órgano regulador competente. **Metodología:** se recopilaron datos. En particular, RDC nº 52/2011, Ley nº 13.454/2017 y ADI nº 5.779-DF. Se buscó doctrina jurídica especializada sobre los temas centrales y periféricos. Los datos recogidos se analizaron mediante la técnica de revisión crítico-narrativa. **Resultados:** En Brasil, la adopción de las agencias reguladoras como agentes normativos y reguladores de las actividades económicas ha permitido tomar decisiones basadas menos en criterios políticos que en criterios técnicos. El legislador, anclado en criterios políticos, según el poder judicial, no puede ir más allá de los criterios técnicos. **Conclusión:** la sentencia en el asunto ADI 5.779 demuestra que el concepto actual y la naturaleza jurídica del derecho a la salud imponen nuevos paradigmas jurídicos que validan el papel de las agencias reguladoras (que adoptan decisiones técnicas en favor de la máxima efectividad del derecho a la salud), incluso en detrimento de las decisiones políticamente legitimadas del poder legislativo. El paradigma formal no puede impedir la materialización del derecho.
Palabras clave: Comercialización de Medicamentos; Hermenéutica; Normas jurídicas; Riesgo para la Salud Humana; Vigilancia Sanitaria.

Introduction

Law theory (doctrine and jurisprudence) has long since consolidated the solution that the hierarchy between legal norms represents a safe hermeneutic criterion for a fair solution to the apparent conflict between legal norms (overriding the criteria of specialty and posteriority of the norm). For Kelsen[1], the lower rule is only valid if it is in harmony with the higher rule.

In the Brazilian legal system, in which the supremacy of the Constitution over other legal norms has been consolidated (over infra-constitutional legal norms or even a supremacy of the original constituent power over the derived one), it was no different. Although the idea of the supremacy of the constitution has long been consolidated in Brazilian doctrine and judicial practice, Barroso can be mentioned by all:

> "The Constitution is suprema law, being the foundation of validity of all other normas. By virtue of this supremacy, no law or normative act – in fact, no is a legal act – can subsist validly if it's not in conformity with the Supreme Law."[2, p. 23]

The types of legislation provided for in article 59 of the Federal Constitution of October 5, 1988 (FC/1988), especially supplementary laws and ordinary laws, which are infra-constitutional in nature and come from the Legislative Branch, must comply with the formal (legislative process) and material (fundamental rights) constitutional mandates in order to serve the purposes of creating rights and imposing duties (principle of legality, article 5, II, of the Constitution)[3].

Also of an infra-constitutional nature and with the specific purpose of faithfully executing the law, there are the regulatory norms which, constitutionally, are issued by means of Decrees by the head of the Executive Branch (article 84, item IV, of the Constitution)[3], which is called, among administrators, regulatory power. Hierarchically, they are below the law and are only responsible for regulating it, otherwise there will be a crisis of legality or administrative insubordination to the law.

The adoption of the regulatory agency model in Brazil in the 1990s[4, 5] brought about the need to recognize the possibility of legal entities with greater administrative and financial autonomy in relation to direct public administration (federal, state, district and municipal governments), as well as having a predominantly technical nature in their decision-making (to the detriment of political power), to regulate the exercise of economic activities (regulatory power), such as the production and marketing of medicines, whose regulatory agency is the National Health Surveillance Agency. This regulatory activity carried out by the regulatory agencies (special autarchies) is not to be confused with the issuing of autonomous regulations, the competence of which also lies with the head of the Executive Branch (article 84, item VI, of the Constitution)[3].

Thus, from a purely formal perspective and based on internal origins, it is possible to recognize the following hierarchy of legal norms in the Brazilian legal system: constitutional norms, legal norms, regulatory norms and regulatory norms. In other words, at the top of the pyramid, there are the constitutional norms; just below, the legal norms; then, the regulatory norms; and finally, at the bottom of the pyramid, the regulatory norms. This would be the normative hierarchy that, according to a previously consolidated theory of law, offers a fair solution to a normative aporia. Political decision-making, democratically expressed in laws issued by representatives of the people, elected by the citizens themselves to express their will through the text of the legal norm, would take precedence over technical decision-making, based on technical-scientific knowledge about its subject and expressed in norms regulating the exercise of activities which, although economic in nature, still intrinsically belong to society.

It so happens that, when examining Direct Action for Unconstitutionality nº. 5.779-DF[6] and, above all, when judging it to be well founded, the Federal Supreme Court adopted the prohibition of deficient protection and retrogression (in relation to the fundamental human right to health) as its decision-making parameters, since, to the detriment of the hierarchical-normative criterion, it honored a technical decision by National Health Surveillance Agency, which was overruled by a political decision by the Legislative Branch.

It should be remembered that the purpose of an Direct Action for Unconstitutionality is to declare a federal law or a federal or state normative act invalid, in the light of the Federal Constitution. The criteria for this assessment are twofold: formal and material. Formality concerns the (in)observance of the legislative process laid down in the Constitution; materiality, on the other hand, concerns fundamental human rights. A federal law or federal or state normative act must therefore be based on these two parameters. If the Direct Action for Unconstitutionality is unfounded, the validity of a federal law or federal or state normative act is confirmed in the light of the Federal Constitution, i.e. its

constitutionality is confirmed. On the other hand, if the Direct Action for Unconstitutionality is upheld, this presumption is overcome in order to declare a federal law or federal or state normative act unconstitutional.

Thus, it is necessary to reflect on the fact that fundamental human rights, such as health, impose new paradigms so that their main debtor, the state (including the regulatory state), can give them maximum effectiveness.

Methodoloy

The full text of the ruling in Direct Action for Unconstitutionality nº 5.779-DF was collected from the Federal Supreme Court official website, as well as the related legal rules from the Planalto and Ministry of Health websites, respectively, Law nº 13.454/2017[7] and Collegiate Board Resolution nº 52/2011[8]. This research was anchored in specialized legal doctrine (constitutional law, administrative law, medical and health law, human rights), both domestic and foreign. The data collected was analyzed using the critical-narrative review technique[9], adding a dialogical critique to the reasoning adopted by the Federal Supreme Court, the result of comparing the legal norms consulted with the doctrine consulted and adding to the reflections of these authors.

Health as a fundamental human right

A good understanding of the concept and legal nature of health, derived from the fact that it has long been a legally protected good, is essential for reflecting on the paradigms necessary for its effective legal protection.

Today's legal concept of health is not simple, in the sense that it is not the result of a watertight dogmatic model. It is the result of a history of consolidating the necessary evolution of its understanding. This historicity encompasses the recognition and gradual sum of factors that impact it, from an individual to a transindividual or collective perspective, influenced by social, environmental and socio-environmental determinants[3].

The important concept of health from the Preamble to the Constitution of the World Health Organization (WHO), for example, still from an individual perspective, overcame the concept that health was merely the absence of illness or disease, defining it as "a state of complete physical, mental and social well-being".

Posteriormente, agregou-se a esse conceito a influência de determinantes sociais que extrapolam a perspectiva meramente individual desse direito, como bem observaram Marcelo Lamy, Danilo de Oliveira e Carol de Oliveira Abud:

> Again, using the technique of understanding by adding conceptions, the concept of health is broadened to include the absence of illness combined with a state of physical, mental and social well-being, guaranteed by the quality of the standard of living that

[3] According to Macelo Lamy, Danilo de Oliveira and Carol de Oliveira abud: "in order to make health a reality in the lives of human beings, it was necessary to analyze centuries of evolutionary concepts and legal frameworks, in order to finally define that health cannot have a single structured and rigid concept. Health is conceptualized in an open, dynamic, structuring and respective way, learning from what has already been established in the nuclear zone and adding to what is discovered in the perupherak zones. If every human action is representative of an era and carries its historicitym then the concept of health is also in constant representative evolution, following society, technologies, governments, needs and the positive or negative effects of nature. This development determines the consequences and new discoveries affecting human health, individually and collectively, socially and environmentally"[10, p 228].

> can be enjoyed by oneself, one's family or anyone else, whose living conditions are determinants of the healthy virtuous circle (good prospects for food, leisure, housing, remuneration, inclusive participation in society, sporting activities, etc.) or the vicious circle (poor or inadequate nutrition, lack of access to basic services, poor housing, sedentary lifestyle, etc.).) or the vicious circle (poor or inadequate nutrition, lack of access to basic services, lack of education, poor housing, social exclusion, sedentary lifestyle, etc.)[10, p. 222].

Later, while maintaining the trans-individual or collective perspective of health, recognition of the importance of environmental determinants (drinking water, basic sanitation, bathing, solid waste, air quality, exposure to agents harmful to health, etc.) was added to its concept[10, p. 227].

A socio-environmental dimension can also be added to the current legal concept of health, exemplified by the intergenerational responsibility - of present generations towards future generations - expressly provided for in article 225 of the Federal Constitution of 1988[4] and all its consequences, such as the notion of environmental education for a healthy quality of life.

"From then on, there is no longer any need to conjecture a dissociated view of the core concept of health in relation to the other peripheral conditioning factors"[10].

The legal nature of health as a fundamental human right can be extracted from the categorical-legal analysis of its origin. Recognized in international documents (regional and/or global), it is a human right. Consolidated in the constitutions of sovereign states (local level), it is a fundamental right. It is a widespread distinction among human rights scholars, and even constitutionalists, that human rights are those essential to the preservation of rights intrinsically inherent to human dignity when listed in international documents, while fundamental rights are those same rights essential to the protection of human dignity, but provided for in the Constitutions, that is, in the main internal legal documents of each sovereign state. In Brazil, therefore, health has the legal status of a fundamental human right.

However, it is necessary to go further and recognize the legal force resulting from understanding the concept and legal nature of health as a right today. These elements result in characteristic notes that guide the formation of legal paradigms aimed at its effectiveness[12]. These paradigms are imposed on the Public Power, the State, as the main debtor of this right. They are paradigms for the understanding, interpretation and application of legal norms relating to health, as well as guiding the questioning of the respective public policies. In other words, these paradigms guide and thus limit the legislative process relating to the right to health. In other words, those who issue legal norms on health, whether they are constitutionally derived, legal, regulatory or regulatory, must stick to the complex amalgam that surrounds the issue of health, i.e. its political, economic, social and environmental determinants, etc.

In short, the concept and legal nature of the right to health provide guidelines for the state powers to carry out their duties in a way that is compatible with adequate health protection.

It will be seen below that the guidelines of progressivity and non-retrogression greatly influenced the Federal Supreme Court decision on Direct Action for Unconstitutionality nº 5.779-DF[6].

[4] "Everyone has the right to na ecologically balanced environment, wich is a good for the common use of the people and essential to a healthy quality of life, and the public authorities and the community have the duty to defend and preserve it for present and future generations"[3].

The Brazilian regulatory state and its normative power

The Federal Constitution of 1988, in the Title on the Economic and Financial Order (Title VII), expressly provides for indirect state intervention in the economy as a normative and regulatory agent (article 174[5]). In addition to articles 21, item XI, and 177, § 2, III, article 174, all of FC/1988[3], serve as the constitutional basis for what is known as the Regulatory State. The performance of the state's normative and regulatory attributions for economic activities that are relevant to society are the responsibility of agencies under a special regime, created by law, as provided for in article 37, item XIX, of the FC/1988, called regulatory agencies.

A relevant question that arises concerns the *status of* regulatory norms, issued by the regulatory state, by regulatory agencies, in the valid exercise of their powers, within the hierarchy of legal norms that make up the Brazilian legal system.

The normative power of regulatory agencies, to issue regulatory legal rules (regulation), is not to be confused with legislative or regulatory power. In general, the hierarchy already described applies: constitutional norms, legal norms, regulatory norms and regulatory norms. In other words, at the top of the pyramid, we have constitutional norms; just below, legal norms; then, regulatory norms; and finally, at the bottom of the pyramid, regulatory norms.

However, authoritative doctrine clarifies that sometimes the issue is not one of hierarchy, but of competence:

> In relation to the legislature, the regulatory power is subordinate, by virtue of the principle of legality.
> The relationship between regulatory and normative power is not necessarily one of hierarchy. Rather, it is a question of defining competences. In situations where regulation is applicable, the regulatory activity will be subordinate to it. In situations where it is not, the regulatory activity will be exercised within its own limits, in the face of legality - in other words, acting without violating the constitutional guideline that only the law can create rights and obligations for individuals. Examples of such action would be the issuing of acts that regulate internal matters of the regulatory body itself or the clarification of concepts and the definition of technical parameters in the specific area of its activity.
> To conclude this topic, we can therefore outline the portion of the normative power inherent in regulation, which is the power to: (a) deal with *internal* matters of the regulatory body; (b) explain concepts and define technical parameters applicable to the regulated matter; and (c) issue infra-legal acts and - in the case where regulation is applicable - infra-regulatory acts aimed at disciplining details of its activity, thus implementing the provisions of higher standards[5, p. 1023].

This good understanding of the delineation of the normative power attributed to the Regulatory State is a prerequisite for overcoming, when necessary, the legal dogma of the hierarchy of legal norms. In fact, it may even be a question of its impertinence in the specific case.

[5] "Art. 174. As the normative agent and regulator of economic activity, the State shall exercise, in accordance with the law, the functions of supervision, incentive and planning, the latter being determinant for the public sector and indicative for the private sector"[3].

The tension between technical and political decision-making: balancing democracy

In recent years, we have seen a tendency in Brazil to favor decision making about public policies based more and more on technical knowledge than on a purely political nature, which has even been reflected in the election of popular representatives who are disregarded as "career politicians".

"The will of the people is the result of multiple interactions which, far from ending with the passing of a law, are continuous"[13, p. 19].

According to Abramovay, an important interaction for the adoption of good public policies is the balance between technique and politics:

> Public policies and politics itself can make concrete gains when they are combined with technology, improving decision-making processes based on evidence (...). Participation has brought a virtuous element to the new balance of relationship patterns between society and the state. An open public debate based on scientific research has brought about an alliance between the democratic process and high-quality technical production that makes it clear that, in specific cases, public debates in Congress can do without the dynamics of clientelism or corporatism.[13, p. 118]

On October 6, 2011, through Collegiate Board Resolution nº. 52, National Health Surveillance Agency basically banned the use[8] of the substances amfepramone, femproporex and mazindol. In addition, the prescription and use of the substance sibutramine came under greater control. In short, it was a legal rule of a prohibitive regulatory nature, aimed at preserving the health of consumers of these substances, justified by scientific studies that showed the high risks posed by these anorexiants (appetite suppressants used to treat obesity).

> It is important to note that the decision to withdraw a drug from the market is not taken arbitrarily. Rather, it is based on technical and scientific analyses that assess the relationship between the benefits of the drug and the possible risks it may pose. Anvisa considers factors such as the severity of the side effects, the therapeutic relevance of the drug and the existence of safe alternatives for treatment[14, p. 39].

However, on June 23, 2017, the Legislative Branch - the National Congress (CN) - passed Law No. 13,454, which, in short, authorized the use[7] of these same substances under medical prescription.

The validity of this law, in the light of the current Constitution (therefore, a primary normative act coming from the Legislative Branch, traditionally the primary source of law), was challenged before the Supreme Court through Direct Action Unconditionally 5.779-DF[6].

The enactment of Law No. 13,454/2017[7] by the National Congress seemed to easily override National Health Surveillance Agency.

However, the Federal Supreme Court ruled that there was no need to register these substances with ANVISA (otherwise, a doctor's prescription would suffice) and other health surveillance measures, given the material unconstitutionality of Law No. 13,454/2017, basically justified by the risks to consumers' health, which were scientifically disproportionate to the benefits of using these anorexiants.

Although the Federal Supreme Court has not expressly overturned the formal hermeneutic criterion of the hierarchy of legal norms, in the sense of subjugating the political decision (primary normative act, legal norm) to the technical decision (secondary normative act, regulatory norm), it has

validated National Health Surveillance Agency role as a special authority created by law (regulatory agency created by Law no. 9.782/1999) whose institutional purpose is to promote the protection of the health of the population through the production and marketing of products subject to health surveillance (article 6). 9.782/1999) whose institutional purpose is to promote the protection of the population's health, through sanitary control of the production and marketing of products and services subject to sanitary surveillance (article 6).

> Although the Court did not explicitly state that the normative power of regulatory agencies overrides the normative power of the National Congress, it gave unequivocal prestige to the decision of the regulatory agent, overcoming discussions about the legitimacy of the creation of regulatory agencies in Brazil and inaugurating a new context in which it is recognized that, in fact, agencies are central players in safeguarding fundamental rights.[14, p. 41]

It is worth highlighting the grounds for the decision, as set out in the 184-page judgment of the aforementioned Direct Action Unconditionally: a) the duty of National Health Surveillance Agency to ensure, through regulatory legal rules, compliance with minimum standards for the control of medicines, as provided for by law, derives from an express constitutional clause; b) the text of Law nº. 13. 545/2017 is materially unconstitutional nº 545/2017 is materially unconstitutional, the interpretation of which is in the sense of unduly dispensing with health registration and other health surveillance actions; c) the effectiveness of the right to health imposes two guidelines, by means of prohibitions: prohibition of deficient protection - sufficient protection - (progressivity guideline) and prohibition of retrogression (non-retrogression guideline).

The express mention of sufficient protection (progressivity guideline) can be seen in the ruling of ADI nº 5.779-DF[6], at least in the following passages:

> [...] the release of the production and commercialization of any substance that affects human health must be accompanied by the necessary measures to guarantee sufficient protection of the right to health. As Justice Gilmar Mendes warns in a doctrinal work [...].[6, p. 33]

> So many times in this plenary session we have explained the need for the National Congress, the Judiciary and the Executive, through their respective actions, whether by law, administrative act or judicial decisions, to strictly comply with the Constitution in order to sufficiently and efficiently protect rights. On the other hand, the administrative reserve, which, of course, is not generic - the law is generic - must strictly adhere to the constitutional provisions.[6, p. 99]

> The judicial precedents set by this Supreme Court on the right to health point to the construction of this line of decision-making regarding the identification of measures to control (in)adequate and (in)sufficient protection, in compliance with the principles of prevention and inviolability that make up the legal structure of the right to health.
> In particular, the precedents formed in the context of the pandemic, in which the adequate and sufficient protection of the right to health permeated the majority of the constitutional deliberations of this Federal Supreme Court, such as in ADI 6.341, 6.343, 6586, 6.421 and in several original civil actions.
> Thus, the compatibility of normative acts must necessarily pass through this judgment of adequacy to the fundamental duties of sufficient protection, as a method for constitutional validity.[6, p 122]

The express mention of the prohibition of retrogression (non-retrogression guideline) can be seen in the judgment of Direct Action Unconditionally nº 5.779-Federal District, at least in the following excerpts:

> For this reason, the concreteness established by the dictates of Law 6.360/76, as well as the Resolutions approved by the regulatory agency, constitute real achievements in terms of health protection, which is why they cannot be supplanted without a rule that derogates from them not guaranteeing equal protection. At this point, the so-called principle of the prohibition of retrogression applies, defined in the terms of this Court's case law as follows:
> "THE PROHIBITION OF SOCIAL RETROGRESSION AS A CONSTITUTIONAL OBSTACLE TO THE FRUSTRATION AND NON-COMPLIANCE BY THE PUBLIC AUTHORITIES OF RIGHTS TO SERVICES. - The principle of the prohibition of retrogression prevents the deconstruction of the achievements already made by citizens or by the social formation in which they live, in terms of fundamental social rights. - The clause that prohibits retrogression in terms of rights to positive state benefits (such as the right to education, the right to health or the right to public security, for example) means that, in the process of making these individual or collective fundamental rights effective, there is an obstacle to the levels of realization of these prerogatives, once reached, being subsequently reduced or suppressed by the state. Doctrine. As a result of this principle, the state, after having recognized the rights to services, assumes the duty not only to make them effective, but also obliges itself, under penalty of transgression of the constitutional text, to preserve them, refraining from frustrating - through total or partial suppression - the social rights that have already been realized."(6, p. 35)
>
> Thus, although the Legislative Branch is not, in theory, prevented from regulating the commercialization of a certain substance intended for human health, it is necessary that, under penalty of offending the prohibition of retrogression, there is detailed regulation, indicating, for example, forms of presentation of the product, provisions relating to its validity and storage conditions, maximum dosage to be administered, among others.(6, p. 36)
>
> In view of this constitutional architecture of the fundamental right and the related duties of protection, the prohibition of insufficient protection or institutional retrogression that implies a reduction in the scope of protection of the right to health already consolidated by previous legislative and administrative measures is inferred.(6, p. 122)
>
> In fact, invested with the authority deriving from Law 6.360/1976, anchored in the constitutional precepts that give concretion to the fundamental right to health, Anvisa has the competence to issue normative acts that aim to protect health and which, for this reason, cannot be derogated by formal law, without the latter guaranteeing equal protection for the health of the population, under penalty of infringing the principle of the prohibition of retrogression.
> In view of the above, I uphold the action to declare the unconstitutionality of art. 1 of Law 13.454/2017.(6, p. 135)

These legal foundations, adopted as grounds for decision by the Federal Supreme Court, constitute guidelines for the theory that is intended to occupy the still blank role of vector of the New Hermeneutics: the theory of interpretation according to development.

Interpretation according to development

The guidelines of progressivity and non-retrogression[15] derive not only from the legal nature of the right to health, from the fact that it is a fundamental human right. Above all, they have to do with a New Hermeneutics driven by the increasingly widespread perception that fundamental (or human, or fundamental human) rights are not just rights, but hermeneutic vectors.

However, the constant expansion of the list of human rights could make this hermeneutic function difficult or even obstruct it, given the undeniable coexistence of dimensions of human rights that, *a priori*, appear to exclude each other, given an initial appearance of incompatibility. Sometimes, in the same dimension, a given human right can appear incompatible when its individual and collective aspects are compared.

However, the right to development is a fundamental human right whose functions of integration of other fundamental human rights, control of public policies, especially those relating to social rights such as health, and hermeneutics, reveal the appropriate solution in favor of the maximum effectiveness of the dignity of the human person and its related values (guideline of the human person as the central subject of development)[14].

From the integrating function of the right to development[16], we draw the need for the adoption of public health protection policies to take into account not only the economic bias, notably the interest of the drug manufacturing market, but also the social, environmental and socio-environmental biases, which give a technical character to decision-making. In this sense, although the Brazilian market is very active in terms of the consumption of anorexics (anfepramone, femproporex and mazindol), the information on the lack of safety (insecurity) and the lack of information on the efficacy (ineffectiveness) of these drugs should have been taken into account by the legislator, especially when they were taken into account by the regulatory body. In other words, from the function of integrating the right to development comes the state's duty to observe the various determinants that affect the effectiveness of the right to health.

From the control function of public policies performed by the right to development[16], we can see that the technical decision of the regulatory body - in this case, National Health Surveillance Agency (Estado Regulador) –, prévia à atuação do legislador (Rule of Law) - prior to the action of the legislator (Rule of Law), implies a legal paradigm for the questionability of public health surveillance policy, if and when it is the subject of legislative action. Because, as the STF itself has stated, any derogation from the regulatory normative act by formal law will depend on the latter guaranteeing equal protection for the population's health[13].

From the hermeneutic function of the right to development, remembering that the guidelines of progressivity and non-retrogression are inherent to it, we extract that the STF, in upholding ADI nº 5.779-DF to declare Law nº 13.454/2017 unconstitutional, adopting as grounds for decision the prohibition of insufficient protection and the prohibition of retrogression, both in relation to the state's duty to protect the health of the population, recognized, albeit implicitly, the paradigm of interpretation in accordance with development[15].

Final Considerations

By upholding Direct Action Unconditionally 5.779-Federal District (for the declaration of the unconstitutionality - material - of Law nº 13.454/2017) in light of the grounds for deciding the prohibition of deficient protection (progressivity guideline) and the prohibition of retrogression (non-

retrogression guideline), both aspects materially inherent to the effectiveness of the right to health, the STF revealed the possibility of the primacy of the technical criterion of regulation over the political criterion of the law itself (which is often influenced by large economic forces), since National Health Surveillance Agency, in the valid exercise of its regulatory function, had banned the use of certain anorexiants because they caused far more risks than benefits (insecurity).

National Health Surveillance Agency issues regulatory norms aimed at protecting health as part of its remit and, according to the Federal Supreme Court opinion in Direct Action Unconditionally 5.779-Federal District, such normative acts cannot be derogated from by formal law, without the latter guaranteeing equal protection for the population's health, under penalty of infringing the non-retrogression guideline.

Conflict of interest
The authors declare that there is no conflict of interest.

Authors' contribution
The authors also contributed.

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